भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य एवं परिवार
कल्याण मंत्रालय, भारत सरकार

INDIAN COUNCIL OF MEDICAL RESEARCH
Serving the nation since 1911

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

Date: 29.11.2021

No. 5/4/5-10/Diab./20-NCD-III

To,

The Dean
Mahatma Gandhi Institute of Medical Sciences,
Wardha-442102

Sub: Sanction and budget allotment for the new scheme project entitled "Study of mitochondrial DNA polymorphism, mutation and oxidative stress in relation to susceptibility and severity of Type 2 Diabetes mellitus" submitted Dr. Jwalant Waghmare, Wardha.

Dear Sir,

The Director-General of the Council sanctions the above mentioned research scheme initially for a period of one year from **15.12.2021** subject to extension up to the total duration specified in para 3(3) below.

The Director-General of the Council also sanctions the budget allotment of **Rs.12,37,813/- (Rupees twelve lakh thirty seven thousand eight hundred thirteen only)** as detailed in the attached statement for the period ending the **14.12.2022.**

The grant-in-aid will be given subject to the following conditions:-

1. The payment of the grant will be made in lump-sum to the head of the Institution. The first instalment of the grant will be paid generally as soon as a report regarding the commencement of the project and appointment of the staff is received by the Council. The demand for payment of the subsequent instalment of the grant should be placed with the Council in the prescribed proforma attached.

2. The staff appointed on the project should be paid as indicated in the budget statement attached.

3. The approved duration of the scheme is **3 (three)** years. The annual extension will be given after review of the work done on the scheme during the previous year.

4. A report on the progress made will be submitted to the Council as and when called for.

5. The Institute will maintain a separate account of the receipts and the expenditure incurred on the scheme and will furnish a utilization certificate and an audited statement of account pertaining to the grant.

6. The host institute shall utilize the grant after following the provision laid down in GFRs 2017 and T.A. Rules.

Contd.

7. The PI is advised to keep the fund in a separate saving bank account opened for research funds received from ICMR so as to ensure that interest earned thereon is also credited in to the fund account.

8. The other terms and conditions are indicated in Annexure-1

The receipt of this letter may please be acknowledged.

Yours faithfully

(Mahesh Chand)
Sr. Admn. Officer
For Director-General

This issues with the concurrence
of Finance Section vide **RFC No.(P.N.29)NCD/Ad-hoc/144/2021-22 dated 25.11.2021** No. 5/4/5-10/Diab./20-NCD-III

1. Copy together with the budget statement forwarded for information to **Dr. Jwalant Waghmare, Professor of Anatomy, Mahatma Gandhi Institute of Medical Sciences, Wardha- 442102**
2. Copy together with the budget statement forwarded to the **Accounts Section** for information and necessary action.
3. IRIS No. 2020-4115
4. Mr. Hemant, Sr. TO, ICMR
5. Sr. A.O, NCD, ICMR

For Director General

वी. रामलिंगस्वामी भवन, पोस्ट बॉक्स नं. 4911,
अंसारी नगर, नई दिल्ली - 110 029, भारत
V. Ramalingaswami Bhawan, P.O. Box No. 4911,
Ansari Nagar, New Delhi - 110 029, India

Tel: +91-11-26588895 / 26588980 / 26589794
+91-11-26589336 / 26588707
Fax: +91-11-26588662 I icmr.nic.in

MGIMS Online

Prafulla Ambulkar <prafullaambulkar@mgims.ac.in>

SERB-Notification

1 message

Dr. Pramod Kumar Prasad <pk.prasad@serbonline.in> Wed, Nov 10, 2021 at 11:20 AM
To: serbinfo1@gmail.com

Science and Engineering Research Board

(Statutory Body Established Through an Act of Parliament : SERB Act 2008)
Department of Science and Technology, Government of India

SCIENCE & ENGINEERING RESEARCH BOARD (SERB)

(Statutory Body Established Through an Act of Parliament : SERB Act 2008)

Science and Engineering Research Board
5 & 5A, Lower Ground Floor
Vasant Square Mall
Sector-B, Pocket-5
Vasant Kunj
New Delhi - 110 070

Approval Letter

File Number: SRG/2021/001919

Dated: 10-Nov-2021

Subject: Project titled "Genetic study of spermatogenesis specific controlling genes related to non-obstructive azoospermic human male infertility ".

Dear Dr. Prafulla Shriram Ambulkar,

The project cited above has been technically approved by Science and Engineering Research Board (SERB) as per the following :

The committee recommended the following budget

Manpower : -> Project Assistant - 1
Equipment Details : Rs. 0
Consumables : Rs. 1700000
Travel Cost : As per norms
Contingencies : As per norms
Overhead : As per norms

The final budget to be sanctioned would be based on quotations received, existing norms, funds availability etc.

Kindly follow the below steps to acknowledge the approval :

1. Go to www.serbonline.in through your credentials

2. Go to Menu --> Proposal submission --> View submitted proposals

3. Click on the link under Status column "Proposal Approved, Acknowledgment pending from PI"'

You are requested to upload the Quotations of the approved equipment (if any), and salary structure for the project staff (including HRA, Medical Benefits, if applicable etc.) **strictly within 15 days from the date of this letter** so as to enable us to issue the financial sanction.

A certificate stating that any visit abroad for a period more than eight weeks would be undertaken after due permission from SERB, may also be submitted.

SERB has adopted the Scientific Social Responsibility (SSR) Policy which mandates SERB Grantees to undertake some SSR activities during their project period. You are requested to read the SSR guidelines available under SSR menu in the online portal and choose the activities according to your preference. Depending on the activity chosen, additional budget would be provided under separate head to carry out the chosen activities. It is mandatory to submit SSR details along with RTGS and other relevant documents.

Kindly upload RTGS details of the implementing institute to facilitate transfer of the fund as per the template. Kindly quote the reference number in all future correspondence. The project's reference no. SRG/2021/001919 may also be mentioned in all research communications arising from the above project.

Please note that the project starts only after it is accorded financial sanction by SERB and the date of start of the project will be the date on which your host institute receives the first instalment of funds.

Yours sincerely,

(Dr. Pramod Kumar Prasad)

Scientist-D

Email: pk.prasad@serb.gov.in

Dr. Prafulla Shriram Ambulkar

Centre For Genetics And Genomics Department Of Anatomy

Mahatma Gandhi Institute Of Medical Sciences , Sevagram, Wardha, Wardha, Maharashtra-442102

********** LEGAL DISCLAIMER **********

Please do not reply to this mail !!

[SERB is now on Social-Media. Kindly follow us on Twitter: @serbonline https://www.twitter.com/serbonline]

This is a system generated information and does not require any signature.This E-Mail may contain Confidential and/or legally privileged Information and is meant for the intendedrecipient(s) only. If you have received this e-mail in error and are not the intended recipient/s, kindly notify us at info@serbonline.in and then delete this e-mail immediately from your system. Any unauthorized review, use, disclosure, dissemination, forwarding, printing or copying of this email or any action taken in reliance on this e-mail is strictly prohibited and may be unlawful. Internet communications cannot be guaranteed to be timely,secure, error or virus-free. The sender does not accept any liability for any errors, omissions, viruses or computer problems experienced by any recipient as a result of this e-mail.

****

'SAVE PAPER - THINK BEFORE YOU PRINT!'

* Don't want to receive such notification anymore?Click here to send a mail to unsubscribe

Web-site www.icmr.nic.in

भारतीय आयुर्विज्ञान अनुसंधान परिषद

INDIAN COUNCIL OF MEDICAL RESEARCH

वी.रामलिंगस्वामी भवन, अन्सारी नगर, पोस्ट बॉक्स 4911, नई दिल्ली -110 029

V.RAMALINGASWAMI BHAWAN, ANSARI NAGAR, POST BOX 4911, NEW DELHI - 110 029

No. 5/7/MRC/2019-RBMCH **Dated : 24.01.2020**

Subject : Payment of first instalment of 1st year grant-in-aid for UKRI MRC JGHT funded Multicentre Task Force project entitled "Phase III, Multicentre, Randomized, Double Blind, Placebo-Controlled Study to Evaluate Efficacy of Probiotic Supplementation for Prevention of Neonatal Sepsis in 0-2 Months old Low Birth Weight Infants' for Study Coordinator Site for Data Management under Dr. Subodh Sharan Gupta, MGIMS, Wardha.

MEMORANDUM

Reference this office letter of even number dated 24.01.2020.

The Director General, ICMR sanctions the payment of **Rs 19,58,868/-** (Rupees Nineteen Lacs Fifty Eight Thousand Eight Hundred Sixty Eight only) as the 1st instalment of 1st year. The grant for incurring expenditure in connection with the above mentioned research scheme. The amount of **Rs 19,58,868/-** for the period from 1.1.2020 to 31.12.2020 may be debited in the provision of **Rs.35,12,736/-** made for the above mentioned research scheme for the current financial year 2019-2020.

A formal bill for Rs. **19,58,868/-** is sent herewith for payment through RTGS to the Dean, Mahatma Gandhi Institute of Medical Sciences, Wardha. (Mandate form enclosed)

This is issued with the concurrence of the finance year **ICMR-FCRA/2019-2020/ Project -08"**

(Harjeet Kaur Bajaj)
Administrative Officer
For Director General

Copy to :

1. The Dean, , Mahatama Gandhi Institute of Medical Sciences, Sewagram, Wardha 442102.
2. Dr. Subodh Sharan Gupta, Professor of Community Medicine, Mahatama Gandhi Institute of Medical Sciences, Sewagram, Wardha 442102.
3. Copy together with copies of the budget statement forwarded to the Accounts V Section, ICMR for information and necessary action.
4. Mrs. Komal Nagpal, Consultant FCRA, ICMR, New Delhi.
5. Dr. Anju Sinha, Scientist F, ICMR, New Delhi.

Admn. Officer
For Director General

Scanned with CamScanner

PBX: 26588980, 26588981, 26588982, 26588983, 26588984
FAX: 011-26589662, 011-26589704, 011-26589388
ग्राम / GRAM: विज्ञानी / SCIENTIFIC
Website: www.icmr.nic.in
E-mail: icmrhqs@gmail.nic.in

भारतीय आयुर्विज्ञान अनुसंधान परिषद
INDIAN COUNCIL OF MEDICAL RESEARCH

वी.रामलिंगस्वामी भवन, अन्सारी नगर, पोस्ट बॉक्स 4911, नई दिल्ली -110 029
V.RAMALINGASWAMI BHAWAN, ANSARI NAGAR, POST BOX 4911, NEW DELHI - 110 029

To,

The DEAN
Mahatma Gandhi Institute of Medical Science,
Sevagram, Wardha-442 102, Maharashtra

No. 5/7/MRC/2019-RBMCH
Dated: 14.8.2020

Subject: Sanction of Budget Allotment for the UKRI MRC, JGHT (Reference: MR/S004912/1) funded New Multicentre Task Force project entitled: "Phase III, Multicentre, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate Efficacy of Probiotic Supplementation for Prevention of Neonatal Sepsis in 0-2 Months old Low Birth Weight Infants in India" under **Dr. Subodh Sharan Gupta,** Professor of Dept. of Community Medicine, Mahatama Gandhi Institute of Medical Sciences, Sewagram, Wardha Maharashtra .

Dear Sir/Madam,

The Director General of the ICMR sanctions the above mentioned research scheme initially for the period of **one year from 1.09.2020** subject to extension up to total duration specified in para 3 below.

The Director General of the ICMR also sanctions the budget allotment of **Rs. 57,45,968/- (Rupees Fifty Seven Lakhs Forty Five Thousand Nine Hundred Sixty Eight Only)** as detailed in the attached statement for the period from **01.09.2020 to 31.08.2021**. The grant-in-aid will be given subject to the following conditions:

1. The payment of the grant will be paid **through RTGS to the head of the Institute.** The Staff appointed on the project should be paid as indicated in the budget statement.
2. The staff on the project will be recruited as per the rules and procedure of the host institute and second part of the undertaking be obtained from the employees of the project.
3. The approved duration of the scheme is **2 years 6 months (30 months) and the subject recruitment period is for 18 months**. The annual extension will be given after review of the work done on the scheme during the previous year.
4. The annual progress report as per MRC guidelines should be submitted to the Council, as per the MRC guidelines giving complete actual details of the research work done.
5. **The Institute will maintain a separate saving account of the receipts and the expenditure incurred on the research scheme and will furnish a utilization certificate and an audited statement of the account pertaining to the grant. The MRC requires interim expenditure report to be compiled by the sponsor and for this you are requested to comply with the Evidencing Expenditure on UKRI grants (including GCRF) attached herewith (Flag 'A').**
6. **The institute shall utilize the Grant as per the provisions laid down in the GFRs 2017 and T.A Rules.**
7. The above terms and conditions are indicated on ICMR website

Yours faithfully,

(Jaijeet Kaur Bajaj)
Administrative Officer
For Director General

Copy to :

1. **Dr. Subodh Sharan Gupta**, Professor of Dept. of Community Medicine, Mahatama Gandhi Institute of Medical Sciences, Sewagram, Wardha - 442102 Maharashtra.
2. **Accounts V Section**, ICMR for information and necessary action.
3. **Ms. Sneha**, Consultant FCRA, ICMR, New Delhi.
4. **Dr. Anju Sinha**, Scientist F, Div. of RBMCH, ICMR HQRS, New Delhi.

Admn. Officer
For Director General

Scanned with CamScanner

भारतीय गैर न्यायिक

एक सौ रुपये

Rs. 100

रु. 100

ONE HUNDRED RUPEES

सत्यमेव जयते

भारत INDIA

INDIA NON JUDICIAL

తెలంగాణ तेलंगाना TELANGANA

AG 555923

Sl.No.17024 Date:24-08-2021
Sold to: M.Pandu Ranga Reddy
S/o Late M.Seetharam Reddy R/o Hyd
For Whom: Biological E Ltd.

E.VENKATESH
LICENSED STAMP VENDOR
L.No.16-07-08/10,RL.NO.16-07-03/2019
D.No.5-3-856/17,G-17,NANDINI COMPLEX,
M.J.MARKET,HYD-12.CELL :9866313526

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement(the "**Agreement**")is made on 08th Sep, 2021 ("**Effective Date**") by and between **Biological E. Limited**, a company incorporated under the Companies Act, 1956 and having its registered office situated at 18/1&3, Azamabad Hyderabad 500020, Telangana, India ("**Sponsor**"), of the First Part; and **Dr. Bishan Swarup Garg** , a registered medical practitioner holding MCI registration number MCI-20851, currently working as Director-Professor of Community Medicine in Mahatma Gandhi Institute of Medical Sciences, Sewagram, Wardha, Maharashtra, India - 442102 ("Principal Investigator"), of the Second Part; and **Mahatma Gandhi Institute of Medical Sciences**, a hospital established registered under the laws of India, having its place of business at Mahatma Gandhi Institute of Medical Sciences, Sewagram 442102 Wardha District, Maharashtra, India represented by its **Dean Dr. Nitin Gangane** ("Institution"), of the Third Part.

For Biological E. Limited

N. Eswara Reddy
Vice President - Legal

WHEREAS,

A. The Sponsor is a biopharmaceutical company, which develops, manufactures and markets innovative vaccines and biologics. Biological E. Limited has developed CORBEVAX Vaccine product and is desirous of testing the same in humans through a phase III Clinical Trial to be conducted in 30 study centres;

B. The Institution has its own premises fully equipped to conduct the Study mentioned under this Agreement;

C. The Sponsor has already identified the Principal Investigator based on his experience and expertise and also furnished sufficient information regarding the Study drug and the Protocol;

D. The Principal Investigator has, after careful review of the Protocol and other materials relating to the Clinical Trial conveyed his willingness to the Sponsor to conduct the proposed Study;

E. The Sponsor shall provide technical and financial support mentioned in this Agreement to the Principal Investigator to conduct the Clinical Trial and the Principal Investigator in lieu of such support has agreed to enter into this Agreement with the Sponsor; and

F. The Principal Investigator has obtained and shall maintain in full force and effect all permissions, sanctions and approvals from the Institution and relevant governmental and regulatory authorities to undertake and conduct the Clinical Trial;

NOW, THEREFORE, the Parties hereto, in consideration of the mutual covenants and premises contained herein, enter into this Agreement and agree as follows:

1. Definitions

1.1 **"Study"** or **"Clinical Trial"** shall mean study entitled:

"A Prospective, Single-blind, Randomized, Active-controlled Phase III Clinical Study to Evaluate the Immunogenicity and Safety of Biological E's CORBEVAX Vaccine for Protection Against COVID-19 Disease When Administered to RT-PCR Negative Adult Subjects." and all the title amendments thereto as the Parties may from time to time agree in writing.

1.2 **"Protocol"** shall mean:

The description of the Study mentioned in the Study protocol number **BECT/COVID-19-PHASE-III/074** and all amendments thereto as the Parties may from time to time agree in writing.

1.3 **"Study Drug"** or **"Investigational Drug"** shall mean:

CORBEVAX Vaccine (Manufactured by Biological E. Ltd.).

1.4 **"Ethics Committee"** shall mean:

An independent body or an Institutional Ethics Committee, constituted and registered with the licensing authority under the provisions of Drugs and Cosmetic Act, 1945 and rules amended thereof.

For Biological E. Limited

N. Eswara Reddy
Sr. Vice President - Legal

2. Responsibility of the Principal Investigator and the Institution

2.1 The Institution agrees to provide full support to the Principal Investigator who is working in Department of Community Medicine in the Institution, to conduct the Clinical Trial in its premises and utilize reasonably the facilities available in the Institution for the Study and shall allot qualified co-investigators, Co-ordinators and other persons with prior consent of the Sponsor, for proper conduct of the Study in accordance with the terms of this Agreement and the Protocol.

2.2 The Principal Investigator and Institution shall be jointly and severally shall be responsible (a) to conduct and complete the Clinical Trial of the Sponsor strictly in accordance with the applicable regulatory requirements and the Protocol as approved by the Institutional Ethics Committee; (b) to comply with all applicable rules, regulations and guidelines, both national and international, including but not limited to, ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95), Indian GCP and New drugs & Clinical Trial Rules 2019 issued by CDSCO, Directorate General of Health Services, Govt. of India; Drugs and Cosmetics Act 1940 and Rules, gazette notifications made thereunder (as amended from time to time), ethical principles contained in the current revision of Declaration of Helsinki, Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council of Medical Research ("**Applicable Laws & Guidelines**"); (c) to fulfill all other terms and conditions stipulated herein and in the Annexures hereto, during the period of, and also after the completion of, the Clinical Trial as agreed upon by him; and (d) to provide Sponsor a copy of registration certificate issued by the licensing authority to Ethics Committee before initiation of the Clinical Trial.

2.3 The Principal Investigator along with any co-investigator employed/assigned in the Institution shall personally review all case report forms to assure its completeness and accuracy. A case report form is deemed complete when:

(i) the case report form has been completed by the Principal Investigator in accordance with Study requirements;

(ii) it relates to a properly qualified subject who participated in and completed the Study in accordance with all Study requirements and directions from the Sponsor; and

(iii)it can be used in all analyses of the Study results.

The Principal Investigator undertakes that all data shall be submitted in a timely manner to the Sponsor.

2.4 Principal Investigator shall at all-time exercise independent medical judgment as to the compatibility of each subject with the Study as per Protocol requirements. Principal Investigator shall notify the Sponsor, Chairman of Ethics Committee and licensing authority within twenty-four (24) hours of any serious adverse events related to or unrelated to the Study Drugs and of overdoses and any other event as set forth in detail in the Protocol.

2.5 The Principal Investigator and Sponsor shall provide report of serious adverse events after due analysis to the Chairman of the Ethics Committee, Head of the Institution and to the licensing authority of any deviations in the Protocol or serious adverse events immediately and in any event within fourteen (14) calendar days from the date of occurrence of such deviation and/or serious adverse events, as the case may be.

2.6 The Principal Investigator and Sponsor shall provide report of serious adverse events after due analysis to the Chairman of Ethics Committee, licensing authority and to the Head of

For Biological E. Limited

N. Eswara Reddy
Sr. Vice President - Legal

the Institution within fourteen (14) calendar days of occurrence of such serious adverse events.

2.7 In the event the Principal Investigator becomes unwilling or no longer in the employment of the Institution or unable to perform the Study, at any latter stage, the Principal Investigator/Institution shall provide notice to the Study subjects, Ethics Committee and Sponsor at least thirty (30) days before Principal Investigator intends to stop/withdraw from the Clinical Trial. The Principal Investigator and Institution shall endeavor to promptly recommend a replacement Principal Investigator, from among the consultants of the Institution. The Sponsor shall have the exclusive right to approve or reject any such replacement of Principal Investigator. The new principal investigator which is approved by the Sponsor shall be required to agree to the terms and conditions of this Agreement. In the event Sponsor does not approve such new principal investigator, the Study will be terminated immediately and no further payment shall be made to Principal Investigator and the Institution. Upon such termination, Institution shall (i) ensure appropriate therapy and follow-up for enrolled Study subjects; (ii) maintain all Study related documents for such time as may be required by Sponsor and shall take measures to prevent accidental or premature destruction of these documents and (iii) undertake to complete the Study on all the enrolled subjects as per approved Protocol.

3. Conduct of Clinical Trial

3.1 The Sponsor shall appoint it's employee to monitor the Clinical Trial and also reserves it's right to nominate any other person as monitor.

3.2 Principal Investigator shall enroll the allotted number of subjects in a period of 60 calendar days from the date of study site initiation. It is hereby clarified that no payment shall be made to the Principal Investigator, if the Study subject is not participating in that particular visit.

3.3 Principal Investigator and the Institution agrees that if Principal Investigator cannot conduct and complete the Study to the satisfaction of the Sponsor within the time prescribed by the Sponsor on the agreed number of subjects as per clause 3.2 above, the Sponsor may at its sole discretion and without prejudice to its rights under this Agreement, send a notice to the Principal Investigator and the Institution to discontinue the Study. The Principal Investigator and Institution agrees to cease recruiting subjects for the Study immediately upon receiving such notice from the Sponsor to stop recruiting the subjects for the Clinical Trial.

3.4 Principal Investigator shall ensure that the Audio Visual recording of the informed consent form signed by or on behalf of the Study subjects have been reviewed and approved by Ethics Committee prior to initiation of the Study. Upon approval of the informed consent form by the Ethics Committee, a copy of the approval letter shall be provided to the Sponsor by the Principal Investigator, who shall further obtain audio visual informed consent form duly signed by each of the subjects/Legally acceptable representatives on behalf of the Study subjects enrolled in the Study in accordance with Applicable Laws and Guidelines. The Principal Investigator shall ensure to maintain for record an audio-visual recording of the informed consent process of individual subjects including procedure of providing information to the subjects and their understanding on such consent. However, at the request of the Sponsor, Principal Investigator shall handover a copy of such recording for regulatory compliance or any order.

3.5 The Study of the Sponsor is being entrusted to the Principal Investigator and Institution directly by the Sponsor as a technical assignment, based on the skill, knowledge and

For Biological E. Limited

N. Eswara Reddy
Sr. Vice President - Legal

experience of the Principal Investigator in the specialty areas related to the Clinical Trial and Institution's experience as a qualified testing facility in the Clinical Trial. The Principal Investigator shall be personally obligated to conduct and complete the Clinical Trial in accordance with the Protocol as well as other terms and conditions specified by the Sponsor herein. All items received from the Sponsor, from time to time, (including, but not limited to, Study Drug, documents, Confidential Information, communications, instructions etc.), records and registers required to be maintained and all data generated hereunder by the Principal Investigator, shall be under the exclusive care, custody and responsibility of the Principal Investigator throughout the period of the Clinical Trial and thereafter for a period of fifteen (15) years after the Sponsor has discontinued its Study or such longer period as required by Applicable Laws & Guidelines. At the end of such period mentioned above, the Institution shall obtain written approval from Sponsor before destruction of such data.

3.6 Principal Investigator agrees to assume all the legal obligations of the Sponsor for the Study related duties and functions under this Agreement and the Protocol.

3.7 Principal Investigator/Institution shall ensure that all the individuals involved in the conduct of the Study shall strictly adhere to the terms and conditions of this Agreement. Institution and Principal Investigator represents and warrants that it shall not use in any capacity, in connection with the Study, any individual who is not duly qualified or has been debarred pursuant to any Applicable Laws & Guidelines or against whom any action, suit, claim, investigation or legal or administrative proceeding is pending. Principal Investigator represents and warrants that no action, suit, claim investigation or legal or administrative proceeding is pending or threatened relating to Principal Investigator's debarment and/or debarment of the persons engaged by Principal Investigator to assist for the Study.

3.8 Principal Investigator represents and warrants that he has obtained and shall maintain in full force and effect all the necessary approvals, permissions and sanctions from the Institution, Ethics Committee and all the government and regulatory authorities to conduct the Clinical Trial.

4. Study Drug

4.1 The Sponsor will provide the Study Drug to the Principal Investigator/ Institution free of cost/charge and in such quantities sufficient to complete the Study, together with guidelines and descriptions for the safe and proper use, administration, storage and disposal of the Study Drug. Principal Investigator shall use Study Drug and other items provided by the Sponsor only to conduct the Study in accordance with the Protocol and Applicable Laws & Guidelines and instructions of the Sponsor and shall not chemically, physically or otherwise modify the Study Drug, unless specifically required to do so by the Sponsor in writing to the Principal Investigator. Principal Investigator and Institution jointly and severally agrees that they shall administer, handle, use, store, and or dispose the Study Drug and other items provided by the Sponsor in compliance with Sponsor's instructions and all Applicable Laws & Guidelines.

4.2 The Parties hereby clearly understand that the subject matter of the Agreement is to clinically evaluate the safety and tolerability of the Study Drug and that the Clinical Trial shall not constitute complete treatment to cure any disease.

5. Visit and Inspection

5.1 The Sponsor or its authorized representatives, and regulatory authorities to the extent permitted by law, shall have the absolute right to:

For Biological E. Limited

N. Eswara Reddy
Sr. Vice President - Legal

i. examine and inspect the Institution's facilities whenever Principal Investigator is conducting Study;

ii. inspect and copy all data and work products relating to the Study, and

iii. audit all reports and data from Principal Investigator to ensure compliance with the terms of this Agreement and Protocol.

6. Payment

6.1 Institution hereby undertakes that in consideration of Principal Investigator's carrying out Clinical Trial at the Institution in accordance with the terms of this Agreement, Sponsor shall make the payment to the Principal Investigator as per the payment schedule as set forth in Exhibit A. All the payments shall be made directly to the Principal Investigator/designee.

6.2 The Parties agree that the payment of the amount set forth in Exhibit A will be paid by the Sponsor to the Principal Investigator to compensate all the expenses incurred by him in execution and conducting the Clinical Trial at the Institution so that, neither the Study subject, nor the insurance program nor the public assistance agency shall be liable for the same. The payment of the amount set forth in Exhibit A is also meant to compensate Principal Investigator for the professional and clerical allowances, laboratory examinations for all the activities as per the Protocol including but not limited to, preparation of the subject records, medication accountability records and other trial related documentation.

6.3 Institution and Principal Investigator shall not be entitled to any other expenses, benefits, consideration or fee of co-investigator, whether monetary or otherwise under this Agreement or elsewhere and it covers all out of pocket expenses incurred by Principal Investigator in conducting Study at the Institution including but not limited to telephone, telex, travel and office expenses.

6.4 Sponsor shall be entitled to deduct tax at source (if applicable) while making payment to Principal Investigator on behalf of the Institution under this Agreement.

6.5 In case of very slow/no recruitment, after providing stipulated time of recruitment, at any participating site the competitive recruitment strategy of study subjects would be planned to achieve the overall study timeline based upon the decision taken by the Biological. E (Sponsor). The additional supplement payment towards the additional subject's recruitment will be made by Biological E to the payee as per the same budget calculation and payment schedule.

7. Indemnification and Insurance

7.1 The Sponsor agrees that it shall indemnify, defend and hold harmless the Principal Investigator from and against all suits, claims, losses or damages, arising as a result of (i) either breach of any representation/warranty made by the Sponsor herein and or (ii) of personal injury to (including death of) Study subject, which injury is sustained due to serious adverse events of the Study Drug except to the extent such claims are attributable to:

a) the failure of the Principal Investigator, any co-investigator or any other personnel involved in the performance of the Study to adhere to the terms of the Study Protocol or any written instruction relative to the administration, use, handling,

For Biological E. Limited

N. Eswara Reddy
Sr. Vice President - Legal

storage of any drugs used in the performance of the Study, or comply with any Applicable Laws & Guidelines; or

b) Any negligent or wrongful act or omission, or willful malfeasance/ misconduct of the Principal Investigator/ co-investigator/any other personnel (including employees, agents or independent contractors) involved in the performance of the Study.

7.2 It is a condition precedent to the Sponsor's indemnification obligations under above mentioned clause 7.1 that:

a) whenever Principal Investigator has information from which it may reasonably conclude an incident of bodily injury or death has occurred, Principal Investigator shall immediately give notice to Sponsor of all pertinent data surrounding such incident. In addition, Principal Investigator shall comply with all of their obligations with regard to adverse event reporting procedures as set forth in this Agreement and the Protocol; and

b) the Principal Investigator under clause 7.1 above must (i) promptly notify the Sponsor of the assertion of any such claims (ii) authorize and permit Sponsor to conduct and exercise sole control of the defense and deposition (including all decisions relative to litigation, appeal or settlement) of such claims and (iii) fully cooperate with Sponsor regarding any such claims (including access to pertinent records and documents and provision of relevant testimony) and in determining the scope of Sponsor's obligations hereunder. Subject to the foregoing, Principal Investigator may also participate with prior consent of the Sponsor in any such claims at his own cost and expense. Principal Investigator agrees to cooperate with and to authorize Sponsor to carry out sole management and defense of such claim or action. Principal Investigator shall not compromise or settle any claim or action without the prior written approval of Sponsor.

7.3 The Principal Investigator and the Institution hereby irrevocably agree that they shall indemnify and hold harmless the Sponsor, its present and future directors, officers and or employees against any and all consequences, damages, suits, actions, claims, costs and expenses including reasonable attorney's fees and any cost of medical treatment of any illness or injury sustained by a Study subject, cost of fresh studies (collectively the "**Claims**") arising out of or in relation to (i) any breach of any of the representations and/or warranties made/held out by the Principal Investigator and the Institution in this Agreement; or (ii) breach of any of the terms of this Agreement by the Principal Investigator, the Institution or any individual engaged by Principal Investigator to support him in the conduct of the Study; or (iii) intentional deviation or omission or negligence in conducting the Study by the Principal Investigator, the Institution or any individual engaged by Principal Investigator to support him in the conduct of the Study; or (iv) failure to follow the instructions of Sponsor by the Principal Investigator and the Institution; or (v) failure of the Principal Investigator and the Institution to conduct the Study in accordance with the Protocol, Applicable Laws & Guidelines.

7.4 Insurance

a) The Sponsor undertakes that it will secure and maintain in full force and effect throughout the performance of the Study (and following termination or early termination of the Study and to cover any claims arising from the Study) a clinical trial liability insurance policy from an Indian insurance company for an amount

For Biological E. Limited

N. Eswara Reddy
Sr. Vice President - Legal

appropriate to, and in accordance with, the Sponsor's activities and obligations contemplated in this Agreement.

b) The Institution undertakes that it will secure and maintain in full force and effect throughout the performance of the Study (and following termination or early termination of the Study and to cover any claims arising from the Study) a clinical trial liability insurance coverage from an Indian insurance company for the Study for an amount appropriate to, and in accordance with, the its activities and obligations contemplated in this Agreement.

8. Publication of Results

It is the general policy of the Sponsor to encourage publication of results of Clinical Trial on a case to case basis. However, according to good scientific practice no interim data should be published by the Principal Investigator/ Institution unless agreed by the Parties in writing. It is further agreed that when the Principal Investigator/ Institution request for publications, the manuscript shall be based on final report of the Study and before any publication it shall be sent to the Sponsor for its perusal, comments and approval. The Sponsor may at its discretion may either refuse the publication or forward it to the Principal Investigator/ Institution along with its comments or modifications which shall be final and binding on the Principal Investigator/ Institution.

9. Publicity and Product Promoting Activity

It is agreed that no Party shall issue any press release or other third party communication relative to this Agreement without the prior written consent of the other Party except to the extent that the Sponsor shall have absolute right to issue any press release relating to the Study related data. Principal Investigator shall not use the name of the Sponsor and/or its employees in any advertising or sales promotional material or in any other way not required by law or regulation without the prior written consent of the Sponsor.

10. Confidentiality

10.1 The Principal Investigator and the Institution agree to keep confidential and secret all materials, documents and confidential information that the Sponsor discloses to the Principal Investigator and the Institution pursuant to this Agreement and also all materials, documents and information's gathered, generated or developed by Principal Investigator and the Institution under the Study including but without limitation to results and discoveries emanated from the Study, regardless of whether such information is marked as "Confidential," "Proprietary" or the like, which is furnished to the Principal Investigator by or on behalf of the Sponsor whether in written, electronic, oral, visual or other form ("**Confidential Information**").

10.2 The Principal Investigator and the Institution agree, represent and warrant that any Confidential Information that they receive shall be protected at least, with the same degree of care and protection in the strictest confidence as of its own and shall take all reasonable measures to protect it. The Principal Investigator and the Institution shall use such Confidential Information only for the purpose of fulfilling their obligations mentioned herein and shall not disclose such Confidential Information without the prior written consent of the Sponsor to any third party except as required by law provided that the Principal Investigator and the Institution shall:

(i) first give prompt notice of such disclosure requirement to the Sponsor so as to seek any limitations on or exemptions from such disclosure requirement; and

For Biological E. Limited

N. Eswara Reddy
Sr. Vice President - Legal

(ii) reasonably co-operate the Sponsor in any such efforts of defense to be made before appropriate authority.

10.3 Principal Investigator and/or the Institution may disclose Confidential Information to their co-investigator, hospital authorities, Ethics Committee members and others who are required to be involved in the Study on a need-to-know basis provided that: (i) such receiving party shall always remain liable to maintain the confidentiality in terms hereof and (ii) all such receiving party shall be bound by obligations of confidentiality with respect to such Confidential Information at least as stringent as those provided herein. Principal Investigator and the Institution shall be liable for any breach of this Agreement by its representatives. The obligations of confidentiality hereunder shall continue for a period of fifteen (15) years from the date the Confidential Information is disclosed or developed. The obligation of confidentiality hereunder shall not apply to information that Principal Investigator and/or the Institution can prove and produces credible written evidence to establish that such information or material:

(a) at the time of disclosure or after disclosure to the Principal Investigator /Institution becomes part of the public domain by publication or otherwise, except by breach of this Agreement by the Principal Investigator/ Institution or their successors or assigns;

(b) by written records were in the Principal Investigator/ Institution's possession at the time of disclosure by the Sponsor were not acquired directly or indirectly from the Sponsor;

(c) subsequent to disclosure hereunder, the Principal Investigator/ Institution receives from a third party legally in a position to provide with information to the Principal Investigator/ Institution, provided, however, that such was not obtained by said third party directly or indirectly from the Sponsor under an obligation of confidentiality.

10.4 All clinical data, including case report forms and other information and discoveries resulting from the Study (**"Inventions"**) shall be the sole property of the Sponsor and will be treated as "Confidential Information" by the Principal Investigator and the Institution and may be used by the Sponsor in any manner. Further, Principal Investigator and the Institution shall assign to the Sponsor all of their rights, title, and interest in such Inventions.

10.5 All Confidential Information disclosed pursuant to this Agreement, together with all copies thereof, summaries and all information, know-how, data and materials generated by the use of the Confidential Information, shall be returned to the Sponsor by Principal Investigator and the Institution forthwith upon written request or upon termination of this Agreement, whichever is earlier.

10.6 Principal Investigator and the Institution agree that the Confidential Information is of a special and unique kind, the protection of which is essential to the operation of the Sponsor, and that if there is a breach (either actual or threatened) by the Principal Investigator/ Institution or co-investigator or a party in receipt of Confidential Information under this Agreement, the Sponsor would have no complete remedy at law. Therefore, in addition to any other remedies that may be available at law or equity, Principal Investigator and Institution agree that the Sponsor shall be entitled to seek from any court of competent jurisdiction, injunctive relief, specific performance or other equitable relief, for any actual or threatened violation of this Agreement (without the necessity of posting any bond or other security proving special damages) and that the Principal Investigator and Institution shall not oppose the granting of such relief. In the event of any litigation relating to this Agreement, if a court of competent jurisdiction determines that this Agreement has been breached by one Party, then that Party shall reimburse the non-breaching Party for all its costs and expenses (including, without

For Biological E. Limited

N. Eswara Reddy
Sr. Vice President - Legal

limitation, attorney fees and other legal expenses) incurred in connection with all such litigation.

11. Severability & Waiver and Assignment

11.1 The invalidity or unenforceability of any term or provision of this Agreement, the remaining provisions shall stand to the fullest extent permitted by law. The failure of any Party at any time or times to require performance of any provision hereof shall in no manner affect the right of such Party at a later time to enforce such provision or any other provision of this Agreement.

11.2 Waiver by either Party or the failure by either Party to claim a breach of any provision of this Agreement shall not be deemed to constitute a waiver or estoppels with respect to any subsequent breach of any provision hereof.

11.3 This Agreement shall not be assigned as a whole or in part by Principal Investigator and/or Institution without the prior written consent of the Sponsor.

12. Validity & Termination

12.1 This Agreement shall become effective on the date first set forth above and shall continue till the completion of the study thereof or until this Agreement is terminated due to:-

a. Determination by the Sponsor that the Principal Investigator is not performing the Study as required in the Protocol and/ or is not meeting the agreed upon enrollment;

b. Failure of the Principal Investigator's or its associated staff or any other person engaged in the Study (excluding subjects) to be available, upon reasonable prior notice by the Sponsor, to meet at mutually convenient time with the Sponsor enabling it to monitor the course of the Study as necessary and to discuss information relevant to the Study;

c. Determination by the Sponsor that business or scientific considerations require termination;

d. Case report forms provided to the Principal Investigator by the Sponsor to be used in the Study, are not legibly completed and forwarded to the Sponsor or its designated representative;

e. At the request of either DCGI or Ethics Committee;

f. Notification to the Sponsor from central or state regulatory authorities to terminate the Study;

g. Failure of the Principal Investigator/ Institution to provide access by the Sponsor's representatives all original medical records necessary to verify entries on the Study case report forms;

12.2 The Sponsor may terminate this Agreement:

a) At any time upon thirty (30) days written notice to the Principal Investigator/Institution.

b) Immediately for safety reasons relating to the use of the Study Drug.

12.3 Either Party may terminate this Agreement by notice in writing to the other Party if the other Party commits a breach of this Agreement, and which, in the case of a breach

For Biological E. Limited

N. Eswara Reddy
Sr. Vice President - Legal

capable of remedy, shall not have been remedied by the defaulting Party within thirty (30) days of receipt of notice identifying the breach and requiring its remedy.

13. Effect of Termination

13.1 Upon receipt of notice of termination, the Principal Investigator shall immediately stop enrolling subjects into the Study and to the extent medically permissible, cease administering the Study Drug and conducting Clinical Trial on subjects already entered into the Study. In case of early termination of this Agreement, due to any reason the Principal Investigator shall request all Study subjects within one month from the date of termination notice to attend a follow up visit for proper safety assessment of the subjects enrolled. The Principal Investigator shall use all reasonable efforts to complete reports for all subjects that have been entered into the Study prior to the date of termination of this Agreement.

13.2 Upon termination or completion of the Study, the Principal Investigator and Institution shall return to the Sponsor all unused Study drugs, case report forms, whether completed or not and other related materials including but not limited to materials that were furnished to the Principal Investigator/Institution by or on behalf of the Sponsor. In case, the Sponsor desires destruction of aforementioned material, the Principal Investigator/Institution shall destroy such material in front of authorized representative of the Sponsor and shall also provide the Sponsor with a certificate of destruction.

14. Miscellaneous

14.1 It is agreed by the Parties that the Principal Investigator and Institution shall act in the capacity of independent contractor hereunder and not as employees, agents or joint ventures of or with Sponsor. Neither Principal Investigator nor Institution shall have any authority to represent, or bind the Sponsor.

14.2 Principal Investigator shall comply with all the terms of the Investigator undertaking letter he has provided to the Sponsor.

14.3 This Agreement contains the entire understanding of the Parties hereto and supersedes all prior oral and written agreements and understandings of the Parties except confidentiality agreement, if any, pertaining to the subject matter hereof.

14.4 If the terms contained in the Exhibit attached hereto conflict with any provisions contained in this Agreement, the terms contained in this Agreement shall prevail. Unless otherwise provided herein, this Agreement may not be amended, supplemented or otherwise modified except by an instrument in writing signed by the Parties hereto.

14.5 The Parties undertake to notify each other of all events that influence the performance of this Agreement. Notifications shall be made to the following addresses: -

(i) **To Sponsor** : Biological E. Ltd.
18/1 & 3, Azamabad
Azamabad, Hyderabad – 500020
Telangana, India

(i) **To Principal Investigator**: Dr. Bishan Swarup Garg
Title: Director-Professor of Community Medicine
Address: Mahatma Gandhi Institute of Medical Sciences,
Sewagram, Wardha, Maharashtra, India – 442102.
Mobile: +91- 9422141693
Email id: gargbs@gmail.com

For Biological E. Limited

N. Eswara Reddy
Sr. Vice President - Legal

(ii) **To Institution**:: Dr. Nitin M. Gangane
Title: Dean
Address: Mahatma Gandhi Institute of Medical Sciences, Sewagram, Wardha, Maharashtra, India – 442102.
Mobile: +91- 9422144856
Email id: dean@mgims.ac.in

Any dispute or difference whatsoever arising between the Parties out of or relating to the construction, meaning, scope, operation or effect of this Agreement or the validity or the breach thereof shall be exclusively settled by arbitration in Hyderabad, which shall be governed by the Arbitration and Conciliation Act, 1996 as amended from time to time. The arbitral tribunal shall comprise of sole arbitrator to be appointed by the managing director of the Sponsor. The language to be used in the arbitral proceedings shall be English. The award rendered by the arbitrator shall be final and binding upon the Parties hereto.

14.6 Parties agree that for claiming injunctive relief and for the enforcement of arbitral award courts in Hyderabad shall have exclusive jurisdiction in all matters arising out of or with this Agreement

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be duly executed as of the date first set forth above in triplicate each being legally authentic and binding.

For and on behalf of Biological E Limited	**Principal Investigator**	**For and on behalf of Institution**
For Biological E. Limited N. Eswara Reddy Sr. Vice President - Legal		
Signature & Date	**Signature & Date**	**Signature & Date**
Name: Mr. N.Eswara Reddy **Title: Sr.Vice President-Legal**	**Name: Dr. Bishan Swarup Garg** **Title:** Director-Professor of Community Medicine	**Name: Dr. Nitin M Gangane** **Title:** Dean
Seal: BIOLOGICAL E. LTD. HYDERABAD	**Seal:** Professor ... of Community ... M.G.I.M.S: SEWAGRAM	**Seal:** DEAN Mahatma Gandhi Institute of Medical Sciences, SEVAGRAM
Witness:	**Witness:** (Kamalakar S Mahajan) KHS, Sewagram	**Witness:** (Rajesh R. Tiwari) KHS, Sevagram

Exhibit - A

BUDGET AND PAYMENT SCHEDULE

The following budget will apply for the conduct of the ACTIVITY:

BECT074 CORBEVAX STUDY BUDGET					
Description	**No. of Subjects**	**visits**	**Unit Price Per visit**	**Unit price per subject**	**Total Amount Per Site**
Investigator Fee	75	7	**2,000**	14,000	**9,00,000**
Co-Investigator	75	7	**1,250**	8,750	**6,56,250**
Study Co-coordinator /Supporting team (Phlebotomist etc)	75	7	**750**	5,250	**3,93,750**
Institutional Overheads (on Investigator & Co-Investigator)	75		**20%**	4,550	**3,41,250**
Subject Travel Conveyance	75	7	**600**	4,200	**3,15,000**
				Variable cost* (A)	**26,06,250**
Description		Qty.	Uom	Unit Price	Amount
One time Setup Charges (courier, Internet, AV Recording and others)		1	LS	50,000	50,000
Study Archival Fee for 15 years		1	LS	60,000	60,000
				Total Fixed Expenses (B)	**1,10,000**
				Total Cost without Screen Failure	**27,16,250**

Total Cost (in Words): Twenty-seven Lakhs sixteen thousand two hundred fifty rupees only. (GST 18% extra as applicable by government laws, wherever applicable).

Budget Note:

- No charges will be paid for screen failure subjects
- TDS will be deducted on all payments as applicable.

The following ACTIVITY linked Payment Schedule will apply for release of total payment to the SITE:

S. No	Payment Milestone	Description of Milestone
1	1st Milestone	One time setup charges will be paid upon execution of Clinical trial agreement
2	2nd Milestone	30% After completion of subject enrolment
3	3rd Milestone	30% After completion of 56 Days
4	4th Milestone	40% After site close out along with Archival Fee

Payment will be made based on number of visits completed by the enrolled subjects at your site, which would be paid as per the above mentioned budget proposal + GST as applicable.

All study related payments should be made in favour of **The Dean, MGIMS, Sewagram, Wardha PAN No:** AAATK2046G

Bank Account No: 1784800213 **Bank Name:** Central Bank of India **Bank Address-**Sewagram, Wardha

IFSC Code: CBIN0280697.

For Biological E. Limited

N. Eswara Reddy
Sr. Vice President - Legal

తెలంగాణ तेलंगाना TELANGANA

Sl.No.20188 Date:30-09-2021
Sold to: M.PANDU RANGA REDDY
S/o LATE SEETHA RAM REDDY
For Whom: BIOLOGICAL E.LTD

E.VENKATESH AH 875253

LICENSED STAMP VENDOR
L.No.16-07-08/10,RL.NO.16-07-03/2019
D.No.5-3-856/17,G-17,NANDINI COMPLEX,
M.J.MARKET,HYD-12.CELL :9866313526

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement(the "**Agreement**")is made on this 26th day of October, 2021 ("**Effective Date**") by and between **Biological E. Limited**, a company incorporated under the Companies Act, 1956 and having its registered office situated at 18/1&3, Azamabad Hyderabad 500020, Telangana, India ("**Sponsor**"), of the First Part; and **Dr. Bishan Swarup Garg** , a registered medical practitioner holding MCI registration number MCI-20851, currently working as Director-Professor of Community Medicine in Mahatma Gandhi Institute of Medical Sciences, Sewagram, Wardha, Maharashtra, India - 442102 ("Principal Investigator"), of the Second Part; and **Mahatma Gandhi Institute of Medical Sciences**, a hospital established registered under the laws of India, having its place of business at Mahatma Gandhi Institute of Medical Sciences, Sewagram 442102 Wardha District, Maharashtra, India represented by its **Dean Dr. Nitin Gangane** ("Institution"), of the Third Part.

For Biological E. Limited

N. Eswara Reddy
Sr. Vice President - Legal

WHEREAS,

A. The Sponsor is a biopharmaceutical company, which develops, manufactures and markets innovative vaccines and biologics. Biological E. Limited has developed CORBEVAX Vaccine product and is desirous of testing the same in Children and Adolescents through a phase II & III Clinical Trial;

B. The Institution has its own premises fully equipped to conduct the Study mentioned under this Agreement;

C. The Sponsor has already identified the Principal Investigator based on her experience and expertise and also furnished sufficient information regarding the Study drug and the Protocol;

D. The Principal Investigator has, after careful review of the Protocol and other materials relating to the Clinical Trial conveyed her willingness to the Sponsor to conduct the proposed Study;

E. The Sponsor shall provide technical and financial support mentioned in this Agreement to the Principal Investigator to conduct the Clinical Trial and the Principal Investigator in lieu of such support has agreed to enter into this Agreement with the Sponsor; and

F. The Principal Investigator has obtained and shall maintain in full force and effect all permissions, sanctions and approvals from the Institution and relevant governmental and regulatory authorities to undertake and conduct the Clinical Trial;

NOW, THEREFORE, the Parties hereto, in consideration of the mutual covenants and premises contained herein, enter into this Agreement and agree as follows:

1. Definitions

1.1 "**Study**" or "**Clinical Trial**" shall mean study entitled:

"A Prospective, Randomised, Double-blind, Placebo controlled, Phase-II by III Study to Evaluate Safety, Reactogenicity, Tolerability and Immunogenicity of CORBEVAX Vaccine in Children and Adolescents." and all the title amendments thereto as the Parties may from time to time agree in writing.

1.2 "**Protocol**" shall mean:

The description of the Study mentioned in the Study protocol number **BECT072/Covid-19-phase-II&III/CTP-01** and all amendments thereto as the Parties may from time to time agree in writing.

1.3 "**Study Drug**" or "**Investigational Drug**" shall mean:

CORBEVAX Vaccine (Manufactured by Biological E. Ltd.).

1.4 "**Ethics Committee**" shall mean:

An independent body or an Institutional Ethics Committee, constituted and registered with the licensing authority under the provisions of Drugs and Cosmetic Act, 1945 and rules amended thereof.

2. Responsibility of the Principal Investigator and the Institution

2.1 The Institution agrees to provide full support to the Principal Investigator who is working in Department of Community Medicine in the institution, to conduct the Clinical Trial in

For Biological E. Limited

N. Eswara Reddy
Sr. Vice President - Legal

its premises and utilize reasonably the facilities available in the Institution for the Study and shall allot qualified co-investigators, Co-ordinators and other persons with prior consent of the Sponsor, for proper conduct of the Study in accordance with the terms of this Agreement and the Protocol.

2.2 The Principal Investigator and Institution shall be jointly and severally shall be responsible (a) to conduct and complete the Clinical Trial of the Sponsor strictly in accordance with the applicable regulatory requirements and the Protocol as approved by the Institutional Ethics Committee; (b) to comply with all applicable rules, regulations and guidelines, both national and international, including but not limited to, ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95), Indian GCP and New drugs & Clinical Trial Rules 2019 issued by CDSCO, Directorate General of Health Services, Govt. of India; Drugs and Cosmetics Act 1940 and Rules, gazette notifications made thereunder (as amended from time to time), ethical principles contained in the current revision of Declaration of Helsinki, Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council of Medical Research ("**Applicable Laws & Guidelines**"); (c) to fulfill all other terms and conditions stipulated herein and in the Annexures hereto, during the period of, and also after the completion of, the Clinical Trial as agreed upon by him; and (d) to provide Sponsor a copy of registration certificate issued by the licensing authority to Ethics Committee before initiation of the Clinical Trial.

2.3 The Principal Investigator along with any co-investigator employed/assigned in the Institution shall personally review all case report forms to assure its completeness and accuracy. A case report form is deemed complete when:

(i) the case report form has been completed by the Principal Investigator in accordance with Study requirements;

(ii) it relates to a properly qualified subject who participated in and completed the Study in accordance with all Study requirements and directions from the Sponsor; and

(iii)it can be used in all analyses of the Study results.

The Principal Investigator undertakes that all data shall be submitted in a timely manner to the Sponsor.

2.4 Principal Investigator shall at all-time exercise independent medical judgment as to the compatibility of each subject with the Study as per Protocol requirements. Principal Investigator shall notify the Sponsor, Chairman of Ethics Committee and licensing authority within twenty-four (24) hours of any serious adverse events related to or unrelated to the Study Drugs and of overdoses and any other event as set forth in detail in the Protocol.

2.5 The Principal Investigator and Sponsor shall provide report of serious adverse events after due analysis to the Chairman of the Ethics Committee, Head of the Institution and to the licensing authority of any deviations in the Protocol or serious adverse events immediately and in any event within fourteen (14) calendar days from the date of occurrence of such deviation and/or serious adverse events, as the case may be.

2.6 The Principal Investigator and Sponsor shall provide report of serious adverse events after due analysis to the Chairman of Ethics Committee, licensing authority and to the Head of the Institution within fourteen (14) calendar days of occurrence of such serious adverse events.

For Biological E. Limited

N. Eswara Reddy
Sr. Vice President - Legal

2.7 In the event the Principal Investigator becomes unwilling or no longer in the employment of the Institution or unable to perform the Study, at any latter stage, the Principal Investigator/Institution shall provide notice to the Study subjects, Ethics Committee and Sponsor at least thirty (30) days before Principal Investigator intends to stop/withdraw from the Clinical Trial. The Principal Investigator and Institution shall endeavor to promptly recommend a replacement Principal Investigator, from among the consultants of the Institution. The Sponsor shall have the exclusive right to approve or reject any such replacement of Principal Investigator. The new principal investigator which is approved by the Sponsor shall be required to agree to the terms and conditions of this Agreement. In the event Sponsor does not approve such new principal investigator, the Study will be terminated immediately and no further payment shall be made to Principal Investigator and the Institution. Upon such termination, Institution shall (i) ensure appropriate therapy and follow-up for enrolled Study subjects; (ii) maintain all Study related documents for such time as may be required by Sponsor and shall take measures to prevent accidental or premature destruction of these documents and (iii) undertake to complete the Study on all the enrolled subjects as per approved Protocol.

3. <u>Conduct of Clinical Trial</u>

3.1 The Sponsor shall appoint it's employee to monitor the Clinical Trial and also reserves it's right to nominate any other person as monitor.

3.2 Principal Investigator shall enroll the allotted number of subjects in a period of 60 calendar days from the date of study site initiation. It is hereby clarified that no payment shall be made to the Principal Investigator, if the Study subject is not participating in that particular visit.

3.3 Principal Investigator and the Institution agrees that if Principal Investigator cannot conduct and complete the Study to the satisfaction of the Sponsor within the time prescribed by the Sponsor on the agreed number of subjects as per clause 3.2 above, the Sponsor may at its sole discretion and without prejudice to its rights under this Agreement, send a notice to the Principal Investigator and the Institution to discontinue the Study. The Principal Investigator and Institution agrees to cease recruiting subjects for the Study immediately upon receiving such notice from the Sponsor to stop recruiting the subjects for the Clinical Trial.

3.4 Principal Investigator shall ensure that the informed consent form signed by or on behalf of the Study subjects have been reviewed and approved by Ethics Committee prior to initiation of the Study. Upon approval of the informed consent form by the Ethics Committee, a copy of the approval letter shall be provided to the Sponsor by the Principal Investigator, who shall further obtain informed consent form duly signed by each of the subjects/Legally acceptable representatives on behalf of the Study subjects enrolled in the Study in accordance with Applicable Laws and Guidelines. The Principal Investigator shall ensure to maintain informed consent process of individual subjects including procedure of providing information to the subjects and their understanding on such consent.

3.5 The Study of the Sponsor is being entrusted to the Principal Investigator and Institution directly by the Sponsor as a technical assignment, based on the skill, knowledge and experience of the Principal Investigator in the specialty areas related to the Clinical Trial and Institution's experience as a qualified testing facility in the Clinical Trial. The Principal Investigator shall be personally obligated to conduct and complete the Clinical Trial in accordance with the Protocol as well as other terms and conditions specified by the Sponsor herein. All items received from the Sponsor, from time to time, (including, but not limited to, Study Drug, documents, Confidential Information, communications,

For Biological E. Limited

N. Eswara Reddy
Sr. Vice President - Legal

instructions etc.), records and registers required to be maintained and all data generated hereunder by the Principal Investigator, shall be under the exclusive care, custody and responsibility of the Principal Investigator throughout the period of the Clinical Trial and thereafter for a period of fifteen (15) years after the Sponsor has discontinued its Study or such longer period as required by Applicable Laws & Guidelines. At the end of such period mentioned above, the Institution shall obtain written approval from Sponsor before destruction of such data.

3.6 Principal Investigator agrees to assume all the legal obligations of the Sponsor for the Study related duties and functions under this Agreement and the Protocol.

3.7 Principal Investigator/Institution shall ensure that all the individuals involved in the conduct of the Study shall strictly adhere to the terms and conditions of this Agreement. Institution and Principal Investigator represents and warrants that it shall not use in any capacity, in connection with the Study, any individual who is not duly qualified or has been debarred pursuant to any Applicable Laws & Guidelines or against whom any action, suit, claim, investigation or legal or administrative proceeding is pending. Principal Investigator represents and warrants that no action, suit, claim investigation or legal or administrative proceeding is pending or threatened relating to Principal Investigator's debarment and/or debarment of the persons engaged by Principal Investigator to assist for the Study.

3.8 Principal Investigator represents and warrants that he has obtained and shall maintain in full force and effect all the necessary approvals, permissions and sanctions from the Institution, Ethics Committee and all the government and regulatory authorities to conduct the Clinical Trial.

4. Study Drug

4.1 The Sponsor will provide the Study Drug to the Principal Investigator/ Institution free of cost/charge and in such quantities sufficient to complete the Study, together with guidelines and descriptions for the safe and proper use, administration, storage and disposal of the Study Drug. Principal Investigator shall use Study Drug and other items provided by the Sponsor only to conduct the Study in accordance with the Protocol and Applicable Laws & Guidelines and instructions of the Sponsor and shall not chemically, physically or otherwise modify the Study Drug, unless specifically required to do so by the Sponsor in writing to the Principal Investigator. Principal Investigator and Institution jointly and severally agrees that they shall administer, handle, use, store, and or dispose the Study Drug and other items provided by the Sponsor in compliance with Sponsor's instructions and all Applicable Laws & Guidelines.

4.2 The Parties hereby clearly understand that the subject matter of the Agreement is to clinically evaluate the safety and tolerability of the Study Drug and that the Clinical Trial shall not constitute complete treatment to cure any disease.

5. Visit and Inspection

5.1 The Sponsor or its authorized representatives, and regulatory authorities to the extent permitted by law, shall have the absolute right to:

i. examine and inspect the Institution's facilities whenever Principal Investigator is conducting Study;

ii. inspect and copy all data and work products relating to the Study, and

For Biological E. Limited

N. Eswara Reddy
Sr. Vice President - Legal

iii. audit all reports and data from Principal Investigator to ensure compliance with the terms of this Agreement and Protocol.

6. Payment

6.1 Institution hereby undertakes that in consideration of Principal Investigator's carrying out Clinical Trial at the Institution in accordance with the terms of this Agreement, Sponsor shall make the payment to the Principal Investigator as per the payment schedule as set forth in Exhibit A. All the payments shall be made directly to the Principal Investigator/designee.

6.2 The Parties agree that the payment of the amount set forth in Exhibit A will be paid by the Sponsor to the Principal Investigator to compensate all the expenses incurred by him in execution and conducting the Clinical Trial at the Institution so that, neither the Study subject, nor the insurance program nor the public assistance agency shall be liable for the same. The payment of the amount set forth in Exhibit A is also meant to compensate Principal Investigator for the professional and clerical allowances, laboratory examinations for all the activities as per the Protocol including but not limited to, preparation of the subject records, medication accountability records and other trial related documentation.

6.3 Institution and Principal Investigator shall not be entitled to any other expenses, benefits, consideration or fee of co-investigator, whether monetary or otherwise under this Agreement or elsewhere and it covers all out of pocket expenses incurred by Principal Investigator in conducting Study at the Institution including but not limited to telephone, telex, travel and office expenses.

6.4 Sponsor shall be entitled to deduct tax at source (if applicable) while making payment to Principal Investigator on behalf of the Institution under this Agreement.

6.5 In case of very slow/no recruitment, after providing stipulated time of recruitment, at any participating site the competitive recruitment strategy of study subjects would be planned to achieve the overall study timeline based upon the decision taken by the Biological. E (Sponsor). The additional supplement payment towards the additional subject's recruitment will be made by Biological E to the payee as per the same budget calculation and payment schedule.

7. Indemnification and Insurance

7.1 The Sponsor agrees that it shall indemnify, defend and hold harmless the Principal Investigator from and against all suits, claims, losses or damages, arising as a result of (i) either breach of any representation/warranty made by the Sponsor herein and or (ii) of personal injury to (including death of) Study subject, which injury is sustained due to serious adverse events of the Study Drug except to the extent such claims are attributable to:

a) the failure of the Principal Investigator, any co-investigator or any other personnel involved in the performance of the Study to adhere to the terms of the Study Protocol or any written instruction relative to the administration, use, handling, storage of any drugs used in the performance of the Study, or comply with any Applicable Laws & Guidelines; or

b) Any negligent or wrongful act or omission, or willful malfeasance/ misconduct of the Principal Investigator/ co-investigator/any other personnel (including employees, agents or independent contractors) involved in the performance of the Study.

For Biological E. Limited

N. Eswara Reddy
Sr. Vice President - Legal

7.2 It is a condition precedent to the Sponsor's indemnification obligations under above mentioned clause 7.1 that:

a) whenever Principal Investigator has information from which it may reasonably conclude an incident of bodily injury or death has occurred, Principal Investigator shall immediately give notice to Sponsor of all pertinent data surrounding such incident. In addition, Principal Investigator shall comply with all of their obligations with regard to adverse event reporting procedures as set forth in this Agreement and the Protocol; and

b) the Principal Investigator under clause 7.1 above must (i) promptly notify the Sponsor of the assertion of any such claims (ii) authorize and permit Sponsor to conduct and exercise sole control of the defense and deposition (including all decisions relative to litigation, appeal or settlement) of such claims and (iii) fully cooperate with Sponsor regarding any such claims (including access to pertinent records and documents and provision of relevant testimony) and in determining the scope of Sponsor's obligations hereunder. Subject to the foregoing, Principal Investigator may also participate with prior consent of the Sponsor in any such claims at her own cost and expense. Principal Investigator agrees to cooperate with and to authorize Sponsor to carry out sole management and defense of such claim or action. Principal Investigator shall not compromise or settle any claim or action without the prior written approval of Sponsor.

7.3 The Principal Investigator and the Institution hereby irrevocably agree that they shall indemnify and hold harmless the Sponsor, its present and future directors, officers and or employees against any and all consequences, damages, suits, actions, claims, costs and expenses including reasonable attorney's fees and any cost of medical treatment of any illness or injury sustained by a Study subject, cost of fresh studies (collectively the "**Claims**") arising out of or in relation to (i) any breach of any of the representations and/or warranties made/held out by the Principal Investigator and the Institution in this Agreement; or (ii) breach of any of the terms of this Agreement by the Principal Investigator, the Institution or any individual engaged by Principal Investigator to support him in the conduct of the Study; or (iii) intentional deviation or omission or negligence in conducting the Study by the Principal Investigator, the Institution or any individual engaged by Principal Investigator to support him in the conduct of the Study; or (iv) failure to follow the instructions of Sponsor by the Principal Investigator and the Institution; or (v) failure of the Principal Investigator and the Institution to conduct the Study in accordance with the Protocol, Applicable Laws & Guidelines.

7.4 Insurance

a) The Sponsor undertakes that it will secure and maintain in full force and effect throughout the performance of the Study (and following termination or early termination of the Study and to cover any claims arising from the Study) a clinical trial liability insurance policy from an Indian insurance company for an amount appropriate to, and in accordance with, the Sponsor's activities and obligations contemplated in this Agreement.

b) The Institution undertakes that it will secure and maintain in full force and effect throughout the performance of the Study (and following termination or early termination of the Study and to cover any claims arising from the Study) a clinical trial liability insurance coverage from an Indian insurance company for the Study for an amount appropriate to, and in accordance with, the its activities and obligations contemplated in this Agreement.

For Biological E. Limited

N. Eswara Reddy
Sr. Vice President - Legal

8. Publication of Results

It is the general policy of the Sponsor to encourage publication of results of Clinical Trial on a case to case basis. However, according to good scientific practice no interim data should be published by the Principal Investigator/ Institution unless agreed by the Parties in writing. It is further agreed that when the Principal Investigator/ Institution request for publications, the manuscript shall be based on final report of the Study and before any publication it shall be sent to the Sponsor for its perusal, comments and approval. The Sponsor may at its discretion may either refuse the publication or forward it to the Principal Investigator/ Institution along with its comments or modifications which shall be final and binding on the Principal Investigator/ Institution.

9. Publicity and Product Promoting Activity

It is agreed that no Party shall issue any press release or other third party communication relative to this Agreement without the prior written consent of the other Party except to the extent that the Sponsor shall have absolute right to issue any press release relating to the Study related data. Principal Investigator shall not use the name of the Sponsor and/or its employees in any advertising or sales promotional material or in any other way not required by law or regulation without the prior written consent of the Sponsor.

10. Confidentiality

10.1 The Principal Investigator and the Institution agree to keep confidential and secret all materials, documents and confidential information that the Sponsor discloses to the Principal Investigator and the Institution pursuant to this Agreement and also all materials, documents and information's gathered, generated or developed by Principal Investigator and the Institution under the Study including but without limitation to results and discoveries emanated from the Study, regardless of whether such information is marked as "Confidential," "Proprietary" or the like, which is furnished to the Principal Investigator by or on behalf of the Sponsor whether in written, electronic, oral, visual or other form (**"Confidential Information"**).

10.2 The Principal Investigator and the Institution agree, represent and warrant that any Confidential Information that they receive shall be protected at least, with the same degree of care and protection in the strictest confidence as of its own and shall take all reasonable measures to protect it. The Principal Investigator and the Institution shall use such Confidential Information only for the purpose of fulfilling their obligations mentioned herein and shall not disclose such Confidential Information without the prior written consent of the Sponsor to any third party except as required by law provided that the Principal Investigator and the Institution shall:

(i) first give prompt notice of such disclosure requirement to the Sponsor so as to seek any limitations on or exemptions from such disclosure requirement; and

(ii) reasonably co-operate the Sponsor in any such efforts of defense to be made before appropriate authority.

10.3 Principal Investigator and/or the Institution may disclose Confidential Information to their co-investigator, hospital authorities, Ethics Committee members and others who are required to be involved in the Study on a need-to-know basis provided that: (i) such receiving party shall always remain liable to maintain the confidentiality in terms hereof and (ii) all such receiving party shall be bound by obligations of confidentiality with respect to such Confidential Information at least as stringent as those provided herein. Principal Investigator and the Institution shall be liable for any breach of this Agreement

For Biological E. Limited

N. Eswara Reddy
Sr. Vice President - Legal

by its representatives. The obligations of confidentiality hereunder shall continue for a period of fifteen (15) years from the date the Confidential Information is disclosed or developed. The obligation of confidentiality hereunder shall not apply to information that Principal Investigator and/or the Institution can prove and produces credible written evidence to establish that such information or material:

(a) at the time of disclosure or after disclosure to the Principal Investigator /Institution becomes part of the public domain by publication or otherwise, except by breach of this Agreement by the Principal Investigator/ Institution or their successors or assigns;

(b) by written records were in the Principal Investigator/ Institution's possession at the time of disclosure by the Sponsor were not acquired directly or indirectly from the Sponsor;

(c) subsequent to disclosure hereunder, the Principal Investigator/ Institution receives from a third party legally in a position to provide with information to the Principal Investigator/ Institution, provided, however, that such was not obtained by said third party directly or indirectly from the Sponsor under an obligation of confidentiality.

10.4 All clinical data, including case report forms and other information and discoveries resulting from the Study ("**Inventions**") shall be the sole property of the Sponsor and will be treated as "Confidential Information" by the Principal Investigator and the Institution and may be used by the Sponsor in any manner. Further, Principal Investigator and the Institution shall assign to the Sponsor all of their rights, title, and interest in such Inventions.

10.5 All Confidential Information disclosed pursuant to this Agreement, together with all copies thereof, summaries and all information, know-how, data and materials generated by the use of the Confidential Information, shall be returned to the Sponsor by Principal Investigator and the Institution forthwith upon written request or upon termination of this Agreement, whichever is earlier.

10.6 Principal Investigator and the Institution agree that the Confidential Information is of a special and unique kind, the protection of which is essential to the operation of the Sponsor, and that if there is a breach (either actual or threatened) by the Principal Investigator/ Institution or co-investigator or a party in receipt of Confidential Information under this Agreement, the Sponsor would have no complete remedy at law. Therefore, in addition to any other remedies that may be available at law or equity, Principal Investigator and Institution agree that the Sponsor shall be entitled to seek from any court of competent jurisdiction, injunctive relief, specific performance or other equitable relief, for any actual or threatened violation of this Agreement (without the necessity of posting any bond or other security proving special damages) and that the Principal Investigator and Institution shall not oppose the granting of such relief. In the event of any litigation relating to this Agreement, if a court of competent jurisdiction determines that this Agreement has been breached by one Party, then that Party shall reimburse the non-breaching Party for all its costs and expenses (including, without limitation, attorney fees and other legal expenses) incurred in connection with all such litigation.

11. <u>Severability & Waiver and Assignment</u>

11.1 The invalidity or unenforceability of any term or provision of this Agreement, the remaining provisions shall stand to the fullest extent permitted by law. The failure of any Party at any time or times to require performance of any provision hereof shall in no manner affect the right of such Party at a later time to enforce such provision or any other provision of this Agreement.

For Biological E. Limited

N. Eswara Reddy
Sr. Vice President - Legal

11.2 Waiver by either Party or the failure by either Party to claim a breach of any provision of this Agreement shall not be deemed to constitute a waiver or estoppels with respect to any subsequent breach of any provision hereof.

11.3 This Agreement shall not be assigned as a whole or in part by Principal Investigator and/or Institution without the prior written consent of the Sponsor.

12. Validity & Termination

12.1 This Agreement shall become effective on the date first set forth above and shall continue till the completion of the study thereof or until this Agreement is terminated due to:-

a. Determination by the Sponsor that the Principal Investigator is not performing the Study as required in the Protocol and/ or is not meeting the agreed upon enrollment;

b. Failure of the Principal Investigator's or its associated staff or any other person engaged in the Study (excluding subjects) to be available, upon reasonable prior notice by the Sponsor, to meet at mutually convenient time with the Sponsor enabling it to monitor the course of the Study as necessary and to discuss information relevant to the Study;

c. Determination by the Sponsor that business or scientific considerations require termination;

d. Case report forms provided to the Principal Investigator by the Sponsor to be used in the Study, are not legibly completed and forwarded to the Sponsor or its designated representative;

e. At the request of either DCGI or Ethics Committee;

f. Notification to the Sponsor from central or state regulatory authorities to terminate the Study;

g. Failure of the Principal Investigator/ Institution to provide access by the Sponsor's representatives all original medical records necessary to verify entries on the Study case report forms;

12.2 The Sponsor may terminate this Agreement:

a) At any time upon thirty (30) days written notice to the Principal Investigator/Institution.

b) Immediately for safety reasons relating to the use of the Study Drug.

12.3 Either Party may terminate this Agreement by notice in writing to the other Party if the other Party commits a breach of this Agreement, and which, in the case of a breach capable of remedy, shall not have been remedied by the defaulting Party within thirty (30) days of receipt of notice identifying the breach and requiring its remedy.

13. Effect of Termination

13.1 Upon receipt of notice of termination, the Principal Investigator shall immediately stop enrolling subjects into the Study and to the extent medically permissible, cease administering the Study Drug and conducting Clinical Trial on subjects already entered into the Study. In case of early termination of this Agreement, due to any reason the

For Biological E. Limited

N. Eswara Reddy
Sr. Vice President - Legal

Principal Investigator shall request all Study subjects within one month from the date of termination notice to attend a follow up visit for proper safety assessment of the subjects enrolled. The Principal Investigator shall use all reasonable efforts to complete reports for all subjects that have been entered into the Study prior to the date of termination of this Agreement.

13.2 Upon termination or completion of the Study, the Principal Investigator and Institution shall return to the Sponsor all unused Study drugs, case report forms, whether completed or not and other related materials including but not limited to materials that were furnished to the Principal Investigator/Institution by or on behalf of the Sponsor. In case, the Sponsor desires destruction of aforementioned material, the Principal Investigator/Institution shall destroy such material in front of authorized representative of the Sponsor and shall also provide the Sponsor with a certificate of destruction.

14. Miscellaneous

14.1 It is agreed by the Parties that the Principal Investigator and Institution shall act in the capacity of independent contractor hereunder and not as employees, agents or joint ventures of or with Sponsor. Neither Principal Investigator nor Institution shall have any authority to represent, or bind the Sponsor.

14.2 Principal Investigator shall comply with all the terms of the Investigator undertaking letter he has provided to the Sponsor.

14.3 This Agreement contains the entire understanding of the Parties hereto and supersedes all prior oral and written agreements and understandings of the Parties except confidentiality agreement, if any, pertaining to the subject matter hereof.

14.4 If the terms contained in the Exhibit attached hereto conflict with any provisions contained in this Agreement, the terms contained in this Agreement shall prevail. Unless otherwise provided herein, this Agreement may not be amended, supplemented or otherwise modified except by an instrument in writing signed by the Parties hereto.

14.5 The Parties undertake to notify each other of all events that influence the performance of this Agreement. Notifications shall be made to the following addresses: -

(i) **To Sponsor** : Biological E. Ltd.
18/1 & 3, Azamabad
Azamabad, Hyderabad – 500020
Telangana, India

(ii) **To Principal Investigator**: Dr. Bishan Swarup Garg
Title: Director-Professor of Community Medicine
Address: Mahatma Gandhi Institute of Medical Sciences,
Sewagram, Wardha, Maharashtra, India – 442102.
Mobile: +91- 9422141693
Email id: gargbs@gmail.com

(iii) **To Institution**:: Dr. Nitin M. Gangane
Title: Dean
Address: Mahatma Gandhi Institute of Medical Sciences,
Sewagram, Wardha, Maharashtra, India – 442102.
Mobile: +91- 9422144856
Email id: dean@mgims.ac.in

For Biological E. Limited

N. Eswara Reddy
Sr. Vice President - Legal

Any dispute or difference whatsoever arising between the Parties out of or relating to the construction, meaning, scope, operation or effect of this Agreement or the validity or the breach thereof shall be exclusively settled by arbitration in Hyderabad, which shall be governed by the Arbitration and Conciliation Act, 1996 as amended from time to time. The arbitral tribunal shall comprise of sole arbitrator to be appointed by the managing director of the Sponsor. The language to be used in the arbitral proceedings shall be English. The award rendered by the arbitrator shall be final and binding upon the Parties hereto.

14.6 Parties agree that for claiming injunctive relief and for the enforcement of arbitral award courts in Hyderabad shall have exclusive jurisdiction in all matters arising out of or with this Agreement.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be duly executed as of the date first set forth above in triplicate each being legally authentic and binding.

For and on behalf of Biological E Limited	**Principal Investigator**	**For and on behalf of Institution**
For Biological E. Limited N. Eswara Reddy Sr. Vice President - Legal		
Signature & Date	**Signature & Date**	**Signature & Date**
Name: Mr.N.Eswara Reddy **Title:** Sr. Vice President-Legal	**Name: Dr. Bishan Swarup Garg** **Title:** Director-Professor of Community Medicine	**Name: Dr. Nitin M Gangane** **Title:** Dean
Seal:	**Seal:** Dr. B. S. Garg Director Dr. Sushila Nayar School of Public Health Mahatma Gandhi Institute of Medical Sciences Sewagram 442... Wardha	**Seal:** DEAN Mahatma Gandhi Institute of Medical Sciences, SEVAGRAM
Witness:	**Witness:** (Rameshwar Mahija) KHS, Sevagram	**Witness:** (Rajesh R. Tiwari) KHS, Sevagram

Exhibit - A

BUDGET AND PAYMENT SCHEDULE

The following budget will apply for the conduct of the ACTIVITY:

BECT072– COVID-19-PHASE-II&III STUDY BUDGET			
Description	**Visits**	**Unit Price Per visit**	**Per subject cost**
Investigator Fee	9	1800	16,200
Co-Investigator	9	1000	9000
Study Co-ordinator/Supporting team (Phlebotomist etc)	9	750	6750
Institutional Overheads (on Investigator & Co-Investigator)		20%	5040
Subject Travel Conveyance	9	600	5400
Variable cost Per Subject (A)			**42,390**
Description	Qty.	Uom	
One time Setup Charges (courier, Internet, AV Recording and others)	1	LS	50000
Study Archival Fee for 15 years	1	LS	60000
Total Fixed Expenses (B)			**1,10,000**

(GST 18% extra as applicable by government laws, wherever applicable).

Budget Note:

- INR. 2600 will be paid for each screen failure subject.
- TDS will be deducted on all payments as applicable.

The following ACTIVITY linked Payment Schedule will apply for release of total payment to the SITE:

S. No	Payment Milestone	Description of Milestone
1	1st Milestone	50,000 (Setup cost)
2	2nd Milestone	30% After completion of subject enrolment
3	3rd Milestone	30% After completion of 56 Days
4	4th Milestone	40% After site close out along with Archival Fee

Payment will be made based on number of visits completed by the enrolled subjects at your site, which would be paid as per the above mentioned budget proposal + GST as applicable.

All study related payments should be made in favour of **The Dean, MGIMS, Sewagram, Wardha PAN No:** AAATK2046G

Bank Account No: 1784800213 **Bank Name:** Central Bank of India **Bank Address-**Sewagram, Wardha

IFSC Code: CBIN0280697.

For Biological E. Limited

N. Eswara Reddy
Sr. Vice President - Legal

unicef | for every child

United Nations Children's Fund | UNICEF Field Office for Maharashtra
B wing, 4th Floor, 215 Atrium, Andheri Kurla Road, Chakala, Andheri (East), Mumbai - 400 093, Maharashtra, INDIA
Telephone;+ 91 22 49791469; Telefax: + 91 22 49791496; website:www.unicef.org;

MAH/CDN/2021/117

7th September 2021

Dr. Subodh Gupta,
Professor & Head of Department,
Department of Community Medicine,
Mahatma Gandhi Institute of Medical Sciences
Sewagram
Wardha-442102

Dear Dr. Gupta,

Sub: Revised letter of commitment to Support for project 'Aarambh'-Nurturing and Nourishing care for ECD- Scale up phase for the period April to December 2021.

This has reference to your letter No. DSNSPH/ECD/85/2021 dated 6th September 2021 explaining the change of budget with reasons and detailed proposal and activities budget for supporting the scale up of ECD project-Aarambh in the state jointly with ICDS Commissionerate and DWCD. We wish to place it on record that the successful pilot of ECD in Yavatmal and Aurangabad lead by MGMIS Sewagram team is highly appreciated by the Principal Secretary DWCD, GoM and Commissioner ICDS. It is encouraging to see the programme being scaled up in the state. We are committed to support this scale up phase of the programme for taking the agenda of Early Childhood Development forward. We have reviewed the proposal and confirm our support up to a maximum of Rs**. 1,88,41,800/- (Rupees One Crore, Eighty Eight Lakh, Forty One Thousand and Eight Hundred only) for the period from April to December 2021** as follows:

Sr.No	Particulars / Outputs	Approved budget (Rs)
1	Team building for program implementation	47,47,000
2	Travel of Program staff / Investigators* (To be undertaken based on government guidance and directives on lockdown and restrictions in view of COVID pandemic)	22,42,000
3	IT support for scale up	4,85,800
4	Development of ECD package for scale up	15,60,000
5	Organize batches for Master Trainers, workshops and advocacy meetings	66,06,000
6	Additional activities in intensive districts	2,00,000
7	Consultancy support for scale up	25,00,000
8	Office management Expenses	5,01,000
Total		**188,41,800**

The approved budget is in the attached annex. The expenditure shall be guided as follows:

1. The cash assistance released should be utilized only for those activities indicated above and in accordance with the approved detailed budget attached that was submitted by your office.
2. The cash assistance released by UNICEF cannot be used for procurement of any supplies and equipment other than agreed in the proposal and approved budget.
3. The cash assistance released should be utilized within three months from the date of release of funds.
4. If your department / organization is not in a position to utilize UNICEF's cash assistance within a period of four months from the date of release of the funds, the unutilized cash assistance should be refunded to UNICEF.
5. Deviation in any budget line item should not exceed 20%. Deviations, if any, should be agreed to in writing by UNICEF prior to expenditure and provided that the total approved budget is not exceeded.

As per our financial norms, on completion of the project / tranche, we would request you to let us have the completed FACE form, a budget vs actual expenditure statement (SOE), and an activity report to enable us to liquidate this amount and release reimbursement, as appropriate.

As a part of our standard operating procedure, we need to undertake the financial assessment of implementing partners. In this regards, UNICEF operation and finance team may visit your office on periodic basis, upon mutually convenient dates, and review the financial process and systems with your accounts and finance staff.

With best wishes,

OIC for
Rajeshwari Chandrasekar
Chief of Field Office
UNICEF Maharashtra

unicef | for every child

United Nations Children's Fund | UNICEF Field Office for Maharashtra
B wing, 4th Floor, 215 Atrium, Andheri Kurla Road, Chakala, Andheri (East), Mumbai - 400 093, Maharashtra, INDIA
Telephone;+ 91 22 49791469; Telefax: + 91 22 49791496; website:www.unicef.org;

MAH/CDN/2021/194 21st December 2021

Dr. Subodh Gupta,
Professor & Head of Department,
Department of Community Medicine,
Mahatma Gandhi Institute of Medical Sciences
Sewagram
Wardha-442102

Dear Dr. Gupta,

Sub: Commitment to Support for project 'Aarambh'-Nurturing and Nourishing care for ECD-Scale up phase for the period January to March 2022.

This has reference to your letter No. C/Gen/6792 dated 16th December 2021 with budget and detailed proposal and activities budget for supporting the scale up of ECD project-Aarambh in the state jointly with ICDS Commissionerate and DWCD. We wish to place it on record that the successful pilot of ECD in Yavatmal and Aurangabad lead by MGMIS Sewagram team is highly appreciated by the Principal Secretary DWCD, GoM and Commissioner ICDS. It is encouraging to see the programme being scaled up in the state. We are committed to support this scale up phase of the programme for taking the agenda of Early Childhood Development forward. We have reviewed the proposal and confirm our support up to a maximum of Rs**. 86,90,800/- (Rupees Eighty-six Lakh, ninety thousand and eight hundred only) for the period from January to March 2022** as follows:

Sr.No	Particulars / Outputs	Approved budget (Rs)
1	Team building for program implementation	18,60,800
2	Travel of Program staff / Investigators* (To be undertaken based on government guidance and directives on lockdown and restrictions in view of COVID pandemic)	14,05,000
3	IT support for scale up	2,50,000
4	Development of ECD package for scale up	3,92,000
5	Trainings, workshops / review and advocacy meetings	35,98,000
6	Additional activities in intensive districts	1,00,000
7	Consultancy support for scale up	8,90,000
8	Office management Expenses	1,95,000
Total		**86,90,800**

The approved budget is in the attached annex. The expenditure shall be guided as follows:

1. The cash assistance released should be utilized only for those activities indicated above and in accordance with the approved detailed budget attached that was submitted by your office.
2. The cash assistance released by UNICEF cannot be used for procurement of any supplies and equipment other than agreed in the proposal and approved budget.
3. The cash assistance released should be utilized within three months from the date of release of funds.
4. If your department / organization is not in a position to utilize UNICEF's cash assistance within a period of four months from the date of release of the funds, the unutilized cash assistance should be refunded to UNICEF.
5. Deviation in any budget line item should not exceed 20%. Deviations, if any, should be agreed to in writing by UNICEF prior to expenditure and provided that the total approved budget is not exceeded.

As per our financial norms, on completion of the project / tranche, we would request you to let us have the completed FACE form, a budget vs actual expenditure statement (SOE), and an activity report to enable us to liquidate this amount and release reimbursement, as appropriate.

As a part of our standard operating procedure, we need to undertake the financial assessment of implementing partners. In this regards, UNICEF operation and finance team may visit your office on periodic basis, upon mutually convenient dates, and review the financial process and systems with your accounts and finance staff.

With best wishes,

Rajeshwari Chandrasekar
Chief of Field Office
UNICEF Maharashtra

World Health Organization

COVERING LETTER
LETTRE D'ACCOMPAGNEMENT

GLOBAL PROCUREMENT AND LOGISTICS
Global Service Centre
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Registration	2022/1202698-0
Purchase Order	202800501
Unit Reference	CAH

Dr Subodh S Gupta
MAHATMA GANDHI INSTITUTE OF MEDICAL SCIENCES
WARDHA
P.O. Sewagram
WARDHA
MAHARASHTRA
442102
India

AGREEMENT FOR PERFORMANCE OF WORK (APW)

Re: Helping children and adolescents thrive and social inclusion of elderly by implementation of age-integrated interventions - Sahjeevan

We are enclosing the Agreement for Performance of Work between the World Health Organization and MAHATMA GANDHI INSTITUTE OF MEDICAL SCIENCES, WARDHA, in the amount of INR 1,806,800.00 (One Million Eight Hundred Six Thousand Eight Hundred), for conducting the above-mentioned work. We also enclosed two attachment(s) referenced in the Agreement.

Kindly acknowledge your acceptance of this contract by returning the email with a copy of duly signed Purchase Order (all pages).

For any technical questions relating to this Agreement, please contact the responsible technical officer, Rajesh MEHTA, +91-9810034685, mehtara@who.int.

Invoicing Instructions for Contractors who are legal entities (Company Contractors):
Invoices must be sent via email to accountspayable@who.int. Other than invoices, please do not send any enquiry to this email address. You may contact the above responsible technical officer for enquiries.

In order to ensure timely and accurate payment, invoices must include:

- Invoice number
- Purchase Order number against each invoice line;
- Invoice descriptions matching with PO descriptions
- Invoice currency same as the Purchase Order Currency also corresponding with the currency of the bank account provided to WHO;
- Supplier name as in the PO

Invoices shall be clearly readable and stamps or any other additional markings should not obscure the original invoice content. Invoices shall not be handwritten.

On behalf of the World Health Organization, we would like to thank you for your collaboration.

WHO Global Service Centre

cc: WHO India

Concerne: Helping children and adolescents thrive and social inclusion of elderly by implementation of age-integrated interventions - Sahjeevan

Veuillez trouver ci-joint l' Accord pour Exécution de Travaux entre l'Organisation Mondiale de la Santé et MAHATMA GANDHI INSTITUTE OF MEDICAL SCIENCES, WARDHA, pour un montant de INR 1,806,800.00, vous permettant de mener à bien le travail susmentionné. Veuillez également trouver 2 pièce(s) jointe(s) mentionnée(s) dans l'Accord.

Merci de confirmer votre acceptation de ce contrat en nous retournant le courriel et une copie dûment signee du Bon de Commande (complet)

World Health Organization

AGREEMENT FOR PERFORMANCE OF WORK
ACCORD POUR EXECUTION DE TRAVAUX

GLOBAL PROCUREMENT AND LOGISTICS
Global Service Centre
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Registration	2022/1202698-0
Purchase Order	202800501
Unit Reference	CAH

Pour toutes questions à caractère technique ayant trait à cet Accord, veuillez contacter le responsible Rajesh MEHTA, +91-9810034685, mehtara@who.int.

Instructions concernant la facturation pour les contractants qui sont des personnes morales.(Personne Morale):
Les factures doivent être envoyées par courriel à accountspayable@who.int. Outre les factures, n'envoyez aucune enquête à cette adresse de courrier électronique.Vous pouvez contacter le responsable technique responsable ci-dessus pour toute demande de renseignements.

De manière à garantir un paiement exact et ponctuel, les factures doivent impérativement comporter:

- Le Numéro de facture
- Le Numéro du bon de commande , répété à chaque ligne de facturation
- Des descriptifs des produits identiques à ceux du Bon de commande
- Une devise de facturation identique à celle du Bon de commande et à celle du compte en banque fourni à l'OMS
- Un intitulé de facture (nom de fournisseur) identique à celui du Bon de commande.

Les factures doivent être parfaitement lisibles. Le contenu de la facture ne doit en aucun cas être masqué par un tampon ou tout autre marquage. La facture ne doit pas être manuscrite.

Au nom de l'Organisation mondiale de la Santé, nous vous remercions de votre collaboration.

Centre mondial de services de l'OMS

cc: OMS India

Sensitivity: Internal & Restricted

World Health Organization

AGREEMENT FOR PERFORMANCE OF WORK
ACCORD POUR EXECUTION DE TRAVAUX

GLOBAL PROCUREMENT AND LOGISTICS
Global Service Centre
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Registration	2022/1202698-0
Purchase Order	202800501
Unit Reference	CAH

The WORLD HEALTH ORGANIZATION hereby agrees to provide to
L'ORGANISATION MONDIALE DE LA SANTÉ s'engage par la présente à fournir à
MAHATMA GANDHI INSTITUTE OF MEDICAL SCIENCES
WARDHA

WARDHA
INDIA

The Maximum amount of/*Un montant Maximum de*: INR 1,806,800.00 (One Million Eight Hundred Six Thousand Eight Hundred) **in respect of/*en vue de:*** Helping children and adolescents thrive and social inclusion of elderly by implementation of age-integrated interventions - Sahjeevan

For the period financed by this Agreement
Période du projet *financée par le présent Accord*
From/*De*: 19-JAN-2022
To/*A*: 18-JAN-2023

Summary of work/ *Description sommaire des travaux:*

Description of work under this Agreement/ *Description des travaux faisant l'objet du présent Accord:*

Detailed Terms of Reference attached

Financial arrangements/ *Dispositions financières:*

Payments will be made as follows/*Les versements seront effectués comme suit:*

	Deliverable/ Résultat	Due date/ *Date remise*	%	Currency amount/ *Montant en devise*
1	Upon counter signed contract	19-JAN-2022	25.00	451,700.00
2	Upon submission of resource materials	31-MAR-2022	25.00	451,700.00
3	Upon submission of an interim report of progress	01-JUL-2022	25.00	451,700.00
4	Upon submission of end line assessment and data analysis report along with a signed statement of expenditure	18-JAN-2023	25.00	451,700.00

Annexes

The following annexes form an integral part of this Agreement/ *Les annexes listées ci-dessous font partie intégrante de l'Accord:*

Annex/Annexes	File Name/ *Nom du fichier*
1	2022/1202698 | Contractual - Terms of Reference | Attached ToRs
2	2022/1202698 | Contractual - Budget Breakdown | Attached estimated budget

In the event that the annexes contain any provisions which are contrary to the terms of this Agreement, the terms of this Agreement shall take precedence/ *En cas de contradiction entre les dispositions des annexes et celles de l'Accord, les dispositions de l'Accord prévaudront dans tous les cas.*

Sensitivity: Internal & Restricted

World Health Organization

AGREEMENT FOR PERFORMANCE OF WORK
ACCORD POUR EXECUTION DE TRAVAUX

GLOBAL PROCUREMENT AND LOGISTICS
Global Service Centre
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Registration	2022/1202698-0
Purchase Order	202800501
Unit Reference	CAH

The undersigned parties, having read the terms and General Conditions, hereby conclude the present Agreement and confirm their agreement and acceptance thereof.
ON BEHALF OF WHO/ *POUR L'OMS*

Responsible WHO Technical Officer:
Fonctionnaire technique responsable de l'OMS:

Rajesh Mehta
Medical Officer – CAH (Newborn Child & Adolescent Health)
SE/FGL Family Health, Gender and Life Course

Approved by:
Approuvé par:

Neena RAINA
Coordinator
SE/FGL Family Health, Gender and Life Course

Authorized Signatory:
Signataire autorisé:

Santiago MILLAN

Mr Santiago Millan
Unit Head
Global Procurement and Logistics
(HQ/BOS/SUP/GPL)

Processed by:
Traité par:

Wan Nurul Asyikin Wan Adnan
Procurement Assistant
HQ/BOS Business Operations

PO Approved Date:
PO approuvé le:
21-JAN-22

Les parties soussignées, ayant lu les modalités et les Conditions Générales, ratifient l'Accord et confirment leur acceptation.

CONTRACTOR/ CONTRACTANT

Signature : .....

Date: ....

Name & Title/ Nom & Fonction : .....

Sensitivity: Internal & Restricted

World Health Organization

AGREEMENT FOR PERFORMANCE OF WORK
ACCORD POUR EXECUTION DE TRAVAUX

GLOBAL PROCUREMENT AND LOGISTICS
Global Service Centre
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Registration	2022/1202698-0
Purchase Order	202800501
Unit Reference	CAH

GENERAL CONDITIONS

1. **Relationship of the Parties.** It is understood that the execution of the work does not create any employer/employee relationship. In this respect, the contractor shall be solely responsible for the manner in which the work is carried out. Thus, WHO shall not be responsible for any loss, accident, damage or injury suffered by any person whatsoever arising in or out of the execution of this work, including travel. Insurance coverage for any such loss, accident, damage or injury will be the contractor's responsibility, including where appropriate, insurance coverage for persons used by the contractor to carry out the work.

Without prejudice to the foregoing, WHO may in certain cases provide insurance coverage for the contractor for travel in WHO vehicles. WHO declines all responsibility for non-payment by the insurance company of all or part of a claim submitted by or for the contractor for any accident. In case of such non-payment, the contractor shall be obliged to immediately reimburse all or part of any advance which WHO may have paid to the contractor.

2. **Rights.** All rights in the work, including ownership of the original work and copyright thereof, shall be vested in WHO, which reserves the right (a) to revise the work, (b) to use the work in a different way from that originally envisaged, or (c) not to publish or use the work.

3. **Payment and use of funds.** If the option, on the face of this agreement, for payment of a fixed sum applies, that sum is payable in the manner provided, subject to proper performance of the work.
If the option for payment of a maximum amount applies:
(i) the funds shall be used exclusively for the work specified in this agreement and any unspent balance shall be refunded to WHO. In this latter case, any financial statement required shall reflect expenditures according to the relevant main categories of expenditure; and
(ii) to the extent the contractor is required to purchase any goods and/or services in connection with its performance of this agreement, the contractor shall ensure that such goods and/or services shall be procured in accordance with the principle of best value for money. "Best value for money" means the responsive offer that is the best combination of technical specifications, quality and price.

Contractors who are legal entities (hereinafter referred to as "Company Contractors") must submit an invoice to the contracting WHO department or the WHO Global Service Center in order to receive payment. Invoices are not required from contractors who are individuals (hereinafter referred to as "Individual Contractors"), who can be paid upon receipt by the contracting WHO department of the required deliverables (including any required technical reports and financial statements) in a satisfactory manner.

The invoice from Company Contractors shall reflect any tax exemption to which WHO may be entitled by reason of the immunity it enjoys. WHO is, as a general rule, exempt from all direct taxes, custom duties and the like, and the Company Contractor will consult with WHO so as to avoid the imposition of such charges with respect to this agreement and the work performed hereunder. As regards excise duties and other taxes imposed on the provision of goods and services (e.g. value added tax), the Company Contractor agrees to verify in consultation with WHO whether in the country where the tax would be payable, WHO is exempt from such tax at the source, or entitled to claim reimbursement thereof. If WHO is exempt from value added tax, this shall be indicated on the invoice, whereas if WHO can claim reimbursement thereof, the Company Contractor agrees to list such charges on its invoices as a separate item and, to the extent required, cooperate with WHO to enable reimbursement thereof.

WHO shall have no responsibility whatsoever for any taxes, duties or other contributions payable by contractors. Payment of any taxes, duties and other contributions which a contractor may be required to pay shall be the sole responsibility of that contractor who shall not be entitled to any reimbursement thereof by WHO.

4. **Satisfactory performance.** If the work is not satisfactorily completed (and, where applicable, delivered) by the date fixed in this agreement and/or if any financial statement required is not satisfactorily submitted to WHO in accordance with general condition 5 below, WHO may specify an additional period within which this agreement must be satisfactorily performed. Normally such additional period should be of at least one week's

CONDITIONS GENERALES

1. **Relation entre les Parties**.Il n'est pas institué de relations d'employeur à employé aux fins de l'exécution des travaux. À cet égard, le contractant est seul responsable de la manière dont les travaux sont exécutés. Ainsi, l'OMS ne saurait assumer, à l'égard de quelque personne que ce soit, aucune responsabilité pour toute perte, tout accident, tout dommage ou toute blessure subis au cours ou en raison de l'exécution des travaux ou d'un déplacement les concernant. La mise en place d'une couverture d'assurance pour toute perte, tout accident, tout dommage ou toute blessure subis au cours ou en raison de l'exécution des travaux sera de la responsabilité du contractant y compris le cas échéant, toute couverture d'assurance pour les personnes auxquelles le contractant recourt pour l'exécution des travaux.

Sans préjudice de ce qui précède, l'OMS peut, dans certains cas, fournir une couverture d'assurance au contractant en cas de déplacement dans un véhicule de l 'OMS. L'OMS décline toute responsabilité pour le non-paiement par la compagnie d'assurance de la totalité ou d'une partie d'une demande d'indemnisation soumise par ou pour le contractant suite à un accident. En cas de non-paiement, le contractant sera obligé d' immédiatement rembourser la totalité ou une partie des avances que l'OMS pourrait lui avoir versées.

2. **Droits**. Tous les droits attachés aux travaux, y compris la propriété des travaux originaux et le droit d'auteur y afférent, seront dévolus à l'OMS qui se réserve le droit a) de réviser les travaux, b) d'utiliser les travaux d'une autre manière que celle initialement envisagée, ou c) de ne pas publier ni utiliser les travaux.

3. **Paiement et utilisation des fonds**. Si l'option applicable - prévue au recto du présent accord - est celle du paiement d'une somme fixe, cette somme est payable dans les conditions prévues, sous réserve de l'exécution satisfaisante des travaux.
Si l'option applicable est celle du paiement d'un montant maximum :
(i) les fonds seront utilisés exclusivement aux fins des travaux précisés dans l'accord et tout solde non utilisé sera remboursé à l'OMS. Dans ce dernier cas, les états financiers requis devront indiquer les montants engagés pour les principaux postes de dépense ; et
(ii) dans la mesure où le contractant doit acheter des biens et/ou des services quelconques dans le cadre de l'exécution du présent accord, il devra veiller à ce que l'achat de ces biens et/ou services soit effectué sur la base du principe du meilleur rapport qualité-prix. On entend par « meilleur rapport qualité-prix » l'offre qui présente la meilleure combinaison du point de vue des spécifications techniques, de la qualité et du prix.

Afin d'être payé, les contractants qui sont des personnes morales (ci-après dénommés « Personnes Morales ») doivent présenter une facture au département contractant de l'OMS ou au centre mondial de services de l'OMS. Les contractants qui sont des personnes physiques (ci-après dénommés « Personnes Physiques ») ne sont pas tenus de présenter de facture et peuvent être payés au moment de la réception, sous une forme satisfaisante, des livrables requis (y compris tout rapport technique et état financier requis) par le département contractant de l'OMS.

La facture des Personnes Morales devra refléter toute exonération d'impôt à laquelle l'OMS pourrait avoir droit en vertu de l'immunité dont elle jouit. De manière générale, l'OMS est exonérée de tout impôt direct, de tout droit de douane et de tous droits et taxes similaires, et la Personne Morale devra se mettre en rapport avec l'OMS afin d'éviter l'application des dites charges en rapport avec le présent accord et les travaux qui en résultent. En ce qui concerne les impôts et autres charges indirects imposés sur la fourniture de biens et de services, (par ex: taxe à la valeur ajoutée), la Personne Morale accepte de vérifier en consultation avec l'OMS si, dans le pays où la charge serait exigible, l'OMS est exonérée de ladite charge à la source ou est en droit d'en réclamer le remboursement. Si l'OMS est exonérée de la taxe à la valeur ajoutée, cela devra être indiqué sur la facture, tandis que si l'OMS est en droit d'en réclamer le remboursement, la Personne Morale accepte de mentionner cette charge de façon séparée sur ses factures et, si nécessaire, de coopérer avec l'OMS afin d'en obtenir le remboursement.

L'OMS n'encourra aucune responsabilité pour quelque taxe, droit ou autre contribution dû par les contractants. Le paiement de quelque taxe, droit ou autre contribution qu'un contractant pourrait être tenu de payer sera de l'entière responsabilité de celui-ci et il n'aura droit à aucun remboursement de la part de l'OMS à ce titre.

4. **Exécution satisfaisante**. Si les travaux ne sont pas accomplis correctement (et, le cas échéant, fournis) à la date prévue par l'accord ou si tout état financier requis n'est pas soumis de façon satisfaisante à l'OMS conformément à la condition générale 5 ci-dessous, l'OMS peut accorder un délai supplémentaire à l'expiration duquel l'accord doit être exécuté de façon satisfaisante. En règle générale, ce délai supplémentaire est d'une semaine au moins, à moins

Sensitivity: Internal & Restricted

duration, unless it is clear from the agreement that it was particularly important that the performance be completed on the date specified, in which case WHO may specify a shorter period or refuse to grant any additional period at all. In the event that the work is not satisfactorily completed and delivered on the date fixed, or any additional period granted by WHO and/or if any financial statement required is not satisfactorily submitted to WHO in accordance with general condition 5 below, WHO may immediately terminate this agreement (in addition to the other remedies), in accordance with general condition 13 below (without being held to grant the contractor an additional period of thirty (30) days to perform, complete and deliver the work).

5. **Completion and delivery.** The contractor shall complete and deliver the work to WHO (including any technical report that may be required) by the date fixed in this agreement or any additional period that may be granted by WHO under general condition 4 above. Any financial statement required shall be submitted within thirty (30) days thereafter at the latest. If the payment schedule on the face of this agreement provides for a final payment upon completion of the work, this final payment shall be made only after satisfactory receipt of all deliverables called for under this agreement, including any technical report and financial statement.

6. **Certification of status of individual contractors.** Each Individual Contractor certifies that he/she does not presently, and will not during the term of this agreement, hold any form of contractual relationship with WHO (including any WHO regional, country or project office, as well as any programme, center or other entity where staff is subject to WHO Staff Regulations and Rules) that confers upon the Individual Contractor the status of a WHO staff member. The Individual Contractor understands that a false statement may result in the cancellation of any or all contracts, and/or the withdrawal of any offer of a contract, with WHO.

7. **Research involving human participants. .**If and to the extent the work to be performed under this agreement includes surveys or interviews involving human participants (hereinafter referred to as "research"), the following shall apply:
7.1 Ethical Aspects
It is the responsibility of the contractor to safeguard the rights and welfare of human subjects involved in research performed under this agreement, in accordance with the appropriate national code of ethics or legislation, if any, and in the absence thereof, the Helsinki Declaration and any subsequent amendments. Prior to commencing any such research, the contractor shall ensure that (a) the rights and welfare of the subjects involved in the research are adequately protected, (b) freely given informed consent has been obtained for all participants, (c) the balance between risk and potential benefits involved has been assessed and deemed acceptable by a panel of independent experts appointed by the contractor, and (d) any special national requirements have been met.
7.2 Regulatory Requirements
It is the responsibility of the contractor to comply with the relevant national regulations pertaining to research involving human subjects.
7.3 Protection of Subjects
Without prejudice to obligations under applicable laws, the contractor shall make appropriate arrangements to eliminate or mitigate any negative consequences to subjects or their families resulting from the conduct of the research under this agreement. Such arrangements shall to the extent feasible include appropriate counseling, medical treatment and financial relief. The contractor furthermore undertakes to protect the confidentiality of the information relating to the possible identification of subjects involved in the research.

8. **Compliance with WHO Policies.** By entering into this agreement, the contractor acknowledges that it has read, and hereby accepts and agrees to comply with, the WHO Policies (as defined below). In connection with the foregoing:
- Company Contractors shall take appropriate measures to prevent and respond to any violations of the standards of conduct, as described in the WHO Policies, by their employees and any other persons engaged by them to perform the work under the agreement; and
- Individual Contractors shall not engage in any conduct that would constitute a violation of the standards of conduct, as described in the WHO Policies.
Without limiting the foregoing, the contractor shall promptly report to WHO, in accordance with the terms of the applicable WHO Policies, any actual or suspected violations of any WHO Policies of which the contractor becomes aware. For purposes of this agreement, the term "WHO Policies" means collectively: (i) the WHO Code of Ethics and Professional Conduct; (ii) the WHO Policy on Sexual Exploitation and Abuse Prevention and Response; (iii) the WHO Policy on Preventing and Addressing Abusive Conduct; (iv) the WHO Code of Conduct for responsible Research; (v) the WHO Policy on Whistleblowing and Protection Against Retaliation; and (vi) the UN Supplier Code of Conduct, in each case, as amended from time to time and which are publicly available on the WHO website

qu'il ne ressorte clairement de l'accord qu'il était particulièrement important d'achever les travaux à la date initialement prévue, auquel cas l'OMS peut accorder un délai plus court ou refuser la moindre prorogation. Si les travaux ne sont pas achevés et livrés de façon satisfaisante à la date prévue ou à l'expiration de tout délai supplémentaire accordé par l'OMS, et/ou si tout état financier requis n'est pas soumis de façon satisfaisante à l'OMS conformément à la condition générale 5 ci-dessous, l'Organisation peut immédiatement résilier le présent accord (sans préjudice d'autres recours dont elle peut disposer), conformément à la condition générale 13 ci-dessous (sans être tenue d'accorder au contractant une période supplémentaire de trente (30) jours pour exécuter, achever et livrer les travaux).

5. **Achèvement et livraison**. Le contractant achève et livre les travaux à l'OMS (y compris tout rapport technique qui pourrait être requis) à la date prévue par l'accord ou à l'expiration de tout délai supplémentaire accordé par l'OMS en application de la condition générale 4 ci-dessus. Tout état financier requis est soumis au plus tard dans les trente (30) jours qui suivent. Si le calendrier de paiement prévu au recto de l'accord prévoit le paiement à la fin des travaux, celui-ci n'est effectué qu'après réception, sous une forme satisfaisante, de tous les livrables exigés aux termes de l'accord, y compris les rapports techniques et les états financiers.

6. **Certification du statut des personnes physiques**. Toute Personne Physique certifie qu'elle n'a pas actuellement et n'aura pas pour la durée du présent accord, de relation contractuelle avec l'OMS (y compris les bureaux régionaux de l'OMS, les bureaux de pays ou de projet, les programmes, centres ou entités où le personnel est soumis au Statut et au Règlement du Personnel de l'OMS) lui conférant le statut de membre du personnel de l'OMS. Toute Personne Physique comprend qu'une fausse déclaration de sa part peut entraîner l'annulation de tous les contrats, et/ou le retrait de toute offre de contrat, avec l'OMS.

7. **Recherches impliquant des êtres humains**. Si et dans la mesure où les travaux à effectuer dans le cadre du présent accord incluent des études ou interviews impliquant des êtres humains (ci-après dénommés "recherches" ou "étude de sujets humains"), les points suivants sont applicables:
7.1 Aspects éthiques
Il incombe au contractant de s'assurer qu'au cours des travaux effectués dans le cadre de cet accord et impliquant l'étude de sujets humains, les droits et la santé de ces derniers soient protégés conformément au code d'éthique ou à la législation du pays, ou, à défaut, à la Déclaration d'Helsinki et aux amendements qui pourraient lui être ultérieurement apportés. Avant de commencer toute recherche, le contractant doit s'assurer que: a. les droits et le bien-être des sujets impliqués sont suffisamment protégés; b. le consentement libre et éclairé a été obtenu pour tous les participants; c. des experts indépendants désignés par le contractant ont évalué les risques et les avantages potentiels et ont jugé qu'ils s'équilibrent de manière acceptable et; d. toute exigence particulière de la réglementation nationale a été satisfaite.
7.2 Exigences réglementaires
Il incombe au contractant de respecter la réglementation nationale relative aux recherches impliquant l'étude de sujets humains.
7.3 Protection des sujets humains
Sans préjudice des obligations lui incombant aux termes des lois en vigueur, le contractant prendra des mesures appropriées en vue d'éliminer ou d'atténuer toute conséquence négative pour les sujets ou leur famille résultant de la conduite des recherches dans le cadre de cet accord. Ces mesures comprendront, dans la mesure du possible, des conseils appropries, un traitement médical et un dédommagement financier. Le contractant s'engage en outre à protéger le caractère confidentiel des informations qui pourraient permettre d'identifier les sujets impliqués dans les études.

8 **Respect des politiques de l'OMS.** En concluant cet accord, le contractant reconnaît qu'il a lu les Politiques de l'OMS (telles que définies ci-dessous), et qu'il les accepte et convient de s'y conformer. En lien avec ce qui précède :
- les Personnes Morales doivent prendre des mesures appropriées afin de prévenir et répondre à toute violation des normes de conduite, telles que décrites dans les Politiques de l'OMS, par leurs employés et par toute autre personne qu'elles ont engagées pour exécuter les travaux en vertu de cet accord; et
- les Personnes Physiques ne doivent pas adopter un comportement pouvant constituer une violation des normes de conduite, telles que décrites dans les Politiques de l'OMS.
Sans limiter la portée de ce qui précède, le contractant doit immédiatement signaler à l'OMS, conformément aux dispositions des Politiques de l'OMS applicables, toute violation réelle ou présumée dont il a connaissance concernant toute Politique de l'OMS. Aux fins du présent accord, l'expression « Politiques de l'OMS » signifie collectivement : (i) le Code d'éthique et de déontologie de l'OMS, ii) la Politique de l'OMS relative à la prévention et à la lutte contre l'exploitation et les abus sexuels, iii) la Politique de l'OMS relative à la prévention et la lutte contre les comportements abusifs, iv) le Code de conduite de l'OMS pour une recherche responsable, v) la Politique de l'OMS sur le signalement des actes répréhensibles et la protection contre les représailles, et vi) le Code de conduite des fournisseurs des Nations Unies, y compris leurs modifications éventuelles et qui sont publiquement accessibles sur le site internet de l'OMS aux liens suivants : http://www.who.int/about/finances-

Sensitivity: Internal & Restricted

at the following links: http://www.who.int/about/finances-accountability/procurement/en/ for the UN Supplier Code of Conduct and at http://www.who.int/about/ethics/en/ for the other WHO Policies.

9. **Zero tolerance for sexual exploitation and abuse, sexual harassment and other types of abusive conduct.** WHO has zero tolerance towards sexual exploitation and abuse, sexual harassment and other types of abusive conduct. In this regard, and without limiting any other provisions contained herein:

- each Company Contractor warrants that it shall: (i) take all reasonable and appropriate measures to prevent sexual exploitation or abuse as described in the WHO Policy on Sexual Exploitation and Abuse Prevention and Response and/or sexual harassment and other types of abusive conduct as described in the WHO Policy on Preventing and Addressing Abusive Conduct by any of its employees and any other persons engaged by it to perform any work under the Contract; and (ii) promptly report to WHO and respond to, in accordance with the terms of the respective Policies , any actual or suspected violations of either Policy of which the Contractor becomes aware; and
- each Individual Contractor warrants that he/she shall: (i) not engage in any conduct that would constitute sexual exploitation or abuse as described in the WHO Policy on Sexual Exploitation and Abuse Prevention and Response, and/or sexual harassment and other types of abusive conduct as described in the WHO Policy on Preventing and Addressing Abusive Conduct; and (ii) promptly report to WHO, in accordance with the terms of the respective Policies, any actual or suspected violations of either Policy of which the Individual Contractor becomes aware.

10. **Tobacco/Arms Related Disclosure Statement.** Company Contractors may be required to disclose relationships they may have with the tobacco and/or arms industry through completion of the WHO Tobacco/Arms Disclosure Statement. In the event WHO requires completion of this Statement, the Company Contractor undertakes not to permit work on the agreement to commence, until WHO has assessed the disclosed information and confirmed to the Company Contractor in writing that the work can commence.

11. **Anti-terrorism and UN sanctions; Fraud and Corruption.** The contractor warrants for the entire duration of the agreement that:

(i) it is not and will not be involved in, or associated with, any person or entity associated with terrorism, as designated by any UN Security Council sanctions regime, that it will not make any payment or provide any other support to any such person or entity and that it will not enter into any employment or subcontracting relationship with any such person or entity;

(ii) it shall not engage in any illegal, corrupt, fraudulent, collusive or coercive practices (including bribery, theft and other misuse of funds) in connection with the execution of the agreement; and

(iii) the contractor shall take all necessary precautions to prevent the financing of terrorism and/or any illegal corrupt, fraudulent, collusive or coercive practices (including bribery, theft and other misuse of funds) in connection with the execution of the agreement.

Any payments used by the contractor for the promotion of any terrorist activity or any illegal, corrupt, fraudulent, collusive or coercive practice shall be repaid to WHO without delay.

12. **Breach of essential terms.** The contractor acknowledges and agrees that each of the provisions of general conditions 8, 9, 10 and 11 above constitutes an essential term of this agreement, and that in case of breach of any of these provisions, WHO may, in its sole discretion, decide to:

(i) terminate this agreement, and/or any other contract concluded by WHO with the contractor, immediately upon written notice to the contractor, without any liability for termination charges or any other liability of any kind; and/or

(ii) exclude the contractor from participating in any ongoing or future tenders and/or entering into any future contractual or collaborative relationships with WHO.

WHO shall be entitled to report any violation of such provisions to WHO's governing bodies, other UN agencies, and/or donors.

13. **Termination.** WHO may terminate this agreement or any part thereof with immediate effect (in addition to any other rights or remedies to which WHO may be entitled, including the right to claim damages), on written notice to the contractor if the contractor is:

(i) in breach of any material obligation(s) under this agreement and, to the extent such breach is capable of being remedied, fails to correct such breach within a period of thirty (30) days after having received a written notification to that effect from

accountability/procurement/en/ pour ce qui est du Code de conduite des fournisseurs des Nations Unies, et http://www.who.int/about/ethics/en/ pour ce qui est des autres Politiques de l'OMS.

9. **Tolérance zéro pour l'exploitation et les abus sexuels, le harcèlement sexuel ainsi que toute autre forme de comportement abusif.** L'OMS applique la tolérance zéro en matière d'exploitation et d'abus sexuels, de harcèlement sexuel et de toute autre forme de comportement abusif. À cet égard, et sans limiter la portée de toute autre disposition du présent accord :

- chaque Personne Morale garantit: i) qu'elle prendra toutes les mesures raisonnables et appropriées pour prévenir tout acte d'exploitation ou d'abus sexuels tels que décrits dans la Politique de l'OMS relative à la prévention et à la lutte contre l'exploitation et les abus sexuels, et/ou tout acte de harcèlement sexuel ou de toute autre forme de comportement abusif tels que décrits dans la Politique de l'OMS relative à la prévention et la lutte contre les comportements abusifs par l'un quelconque de ses employés et toute autre personne engagée par elle pour exécuter le travail prévu au titre du Contrat ; et ii) qu'elle signalera immédiatement à l'OMS et donnera suite à toute violation réelle ou présumée de l'une ou l'autre de ces Politiques dont elle a connaissance, conformément à leurs dispositions respectives ; et
- chaque Personne Physique garantit: i) qu'elle n'adoptera aucun comportement qui relèverait de l'exploitation ou abus sexuels tels que décrits dans la Politique de l'OMS relative à la prévention et à la lutte contre l'exploitation et les abus sexuels et/ou du harcèlement sexuel ou de toute autre forme de comportement abusif tels que décrits dans la Politique de l'OMS relative à la prévention et la lutte contre les comportements abusifs ; et ii) qu'elle signalera immédiatement à l'OMS toute violation réelle ou présumée de l'une ou l'autre de ces Politiques dont la Personne Physique a connaissance, conformément à leurs dispositions respectives.

10. **Déclaration relative à l'industrie du tabac/de l'armement.** Il peut être demandé aux Personnes Morales de déclarer leurs éventuelles relations avec l'industrie du tabac et/ou de l'armement en remplissant la déclaration requise par l'OMS relative à l'industrie du tabac/de l'armement. Dans les cas où l'OMS demande une telle déclaration, la Personne Morale s'engage à ne pas autoriser le commencement des travaux au titre de l'accord tant que l'OMS n'a pas évalué les informations communiquées et confirmé par écrit à la Personne Morale que ces travaux peuvent commencer.

11. **Anti-terrorisme et sanctions de l'ONU; fraude et corruption.** Le contractant garantit, pour toute la durée de l'accord :

(i) qu'il n'est ni ne sera impliqué à l'égard de, ni associé à, aucune personne ou entité que le régime de sanctions du Conseil de sécurité de l'ONU a désignée comme étant associée au terrorisme, qu'il ne fera aucun paiement à, ou ne soutiendra d'aucune autre manière, une telle personne ou entité, et qu'il ne conclura aucune relation d'emploi ni de sous-traitance avec une telle personne ou entité ;

(ii) qu'il ne prendra part à aucune pratique illégale, de corruption, de fraude, de collusion ou de coercition (y compris, pots de vin, vol ou autre utilisation abusive de fonds) en lien avec l'exécution de l'accord ; et

(iii) le contractant prendra toutes les précautions nécessaires pour empêcher le financement du terrorisme et/ou toute pratique illégale, de corruption, de fraude, de collusion ou de coercition (y compris, pots de vin, vol ou autre utilisation abusive de fonds) en lien avec l'exécution de l'accord.

Tout paiement utilisé par le contractant pour la promotion de toute activité terroriste ou de toute pratique illégale, de corruption, de fraude, de collusion ou de coercition doit être immédiatement remboursé à l'OMS.

12. **Violation de clauses essentielles**. Le contractant reconnaît et accepte que chacune des dispositions des conditions générales 8, 9, 10 et 11 ci-dessus constitue une clause essentielle du présent accord, et qu'en cas de manquement à l'une quelconque de ces dispositions, l'OMS peut, à sa seule discrétion, décider :

(i) de résilier immédiatement cet accord, et/ou tout autre contrat conclu par l'OMS avec le contractant, moyennant une notification écrite adressée au contractant, sans être redevable d'aucune pénalité au titre d'une telle résiliation et sans que sa responsabilité ne soit engagée d'une quelconque manière que ce soit; et/ou

(ii) d'exclure le contractant de toute participation à des appels d'offres en cours ou à venir et/ou de toute relation contractuelle ou de collaboration future avec l'OMS.

L'OMS sera en droit de rapporter toute violation de ces dispositions aux organes directeurs de l'OMS, aux autres organismes des Nations Unies et/ou aux donateurs.

13. **Résiliation.** L'OMS peut résilier avec effet immédiat le présent accord ou toute partie de celui-ci (en plus de tous les autres droits ou recours dont l'OMS peut se prévaloir, y compris

Sensitivity: Internal & Restricted

WHO; or
(ii) adjudicated bankrupt or formally seeks relief of its financial obligations.

14. **Use of WHO name and emblem.** Without WHO's prior written approval, the contractor shall not, in any statement or material of an advertising or promotional nature, refer to this agreement or the contractor's relationship with WHO, or otherwise use the name (or any abbreviation thereof) and/or emblem of the World Health Organization.

15. **Publication of agreement.** Subject to considerations of confidentiality, WHO may acknowledge the existence of this agreement to the public and publish and/or otherwise publicly disclose the contractor's name and for Company Contractors, the country of incorporation, general information with respect to the work described herein and the agreement's value. Such disclosure will be made in accordance with WHO's Information Disclosure Policy and shall be consistent with the terms of this agreement.

16. **Audit.** WHO may request a financial and operational review or audit of the work performed by Company Contractors under this agreement, to be conducted by WHO and/or parties authorized by WHO, and the Company Contractor undertakes to facilitate such review or audit. This review or audit may be carried out at any time during the implementation of the work performed under this agreement, or within five years of completion of the work. In order to facilitate such financial and operational review or audit, the Company Contractor shall keep accurate and systematic accounts and records in respect of the work performed under this agreement.
The Company Contractor shall make available, without restriction, to WHO and/or parties authorized by WHO:
(i) the Company Contractor's books, records and systems (including all relevant financial and operational information) relating to this agreement; and
(ii)reasonable access to the Company Contractor's premises and personnel.
The Company Contractor shall provide satisfactory explanations to all queries arising in connection with the aforementioned audit and access rights.

WHO may request the Company Contractor to provide complementary information about the work performed under this agreement that is reasonably available, including the findings and results of an audit (internal or external) conducted by the Company Contractor and related to the work performed under this agreement.

17. **Surviving provisions.** Those provisions of this agreement that are intended by their nature to survive its expiration or earlier termination shall continue to apply.

18. **Settlement of disputes**. Any matter relating to the interpretation or application of this agreement which is not covered by its terms shall be resolved by reference to Swiss law. Any dispute relating to the interpretation or application of this agreement shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties or, in the absence of agreement, with the Rules of Arbitration of the International Chamber of Commerce. The parties shall accept the arbitral award as final.

19. **Privileges and immunities.** Nothing contained in or relating to this agreement shall be deemed to constitute a waiver of any of the privileges and immunities enjoyed by WHO and/or as submitting WHO to any national court jurisdiction.

celui de réclamer des dommages-intérêts), moyennant une notification écrite adressée au contractant, si ce dernier :
(i) est en violation d'une (ou plusieurs) obligation(s) importante(s) du présent accord et, dans le cas d'une violation susceptible d'être réparée, manque de remédier à une telle violation dans les trente (30) jours suivant la réception d'une notification écrite de l'OMS envoyée à cet effet ; ou
(ii) s'est déclaré en faillite ou a demandé officiellement à être exonéré de ses obligations financières.

14. **Utilisation du nom et de l'emblème de l'OMS.** Le contractant n'a pas le droit, dans aucune déclaration ni aucun support à caractère publicitaire ou promotionnel, de faire référence au présent accord ou à sa relation avec l'OMS, ni d'utiliser d'une autre manière le nom (ou toute abréviation de celui-ci) et/ou l'emblème de l'Organisation mondiale de la Santé, sans l'autorisation écrite préalable de l'OMS.

15. **Publication de l'accord.** Sous réserve de considérations relatives à la confidentialité, l'OMS a le droit de divulguer l'existence de cet accord et de publier, et/ou rendre public d'une autre manière, le nom du contractant ainsi que, le pays d'enregistrement si le contractant est une Personne Morale, des informations générales concernant les travaux décrits dans le présent accord et la valeur de l'accord. Cette divulgation se fera conformément à la politique de l'OMS sur la divulgation des informations et aux dispositions du présent accord.

16. **Vérification.** L'OMS peut demander qu'un examen ou une vérification de type financier et opérationnel des travaux effectués par les Personnes Morales en vertu du présent accord soit effectué(e) par l'OMS et/ou par des parties autorisées par l'OMS, et la Personne Morale s'engage à faciliter cet examen ou cette vérification. Cet examen ou cette vérification peut être effectué(e) à tout moment pendant l'exécution des travaux effectués au titre du présent accord, ou dans les cinq ans suivant l'achèvement des travaux. Afin de faciliter cet examen ou cette vérification de type financier et opérationnel, la Personne Morale doit tenir des comptes et des registres précis et systématiques sur les travaux effectués en vertu du présent accord.
La Personne Morale doit mettre à la disposition de l'OMS et/ou des parties autorisées par l'OMS, sans restriction:
(i) les livres, les archives et les systèmes de la Personne Morale concernant le présent accord (y compris l'ensemble des informations financières et opérationnelles pertinentes); et
(ii) un accès raisonnable aux locaux et au personnel de la Personne Morale.
La Personne Morale doit fournir des explications satisfaisantes en réponse à toutes les questions découlant de la vérification et des droits d'accès susmentionnés.

L'OMS peut demander à la Personne Morale de lui communiquer des informations complémentaires concernant les travaux exécutés au titre du présent accord qui sont raisonnablement à sa disposition, y compris les conclusions et les résultats d'une vérification (interne ou externe) effectuée par la Personne Morale au sujet des travaux exécutés au titre du présent accord.

17. **Dispositions restant en vigueur après la fin du contrat**. Les dispositions du présent accord qui sont, de par leur nature, destinées à survivre à l'expiration ou à la résiliation anticipée dudit accord continueront de s'appliquer.

18. **Règlement des différends**. Toute question concernant l'interprétation ou l'application du présent accord que les dispositions de ce dernier ne permettent pas de résoudre doit être résolue par référence au droit suisse. Tout différend relatif à l'application ou à l'interprétation du présent accord qui n'aurait pu être résolu à l'amiable fera l'objet d'une conciliation. En cas d'échec de celle-ci, le différend sera réglé par arbitrage. Les modalités de l'arbitrage seront convenues entre les parties ou, en l'absence d'accord, déterminées selon le Règlement d'arbitrage de la Chambre de Commerce internationale. Les parties reconnaissent que la sentence arbitrale sera finale.

19. **Privilèges et immunités.** Aucun des termes du présent accord ne sera considéré comme constituant une renonciation à quelque privilège ou immunité que ce soit dont jouit l'OMS en vertu du droit national ou international et/ou interprété comme une soumission de l'OMS à la compétence d'une quelconque juridiction nationale.

Sensitivity: Internal & Restricted

Mass General Brigham

Research Management — Post Award | 399 Revolution Drive, Suite 740

Somerville, Massachusetts 02145-1446 | bwhsubs@partners.org

Consortium Agreement

This Agreement ("Agreement") is entered into to specify the terms and conditions under which The Brigham and Women's Hospital, Inc. ("Hospital") and Mahatma Gandhi Institute of Medical Sciences ("Subrecipient"), each referred to individually as a party ("Party") and collectively as the parties ("Parties"), will collaborate in the conduct of a study titled "An individualized approach to promote nurturing care in low and middle income countries: A hybrid effectiveness/implementation trial of the international Guide for Monitoring Child Development (MPI)**"** ("Project") under an award from NIH-National Institutes of Health ("Sponsor") Grant Number 1R01HD100984-01A1 ("Prime Award"), awarded to Hospital effective April 01, 2021 with Peter Rohloff as Principal Investigator for Hospital ("Hospital Investigator") and Subodh Gupta as Principal Investigator for Subrecipient ("Subrecipient Investigator").

Insofar as they are applicable to Subrecipient and the Statement of Work performed hereunder, the Federal Acquisition Regulations ("FAR") and related Supplements as referenced in the Prime Award are incorporated into the following terms and conditions of this Agreement, either directly or by reference. The following documents are attached and parts of this Agreement:

Appendix A: Statement of Work and Protocol

Appendix B: Budget

Appendix C: Format for Invoices

Appendix D: Prime Award

Appendix E: FFATA Contact Information

Appendix F: Telecommunications Certification

1. Term

This Agreement will begin on April 01, 2021 ("Effective Date") and will not extend beyond March 31, 2022 ("Term"), unless the Term is extended by Hospital or terminated in accordance with the terms of this Agreement.

2. Principal Investigators

2.1. *Hospital Investigator:* The Hospital Investigator is responsible for the overall direction of the Project and for reviewing, evaluating, and monitoring Subrecipient's technical, scientific, programmatic, and financial performance under this Agreement.

2.2. *Subrecipient Investigator:* The Subrecipient Investigator will direct the portion of the Project funded under this Agreement and is responsible to Hospital for proper management, conduct, and

reporting of the work. Subrecipient Investigator is responsible for all the technical, scientific, programmatic, and financial performance consistent with the terms of this Agreement.

3. Statement of Work and Protocol

3.1. Subrecipient will provide all the necessary qualified personnel, equipment, materials, and facilities to accomplish the research described in the statement of work ("Statement of Work") and protocol ("Protocol"), which are incorporated to this Agreement as Appendix A, for the amount outlined in the approved budget, which is incorporated to this Agreement as Appendix B ("Budget").

3.2. Subrecipient represents and warrants that in performance of this Study it will:

a. obtain necessary approvals of the Protocol and signed consent forms ("ICF") from Hospital and the appropriate Institutional Review Board ("IRB"); or obtain a Waiver of Authorization from the appropriate IRB ("Waiver Authorization") prior to any activities involving human subjects under this Agreement;
b. assume all responsibility to enroll and follow subjects according to the most recent approved version of the Protocol;
c. comply with all institutional and U.S. federal regulations concerning informed consent and the participation of human subjects; and
d. ensure regulatory compliance outlined by the Food and Drug Administration ("FDA") regulations.

3.3. Subrecipient will not make any change to the Statement of Work or Protocol without obtaining the prior written approval of the Hospital Investigator, identified in Appendix E, and the appropriate IRB. No provision in this Agreement may override the obligations of this Article 3.3.

4. Notification

4.1. Both Parties will promptly notify the other in writing of all information that could significantly affect the safety or medical care of current or former subjects, or significantly affect current subjects' willingness to continue participation, materially influence the conduct of the Study, or alter IRB approval.

4.2. The Parties, through their respective Investigators or IRB, as appropriate, are responsible for informing subjects of all information learned through this Article that could significantly affect the safety or medical care provided to the subjects. Notifications should be made in accordance with the ICF or Waiver Authorization and Protocol. Hospital will not contact Subrecipient's Study subjects unless authorized to in the ICF.

5. Technical Reporting Requirements

5.1. *Continuation Proposals:* If Sponsor requires a continuation proposal, Subrecipient will obtain appropriate institutional approval and submit a progress report and any additional required documents describing accomplishments and significant research findings derived from the work under this Agreement to the Hospital Grant Administrator not later than seventy-five (75) days

prior to the last day of the Term for this Agreement, for inclusion in Hospital's continuation proposal.

5.2. *Interim Progress Report*: Upon reasonable advance notice from Hospital, Subrecipient may be required to submit interim progress reports as these may be necessary for Hospital to fulfill its obligations under the Prime Award.

5.3. *Final Progress Report*: Subrecipient will submit a final progress report describing accomplishments and significant research findings derived from the work under this Agreement, and any other documentation or information required by the Prime Award, to the Hospital Investigator within sixty (60) days of the close of the Term, or from the effective date of early termination, for inclusion in Hospital's final progress report to Sponsor.

5.4. *Final Invention Report*: No later than sixty (60) days following the conclusion or early termination of this Agreement, Subrecipient must submit Form HHS-568 to the Hospital Grant Administrator detailing any Inventions developed under this Agreement, defined in accordance with Article 0. In the event no Inventions were developed, a negative report is required.

5.5. *Other Reports*: Subrecipient is required to assist Hospital in fulfilling its obligations for reporting requirements to the Sponsor, which are incorporated by reference in Appendix D. Accordingly, in addition to those requirements listed in this Agreement, Hospital may be required to fulfill additional reporting requirements at Sponsor's request. Subject to the nature of Sponsor's request for additional reporting, Hospital will provide Subrecipient advance notice and will be afforded time for its submission.

6. Financial Reporting Requirements

6.1. *Annual Financial Report:* Subrecipient will submit an annual final financial report of expenditures, in the form of an annual final invoice, to the Hospital Financial Contact, listed in Appendix E within sixty (60) days of the close of each Year or from the effective date of early termination, using a format substantially similar to Appendix C and indicating that the invoice is "Final."

6.2. In the event that Subrecipient seeks carry forward of an unobligated balance into the next Year and carry forward is not automatic per Article 13 below, the amount must be specified on the final invoice and a separate request must be submitted to the Hospital Grant Administrator.

7. Change of Investigators

7.1. Subrecipient must promptly notify the Hospital Grant Administrator and Hospital Investigator if the Subrecipient Investigator is unable to serve as Subrecipient Investigator under this Agreement or becomes unavailable to the Project for a period exceeding three (3) consecutive months. Subrecipient may submit a written request to replace the Subrecipient Investigator to the Hospital Investigator and Hospital Grant Administrator, identified in Appendix E. If neither Party can agree on a replacement, this Agreement will be terminated in accordance with Article 8.

7.2. An authorized official of Hospital must approve the appointment of a new Subrecipient Investigator. Hospital will amend this Agreement to authorize a change of Investigators. Approval will not be unreasonably withheld.

8. Termination

8.1. This Agreement may be terminated for any of the following cases:

a. by either Party with thirty (30) days prior notice to the other;
b. by either Party immediately and with prompt notification when such action is necessary to protect the health, safety or welfare of human subjects; or
c. immediately in the event that the Sponsor terminates the Prime Award.

8.2. In all cases, written notice must be provided to the other Party's contacts identified in Appendix E.

8.3. In the event of an early termination, Subrecipient will be reimbursed for allowable costs and non-cancellable obligations, defined in Article **Error! Reference source not found.**, for work satisfactorily completed in accordance with the Protocol and the terms of this Agreement, and accepted by Hospital up to the date of termination. As applicable, Subrecipient must promptly furnish to Hospital all data and reports required under this Agreement up to the effective date of termination. If this Agreement is terminated due to a deviation from the Protocol, payment will only be made for activities completed in accordance with the Protocol prior to the date of deviation.

8.4. At any time, and only when necessary to protect the health and safety of human subjects or the scientific integrity of the Study, an authorized official of Hospital will issue a stop-work order in accordance with this Article. Upon receipt, Subrecipient must immediately cease all or part of the work performed under this Agreement, unless such actions are reasonable and necessary to protect the health and safety of the human subjects. During the stop work order, Subrecipient will take all reasonable steps to minimize the incurrence of costs.

8.5. If the Sponsor issues a stop-work order, Hospital will promptly notify Subrecipient and provide any instructions issued by the Prime Sponsor. Subrecipient will take all necessary action as required by Prime Sponsor's direction.

9. Contacts

The individuals identified in the incorporated Appendix E are the designated representatives for Hospital and Subrecipient. The Investigators for both Parties will be contacted for resolution of technical questions. The Authorized Officials for both Parties have the authority described throughout this Agreement.

9.1. *Hospital Contacts.* The Hospital Grant Administrator will be the primary point of contact for resolution of administrative questions with a copy to the Hospital Financial Contact. The Hospital Financial Contact is the primary contact for invoices and questions concerning payments.

9.2. *Subrecipient Contacts.* The Subrecipient Grant Administrator will be the primary point of contact for resolution of administrative questions. The Subrecipient Financial Contact will be contacted for resolution financial questions.

10. Disputes

10.1. The Parties will attempt to amicably settle any controversy or claim arising out of this Agreement between themselves before seeking any other kind of resolution or available remedy under applicable law.

10.2. Only if agreed by both Parties, any conflict which the Parties are unable to resolve independently may be settled through arbitration conducted in accordance with the rules of the American Arbitration Association. A demand for arbitration must be filed within a reasonable time after the controversy or claim has arisen, and in no event after the applicable statute of limitations has expired.

10.3. Subrecipient will provide reasonable assistance and cooperation to Hospital if a dispute arises with the Sponsor.

11. Consideration

11.1. For the budget period April 01, 2021 to March 31, 2022 ("Year 1"), Subrecipient's Budget is 110,808, U.S. Dollars ("USD") in total costs, inclusive of 8.00% in Facilities and Administration costs ("F&A"), apportioned in accordance with the Budget in Appendix B. The allowability of costs is determined in accordance with the Prime Award, the FAR, and the approved Budget.

11.2. Once enrollment is initiated under the project, Subrecipient is expected to enroll at least 10-15 subjects each month. Subrecipient must submit quarterly progress reports detailing the number of subjects enrolled and the progress achieved on the aims outlined in Appendix A. If enrollment targets are not met, Subrecipient must provide a detailed justification in the quarterly progress report.

12. Invoicing

12.1. Payments will be made within the total authorized amount in USD upon Hospital's receipt and approval of invoices for costs incurred. Invoices must be submitted, no more often than monthly, to Hospital's Financial Contact listed in Appendix E in a format substantially similar to Appendix C. All invoices from Subrecipient must be submitted in USD and include:

a. Hospital's Agreement reference number: #125594;
b. current and cumulative costs, including cost sharing, as applicable;
c. the signature of an authorized fiscal officer, and
d. a certification as required in 2 CFR § 200.415(a).

12.2. Subrecipient will not be reimbursed for fluctuations in the currency exchange rate. Invoices that do not contain all of the required information may be returned to Subrecipient.

13. **Payment**

13.1. Payment to Subrecipient is contingent on Subrecipient's compliance with this Agreement and the Prime Award. All payments are considered provisional, and subject to adjustment within the total authorized amount, in the event such adjustment is necessary as a result of an adverse audit finding against Subrecipient, or a finding of non-compliance with the terms of this Agreement, or any applicable law or regulation. Acceptance of final payment from Hospital releases and forever discharges Hospital of and from all financial claims for research performed under this Agreement.

13.2. Payments will be submitted to Subrecipient via the address provided in Appendix E.

14. Prior Approvals

14.1. Subrecipient shall not re-budget between cost categories or add new cost categories to the Budget without prior approval from Hospital.

14.2. Requests for re-budgeting that require prior approval, requests for carry-forward of unspent balances from one budget period to the next, if carry forward is not automatic as determined below, and requests for no-cost extensions must be directed to the Hospital Investigator and Hospital Grant Administrator. Such requests will be reviewed and, as appropriate, approved by Hospital in accordance with Sponsor policy, or, if applicable, forwarded to Sponsor for action.

14.3. Automatic Carry Forward: Prior approval required

15. Audit and Records

15.1. *Technical Record Retention:* Any pertinent books, documents, papers, records, notebooks and data related to the Project provided by Subrecipient under this Agreement, including subject records, and other technical records pertinent to this Agreement, must be retained by Subrecipient for a period of seven (7) years from Subrecipient's receipt of its final payment under this Agreement. This retention period is required pursuant to *Accounting of Disclosures of Protected Health Information*, HIPAA § 164.528, so that Hospital may fulfill its obligations to the Sponsor under the Prime Award.

15.2. *Technical Audit:* The Sponsor, the Comptroller General of the United States, Hospital, or any of their duly authorized representatives, upon reasonable advance notice and during normal business hours, will have access to and the rights to examine such technical records in accordance with the requirements of this Agreement and as related to this Agreement. Such technical audit may include an audit of Subrecipient's data security plan as applicable.

15.3. *Financial Record Retention:* Subrecipient will maintain a systematic accounting record of the receipt and disbursement of funds and expenditures incurred under the terms of this Agreement and retain the substantiating documents, such as bills, invoices, cancelled checks, and receipts, for a period not less than three (3) years after Subrecipient's receipt of its final payment under this Agreement.

15.4. *Financial Audit:* The Sponsor, the Comptroller General of the United States, Hospital, or any of their duly authorized representatives, upon reasonable advance notice and during normal

business hours, will have access to and the rights to examine such financial records as described in Article 15.3.

16. Data

16.1. Subrecipient must record all data elements required to be delivered to Hospital through this Agreement's Statement of Work and Protocol ("Project Data") in accordance with the IRB, Protocol, and ICF or Waiver Authorization. Subrecipient must record all Project Data in a timely, accurate, complete, and legible manner in a format or database as required by the Protocol. Subrecipient will take reasonable and customary precautions, including periodic backup of computer files, to prevent the loss or alteration of any Project Data.

16.2. Hospital will use the Project Data consistent with the appropriate ICF or Waiver Authorization, Hospital's Protocol and all applicable U.S. federal, state or local government laws or regulations. Both Parties may use Project Data for their own non-commercial research and educational purposes, in accordance with the restrictions outlined in this Agreement, and consistent with the IRB, Protocol, and ICF or Waiver Authorization, and all applicable U.S. federal, state or local government laws or regulations.

17. RESERVED

18. Human Materials

No human materials will be exchanged under this Agreement.

19. Publications and Copyrights

The Investigators are encouraged to publish or otherwise publicly present the results of the research conducted under this Agreement.

19.1. Subject to any applicable terms of the Prime Award and generally accepted academic standards, the Investigators will together make the decision regarding the authorship on jointly-authored publications and other public presentations arising out of this Agreement. Subrecipient must provide drafts of all publications or presentations arising out of this Agreement to the Hospital Investigator for review and comment within a reasonable time prior to submission for publication or presentation. Thereafter, Subrecipient will submit finalized copies to Hospital following its submission.

19.2. Subrecipient must acknowledge the support of the Prime Sponsor whenever publicizing the work based on, or developed under this Agreement, in any media, whether copyrighted or not, by including the following acknowledgement:

> *"Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number R01HD100984. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health."*

19.3. Subject to any third party rights of a publishing journal, Subrecipient grants to Hospital an irrevocable, royalty-free, non-transferable, non-exclusive world-wide right and license to use, reproduce, make derivative works, display, and perform publicly any copyrights or copyrighted material (including any computer software and its documentation and databases) first developed and delivered under this Agreement for the purpose of and to the extent required to meet Hospital's obligations to the U.S. federal government under its Prime Award and for non-commercial educational and research-related purposes, which includes the creation of derivative works.

20. Inventions and Patents

Subrecipient must ensure that this Article and policy are applicable to all persons who perform any part of the work under this Agreement and who may be reasonably expected to create an Invention.

20.1. The determination of the rights of ownership and disposition of any inventions resulting from the performance of the Project under this Agreement ("Inventions"), is in accordance with Sponsor's policy and will be governed by *Rights to Inventions Made by Nonprofit Organizations and Small Business Firms Under Government Grants, Contracts, and Cooperative Agreements*, 37 CFR § 401.

20.2. Subrecipient will notify Hospital's Grant Administrator in writing within sixty (60) days of Subrecipient's disclosure of any Inventions to Subrecipient personnel responsible for patent matters. A final report of Inventions developed under this Agreement is required no later than sixty (60) days following the conclusion or early termination of this Agreement. Negative reports are required. Subrecipient will use form HHS 568 for its report to Hospital.

20.3. Title to any Inventions made by Subrecipient will vest with Subrecipient. Subrecipient grants to Hospital an irrevocable, world-wide, royalty-free, non-exclusive license to practice any Inventions only to the extent required for Hospital to meet its obligations under the Prime Award. Subrecipient shall grant to Hospital an irrevocable, world-wide, royalty-free, non-exclusive license to practice any Inventions for non-commercial educational and research related purposes, which license shall include terms that are reasonable and customary as between academic/non-profit and for-profit collaborators.

20.4. Subrecipient's assignment of Invention rights to a third party does not require Sponsor approval, but ongoing reporting remains a requirement for each Invention pursuant to the Sponsor policy.

20.5. The Parties will mutually agree in writing to the management of joint Inventions.

21. Confidentiality

21.1. Confidential information ("Confidential Information") will mean any business or proprietary information provided by one Party to the other and clearly identified in writing as "Confidential" by the transmitting Party at the time of disclosure. If such transmittal occurs orally, the transmitting Party will within thirty (30) days reduce such transmittal to written form, mark and identify it as "Confidential", and provide such record to the other Party.

21.2. If a Party discloses Confidential Information to the other Party during the Project, the receiving Party will disclose the Confidential Information only on a need-to-know basis to its employees, directors or other advisors or representatives who are subject to these confidentiality obligations. Each Party will use the Confidential Information only for the purposes contemplated by this Agreement and will use reasonable efforts to prevent its disclosure to third parties.

21.3. Notwithstanding, the receiving Party may disclose the Confidential Information if such information:

a. was already in the public domain or becomes publicly available through no wrongful act of receiving Party;
b. was previously known or developed by the receiving Party without any violation of existing confidentiality obligations;
c. was known by the receiving Party prior to its disclosure by the disclosing Party, as evidenced by tangible records;
d. becomes known to receiving Party after disclosure from a third party having an apparent bona fide right to disclose it;
e. is independently developed or discovered by receiving Party without use of disclosing Party's Confidential Information, as evidenced by tangible records; or
f. is required to be disclosed by operation of law.

21.4. Each Party retains ownership of the Confidential Information it provides to the other. The receiving Party will promptly return the disclosing Party's Confidential Information upon request but receiving Party may retain one copy in a secure location solely for record-keeping and compliance-related purposes.

21.5. The obligations of this Article will survive for a period of five (5) years following termination of this Agreement. Notwithstanding, all Protected Health Information will be considered Confidential Information in accordance with HIPAA.

22. Protection of Human Subjects

22.1. In accordance with laws and regulations for the protection of human subjects, which includes but is not limited to 45 CFR § 46, and specifically 45 CFR § 46.107, the Protocol incorporated through Appendix A of this Agreement, as updated or revised, has been approved by the appropriate IRB at Hospital. Both Parties must maintain compliance with all applicable laws and regulations related to the protection of human subjects for the duration of this Agreement.

22.2. Subrecipient will promptly report to the Hospital Investigator and to the appropriate IRB:

a. any adverse events or unexpected problems;
b. any proposed changes to the Protocol or IFC or Waiver Authorization; and
c. any other information required to be reported pursuant to the Protocol.

22.3. Subject to the regulations *Protection of Human Subjects,* 45 CFR § 46, Subpart A, and 45 CFR § 46.107, Subrecipient must not conduct any work under this Agreement using human subjects without first obtaining approval from the appropriate IRB. Subrecipient will monitor this Project as

appropriate and will submit reports to Hospital documenting current and ongoing review and approval of the Protocol or a copy of Subrecipient's current IRB approval. Subrecipient certifies that it has been assigned an assurance of compliance number by the Office for Human Research Protections ("OHRP") and will comply with the terms of its OHRP-approved assurance.

22.4. In addition, Subrecipient certifies that all its key personnel involved in human subject research as part of this Project have been certified in accordance with the policies outlined in the Prime Award concerning Education in the Protection of Human Research Participants, as further updated or revised. Upon request, Subrecipient will provide documentation of this certification to Hospital.

22.5. All human subjects research funded wholly or in part by NIH, that collects or uses identifiable, sensitive information, including but not limited to identifiable biospecimens or individual-level genomic data ("ISI"), as defined by the NIH Policy for Issuing Certificates of Confidentiality, NOT-OD-17-109 (2017) (the "Policy"), and which was commenced or ongoing on or after December 13, 2016, is deemed under the Policy to be issued a Certificate of Confidentiality ("Certificate"). All institutions and investigators collecting or receiving ISI under a Project that has been issued a Certificate are required to protect the privacy of individuals who are subjects of such research and must do so in accordance with the Policy.

22.6. Accordingly, Subrecipient certifies that if a Certificate has been issued for this Project and Subrecipient collects or receives ISI under this Agreement, Subrecipient and Subrecipient Investigator and its staff will comply with the Policy and the Prime Award when using or disclosing ISI.

22.7. This Article will survive the expiration and early termination of this Agreement.

23. Privacy Laws

23.1. To the extent applicable, Subrecipient will comply with HIPAA PL 104–191 et al., and its accompanying regulations, including but not limited to the *Standards for Privacy of Individually Identifiable Health Information (Privacy Rule)*, codified at 45 CFR §§ 160–164 ("Privacy Rule") and will amend this Agreement, as appropriate, to comply with any federal modifications or additions to HIPAA requirements.

23.2. If Protected Health Information ("PHI"), as defined by the HIPAA Privacy Rule, is generated, used, or disclosed as a result of this Agreement, the Parties certify that the storage, use and disclosure of PHI is in compliance with IRB approval, the Protocol, the ICF or Waiver Authorization, HIPAA and its accompanying regulations, and all applicable laws and regulations.

23.3. If Subrecipient is not a HIPAA covered entity, as defined by HIPAA PL 104–191 et al., Subrecipient must still take all reasonable and customary precautions, including periodic backup of computer files, to prevent the loss or alteration of any data or information related human subjects. In addition, Subrecipient will comply with any applicable laws of Subrecipient's home country that are equivalent in nature to HIPAA regulations. Subrecipient may use its data for its own non-

commercial, internal, research and educational purposes, subject to the limitations listed in this Agreement.

24. Protection of Animal Welfare

No animal research may be conducted under this Agreement.

25. Research Misconduct

Subrecipient certifies that it has established administrative policies and will comply with *Public Health Service Policies on Research Misconduct*, 42 CFR § 93. Subrecipient certifies that it has in place and will enforce written policies and procedures for addressing allegations of research misconduct and has filed an Assurance of Compliance with the DHHS Office of Research Integrity.

26. Debarment and Suspension

Subrecipient certifies that none of its officers, directors, employees, agents and students currently assigned to this Project are presently debarred, suspended, proposed for debarment, or declared ineligible for the award of funds by any U.S. federal agency, in accordance with 45 CFR § 76.

27. Representations and Certifications

27.1. Subrecipient shall complete electronic annual representations and certifications at https://www.sam.gov ("SAM") (see FAR 4.1102). Subrecipient shall update the representations and certifications submitted to SAM as necessary, but at least annually, to ensure they are kept current, accurate, and complete. The representations and certifications are effective until one year from date of submission or update to SAM.

27.2. When any of the conditions in paragraph (b) of the clause at 52.219-28, Post-Award Small Business Program Representation, apply, if Subrecipient represented that it was a small business prior to award of this Agreement, it must update the representations and certifications in SAM as directed by the clause. If Subrecipient represented that it was other than a small business prior to execution of this Agreement, it may update the representations and certifications in SAM as directed by the clause, if its size status has changed since the date of execution.

28. Independent Contractor

28.1. Subrecipient acknowledges that all employees hired by it, under it, or as a result of this Agreement and for the term of this Agreement, are deemed to be employees of Subrecipient and are not entitled to any retirement or other fringe benefits from Hospital.

28.2. Neither Party has the authority to make any statements, representations, or commitments of any kind, nor will take any action which is binding on the other Party, except as may be explicitly provided for in this Agreement or authorized by the other Party in writing.

28.3. Subrecipient will pay all debts for labor and materials contracted for by it, and for the rental of appliances and equipment hired by it both for and on account of the work to be performed. Subrecipient will conform to all requirements of law and all other public authorities, state or local, relating to the methods or materials to be used or to the persons to be employed in performance of the Project.

29. Use of Name

29.1. Neither Party may use the name of the other Party, nor any adaptation of its name, nor the name of any staff member, employee, agent or student of the other Party in any advertising, promotional materials, sales literature or publicity without obtaining prior written approval of the Party whose name is to be used. For Hospital, approval must be obtained from its Department of Communication & Public Affairs, which may be found by visiting: https://www.brighamandwomens.org/about-bwh/newsroom/contact-bwh-communications-and-public-affairs

29.2. Notwithstanding, a Party may, without prior consent, use or disclose the other Party's name as required by law, court order, regulation or for its own internal purposes.

29.3. The Sponsor may, at its discretion, publish information regarding this Project and identify Subrecipient Investigator and their affiliation. In any such statement, the relationship must be accurately and appropriately described.

30. Indemnification

o the extent allowed by law, Subrecipient will indemnify and hold Hospital and its employees harmless from any and all liability of every nature and description arising out of this Agreement including, but not limited to, all third party claims, liabilities, judgments, costs, damages, damage to property or personal injuries including death, and expenses (collectively referred to as the "Losses"), resulting from and to the extent caused by Subrecipient or its employees' or agents' negligent and unlawful acts or omissions in the performance of this Project. Subrecipient will be financially and legally responsible for all such Losses except to the extent where the Losses are the direct result of Hospital and its employees' or agents' negligent acts or omissions.

31. Liability

Each Party will be responsible for its own negligent acts or omissions and the negligent acts or omissions of its employees, officers, or directors in the performance of this Project and the administration of this Agreement, to the extent allowed by law. Neither Party is liable to the other for any special, incidental, or consequential damages that may arise in connection with the execution and performance of this Agreement.

32. Insurance

For the duration of this Agreement each Party will maintain insurance, or a program of self-insurance, in an amount that will be adequate to cover its obligations under this Agreement. The Parties will provide each other proof of insurance upon request.

33. Conflict of Interest

Financial Conflict of Interest ("FCOI") regulations, implemented by the Office of the Secretary of the U.S. Department of Health and Human Services and the Public Health Service, entitled *Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought*, and codified at 42 CFR § 50, Subpart F (2011), collectively referred to as COI regulations ("COI Regulations"), require Hospital to ensure that Subrecipient has policies in place for management of financial conflicts of interest.

33.1. Subrecipient certifies that it has in effect an up-to-date, written and enforced conflicts of interest policy which complies with the COI Regulations. At the time of execution of this Agreement, Subrecipient certifies that there is no FCOI related to the work contemplated by this Agreement. If Subrecipient has identified an FCOI related to the work contemplated by this Agreement, Subrecipient certifies that it has implemented an appropriate management plan and notified Hospital of the existence of the FCOI and submitted all information as required by 42 CFR § 50.605(b)(3) ("FCOI Report").

33.2. In the event that an FCOI is identified by Subrecipient during the term of this Agreement, Subrecipient must submit an FCOI Report to Hospital within forty-five (45) days of Subrecipient Investigator disclosing the significant financial interest. Furthermore, annual updates of reported FCOIs must be provided to Hospital as required by 42 CFR § 50.605(b)(4). FCOI Reports must be submitted to Hospital's Office for Interactions with Industry at: PHSOII@partners.org.

34. Whistleblower Protection

Subrecipient is subject to the requirements of *A Pilot Program for the Enhancement of Employee Protection from Reprisal for Disclosure of Certain Information*, 41 USC § 4712 (2013). Subrecipient will inform its employees working on any U.S. federal award that they are subject to the whistleblower rights and remedies of the pilot program; and will inform their employees in writing of employee whistleblower protections under 41 USC § 4712 in the predominant native language of the workforce; and will include such requirements in any agreement made with a permitted subcontractor or subgrantee.

35. Tax Exempt Status

Subrecipient certifies that it is considered a non-profit organization under the laws of its home country and will immediately notify Hospital should this status change.

36. Export Control

The export of goods or technical data from the United States may require some form of export control license from the U.S. government in accordance with Export Administration Regulations, 15 CFR §§ 730–774. Neither Party will disclose, export or re-export any materials or technical data received under this Agreement to any countries for which the U.S. government requires an export license, unless it has: a) obtained prior written authorization from the appropriate governmental agency responsible for such matters; and b) provided written prior notice to the receiving Party including the applicable export control designation (e.g. ECCN or Munitions List category) giving receiving Party the right to decline the receipt of such export controlled materials or technical data. In the event an export license is required, the Party requiring such a license will be responsible for the cost of obtaining such license.

37. Anti-Terrorist Compliance

Subrecipient warrants that all funds issued under this Agreement will be used in compliance with all applicable United States anti-terrorist financing and asset control laws, regulations, rules and executive orders.

38. Profit or Fee

No profit or fee will be provided to Subrecipient under this Agreement. A profit or fee is not a cost but is an amount in excess of actual allowable direct and indirect costs.

39. Equipment

39.1. Subrecipient may not purchase equipment, other than as listed in the Budget, without prior written approval from the Hospital Investigator and Hospital Grant Administrator.

39.2. If equipment is purchased under this Agreement, Subrecipient must submit a final report of equipment to the Hospital Grant Administrator within sixty (60) days from the close of the Term. Equipment purchased with funds under this Agreement is for the use of Subrecipient Investigator in furtherance of the work outlined in Appendix A.

39.3. By signing this Agreement, Subrecipient represents and certifies compliance with 52.204-25 *Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment* ("Telecommunications Clause") as further described in Appendix F.

40. Amendment

This Agreement may be amended only by a written instrument signed by both Parties. Notwithstanding, Hospital reserves the right to issue unilateral amendments authorizing administrative and non-substantive updates only, such as extensions of the Term and increases to Subrecipient's Budget. Unilateral acceptance does not bypass the internal approval process of Subrecipient. Unless indicated otherwise by Subrecipient, unilateral amendments may be considered valid fourteen (14) days after receipt.

41. Assignment

Neither Party to this Agreement may assign its obligations without the prior written consent of the other Party. Subrecipient may not transfer or assign, by subcontract or other means, any portion of the programmatic effort required under this Agreement without prior written approval from Hospital. Such requests must be submitted to the Hospital Investigator and Hospital Grant Administrator identified in Appendix E.

42. Meeting with Technical Representatives

Subrecipient may be required to meet with technical representatives of Hospital or the Sponsor regarding the Protocol and progress of the Project. Such meeting will take place at mutually agreeable times and during Subrecipient's normal business hours.

43. Force Majeure

Neither Party will be liable to the other Party for any failure or delay in the performance of its obligations to the extent such failure or delay is caused by fire, flood, earthquakes, other elements of nature, acts of war, terrorism, riots, civil disorders, rebellions or revolutions, epidemics, quarantines, delays in visas, changes in laws and governmental policies, or other conditions beyond its reasonable control following execution of this Agreement, and provided such Party continues to follow all laws and regulations applicable to its performance under this Agreement. If the performance by either Party of any of its obligations under this Agreement (including making a payment) shall be prevented by any such

circumstances, then such Party shall communicate the situation to the other Party as soon as possible, and the Parties shall endeavor to limit the impact to the Project. The Parties agree to mitigate risks to the Project and personnel, and to amend the period of performance and milestones if possible. Nothing herein shall limit the rights of either Party to terminate this Agreement as indicated in Article 8 of this Agreement.

44. Compliance

Both Parties warrant that throughout the term of this Agreement they will be and will remain compliant with all U.S. federal, state, national, provincial, and local laws and regulations, as applicable.

45. Waiver

The failure of a Party in any instance to insist upon the strict performance of the terms of this Agreement is not construed to be a waiver or relinquishment of any of the terms of the Agreement, whether at the time of the Party's failure to insist upon strict performance or at any time in the future, and such terms will continue in full force and effect.

46. Severability

Each clause of this Agreement is distinct and severable. If any clause is deemed illegal, void, or unenforceable by any court of competent jurisdiction or are otherwise deemed unenforceable under the current applicable law, the remainder of this Agreement will not be affected. For each provision deemed unenforceable, a provision as similar as possible in its economic and business objectives will be intended.

47. Titles

All the titles and headings contained in the Agreement are inserted only as a matter of convenience and reference and do not define, limit, extend, or describe the scope of this Agreement or the intent of any of its provisions.

48. Counterpart Signatures

This Agreement may be executed in one or more counterparts, each of which counterpart is deemed an original Agreement, and all of which constitute one Agreement.

49. Governing Law

This Agreement is governed in all respects by the laws of the Commonwealth of Massachusetts, without giving effect to principles of conflicts of law thereunder.

Notwithstanding, this Article will not apply if Subrecipient is a state, state-related, or public institution that is afforded sovereign immunity or if Subrecipient is unable to comply with this Article due to restrictions on governing law under Subrecipient's applicable state or national law.

50. Governing Language

In the event that a translation of this Agreement is prepared and signed by the Parties, this English language version will be the official version and will govern if there is a conflict between this English language version and the translation. All disputes under this Agreement must be resolved and conducted in the English language, regardless of the means or authority.

51. Terms and Conditions from Prime Award

The terms and conditions from the Prime Award are in Appendix D and are incorporated into this Agreement. To the extent applicable, the conditions and regulations given in the Prime Award from Sponsor to Hospital are binding upon Subrecipient. Wherever the terms "Government" or "" are used, "Hospital" shall be substituted. Wherever the terms "Contracting Officer" are used, “Hospital Authorized Official” shall be substituted. Wherever the terms "CTO" or "COTR" are used, the "Hospital Principal Investigator" shall be substituted. Wherever the word "Contract" is used, the word “Agreement" shall be substituted. Wherever the word "Contractor" is used, the word “Subrecipient" shall be substituted. Such substitutions shall not be made in clauses addressing intellectual property, such as 52.227-14, or where it is clear, by the context of the provision itself or the conditions under which it is being applied, that the reference is intended to refer to the Government, its officers or agents, or Hospital specifically. References in any provision incorporated by reference herein to the “Disputes” clause shall be construed as references to the “Disputes” provision contained elsewhere in this Subrecipient. No provision herein shall be taken to imply any direct access on the part of the Subrecipient to the Disputes process as defined in the terms of the Prime Award.

52. Order of Precedence

52.1. The order of precedence for interpreting any inconsistencies with respect to the legal and financial administration obligations of Subrecipient will be as follows: 1) the Prime Award; 2) this Agreement; and 3) Appendix A and B.

52.2. The order of precedence for interpreting any inconsistencies with respect to the reporting and technical obligations of Subrecipient will be as follows: 1) this Agreement; 2) Appendix A and B; and 3) the Prime Award.

53. Entire Agreement

This Agreement constitutes the entire understanding between the Parties, and supersedes and replaces all prior agreements, understandings, writings and discussions between them, with respect to the subject matter of this Agreement.

54. Survival

The following Articles will survive the expiration or early termination of this Agreement, as allowed by law: Articles 2 through 6; 8, Termination; 14.1, Audit and Records; 16, Data; 18, Human Materials; 19, Publications and Copyrights; 0, Inventions and Patents; 21, Confidentiality; 22, Protection of Human Subjects; 23, Privacy Laws; 25, Research Misconduct; and 29 through 54 in their entirety. Additionally, any provision that by its nature is intended to survive termination or expiration of this Agreement will survive termination of expiration of this Agreement.

Remainder of page is intentionally left blank.
Signature of the Parties appear on the following page.

IN WITNESS WHEREOF, the Authorized Officials of the Parties have caused this Agreement to be duly executed as of the Effective Date.

The Brigham and Women's Hospital, Inc.	Mahatma Gandhi Institute of Medical Sciences
Joseph Beard Digitally signed by Joseph Beard DN: cn=Joseph Beard, o, ou, email=jbeard2@partners.org, c=US Date: 2021.10.01 09:22:28 -04'00'	
Name: Joseph Beard	Name: Dr. Nitin M Gangane
Title: Senior Grant and Contract Administrator	Title: Dean, MGIMS, Sevagram
10/01/2021	12/10/2021
Date	Date 12 Oct 2021

Appendix A: Statement of Work

Dr. Subodh Gupta at MGIMS will serve as site PI for this subcontract. Dr. Chetna Maliye and Dr. Abhishek Raut will serve as additional Key Persons. For this subcontract, MGIMS will cost-share the FTE commitment of Drs. Gupta, Maliye, and Raut, which is expected to be at a rate of 0.1 FTE for each.

Under this subcontract, MGIMS will perform the following important tasks:

-MGIMS will serve as the primary coordinator for the majority of local research staff on this project in India. This will include a primary study coordinator, a study psychologist, two study recruitment experts, and an informatics specialist.

-MGIMS staff mentioned above will be primarily responsible for subject enrollment and for data collection at the India site.

-The site PI Gupta will coordinate closely with the overall project PI/PD Rohloff to ensure that Deliverables related to data collection and storage are managed appropriately.

-Key deliverables related to completion of these aims will include:

1. We will engage in timely recruitment and informed consent of eligible institutions and subjects.
2. We will coordinate, train, and supervise community health workers delivering the intervention
3. We will process and store locally in a secure fashion on paper enrollment and consent forms
4. MGIMS will securely store identifiable human subjects' data locally in paper or electronic form as appropriate. Subsequently, all data necessary for project analysis will be transferred in fully deidentified form to BWH using BWH Dropbox.
5. The project will be reviewed by our IRB.

Appendix B: Budget

For the budget period of April 01, 2021 to March 31, 2022

Personnel	USD $64,100.00
Supplies/Other	USD $20,500.00
Travel	USD $18,000.00
Direct Costs	USD $102,600.00
F&A Costs (8.00%)*	USD $8,208
Total Costs	**USD $110,808**

**F&A applied on Total Direct Cost (TDC) base*

Appendix C: Format for Invoices

TO: Subcontract Invoice Coordinator
Partners Research Management
399 Revolution Drive, Suite 745
Somerville, MA 02145
bwhsubinvoices@partners.org
Date:

Total Allocation: $
Agreement number**:** 125594

Reimbursable Costs for the Period: _____ To _____

Category	*Current Period*	*To Date*
Salaries and Wages	$	$
Applicable Fringe Benefits		
Equipment		
Supplies		
Travel		
Other Expenses		
Total Direct Cost	_____	_____
Indirect Cost	_____	_____
Total Billed/Expended		
Less Amount Previously Billed/Expended	_____	
Total Billed/Expended Current Period	_____	

By signing this invoice, I certify to the best of my knowledge and belief that the invoice is true, complete, and accurate, and the expenditures, disbursements and cash receipts are for the purposes and objectives set forth in the terms and conditions of the Federal award. I am aware that any false, fictitious, or fraudulent information, or the omission of any material fact, may subject me to criminal, civil or administrative penalties for fraud, false statements, false claims or otherwise. (U.S. Code Title 18, Section 1001 and Title 31, Sections 3729–3730 and 3801–3812).

_____

Name:

Title: Date:

Appendix D: Prime Award

See attached pages

Recipient Information

1. Recipient Name
BRIGHAM AND WOMEN'S HOSPITAL, INC., THE
75 FRANCIS ST

BOSTON, MA 02115

2. Congressional District of Recipient
07

3. Payment System Identifier (ID)
1042312909A1

4. Employer Identification Number (EIN)
042312909

5. Data Universal Numbering System (DUNS)
030811269

6. Recipient's Unique Entity Identifier

7. Project Director or Principal Investigator
Peter Rohloff, MD

prohloff@bwh.harvard.edu
617-732-5500

8. Authorized Official
Ms. Helen M. Wong

Federal Agency Information

9. Awarding Agency Contact Information
Kelly Fritz

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
kelly.fritz@nih.gov
301-827-5429

10. Program Official Contact Information
Sujata Bardhan

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT
sujata.bardhan@nih.gov
301-496-1383

Federal Award Information

11. Award Number
1R01HD100984-01A1

12. Unique Federal Award Identification Number (FAIN)
R01HD100984

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
An Individualized Approach to Promote Nurturing Care in Low and Middle Income Countries: A Hybrid Effectiveness/Implementation Trial of the International Guide for Monitoring Child Development

15. Assistance Listing Number
93.865

16. Assistance Listing Program Title
Child Health and Human Development Extramural Research

17. Award Action Type
New Competing

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 04/01/2021 **– End Date** 03/31/2022	
20. Total Amount of Federal Funds Obligated by this Action	$557,110
20 a. Direct Cost Amount	$491,790
20 b. Indirect Cost Amount	$65,320
21. Authorized Carryover	$0
22. Offset	$0
23. Total Amount of Federal Funds Obligated this budget period	$557,110
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$557,110
26. Project Period Start Date 04/01/2021 **– End Date** 03/31/2026	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$557,110

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Kelly Fritz

30. Remarks

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise

Version:203 - 1/27/2021 10:14 PM | Generated on: 3/25/2021 12:04 AM

requested from the grant payment system.

RESEARCH
Department of Health and Human Services
National Institutes of Health

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

SECTION I – AWARD DATA – 1R01HD100984-01A1

Principal Investigator(s):
Peter Rohloff, MD

Award e-mailed to: bwhgc@partners.org

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $557,110 (see “Award Calculation” in Section I and “Terms and Conditions” in Section III) to Brigham and Women's Hospital in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the recipient when funds are drawn down or otherwise requested from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as “Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number R01HD100984. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.” Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator’s Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website http://grants.nih.gov/grants/policy/coi/ for a link to the regulation and additional important information.

If you have any questions about this award, please direct questions to the Federal Agency contacts.

Sincerely yours,

Kelly Fritz
Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Additional information follows

Version: 203 - 1/27/2021 10:14 PM | Generated on: 3/25/2021 12:04 AM

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$47,029
Fringe Benefits	$15,570
Personnel Costs (Subtotal)	$62,599
Materials & Supplies	$2,580
Travel	$8,600
Other	$1,461
Subawards/Consortium/Contractual Costs	$416,550
Federal Direct Costs	$491,790
Federal F&A Costs	$65,320
Approved Budget	$557,110
Total Amount of Federal Funds Authorized (Federal Share)	$557,110
TOTAL FEDERAL AWARD AMOUNT	$557,110
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$557,110

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$557,110	$557,110
2	$503,171	$503,171
3	$483,975	$483,975
4	$480,273	$480,273
5	$444,233	$444,233

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

Payment System Identifier:	1042312909A1
Document Number:	RHD100984A
PMS Account Type:	P (Subaccount)
Fiscal Year:	2021

IC	CAN	2021	2022	2023	2024	2025
HD	8014702	$557,110	$503,171	$483,975	$480,273	$444,233

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:
PCC: IDDB -SB / **OC**: 41021 / **Released**: Fritz, Kelly 03/18/2021
Award Processed: 03/25/2021 12:04:32 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 1R01HD100984-01A1

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm

SECTION III – STANDARD TERMS AND CONDITIONS – 1R01HD100984-01A1

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.

Version: 203 - 1/27/2021 10:14 PM | Generated on: 3/25/2021 12:04 AM

d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at http://grants.nih.gov/grants/policy/awardconditions.htm for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of "Research and Development" at 45 CFR Part§ 75.2**.** As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See http://grants.nih.gov/grants/policy/awardconditions.htm for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01HD100984. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see http://grants.nih.gov/grants/policy/awardconditions.htm for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: http://publicaccess.nih.gov/.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register "applicable clinical trials" on the ClinicalTrials.gov Protocol Registration System Information Website. NIH encourages registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made

Version: 203 - 1/27/2021 10:14 PM | Generated on: 3/25/2021 12:04 AM

publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.
Treatment of Program Income:
Additional Costs

SECTION IV – HD SPECIFIC AWARD CONDITIONS – 1R01HD100984-01A1

Clinical Trial Indicator: Yes
This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

Due to the impact of the Coronavirus disease 2019 (COVID-19) outbreak, NIH is providing all award recipients with greater flexibilities in meeting administrative, financial management and audit requirements. See OMB Memo M 20-26 (https://www.whitehouse.gov/wp-content/uploads/2020/06/M-20-26.pdf).

****

The clinical trial(s) supported by this award are subject to the Dissemination Plan specified in the **application/correspondence** dated **11/7/2019** and the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. The policy states that the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant and that primary summary results will be reported in ClinicalTrials.gov not later than one year after the trial completion date. The reporting of summary results is required even if the primary trial completion date occurs after the period of performance.

This award is subject to additional certification requirements with submission of the Annual, Interim and Final Research Performance Progress Reports (RPPR). The recipient must agree to the following annual certification when submitting each RPPR. By submitting the RPPR, the Signing Official (SO) signifies compliance, as follows:

In submitting this RPPR, the SO (or PD/PI with delegated authority), certifies to the best of his/her knowledge that, for all clinical trials funded under this NIH award, the recipient and all investigators conducting NIH-funded clinical trials are in compliance with the recipient's plan addressing compliance with the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information. Any clinical trial funded in whole or in part under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the trial completion date, even if the trial completion date occurs after the period of performance.

****

Clinical Trial Study/Studies:
STUDY NUMBER(S) 308835

The Clinical Trial Study or Studies listed above have been determined by NICHD to be considered MEDIUM risk requiring increased oversight by NICHD. An update on the status of the milestones included in Section 6 of the eRA Human Subjects System (HSS) and any additional agreed-upon milestones will be due once a year (generally halfway through the budget period) as well as being included in the annual RPPR. The update cycle due date is based on the budget period start date referenced in this Notice of Award. Information and procedures concerning these requirements are available at https://www.nichd.nih.gov/grants-contracts/process-strategies/policies/clinical-research. Updates must be provided through the eRA HSS accessible through the eRA Commons.

Version: 203 - 1/27/2021 10:14 PM | Generated on: 3/25/2021 12:04 AM

****

In accordance with the NICHD FY2021 fiscal policy, escalation on recurring costs has been removed.

*****

This award includes foreign component at the following site(s):

Wuqu' Kawog/Maya Health Alliance in Guatemala

Ummeed Child Development Center in **India**

Mahatma Gandhi Institute in **India**

Ankara University in **Turkey**

This award is subject to the requirements indicated in **PAR18-835**, which are hereby incorporated by reference. This Funding Opportunity Announcement is available at http://grants.nih.gov/grants/guide/index.html.

In order to meet NICHD program objectives within FY2021 budget constraints, this grant is reduced **14** percent below the level recommended by the Integrated Review Group. Future year levels of support are determined by applying the same administrative reduction.

SPREADSHEET SUMMARY
AWARD NUMBER: 1R01HD100984-01A1

INSTITUTION: Brigham and Women's Hospital

Budget	Year 1	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	$47,029	$44,134	$44,134	$44,134	$47,029
Fringe Benefits	$15,570	$14,557	$14,557	$14,557	$15,570
Personnel Costs (Subtotal)	$62,599	$58,691	$58,691	$58,691	$62,599
Materials & Supplies	$2,580		$2,580		$2,580
Travel	$8,600	$6,450	$8,600	$6,450	$8,600
Other	$1,461				$1,402
Subawards/Consortium/Contractual Costs	$416,550	$419,139	$393,841	$396,241	$330,609
Publication Costs					$12,900
TOTAL FEDERAL DC	$491,790	$484,280	$463,712	$461,382	$418,690
TOTAL FEDERAL F&A	$65,320	$18,891	$20,263	$18,891	$25,543
TOTAL COST	$557,110	$503,171	$483,975	$480,273	$444,233

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	29%	29%	29%	29%	29%
F&A Cost Base 1	$225,240	$65,141	$69,871	$65,141	$88,081
F&A Costs 1	$65,320	$18,891	$20,263	$18,891	$25,543

Version: 203 - 1/27/2021 10:14 PM | Generated on: 3/25/2021 12:04 AM

Appendix E: FFATA Contact Information

See attached pages

Consortium Agreement
Appendix E: Contact Information

Agreement Reference Number: 125594

Hospital Contact Information

Legal Name: The Brigham and Women's Hospital, Inc.

Address: 75 Francis Street
Boston, MA 02115-6110

More information on Hospital can be found under Resources for Collaborators and Sponsors at partners.org

Hospital Grant Administrator

Name: Lewis Seton

Address: 75 Francis Street
BC-3-030-A

City: Boston State: MA Zip Code: 02115

Telephone: 617-278-0936 Email: LSETON@BWH.HARVARD.EDU

COI Contact email (if different to above): PHSOII@partners.org

Hospital Investigator

Name: Peter Rohloff, MD, PhD

Address: 75 Francis Street
PBB-B-4

City: Boston State: MA Zip Code: 02115

Telephone: Email: prohloff@bwh.harvard.edu

Hospital Financial Contact

Name: BWH Subcontracts Invoice Coordinator

Address: Partners Research Management – Research Finance
399 Revolution Drive, Suite 745

City: Somerville State: MA Zip Code: 02145-1446

Telephone: 857-282-5689 Email: BWHSubInvoices@partners.org

Copy To:

Hospital Authorized Official

Name: Paul Anderson, MD, PhD Senior Vice President of Research, Chief Academic Officer c/o Grants Analyst, Post Award

Address: Partners Research Management – Post Award
399 Revolution Drive, Suite 740

City: Somerville State: MA Zip Code: 02145-1446

Central Email: BWHSubs@partners.org

Consortium Agreement

Appendix E: Contact Information

Agreement Reference Number: 125594

Subrecipient Contact Information

Legal Name: Mahatma Gandhi Institute of Medical Sciences

Address: Mahatma Gandhi Institute of Medical Sciences, Sevagram
Wardha - 442102; Maharashtra; India

Subrecipient Grant Administrator

Name: Dr Subodh Sharan Gupta

Address: Department of Community Medicine
Mahatma Gandhi Institute of Medical Sciences, Sevagram
Wardha - 442102; Maharashtra; India

City: Wardha State: Maharashtra Zip Code: 442102

Telephone: +91-9822926934 Email: subodh@mgims.ac.in

COI Contact email (if different to above):

Subrecipient Investigator

Name: Dr Subodh Sharan Gupta

Address: Department of Community Medicine
Mahatma Gandhi Institute of Medical Sciences, Sevagram
Wardha - 442102; Maharashtra; India

City: Wardha State: Maharashtra Zip Code: 442102

Telephone: +91-9822926934 Email: subodh@mgims.ac.in

Subrecipient Financial Contact

Name: Mr Ashok Honale, Chief Accountant

Address: Accounts Section
Mahatma Gandhi Institute of Medical Sciences, Sevagram
Wardha - 442102; Maharashtra; India

City: Wardha State: Maharashtra Zip Code: 442102

Telephone: +91-7152-284345 ext 299 Email: chiefaccountant@mgims.ac.in

Copy To: subodh@mgims.ac.in

Subrecipient Authorized Official

Name: Dr Nitin M Gangane, Dean

Address: Mahatma Gandhi Institute of Medical Sciences, Sevagram
Wardha - 442102; Maharashtra; India

City: Wardha State: Maharashtra Zip Code: 442102

Central Email: dean@mgims.ac.in

Appendix F: Telecommunications Clause

52.204-25 Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment (Aug 2020)

(a) *Definitions.* As used in this clause—

Backhaul means intermediate links between the core network, or backbone network, and the small subnetworks at the edge of the network (*e.g.*, connecting cell phones/towers to the core telephone network). Backhaul can be wireless (e.g., microwave) or wired (*e.g.*, fiber optic, coaxial cable, Ethernet).

Covered foreign country means The People's Republic of China.

Covered telecommunications equipment or services means–

(1) Telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities);

(2) For the purpose of public safety, security of Government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities);

(3) Telecommunications or video surveillance services provided by such entities or using such equipment; or

(4) Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise connected to, the government of a covered foreign country.

Critical technology means–

(1) Defense articles or defense services included on the United States Munitions List set forth in the International Traffic in Arms Regulations under subchapter M of chapter I of title 22, Code of Federal Regulations;

(2) Items included on the Commerce Control List set forth in Supplement No. 1 to part 774 of the Export Administration Regulations under subchapter C of chapter VII of title 15, Code of Federal Regulations, and controlled-

(i) Pursuant to multilateral regimes, including for reasons relating to national security, chemical and biological weapons proliferation, nuclear nonproliferation, or missile technology; or

(ii) For reasons relating to regional stability or surreptitious listening;

(3) Specially designed and prepared nuclear equipment, parts and components, materials, software, and technology covered by part 810 of title 10, Code of Federal Regulations (relating to assistance to foreign atomic energy activities);

(4) Nuclear facilities, equipment, and material covered by part 110 of title 10, Code of Federal Regulations (relating to export and import of nuclear equipment and material);

(5) Select agents and toxins covered by part 331 of title 7, Code of Federal Regulations, part 121 of title 9 of such Code, or part 73 of title 42 of such Code; or

(6) Emerging and foundational technologies controlled pursuant to section 1758 of the Export Control Reform Act of 2018 (50 U.S.C. 4817).

Interconnection arrangements means arrangements governing the physical connection of two or more networks to allow the use of another's network to hand off traffic where it is ultimately delivered (*e.g.*, connection of a customer of telephone provider A to a customer of telephone company B) or sharing data and other information resources.

Reasonable inquiry means an inquiry designed to uncover any information in the entity's possession about the identity of the producer or provider of covered telecommunications equipment or services used by the entity that excludes the need to include an internal or third-party audit.

Roaming means cellular communications services (*e.g.*, voice, video, data) received from a visited network when unable to connect to the facilities of the home network either because signal coverage is too weak or because traffic is too high.

Substantial or essential component means any component necessary for the proper function or performance of a piece of equipment, system, or service.

(b) *Prohibition*.

(1) Section 889(a)(1)(A) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2019, from procuring or obtaining, or extending or renewing a contract to procure or obtain, any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. The Subrecipient is prohibited from providing to the Government any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless an exception at paragraph (c) of this clause applies or the covered telecommunication equipment or services are covered by a waiver described in FAR 4.2104.

(c) *Exceptions.* This clause does not prohibit contractors from providing—

(1) A service that connects to the facilities of a third-party, such as backhaul, roaming, or interconnection arrangements; or

(2) Telecommunications equipment that cannot route or redirect user data traffic or permit visibility into any user data or packets that such equipment transmits or otherwise handles.

(d) Reporting requirement.

(1) In the event the Contractor identifies covered telecommunications equipment or services used as a substantial or essential component of any system, or as critical technology as part of any system, during contract performance, or the Contractor is notified of such by a subcontractor at any tier or by any other source, the Contractor shall report the information in paragraph (d)(2) of this clause to the Hospital.

(2) The Contractor shall report the following information pursuant to paragraph (d)(1) of this clause

(i) Within one business day from the date of such identification or notification: the Agreement number; the order number(s), if applicable; supplier name; supplier unique entity identifier (if known); supplier Commercial and Government Entity (CAGE) code (if known); brand; model number (original equipment manufacturer number, manufacturer part number, or wholesaler number); item description; and any readily available information about mitigation actions undertaken or recommended.

(ii) Within 10 business days of submitting the information in paragraph (d)(2)(i) of this clause: any further available information about mitigation actions undertaken or recommended. In addition, the Subrecipient shall describe the efforts it undertook to prevent use or submission of covered telecommunications equipment or services, and any additional efforts that will be incorporated to prevent future use or submission of covered telecommunications equipment or services.

(e) *Subcontracts.* The Contractor shall insert the substance of this clause, including this paragraph (e) and excluding paragraph (b)(2), in all subcontracts and other contractual instruments, including subcontracts for the acquisition of commercial items.

Representation. **By signing this Agreement, Subrecipient represents that:**

(1) it does not provide covered telecommunications equipment or services, as defined above, as a part of its offered products or services to the United States Government in the performance of any contract, subcontract, or other contractual instrument, including this Agreement; and

(2) After conducting a reasonable inquiry for purposes of this representation, the Subrecipient represents that it does not use covered telecommunications equipment or services, or any equipment, system, or service that uses covered telecommunications equipment or services, as defined above.

Coworks, Coworking Spaces Pvt. Ltd-RMZ Eco world,
Ground floor, Bay Area - Adjacent to Building 6A,
Outer Ring Road, Devarabeesanahalli Village,
BENGALURU, INDIA-560103

in capacity of the authorized agent of

(2) Serum Institute of India Private Limited,
212/2, Off Soli Poonawalla Road, Hadapsar, Pune 411 028, India
(hereinafter SPONSOR)
and

(3) Mahatma Gandhi Institute of Medical Sciences (MGIMS) Sewagram, Wardha, 422102, Maharashtra, India (hereinafter Institution)

and

(4) Dr. Bishan Swarup Garg,
Dr. Sushila Nayar School of Public Health, Department of Community Medicine,
Mahatma Gandhi Institute of Medical Sciences- MGIMS, Sewagram, Wardha, 442102, Maharashtra, India
(hereinafter Existing Investigator)

(5) Dr.Abishek.V.Raut, Mahatma Gandhi Institute of Medical Sciences, Sewagram, Wardha (M.S.), INDIA – 442102, India (hereinafter **New Investigator**)

Protocol No: VPM1002-IN-3.01TBR (hereinafter Protocol)
"A MULTICENTER PHASE II/III DOUBLE-BLIND, RANDOMIZED, PLACEBO CONTROLLED STUDY TO EVALUATE THE EFFICACY AND SAFETY OF VPM1002 IN THE PREVENTION OF TUBERCULOSIS (TB) RECURRENCE IN PULMONARY TB PATIENTS AFTER SUCCESSFUL TB TREATMENT IN INDIA" (hereinafter Study)
VPM1002 (hereinafter Study Drug)

WHEREAS, SPONSOR is the sponsor of the multi-center/multi-centre Study to clinically evaluate the Study Drug;

WHEREAS, SPONSOR and PAREXEL International Clinical Research Private Limited (hereinafter CRO) or an Affiliate have agreed (under a separate written agreement) that CRO will act on behalf of SPONSOR as its authorized representative and agent;

WHEREAS, the parties have entered into the above-referred Agreement dated 29 July 2017;

WHEREAS, the purpose of this Amendment is to address the following subjects:

a) Revised Protocol Title
b) Revised Section 15.1 Payment Terms and Conditions
c) Replacement of the Investigator
d) Revised Exhibit A-section 2 Disbursement of Study/Research Grant and per completed subject cost
e) Revised Section 6 & 7 of the Exhibit A-Enrolment and Payment Schedule

Now, therefore the above-referred Agreement shall be amended, and the following amended wordings shall be effective as of 30 Jan 2020

a) Protocol Title:

A MULTICENTER PHASE II/III DOUBLE-BLIND, RANDOMIZED, PLACEBO CONTROLLED STUDY TO EVALUATE THE EFFICACY AND SAFETY OF VPM1002 IN THE PREVENTION OF TUBERCULOSIS (TB) RECURRENCE IN PULMONARY TB PATIENTS AFTER SUCCESSFUL TB TREATMENT

b) Revised section 15.1 Payment Terms and Conditions:

15.1 In full consideration for the Services of Institution, Investigator and Study Personnel rendered in compliance with the Protocol, SPONSOR agrees to pay the fees and expenses set forth on Exhibit A as a research grant. Such fees and expenses will be paid solely to the

(1) **PAREXEL International Clinical Research Private Limited**

(Signature of Authorized Official)

Dr. Roopa Basur — 11 Mar 2020

(Typed or Printed Name) — Date

(2) **Mahatma Gandhi Institute of Medical Sciences (MGIMS)**

(Signature of Authorized Official)

Dr Nitin M Gokhale — 16 | Mar | 2020

(Typed or Printed Name) — Date

(3) **Investigator: Dr. Bishan Swarup Garg**

(Signature of Existing Investigator)

Dr. Bishan Swarup Garg. — 18 | MARCH | 2020

Date

(4) **Investigator: Dr. Abishek.V.Raut**

(Signature of New Investigator)

Dr. Abishek.V Raut — 18 | MAR | 2020

Date

(5) **Serum Institute of India Private Limited**

(Signature of Authorized Official)

Dr. Prasad Kulkarni — 13/03/2020.

(Typed or Printed Name) — Date

MEMORANDUM OF UNDERSTANDING

This Agreement made at Mumbai on this day of 31 July 2020 for collaboration between Kasturba Health Society's Mahatma Gandhi Institute of Medical Sciences (KHS-MGIMS), Sevagram and Ummeed Child Development Centre, Mumbai for implementing an inclusive Early Childhood Development project.

By and between:

Kasturba Health Society's Mahatma Gandhi Institute of Medical Sciences, Sevagram, Wardha, Maharashtra hereinafter referred to as KHS-MGIMS having its registered office at Sevagram, Dist.: Wardha, Maharashtra, INDIA. Kasturba Health Society is a charitable trust that manages Mahatma Gandhi Institute of Medical Sciences and which includes its associates, subsidiaries, affiliates, successors, permitted assigns and administrator of the **FIRST PART.**

And

Ummeed Child Development Center, having its registered office at Ground Floor, 1-B, 1/62, Mantri Pride, N.M. Joshi Marg, Subhash Nagar, Lower Parel, Mumbai – 400011 hereinafter referred to as **"Ummeed",** a non-profit organization incorporated under section 25 of the Companies Act 1956 (corresponding to Section 8 of Companies Act 2013), and which includes its associates, subsidiaries, affiliates, successors, permitted assigns and administrator of the **SECOND PART.**

Hereinafter, KHS-MGIMS and Ummeed will be collectively referred to as "Parties" and separately as "Party".

AND WHEREAS Ummeed is a Mumbai based NGO that promotes child development and provides services to children with, and at risk of, developmental disabilities, and runs various training and capacity building programs for individuals and organizations, including the Early Childhood Development and Disabilities (ECDD) program for community health workers.

Ummeed has received a grant from Stiftung Auxilium for its project titled "Inclusive early childhood development (0-3) in the Integrated Child Development Services (ICDS) scheme" hereinafter referred to as "Project".

Ummeed has approached KHS-MGIMS, Wardha to be its implementation partner for this Project, i.e., support the implementation of Ummeed's inclusive ECD program with a group of Anganwadi workers from one block of Wardha district in Maharashtra. KHS-MGIMS has agreed to the same.

Scanned with CamScanner

INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

सत्यमेव जयते

Certificate No.	:	IN-KA49884117722415P
Certificate Issued Date	:	12-Jun-2017 03:03 PM
Account Reference	:	NONACC (FI)/ kaksfcl08/ BANGALORE8/ KA-BA
Unique Doc. Reference	:	SUBIN-KAKAKSFCL0848422861527504P
Purchased by	:	PAREXEL INTERNATIONAL CLINICAL RESEARCH PVT LTD
Description of Document	:	Article 12 Bond
Description	:	AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	PAREXEL INTERNATIONAL CLINICAL RESEARCH PVT LTD
Second Party	:	INSTITUTION AND INVESTIGATOR
Stamp Duty Paid By	:	PAREXEL INTERNATIONAL CLINICAL RESEARCH PVT LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Sri Siddeshwara Souharda Sahakari Niyamita, Sahakaranagar, Bhore-82

Please write or type below this line

THIS AGREEMENT is made by and Among

(1) **PAREXEL International Clinical Research Private Limited**
Coworks, Coworking Spaces Pvt.Ltd-RMZ Eco world,
Ground floor, Bay Area- Adjacent to Building 6A,
Outer Ring Road, Devarabeesanahalli Village,
BENGALURU,INDIA-560103

Statutory Alert:
1. The authenticity of this Stamp Certificate should be verified at "www.shcilestamp.com". Any discrepancy in the details on this Certificate and as available on the website renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority.

BENEVOLENTIA

Dr B S Garg
Secretary
Kasturba Health Society
Sevagram
442102 Wardha
India

Amsterdam, February 16, 2022

Project No. GR-075113

GRANT AGREEMENT

Dear Dr. Garg,

We are pleased to inform you that the Stichting Benevolentia (hereinafter: "**the Foundation**") has agreed to provide Kasturba Health Society (hereinafter: "**the Grantee**") with a grant of EUR 50,000.00 to support the project, Community Resilience during Covid, pursuant to the terms and conditions set out in Annexes A through D of this letter agreement (hereafter: the "**Grant Agreement**").

This Grant Agreement is subject to your signature. Please have this Grant Agreement duly signed and returned to us to confirm your agreement with the terms and conditions of the Grant Agreement.

We look forward to working with your organisation and wish you every success with this project.

Yours sincerely,

DocuSigned by:
4E0F1948DFF442A...

Name: **Niels Levitus**
Authorised signatory
Date: **18/02/2022**

DocuSigned by:
Linda ten Broeke
41C3248F19794A6...

Name: **Linda ten Broeke**
Authorised Signatory
Date: **18/02/2022**

Name: Dr. B.S. Garg
Kasturba Health Society
Date: 21/Feb/2022

Secretary,
Kasturba Health Society
P. O. Sevagram, Wardha.
Pin 442 102

Annex A: Grant Summary
Annex B: General Terms & Conditions
Annex C: Grantee Privacy Statement
Annex D: Grant Information

BENEVOLENTIA

ANNEX A: GRANT SUMMARY

GRANTEE:	Kasturba Health Society
PROJECT NO.:	GR-075113
PURPOSE OF GRANT:	Community Resilience during Covid (hereinafter: the **"Project"**)
DURATION:	The grant is to be used for the Project implemented from March 1, 2022 to February 28, 2023.
AMOUNT:	EUR 50,000.00
DISBURSEMENT:	The disbursements pursuant to this Grant Agreement are subject to receipt by the Foundation of the Grantee's complete banking information and will be made within thirty (30) business days of the Foundation's payment schedule or acceptance/approval of Project milestones, as set forth in Annex D. The Grantee waives any right to late payment interest in case of the Foundation's default and no claim to such interest will accrue to the Grantee under any circumstances.
CORRESPONDENCE:	The grant and this Grant Agreement are managed on behalf of the Foundation by the Porticus organisation (www.porticus.com). Any communication or notice which either party sends to the other shall be sent by regular or electronic mail as per the details below. For any communication, please include the project number given at the head of this Grant Agreement. On behalf of the Foundation: Vrinda Kapur Porticus Asia Ltd. 1505B,15/F, Sino Plaza 255-257, Gloucester Road Causeway Bay, Hong Kong porticusasia@porticus.com The Grantee: Dr B S Garg Kasturba Health Society Sevagram 442102 Wardha India

ANNEX B: GENERAL TERMS AND CONDITIONS

Version January 2020

GENERAL: These general terms and conditions ("**General Terms**") apply to the offering, announcement and provision of all donations by or on behalf of the Foundation.

In these General Terms a reference to the Foundation shall as applicable be construed as to include its grant adviser and manager operating under the name Porticus.

The General Terms supersede any and all prior oral and written communications, negotiations, agreements and understandings of the parties and shall apply in preference to and supersede any and all terms and conditions applied or submitted by the Grantee. Any terms in the Grantee's communications, including pre-printed terms, additional to or contrary to these General Terms are not effective.

All annexes to the Grant Agreement, as may be modified from time to time, ("**Annexes**") form an integral part of the Grant Agreement. In case of conflict between these General Terms and the other Annexes, the latter will prevail.

ADDITIONAL FUNDING: Any request for additional funding beyond the amount committed to the Project will only be considered after the Grantee's submission to the Foundation of documents as requested by the Foundation (at its sole discretion). The Foundation is by no means required to grant additional funding beyond the amount committed to the Project.

DISSEMINATION OF RESULTS: Subject to the conditions of this Grant Agreement (including confidentiality), in case of a research grant, the Grantee shall make the outcomes of the Project, including the methodology, scholarly results or research findings (the **Results**), publicly available within a reasonable time period for the purpose of advancing knowledge and research to the benefit of the public. The Grantee explicitly authorizes the Foundation to share lessons learned from its project and any other project information with the public.

INTELLECTUAL PROPERTY AND LICENSING: The Grantee shall own the entire right, title and interest, including all copyrights and other intellectual property rights, in and to all materials, inventions, works of authorship, software, information and data conceived or developed by the Grantee in the performance of this Grant Agreement.

The Grantee acknowledges that the Foundation strives to be a learning organisation and wishes to disseminate the Project's lessons learned, subject to the restrictions set out in this Grant Agreement. To accommodate this, the Grantee hereby grants the Foundation, and for the avoidance of doubt Porticus, an irrevocable, worldwide, royalty-free and unlimited license to use, reproduce, edit and publish for the purpose of the Foundation's internal and external communication activities:

1. the contents of the Grantee's reports;
2. all images and videos relating to the Grantee's activities under this Grant Agreement; and
3. all other materials provided by the Grantee to the Foundation in connection with the Grant Agreement

(1. 2. and 3. collectively hereinafter: the "**Materials**").

For the avoidance of doubt, the Results shall not be included in the scope of the license issued to the Foundation unless the Results are contained in the Materials.

The Grantee guarantees and represents that it has obtained all intellectual property rights (including, but not limited to, the copyrights) in respect of all Materials, or has obtained all the necessary licenses and consents to license all Materials to the Foundation in this Grant Agreement.

CONFIDENTIALITY: Both during the term of the Grant Agreement and after its suspension or termination, the Grantee shall duly protect all information of whatever nature relating to the Foundation or Porticus or any of their affiliated or related entities or persons, which the Grantee has become aware of or has (had) access to as a result (whether directly or indirectly) of the Grant Agreement (the Grant Information).

The Grantee may disclose Grant Information to third parties in accordance with this Grant Agreement if such disclosure serves a Legitimate Business Purpose in respect of the Project. For the purposes of this clause, Legitimate Business Purpose means: (i) compliance with all present and future applicable laws and regulations; (ii) internal reporting requirements; (iii) KYC requirements; (iv) non-public means of securing additional funding for a project relating to this Grant Agreement, or (v) sharing learnings about the Project with peer organisations.

In the event the Grantee is unclear as to whether an intended disclosure of Grant-related Information is permitted under this Grant Agreement, the Grantee shall first clarify with Porticus or the Foundation whether the Grant Information can be freely disclosed.

The Grantee may not disclose Grant Information for any purpose other than a Legitimate Business Purpose, and shall not use the Foundation's' or Porticus' brand for external communication, without prior approval of the Foundation. To the extent permissible under applicable law, the Grantee hereby agrees to provide all reasonable cooperation to limit a disclosure, or to ensure that the recipient of the Grant Information is bound by an obligation of confidentiality, should the Foundation require that such measures are taken.

For the avoidance of doubt, this confidentiality provision does not prohibit the Grantee from publishing, disseminating or otherwise disclosing the Results unless the Results contain Grant Information.

The Foundation agrees to keep confidential information that the Grantee has explicitly marked as being confidential.

REPRESENTATIONS: The Grantee represents to the Foundation that:

(a) Legal capacity and necessary power: The persons entering into the Grant Agreement and any related documents have full power, authority and legal capacity to execute and deliver the Grant Agreement and any related documents and to conduct the activities contemplated under the Project on behalf of the Grantee.
(b) Compliance with laws: The Grant Agreement constitutes a legal, valid and binding obligation of the Grantee, enforceable against it in accordance with its terms. The activities under the Project are operated in compliance with applicable laws.
(c) No claims or investigations: Except as disclosed in writing to the Foundation prior to the date of the Grant Agreement, there are no claims, investigations or proceedings in progress, pending or (to its knowledge) threatened against the Grantee, officials or individuals in charge of or working on the Project which, if determined adversely, would have a material adverse impact on the implementation of the Project.
(d) Accuracy of information: All information that is provided to the Foundation including, its applications, progress reports, any supporting documentation, and other related operational and financial information or reports, is accurate and correct as of the date of the provision of such information.
(e) Absence of certain events: Except as disclosed in writing to the Foundation prior to the date of the Grant Agreement, no actual or suspected breach of obligations by the Grantee under the Grant Agreement has occurred and is continuing.

The representations by the Grantee set out above shall be deemed to be repeated on the date of any disbursement of funds under the Grant Agreement by reference to the facts and circumstances then existing.

COMPLIANCE WITH LAWS AND POLICIES: The Grantee shall comply, and shall ensure that its affiliated and related entities, officers and employees comply, with all present and future applicable laws and regulations, including, but not limited to, laws and regulations concerning (1) child protection and the protection of vulnerable adults; (2) bribery and corruption; (3) conflicts of interest; (4) antitrust and fair dealing; (5) labour and labour conditions, including anti-modern slavery regulations; (6) discrimination and harassment, (7) local financial and tax, and (8) anti-terrorism.

In particular, the Grantee shall not, and shall ensure that its affiliated and related entities, officers and employees do not:

1. do anything in the delivery of the Project which may put children or vulnerable adults at risk of harm or exploitation;
2. offer, give or authorize any payment, gift or other advantage, directly or indirectly, to any third party which could act as an inducement or a reward for any act or failure to act in connection with this Grant Agreement, or any other agreement, or in any other way act in violation of applicable anti-bribery and anti-corruption laws and regulations;
3. use any grant moneys or funding received from the Foundation directly or indirectly in support of any activities (a) prohibited by any laws combatting terrorism; (b) with or related to parties on any applicable International Sanctions List; or (c) with or related to countries against which there are comprehensive embargos; and
4. pursue any business, professional, personal, private or other interest that would in any manner conflict with the performance of the Grantee's obligations under the Grant Agreement or with the execution of the Project.

For the purposes of this clause, International Sanctions List means (1) the Specially Designated Nationals and Blocked Persons List (SDN List) of the U.S. Department of Treasury Office of Foreign Asset Control (OFAC); (2) the Consolidated List of Persons, Groups and Entities Subject to EU Financial Sanctions (CFSP List) of the European Union (EU); (3) the Consolidated United Nations Security Council Sanction List of the United Nations (UN); and (4) the List of Subjects of Sanctions of the State Secretariat for Economic Affairs (SECO) of Switzerland (any person listed on any such list hereinafter: a "**Prohibited Person**"). The Grantee shall at all times ensure that any necessary licenses and approvals have been obtained and are in place during the term of this Grant Agreement.

TAX: The Foundation has qualified the disbursement of funds under this Grant Agreement as a charitable donation. The Grantee guarantees that it is qualified to receive the charitable funds in accordance with the laws that apply to it. The Parties acknowledge and agree that any gift tax payable or chargeable in connection with this Grant Agreement shall be for the account of the Grantee.

PRIVACY: The Grantee shall inform its employees and any other persons involved with the performance of this Grant Agreement that their personal data, if and to the extent provided to the Foundation and/or Porticus, may be (i) processed by the Foundation and/or Porticus (as the case may be) in connection with the performance of this Grant Agreement; (ii) transferred to countries that do not provide an adequate level of protection; and (iii) shared with third parties affiliated with the Foundation and/or Porticus (as the case may be), each in accordance with the Grantee Privacy Statement attached hereto as Annex C.

SAFEGUARDING: In so far as the Project involves work with children, young people or vulnerable adults (hereinafter: jointly "**Vulnerable Persons**" or individually a "**Vulnerable Person**"), the Grantee will take all steps reasonably necessary to ensure their safety including compliance with any local laws and regulations in this respect.

The Grantee will have and will comply with an appropriate written policy and set of procedures to safeguard Vulnerable Persons. Such policy and procedures shall comply with the minimum standards set by the Foundation from time to time. The Foundation reserves the right to review and recommend amendments to the Grantee's safeguarding policy and procedures to ensure it meets the minimum standards.

To the extent permitted under applicable law, the Grantee shall notify Porticus (on behalf of the Foundation) of all serious incidents in which a Vulnerable Person is harmed or placed at risk of harm (including any breach of laws) and shall provide such details as the Foundation shall reasonably require. The Grantee shall comply with all local (safeguarding) reporting requirements in addition to notifying the Foundation.

The Foundation shall, upon giving reasonable notice, be entitled to receive information on the Grantee's safeguarding practices and to visit the Project, while taking into account relevant privacy considerations.

MODIFICATIONS: The Foundation may reasonably add Annexes or modify the terms in the existing Annexes (excluding annexes to which the Grantee has provided input) and such additions and modifications shall apply to the Grantee as of the date of notification to it of such changes. If the Grantee does not agree with any of the changes proposed by the Foundation in the Annexes, it shall notify the Foundation in writing of any disagreements within thirty (30) calendar days of notice of such changes. If the Parties fail to resolve any disagreements about such proposed changes, either party shall have the right to terminate the Grant Agreement.

SUSPENSION/TERMINATION: The support to the Grantee may be suspended or terminated by the Foundation at any time, with immediate effect, in whole or in part, if, to be determined at the sole discretion of the Foundation:

1. the Grantee has materially failed to comply with any term or provision of this Grant Agreement;
2. the Grantee has used the grant in whole or in part for any other purpose than the Project as set forth in the Grant Agreement;
3. the Grantee has made any material misrepresentation of any nature with respect to any information or statements furnished to the Foundation in connection with the Grant Agreement.
4. the Grantee, the Project, or any of the Grantee's affiliated or related entities, officers or employees are involved in any activity that
   does not or may not conform to the Foundation's charitable purposes;
5. the Grantee or any of its affiliated or related entities, officers or employees becomes subject to a criminal investigation into, or is found guilty of, bribery, corruption, misappropriation, embezzlement, fraud, forgery or any other criminal offence;
6. the Grantee becomes subject to a change of control that exposes the Foundation to reputational risks or materially threatens the execution of the Project;
7. the Grantee or any of its affiliated or related entities, officers or employees becomes a Prohibited Person;
8. The financial performance of the Project materially deviates from the budget or results set forth in the Grant Agreement.

In addition, the Foundation may, at its sole discretion, suspend performance of the Grant Agreement for the above grounds 1. to 8. and request the Grantee to take any action

necessary or advisable to remedy the Grantee's default. For the sake of clarity, any suspension under the preceding sentence will be without prejudice to termination and the Foundation will be entitled to terminate the Grant Agreement on the above grounds 1. to 8. at any time during such suspension.

UNUSED FUNDS: The Foundation may request, and the Grantee will be obliged to the extent permissible under applicable law, to return or re-allocate any unexpended grant funds remaining at the time of termination of the Grant Agreement or at the end of the Project period.

INFORMATION: The Grantee shall keep proper record of all reports, files, accounts and documents related to the grant or the Project. The Grantee shall provide promptly such information, reports, files, accounts or documents as the Foundation may request.

EXCLUSION OF LIABILITY: To the extent permitted under applicable law, the Foundation, its board members, officers, employees and affiliates cannot be held liable in connection with this Grant Agreement, except in case of gross negligence, wilful misconduct or default and fraud. In particular, the Foundation will not be liable to the Grantee for any damages, costs, losses, liabilities or other detriments caused by the lawful suspension or termination of this Grant Agreement.

COUNTERPARTS AND EXECUTION: The Grant Agreement and all other documents may be executed in one or more counterparts, each of which will constitute an original and all of which taken together will constitute one and the same Grant Agreement or document. Electronic or digital signatures by duly authorized representatives will be of equal effect and validity as handwritten signatures on original copies.

SEVERABILITY: If a provision of the Grant Agreement is or becomes illegal, invalid or unenforceable in any jurisdiction, that shall not affect:

1. The validity or enforceability in that jurisdiction of any other provision of the Grant Agreement; or
2. The validity or enforceability in other jurisdictions of that or any other provision of the Grant Agreement.

Each party agrees that it will negotiate in good faith to replace any provision of the Grant Agreement which may be held unenforceable with a provision which is enforceable and which is as similar as possible in substance to the unenforceable provision.

MISCELLANEOUS: Without prejudice to the Modifications provision set out above, any amendment to the Grant Agreement will not be valid unless agreed upon in writing and duly signed by both parties. This also applies to any amendment to this written form requirement.

The Grantee shall not have the right to assign, transfer or pledge the Grant Agreement or any rights or obligations under the Grant Agreement without the Foundation's prior written consent. Any assignment, transfer or pledge in violation of the preceding sentence shall be deemed null and void.

Unless expressly stated to the contrary, no part of the Grant Agreement shall create any rights in favour of any third party that is not a party to the Grant Agreement which shall impose any obligation on, or be enforceable against the Foundation.

No delay or omission by a party in the exercise of any power or right under the Grant Agreement will impair such power or right or be construed as a waiver thereof or of the event giving rise to such power of right and no waiver of any past event shall be construed to be a waiver of any power or right accruing to a party by reason of any future event.

After suspension or termination of the Grant Agreement, each party shall remain bound to the provisions of the Grant Agreement which by their nature are meant to remain applicable including, but not limited to, the clauses: Confidentiality, Intellectual Property and Licensing, Suspension/Termination, Information, Exclusion of Liability, Miscellaneous, Governing Law and Dispute Resolution.

GOVERNING LAW: This Agreement and any amendment hereof and any waiver or consent hereunder and any claims therefrom resulting shall be governed by and interpreted and construed exclusively in accordance with the substantive domestic Laws of the Netherlands. All disputes arising out of or in connection with this Agreement, including disputes concerning the existence and validity, will be finally and exclusively resolved by arbitration in accordance with the Arbitration Rules of the Arbitration Institute of the Netherlands (*Arbitragereglement van het Nederlands Arbitrage Instituut*, the "NAI Arbitration Rules").

The legal seat of the arbitration (*plaats van arbitrage*) will be Amsterdam, the Netherlands.

The language of the arbitration will be English.

The arbitral tribunal will consist of three arbitrators.

The arbitral tribunal shall decide and make its arbitral award or awards in accordance with the rules of law (*naar de regelen des rechts*).

DISPUTE RESOLUTION: Any dispute and the existence and content of any arbitral proceedings under this Clause must be kept confidential by the Parties, the members of the arbitral tribunal and the Netherlands Arbitration Institute, and no publication of any arbitral award, any other decision of the arbitral tribunal or any materials produced or exchanged in the course of such arbitral proceedings is permitted, except (a) to the extent that disclosure or publication is required to fulfil a legal duty, protect a legal right, or enforce or challenge an arbitral award in legal proceedings before a court or other judicial authority, (b) with the written consent of the Parties, (c) where required for the preparation or presentation of a claim or defence in arbitral proceedings under this Clause, or (d) by order of the arbitral tribunal at the request of a Party.

ANNEX C: GRANTEE PRIVACY STATEMENT

Version 1 September 2018

INTRODUCTION
This Privacy Statement applies to grant applicants and (potential) grantees (**Grantees**) of Stichting Benevolentia (**Benevolentia**).

Benevolentia uses the expertise and services of Porticus Amsterdam CV and its affiliated Porticus group entities (**Porticus**). Porticus is the international organization that manages the philanthropic programs of charitable institutions set up by entrepreneurs from the Brenninkmeijer family, including Benevolentia. Porticus provides these institutions with strategic advice on their donation programs and offers a wide range of services in the field of donation management. Porticus processes personal data of Grantees of Benevolentia in the course of providing its services to Benevolentia. When processing personal data of Grantees, Benevolentia and Porticus are joint data controllers.

With this Privacy Statement, Benevolentia and Porticus aim to be transparent about the way in which personal data relating to Grantees (if any) is processed.

Porticus' entities are located across the globe. Each Porticus entity shall adhere to this Privacy Statement, unless local law requirements demand otherwise.

For the purposes of this Privacy Statement, the following definitions apply:

- Personal data means any information relating to an identified or identifiable natural person (a 'Data Subject'). An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier (such as a name, an identification number, location data, or one or more factors specific to the physical, economic, cultural or social identity of that natural person.

- Processing means any (set of) operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as the collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, alignment, combination, restriction, erasure or destruction.

- Controller means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data.

- Joint Controller means two or more controllers who jointly determine the purposes and means of processing.

This Privacy Statement may be changed over time. You are advised to regularly review the website of Porticus and/or Benevolentia for possible changes to this Privacy Statement. This Privacy Statement was last amended on 1 September 2018.

HOW WE COLLECT PERSONAL DATA
At Benevolentia and Porticus, we are committed to maintaining the accuracy, confidentiality and security of personal data.

We may process your personal data:
- in order to assess grant applications diligently, when such personal data is included in the information provided to us in the context of a grant application or proposal.
- as part of our relationship management with Grantees, and for Porticus also in the context of developing strategic grant making advice.
- to enter into an agreement, to facilitate a payment, or to fulfil obligations under an agreement.

WHAT PERSONAL DATA DO WE COLLECT
We may, in the context of grant management and depending on the relevant circumstances, collect the following categories of personal data (not limitative, and not always applicable):
- Name and contact details (including title, address, telephone numbers, email addresses)
- Logs of communications with us (including emails)
- Photos (relating to approved projects and grants)
- References
- Financial information (relating to payment details)
- Incident reports

We also collect certain information through our websites, including technical data (such as the IP address, web browsers, click and surfing behaviour). Please refer to the Benevolentia Website Privacy Statement or Porticus Website Privacy Statement for more information.

We process such personal data on the basis of the following grounds:
1. Consent by the data subject
2. Requirement to fulfil contractual obligations
3. Legitimate business purpose (such as relationship management and cross referencing Grantees)
4. Compliance with local laws

WHY WE PROCESS YOUR PERSONAL DATA
We collect and process personal data to enter into agreements and/or to comply with applicable statutory requirements. More specifically, we process personal data for the below purposes:

- Assessing submitted grant applications and proposals
- In respect of Porticus, for developing strategic advice for Benevolentia
- Relationship management with Grantees and co-funders
- Compliance with laws and regulations (identification obligations, fraud prevention, internal controls and company security, tax law, archiving)
- Regular course of business (for example, when you send an email, we process your contact details, the contents of your message, any attachments you add to your message)

Please note that you are not obliged to provide personal data to us. However, in order for us to enter into agreements and / or to comply with statutory requirements, we require personal data to be provided. If you decide not to provide us with personal data, we may not be able to enter into an agreement with you or the organisation (as applicable).

BENEVOLENTIA

HOW WE PROCESS PERSONAL DATA
Benevolentia and Porticus are the joint controllers for your personal data, which means that Benevolentia and Porticus jointly determine what personal data is collected and for what purpose, and is responsible for the protection of such personal data.

Benevolentia and Porticus have entered into a joint controller agreement together pursuant to which they have allocated their responsibilities in respect of the protection of personal data.

Porticus comprises of different group companies, located in- and outside the EU. Personal data submitted to one Porticus entity may be shared with other Porticus entities. All Porticus entities have agreed to adhere to the standard model clauses of the European Commission for data transfer.

Depending on the specific circumstances, our affiliated and related entities may be granted access to your data, for example to assess and review Grantees or to execute grant agreements.

In general, we enter into processing agreements with all third party data processors. These agreements include adequate obligations to safeguard that your personal data is being shared with that data processor only for the purpose of providing the agreed services to us.

If it is required that your personal data is transferred to a country that does not provide an adequate level of protection of personal data, we will take measures to ensure that your personal data are adequately protected in accordance with the applicable legal requirements.

HOW DO WE STORE PERSONAL DATA
We may use various systems to collect and store your personal data, such as a management information system. We have taken adequate safeguards to ensure the confidentiality and security of your personal data. We have, and ensure that our data processors have, implemented appropriate technical, physical and organisational measures to protect personal data against accidental or unlawful destruction or accidental loss, damage, alteration, unauthorised disclosure or access, and against all other forms of unlawful processing (including, but not limited to, unnecessary collection). The retention period for storing personal data varies, depending on the type of personal data, the purpose for which it was collected, and local laws. We do not store personal data beyond the permitted retention period in accordance with applicable law.

WHAT ARE YOUR RIGHTS?
You can request access, correction, restriction, portability, objection or removal of your personal data at any time by sending a request to Porticus via privacy@porticus.com.

In the event we are processing your personal data on the basis of consent, you have the right to withdraw your consent at any time. Should you have any questions regarding the collecting or processing of your personal data, or if you are unsatisfied about the way in which we are processing your personal data, please contact privacy@porticus.com.

In the event you are an EU data subject and you are unsatisfied with the response you receive from us in relation to your request or complaint, please be aware that you have the right to submit a complaint with the local data protection authorities in your country. We also have an obligation to report all material data breaches to relevant data protection authorities within 72 hours of the data breach occurring.

BENEVOLENTIA

ANNEX D: GRANT INFORMATION

CONDITIONS

REPORTING SCHEDULE

Date	Report Type	Report ID
31st March 2023	End of Project report	AS-21-027078

PAYMENT SCHEDULE

Date	Disbursement	Contingent Upon
March 2022	EUR 33,300.00	
July 2022	EUR 16,700.00	
Total	EUR 50,000.00	

OTHER GRANT CONDITIONS

The grant amount will be paid in two instalments-

- the first instalment upon contract signing and bank account details confirmation
- the second instalment upon successful FCRA license renewal by KHS

PARTNER PROJECT SUMMARY

The ongoing Covid-19 pandemic is a global health crisis unlike any other pandemics that the mankind has seen before that not only is leading to deaths but also spreading suffering and upending the human lives. It is attacking societies at their core, the effects of which move much beyond a health crisis making it a human, economic and social crisis. How the communities cope with this global crisis and emerge from it will depend a lot on how resilient the communities are, else, the social crisis created by the COVID-19 pandemic will increase inequity, exclusion and discrimination in the long term.

The capacity of communities to cope with and recover from large-scale emergencies like Covid-19 is referred to as 'community resilience'. Building resilient communities and supportive environments is a public health priority that cannot be delayed further or left to posterity. We need to work collaboratively through a systems approach to create resilient communities that not only prepares them to cope with the pandemic and its after effects but also to strengthen protective factors, such as supportive community networks, community action and community capacity including volunteerism that will enable individuals and communities to manage, adapt, and ultimately recover well. As the long-term social, health and economic impacts of COVID-19 unfold, enhancing community resilience will have a critical role to play in the recovery process.

Through this grant we intend to build community resilience by ensuring preparedness of villages to respond to the challenges imposed by the Covid-19 pandemic in compliance with the GOI SOP on COVID-19 Containment & Management in rural areas. The work will be carried out in villages from our field practice area with the focus to demonstrate field implementation of the above-mentioned SOP. It is critical to establish such field demonstartion models so as to show how to translate the given guidelines into practice in real-life settings. From our past experiences, effective implementation of the given guidelines needs mentoring and sustained hand-holding to be translated into practice at the ground level. The proposed program will precisely look to do so, with DCM MGIMS being the mentor for catalysing the community preparedness and resilience to respond to the Covid-19 pandemic at village level.

All the villages in our field practice area will be invited to participate in this Community resilience building program. Only those villages that are willing to participate in the proposed program will be included. The village council will be needed to provide a community consent letter and commitment letter for participation in the program. All the residents of the participating villages will be potential beneficiaries of the proposed work. We assume that around 30-40 villages would volunteer to be part of the proposed work.

The **main activities** in the proposed work would include –
1.Identification and capacity building of village volunteers nominated by the village council
2.Facilitating preparation of Village preparedness plan through the volunteers
3.Community mobilization and behaviour change communication for observing covid appropriate behaviour
4.Capacity building for surveillance, referral, home and community-based isolation including monitoring of active cases in isolation
5.Capacity building for provision of psychological support at family and community
6.Post COVID follow-up and support to Covid-19 patients
7.Establishment of telehealth facilities to link the villages with MGIMS

Village volunteers will be trained on:
•Contact tracing and risk stratification
•To assess oxygen saturation by using oximeter
•To assess body temperature by using thermometer
•Perform 6-minute walk test and its interpretation
•Tele-consultation with staff of DCM MGIMS and Primary Health Centre
•Arranging referral for patients
•Appropriate use of safety gear like masks, face shield, gloves
•Conducting sensitization meetings with villagers

Village volunteers will do surveillance to identify Covid suspects and will have minimal risk. From the village volunteers, a team of 2-3 volunteers, preferably who are young (<40 years of age), had previously been infected with Covid-19, have been vaccinated against Covid-19 and are willing to comply with recommended Covid appropriate behaviour will be selected and trained to monitor those who are found to be Covid-19 positive (with no or mild symptoms not requiring any hospital admission) and have been advised home/community isolation and/or for referral transport of such patients to hospital if needed. As this set of volunteers will have some risk for contracting Covid-19 infection, they will be provided adequate protective safety gear including N95 masks, sanitizer, face shields, plastic coats, gloves etc to ensure their safety and risk minimization. The village volunteers will also be covered under the health insurance scheme of the MGIMS as an incentive to them.

The emphasis under the proposed work will be on catalysing the process of micro-planning as per the village preparedness plan for respective village and ensuring action on it at the village level. Facilities for tele-consultation will be devised at the village level through android based tablets/devices to help them consult Doctors/Physicians at MGIMS or the staff from Primary Health Centre under which the village falls. Also sensitization of existing CBOs (women's SHGs, KP, KVM), members of VHNSC/non-governmental/civil society/voluntary organizations will be done to help build a community-norm for supporting covid-19 affected individuals and families with an aim to facilitate inclusion and stop discrimination against them. Also in all the villages, social media platforms will be utilized to disseminate customized covid related messages on a pre-decided frequency.

From catalyzing this process, 2 dedicated project staff of prior experience of working with the communities will be recruited. They will be responsible for identification and training of village volunteers and catalyzing the process of preparation of village preparedness plan. Beyond this the existing staff of DCM and Porticus supported Inclusive ECD project will be used for conducting sensitization meetings in the participating villages and training purpose. The team working on this project will be provided with adequate safety gear (including N95 masks, sanitizer, face shields, plastic coats, gloves) to ensure their safety and risk minimization.

Before initiation of the work District Health Authorities will be taken on board to synergize the implementation efforts with that of Government public health functionaries. The work will be implemented in close collaboration and consultation with them. The learning from the proposed work will be disseminated to district administration for adaptation/replication in remaining villages of the district. A virtual advocacy meeting would also be conducted to disseminate the findings and lessons learnt to all other concerned stakeholders.

The total duration of proposed work is around 12 months, within first three months the preparatory work of identifying volunteers, preparing village wise micro-plans and training of volunteers will be conducted. The next 6-months will be utilized to implement the micro-plans and the last three months will be used to disseminate the learnings to other villages and advocacy to concerned stakeholders.

INDIAN COUNCIL OF MEDICAL RESEARCH
serving the nation since 1911

भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health and Family Welfare, Government of India

No: 5/4/8-23/CD/AVR/2021-NCD-II

Dated: 27.12.2021

To

The Dean
Mahatma Gandhi Institute of Medical Sciences
Sevagram, Distt-Wardha.
Maharashtra-442102.

Sub.: Ad-hoc Project entitled "***Vitalizing Community against Non-communicable diseases (V-CaN): a cluster field trial for health promotion against Non-communicable diseases risk factors in rural India***" under Dr. Abhishek Vijaykumar Raut, Professor, Mahatma Gandhi Institute of Medical Sciences, MGIMS Sevagram Wardha, Maharashtra -reg.

Dear Sir/Madam,

The Director-General of the Council sanctions the above mentioned research scheme for a period of One Year from **01.01.2022 to 31.12.2022** subject to extension up to the total duration specified in para 3(3) below.

The Director-General of the Council also sanctions the budget allotment of Rs. **40,88,308/-** **(Rupees forty lakhs eighty eight thousand three hundred eight only)** as detailed in the attached statement for the period 2021-2022.

The grant-in-aid will given be subject to the following conditions:-

1. The payment of the grant will be made in lump-sum to the head of the Institution. The first instalment of the grant will be paid generally as soon as a report regarding the commencement of the project and appointment of the staff is received by the Council. The demand for payment of the subsequent instalment of the grant should be placed with the Council in the prescribed format attached.

2. The staff appointed on the project should be paid as indicated in the budget statement attached.

3. The approved duration of the scheme is **(36 month s)3 years.** The annual extension will be given after review of the work done on the scheme during the previous year.

4. A report on the progress made will he submitted to the Council as and when called for.

5. The Institute will maintain a separate account of the receipts and the expenditure incurred on the scheme and will furnish a utilization certificate and an audited statement of account pertaining to the grant.

वी रामलिंगस्वामी भवन, पोस्ट बॉक्स न 4911,
अंसारी नगर, नई दिल्ली - 110 029. भारत
V. Ramalingaswami Bhawan, P.O Box No. 4911,
Ansari Nagar, New Delhi - 110 029. India

Tel: +91-11-26588895 / 26588980 / 26589794
+91-11-26589336 / 26588707
Fax +91-11-26588662 | icmr.nic.in

6 The Host Institute shall utilize the grant after following the provisions laid down in the GFRs 2017 and T.A Rules.

7. The PI is advised to keep the fund in a separate Saving Bank Account opened for research funds received from ICMR so as to ensure that interest earned thereon is also credited in to the Fund Account.

8. Kindly see the terms & conditions in the ICMR website.

The receipt of this letter may please be acknowledged.

Yours faithfully,

(Mahesh Chand)
Sr. Administrative Officer
For Director-General

Copy to:

1. Dr. Abhishek V. Raut, Professor, Dr. Sushila Nayar School of Public Health (incorporating the D/o Community Medicine) MGIMS. Sevagram, Wardha-442102.
2. Accounts Section – V, **RFC No. (P-61): NCD/Adhoc/190/2021-22 dated 15.12.2021**.
3 IRIS Section (2020-4652).
4. A.O.
5 Mr. Hemant Kumar, T.O.

For Director-General

No: 5/4/8-23/CD/AVR/2021-NCD-II

Ad-hoc Research Scheme

Dated: 27 .12.2021

Sub.: Ad-hoc Project entitled "***Vitalizing Community against Non-communicable diseases (V-CaN): a cluster field trial for health promotion against Non-communicable diseases risk factors in rural India***" under Dr. Abhishek Vijaykumar Raut, Professor, Mahatma Gandhi Institute of Medical Sciences, MGIMS Sevagram Wardha, Maharashtra -reg.

Budget (01.01.2022 to 31.12.2022)

			1st Year
I	**STAFF**		
	Project Assistant (Nos. 3) @ Rs.31,000/-pm For 2nd year @ Rs.31000+1350 = Rs. 32,350/-pm (10% Increment) For 3rd year @ Rs.32350+1350 = Rs. 33,700/-pm (10% Increment) (PB+GP 9300+4200 Rs. 13500*10% 1350)		11.16,000
	Field Worker (Nos. 8) @ Rs.18,000/-pm **(1st Year & 3rd Year : Only for 3 months)**		4.32,000
	Lab Technician (Nos. 1) @ Rs.18.000/-pm **(1st Year & 3rd Year: Only for 3 months)**		54,000
	DEO Gr. A @ Rs.17000/-PM For 2nd year @ Rs.17760/- PM (17000+760) For 3rd year @ 18520/- PM (17760+760) After 12 months of service @ 10% increment every year (PB+GP 5200+2400 Rs. 8000*10% 760/-		2.04,000
		Total of Staff Salary (I)	**18,06,000**
II	**CONTINGENCY (Recurring)**		1,00,000
	Consumables		-
	Health Promotion module printing		3.00,000
	Health Promotion Handouts		2,50,000
	Community Based Events		6,75,000
	Biochemical Investigations		4,80,000
	Communication and Internet		12,600
	Documentation		-
		Total (I+II)	**36,23,600**
		Overhead charges 3%	**1,08,708**
	NON-RECURRING		2,25,000
III	**TRAVEL**		1,31,000
		Grand Total	**40 88,308**

RFC No. (P-61): NCD/Adhoc/190/2021-22 dated 15.12.2021

(Mahesh Chand)
Sr. Administrative Officer
For Director-General

File No: BIO/CT/20/000186

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FORM CT-06

(See rules 22, 25, 26, 29 and 30)

PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

The Central Licencing Authority hereby permits M/s Serum Institute of India Pvt. Ltd., S. No. 105-110, Manjari Bk. Pune (India) - 412307 Telephone No.: null, to conduct clinical trial of the new drug or investigational new drug as per **Protocol No.: ICMR/SII-COVOVAX Version No: 4.0 Date: 25 JAN 2021** in the below mentioned clinical trial sites.

CT No.: CT- 03/2021

2. Details of new drug or investigational new drug and clinical trial site [As per Annexure].

3. This permission is subject to the conditions prescribed in part A of Chapter V of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

VENUGOPAL GIRDHARILAL SOMANI

Digitally signed by VENUGOPAL GIRDHARILAL SOMANI
DN: c=IN, o=MINISTRY OF HOME AFFAIRS, ou=CDSCO DGHS, postalCode=431401, st=Maharashtra, 2.5.4.20=173d03345df62d489632379a1471bfdae9f0b2bea56c83bfbbe2154e399b1af7, cn=VENUGOPAL GIRDHARILAL SOMANI
Date: 2021.02.11 15:46:41 +05'30'

Place: New Delhi
Date: 11.02.2021

(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licencing Authority
Stamp

CDSCO CDSCO
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

Annexure:

Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	SARS-CoV-2 rS Protein (COVID-19) recombinant spike protein Nanoparticle Vaccine	
Therapeutic class:	Vaccine	
Dosage form:	Liquid for intramuscular administration	
Composition:	Each dose of 0.5 mL of vaccine contains:	
	Name of ingredients	**Quantity**
	SARS-CoV-2 rS	5 µg
	Matrix-M1	50 µg
	Sodium Phosphate Dibasic Heptahydrate	12.63 mM
	Sodium Phosphate Monohydrate Monobasic	12.36 mM
	Sodium Chloride	300 mM
	Polysorbate 80	0.01% w/v
Indication(s):	Prevention of COVID 19 infection	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	Sahyadri Super Speciality Hospital, Survey no.185A, Shastri Nagar, Yerwada, Nagar road, Pune, Maharashtra- 411004, India	Sahyadri Hospitals Ltd. Ethics committee, Sahyadri Clinical Research & Development Center (A Unit of Sahyadri Hospitals Ltd.), 33/34B,Makarand Bhave Path, Karve Road, Pune-411004, Maharashtra, India ECR/493/Inst/MH/2013/RR-19	Dr. Govind Kulkarni
2	KLES Dr. Prabhakar Kore Hospital & Medical Research Center, Nehru Nagar, Belgavi Karnataka 590010, India	Institutional Ethics Committee, KLE University, KLE Dr.PK Hospital and MRC, Nehru Nagar Belagavi Belagavi (Belgaum), Karnataka - 590010 IndiaECR/211/Inst/KA/2013/RR-19	Dr. Madhav Prabhu
3	Jawaharlal Institute of Postgraduate Medical Education and Research, Dhanvantri Nagar, Puducherry-605006, India	IEC Intervention Studies, JIPMERJIPMER Dhanvantari Nagar Puducherry –605006, India,ECR/342/Inst/PY/2013/RR-19	Dr. Tamilarasu Kadhiravan
4	Department of Community Medicine, Christian Medical College & Hospital, Brown Rd, Ludhiana, Punjab 141008, India	Institutional Ethics Committee, Christian Medical College & Hospital,2nd Floor, Nr. Ward 15, Room no: 3201,Chrsitian Medical College & Hospital, Brown road, Ludhiana-141008,Punjab, India ECR/120/Inst/PB/2013/RR-19	Dr. Clarence Samuel
5	Hamdard Institute of Medical Sciences and Research with Centre for	Jamia Hamdard Institutional Ethics Committee, Hamdard Nagar, New Delhi South, Delhi Delhi -110062	Dr. Sunil Kohli

	health Research and Development (CHRD), Society for Apllied Studies (SAS),Guru Ravidas Marg, Hamdard Nagar, New Delhi-110062, India	India ECR/48/Inst/DL/2013/RR-19	
6	KIMS Hospital and Research centre, Krishna Rajendra Rd, Vishweshwarapura, Bengaluru, Karnataka 560004	KIMS Institutional Ethics Committee Kempegowda Institute Of Medical Sciences Attimabbe Road Banashankari 2nd Stage Bangalore 560070 ECR/216/Inst/Kar/2013/RR-19	Dr. Ashwath Narayana
7	Dr. D. Y. Patil Medical College Hospital and Research Centre, Department of Medicine, Sant Tukaram Nagar, Pimpri, Pune, Maharashtra-411018, India	Ethics Committee, Dr. D. Y. Patil Vidyapeeth, Sant Tukaram Nagar, Pimpri, Pune 411018 ECR/361/Inst/MH/2013/RR-19	Dr. Varsha Bhatt
8	Acharya Vinoba Bhave Rural Hospital, Datta Meghe Institute of Medical Sciences, Sawangi (M), Wardha, Maharashtra-442004,India	Institutional Ethics Committee of DMIMS, Datta Meghe Institute of Medical Sciences, Sawangi (Meghe) Wardha Maharashtra - 442004 India ECR/440/Inst/MH/2013/RR-19	Dr. Abhay Gaidhane
9	Institution of Medical Science and SUM Hospital, K8,Lane 1, Kalinganagar, Bhubaneswar, Khordha, Orissa –751003,India	Institutional Ethics Committee, IMS & SUM Hospital Bhubaneswar, K-8 Kalinga Nagar, Shampur, Bhubaneswar, Khordha Orissa – 751003 ECR/627/Inst/OR/2014/RR-20	Dr. Rakhi Ludam
10	Amrita Institute of Medical Sciences, Department of General Medicine, Ponekkara, Kochi, Kerala-682041, India	Institutional Ethics Committee Amrita Institute of Medical Sciences AIMS-Ponekkara Kochi Edappally Ernakulam Kerala-682041 India ECR/129/Inst/KL/2013/RR-19	Dr. Dipu Thareparambil S
11	School of Tropical Medicine108, Chittaranjan Ave, Calcutta Medical College, College Square, Kolkata, West Bengal 700073, India	Clinical Research Ethics Committee, C/o. Department of Clinical and Experimental Pharmacology, School of Tropical Medicine, 108 Chittaranjan Avenue, Kolkata –700073 ECR/194/Inst/WB/2013/RR-20	Dr. Santanu Tripathy
12	Noble Hospital, 153, Road, Magarpatta, Hadapsar, Pune, Maharashtra-411013, India	Noble Hospital Institutional Ethics Committee, Noble Hospitals Pvt. Ltd. ,Room No 5, Clinical, Research Department Noble Annex, 153 A, Magarpatta City Road, Hadapsar 411013, India ECR/259/Inst/MH/2013/RR-19	Dr. Sidram Raut

13	Kalinga Institute of Medical Sciences, Kushabhadra Campus , KIIT Campus, 5, KIIT Road, Patia, Bhubaneswar, Odisha 751024, India	Institutional Ethics Committee-KIMS, Kalinga Institute of Medical Sciences, Khushabhadra Campus 5, KIIT University, Patia Bhubneswar Khorda, Orissa – 751024 India ECR/321/Inst/OR/2013/RR-20	Dr. Sonali Kar
14	Department of Community Medicine, Dr. Sushila Nayar School of Public Health, Mahatma Gandhi Institute of Medical Sciences, Sevagram, Wardha, Maharashtra - 442102, India	Institutional Ethics Committee, (Department of Pharmacology) Mahatma Gandhi Institute of Medical Sciences, Sewagram, Wardha, Maharashtra –442102 ECR/47/Inst/MH/2013/RR-19	Dr. Abhishek Raut
15	JSS Academy of Higher Education and Research, Bannimantap Road, Sri Shivarathreeshwara Nagara, Bannimantap A Layout, Bannimantap, Mysore, Karnataka-570015, India	Institutional Ethics Committee, 3rd Floor, JSS Medical College, SS Nagar, Mysuru –570015 ECR/387/Inst/KA/2013/RR-19	Dr. Praveen Kulkarni
16	KEM Hospital Research Centre, Vadu Rural Health Program,Vadu Budruk, Taluka Shirur, Pune, Maharashtra-412216, India	KEM Hospital Research Centre Ethics Committee, KEM Hospital Research Centre, TDH building, Sardar Moodliar Road, Rasta Peth, Pune-411011, Maharashtra, India. ECR/272/Inst/MH/2013/RR-19	Dr. Ashish Bavdekar
17	Super Speciality Hospital, Government Medical College and Hospital, Tukdoji Square, Nagpur, Maharashtra-440009, India	Institutional Ethics Committee, GMC Nagpur, Government Medical College and Hospital, Medical Square, Hanuman Nagar, Nagpur, Maharashtra –440003, India ECR/43/Inst/MH/2013/RR-19	Dr. Sushant Meshram
18	Department of Pulmonary, Critical Care and Sleep Medicine, All India Institute of Medical Sciences, Ansari Nagar, New Delhi-110029, India	Institutional Ethics Committee, All India Institute of Medical Sciences (AIIMS),Room No. 102, 1stFloor, Old OT Block, Ansari Nagar, New Delhi –110029 India ECR/538/Inst/DL/2014/RR-20	Dr.Vijay Hadda
19	All India Institute of Medical Sciences, Department of Pharmacology, Gorakhpur, Uttar Pradesh 273008, India	Institutional Human Ethics Committee, All India Institute Of Medical Sciences, Gorakhpur, Opp Army Public School Kunraghat, Gorakhpur Uttar Pradesh -273008 India ECR/1476/Inst/UP/2020	Dr. Hira Lal Bhalla

In addition to point 3, the permission is subject to following condition(s):

1. The Phase II/III clinical trial should be conducted as per protocol titled "A phase 2/3, observer-blind, randomized, controlled study to determine the safety and immunogenicity of COVOVAX [SARS-CoV-2 recombinant spike protein nanoparticle vaccine (SARS-CoV-2 rS) with Matrix-M1™ adjuvant] in Indian adults"
2. Firm is required to submit revised clinical trial protocol with double blind study design and as per recommendations of Subject Expert Committee (SEC) meeting dated 03.02.2021 that the participants randomized to the placebo arm may be unblinded 60 days after the second dose upon request of the clinical trial participant only. Such participant may be offered investigational vaccine as per the dose and schedule prescribed in the protocol.
3. Firm is required to submit copy of contract entered by the ICMR with the investigator/institutions.
4. The firm is required to constitute a DSMB to review the safety data.
5. Firm is required to submit Principal Investigators undertaking & Ethics committee approvals for revised clinical trial protocol.
6. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions using validated procedures and shall have ongoing stability programme.
7. Only CDL, Kasauli certified batches shall be used in the clinical trial.

VENUGOPAL GIRDHARILAL SOMANI

Digitally signed by VENUGOPAL GIRDHARILAL SOMANI
DN: c=IN, o=MINISTRY OF HOME AFFAIRS, ou=CDSCO DGHS, postalCode=431401, st=Maharashtra, 2.5.4.20=173d03345df62d489632379a1471bfdae9f0b2bea56c83bfbbe2154e399b1af7, cn=VENUGOPAL GIRDHARILAL SOMANI
Date: 2021.02.11 15:46:53 +05'30'

Place: New Delhi
Date: 11.02.2021

(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licencing Authority
Stamp

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
CDSCO CDSCO
सत्यमेव जयते
MINISTRY OF HEALTH, GOVERNMENT OF INDIA

महाराष्ट्र MAHARASHTRA ◑ 2021 ◑ BC 898535

अनुक्रमांक 1293 दिनांक 29 JUL 2021 रुपये 500/-

मुद्रांक कोणत्या कारणासाठी वापरावयाचा आहे. Agreement

मुंबई मुद्रांक अधिनियम १९५८ चे अनुच्छेद क्र. 25

मुद्रांक वापरणाऱ्याचे पूर्ण नाव Forum Institute of India Pvt Ltd

मुद्रांक खरेदीदाराचे पूर्ण नाव Hadapsar Pune 28

मुद्रांक खरेदीदाराचे संपूर्ण नाव PRD Pharmaceutical Development India Pvt Ltd & Others

मुद्रांक खरेदीदाराचे पूर्ण पत्ता Andheri (E) Mumbai 400099

हस्ते व्यक्तीचे संपूर्ण नाव Mahendra Mane

पत्ता Hadapsar

मुद्रांक वाल्याची/हस्ते व्यक्तीची सही श्री. प्रमोद ह. पवार स्टॅम्प व्हेन्डर
स.न. ४, १११ बस स्टॉप समोर,
गाडीतळ, हडपसर, पुणे-२८.
ना. नं. २२०१६३०

वरिष्ठ ... र अधिकारी
सत्यमेव जयते
पुणे
23 JUL 2021
प्रथम मुद्रांक लिपीक
कोषागार पुणे करिता

CLINICAL TRIAL AGREEMENT

CLINICAL TRIAL AGREEMENT
between

SERUM INSTITUTE OF INDIA PRIVATE LIMITED
212/2, Off Soli Poonawalla Road,
Hadapsar, Pune – 411028, India
(hereinafter referred to as "**Sponsor**")

and

PPD Pharmaceutical Development India Private Limited
having its registered office at
101-A Wing Fulcrum, Hiranandani Business Park, Sahar Road,
Andheri East, Mumbai 400099, India
(hereinafter referred to as the **"PPD"**)

and

Kasturba Health Society's Mahatma Gandhi Institute of Medical Sciences
Sevagram Wardha Maharashtra-442102
(hereinafter referred to as the "**Institution**")

and

Dr. Abhishek V. Raut
Dr. Sushila Nayar School of Public Health
Mahatma Gandhi Institute of Medical Sciences, Sevagram

(hereinafter referred to as the "**Principal Investigator**")

Protocol number: ICMR/SII-COVOVAX

1 Introduction

Sponsor is a leading global organization engaged in the business of developing, manufacturing, and marketing pharmaceutical products.

PPD is serving as Sponsor's contract research organization for the Study as per the terms agreed between the Sponsor and the PPD.

Institution is Kasturba Health Society's Mahatma Gandhi Institute of Medical Sciences.

Principal Investigator is Dr Abhishek V. Raut as appointed and authorised by PPD in consultation with

Sponsor.

The discussions between Parties have resulted into this agreement wherein the Parties participate in and conduct the collaborative clinical trial as described below. The Institution and Principal Investigator shall perform the collaborative clinical trial as per the Protocol mentioned herein below and in accordance with the terms of this Agreement.

In order to make this Study (as defined below) mutually rewarding, it is essential that the Parties are in agreement with regard to the basic policies applicable to the Study. Accordingly, this Clinical Trial Agreement in conjunction with Sponsor's protocol no **ICMR/SII-COVOVAX** ("the Protocol") entitled "A PHASE 2/3, OBSERVER-BLIND, RANDOMIZED, CONTROLLED STUDY TO DETERMINE THE SAFETY AND IMMUNOGENICITY OF COVOVAX [SARS-CoV-2 RECOMBINANT SPIKE PROTEIN NANOPARTICLE VACCINE (SARS-CoV-2 rS) WITH MATRIX-M1™ ADJUVANT] IN INDIAN ADULTS AGED ≥18 YEARS AND CHILDREN AGED 2 TO 17 YEARS" (the "Study")(and any amendments thereto which may be adapted from time to time), which is incorporated by reference herein, will serve together as an agreement, delineating the terms and conditions applicable (the "Agreement").

It is expressly agreed and understood by and between the Parties that the trial / Study conducted under this Agreement is specific to paediatric study i.e. children aged 2 to 17 years and nothing contained under this Agreement shall govern the studies in respect of adults.

2 Study Conduct

2.1 The scope and nature of the Study and services to be performed at Institution will be in accordance with the Protocol.

2.2 The Institution and Principal Investigator each warrants to Sponsor and PPD that they have all the requisite expertise, education, experience, capabilities, adequate patient population, adequate personnel, equipment and other resources to conduct the Study in a professional and competent manner in accordance with the Protocol and that they are fully aware of applicable regulations; furthermore, they agree that they will not participate in any other clinical trial that by its nature will prevent them from fulfilling their obligations in the Study hereunder.

2.3 As it is essential that the Study is carried out exactly in accordance with the terms of the protocol. Each of the Institution and Principal Investigator agrees to study the Protocol and satisfy themselves that they fully understand it and are able to conduct the Study in the manner specified therein. Any change to the terms of this Agreement shall be valid only if the change is made by mutual written agreement of authorised representatives of all parties hereto. No changes or deviations to the Protocol should be implemented without agreement by the Sponsor and prior review and documented approval from the Ethics Committee ("**EC**"), except when necessary to eliminate immediate hazards to the Study subjects under this Agreement, or when the change(s) involves only logistical or administrative aspects of the

Study (e.g., change of monitor(s), telephone number(s)unless to eliminate an immediate hazard to Study subjects under this Agreement.

2.4 The Institution and Principal Investigator will ensure that they are thoroughly familiar with the appropriate use of the investigational product(s), as described in the Protocol, the current Principal Investigator's Brochure, the product information leaflet and all information provided to them in connection with the Study.

2.5 the Institution and the Principal Investigator each agree to carry out the Study in accordance with:

2.5.1 this Agreement;

2.5.2 the Protocol;

2.5.3 the provisions of the current version of the World Medical Association's Declaration of Helsinki, in particular, neither the Institution nor the Principal Investigator must at any time jeopardise the health or well-being of any Study subject under this Agreement by unwarranted continuation of the Study;

2.5.4 applicable national laws, regulations and guidelines including without limitation Good Clinical Practice Guidelines for conduct of clinical trials in India, the Ethical Guidelines for Biomedical Research on Human Subjects" laid down by Indian Council of Medical Research ("**ICMR**"), and the Guideline for Good Clinical Practice ("**GCP**") of the International Conference on Harmonisation (ICH) of Technical Requirements for the Registration of Pharmaceuticals for Human Use and with other generally accepted applicable Guidelines of the ICH a copy of which has been provided to Institution and Principal Investigator(ICH Topic E6, Consolidated Guideline 1.5.96);

2.5.5 if the Study is conducted under an Investigational New Drug (IND) the conditions specified in the Agreement and in accordance with the "New Drugs and Clinical Trials rules, 2019", as applicable, including any amendments thereto, which subsist from time to time and are in force(the "**Act**"); and

2.5.6 all applicable laws, rules and regulations, including those related to anti-corruption compliance as more specifically set forth in **Exhibit C** attached hereto and incorporated by reference herein.

2.5.7 PPD shall keep track and keep the Sponsor informed at all times as to the status of study protocol and upon PPD providing confirmation to Sponsor in respect of the study performed by Principal Investigator and Institution under this Agreement.

3 Commencement and Duration

3.1 The Parties Agree and confirm that this Agreement shall be effective and in force from **02 Sep 2021**("Effective Date"). The Study will commence from the Effective Date mentioned in this Agreement.

The Principal Investigator has received Ethics Committee("**EC**") approval and any national regulatory approval as appropriate has been obtained by Sponsor/PPD.

3.2 Study subject recruitment for the purpose of this Agreement is scheduled to start on **20 Aug 2021**.The entire Study is scheduled to be completed by **09-Feb-2022**.

3.3 Enrolment to the Study is performed on competitive basis. Approximately **100** Study subjects shall be enrolled at the Institution. Any alteration of above-mentioned timelines, or number of enrolled Study subjects shall not necessitate an amendment to this Agreement and may be communicated to Institution/Principal Investigator in writing; e-mail as may be agreeable to Sponsor.

4 Compensation

4.1 Sponsor will provide the complete financial support set out in the budget and payment schedule attached as **Exhibit A** inclusive of Subject Injury reimbursement as mentioned in clause 9 herein under and any other expenses towards medical management of adverse events and serious adverse events as may be required and directed by applicable law and competent government authority upon completion by Institution and Principal Investigator of the Payment Authorisation Form attached as **Exhibit B**, for the conduct of the Study in accordance with the applicable national laws, and regulations as set out in Sections 2.5.4-2.5.6 above.

The payment under this Agreement shall be made by the Sponsor and therefore site will invoice these expenses along with original bills or copies of the bills to Sponsor for release of payment to the site and upon approval of such invoices by Sponsor/ PPD, such payment shall be made by the Sponsor. Thus, Parties agree that:

a. Sponsor shall be making the payment on receipt of actual invoices. Such invoices are subjected to Sponsor approval and (The Goods and Services Tax to be charged, if applicable).
b. Each of Institution and Principal Investigator will make all necessary notifications, filings and arrangements with the appropriate authorities in connection with their respective tax affairs and shall deal directly with such authorities.
c. Sponsor will deduct appropriate taxes as required by the applicable laws. In these circumstances Sponsor will account to the appropriate authorities in respect of such deduction made on behalf of the Institution and Principal Investigator (as appropriate). However, upon Institution / Principal Investigator furnishing adequate tax exemption documents (under the law) to Sponsor, the TDS deduction will not be applicable.

4.2 A valid invoice (showing the amount of The Goods and Services Tax to be charged, if applicable) will be required before any payment is made under this Agreement and the same shall be provided by the Institution / Principal Investigator as the case may be, in accordance with section 4.1 hereinabove.

4.3 Each of Institution and Principal Investigator will make all necessary notifications, filings and arrangements with the appropriate authorities in connection with their respective tax affairs and shall deal directly with such authorities and (save as specified in 4.5 below in respect of deductions required by law) and at all times shall be exclusively responsible in respect of any liability for income, social,

corporate or other taxes, which shall be incurred as a result of this Agreement. The Sponsor/PPD shall not be responsible for payment of any compensation and taxes referred in this clause.

4.4 Institution and Principal Investigator shall invoice Sponsor by the earlier of:

-Ninety (90) days after the services are provided; or
-one month after termination of the Study.
Sponsor reserves the right to refuse payment of invoices that have not been submitted to Sponsor within these periods.

All the Parties are aware and understand that the Sponsor is entitled to exemption from GST by claiming status of Special Economic Zone (SEZ) unit and accordingly invoices will be raised without levying GST. Further, as per Rule 96A of Central Goods and Service Tax Act, 2017 Parties agree that:

(i) If invoices issued by Principal Investigator and Institution are without levying GST, then such invoices shall specifically mention – **"Supply to SEZ Unit or SEZ Developer for Authorized Operations under Bond or Legal Undertaking without payment of Integrated Tax."** Every such invoice must also mention the GSTIN No. 27AABCS4225M2Z6 of SEZ unit of Sponsor.

(ii) However, if, Principal Investigator and Institution opt to levy GST, then such invoices shall specifically mention – **"Supply to SEZ Unit or SEZ Developer for Authorized Operations on payment of Integrated Tax. The Integrated Tax paid will have to be claimed as refund and Sponsor will not reimburse GST paid."** Further these invoices should also mention GSTIN No. 27AABCS4225M2Z6 of SEZ unit of Sponsor.

4.6 Institution has received funding from Biotechnology Industry Research Assistance Council (BIRAC), Department of Biotechnology (DBT), Government of India under the Mission Covid Suraksha project. The resources of BIRAC project will be utilised for implementation of the ICMR/SII-COVOVAX paediatric cohort trial. Any understanding or agreement in relation to the aforementioned funding shall be at Institution's sole risk and responsibility and the Sponsor shall neither be a party nor connected in any manner whatsoever to any such understanding or agreement between Institution and BIRAC, DBT, Government of India or any other party as the case may be, under the Mission Covid Suraksha project.

Further, in the event of any dispute and differences arising in respect of the invoices and payment pertaining to this Agreement as mentioned hereinabove, the Institution and Principal Investigator shall settle the same with the Sponsor.

5 Confidentiality and Intellectual Property

5.1 Neither the Institution nor the Principal Investigator(nor any of their employees, directors, officers or agents) shall disclose to any third party or use for any purpose other than for the performance of the Study any data, records, material or other information, disclosed to Institution or Principal Investigator by Sponsor and/or PPD or generated as a result of the Study (hereinafter, collectively "**Confidential Information**") without the prior written consent of Sponsor with respect to their respective confidential information. Such Confidential Information shall remain the confidential and proprietary property of

Sponsor at all times after the execution of this Agreement and shall be disclosed only to Institution and Principal Investigator or their employees or agents who "need to know" and who have agreed to terms of confidentiality substantially similar to those terms contained herein. The obligation of nondisclosure shall not apply to the following Confidential Information:

5.1.1 Confidential Information that is or becomes publicly available through no fault of Institution and Principal Investigator;

5.1.2 Confidential Information that is disclosed to Institution and Principal Investigator by a third party legally entitled to disclose such Confidential Information (with documentary evidence);

5.1.3 Confidential Information that is already known to Institution and Principal Investigator as shown by their prior written records (as documentary evidence),provided they so advise PPD or Sponsor within twenty (20) days after disclosure of the Confidential Information to them by PPD or Sponsor; and

5.1.4 Confidential Information disclosed to a government authority or by order of a Court of competent jurisdiction, provided that a) such disclosure is subject to all applicable governmental or judicial protection available for like material; b) reasonable advance notice is given to Sponsor; and c) Institution and Principal Investigator take reasonable steps to limit the scope of such disclosure.

5.2 All Confidential Information containing personal data shall be handled in accordance with the relevant provisions of the Information Technology Act, 2000 and all applicable laws. In the event that Institution or Principal Investigator should receive a request for information, relating to this Agreement or the subject matter specified herein, in terms of the provisions of the Right to Information Act, 2005 from a third party, Institution or Principal Investigator will immediately notify and consult with Sponsor prior to making any disclosures.

5.3 Any inventions or discoveries (whether patentable or not), innovations, suggestions, ideas, reports or other intellectual property made or developed by Institution or Principal Investigator in connection with this Study shall be promptly disclosed to Sponsor and shall become the sole and exclusive property of Sponsor alone. Upon Sponsor request, Institution and Principal Investigator shall take such actions as Sponsor deems necessary or appropriate to obtain patent or other proprietary protection in Sponsor's name with respect to any of the foregoing to which none of the Parties herein shall have any objection of any nature whatsoever.

5.4 Sponsor shall not transfer to Institution and Principal Investigator by operation of this Agreement or otherwise any patent right, copyright or other proprietary right of Sponsor.

5.5 Upon termination of the Study, all such materials, information and data in Institution and Principal Investigator custody, except as required for archiving under ICH GCP and applicable national and local regulations, shall be promptly delivered as per the instructions of the Sponsor in consultation.

6 Ethics Committee Approval

6.1 Written approval for the conduct of the Study, the terms of the Protocol and the Informed Consent must be obtained from a properly constituted EC, according to ICH GCP (Section 3.0) prior to the commencement of the Study. A copy of such approval, clearly identifying the documents reviewed and approved (including version dates/numbers) along with other such documents required by the ICH GCPs must be obtained and copies provided to all parties before release of the Study drug will be permitted. Such approval must indicate the date approval was given and the name and signature of the Chairman/or authorised personnel. The names, occupations and institutional affiliations of the EC must also be informed to PPD, along with a statement to the effect that they are organised and operate according to ICH GCP and the applicable national laws and regulations.

6.2 Institution and Principal Investigator agree to submit reports to the EC regularly and at least annually.

7. Representations and Warranties of Parties

7.1 Sponsor

a) Sponsor shall be only responsible for arranging the supply and shipment of the Sponsor's product and any other products required for the Study in accordance with the Protocol to the Institution.

b) Sponsor does not provide any warranty of any kind, either express or implied, with respect to the merchantability, fitness for a particular purpose, and non-infringement of third party rights in relation to Sponsor's product and any other products required for the Study.

7.2 Institution and Principal Investigator

a) The Sponsor's product and any other products required for the Study and all information related thereto, will be used by Institution and the Principal Investigator only in connection with the applicable Protocol and for no other purpose without the prior written consent of Sponsor, and the same will be considered Confidential Information of the Sponsor. In the event, Institution and the Principal Investigator need to disclose any such Confidential Information of the Sponsor to regulatory authorities when required by applicable law; any such delivery shall be solely for this limited purpose and with all the protections of confidentiality permitted by law.

b) Institution and the Principal Investigator will ensure that the Sponsor's product and any other products required for the Study are at all times handled, stored, and administered in full compliance with the Protocol and the applicable law.

c) Institution and the Principal Investigator shall not reverse engineer, decompile, disassemble, as the case may be, any part of the Sponsor's product and any other products required for the Study and shall keep the Sponsor fully indemnified for any such unauthorized use thereof. Institution and Principal investigator shall not use any other drug/product in combination with Sponsor's product for

this Study as well as shall not use Sponsor's product in any other project/study whether alone or in combination with any other drug/product.

d) Any unused or expired quantities of the Sponsor's product and any other products required for the Study remaining in the possession of Institution and the Principal Investigator upon expiration or earlier termination of the applicable Protocol shall, at Sponsor's direction and request, be promptly returned to Sponsor or its designee, or be disposed of in compliance with applicable law with written certification of same to Sponsor.

7.3 PPD

a) PPD shall be responsible for the overall management and coordination activities and shall keep the Sponsor fully updated and informed regarding the conduct and results of the Study by the Institution and Principal Investigator.

b) PPD shall use best efforts to meet and cause Institution and Principal Investigator to meet the timelines stated in the Protocol.

c) PPD shall ensure and cause the Institution and Principal Investigator to ensure that the respective operative infrastructure for the Study is sufficient to enable the performance of the Protocol;

d) PPD shall comply and cause the Institution and Principal Investigator to comply with any applicable data protection laws and shall keep the Sponsor fully indemnified against any third party claims in relation to breach of personal data. For the sake of clarity, the Sponsor shall not be responsible for any act or omission on part of either PPD or the Institution and Principal Investigator with respect to personal data from Study Subjects / parent and / or legal guardian of the Study subject (in case the Study subject is aged between 2 to 17 years) and Sponsor shall deal only with data in accordance with applicable data protection law.

e) PPD shall, and cause the Institution and Principal Investigator to keep all samples and all materials and data obtained or generated in performance of their responsibilities towards the Study, securely and make, keep and maintain detailed, complete and accurate records of its work in accordance with (i) best industry standards, (ii) any and all applicable laws and regulations, (iii) any additional instructions of the Sponsor. Such records and data (including but not limited to source data) must be made using an appropriate medium, whether paper or electronic and kept in a manner appropriate.

"**Results**" / "**Data**" generated pursuant to the Study under this Agreement shall be owned as the exclusive property of the Sponsor alone. Results shall mean and include, any and all data and information conceived, discovered, or generated including, without limitation, deliverables, work products, all reports, tests, assays, results, findings, clinical data, discoveries, data, inventions, developments, structures, designs, protocols, biochemical strategies, biological materials,

formulations, compositions, analytic methodology, chemical and quality control procedures, devices, know-how, trade secrets, technologies, techniques, systems methods, processes, products, algorithms, concepts, formulas, ideas, inventions, writings, technical research, development and manufacturing data, business or research plans, whether patentable or not, whether reduced to practice or not, and all and improvements, modifications, derivatives thereto, and is inclusive of rights to seek registration and recordal thereof.

8. Adverse Event Reporting

For the purposes of this Agreement an Adverse Event ("**AE**"), Serious Adverse Event ("**SAE**") shall mean as defined in Good Clinical Practice Guidelines of Central Drugs Standard Control Organization

8.1 Any untoward medical occurrence in a Study subject administered a pharmaceutical product, and which does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product. An SAE is an untoward medical occurrence during Study that is associated with death, in-patient hospitalization (in case the Study was being conducted on out-patient), prolongation of hospitalization (in case the Study was being conducted on in-patient), persistent or significant disability or incapacity, a congenital anomaly or birth defect or is otherwise life-threatening.

8.2 The Principal Investigator must report all Serious Adverse Events to the Central Licensing Authority, the Sponsor or their designee and the Ethics Committee that accorded approval to the Study within twenty-four (24) hours of their occurrence. After 24 hours of initial reporting of SAE, Principal Investigator have to file a detailed final reporting and interim reporting within 14 days of occurrence of the event. This is as per CDSCO norms. (In case a final report is not possible within this timeline, then an interim has to be filed). All reports can be provided via telefax or telephone as per the Act, as applicable, including any amendments thereto, which subsist from time to time and are in force. The Principal Investigator will comply with any orders that the Central Licensing Authority deem necessary.

9. Subject Injury Reimbursement

Sponsor will reimburse for the treatment of Study related injuries to Study subjects / parent and / or legal guardian of the Study subject (in case the Study subject is aged between 2 to 17 years) as the case may be, for reasonable and standard medical expenses as per the regulatory requirement provided under the applicable law and as may be directed by the regulatory authorities, the same being subject to the following:

a) the illness or injury must be a direct result of the Study drug or procedure.

b) the illness or injury must not be a medical condition, or the natural progress of a medical condition, that the Study participant had before starting the Study.

c) the Study subject's medical costs are not the result of the Institution or Principal Investigator's negligence.

d) the directions of the Principal Investigator, Institution's staff and the consent form (as specified below) were followed by the Study subject / parent and / or legal guardian of the study subject (in case the Study subject is aged between 2 to 17 years) as the case may be.

e) the Principal Investigator was notified as soon as possible of the Study subject's illness and/or injury and the Principal Investigator's medical advice regarding the injury/illness was followed by the Study subject / parent and / or legal guardian of the study subject (in case the Study subject is aged between 2 to 17 years) as the case may be.

f) A failure on the part of the Institution and Principal Investigator to adhere to the terms of this Agreement and written instructions relating to the Study (including the Study Protocol) and/or Good Clinical Practice guidelines and/or all applicable standards.

g) Institution and Principal Investigator shall be responsible for all the medical management expenses for the injury caused by negligent acts or omissions or intentional, reckless, or wilful malfeasance by Principal Investigator and Institute.

h) Failure by Institution its directors, officers, employees, agents, assigns and the Principal Investigator to conduct Study in accordance with i) this Agreement ii) the Protocol iii) instructions of the PPD and /or Sponsor concerning conduct and administration of the Study iv) all applicable laws, rules and regulation and v)the manner required of a reasonable and prudent clinical investigator or physician.

i) The negligence or wilful malfeasance of Institution its directors, officers, employees, agents, assigns and the Principal Investigator or any other person at the Institution's property or under its control, exclusive of PPD and/or Sponsor.

Notwithstanding the foregoing, Institution shall not be required to submit any request for reimbursement to a Study subject's insurance as evidence that a medical expense is not covered. No other compensation of any type will be provided to the Study subject / parent and / or legal guardian of the study subject (in case the Study subject is aged between 2 to 17 years) as the case may be.

10. Monitoring

10.1 The Study will be monitored by Sponsor through PPD's own clinical monitor, any other sponsor or and cosponsor's representative, Institution and Principal Investigator must allow a reasonable amount of time to be set aside at each monitoring visit for discussions and to make corrections to the case record forms ("**CRF**"). The monitor will give as much notice as possible when scheduling visits, and these will occur at a mutually convenient time. In accordance with the Indian GCP,ICH GCP and the Act, the Principal Investigator and the Institution will provide direct and prompt access to source data and documents for Study related monitoring, audits, EC review, and regulatory inspection and provide adequate replies to any queries raised by the inspecting authority in relation to the conduct of the Study.

10.2 If any source data is kept on computer files only, for the purpose of source data verification, the Institution and the Principal Investigator agree to make a printout of all Study subject data relevant to the Study. These printouts will be dated and signed and retained as source documents. This includes relevant history information and all data obtained during the Study period.

10.3 Study subject and allied personal data (including but not limited to parents and/ or legal guardian information in case of study subject being of age between 2 to 17 years) confidentiality will be respected by all the parties as required by local law, and neither the Institution nor the Principal Investigator will remove (or permit to be removed) any documents bearing Study subject and parent and / or legal guardian names / details from the Study Institution. Study subjects will be identified by code numbers and initials.

11. Consent of Study Subject / Parent and / or Legal Guardian of Study Subject

11.1 The Principal Investigator must obtain written informed consent from parent and / or legal guardian of each Study subject (in case the Study subject is aged between 2 to 17 years) and each Study subject (upon completing 18 years of age during the conduct of Study) as the case may be; enrolling in the Study prior to commencement of any Study-related procedures, in accordance with the applicable local laws and regulations of India, including completion of the approved Informed Consent Form. The Principal Investigator must not make any changes to the Informed Consent Form without the prior written approval of Sponsor in consultation with PPD (including any revisions made during the course of the Study or required by IRB/IEC), such approval to be obtained before the revised informed consent document is used.

As part of the informed consent process, the Principal Investigator shall inform Study subjects / parent and / or legal guardian of the Study subject (in case the Study subject is aged between 2 to 17 years) as the case may be, that Study subject's medical records will be reviewed by representatives of PPD (in capacity of research organisation of Sponsor for this Agreement) and Sponsor, EC and regulatory authorities. The Principal Investigator shall provide information to the Study subject / parent and / or legal guardian of the Study subject (in case the Study subject is aged between 2 to 17 years) as the case may be, through the informed consent process.

11.2 The Principal Investigator shall also inform the Study subject / parent and / or legal guardian of the Study subject (in case the Study subject is aged between 2 to 17 years) as the case may be or Study subject's nominee(s), of Study subject's rights to contact the Sponsor or their designee whosoever had obtained the permission from the Central Licensing Authority for conduct of the Study for the purpose of making claims in the case of Study-related injury or death as per the "New Drugs and Clinical Trials rules, 2019".

11.3 The Principal Investigator shall give a copy of the Study subject information sheet and the signed consent form to all Study subject's parent and/ or legal guardian for them to keep.

11.4To the extent permitted by applicable law, PPD and the Sponsor assume no liability for any case in which written informed consent was not given by the Study subject / parent and / or legal guardian of the Study subject (in case the Study subject is aged between 2 to 17 years) or a duly authorised representative as the case may be.

12. Quality Assurance Audit

This Study may be audited by the Quality Assurance Department of PPD and/or by Sponsor, or inspected by governmental or regulatory bodies, in order to document the authenticity of recorded data and protocol adherence. Both the Institution and the Principal Investigator agree, following written notification, to allow an independent audit of all Study documentation and processes at Institution during business hours.

13. Record Retention

All documentation, records and correspondence relating to this Study, including that with the EC, Sponsor, and PPD shall be retained by the Institution and the Principal Investigator for the longer of:

i. All records must be archived for a period of at least 3 years after the completion/ termination of the study;

OR

ii. two (2) years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region for the IND;

OR

iii. two (2) years have elapsed since the formal discontinuation of clinical development of the investigational product.

The documentation mentioned herein shall be construed as confidential information and thus Sponsor must be informed in writing of any change of address or relocation of the Study files during this period. The Sponsor shall inform Institution and Principal Investigator as to when these documents no longer need to be retained.

14. Publications

For the purpose of this Agreement, the Parties expressly agrees that the Sponsor shall have the exclusive right to publish the Results and Data of the Study under this Agreement. It is expressly agreed that the Institution and Principal Investigator and PPD will not publish individual results and any finding on the Study in any form or fashion prior to consultation and written consent of the Sponsor. Furthermore, any manuscripts written using information obtained directly or indirectly from this Study must be submitted to Sponsor for evaluation prior to publication.

15. Independent Contractor

All the Parties to this Agreement are independent and do not form any relationship such as agent, partner, joint venturer or employee between the Parties.

16. Insurance /Indemnity

16.1 Sponsor shall during the term of this Agreement obtain and maintain clinical trial insurance policy with respect to its activities as required by the applicable laws. The Sponsor has agreed to comply with the Act, as applicable, including any amendments thereto, which subsist from time to time and are in force.

16.2 Each of the Institution and the Principal Investigator hereby agrees that neither Sponsor nor PPD shall be responsible for, and that they each (Institution and the Principal Investigator) undertake to indemnify and hold Sponsor and PPD, harmless for all losses, damages and liabilities (including reasonable legal fees) resulting from their negligence, wilful misconduct or other actions or omissions.

16.3 Each of the Institution and the Principal Investigator warrants that they (Institution and the Principal Investigator) have adequate insurance coverage for any claims arising from their negligence, wilful misconduct or other actions or omissions. The Institution and the Principal Investigator will provide a copy of their insurance certificate to Sponsor,-and PPD upon signature of this Agreement.

16.4 The Sponsor, and PPD will not be liable for and are not a party to unauthorized representations or warranties made by the Institution or the Principal Investigator or their agents relating to the product.

17. Termination

17.1 Sponsor may terminate the Study and/or this Agreement prior to its completion/expiration by thirty (30) days' written notice without cause, or immediately upon written notification for any of the following reasons:

17.1.1 if available data indicates that it is, in their sole opinion, not safe to continue to administer the study drug to Study subjects under this Agreement;

17.1.2 if the Institution or the Principal Investigator is in breach of any term of this Agreement (including but not limited to any warranty or undertaking);

17.1.3 by agreement, in writing, between Sponsor, and the Institution and the Principal Investigator;

17.1.4 if the entry of valid Study subjects in the Study is too slow to meet the agreed time scheduled;

17.1.5 if adherence to the Protocol is poor or data recording is materially inaccurate or incomplete; or

17.1.6 if overall Study enrolment has been met even if enrolment in terms of this Agreement has not been completed.

17.2 All the data, information copies pertaining to the Study shall be immediately returned to the Sponsor save and except as may be required to be kept by the Institution and the Principal Investigator for the archival purpose under any prescribed applicable law.

17.3 In the event of termination, the Institution and the Principal Investigator will be obliged to notify the EC.

18. Debarment & Disqualification

18.1 Each of the Institution and the Principal Investigator represents and warrants that neither they, their employees, offices, agents or affiliates, nor any other person retained by them to perform the Study pursuant to this Agreement: (i) is under investigation and facing debarment action under any law or regulation or is presently debarred under any law or regulation or (ii) has a disqualification hearing pending or has been disqualified under any law or regulation. In addition, each of the Institution and the Principal Investigator represents and warrants that they have not engaged in any conduct or activity which could lead to any of the above-mentioned disqualification or debarment actions. If during the term of this Agreement either the Institution or the Principal Investigator or any person employed or retained by them to perform the Study (i) come under investigation under any law or regulation for debarment action or disqualification; (ii) are debarred or disqualified; or (iii) engage in any conduct or activity which could lead to any of the above-mentioned disqualification or debarment actions, said party shall immediately notify Sponsor and PPD of same.

18.2 For the purposes of this Agreement, reference to any law or regulation shall also be deemed a reference to any law or regulation made or passed by any governmental or regulatory authorities having jurisdiction over the subject matter of the particular Study or any other laws and regulations applicable to the Study.

18.3 It is expressly agreed by and between the Parties that Sponsor is at liberty to take necessary decision in consultation with EC in respect of the issues that may arise in view of section 18.1 hereinabove.

19 Publicity

19.1 Sponsor independently (at its sole discretion) may use, refer to and disseminate reprints of scientific, medical and other published articles which disclose the name of the Institution and/or the Principal Investigator consistent with applicable copyright laws, provided such use does not constitute an endorsement of any commercial product or service by the Institution or the Principal Investigator. Neither the Institution nor the Principal Investigator shall disclose the existence of this Agreement or its association with Sponsor or PPD or use the name of Sponsor or PPD in any press release, article or other method of communication with the general public, without the express prior written approval of the party whose name is the subject of the potential disclosure.

19.2 Parties may without prior consent from Sponsor list any information regarding the Study which is available on www.clinicaltrials.gov website.

19.3 No communication/ interaction shall be made by Principal Investigator and Institution with media or any third party without prior written permissions from Sponsor.

20. Relief:

The Institution and Principal Investigator agrees and acknowledges that any breach by either of them of any of their obligations under this Agreement may result in irreparable harm to Sponsor; and the Sponsor reserves all rights under the law to seek any monetary damages and further reserves all rights to seek any adequate equitable remedies including but not limited to injunction or rescission or specific performance.

21. Data Privacy

21.1 Definitions

(a) "**Data Protection and Privacy Laws**" means all applicable laws, regulations, and regulatory requirements and guidance relating to data protection and privacy in force or that may in future come into force governing the Processing of Personal Data applicable to any party to this Agreement, and including those relating to security breaches, identity theft, and unauthorized disclosures of Personal Data.

(b) "**Personal Data**" shall include "**personal data**" or "**personal information**" as defined by applicable Data Protection and Privacy Laws.

(c) "**Process**" means to access, acquire, maintain, transmit, store, or otherwise process Personal Data.

(d) "**Individual**" shall include a "**person,**" "**individual,**" or "**data subject**" as defined by applicable Data Protection and Privacy Laws.

21.2 Compliance

The Institution and Principal Investigator warrant to other parties that they will process Personal Data in compliance with all Data Protection and Privacy Laws.

21.3 Data Privacy Developments

The Institution and Principal Investigator shall stay informed of any relevant developments in Data Protection and Privacy Laws.

21.4 Security

All Institution and Principal Investigator shall implement appropriate technical and organisational measures to protect the Personal Data as required by ICH-GCP and applicable Data Privacy Laws.

21.5 Data Privacy Requests

The Institution and/or Principal Investigator shall promptly notify Sponsor and PPD in writing if they receive any communication with regards to data privacy relating to the services from an individual, a privacy authority or other regulatory authority and provide Sponsor or PPD with full cooperation and assistance in relation to any such communication, at no additional cost to PPD or the Sponsor.

21.6 Security Breaches

The Institution and/or Principal Investigator shall immediately notify Sponsor and PPD if they become aware of any unauthorized access, acquisition, or disclosure of Personal Data relating to the services.

21.7 Consequences of Expiry or Termination

The obligations contained in this Section 17 shall survive the termination or expiry of this Agreement.

22. Miscellaneous

22.1This Agreement supersedes all prior written and oral agreements and representation between parties with respect to the subject matter hereof. All obligations contained herein as to which performance is required after termination shall survive termination. This Agreement may not be assigned or transferred by the Institution or the Principal Investigator without the prior written consent of Sponsor. Sponsor may assign or transfer this Agreement upon written intimation to the Institution or the Principal Investigator. In the event Sponsor assigns or transfers this Agreement to a third party who will assume all obligations hereunder, the Institution and the Principal Investigator shall each release and forever discharge Sponsor and PPD and its subsidiaries and affiliates from any and all liabilities and obligations of Sponsor/-PPD arising under the Agreement from and after the effective date of such assignment.

22.2In case of any dispute or difference between parties hereto regarding the construction, meaning, effect or obligation of the parties hereto under this Agreement, the same shall be settled by amicable consultation.

22.3If any provision of this Agreement conflicts with the law under which this Agreement is to be construed, or if any such provision is held invalid by a court, such provision shall be deemed to be restated to reflect as nearly as possible the original intentions of the parties in accordance with applicable law and the remainder of this Agreement shall remain in full force and effect.

22.4This Agreement shall be binding upon the parties, their heirs, successors, and permitted assigns.

22.5Waiver or forbearance by either party with respect to a breach of any provision of this Agreement or any applicable law shall not be deemed to constitute a waiver with respect to any subsequent breach of any provision hereof.

22.6Any notice required or permitted to be given hereunder by either party hereto shall be in writing and shall be deemed given on the date received if delivered personally, by recognized overnight courier, or by facsimile, or five (5) days after the date postmarked if sent by registered or certified mail, return receipt requested postage prepaid, to the following address:

If to Sponsor:
Serum Institute of India Private Limited
212/2 Off Soli Poonawalla Road, Hadapsar, Pune 411028
Telephone: +91 20 26 2384
Attn.: Dr Prasad Kulkarni

If to PPD:
PPD Pharmaceutical Development India Private Limited
Office 101 A-Wing, 'Fulcrum', Hiranandani Business Park,
Sahar Road, Andheri (East), Mumbai 400 099, India
E-mail address: Rashmi.chitgupi@ppd.com

If to Institution:
The Dean
MGIMS Sevagram
Telephone: +91-7152-284341
Facsimile: +91-7152-284343
Attn.: Dr. Nitin M. Gangane

If to Principal Investigator:
Dr. Abhishek V. Raut
Professor, Dr Sushila Nayar School of Public Health, MGIMS Sevagram
Telephone: +91-7152-284341
Facsimile: +91-7152-284343

Any party may change its notice address and contact person by giving notice of same in the manner herein provided.

INSTITUTION ANDPRINCIPAL INVESTIGATOR UNDERSTAND AND ACKNOWLEDGE THAT FABRICATION, FALSIFICATION OR ALTERATION BY INSTITUTION, PRINCIPAL INVESTIGATOR OR ANY EMPLOYEES OR AGENTS OF INSTITUTION OF ANY STUDY SUBJECT RELATED DATA OR OTHER INFORMATION PROVIDED BY INSTITUTION OR PRINCIPAL INVESTIGATOR PURSUANT TO THIS AGREEMENT CAN RESULT IN CRIMINAL ACTIONS AND SANCTIONS AGAINST INSTITUTION ANDPRINCIPAL INVESTIGATOR AND IN CIVIL LIABILITY TO SPONSOR OR PPD.

23. Agreement

23.1The fee quoted in the budget schedule appended is exclusive of any taxes, if applicable, chargeable thereon.

23.2 It is the Institution and Principal Investigator's responsibility to ensure that the hospital Trust management is made aware of their participation in this Study and approval is obtained prior to commencing the Study.

24.Governing Law and Jurisdiction

This Agreement shall be governed by the laws of India and shall be subject to the exclusive jurisdiction of Courts in Pune, Maharashtra.

25.Further Assurance: Each Party hereby represents, warrants and covenants to the other Party as of the Signature Date, as follows:

a. it has the power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder, and has taken all necessary action on its part required to authorise the execution and delivery of this Agreement;

b. this Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party and is enforceable against it in accordance with its terms;

c. the execution and delivery of this Agreement and the performance of such Party's obligations hereunder (i) do not conflict with or violate in any material way any requirement of applicable law, (ii) do not conflict with or violate any provision of the articles of incorporation, bylaws, limited partnership agreement or any similar instrument of such Party and (iii) do not conflict with, violate, or breach or constitute a default or require any consent under, any contractual obligation or court or administrative order by which such Party is bound;

d. all necessary consents, approvals and authorizations of all government entities and other Persons required to be obtained by such Party in connection with the execution and delivery of this Agreement and the performance of its obligations under this Agreement have been obtained.

26.Waiver. No failure on the part of either Party to exercise, and no delay in exercising, any right, power, remedy, or privilege under this Agreement or provided by statute or law or in equity or otherwise, will impair, prejudice, or constitute a waiver of any such right, power, remedy, or privilege or be considered as a waiver of any breach of this Agreement or as an acquiescence therein, nor will any single or partial exercise thereof or the exercise thereof or the exercise of any other right, power, remedy or privilege.

27. Execution in Counterparts. This Agreement may be executed in counterparts, each of which counterparts, when so executed and delivered, will be deemed an original, and all of which counterparts, taken together, will constitute one and the same instrument. Delivery of an executed counterpart of a signature page of this Agreement by facsimile transmission, by electronic mail in "portable document format" (".pdf" format), or by any other electronic means intended to preserve the original graphic and pictorial appearance of a document, or by a combination of such means, shall be bounded to the all parties.

We hereby agree to the conditions in this agreement:

Signed by Serum institute of India Private Limited

Signature: ..... For SERUM INSTITUTE OF INDIA PVT. LTD.

Name: ..... Dr. Prasad Kulkarni

Title: ..... Executive Director

02 SEP 2021

Serum Institute Of India Pvt. Ltd. ★ Pune-411 028. INDIA ★

Narwadkar
02 Sep 2021

Witness: Dr. Jyoti Narwadkar
SIIPL Pune.

Signed for and on behalf of PPD

Signature: .....

Name: .....

Title: ..... DocuSign

Witness:

Signed for and on behalf of Institution:

Signature: ..... DEAN Mahatma Gandhi Institute of Medical Sciences, SEVAGRAM

Name: Dr. Nitin M. Gangane 09/Sep/2021

Title: Dean MGIMS

Witness: Sukhdeo 9/9/21
Professor & Head
Dept. of Community Medicine
M. G. I. M. S; SEVAGRAM

Signed by Principal Investigator:

Signature: 9/Sep/21

Name: Dr. A. V. Raut Professor
Department of Community Medicine
M.G.I.M.S; SEWAGRAM

Witness: 9/9/21
Professor & Head
Dept. of Community Medicine
M. G. I. M. S; SEVAGRAM.

EXHIBIT A
BUDGET AND PAYMENT SCHEDULE

Payments: Payment should be made to the following:

Payee Name: The Dean MGIMS
Payee Address: Mahatma Gandhi Institute of Medical Sciences Sewagram
Bank Name: Central Bank of India
Account Number:1784800213
IFSC Code: CBIN0280697
GST Number: 27AAATK2046G1ZV

Invoices: Please send original, correct and itemized invoices to the following.

Namdev Mohite
Serum Institute of India Pvt. Ltd.
First Floor, Corporate Building,Clinical Trial Department,
212/2, Off Soli Poonawalla Road, Hadapsar, Pune 411028
Phone No.: +91-20-2660 2855

All invoices for Study payments, as outlined in the budget and payment schedule, should be submitted to Serum Institute of India Pvt. Ltd. within 90 days following the occurrence of the applicable expense to ensure reimbursement for work performed. Invoices submitted for payment must be correct and include but not limited to:
- Protocol Number
- Institution and Payee Name
- PI Name - Site Invoice Number (if applicable)
- Itemized detail of costs - Date of Invoice submission
- VAT/GST Amount (if applicable)
- Payment information (bank account number

The Study shall be payable as follows:

Cost Per Subject: Institution will be paid per completed and evaluable subject as defined below based on the rates set forth in the **Table 1**, which is inclusive of overhead. Payments will be made on a quarterly basis *(or Monthly Basis, only if applicable)* in Indian rupee (**INR**) and will be based on completed visits verified in the subject electronic case report forms (eCRFs). A complete and evaluable patient is defined as follows: (i) all procedures must be performed according to the protocol and ICH GCP guidelines, (ii) a patient will only be included according to the inclusion/exclusion criteria, and (iii) all data are documented accurately, completely. In the event that a patient does not complete all visits as specified in the Protocol, PPD shall only be obligated to make payment for such patient on a pro-rated, completed visit, and eCRF basis.

भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार
कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

No.3/2/December-2021/PG-Thesis-HRD(40) **Date:** 18/07/2022

Dr. Devyani Suresh Wanjari,
Department of Community Medicine,
Mahatma Gandhi Institute of Medical Sciences,
Sevagram, Wardha,
Maharashtra-442102
Registration No:- MD21DEC-0181

Subject: Payment of Rs.30,000/- under ICMR - MD/MS/DM/MCH/DNB/DrNB/MDS thesis financial assistance for the project entitled:- **"Effect of inclusive early childhood development (IECD) on the growth and development of children in the rural part of Central India: A cohort Study."**

Sir/Madam,

The Director General, ICMR sanctions the payment of 1st installment of **Rs. 30,000/- (Rupees Thirty Thousand only)** as the award under ICMR MD/MS/DM/MCH/DNB/DrNB/MDS thesis financial assistance.

A RTGS for the amount of Rs. 30,000/- will be sent to you in due course. The grant has been sanctioned as laid down in ICMR rules.

Second installment of Rs. 20,000/- will be given after receiving the copy of publication as mentioned in award letter.

Yours faithfully,

(Harjeet Kaur Bajaj)
Administrative Officer
For Director General

Copy to:

1. **Account-I**:- ICMR along with a formal bill of Rs 30,000/- for payment of 1st installment at an early date from allocation made under the scheme (2022-23), Division of HRD. The expenditure may be met related to "17-P" Human Resource Development Plan.
2. **Guide**:- Dr. Abhishek V. Raut, Professor, Department of Community Medicine, Mahatma Gandhi Institute of Medical Sciences, Sevagram, Wardha, Maharashtra-442102

वी. रामलिंगस्वामी भवन, पोस्ट बॉक्स नं. 4911,
अंसारी नगर, नई दिल्ली - 110 029, भारत
V. Ramalingaswami Bhawan, P.O. Box No. 4911,
Ansari Nagar, New Delhi - 110 029, India

Tel: +91-11-26588895 / 26588980 / 26589794
+91-11-26589336 / 26588707
Fax: +91-11-26588662 | icmr.nic.in

MGIMS Online

Anuj Mundra <anuj_mundra87@mgims.ac.in>

Fwd: Padvyuttar Sanshodhan Prakalp Anudan 2021

Devyani Wanjari <devyaniwanjari@mgims.ac.in> Wed, Apr 20, 2022 at 1:55 PM
To: Anuj Mundra <anuj_mundra87@mgims.ac.in>

Respected Sir,
Forwarding you the thread of IPHA mails. PFA documents.

Regards,
Devyani

---------- Forwarded message ---------
From: **IPHA Maharashtra** <iphamahabranch@rediffmail.com>
Date: Sun, Mar 6, 2022 at 9:04 PM
Subject: Padvyuttar Sanshodhan Prakalp Anudan 2021
To: <devyaniwanjari@mgims.ac.in>

Congratulations !

Your research study proposal has been selected for funding support of Rs. 15000/- under the scheme of Padvyuttar Sanshodhan Prakalp Anudan - 2021 of IPHA Maharashtra.

Please find enclosed scheme result and declaration form which is self explanatory.

Please take print out of this Declaration and fill it up in clean and neat handwriting (use blue ink).

Submit this declaration (Hard copy/ Original) within 7 days along with copy of IEC approval (Hard Copy) to -

==========

Dr. Nandkumar Salunke,

Department of Community Medicine,

B. J. Government Medical College,

Sassoon Hospital Compound, Station Road,

Pune - 411001

Mobile: 9764570655

==========

The first installment of funding of Rs.10,000/- will be released only after receipt of these documents.

Wishing you All the Best in your research work !

* Please forward this mail to your guide.

--
Dr. Prasad Waingankar
Secretary, IPHA MH EC'21
Professor & Head, Community Medicine,
MGM Medical College, Navi Mumbai
+91-9324714313

Dr. Gajanan Velhal
President, IPHA MH EC'21
Professor & Head, Community Medicine
Seth G. S. Medical College & KEM Hospital, Mumbai
+91-9920446233

--
.

2 attachments

IPHA PG RESEARCH.jpg
243K

Declaration_PG Research.pdf
63K

INTEGRATED DISEASE SURVEILLANCE PROJECT (IDSP)

Memorandum of Understanding (MoU)

Between

State Surveillance Unit, Maharashtra

And

Sevagram Medical College, Wardha

The IDSP aims to improve the disease surveillance in the country and supports the strengthening of the public health laboratories at different levels to enable confirmation of agents causing outbreaks to enable appropriate local response.

The two authorities, namely State Surveillance Unit (SSU), **Maharashtra and Sevagram Medical College, Wardha** have decided to cooperate and collaborate with each other in order to provide access, to the selected districts of the state. to a quality assured referral lab for confirmation of disease outbreaks of epidemic prone diseases under the state referral lab network plan using an output based arrangement.

Parties of MoU:

This MoU is an agreement between State Surveillance Unit of **Maharashtra and Sevagram Medical College, Wardha**.

Duration of MoU:

This MoU will be operative from the **01/04/2021** and remain in force for 12 months. The parties can renew MoU through mutual agreement.

Commitments of the Sevagram Medical College, Wardha

1. Will provide services as a state referral laboratory under IDSP for the following districts as per agreed terms in MoU.
   - ✓ **a. Wardha**
   - **b. Chandrapur**
2. Shall maintain minimum performance standards described in Annexure 1. This includes adequate infrastructure, equipment and consumables for the laboratory to be functional at all times for outbreak investigations.
3. Already performing the tests mentioned in Annexure-2 or will be able to perform them within 3 months of inspection.
4. Designate a dedicated focal point, preferably a microbiologist (regular staff or consultant), who would be responsible for IDSP related activities and will liaison with the state lab coordinator and the DSOs of the linked districts (as stated under point 1).

*Name, contact number and e - mail of focal Point

Dr. Vijayshri Deotale.
9822501099.
vijayshri@mgims.ac.in

5. Comply with the State Biomedical Waste Management Guidelines.

6. Share with CSU, SSU, DSU the data of routine laboratory surveillance data through the weekly L forms.
7. Report the details of outbreak samples tested from the linked districts on a quarterly basis on prescribed format (provided by Central surveillance Unit (CSU), NCDC, Delhi) to CSU and SSU.
8. Participate in external quality assessment scheme mandated by IDSP
9. Effectively co-ordinate with the State Coordinator for Laboratory services under IDSP

Services to be provided by Sevagram Medical College, Wardha

1. Undertake microbiological testing for outbreak investigations in the linked districts,
2. Provide support to the Rapid Response Teams of the linked districts (such as providing the transport media etc)
3. Participate in training/mentoring of lab technicians of attached district laboratories,
4. Strengthen internal quality control following Standard Operating Procedures
5. Report the lab results of outbreak related samples to the DSO and SSO expeditiously maintaining confidentiality.

Commitments of SSU, IDSP,

1. Will constitute an expert team consisting of at least three members (SSO, State lab coordinator and State microbiologist/ one senior microbiologist from the state) to carry out initial assessment of compliance to the performance level criteria described in annexure 1.The lab is to be certified through onsite visits and certificate signed.
2. Provide the referral laboratories the state waste management guidelines
3. Provide the referral laboratories of the necessary reporting forms (L forms)
4. SSO will disburse Rs 5,00000/- (Five Lakh only) to the referral laboratories once they have signed MOU and achieved the performance levels described in annexure 1. The expenditure guidelines for this amount will be provided to SSU by the CSU.
5. Reimburse the referral laboratory every quarter based on reporting on the number of tests carried out for public health purposes (referred samples from linked districts) and based on the reimbursement levels defined.
6. Will monitor the progress of each referral laboratory; provide an oversight role to ensure timely quality reporting.
7. Will ensure proper use of funding provided to referral laboratories
8. Organize annual state level workshop for the focal points of the referral laboratories, DSO s, microbiologists and epidemiologists under IDSP to share the findings of syndromic laboratory surveillance as well as successful investigation of outbreaks supported by laboratory diagnosis.

Termination of MoU:

Commitments agreed to by the Parties are meant for prevention and control of important outbreak prone diseases in the community and therefore MoU should generally not be suspended or terminated, unless upon non compliance with one of the above mentioned agreements or a negative assessment of compliance to the performance level criteria .

However, both parties can decide to suspend or terminate the MoU.

IN WITNESS WHEREOF, THE PARTIES HAVE EXECUTED THIS AGREEMENT ON THIS

Joint Director of Health Services
(Malaria, Filaria & Water Borne Disease)
Central Building, Pune-01.
I/C

* **Signature of the Head of the Institute**
Sevagram Medical College, Wardha
DEAN
Mahatma Gandhi Institute of
Medical Sciences, SEVAGRAM

Annexure:

1. MOU annexure- 01- Performance Standards for State Referral Lab.
2. MOU annexure- 02- List of tests to be performed by referral Lab under IDSP.
3. Reporting forms-
   - L form for submission of weekly surveillance date of the lab
   - Quarterly reporting format for the compiled data on investigations carried out for Outbreaks in the linked districts.
4. Prototype SOPs for common epidemic diseases, including guidelines regarding sample collection and transport – download from the IDSP portal- www.idsp.nic.in

राष्ट्रीय आरोग्य अभियान

जिल्हा एकात्मिक आरोग्य व कुटुंब कल्याण संस्था, वर्धा

डॉ. अजय डवले
सचिव, जि.ए.आ.व कु.क. संस्था तथा
जिल्हा आरोग्य अधिकारी, जि.प.वर्धा
आरोग्य सेवा

Phone No.: 07152-242014
Email: dpmwardha@gmail.com

जा.क्र./जि.आ.अ./रा.आ.अ./मंजुर
पि.आय.पी.२०२०-२१//276/२१
दि.१०.०३.२०२१

प्रति,

मा. अधिष्ठाता

महात्मा गांधी आयुर्विज्ञान संस्था सेवाग्राम

विषय - M.G.I.M.S सेवाग्राम यांचेकडे जिल्हा एकात्मिक आरोग्य व कुटुंब कल्याण सोसायटी मार्फत अनुदान वळते करणेबाबत.

संदर्भ - Sentinel Surveillance Hospital मंजुर PIP 2020-21

उपरोक्त संदर्भिय विषयान्वये NVBDCP कार्यक्रमा अंतर्गत डेंगु/चिकनगुण्या रोग निदानासाठी राज्यातील कार्यरत ३५ Sentinel Surveillance Hospital यांना त्यांच्या प्रयोगशाळा सबलिकरणासाठी, उपकरणे, केमिकल खरेदी तसेच कार्यालयीन खर्चासाठी संबंधीत रुग्णालय (M.G.I.M.S. Sewagram Hospital) यांना रु. १,००,०००/- PFMS NO. C022123182431 व्दारे अनुदान वितरित करण्यात येत आहे.

तसेच निधीचा विनियोग करुन या कार्यालयास मार्च २०२१ अखेरपर्यंत खर्चाचे प्रमाणपत्र तसेच उपयोगिता प्रमाणपत्र सादर करावे.

सचिव
जि.ए.आ.व कु.क.संस्था तथा
जिल्हा आरोग्य अधिकारी
जिल्हा परिषद, वर्धा

राष्ट्रीय आरोग्य अभियान

जिल्हा एकात्मिक आरोग्य व कुटुंब कल्याण संस्था, वर्धा

डॉ. अजय डवले
सचिव, जि.ए.आ.व कु.क. संस्था तथा
जिल्हा आरोग्य अधिकारी, जि.प.वर्धा
आरोग्य सेवा

Phone No.: 07152-242014
Email: dpmwardha@gmail.com

जा.क्र./जि.आ.अ./रा.आ.अ./मंजुर
पि.आय.पी.२०२०-२१//276/२१
दि.१०.०३.२०२१

प्रति,

मा. अधिष्ठाता

महात्मा गांधी आयुर्विज्ञान संस्था सेवाग्राम

विषय - M.G.I.M.S सेवाग्राम यांचेकडे जिल्हा एकात्मिक आरोग्य व कुटुंब कल्याण सोसायटी मार्फत अनुदान वळते करणेबाबत.

संदर्भ - Sentinel Surveillance Hospital मंजुर PIP 2020-21

उपरोक्त संदर्भिय विषयान्वये NVBDCP कार्यक्रमा अंतर्गत डेंगु/चिकनगुण्या रोग निदानासाठी राज्यातील कार्यरत ३५ Sentinel Surveillance Hospital यांना त्यांच्या प्रयोगशाळा सबलिकरणासाठी, उपकरणे, केमिकल खरेदी तसेच कार्यालयीन खर्चासाठी संबंधीत रुग्णालय (M.G.I.M.S. Sewagram Hospital) यांना रु. १,००,०००/- PFMS NO. C022123182431 व्दारे अनुदान वितरित करण्यात येत आहे.

तसेच निधीचा विनियोग करुन या कार्यालयास मार्च २०२१ अखेरपर्यंत खर्चाचे प्रमाणपत्र तसेच उपयोगिता प्रमाणपत्र सादर करावे.

सचिव
जि.ए.आ.व कु.क.संस्था तथा
जिल्हा आरोग्य अधिकारी
जिल्हा परिषद, वर्धा

File no. AMR/RC/62/2014-ECD-II

Dated: 22/5/19

To

The Dean,
Mahatma Gandhi Institute of Medical Sciences,
Sevagram,
Wardha (M.S.) 442102

1342
29/5/19

Subject:- Continuation of 3rd year project **"Mahatma Gandhi Institute of Medical Sciences, Sevagram: Regional Centre for Antimicrobial resistance Surveillance Network"** under **Dr. Vijayshri Deotale**

Dear Sir,

The Director-General of ICMR accords sanction for continuation of the above project into 3nd year with an allotment for **Rs. 9,00,840/- (Rs. Nine Lakh Eight Hundred Forty Only)** as detailed in the attached budget statement for the above mentioned project for a period w.e.f. 01.03.2019 to 28.02.2020 during the year 2019-20 subject to the following conditions :-

1. The grant will be released to the head of the Institute in two installments during the financial year on receipt of the demand in the prescribed form (Appendix-I) as indicated below :-

1st installment	**Rs. 4,50,420/-**
2nd installment	**Rs. 4,50,420/-**
Total	**Rs. 9,00,840/-**

While asking for the release of the installment, it may be ensured that the amount for the pay and allowances of the staff who are actually in position is included. The unspent balance available as on 31th March, 2019 out of the funds paid during the year 2018-2019 should be intimated. This will be adjusted against the current year's grant.

2. A separate account for the grant received and expenditure incurred shall be maintained. The account will be subjected to audited by the authorized auditors of the Institute. In case, facilities are not available for such auditing, the account will be audited by the Council's own internal auditors. Latest by the end of December, following the financial year for which the grant is paid, and audit certificate from the auditors to the effect that the accounts have been audited and that the money was actually spent on the objects for which it was sanctioned shall be submitted to the Council along with a list of non-expendable articles purchased out of the grant

Gmail

suraj girdhar <sg.195610@gmail.com>

Fwd: sanction letter of funds

1 message

Dipak Thamke <dipak.thamke@gmail.com>
To: suraj girdhar <sg.195610@gmail.com>

Mon, Dec 20, 2021 at 4:08 PM

---------- Forwarded message ---------
From: **shreya singh** <shreya_thedoc@rediffmail.com>
Date: Mon, Dec 20, 2021 at 12:41 PM
Subject: Re: sanction letter of funds
To: Dipak Thamke <dipak.thamke@gmail.com>

Respected Sir,
PFA the sanction letter and yearly budget breakup signed by ICMR. The money allotted for skilled worked is to be divided equally among the 29 participating centres so that amounts to Rs.164250/-. Since the overall budget has been sent to PGIMER as host institute there is no mention of MGIMS Sevagram.Please see if these will do.
If not then I can arrange an undertaking on the department letter-head signed by the PI (Dr.Shivaprakash) about the funds sanctioned for MGIMS Sevagram or we can have an MOA if that would be better.
Warm Regards,
Dr. Shreya Singh
Senior Research Associate
Mycology Division
(WHO Collaborating Center
Center of Advanced Research in Medical Mycology)
Department of Medical Microbiology
Postgraduate Institute of Medical Education and Research,
Chandigarh
160012

From: Dipak Thamke <dipak.thamke@gmail.com>
Sent: Fri, 17 Dec 2021 15:34:49
To: shreya singh <shreya_thedoc@rediffmail.com>
Subject: No Subject

Dear
Dr. Shreya Singh,
Thanks for transferring the funds. However, our account section is asking for the sanction letter of funds allotted to MGIMS Sevagram (Rs.164250/-) by PGI.
PI do the needful.

With regards.

Dr. Dipak Thamke
Principal Investigator
Candidaemia Project Sevagram
MGIMS, Sevagram

---

2 attachments

sanction_for_1_year.jpg
1385K

Utilization Certificate For Fund Recipient Contribution

For the period from 01st April 2021 to 05th November 2021

1.	Proposal Ref. No.	BIRAC/BT/NBM0257/05/19 BCX1XD
2.	Title of the Project	To Establish a GCP Compliant Clinical Trial Network CTN for faster, cost effective hospital based trial in Rheumatology
3.	Name of the Institute	Run Through Department of Medicine, Mahatma Gandhi Institute of Medical Sciences, Sewagram
4.	Name of Principal Investigator	Dr. Bharati Taksande
5.	BIRAC Sanction Order No/GLA.	BIRAC/BT/NBM0257/05/19BCX1XD
6.	Date of Sanction Order/GLA	Date of Sanction : 03.06.2020 Date of Acceptance as per GLA : 29.06.2020
7.	Fund Recipient's contribution during this period	Bank Account No.: 3858053013
		Rs. NIL
8.	Actual expenditure	Rs.NIL

Certified that an amount of Rs. NIL mentioned against Sl. No. 8 has been utilized on the project for the purpose as per the agreement executed by the Institute with BIRAC.

Date: 27th November 2021

(Principal Investigator)

29.11.2021

(Head of the Institute)

DEAN
Mahatma Gandhi Institute of
Medical Sciences, SEWAGRAM

(Finance Officer)

For RAJENDRA BHUTADA & CO.
CHARTERED ACCOUNTANTS

(RAJENDRA BHUTADA - PROP.)
Membership No. 43283

(Chartered Accountant)

Rajendra Bhutada & Co. * Chartered Accountants * WARDHA

UDIN : 21043283AAAANV9880

Utilization Certificate for BIRAC Contribution

(For the period from 01st April 2021 to 05th November 2021)

(Rs. In Lakhs)

1.	Project Ref. No.	BIRAC/BT/NBM0257/05/19BCX1XD	
2.	Title of the Project	To Establish a GCP Compliant Clinical Trial Network CTN for faster, cost effective hospital based trial in Rheumatology	
3.	Name of the Institute	Run Through Department of Medicine, Mahatma Gandhi Institute of Medical Sciences, Sewagram	
4.	Principal Investigator	Dr. BharatiTaksande	
5.	BIRAC sanction order No./GLA	BIRAC/BT/NBM0257/05/19BCX1XD	
6.	Date of Sanction of Project	03.06.2020	
7.	Date of signing of GLA	29.06.2020	
8.	Bank Account No.	With Central Bank of India, Sewagram, Ac. No. 3858053013	
9.	Amount brought forward from the previous period quoting BIRAC letter No. & date in which the authority to carry forward the said amount was given	Grants -in-aid	21.43
		Loan	NIL
		Total	21.43
10.	Amount received from BIRAC during this period (Please give No. & dates of Sanction order showing the amounts)	Grants -in-aid	NIL
		Loan	NIL
		Total	NIL
11.	Other receipts/interest and/or GST input credits earned, if any, on the BIRAC grants and/or loan	NIL	
12.	Total amount that was available for expenditure during this period (Sl nos.8+ 9 + 10)	Grants -in-aid	21.43
		Loan	NIL
		Total	21.43
13.	Actual expenditure (excluding commitments) Incurred during the period (Statement of Expenditure is enclosed)	Grants -in-aid	19.98
		Loan	NIL
		Total	19.98
14.	Unspent balance refunded, if any to the BIRAC (Please give details of cheque no. etc.)	NIL	

Rajendra Bhutada & Co. Chartered Accountants WARDHA

15.	Balance amount available at the end of the period	Grants -in-aid	1.45
		Loan	NIL
		Total	1.45
16	Amount carried forward to the next period (11-12-13) vide letter no. dated	Grants -in-aid	1.45
		Loan	NIL
		Total	1.45

Certified that an amount of Rs.19.98 lakhs mentioned against Sl. No.13 has been utilized on the project for the purpose for which it was sanctioned. Certified that the conditions on which the grants in aid and/or loan was sanctioned have been duly fulfilled / are being fulfilled and that the checks have been exercised to see that the money was actually utilized for the purpose for which it was sanctioned.

Date : 27th November 2021

(Principal Investigator)

29.11.2021

(Head of the Institute)

DEAN
Mahatma Gandhi Institute of
Medical Sciences, SEVAGRAM

Rajendra Bhutada & Co. Chartered Accountants WARDHA

(Finance Officer)

For RAJENDRA BHUTADA & CO.
CHARTERED ACCOUNTANTS

(RAJENDRA BHUTADA - PROP.)
Membership No. 43283

(Chartered Accountant)

Proposal Reference No./ Report No.

Statement of Expenditure

Table 1

For the period from 01st April 2021 to 05th November 2021

(Rs. in Lakhs)

Item	Part A: Receipt details						Part B: Expenditure details			Part C: Balance/ Unspent amount		
	Unspent balance Carried forward from the previous period			Contribution by company during this period	Contribution by BIRAC during this period	Total amount available during this period	Actual Expenditure incurred during the period			Balance/Unspent amount (Amount to be carried forward to the next period)		
	by company	by BIRAC	Total				by company	by BIRAC	Total	by company	by BIRAC	Total
1	2a.	2b.	2 (2a.+2b	3a.	3b.	3 (2 + 3a+3b)	4a.	4b.	4 (4a.+4b.)	5a (2a+3a-4a)	5b (2b.+3b.-4b.)	5(5a+5b)
(A) Non –Recurring (Details of items procured and/or ordered to be provided in Table 2)												
(1) Equipments	0	0	0	0	0	0	0	0	0	0	0	0
(2) Accessories	0	0	0	0	0	0	0	0	0	0	0	0
Total A	0	0	0	0	0	0	0	0	0	0	0	0
(1) Manpower	0	18.51	18.51	0	0	18.51	0	13.39	13.39	0	5.12	5.12
(2) Consumables	0	0.03	0.03	0	0	0.03	0	6.24	6.24	0	-6.21	-6.21
(3) Travel	0	1.50	1.50	0	0	1.50	0	0	0	0	1.50	1.50
(4) Contingency	0	1.39	1.39	0	0	1.39	0	0.35	0.35	0	1.04	1.04
(5) Outsourcing	0	0	0	0	0	0	0	0	0	0	0	0
Total B	NIL	21.43	21.43	NIL	NIL	21.43	NIL	19.98	19.98	NIL	1.45	1.45

Rajendra Bhutada & Co. * Chartered Accountants * WARDHA

Total A+B	NIL	21.43	21.43	NIL	NIL	21.43	NIL	19.98	19.98	NIL	1.45	1.45
Interest Earned(C)											0	0
Net Total (A+B+C)	NIL	21.43	21.43	NIL	NIL	21.43	NIL	19.98	19.98	NIL	1.45	1.45

(Principal Investigator)

29.11.2021

(Head of the Institute)

Rajendra Bhutada & Co. * Chartered Accountants * WARDHA

For RAJENDRA BHUTADA & CO.
CHARTERED ACCOUNTANTS

(RAJENDRA BHUTADA - PROP.)
Membership No. 43283

(Chartered Accountant)

Mahatma Gandhi Institute of Medical Sciences, SEVAGRAM

Details of Committed Expenditure

Table 2

S. No.	Head of Expenditure	Particulars	Tentative Amount (Rs. in Lakhs)*	Tentative date of Actual Expenditure
1.	Equipments			
2.	Accessories			
3.	Manpower			
4.	Consumables			
5.	Travel			
6.	Contingency			
7.	Outsourcing			
8.	Others			

Nil

* Supporting documents like purchase order, quotation, performa invoice etc. has to be annexed

Rajendra Bhutada & Co. Chartered Accountants WARDHA

Detail of Capital Assets

Table 3

Details of Capital Assets acquired and Insurance Status (as a part of the project)							
Date of Purchase	Invoice No.	Amount	Name and Particulars of Capital Assets	Period of Insurance	Amount insured	Coverage	Date of Renewal
A. THROUGH BIRAC FUNDS							
04/10/2021	015	42,067	CUPBOARD (2 NO) COMPUTER TABLE (5 NOS) TABLE GLASS (1 NOS)				
10/05/2021	APS/2020-21/91	15,300	CANON PRINTER (1 NOS)				
21/09/2021	RI-18	33,300	OFFICE CHAIRS (9 NOS)				
21/10/2021	ET/PI/908/21-22	5,19,200	STABILITY CHAMBER (1 NOS)				
13/10/2021	516	13,900	COOLING WATER CABINATE (1 NOS)				
	TOTAL	6,23,767					
B.							
C. THROUGH COMPANY'S CONTRIBUTION							
NIL							
D. ADDITIONAL EQUIPMENTS							
NIL							

(Principal Investigator)
29.11.2021

(Finance Officer)

(Head of the Institute)

DEAN
Mahatma Gandhi Institute of Medical Sciences, SEVAGRAM

Rajendra Bhutada & Co. Chartered Accountants WARDHA

For RAJENDRA BHUTADA & CO.
CHARTERED ACCOUNTANTS
(RAJENDRA BHUTADA - PROP.)
Membership No. 43283

(Chartered Accountant)

BCX1XD

BT/NBM0257/05/19 **Dated:**

Sanction Order

Subject: Support under Industry-Academia Collaborative Mission For Accelerating Discovery Research To Early Development For Biopharmaceuticals - "Innovate in India (i3) Empowering biotech entrepreneurs & accelerating inclusive innovation" for the project entitled"To establish a GCP compliant Clinical Trial Network CTN for faster, cost effective hospital-based trials in Rheumatology" submitted by Medanta Institute of Education and Research (MIER).

Sanction of the Competent Authority is hereby accorded for the proposal entitled **"To establish a GCP compliant Clinical Trial Network CTN for faster, cost effective hospital-based trials in Rheumatology"** submitted by **Medanta Institute of Education and Research (MIER)** at an estimated total budget of **Rs. 854.95 Lakhs (Rupees Eight Hundred Fifty-Four Lakhs and Ninety-Five Thousands only)** with BIRAC (an implementation agency of NBM) funding of **Rs. 854.95 Lakhs (Rupees Eight Hundred Fifty-Four Lakhs and Ninety-Five Thousands only)**as grant-in-aid.

On the terms and conditions detailed hereunder:

1.

S. No.	Name of Applicants	Designated Project Investigator	Grant to Applicant (Amount Rupees in Lakhs)		Total Budget (Amount Rupees in Lakhs)
			Recurring	Non-Recurring	
1.	**Medanta Institute of Education & Research,** an institution registered as a trust with its registered office at E-18, Defence Colony, New Delhi-110024 hereinafter referred to as "**MIER"**	**Dr. Rajiva Gupta,** Senior Director-Medanta Division of Rheumatology & Clinical Immunology **Landline**: 91-124-4141414 **Phone**: 91-9971918887 **Email**:rajiva.gupta@medanta.org	**211.50**	**0.00**	**211.50**
2.	**Mahatma Gandhi Institute**	**Dr. Bharati**	**128.69**	**0.00**	**128.69**

	of Medical Sciences, Sevagram, Maharashtra is affiliated to Maharashtra University of Health Sciences, Nashik and Recognized by University Grants Commission (if applicable). It is an institution having its registered office at Sevagram, Wardha (Dist.)-442 102 Maharashtra State hereinafter referred to as **"MGIMS"**	**Taksande , Professor,** Department of medicine. New medicine building, Mahatma Gandhi Institute of Medical Sciences, Sevagram, Maharashtra **Landline**: 91-71-52284341 **Phone**: 91-9881017505 **Email**: bharati.taksande@gmail.com			
3.	**Centre for Arthritis & Rheumatism Excellence, Kerala** is an institution registered under Kerala Municipality (Registration of the private hospitals and private Para Medical Institutions rules 1997 having its registered office at 23/793-2, Shenoy‟s Care Pvt Ltd, Near Nippon Toyotta, NH-47, Nettoor, Maradu Kochi, Kerela, India- 682040 hereinafter referred to as **"CARE"**	**Dr. Padmanabha Shenoy, Medical director and consultant rheumatologist**, 2rd Floor Dept of Rheumatology, Centre for Arthritis & Rheumatism Excellence, Kerala-682040 **Landline**: 0-484-270 4400 **Phone**:91-9446567000 **Email**: drdpshenoy@gmail.com	**128.69**	**0.00**	**128.69**
4.	**CBCI Society for Medical Education**, a registered society under Societies Registration Act, having its office at St. John‟s National Academy of Health Sciences, Sarjapura Road, Koramangala, Bangalore 560034, India, represented by	**Dr. C Chanakya, Assistant Professor, Clinical Immunology &Rheumatology,** St. John‟s Medical College and Hospital,	**128.69**	**0.00**	**128.69**

	its Secretary hereinafter referred to as "**CBCI-SME**", and **St. John's Research Institute**, (a unit of CBCI Society for Medical Education), having its registered office at St. John"s National Academy of Health Sciences, Sarjapura Road, Koramangala, Bangalore 560034, India, represented by its Dean hereinafter referred to as "**SJRI**", and hereinafter both CBCI-SME and SJRI are jointly referred to as "**St. John's, NAHS".**	Sarjapur Main Rd,John Nagar, Koramanga, Bengaluru-560034 KARNATAKA **Landline**: 0-80-220653003 **Phone-91-8050989679** **Email**: drchanakya41@gmail.com			
5.	**Kusum Dhirajlal Hospital, Ahmedabad, Gujarat** is registered under Section 5 of the Bombay Nursing Homes is an institution having its registered office at **Vaishno devi Circle, S G Highway, Khodiyar, Ahmedabad-382421, Gujarat, India.** hereinafter referred to as **"KD Hospital"**	**Dr. Dhiren N Raval, Consultant,** Research Department, Kusum Dhirajlal Hospital, Ahmedabad, Gujarat-382421 **Landline:** 0-79-66770000 **Phone:91-9619177085** **E-mail:**drdhirenraval@gmail.com	**128.69**	**0.00**	**128.69**
6.	**Post Graduate Institute of Medical Education & Research, Chandigarh** is an institution having its registered office at Sector 12, Chandigarh - 160012 hereinafter referred to as **"PGIMER".**	**Dr. Varun Dhir, Additional Professor,** Rheumatology Lab Room 3031, Research Block B, PGIMER, Chandigarh-160012 **Landline:** 91-172-2755569 **Mobile:** 91-9891807756 **Email:** varundhir@gmail.com	**128.69**	**0.00**	**128.69**
	Sub-total		**854.95**	**0.00**	**854.95**

	Grand Total	**854.95**

2. **ProjectDuration: 36months (Thirty-six months)**

3. **Project Implementation site:**
The above Project components shall be carried out at different implementations sites as described below:

S.No.	Name of Organization	Designated Project Investigator	Implementation Site
1.	**Medanta Institute of Education & Research**	**Dr. Rajiva Gupta ,** Senior Director, Medanta Division of Rheumatology & Clinical Immunology **Landline**: 91-124-4141414 **Phone**: 91-9971918887 **Email**: rajiva.gupta@medanta.org	4th Floor , Medanta Division of Rheumatology & Clinical Immunology; Medanta –The Medicity Hospital Gurugram Haryana
2.	**Mahatma Gandhi Institute of Medical Sciences, Sevagram, Maharashtra**	**Dr. Bharati Taksande , Professor,** Department of medicine. New medicine building, Mahatma Gandhi Institute of Medical Sciences, Sevagram, Maharashtra **Landline**: 91-71-52284341 **Phone**: 91-9881017505 **Email**: bharati.taksande@gmail.com	Department of medicine. New medicine building, Mahatma Gandhi Institute of Medical Sciences, Sevagram, Maharashtra
3.	**Centre for Arthritis & Rheumatism Excellence, Kerala**	**Dr. Padmanabha Shenoy,** **Medical director and consultant rheumatologist**, 2rd Floor Dept of Rheumatology, Centre for Arthritis & Rheumatism Excellence, Kerala-682040 **Landline**: 0-484-270	2rd Floor Dept of Rheumatology, Centre for Arthritis & Rheumatism Excellence, Kerala

		4400 **Phone**:91-9446567000 **Email**: drdpshenoy@gmail.com	
4.	**St. John's Research Institute, A Unit of CBCI Society for Medical Education**	**Dr. C Chanakya, Assistant Professor, Clinical Immunology &Rheumatology,**St. John"s Medical College and Hospital, Sarjapur Main Rd,John Nagar, Koramanga, Bengaluru-560034 KARNATAKA **Landline**: 0-80-220653003 **Phone-91-8050989679** **Email**: drchanakya41@gmail.com	St. John"s Medical College and Hospital, A Unit of CBCI Society for Medical Education
5.	**Kusum Dhirajlal Hospital, Ahmedabad, Gujarat**	**Dr. Dhiren N Raval, Consultant,**Research Department , Kusum Dhirajlal Hospital, Ahmedabad, Gujarat-382421 **Landline:** 0-79-66770000 **Phone:91-9619177085** **E-mail:** drdhirenraval@gmail.com	Research Department,Kusum Dhirajlal Hospital, Ahmedabad, Gujarat
6.	**Post Graduate Institute of Medical Education & Research, Chandigarh**	**Dr. Varun Dhir , Additional Professor,** Rheumatology Lab Room 3031, Research Block B, PGIMER, Chandigarh-160012 **Landline:** 91-172-2755569 **Mobile:** 91-9891807756 **Email:** varundhir@gmail.com	Rheumatology Lab Room 3031, Research Block B, PGIMER, Chandigarh

4. Budget as Sanctioned by BIRAC for implementation of the program under NBM:
In Figures: Rs.854.95 Lakhs
In words: Rupees Eight Hundred Fifty-Four Lakhs and Ninety-Five Thousands only

5. **Lead Institute**: **Medanta Institute of Education & Research(MEDANTA)** shall be Lead Institute for implementation of the program under NBM which includes project and data management.

6. **Objectives and activities of the network:**

Objective 1:	**Capacity building across all the sites of Network**
Activities	Through survey assess the gaps in terms of human resources, equipment, pharmacy, existing processes (patient database, registries, IT systems, record keeping, EC approval timelines), storage and archival, SOPs, and training.
	Development of few critical SOPs to meet the stated objectives within the recommended regulatory framework
	Harmonized SOPs, processes and required infrastructure across all sites to comply with GCP requirements
	Manpower Recruitment
	Development of Training modules
	Training of the manpower on SOPs and GCP compliance on all clinical trial related activities
	IP storage at site as per GCP requirements
	Procurement of common equipment and software for documentation and research
Objective 2:	**Multi-centric REGISTRY of the Network**
Activities	Identification of the IT vendor for creating a software for the registry – **Have a common Electronic Data Capture platform for data capture, storage and analysis**
	Develop a common protocol for establishing REGISTRY of the target population and identify Data elements to be collected - **Indications must include those for which biosimilars are being developed by Indian manufacturers**
	Seek Ethics Committee approval for protocol
	Establish electronic database for data entry
	Training of data entry operators for data entry
	Governance and oversight mechanism in place for periodic checking of entry validity of REGISTRY
	Data entry, data verification, validation and cleaning
	Data analysis
	Applicant's first REGISTRY report based on common protocol established for the network - submitted to BIRAC
	Report of collated REGISTRY data for all the diseases of all applicants of the network - submitted to BIRAC
	Registry data availability to Indian Biologics manufacturers for planning a clinical trial

Objective 3:	**To make the sites ready for clinical trial conduct**
Activities	Conduct activities to create Patient Awareness for participation in clinical research
	Ensure DCGI or any other authorized regulatory body (as applicable) for registration of Ethics committee
	Assessment of all sites by Industry/third party for readiness to take up a clinical trial

7. Schedule of Milestones, Timelines along with fund release:

i. Name of the Institute:Medanta Institute of Education & Research, (MIER)

S.No.	Milestones	Month of start of activity	Month of end of activity	BIRAC release under NBM (In Lakhs) to MIER	The Fund Recipient (Medanta Institute of Education and Research) Release (Amount in Lakhs Rs.)	Required financial input
1.	**Acceptance of Undertaking under GLA** and Signing of contract Fulfillment of fund release requirements.	0	1	63.45	0.00	30% of BIRAC fund
2.	Status report on **Development of few critical SOPs for GCP compliance based on survey** And Submission of UC/SOE for the corresponding milestone certified by internal finance.	2	9	42.30	0.00	20% of BIRAC fund
3.	Status report on **Applicants first REGISTRY report based on common protocol established for the network submitted to**	10	18	42.30	0.00	20% of BIRAC fund

	BIRAC And Submission of UC/SOE for the corresponding milestone certified by internal finance.					
4.	Status report on **Report of collated REGISTRY data of all the diseases of all applicants of the network - submitted to BIRAC** And Submission of UC/SOE for the corresponding milestone certified by internal finance.	19	28	42.30	0.00	20% of BIRAC fund
5.	**Submission of final completion report** And Consolidated Utilization Certificate (UC) and Statement of Expenses (SOE) certified by internal finance.	29	36	21.15	0.00	10% of BIRAC fund

ii) <u>Name of the Institute</u>: Mahatma Gandhi Institute of Medical Sciences, Sevagram, Maharashtra (MGIMS)

S.No.	**Milestones**	**Month of start of activity**	**Month of end of activity**	**BIRAC Release under NBM to the Fund Recipient (Mahatma Gandhi Institute of Medical Sciences) (Amount in Lakhs Rs.)**	**The Fund Recipient (Mahatma Gandhi Institute of Medical Sciences) Release (Amount in Lakhs Rs.)**	**Required financial input**

1	**Acceptance of Undertaking under GLA** and Signing of contract Fulfillment of fund release requirements.	0	1	38.61	0.00	30% of BIRAC
2	Status report on **Development of few critical SOPs for GCP compliance based on survey** And Submission of UC/SOE for the corresponding milestone certified by internal finance.	2	9	25.74	0.00	20% of BIRAC
3	Status report on **Applicants first REGISTRY report based on common protocol established for the network submitted to BIRAC** And Submission of UC/SOE for the corresponding milestone certified by internal finance.	10	18	25.74	0.00	20% of BIRAC
4	Status report on **Report of collated REGISTRY data of all the diseases of all applicants of the network - submitted to BIRAC** And Submission of UC/SOE for the corresponding milestone	19	28	25.74	0.00	20% of BIRAC

	certified by internal finance.					
5	**Submission of final completion report** And Consolidated Utilization Certificate (UC) and Statement of Expenses (SOE) certified by internal finance.	29	36	12.87	0.00	10% of BIRAC

iii) <u>Name of the Institute</u>:Centre for Arthritis & Rheumatism Excellence, Kerala(CARE)

S. No.	Milestones	Month of start of activity	Month of end of activity	BIRAC release under NBM to CARE (Amount In Rs. Lakhs)	The Fund Recipient (Centre for Arthritis & Rheumatism Excellence, Kerala) Release (Amount in Lakhs Rs.)	Required financial input (Amount In Rs. Lakhs)
1	**Acceptance of Undertaking under GLA** and Signing of contract Fulfillment of fund release requirements.	0	1	38.61	0.00	30% of BIRAC
2	Status report on **Development of few critical SOPs for GCP compliance based on**	2	9	25.74	0.00	20% of BIRAC

	survey And Submission of UC/SOE for the corresponding milestone certified by internal finance.					
3	Status report on **Applicants first REGISTRY report based on common protocol established for the network submitted to BIRAC** And Submission of UC/SOE for the corresponding milestone certified by internal finance.	10	18	25.74	0.00	20% of BIRAC
4	Status report on **Report of collated REGISTRY data of all the diseases of all applicants of the network - submitted to BIRAC** And Submission of UC/SOE for the corresponding milestone certified by internal finance.	19	28	25.74	0.00	20% of BIRAC

5	**Submission of final completion report** And Consolidated Utilization Certificate (UC) and Statement of Expenses (SOE) certified by internal finance.	29	36	12.87	0.00	10% of BIRAC

iv) **Name of the Institute:**St. John"s Research Institute, A Unit of CBCI Society for Medical Education

S. No.	Milestones	Month of start of activity	Month of end of activity	BIRAC release under NBM to St. Johns NAHS, Bangalore (Amount In Rs. Lakhs)	The Fund Recipient (St. John's Research Institute, A Unit of CBCI Society for Medical Education) Release (Amount in Lakhs Rs.)	Required financial input (Amount In Rs. Lakhs)
1	**Acceptance of Undertaking under GLA** and Signing of contract Fulfillment of fund release requirements.	0	1	38.61	0.00	30% of BIRAC
2	Status report on **Development of few critical SOPs for GCP compliance based on survey** And Submission of UC/SOE for the corresponding milestone certified by internal finance.	2	9	25.74	0.00	20% of BIRAC

3	Status report on **Applicants first REGISTRY report based on common protocol established for the network submitted to BIRAC** And Submission of UC/SOE for the corresponding milestone certified by internal finance.	10	18	25.74	0.00	20% of BIRAC
4	Status report on **Report of collated REGISTRY data of all the diseases of all applicants of the network - submitted to BIRAC** And Submission of UC/SOE for the corresponding milestone certified by internal finance.	19	28	25.74	0.00	20% of BIRAC
5	**Submission of final completion report** And Consolidated Utilization Certificate (UC) and Statement of Expenses (SOE) certified by internal finance.	29	36	12.87	0.00	10% of BIRAC

v) <u>Name of the Institute</u>:Kusum Dhirajlal Hospital, Ahmedabad, Gujarat(KD Hospital)

S. No.	Milestones	Month of start of activity	Month of end of activity	BIRAC release under NBM to KD Hospital (Amount In Rs. Lakhs)	The Fund Recipient (Kusum Dhirajlal Hospital, Ahmedabad, Gujarat) Release (Amount in	Required financial input (Amount In Rs. Lakhs)

					Lakhs Rs.)	
1	**Acceptance of Undertaking under GLA** and Signing of contract Fulfillment of fund release requirements.	0	1	38.61	0.00	30% of BIRAC
2	Status report on **Development of few critical SOPs for GCP compliance based on survey** And Submission of UC/SOE for the corresponding milestone certified by internal finance.	2	9	25.74	0.00	20% of BIRAC
3	Status report on **Applicants first REGISTRY report based on common protocol established for the network submitted to BIRAC** And Submission of UC/SOE for the corresponding milestone certified by internal finance.	10	18	25.74	0.00	20% of BIRAC
4	Status report on **Report of collated REGISTRY data of all the diseases of all applicants of the network - submitted to BIRAC** And Submission of UC/SOE for the corresponding milestone certified	19	28	25.74	0.00	20% of BIRAC

	by internal finance.					
5	**Submission of final completion report** And Consolidated Utilization Certificate (UC) and Statement of Expenses (SOE) certified by internal finance.	29	36	12.87	0.00	10% of BIRAC

vi) Name of the Institute:Post Graduate Institute of Medical Education & Research, Chandigarh (PGIMER)

S. No.	Milestones	Month of start of activity	Month of end of activity	BIRAC release under NBM to PGIMER (Amount In Rs. Lakhs)	The Fund Recipient (Post Graduate Institute of Medical Education & Research, Chandigarh) Release (Amount in Lakhs Rs.)	Required financial input (Amount In Rs. Lakhs)
1	**Acceptance of Undertaking under GLA** and Signing of contract Fulfillment of fund release requirements.	0	1	38.61	0.00	30% of BIRAC

2	Status report on **Development of few critical SOPs for GCP compliance based on survey** And Submission of UC/SOE for the corresponding milestone certified by internal finance.	2	9	25.74	0.00	20% of BIRAC
3	Status report on **Applicants first REGISTRY report based on common protocol established for the network submitted to BIRAC** And Submission of UC/SOE for the corresponding milestone certified by internal finance.	10	18	25.74	0.00	20% of BIRAC
4	Status report on **Report of collated REGISTRY data of all the diseases of all applicants of the network - submitted to BIRAC** And Submission of UC/SOE for the corresponding milestone certified by internal finance.	19	28	25.74	0.00	20% of BIRAC
5	**Submission of final completion report** And Consolidated Utilization Certificate (UC) and Statement of Expenses (SOE) certified by internal finance.	29	36	12.87	0.00	10% of BIRAC

8. The Institutes will maintain an interest-bearing account with a Scheduled Bank (as defined under the RBI Act, 1934), the withdrawals and payments from which account shall be subject to verification by BIRAC.

9. The Institutes would submit the Utilization Certificate (UC) and Statement of Expenditure (SoE) to BIRAC, duly audited by competent authority pertaining to the fund released after attainment of every milestone. A consolidated UC/SoE would be submitted immediately after the end of each financial year.

10. The expenditure incurred before the Effective Date of the governing Agreement of the Project will not be accounted for this Project.

11. No change in equipment proposed to be purchased for the project will be accepted without prior approval of the BIRAC.

12. No Budget Re-appropriation should be done without prior approval from BIRAC.

13. The request for extension for the timelines may be submitted by the Institutes in advance. Non-completion of the milestones/project within a specific timeline without prior information to the BIRAC will take the project as closed on the date as mentioned in the agreement.

14. The Sanctioned amount for the Project does not automatically confirm release of the complete sanctioned amount; the fund disbursement will be based on technical progress of the Project and actual expenditure based on evaluation of UC/SoE submitted by the Institutes if any.

15. The accounts of institutes shall be open to inspection by the sanctioning authority/ audit as per the rules.

16. Manage the Study Data developed through the funding Assistance of BIRAC in a manner that ascertains Department of Biotechnology (DBT) as third party beneficiary, a perpetual, non-exclusive, non-transferable, paid-up license, without right to sublicense to use the study Data subject to the obligations set forth in „Confidentiality", for purposes of national and public interest regardless of whether this GLA expires, foreclosed or terminated.

17. The present order confirming the support for the implementation of the project is not legally binding in any way unless the relevant funding agreement is duly executed by the parties and the terms and conditions stated in the agreement shall be legally binding on the parties thereto.

18. The Expenditure is debitable to "……..", Head of Account: **……..** for financial year 2020-2021.

19. This issue with the approval of competent authority vides BFD No**……..** dated **……**

20. The Sanction order has been noted a serial no …… in the register of grant.

21. This Sanction order will be followed and supported by GLA and other relevant funding agreements issued by BIRAC.

BCX1XD

22. The agreement execution fulfilment of collateral or security requirements & completion of associated formalities should be a carried out within a period of four weeks form the issue of the present order unless express waiver is obtained for delay from BIRAC.

In consideration of the foregoing, Medanta Institute of Education & Research(MIER) agrees to be bound by the terms set forth in the sanction order and affixes his/her signature (and seal/stamp if any) below:

For and on behalf of **Medanta Institute of Education & Research (MIER)**
Signature
Name
Designation
Official Seal

In consideration of the foregoing Mahatma Gandhi Institute of Medical Sciences, Sevagram, Maharashtraagrees to be bound by the terms set forth in the sanction order and affixes his/her signature (and seal/stamp if any) below:

For and on behalf of **Mahatma Gandhi Institute of Medical Sciences (MGIMS), Sevagram, Maharashtra**
Signature
Name
Designation
Official Seal

In consideration of the foregoing, Centre for Arthritis & Rheumatism Excellence, Kerala (CARE)agrees to be bound by the terms set forth in the sanction order and affixes his/her signature (and seal/stamp if any) below:

For and on behalf of **Centre for Arthritis & Rheumatism Excellence, Kerala (CARE)**
Signature
Name
Designation
Official Seal

In consideration of the foregoingSt. John's Research Instituteagrees to be bound by the terms set forth in the sanction order and affixes his/her signature (and seal/stamp if any) below:

For and on behalf of **St. John's Research Institute**
Signature
Name
Designation
Official Seal

In consideration of the foregoing, Kusum Dhirajlal Hospital, Ahmedabad, Gujarat (KD Hospital) agrees to be bound by the terms set forth in the sanction order and affixes his/her signature (and seal/stamp if any) below:

For and on behalf of **Kusum Dhirajlal Hospital, Ahmedabad, Gujarat (KD Hospital)**
Signature
Name
Designation
Official Seal

In consideration of the foregoing, Post Graduate Institute of Medical Education & Research,Chandigarh (PGIMER)agrees to be bound by the terms set forth in the sanction order and affixes his/her signature (and seal/stamp if any) below:

For and on behalf of **Post Graduate Institute of Medical Education & Research, Chandigarh (PGIMER)**
Signature
Name
Designation
Official Seal

Dr.Kavita Singh

Mission Director,
National Biopharma Mission

BCX1XD

To,

Dr. …….

Copy to:
1. BIRAC- Folder
2. Finance Folder
3. NBM -Folder

Dr. Kavita Singh
Mission Director,
National Biopharma Mission

आई सी एम आर - राष्ट्रीय रोग सूचना विज्ञान एवं अनुसंधान केंद्र
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार
ICMR - National Centre for Disease Informatics and Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

No: NCDIR/HBSR/2123 Date: 19-05-2021

Dr N Gangane,
Dean
Mahatma Gandhi Institute of Medical Sciences
Sevagram, Dist: Wardha, Maharashtra

Dear Dr Gangane,

Sub: Invitation to establish Hospital Based Stroke Registry under the project "HTA of National Stroke Care Registry Programme development of Hospital Based Stroke Registries (HBSR) in different regions of India" of ICMR-NCDIR, regarding

We are pleased to inform you that the ICMR- NCDIR has initiated the "HTA of National Stroke Care Registry Programme development of Hospital Based Stroke Registries (HBSR) in different regions of India" funded by DHR, to be implemented through selected institutions.

In this regard, NCDIR would like to invite your institution as a centre to establish the Hospital Based Stroke Registry. Kindly identify the faculty from Neurology/Medicine department of your institution as PI/co-PI for this project. Each participating centre will be provided a budget for purpose of data collection, data entry and contingency. Each centre is required to submit a yearly report.

If your institution is keen to participate, we request you to kindly send us the signed letter of concurrence to ICMR-NCDIR with the completed registration form enclosed with signature and seal of institution. These can be sent to NCDIR by post and as scanned copies by email.

NCDIR as a coordinating centre will be responsible for implementation, supervision and monitoring of the project. NCDIR will conduct training workshops for the selected centres that initiate HBSR. The functions of a HBSR centre and the roles, responsibilities of Principal Investigator and HBSR centre will be explained and discussed in the ensuing workshops.

Dr. Deepadarshan H, Scientist-B (Ph. No 080 22176347 /9964001076) shall be coordinating this programme. Please write to deepadarshan.h@icmr.gov.in for any further clarifications or assistance.

Thanking you,

Yours sincerely,

Dr Deepadarshan H
Scientist-B
For Director, ICMR-NCDIR

Encl:
1. Registration Form
2. Concept note

निर्मल भवन, आई सी एम आर कॉम्प्लेक्स, पूजनहल्ली रोड,
कन्नमंगला पोस्ट, बेंगलुरु - 562 110. कर्नाटक (भारत)
Nirmal Bhawan-ICMR Complex, Poojanahalli Road,
Kannamangala Post, Bengaluru - 562 110. Karnataka (India)
Tel:+91 080 22176400,
Fax: 080 30723643,
Email: admin@ncdirindia.org /
accounts@ncdirindia.org
www.ncdirindia.org

आई सी एम आर - राष्ट्रीय रोग सूचना विज्ञान एवं अनुसंधान केंद्र
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार
ICMR - National Centre for Disease Informatics and Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

No. NCDIR/HBSR/27/2021/ 2503

01-10-2021

Dr. Jyoti Jain,
Professor & Head, Department of Medicine,
Mahatma Gandhi Institute of Medical Sciences,
Sevagram Dist. Wardha, Maharashtra-442102

Madam,

Sub: "HTA of National Stroke Care Registry Programme Development of Hospital Based Stroke Registries (HBSR) in different regions of India" for the FY 2021-22.

This is with reference to your email dated: 29th September 2021, I am directed to inform you that a sum of Rs.5,00,000/- (Rupees Five Lakh Only) has been allocated towards data collection, data entry and contingency purpose to the afore mentioned project as "Lumpsum Grant to the Registry" as per the funding agency.

The Principal Investigator of the registry may fix the emoluments for staff as per the norms of their Institution but in no case; it should not exceed the budget allocated to the centre.

Thanking you,

Yours faithfully,

(Ramesha N.M.)
Administrative Officer

निर्मल भवन, आई सी एम आर कॉम्प्लेक्स, पूजनहल्ली रोड,
कन्नमंगला पोस्ट, बेंगलुरु - 562 110. कर्नाटक (भारत)
Tel:+91 080 22176400,
Fax: 080 30723643,
Email: admin@ncdirindia.org /

GYNUITY HEALTH PROJECTS

INVESTIGATOR AGREEMENT
FOR ACLINICAL INVESTIGATION OF

GHP Protocol 4006MOLI - Misoprostol or Oxytocin for Induction of Labour Study

(Protocol Number and Study Title)

I AGREE AND/OR CERTIFY THAT:

1. I agree to participate as the Principal Investigator in *a clinical investigation of GHP Protocol 4006 MOLI - Misoprostol or Oxytocin for Induction of Labour Study*

2. Iwill conduct the clinical investigation in accordance with this agreement;with all requirements of the relevant current protocol and other applicable local regulations for the conduct of clinical trials, specifically, the India Drugs and Cosmetics Act (1940) and Cosmetics Rules (1945), specifically Schedule Y and rules 122A, 122b, 122D, 122DA, 122DAC and 122E, as appropriate; the Ethical Guidelines of the Indian Council of Medical Research (2006), and Indian Good Clinical Practice Guidelines (2001);with adherence to the principles of good clinical practices; and any conditions of approval imposed by my Institutional Review Board (IRB), by any other IRB or Ethics Committee that reviews and approves this study, or by relevant regulatory authority. I agree to abide by all of the investigator responsibilitiesas follows:

a. I will obtain written approval from my institution's Institutional Review Board in advance of undertaking any activities with human subjects. I will submit the certification of IRB approval and any conditions of this approval to Gynuity Health Projects. I also agree to promptly report to my institutional IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without prior approval of Gynuity Health Projects or IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

b. I will supervise all conduct of the trial and will allow only those individuals who are qualified by education, licensure, and/or the governance of the local medical board to perform duties specified in the study protocol.

c. I will ensure that Informed Consent is obtained from each subject participating in this clinical investigation in accordance with the informed consent regulations found in Ethical Guidelines of the Indian Council of Medical Research (2006), and Indian Good Clinical Practice Guidelines (2001), and that a signed copy of the informed consent shall be available to the Gynuity Health Projects and Gynuity Health Project's designated monitor.

d. I will be responsible for accountability of all investigational drugs and study suppliesat the study site. I will return all unused study supplies to Gynuity Health Projects or otherwise follow the instructions of Gynuity Health Projects for disposal of the unused drugs or devices.

e. I will put and keep in place arrangements to allow all to conduct the Trial in accordance with the Protocol.

3. I have the appropriate, relevant qualifications to conduct and to oversee the conduct of the investigation as documented by the following: *(Check applicable statement)*

____ My relevant qualifications, including dates, location, extent, and type of experience, are listed in my most recent curriculum vitae (CV), which is attached to this Agreement and which will be maintained by Gynuity Health Projects in the trial master file.

PRINCIPAL INVESTIGATOR:

Poonam Varma Shivkumar
Name of Principal Investigator (please print or type)

PVaskumar _11/12/2020_
Signature of Principal Investigator Date

CO-PRINCIPAL INVESTIGATORS: A current CV or statement of relevant experience is required to be submitted to Gynuity Health Projects for each Co-Principal Investigator listed below.

Dr. Shila Shelke
Name (please print or type)

_____ _11/12/2020_
Signature Date

Name (please print or type)

_____ _____
Signature Date

Name (please print or type)

_____ _____
Signature Date

भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health and Family Welfare, Government of India

3551
16/11/20

F. No. RCH/Adhoc/MH/2014-1375/15-16/2/Maharashtra/Central

Dated: 29/10/2020
5/11/2020

To,

The Dean,
Mahatma Gandhi Institute of Medical Science,
Sevagram, Wardha
Maharastra - 422102

Subject : "Continuation of Ad-hoc Research Scheme entitled "Community based study of effects of biomass fuel, water intake, haemoglobin on pregnancy outcome with special reference to birth weight in Melghat, Maharashtra, India under Dr. S.Chhabra.

Madam,

The Director General of the Indian Council of Medical Research sanctions the continuation of above mentioned scheme with an allotment of **Rs. 8,50,020/-(Rupees Eight Lakhs Fifty Thousand Twenty Only)** the 3rd year from **28/03/2020 to 27/03/2021.**

The grant will be released to the head of the institute in installments during the financial year on receipt of the demand in the prescribed form as indicated below:

Total: Rs. 8,50,020/-

While asking for the release of the installment it may be ensured that the amount for the pay and allowances of the staff that are actually in position is included.

The others terms and condition will remain the same as mentioned in this office letter of even number dated 31/07/2018 These issues with the concurrences of the Finance Div.

RFC No. CH/Ad-hoc/7/2017-18 dated : 23/03/2018

Yours faithfully,

05/11/2020

(Ramesh Kumar)
Administrative Officer
For Director General

Copy to:

1. Accounts. V. for information.
2. Dr. S. Chhabra, Director Professor, Officer on Special Duty, Mahatma Gandhi Adiwasa Devakhana, Utavali, Dharni, District Amravti, Kasturba Health Society, Sewagram, Maharastra - 442102
3. Shri Birender Singh Sr. T O. RBMH, ICMR

Admn. Officer
For Director General

23/11

INDIAN COUNCIL OF MEDICAL RESEARCH
Serving the nation since 1911

भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य एवं परिवार
कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

F. No. RCH/Adhoc/MH/2014-1375/15-16/2/Maharashtra/Central **Dated: 29/10/2020**

Subject : Payment of full & final 3rd year grant-in-aid for "Community based study of effects of biomass fuel, water intake, haemoglobin on pregnancy outcome with special reference to birth weight in Melghat, Maharashtra, India under Dr. S.Chhabra.

MEMORANDUM

Reference this office letter of even number dated 21/09/2020.

The Director General, ICMR sanctions the payment of **Rs. 7,65,018/- (Rupees Seven Lakhs Sixty Five Thousand Eighteen Only)** as the **full & final 3rd year** the grant for incurring expenditure in connection with the above mentioned research scheme. The amount of **Rs. 7,65,081/-**may be debited in the provision of **Rs 8,50,020/-** made for the above mentioned research scheme for the current financial year 2019-2020.

A formal bill for **Rs . 7,65,018/-** is sent herewith for through RTGS (mandate form enclosed) for payment to **The Dean, Mahatma Gandhi Institute of Medical Science, Sevagram, Wardha, Maharastra - 422102.** After adjusting **unspent balance of Rs. 2,96,473.50/- with third year sanction budget and hold 10%(Rs. 85,002/-) of third year sanctioned budget.**

A net amount of Rs. 7,65,018/- may be released as third year sanctioned budget.

This is issued with the concurrence of the finance Division and Divisional Chief after completing all coadal formalities. RFC No. CH/Ad-hoc/7/2017-18 dated : 23/03/2018

(Ramesh Kumar)
Administrative Officer
For Director General

Accounts Sections V, ICMR
Copy to :-

1. The Dean, Mahatma Gandhi Institute of Medical Science, Sevagram, Wardha, Maharastra - 422102
2. Dr. S. Chhabra, Director Professor, Officer on Special Duty, Mahatma Gandhi Adiwasa Devakhana, Utavali, Dharni, District Amravti, Kasturba Health Society, Sewagram, Maharastra - 442102
3. Shri Birender Singh Sr. T O. RBMH, ICMR

29/10/20
Admn. Officer
For Director General

MaatHRI
Maternal and perinatal Health Research collaboration India

08 September, 2021

To
Dr. S Chhabra
Mahatma Gandhi Institute of Medical Sciences (MGIMS)
Sevagram, Wardha,
Maharashtra, India

Re: Fund transfer for MaatHRI (Maternal and Perinatal Health Research collaboration, India) project

Dear Dr. Chhabra,

This is to inform you that the University of Oxford has transferred a total amount of INR 2,35,400/- to Kasturba Health Society's bank account against an invoice raised for the MaatHRI project expenses (MaatHRI Project MGIMS, Sevagram, India).

Yours sincerely,

Dr. Manisha Nair (Chief Investigator of MaatHRI project)
Associate Professor, Senior Epidemiologist and Research Fellow,
National Perinatal Epidemiology Unit, Nuffield Department of Population Health,
University of Oxford
Email: Manisha.nair@npeu.ox.ac.uk;
Phone: +44-1865617820

MaatHRI
Maternal and perinatal Health Research collaboration India

Date: 05 March 2020

To
Professor S Chhabra,
Director & Professor, Obstetrics and Gynaecology,
Mahatma Gandhi Institute of Medical Sciences (MGIMS),
Wardha, Maharashtra

Re: Transfer of funds to Kasturba Health Society's bank account

Dear Prof. Chhabra,

I am writing to confirm that a sum of Rs 2,35,400 was transferred to Kasturba Health Society's bank account at the Central Bank of India, Sevagram Branch against invoice number 03, dated 17/12/2019. The funds are for the Maternal and perinatal Health Research collaboration, India (MaatHRI) project at MGIMS, Sevagram.

Yours sincerely,

Dr Manisha Nair (Chief Investigator, MaatHRI)

Senior Epidemiologist and Research Fellow
National Perinatal Epidemiology Unit (NPEU)
Nuffield Department of Population Health, University of Oxford,
Old Road Campus, Headington, Oxford, OX3 7LF
01865 617820
www.npeu.ox.ac.uk
https://www.npeu.ox.ac.uk/maathri

International Federation of Gynecology and Obstetrics
the Global Voice for Women's Health

Memorandum of Understanding

Parties	**The International Federation of Gynecology & Obstetrics (FIGO)** FIGO House, Suite 3 – Waterloo Court, 10 Theed Street, London SE1 8ST, UK Prof Mary Ann Lumsden, Chief Executive Telephone: +44 (0)20 7928 1166 Fax: +44 (0)20 7928 7099 Email: MaryAnn@figo.org
	Mahatma Gandhi Institute of Medical Sciences (MGIMS) Sevagram, Wardha 442102 Maharashtra, India Contact: Dr Bishan Garg gargbs@gmail.com
Project Title	ENGAGING NATIONAL PROFESSIONAL SOCIETIES TO COMBAT POSTPARTUM HAEMORRHAGE– Uttar Pradesh, India.
Project Duration	1 December 2019 – 31 May 2022

PREAMBLE

The International Federation of Gynecology & Obstetrics (FIGO) is pleased and proud to work together with its national level partners to implement projects that benefit women and children as well as strengthen capacity. This Memorandum of Understanding (MOU) sets out the rights and obligations of both parties in order to work effectively, and with mutual respect and understanding.

ARTICLE 1 – SCOPE AND OBJECTIVES OF THE AGREEMENT

This MOU sets out the terms and understanding between FIGO and MGIMS for the Capacity building, monitoring and supervision of the "Combat Postpartum Haemorrhage" (CPH) in Uttar Pradesh.

The Combat Postpartum Haemorrhage project, run by FIGO, will be implemented in partnership with the MGIMS and UPTSU from 1 January 2020 until 31 May 2022. This Memorandum of Understanding covers the project capacity building, monitoring and supervision aspects for this whole period. Any extension to this period should be covered by a new MOU.

This MOU has been created to guide the partnership between FIGO and MGIMS in relation to the implementation of the aforementioned project elements

ARTICLE 2 – COMMITMENTS OF FIGO

FIGO commit to the provision of funds as per the agreed budget (appendix A) to a maximum total of $45,634, to be disbursed in accordance with the disbursements protocol outlined by the FIGO team.

FIGO commit to providing timely headquarter support and country visits by Implementation Partner, MGH, to aid project start-up, implementation and close out.

ARTICLE 3 – COMMITMENTS OF MGIMS

MGIMS commit to supervising the implementation and monitoring of the project in accordance with the approved proposal and action plan (appendix B), providing the necessary professional and administrative support, personnel services and any other resources required.

MGIMS commit to ensuring administration and internal control of the project resources provided are conducted in accordance with agreed Project, National MGIMS financial/procurement policies and country law.

MGIMS commit to report on project progress in accordance with the FIGO-CPH reporting procedures and schedule (Section 5).

MGIMS commit to ensuring that at the close of this project they will continue to work with country government and network partners on the promotion of effective approaches to the prevention and treatment of Postpartum haemorrhage.

MGIMS commit to uphold clear and regular communications between their project team and FIGO (CPH team, secretariat and working group) and ensure the project remains embedded,

and coordinating with UPTSU, the responsibility of MGIMS regardless of position changes in either PMU or secretariat.

ARTICLE 4 – PROJECT HIRING, PLANNING, REVIEW, REPORTING AND EVALUATION

MGIMS will share terms of employment (contract) and job descriptions for any project roles being hired for FIGO to sign off before initiating the hiring process. The MGIMS will share information by email on their preferred candidates and consider FIGO input. The MGIMS President, Secretary or Treasurer will be involved in the recruitment of the project team.

MGIMS will not issue employment contracts until this MOU has been signed by all parties. Staff, including consultants and honorariums can only be paid with project funds within the official start and end dates of the project, namely 1 December 2019 to 31 May 2022. The MGIMS is responsible for employment contracts (must be in the name of the MGIMS), and managed according to local laws.

MGIMS will plan project activities in accordance with the approved country action plan, particularly in terms of timing and deliverables.

FIGO, through their technical partner MGH, will support and monitor project implementation, including but not limited to the agreed schedule of workshops and regular support calls per year, by designated FIGO and MGH representative(s). The purpose of these meetings will be to implement training, monitor project progress and provide support.

MGIMS will take measures to support the safety of FIGO and MGH staff while on project support trips, including advise during the planning stage, and ongoing monitoring of safety throughout, with any adjustments and communications as necessary.

MGIMS will take responsibility for governance of the outlined aspects of the project including clear documentation and trails of any major decisions made, to be shared with FIGO when required.

MGIMS shall promptly inform FIGO if activities cannot be undertaken as planned and/or if reports cannot be submitted as agreed, MGIMS will be responsive to FIGO CPH staff, through email and skype/telephone calls on a regular basis, and will aim to respond to all communications within 48 hours (Monday-Friday) unless previously communicated otherwise.

FIGO will provide appropriate templates for the purpose of reporting.

MGIMS will provide project reports according to the following schedule:

Report	Monthly[1]	Quarterly[2]	6-monthly	Annual
Bank statements	X			
Financial report		X		
Narrative report		X		
Action plan report		X		
Audit Report				X
Asset Inventory			X	

MGIMS will submit reports in the CPH project template to FIGO fourteen days following the end of each reporting period.

MGIMS will provide responses to any requests for clarification and/or additional information from FIGO in a timely manner (5 working days after submission of responses). Failure to submit reports to FIGO on time and/or to answer queries may delay project funding.

The quarterly reporting schedule for narrative and financial reports will be as follows:

Year Quarter	Reporting period	Latest report due date to FIGO
Year 1-Q1	Dec - Feb 2020	14th March 2020
Year 1-Q2	Mar-May 2020	14th Jun 2019
Year 1-Q3	Jun-Aug 2020	14th Sept 2020
Year 1-Q4	Sept-Nov 2020	14th Dec 2020
Year 2–Q1	Dec-Feb 2021	14th Mar2020
Year 2–Q2	Mar-May 2021	14th Jun 2020
Year 2–Q3	Jun-Aug 2021	14th Sept 2021
Year 2–Q4	Sept-Nov 2021	14th Dec 2021
Year 3-Q1	Dec-Feb 2022	14th Mar 2021
Year 3-Q2	Mar-May 2022	14th Jun 2021

Quarterly narrative reports: The MGIMS shall prepare quarterly narrative reports covering the activities performed and the results obtained by the project in the templates provided. The reports shall be analytical in approach and include a presentation of activities undertaken, challenges and lessons learned.

---

1 Bank statements should be obtained from bank accounts on a monthly basis (the 14th of each month) and submitted to FIGO with the quarterly financial report

2 Quarterly reports are due to FIGO on the 14th of March, 14th of June, 14th of Sept and 14th of Dec

Financial reports:

Quarterly Financial Reports: The MGIMS shall prepare financial reports as per the agreed template detailing all expenses incurred against the total approved budget as well as provide bank reconciliation and access to financial supporting documents.

The MGIMS shall comment on and explain all over- and under- expenditure and what actions are proposed for addressing it. Care should be taken to ensure that comments provided to explain expenditure variances are consistent with reported programme activities.

Information on expenditure should be maintained locally in the currency in which it is incurred, including an indication of the exchange rate used to translate the expenditure from the primary currency to the US Dollar equivalent. For reporting purposes, information should be provided in local currency as well as the US Dollar equivalent.

MGIMS will work with FIGO staff and MGH technical leads to develop their monitoring and evaluation tools and will be responsible for collection and quality of data.

Other information: The MGIMS shall provide FIGO with any other information regarding the project that FIGO Director of Projects, Project Coordinator, Head of Finance or any persons from the Finance team may reasonably request and shall enable FIGO representatives to visit project locations and inspect property, goods, records and documents. The MGIMS shall respond to requests for Finance information and for project information within 3 to 5 working days. The MGIMS shall co-operate with and assist FIGO in the performance of follow-ups and evaluations of the impact of the project.

In case of concerns in financial accountability or failure to provide comprehensive reports or progress project according to agreed timelines without justification, the following procedure will be followed by FIGO and MGIMS:

1: First formal written communication from FIGO HQ (Director of Projects or Project Coordinator) to Project Lead copying in President/CEO & Treasurer detailing issue, next steps and deadline for response.

2: Second formal written communication from FIGO HQ (Director of Projects or Project Coordinator) to Project Lead copying in President/CEO & Treasurer if no response within timeline communicated in first formal written communication.

3: FIGO Director of Projects calls President/CEO if no adequate response within timeline communicated in second formal written communication.

All documents will be saved and minutes of calls taken to document actions taken by each party to overcome the identified concerns. If these steps do not result in a satisfactory resolution, no further funds will be sent. If no satisfactory solution can be found after 2 months from first formal written communication, FIGO CEO can select to discontinue the project, if this was to happen all funds held in country would need to be returned to FIGO immediately.

As per Article 14, the contract can also be terminated effective immediately in the case of a serious breach of the MOU.

ARTICLE 5: DATA

MGIMS and FIGO will sign a Data Sharing Agreement prior to any research activities that involve collection of data as part of the project, either conducted by MGIMS or another organisation/consultant on their behalf.

MGIMS will ensure that all ethics regulations in country are adhered to and regularly update, or provide official explanation as to why ethics clearance is not needed.

MGIMS will use appropriate administrative, physical and technical safeguards to prevent inadvertent disclosure of the data set to any third party.

FIGO may use or contract the support of third parties to undertake data analysis for research purposes. The data communicated with any third parties will be unidentifiable.

ARTICLE 6: DISBURSEMENTS

FIGO shall pay the funds in such instalments as are outlined in the budget, on the basis of receipt of a disbursement request (included in the Finance Manual) and approval of reports by the due date, evidence of implementation according to the original budget and receipt of funds. FIGO reserves the right to alter the timing and value of instalments.

MGIMS must request funds through submission of a 'disbursement request'. All sections of the form must be correctly completed before any disbursement can be authorised from FIGO. The persons authorised to sign the disbursement request on behalf of MGIMS will be the National Project Lead or National Coordinator or his/her nominated deputy.

MGIMS shall inform FIGO of any change in the National Project Lead, National Coordinator or nominated deputies.

FIGO shall disburse funds every quarter, following MGIMS submission of the financial report (as per section 5) and a disbursement request. Disbursement of any funds will remain contingent on FIGO having a positive balance in project funds.

The disbursement request shall contain the following information and shall be signed and addressed to the Projects Accountant and the Project Coordinator at FIGO:

- the word "disbursement request" shall be included in the heading
- the name of the project
- details of activities planned against the funds requested
- the requested amount in United States Dollars
- the recipient's bank, bank address, account number/IBAN No, account name, clearing number/sort code, SWIFT-code, currency of the account; and physical address of the beneficiary as registered with the bank
- an updated financial report on the use of previous disbursements or reference to such report

No disbursements will be made until FIGO has approved the request. This may be adjusted for any opening cash balance held by MGIMS.

FIGO will withhold disbursement, wholly or in part, if substantial deviations to the restricted program budget occur; if the activities cannot be undertaken, if reports are not delivered as agreed, or if the activities change in any other important respect in terms of the objectives. In the event of such occurrences, MGIMS may be required to return all or part of any unexpended grant funds to FIGO for possible onwards transfer back to the ultimate donor. Before taking such a decision, FIGO shall initiate discussions with MGIMS.

MGIMS shall ensure that all funds received are used for the implementation of the project as specified in the project description (appendix B) and in accordance with both the approved budget (appendix A).

Within the budget template provided by FIGO the Project Management category should include all necessary administrative costs for the project. This must be used to cover expenditures including but not limited to: any management fees, rent and bills, administrative support costs, bank taxes, currency fluctuations etc.

MGIMS will send FIGO any contracts to sign off for service level agreements which should be in line with the suppliers guidelines outlined in the Finance Manual.

MGIMS may be entitled to expenditure variations within budget lines. MGIMS will seek; prior written approval from FIGO **before** making any amendments.

MGIMS will deal with increased costs in relation to inflation and exchange rates through savings, general administration line, or reduced activities in order to meet the overall allocation of funding. Any gains made on currency exchange will be held until the end of the project period to mediate any later currency losses. Decisions between the use of these funds will be taking alongside FIGO at this stage.

In the event that there are some unspent funds from the previous quarter, MGIMS may carry these over into the next quarter. This is subject to full explanations being given within the appropriate section of the Finance Report and subsequent approval from FIGO.

MGIMS shall provide authorisation of expenditure as per CPH project limits defined by FIGO

Should circumstances arise calling the feasibility or validity of the project into question or causing MGIMS to make major changes in its objectives, or if MGIMS decides to make any substantial deviation from the plan presented, they must obtain FIGO's written approval before continuing the project or before implementing such changes.

FIGO are required under the terms of the grant to repay any portion of the funds not expended or committed for the purpose of the programme, or not needed to meet obligations incurred to third parties, in good faith, for purposes of the programme.

MGIMS will therefore ensure that records (audit trail) of all unspent balances are retained, and that such funds are taken into account in requesting for subsequent cash remittances, thereby limiting any unspent funds held locally.

The final financial report submitted by MGIMS shall provide information on interest income. Interest income shall be refunded to FIGO by MGIMS within 6 months of the end of the project, unless otherwise agreed.

FIGO will provide details of the bank account to which funds should be remitted. MGIMS will inform FIGO of any bank account change in written to the CPH Project Coordinator and the Project Accountant.

ARTICLE 7: PROCUREMENT

FIGO require that the procurement of goods, works and services be carried out in accordance with internationally accepted principles and good procurement practices.

MGIMS shall share their procurement policy with FIGO, if MGIMS does not have one, they will prepare a written 'Procurement Regulation' for submission to FIGO in respect of the CPH project. These regulations together with this MOU shall apply to the procurement of goods, works and services carried out by MGIMS, or an agency/consultant appointed by MGIMS to conduct activities under the CPH project.

MGIMS will not accept any offer, gift or payment, consideration or benefit of any kind that could be construed as an illegal or corrupt practice, either directly or indirectly, as an inducement or reward for the award or execution of contracts financed within this project.

FIGO may carry out checks on procurements which may take the form of a procurement audit. MGIMS shall provide FIGO with all the necessary documentation for this purpose.

ARTICLE 8: RECORDS

MGIMS will maintain financial books showing all expenditure made in the furtherance of carrying out its commitments as outlined within the approved proposal that have been charged against this grant, and keep adequate records/evidence to substantiate such expenditure. Such books/records must be made available to appropriate personnel from FIGO and/or the donor at reasonable times for review and audit, and copies of all relevant evidence and records, and all reports must be kept for at least seven years after completion of the use of the grant funds. This is in accordance with UK law.

ARTICLE 9: AUDIT

The project shall be audited annually, arranged in country by MGIMS. The audit shall be carried out by an independent Chartered Accountant. The audit shall be carried out in accordance with international standards issued by the International Federation of Accountants (IFAC). The terms of reference for the audit and the selection of auditor shall be approved by FIGO.

The Audit Report shall express an opinion as to whether submitted Financial Reports are correct and give a true and fair view of the activities of the project and whether the execution has complied with the rules and conditions governing the use of funds as expressed or referred to in this Agreement.

The auditor shall submit a Management Letter, which reviews the management and the

internal control system of the project. The letter shall state which measures have been taken as a result of previous audit reports/management letters and whether measures taken have been adequate to deal with reported shortcomings.

If requested by FIGO the audit shall also cover the progress report of the project.

MGIMS' Auditor shall submit the Audit Report and the Management Letter to FIGO; and no later than 2 months after the close of the 1-year period. A management response shall be produced by the National Project Manager and submitted to the auditor and to FIGO within three weeks.

MGIMS will undertake a final audit covering the final six months of the project.

MGIMS shall co-operate with and assist FIGO in the performance of any additional audits, follow-ups and financial studies that FIGO may request.

ARTICLE 11: ANTI-CORRUPTION

Both FIGO and MGIMS agree to co-operate in preventing corruption and will undertake rapid legal measures to stop, investigate and charge any party suspected on good grounds of corruption or other wilful misuse of resources.

ARTICLE 12: PUBLICITY

MGIMS will request approval before referencing FIGO in any public material.

MGIMS will reference FIGO's cooperation as financier when reports, studies or other information relating to the project are produced, however, the FIGO name must not be used in such a way that would imply contribution or endorsement of content.

MGIMS will provide content about progress and achievements of the CPH project in their country for inclusion in the FIGO newsletter on request.

If MGIMS wishes to use the FIGO logo on any promotional materials it must be signed off by FIGO.

MGIMS to share any related, field based, photographs of the CPH project with FIGO for use in broader FIGO promotion of the project.

ARTICLE 13: ARBITRATION AND APPLICABLE LAW

Any dispute, controversy or claim arising out of or in connection with this MOU that cannot be settled amicably shall be definitively resolved by arbitration. A single arbitrator shall be appointed. The place of arbitration shall be London and the language used in the proceedings shall be English.

This agreement shall be governed by the substantive law of England without regard to its conflict of law rules.

ARTICLE 14: DURATION AND TERMINATION

This MOU shall remain valid until 31st May, 2022, unless terminated earlier by six months' written notice by either Party. In the event of termination by FIGO the termination shall not apply to funds irrevocably committed in good faith by MGIMS to third parties before the date of the notice of termination, provided that the commitments were made in accordance with this agreement.

In the event of termination by MGIMS, no funds shall be made available for activities after the termination date.

In case of serious breach of the MOU, FIGO or MGIMS may terminate the MOU with immediate effect.

This MOU shall become effective on signing by the two parties. Two originals of the text of this MOU, written in English, have been signed, of which the parties have taken one each.

For the International Federation of Gynecology & Obstetrics (FIGO)	**For Mahatma Gandhi Institute of Medical Sciences (MGIMS)**
Date:	**Date:** 16/11/21
Signed:	**Signed:**
Title: Chief Executive	**Title:** Secretary
Date:	**Date:** 16/11/21

Dr. B. S. Garg
Secretary
Kasturba Health Society
P.O. Sevagram, Wardha-442 102

Appendix A: Budget

Budget Category	Item Nr	Activity Title	Item	Description	Y2 Unit Cost	Unit Number	Y2 Frequen	Y2Q1	Y2Q2	Y2Q3	Y2Q4	Y2 Total	Y3 Unit Cost	Unit Numbe	Y3 Frequen	Y3Q1	Y3Q2	Y3 Total	Y1-Y3 Totals	Column1
Personnel	1	MGIMS	Principle Investigator	$620 a month	620	3	4	0	1860	1860	1860	5580	620	3	2	1860	1860	3720	[illegible]	
Personnel			Data Manager	$430 a month	430	3	4	0	1290	1290	1290	3870	430	3	2	1290	1290	2580	[illegible]	
Personnel			Attendant	$170 a month	170	3	4	0	510	510	510	1530	170	3	2	510	510	1020	[illegible]	
Subtotals								0	3660	3660	3660	10980				3660	3660	7320	$18,300	
Budget Category		**Activity Title**	**Item**	**Description**	**Y2 Unit Cost**	**Y2 Unit Number**	**Y2 Frequency**	**Y2Q1**	**Y2Q2**	**Y2Q3**	**Y2Q4**	**Y2 Total**	**Y3 Unit Cost**	**Y3 Unit Number**	**Y3 Frequency**	**Y3Q1**	**Y3Q2**	**Y3 Totals**	**Y1-Y3 Totals**	
Programme management	1	MGIMS Programme Management	Stationary, postal costs, communication costs		270	1	4	270	270	270	270	1080	270	1	2	270	270	540	[illegible]	
Programme management			Computers with printer/laptop		815	1	1	815				815						0	[illegible]	
			Audit						110			110				110	110	220	[illegible]	
Programme management	2	Final Monitoring and Evaluation Meeting: District Hospital - Lucknow and Varanasi - MGIMS travel up once and attend both M&E meetings - 5 days	Travel for MGIMS Trainers	$204 for each trainer (x3)								0	204	3	1		612	612	[illegible]	
Programme management			Local Travel for MGIMS trainers	$40 each for 3 Trainers per day for 5 days								0	40	3	5		600	600	[illegible]	
Programme management			Accommodation for MGIMS Trainers	$340 each for 3 Trainers for the 5 days ($68 a day)								0	340	3	1		1020	1020	[illegible]	
Programme management			Food for MGIMS Trainers	$13.5 for each Trainer per day for 5 days (3 Trainers)								0	67.5	3	1		202.5	202.5	[illegible]	
Programme management			DA for Trainers	$30 a day x 3 trainers for 5 days								0	30	3	5		450	450	[illegible]	
Programme Management	3	Policy and Advocacy Meeting	Travel for MGIMS	4 MGIMS								0	255	4	1		1020	1020	[illegible]	
								1085	380	270	270	2005				$380	$4,285	$4,665	$6,670	
Budget Category		**Activity Title**	**Item**	**Description**	**Y2 Unit Cost**	**Y2 Unit Number**	**Y2 Frequency**	**Y2Q1**	**Y2Q2**	**Y2Q3**	**Y2Q4**	**Y2 Total**	**Y3 Unit Cost**	**Y3 Unit Number**	**Y3 Frequency**	**Y3Q1**	**Y3Q2**	**Y3 Totals**	**Y1-Y3 Totals**	
Training Workshops	1	Follow up Workshops: Lucknow	Travel for MGIMS Trainers	$204 for each trainer (x3)								0	204	3	1	612		612	[illegible]	
Training Workshops			Local Travel for MGIMS trainers	$40 each for 3 Trainers per day for 4 days								0	160	3	1	480		480	[illegible]	
Training Workshops			Accommodation for MGIMS Trainers	$272 each for 3 Trainers for the 4 days ($68 a day)								0	272	3	1	816		816	[illegible]	
Training Workshops			Food for MGIMS Trainers	$13.5 for each Trainer per day for 4 days (3 Trainers)								0	54	3	1	162		162	[illegible]	
			DA for Trainers	$30 a day x3 trainers for 4 days								0	30	3	4	360		360	[illegible]	
Training Workshops		Follow up Workshops: Varanasi	Travel for MGIMS Trainers	$204 for each trainer (x3)								0	204	3	1	612		612	[illegible]	
Training Workshops			Local Travel for MGIMS trainers	$40 each for 3 Trainers per day for 4 days								0	160	3	1	480		480	[illegible]	
Training Workshops			Accommodation for MGIMS Trainers	$272 each for 3 Trainers for the 4 days ($68 a day)								0	272	3	1	816		816	[illegible]	
Training Workshops			Food for MGIMS Trainers	$13.5 for each Trainer per day for 4 days (3 Trainers)								0	54	3	1	162		162	[illegible]	
			DA for Trainers	$30 a day x3 trainers for 4 days								0	30	3	4	360		360	[illegible]	
Training Workshops	2	Lessons Learnt Workshop - to be hosted at MGIMS *(UP participant travel for 15 people is in UPTSU budget)*	Overall local travel	20 participants, for 2 days								0	136	20	1		2720	2720	[illegible]	
Training Workshops			Accommodation	$68 a night for 2 nights								0	136	20	1		2720	2720	[illegible]	
Training Workshops			Catering	$50 a day for 2 days for 20 people								0	100	20	1		2000	2000	[illegible]	
Training Workshops			DA	$30 per person x20 x2 days								0	30	20	2		1200	1200	[illegible]	
Training Workshops			Venue	2 days								0	272	1	1		272	272	[illegible]	
Training Workshops			Stationary and Office Supplies									0	272	2	1		544	544	[illegible]	
								0	0	0	0	0				$4,860	$9,456	$14,316	$14,316	
Budget Category		**Activity Title**	**Item**	**Description**	**Y2 Unit Cost**	**Y2 Unit Number**	**Y2 Frequency**	**Y2Q1**	**Y2Q2**	**Y2Q3**	**Y2Q4**	**Y2 Total**	**Y3 Unit Cost**	**Y2 Unit Number**	**Y3 Frequency**	**Y3Q1**	**Y3Q2**	**Y3 Totals**	**Y1-Y3 Totals**	
Site Visits	1	Visit by MGH Team - Meeting at UPTSU	Travel for MGIMS	4 people	270	4	1			1080	0	1080	128.5	4	1	0	0	0	[illegible]	
Site Visits			Local Travel for MGIMS	$102 each for 4 people	102	4	1			408		408						0	[illegible]	
Site Visits	2	Site Visit - Lucknow	Travel for MGIMS Trainers	$204 for each trainer (x3)	204	3	1			612		612	204	3	1	0	0	0	[illegible]	
Site Visits		Second Site visit in Y3 Q2 removed. Will be put back in if there are funds available.	Local Travel for MGIMS trainers	$40 each for 3 Trainers per day for 4 days	160	3	1			480		480	160	3	1	0	0	0	[illegible]	
Site Visits			Accommodation for MGIMS Trainers	$272 each for 3 Trainers for the 4 days ($68 a day)	272	3	1			816		816	272	3	1	0	0	0	[illegible]	
Site Visits			Food for MGIMS Trainers	$13.5 for each Trainer per day for 4 days (3 Trainers)	54	3	1			162		162	54	3	1	0	0	0	[illegible]	
			DA for Trainers	$30 a day x3 trainers for 4 days	30	3	4			360		360	30	3	4	0	0	0	[illegible]	
Site Visits		Site Visit - Varanasi	Travel for MGIMS Trainers	$204 for each trainer (x3)	204	3	1			612		612	204	3	1	0	0	0	[illegible]	
Site Visits			Local Travel for MGIMS trainers	$40 each for 3 Trainers per day for 4 days	160	3	1			480		480	160	3	1	0	0	0	[illegible]	
Site Visits			Accommodation for MGIMS Trainers	$272 each for 3 Trainers for the 4 days ($68 a day)	272	3	1			816		816	272	3	1	0	0	0	[illegible]	
Site Visits			Food for MGIMS Trainers	$13.5 for each Trainer per day for 4 days (3 Trainers)	54	3	1			162		162	54	3	1	0	0	0	[illegible]	
			DA for Trainers	$30 a day x3 trainers for 4 days	30	3	4			360		360	30	3	4	0	0	0	[illegible]	
								0	0	4348	0	4348				$0	$0	$0	$4,348	
[illegible]					[illegible]			[illegible]	[illegible]	[illegible]	[illegible]	[illegible]				[illegible]	[illegible]	[illegible]	[illegible]	

Appendix B: Activity Plan

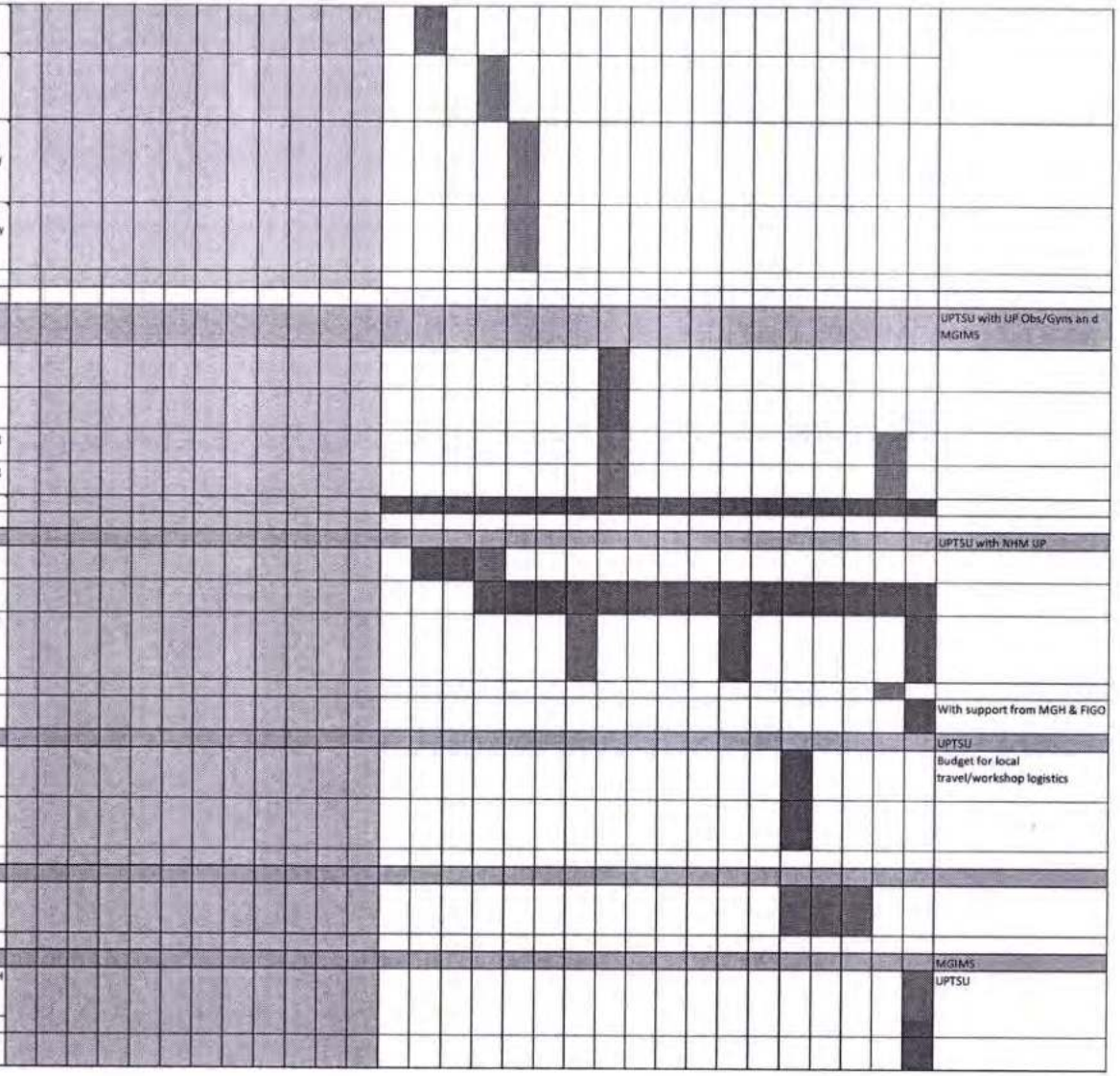
BMGF FIGO PROJECT: ENGAGING NATIONAL PROFESSIONAL SOCIETIES TO COMBAT POSTPARTUM HEMORRHAGE

Activity Workplan Gantt Chart (Dec 2019 - May 2022)

MGIMS - Uttar Pradesh

No.	Activity/Task	Details	Timeline																													Notes and Rsponsibility
			19	2020											2021												2022					
			Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	
1	Stakeholder Engagement and Partnership Development																															MGIMS and/or UPTSU
1.1	Formal communication regarding PPH bundle pilot to GOUP & stakeholders																															
1.2	FORMAL COMMUNICATION FROM GOUP TO CMOs of Lucknow and Varanasi for: a) Conduct of PPH bundle pilot b) selection of government health facilities in district Lucknow & Varanasi for conduct of PPH pilot																															
1.3	Meetings with PPH pilot stakeholders - GOUP: MD-NHM & GOUP - UPTSU - KGMU & BHU - MGIMS - FOGSI - UP Rep																															
1.4	Budgetary meetings with: - UPTSU - MGIMS - FOGSI																															
1.5	Meetings on data collection tools and data flow - UPTSU - MGIMS - KGMU - BHU																															
1.7	Orientation / introduction meeting with LKO & VAR - DISTRICT CMO / ACMO / MOIC/MS																															
1.8	Assessment of health facilities selected for PPH pilot in LKO/ VAR																															
1.9	Ethical committee approval or exemption as implementation project																															
2	Administration and Reporting																															
2.1	Finalize activity workplan and budget																															
2.2	Signing of MOU with MGIMS																															With support from FIGO/MGH as needed
2.3	Prepare job descriptions, share with FIGO prior to hiring project staff																															With support from FIGO/MGH as needed
2.4	Financial/technical reporting to FIGO																															
3	Identify in-country project team and key roles to support implementation																															MGIMS and UPTSU
3.3	Recruit and hire staff across the partners including: Project Coordinators, Data Collectors and Facility level Nurse Trainers																															
4	Facility Assessments																															UPTSU
4.1	Provide support to conduct facility assessments in project facilities (template/guidance to be provided by MGH)	UPTSU - with support from MGIMS																														
4.2	Report back to MGH and FIGO on the baseline assessments	Support the preparation of the baseline assessment report for FIGO/MGH as required.																														

5.2	**PHASE 1**: TOT Training of Master Trainers from BHU, KGMU , UPTSU, all 8 centres faculty and local society of FOGSI	2 days (Early March 2021) 25 participants, led by KGMU and BHU - VIRTUAL EVENT		
5.7	**PHASE 2**: training of staff of BHU and KGMU on separate dates in thier own places. Kgmu to also include uptsu staff	2 days run twice Face to Face - once at KGMU and once at BHU with MGH and MGIMS online for support. 30 participants each time.		
5.8	**PHASE 3**: Training of staff of district hospital Nodal officers medical officers from CHCs and PHCs and state nodal officers	Lucknow: 2 days training of 4 batches, each batch of 25 participants (25x4=100 participants) Varanasi: 2 days training of 3 batches, each batch of 25 participants (25x3=75 participants)		
5.9	**PHASE 4**: further simulation training of staff of district hospital , CHCS AND PHCS	Lucknow: 1 day at each facility total 100 participants (5 facilities) Varanasi: 1 day at each facility total 75 participants (5 facilities)		
6	**Regular mentorship / facilitation and site visits**			UPTSU with UP Obs/Gyns and MGIMS
	Visit by MGH team	Meeting at UPTSU with GOUP, MGIMS, KGMU and BHU		
	Project follow up meeting for retrospective changes and M&E	KGMU, BHU and MGIMS - Virtually/Online.		
	Site Visits - Lucknow	MGIMS to participate in site visits during Y2Q3 and Y3Q2 - or as required		
	Site Visits - Varanasi	MGIMS to participate in site visits during Y2Q3 and Y3Q2 - or as required		
	Monthly support calls with MGH	With UP facilitators		
7	**Monitoring & Evaluation**			UPTSU with NHM UP
	Support development of M&E framework in coordination with UPTSU/MGH/FIGO			
	Monthly data reviews between staff, facility champions, M&E focal person			
	Project Evaluation Meetings	To include BHU, KGMU, GOUP, MGH and MGIMS. To be held Virtually until the final set at the end of the project which will be in person except for MGH online.		
	Data review and compilation analysis meeting			
	Final in-country M&E report to FIGO/MGH			With support from MGH & FIGO
8	**Follow-up Workshops**			UPTSU
	Lucknow - Follow up Workshop	KGMU and BHU to run these separately in own facilities. MGIMS and MGH online		Budget for local travel/workshop logistics
	Varanasi - Follow up Workshop	KGMU and BHU to run these separately in own facilities. MGIMS and MGH online		
9	**Quality Improvement Workshop**			
	Quality Improvement	Quality Improvement aspects to be covered in follow up workshops and as part of site visits.		
10	**Lessons Learned Workshop**			MGIMS
	Internal meeting to share the findings and finally evaluate the pph emc package impact in different facilities	BHU, KGMU, UPTSU MGIMS, GOUP, MGH AND FIGO		UPTSU
	Travel logistics for participants	Run by MGIMS		
	Host Lessons Learned Workshop in Sevagram	UPTSU, KGMU, BHU, MGIMS, MGH and GOUP		



11	**Policy / Advocacy meetings and activities**																															GoI to support this element
	Attend Policy and Advocacy Meeting in Delhi - hosted by FOGSI																															
12	**Dissemination meetings and activities**	UPTSU/GOUP and MGIMS																														GOI and FOGSI to support this element
	Dissemination activities to be considered depending on budget and timings. Opportunities to highlight the project during other key events already being attended to be made the most of.																															FIGO/MGH to support as needed

Appendix C: Data Agreement

DATA USE AGREEMENT BETWEEN

The International Federation of Gynecology and Obstetrics (FIGO)

and

Mahatma Gandhi Institute of Medical Sciences (MGIMS)

1. This Data Use Agreement is made and entered into on **1 November 2020** by and between the **International Federation of Gynecology and Obstetrics** and on behalf of, the **Mahatma Gandhi Institute of Medical Sciences (MGIMS)**

2. This agreement sets forth the terms and conditions pursuant to which FIGO will disclose certain Protected Health Information, hereafter "PHI" in the form of a Limited Data Set to MGIMS.

3. The PPH data relates to data collected as part of the FIGO/ MGIMS work on the project "Leveraging OB/GYN Professional Societies to Combat Postpartum Hemorrhage'

4. MGIMS Responsibilities

   4.1. MGIMS will use the data only for the purposes of research on the project "Leveraging OB/GYN Professional Societies to Combat Postpartum Hemorrhage' in Bangladesh.

   4.2. Access to the data by the MGIMS shall be limited to the named principle investigators, and other researchers employed on the project

   4.3. MGIMS will not share any data provided by FIGO with a third party.

   4.4. MGIMS will use appropriate administrative, physical and technical safeguards to prevent inadvertent disclosure of the data set to any third party.

4.5. MGIMS will not attempt to identify the individuals or households contained in the Limited Data Set.

5. FIGO Responsibilities

5.1. FIGO will provide all relevant data collected on the project to MGIMS in a timely manner.

5.2. FIGO will ensure that the Investigator has obtained any information that would identify respondents or households before being passed to the MGIMS. Under no circumstances will FIGO make information that would identify individuals or households available to MGIMS.

6. Termination

6.1. Following termination of the contract MGIMS is no longer entitled to analyze or use the data unless specifically requested to do so by FIGO.

IN WITNESS WHEREOF, the parties hereto execute this agreement as follows:

Date: _____ By: _____

Project Director
On behalf of The International Federation of Gynecology and Obstetrics

Date: 16/2/2022

By: _____

On behalf of Mahatma Gandhi Institute of Medical Sciences (MGIMS)

Dr. B. S. Garg
Secretary
Kasturba Health Society
P.O. Sevagram, Wardha-442 102

DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY

MAHATAMA GANDHI INSTITUTE OF MEDICAL SCIENCES SEVAGRAM

Standardizing data collection and cervical cancer screening protocols to improve facility preparedness and capacity building for cervical cancer elimination

1. Background

Cervical cancer is the second most common form of cancer in Indian women. According to GLOBOCAN 2020 estimates, India contributes 123,907 cervical cancer cases every year, with 77,348 deaths, nearly one-fourth of the global burden. Despite the clear and proven benefits of population-based screening programs, screening for cervical and breast cancers in low- and middle-income countries, including India, remains a challenge. Until recently, there was little evidence pertaining to screening for cervical and breast cancers in India. Information on examination of the breast and cervix from over 699,000 women aged 15–49 years was collected for the first time in the fourth round of the National Family Health Survey, 2015–16 (NFHS-4).

The aim of cervical screening programs is to detect cervical intraepithelial neoplasia (CIN), whose high-grade forms, CIN2 and CIN3 are premalignant lesions that can progress to cervical cancer if left untreated. Various methods currently available for cervical cancer screening include: cytology (Pap smear); visual inspection with acetic acid (VIA); and HPV tests.HPV tests have the highest sensitivity but are expensive and not widely available.

In 2016, the Ministry of Health and Family Welfare (MoHFW) constituted a Non-Communicable Disease Technical Advisory Group (NCD TAG) to operationalize the roll out for Prevention, Screening and Control of Common Non-Communicable Diseases (NCD): Hypertension, Diabetes and Common Cancers (Oral, Breast, Cervix). The cervical screening test in this program is VIA, mainly because of its low cost and feasibility. Availability of immediate results in VIA-based programs is an additional advantage, making it possible to treat lesions suitable for ablative therapy in the same visit in what is termed a ‘screen-and-treat’ approach. Despite this, cervical screening is lagging far behind in this program, with training and secondary linkages yet to be fully functional. WHO, as part of its global strategy for elimination of cervical cancer as a public health problem, which was first declared in May 2018 and formally launched in November 2020, has recommended HPV testing of all women at age 35

and 45 years. However, the tests are expensive and not yet widely available. The Federation of Obstetrics & Gynecological Societies of India (FOGSI) published resource-based recommendations in 2018 that provide guidance on the use of various types of tests. Despite these various recommendations that support the use of any available modality in any type of resource setting, uptake of screening in India continues to be poor, with an estimated 5% of women having received appropriate screening. The proportion of screen positive women who receive treatment is also very low. Most of the research on cancers in females is concentrated only on the incidence and mortality rates of cervical and breast cancers. A review of cancer screening-related literature in India reveals that the spatial perspective of cancer screening has not been explored yet.

WHO CCR in Human Reproduction, Department of Obstetrics &Gynaecology, AIIMS New Delhi, in collaboration with WHO SEARO plans to undertake a situational analysis of cervical cancer screening practices being carried out by major hospitals in India, to identify gaps and plan an assessment based interventional strategy. During the course of this activity, a data capturing tool will be developed and utilized to collect baseline data regarding the current barriers to cervical cancer screening and also the barriers to implementing proper management protocols. It is proposed to undertake this activity as a multicentric project with a satellite community outreach facility attached to each of the centres. The present activity will attempt to address some of research gaps of assessing the ground reality of the likelihood of a woman receiving cervical cancer screening in India.

2. Aim of the Surveillance

This surveillance aims to undertake a situational analysis of the cervical cancer screening program among women in the age group of 30-49 yearsattending the Gynaecology and other outpatient departments of selected hospitals across India, to undertake a needs assessment, identify gaps and plan an assessment-based interventional strategy for training and capacity building.

The aim is also to strengthen capacity in implementing standard screening and treatment modalities and documenting by standard data collection including clinical outcomes.

3. Objectives of the present activity

- To identify the uptake of appropriate screening tests and the diagnostic and therapeutic facilities and algorithms for follow-up of precancerous lesions.
- To assess the barriers to screening for cervical cancer among women aged 30 to 49 years, attending gynaecology clinics in secondary and tertiary care centers.
- To suggest feasible mechanisms within a hospital with appropriate linkages between different departments to offer opportunistic cervical cancer screening to all women who come to hospital for any disease.
- To study the feasibility and impact of creating a separate area with dedicated personnel for counselling and screening for cervical cancer in a busy gynecological OPD for the screen-and-treat approach.
- To develop an online web-based data capture system that can be linked with cancer registry data systems.
- To explore the possibility to work with ANM /Field workers to motivate women to uptake the screening test among 30-49 years

4. Study Methodology

Phase 1

Baseline Assessment (2 months)

Baseline data of current cervical cancer screening status at various tertiary care centers will be assessed.

Step 1. Development and validation of tool for data collection for understanding barriers to screening among service providers and clients.

Following data will be collected:

- OPD attendance
- Number of women in the target group
- Type of test /Number of tests performed
- Whether tests are free or charged
- Number of doctors available to administer these tests
- The methods for creating awareness among patients
- Is breast screening included as a practice among the health care providers
- The turnover time for reporting

- Presence of quality checks in place for reporting formats
- Retraining mechanisms for medical and paramedical staff regarding screening methods for cervical screening
- Number of clinic attendance and number % undergoing screening
- Availability of infrastructure, equipment and capacities to carry out screening and management of pre cancers.
- Assessment of situation of task shifting and task sharing

Step 2.

- Percentage of women counseled for cervical cancer screening among those attending clinics (non-pregnant in age group of 30 to 49 years) over two-month time
- Percentage of women tested for cervical cancer screening (Pap/HPV/VIA) among those attending clinics (non-pregnant in age group of 30 to 49 years) over two-month time
- Feasibility of task-shifting to paramedical staff
- Facilities for treatment available and in working condition
- To confirm whether there is a dedicated place for colposcopy and treatment, or if treatment is provided as a part of the general OT set up at the facility.
- Baseline assessment of knowledge, attitude and practices of providers and clients towards cervical cancer screening based on the validated tool.

Phase 2:

Step 1

A root cause analysis of problem would be done to understand the barriers to cervical screening. The problem would be considered under the following perspectives:

People: Lack of awareness (HCW/clients)/lack of training of the HCW

Policy: Lack of uniform policy for screening

Place: No designated place in a busy OPD

Procedure: The method may not be available easily or feasible.

Each of the participating centres may have an individualistic approach to the implementation and will be planning a contextual intervention.

Step 2:

The following interventions are planned:

1. Recruitment of designated para-medical staff for cervical cancer screening in all routine OPDs for creating awareness

2. Installation of posters, video displays regarding cervical cancer screening in OPD areas
3. Routine sensitization of doctors for cervical cancer screening by the designated resource person.
4. Identifying and designating an area in OPD specially for cervical cancer screening to be run by the trained para-medical staff
5. Training of paramedical staff for performing VIA in women as a cervical cancer screening method (as the resources might not be sufficient to collect Pap smears and HPV tests in all women)
6. Pre- and post-test counselling of all women attending the gynaecology clinics for cervical cancer screening
7. Allocation of days for the purpose of cervical cancer screening; for example, second Saturday of every month.

Outcome Indicators/Deliverables

- Establishment of designated areas for screening by para-medical staff
- Record of pre-test and post-test counselling practice for cervical cancer screening conducted by para-medical staff
- Record of regular awareness activities conducted by the paramedical staff
- Percentage of women counseled for cervical cancer screening among those attending clinics (non-pregnant women in the age group 30 to 49 years).
- Percentage of women tested for cervical cancer screening (Pap/HPV/VIA) among those attending
    - Number of visits needed for testing
    - Percent screen positives
    - Treatment provided
    - Number of dropouts
    - Number of missing reports
- Percentage of women who denied cervical screening

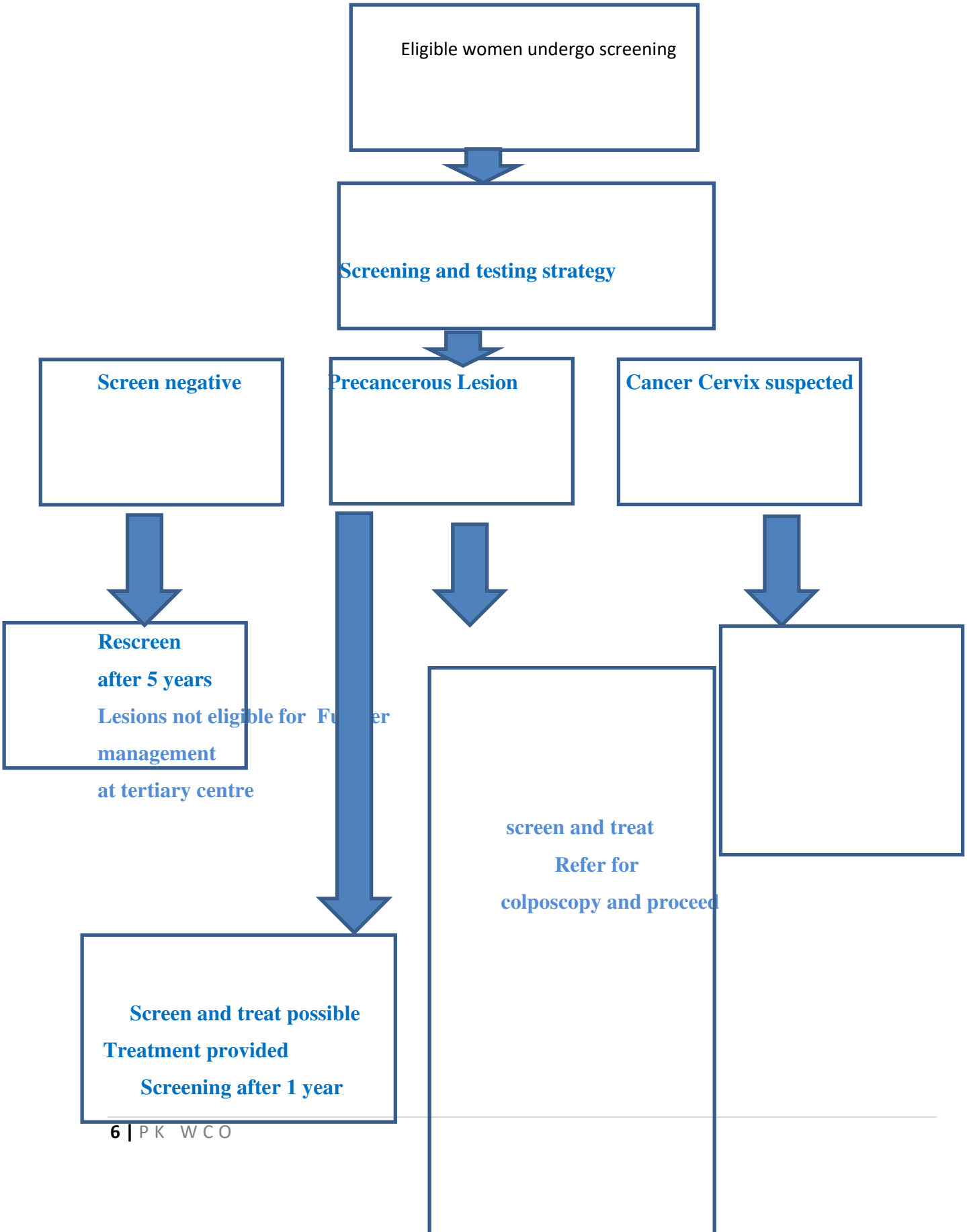
Numerator: Number of patients getting adequately counseled and tested

Denominator: Number of patients attending gynecology clinic in the age group of 30 to 49 years.

5. Data Collection Protocol at Site

Each center participating in the surveillance will have a Site Coordinator equivalent to Co-Principal Investigator (PI) and two Co-PIs one each from Gynaecology and Pathology who will facilitate data collection with the help of a research associate provided from the WHO-CC.

Algorithm for 'Screen-and-Treat' Approach



6. Work to be performed

- Surveillance of all women in the age group of 30-49 yearsattending various departments of the selected hospitals; how many of these are advised or referred for screening, how many actually get cervical screening; to know the screening modality, diagnosis, treatment provided and outcome of the screen-and-treat strategy.
- Record of Follow-up advice given :Standard form with detailed information filled for all women with diagnosis, screening modality and treatment strategy and outcome
- Capacity building of health providers on how to capture all eligible women attending hospital in the screening program
- Data Capturing Tool to be initiated so as to cover all women

7. A. Scope and Duration

In this multicenter, cohort surveillance, we will include women in the age group of 30-49 years coming to department of Obstetrics & Gynaecology and are referred for cervical screening.

B. Ethical Clearance

–IRB by facility at the institutional level to be obtained by the center

–Center to also obtain patient consent/authorization to release medical records

–WHO to provide supporting letters to participating centers

C. Data Custodian and Sharing

–Facilities will be data custodians for their centres and will retain the ownership of their data and any inference or analysis will be done in consensus with facility faculty

–The individual facility will have the right to analyse and publish their respective data at their discretion.

–Analysis of the pooled data will be done after data collection is completed with WHO technical guidance, support and participating centers inputs

7. Budget(Annexure)

–AIIMS will develop a standard data collection tool for the surveillance together with WHO

–Center co-ordination will be done via the WHO Collaborating Centre (see Annex)

8. Annex: Deliverables and Payment Schedule

1. Monthly Denominator Report to Co-ordinating Center (see annex)
2. Completed CRF forms through online submission
   - Screening modality
   - Treatment strategy
   - Outcomes
3. Completed Excel file and Technical Report to Co-ordinating Center

9. Annex: Network Resource Persons

	Name of Institution	Principal Investigator (HoD)	Co-Principal Investigators	Co-Investigators	Co-Principal Investigators	Co-Investigators
			Gynaecology		Pathology	
1.	AIIMS,New Delhi	DrNeerja Bhatla				
2.	SJH, New Delhi	Dr Sunita Malik				
3.	MGIMS,Wardha	Dr. B. S. Garg	Dr Poonam Varma Shivkumar	Dr. Shuchi Jain	Dr. V B. Shivkumar	Dr. Abhay Deshmukh
4.	GKNM Hospital, Coimbatore	Dr Latha Balasubramani				
5.	AIIMS, Rishikesh	Dr Shalini Rajaram				

……

Note: Intellectual Property Rights

All rights, including ownership of the pooled data and copyright thereof, shall be vested in WHO, which reserves the right (a) to revise the work; (b) to use the work in a different way from that originally envisaged; or (c) not to publish or use the work.

For Contractual Partner:

Signature: _____

Name: _____

Title: _____

Date: _____

Project Name: "Standardizing data collection and cervical cancer screening protocols to improve facility preparedness and capacity building for cervical cancer elimination"

WHO CC, MGIMS Sewagram at Department of Obstetrics & Gynaecology, funded by WHO SEARO

S.No	Name of Post	No of Posts	Qualification	Upper Age Limit	Duration of project	Emoluments
1	Project Research Associate	1	MBBS/MSc or BSc Nursing with 2 years' experience / Master's degree in Natural or agricultural Sciences/ MVSc (all from Recognized University or Equivalent)	35 years	6 Months	Rs 35000/Month (consolidated)
	Field Worker/ANM	1	High school Experience with one year experience in related field wok from a recognized Institute /ANM Qualifications	35 years	6 Months	Rs 17000/Month (consolidate)d

*** No TA/DA will be given for appearing for the interview**

World Health Organization

COVERING LETTER
LETTRE D'ACCOMPAGNEMENT

GLOBAL PROCUREMENT AND LOGISTICS
Global Service Centre
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Registration	2021/1101610-0
Purchase Order	202652451
Unit Reference	SRH/MCA/SEARO

Dr B S Garg
MAHATMA GANDHI INSTITUTE OF
MEDICAL SCIENCES
WARDHA
P.O. Sewagram
WARDHA
MAHARASHTRA
442102
India

AGREEMENT FOR PERFORMANCE OF WORK (APW)

Re: Piloting of pre-service, comprehensive abortion care training tool for undergraduate medical students.

We are enclosing the Agreement for Performance of Work between the World Health Organization and MAHATMA GANDHI INSTITUTE OF MEDICAL SCIENCES, WARDHA, in the amount of INR 868,000.00 (Eight Hundred Sixty-Eight Thousand), for conducting the above-mentioned work. We also enclosed one attachment(s) referenced in the Agreement.

Kindly acknowledge your acceptance of this contract by returning the email with a copy of duly signed Purchase Order (all pages).

For any technical questions relating to this Agreement, please contact the responsible technical officer, Meera Thapa UPADHYAY, upadhyaym@who.int.

Invoicing Instructions for Contractors who are legal entities (Company Contractors):
Invoices must be sent via email to accountspayable@who.int. Other than invoices, please do not send any enquiry to this email address. You may contact the above responsible technical officer for enquiries.

In order to ensure timely and accurate payment, invoices must include:

- Invoice number
- Purchase Order number against each invoice line;
- Invoice descriptions matching with PO descriptions
- Invoice currency same as the Purchase Order Currency also corresponding with the currency of the bank account provided to WHO;
- Supplier name as in the PO

Invoices shall be clearly readable and stamps or any other additional markings should not obscure the original invoice content. Invoices shall not be handwritten.

On behalf of the World Health Organization, we would like to thank you for your collaboration.

WHO Global Service Centre

cc: WHO India

Concerne: Piloting of pre-service, comprehensive abortion care training tool for undergraduate medical students.

Veuillez trouver ci-joint l' Accord pour Exécution de Travaux entre l'Organisation Mondiale de la Santé et MAHATMA GANDHI INSTITUTE OF MEDICAL SCIENCES, WARDHA, pour un montant de INR 868,000.00, vous permettant de mener à bien le travail susmentionné. Veuillez également trouver 1 pièce(s) jointe(s) mentionnée(s) dans l'Accord.

Merci de confirmer votre acceptation de ce contrat en nous retournant le courriel et une copie dûment signee du Bon de Commande (complet)

Pour toutes questions à caractère technique ayant trait à cet Accord, veuillez contacter le responsible Meera Thapa UPADHYAY, upadhyaym@who.int.

World Health Organization

AGREEMENT FOR PERFORMANCE OF WORK
ACCORD POUR EXECUTION DE TRAVAUX

GLOBAL PROCUREMENT AND LOGISTICS
Global Service Centre
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Registration	2021/1101610-0
Purchase Order	202652451
Unit Reference	SRH/MCA/SEARO

Instructions concernant la facturation pour les contractants qui sont des personnes morales.(Personne Morale):
Les factures doivent être envoyées par courriel à accountspayable@who.int. Outre les factures, n'envoyez aucune enquête à cette adresse de courrier électronique.Vous pouvez contacter le responsable technique responsable ci-dessus pour toute demande de renseignements.

De manière à garantir un paiement exact et ponctuel, les factures doivent impérativement comporter:

- Le Numéro de facture
- Le Numéro du bon de commande , répété à chaque ligne de facturation
- Des descriptifs des produits identiques à ceux du Bon de commande
- Une devise de facturation identique à celle du Bon de commande et à celle du compte en banque fourni à l'OMS
- Un intitulé de facture (nom de fournisseur) identique à celui du Bon de commande.

Les factures doivent être parfaitement lisibles. Le contenu de la facture ne doit en aucun cas être masqué par un tampon ou tout autre marquage. La facture ne doit pas être manuscrite.

Au nom de l'Organisation mondiale de la Santé, nous vous remercions de votre collaboration.

Centre mondial de services de l'OMS

cc: OMS India

Sensitivity: Internal & Restricted

World Health Organization

AGREEMENT FOR PERFORMANCE OF WORK
ACCORD POUR EXECUTION DE TRAVAUX

GLOBAL PROCUREMENT AND LOGISTICS
Global Service Centre
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Registration	2021/1101610-0
Purchase Order	202652451
Unit Reference	SRH/MCA/SEARO

The WORLD HEALTH ORGANIZATION hereby agrees to provide to
L'ORGANISATION MONDIALE DE LA SANTÉ s'engage par la présente à fournir à
MAHATMA GANDHI INSTITUTE OF MEDICAL SCIENCES
WARDHA
WARDHA
INDIA

The Fixed amount of/*Un montant Fixe de*: INR 868,000.00 (Eight Hundred Sixty-Eight Thousand) **in respect of/*en vue de*:** Piloting of pre-service, comprehensive abortion care training tool for undergraduate medical students.

For the period financed by this Agreement
Période du projet *financée par le présent Accord*
From/*De*: 01-MAR-2021
To/*A*: 30-APR-2021

Summary of work/ *Description sommaire des travaux:*

Description of work under this Agreement/ *Description des travaux faisant l'objet du présent Accord:*

Review the course outline, training curriculum, schedule and training materials provided by SEARO before starting the training.
Conduct training using the facilitator's guide for each session.
The theory session for knowledge update will be conducted as outlined.
Various training methods illustrated lectures, case studies, drills, group discussions, demonstration in model, demonstration in clients and other innovative approaches will be practiced.
Some demonstration on counselling and other CAC procedures will be tested using provided animated videos.
Review and comment on the training tool based on the experience of the training.
Provide feedback loop on content, training methods, training duration, use of appropriate training tools as planned in the draft training tool.

Financial arrangements/ *Dispositions financières:*

Payments will be made as follows/*Les versements seront effectués comme suit:*

	Deliverable/ Résultat	Due date/ *Date remise*	%	Currency amount/ *Montant en devise*
1	Upon signature of Agreement	01-MAR-2021	25.00	217,000.00
2	Upon submission of training plans in detail to SEARO Team	15-MAR-2021	65.00	564,200.00
3	Upon submission of all deliverables and certified financial statement	30-APR-2021	10.00	86,800.00

Annexes

The following annexes form an integral part of this Agreement/ *Les annexes listées ci-dessous font partie intégrante de l'Accord:*

Annex/Annexes	File Name/ *Nom du fichier*
1	2021/1101610 | Contractual - Terms of Reference |

In the event that the annexes contain any provisions which are contrary to the terms of this Agreement, the terms of this Agreement shall take precedence/ *En cas de contradiction entre les dispositions des annexes et celles de*

World Health Organization

AGREEMENT FOR PERFORMANCE OF WORK
ACCORD POUR EXECUTION DE TRAVAUX

GLOBAL PROCUREMENT AND LOGISTICS
Global Service Centre
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Registration	2021/1101610-0
Purchase Order	202652451
Unit Reference	SRH/MCA/SEARO

l'Accord, les dispositions de l'Accord prévaudront dans tous les cas.

The undersigned parties, having read the terms and General Conditions, hereby conclude the present Agreement and confirm their agreement and acceptance thereof.
ON BEHALF OF WHO/ *POUR L'OMS*

Responsible WHO Technical Officer:
Fonctionnaire technique responsable de l'OMS:

Meera Thapa Upadhyay
Technical Officer (Reproductive Health)
SE/FGL Family Health, Gender and Life Course

Approved by:
Approuvé par:

Neena RAINA
Coordinator
SE/FGL Family Health, Gender and Life Course

Authorized Signatory:
Signataire autorisé:

Mr Prem Prakash Chopra
Team Lead, a.i.
Global Procurement, Processing and Logistics
(WHO BOS/SUP/GPL)

Processed by:
Traité par:

Suganthi Nallasamy
Senior Procurement Assistant
HQ/BOS Business Operations

PO Approved Date:
PO approuvé le:
03-MAR-21

Les parties soussignées, ayant lu les modalités et les Conditions Générales, ratifient l'Accord et confirment leur acceptation.

CONTRACTOR/ CONTRACTANT

Signature : .....

Date: 5th March 2021

Name & Title/ Nom & Fonction : Dr B.S Garg
Secy
Kamrup Health Society

World Health Organization

AGREEMENT FOR PERFORMANCE OF WORK
ACCORD POUR EXECUTION DE TRAVAUX

GLOBAL PROCUREMENT AND LOGISTICS
Global Service Centre
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Registration	2021/1101610-0
Purchase Order	202652451
Unit Reference	SRH/MCA/SEARO

GENERAL CONDITIONS

1. **Relationship of the Parties.** It is understood that the execution of the work does not create any employer/employee relationship. In this respect, the contractor shall be solely responsible for the manner in which the work is carried out. Thus, WHO shall not be responsible for any loss, accident, damage or injury suffered by any person whatsoever arising in or out of the execution of this work, including travel. Insurance coverage for any such loss, accident, damage or injury will be the contractor's responsibility, including where appropriate, insurance coverage for persons used by the contractor to carry out the work.

Without prejudice to the foregoing, WHO may in certain cases provide insurance coverage for the contractor for travel in WHO vehicles. WHO declines all responsibility for non-payment by the insurance company of all or part of a claim submitted by or for the contractor for any accident. In case of such non-payment, the contractor shall be obliged to immediately reimburse all or part of any advance which WHO may have paid to the contractor.

2. **Rights.** All rights in the work, including ownership of the original work and copyright thereof, shall be vested in WHO, which reserves the right (a) to revise the work, (b) to use the work in a different way from that originally envisaged, or (c) not to publish or use the work.

3. **Payment and use of funds.** If the option, on the face of this agreement, for payment of a fixed sum applies, that sum is payable in the manner provided, subject to proper performance of the work.
If the option for payment of a maximum amount applies:
(i) the funds shall be used exclusively for the work specified in this agreement and any unspent balance shall be refunded to WHO. In this latter case, any financial statement required shall reflect expenditures according to the relevant main categories of expenditure; and
(ii) to the extent the contractor is required to purchase any goods and/or services in connection with its performance of this agreement, the contractor shall ensure that such goods and/or services shall be procured in accordance with the principle of best value for money. "Best value for money" means the responsive offer that is the best combination of technical specifications, quality and price.

Contractors who are legal entities (hereinafter referred to as "Company Contractors") must submit an invoice to the contracting WHO department or the WHO Global Service Center in order to receive payment. Invoices are not required from contractors who are individuals (hereinafter referred to as "Individual Contractors"), who can be paid upon receipt by the contracting WHO department of the required deliverables (including any required technical reports and financial statements) in a satisfactory manner.

The invoice from Company Contractors shall reflect any tax exemption to which WHO may be entitled by reason of the immunity it enjoys. WHO is, as a general rule, exempt from all direct taxes, custom duties and the like, and the Company Contractor will consult with WHO so as to avoid the imposition of such charges with respect to this agreement and the work performed hereunder. As regards excise duties and other taxes imposed on the provision of goods and services (e.g. value added tax), the Company Contractor agrees to verify in consultation with WHO whether in the country where the tax would be payable, WHO is exempt from such tax at the source, or entitled to claim reimbursement thereof. If WHO is exempt from value added tax, this shall be indicated on the invoice, whereas if WHO can claim reimbursement thereof, the Company Contractor agrees to list such charges on its invoices as a separate item and, to the extent required, cooperate with WHO to enable reimbursement thereof.

WHO shall have no responsibility whatsoever for any taxes, duties or other contributions payable by contractors. Payment of any taxes, duties and other contributions which a contractor may be required to pay shall be the sole responsibility of that contractor who shall not be entitled to any reimbursement thereof by WHO.

4. **Satisfactory performance.** If the work is not satisfactorily completed (and, where applicable, delivered) by the date fixed in this agreement and/or if any financial statement required is not satisfactorily submitted to WHO in accordance with general condition 5 below, WHO may specify an additional period within which this agreement must be satisfactorily performed. Normally such additional period should be of at least one week's

CONDITIONS GENERALES

1. **Relation entre les Parties.** Il n'est pas institué de relations d'employeur à employé aux fins de l'exécution des travaux. À cet égard, le contractant est seul responsable de la manière dont les travaux sont exécutés. Ainsi, l'OMS ne saurait assumer, à l'égard de quelque personne que ce soit, aucune responsabilité pour toute perte, tout accident, tout dommage ou toute blessure subis au cours ou en raison de l'exécution des travaux ou d'un déplacement les concernant. La mise en place d'une couverture d'assurance pour toute perte, tout accident, tout dommage ou toute blessure subis au cours ou en raison de l'exécution des travaux sera de la responsabilité du contractant y compris le cas échéant, toute couverture d'assurance pour les personnes auxquelles le contractant recourt pour l'exécution des travaux.

Sans préjudice de ce qui précède, l'OMS peut, dans certains cas, fournir une couverture d' assurance au contractant en cas de déplacement dans un véhicule de l 'OMS. L'OMS décline toute responsabilité pour le non-paiement par la compagnie d'assurance de la totalité ou d'une partie d'une demande d'indemnisation soumise par ou pour le contractant suite à un accident. En cas de non-paiement, le contractant sera obligé d' immédiatement rembourser la totalité ou une partie des avances que l'OMS pourrait lui avoir versées.

2. **Droits**. Tous les droits attachés aux travaux, y compris la propriété des travaux originaux et le droit d'auteur y afférent, seront dévolus à l'OMS qui se réserve le droit a) de réviser les travaux, b) d'utiliser les travaux d'une autre manière que celle initialement envisagée, ou c) de ne pas publier ni utiliser les travaux.

3. **Paiement et utilisation des fonds**. Si l'option applicable - prévue au recto du présent accord - est celle du paiement d'une somme fixe, cette somme est payable dans les conditions prévues, sous réserve de l'exécution satisfaisante des travaux.
Si l'option applicable est celle du paiement d'un montant maximum :
(i) les fonds seront utilisés exclusivement aux fins des travaux précisés dans l'accord et tout solde non utilisé sera remboursé à l'OMS. Dans ce dernier cas, les états financiers requis devront indiquer les montants engagés pour les principaux postes de dépense ; et
(ii) dans la mesure où le contractant doit acheter des biens et/ou des services quelconques dans le cadre de l'exécution du présent accord, il devra veiller à ce que l'achat de ces biens et/ou services soit effectué sur la base du principe du meilleur rapport qualité-prix. On entend par « meilleur rapport qualité-prix » l'offre qui présente la meilleure combinaison du point de vue des spécifications techniques, de la qualité et du prix.

Afin d'être payé, les contractants qui sont des personnes morales (ci-après dénommés « Personnes Morales ») doivent présenter une facture au département contractant de l'OMS ou au centre mondial de services de l'OMS. Les contractants qui sont des personnes physiques (ci-après dénommés « Personnes Physiques ») ne sont pas tenus de présenter de facture et peuvent être payés au moment de la réception, sous une forme satisfaisante, des livrables requis (y compris tout rapport technique et état financier requis) par le département contractant de l'OMS.

La facture des Personnes Morales devra refléter toute exonération d'impôt à laquelle l'OMS pourrait avoir droit en vertu de l'immunité dont elle jouit. De manière générale, l'OMS est exonérée de tout impôt direct, de tout droit de douane et de tous droits et taxes similaires, et la Personne Morale devra se mettre en rapport avec l'OMS afin d'éviter l'application des dites charges en rapport avec le présent accord et les travaux qui en résultent. En ce qui concerne les impôts et autres charges indirects imposés sur la fourniture de biens et de services, (par ex taxe à la valeur ajoutée), la Personne Morale accepte de vérifier en consultation avec l'OMS si, dans le pays où la charge serait exigible, l'OMS est exonérée de ladite charge à la source ou est en droit d'en réclamer le remboursement. Si l'OMS est exonérée de la taxe à la valeur ajoutée, cela devra être indiqué sur la facture, tandis que si l'OMS est en droit d'en réclamer le remboursement, la Personne Morale accepte de mentionner cette charge de façon séparée sur ses factures et, si nécessaire, de coopérer avec l'OMS afin d'en obtenir le remboursement.

L'OMS n'encourra aucune responsabilité pour quelque taxe, droit ou autre contribution dû par les contractants. Le paiement de quelque taxe, droit ou autre contribution qu'un contractant pourrait être tenu de payer sera de l'entière responsabilité de celui-ci et il n'aura droit à aucun remboursement de la part de l'OMS à ce titre.

4. **Exécution satisfaisante**. Si les travaux ne sont pas accomplis correctement (et, le cas échéant, fournis) à la date prévue par l'accord ou si tout état financier requis n'est pas soumis de façon satisfaisante à l'OMS conformément à la condition générale 5 ci-dessous, l'OMS peut accorder un délai supplémentaire à l'expiration duquel l'accord doit être exécuté de façon satisfaisante. En règle générale, ce délai supplémentaire est d'une semaine au moins, à moins

Sensitivity: Internal & Restricted

GLOBAL PROCUREMENT AND LOGISTICS
Global Service Centre
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Registration	2021/1101610-0
Purchase Order	202652451
Unit Reference	SRH/MCA/SEARO

duration, unless it is clear from the agreement that it was particularly important that the performance be completed on the date specified, in which case WHO may specify a shorter period or refuse to grant any additional period at all. In the event that the work is not satisfactorily completed and delivered on the date fixed, or any additional period granted by WHO and/or if any financial statement required is not satisfactorily submitted to WHO in accordance with general condition 5 below, WHO may immediately terminate this agreement (in addition to the other remedies), in accordance with general condition 13 below (without being held to grant the contractor an additional period of thirty (30) days to perform, complete and deliver the work).

qu'il ne ressorte clairement de l'accord qu'il était particulièrement important d'achever les travaux à la date initialement prévue, auquel cas l'OMS peut accorder un délai plus court ou refuser la moindre prorogation. Si les travaux ne sont pas achevés et livrés de façon satisfaisante à la date prévue ou à l'expiration de tout délai supplémentaire accordé par l'OMS, et/ou si tout état financier requis n'est pas soumis de façon satisfaisante à l'OMS conformément à la condition générale 5 ci-dessous, l'Organisation peut immédiatement résilier le présent accord (sans préjudice d'autres recours dont elle peut disposer), conformément à la condition générale 13 ci-dessous (sans être tenue d'accorder au contractant une période supplémentaire de trente (30) jours pour exécuter, achever et livrer les travaux).

5. **Completion and delivery.** The contractor shall complete and deliver the work to WHO (including any technical report that may be required) by the date fixed in this agreement or any additional period that may be granted by WHO under general condition 4 above. Any financial statement required shall be submitted within thirty (30) days thereafter at the latest. If the payment schedule on the face of this agreement provides for a final payment upon completion of the work, this final payment shall be made only after satisfactory receipt of all deliverables called for under this agreement, including any technical report and financial statement.

5. **Achèvement et livraison.** Le contractant achève et livre les travaux à l'OMS (y compris tout rapport technique qui pourrait être requis) à la date prévue par l'accord ou à l'expiration de tout délai supplémentaire accordé par l'OMS en application de la condition générale 4 ci-dessus. Tout état financier requis est soumis au plus tard dans les trente (30) jours qui suivent. Si le calendrier de paiement prévu au recto de l'accord prévoit le paiement à la fin des travaux, celui-ci n'est effectué qu'après réception, sous une forme satisfaisante, de tous les livrables exigés aux termes de l'accord, y compris les rapports techniques et les états financiers.

6. **Certification of status of individual contractors.** Each Individual Contractor certifies that he/she does not presently, and will not during the term of this agreement, hold any form of contractual relationship with WHO (including any WHO regional, country or project office, as well as any programme, center or other entity where staff is subject to WHO Staff Regulations and Rules) that confers upon the Individual Contractor the status of a WHO staff member. The Individual Contractor understands that a false statement may result in the cancellation of any or all contracts, and/or the withdrawal of any offer of a contract, with WHO.

6. **Certification du statut des personnes physiques.** Toute Personne Physique certifie qu'elle n'a pas actuellement et n'aura pas pour la durée du présent accord, de relation contractuelle avec l'OMS (y compris les bureaux régionaux de l'OMS, les bureaux de pays ou de projet, les programmes, centres ou entités où le personnel est soumis au Statut et au Règlement du Personnel de l'OMS) lui conférant le statut de membre du personnel de l'OMS. Toute Personne Physique comprend qu'une fausse déclaration de sa part peut entraîner l'annulation de tous les contrats, et/ou le retrait de toute offre de contrat, avec l'OMS.

7. **Research involving human participants.** .If and to the extent the work to be performed under this agreement includes surveys or interviews involving human participants (hereinafter referred to as "research"), the following shall apply:
7.1 Ethical Aspects
It is the responsibility of the contractor to safeguard the rights and welfare of human subjects involved in research performed under this agreement, in accordance with the appropriate national code of ethics or legislation, if any, and in the absence thereof, the Helsinki Declaration and any subsequent amendments. Prior to commencing any such research, the contractor shall ensure that (a) the rights and welfare of the subjects involved in the research are adequately protected, (b) freely given informed consent has been obtained for all participants, (c) the balance between risk and potential benefits involved has been assessed and deemed acceptable by a panel of independent experts appointed by the contractor, and (d) any special national requirements have been met.
7.2 Regulatory Requirements
It is the responsibility of the contractor to comply with the relevant national regulations pertaining to research involving human subjects.
7.3 Protection of Subjects
Without prejudice to obligations under applicable laws, the contractor shall make appropriate arrangements to eliminate or mitigate any negative consequences to subjects or their families resulting from the conduct of the research under this agreement. Such arrangements shall to the extent feasible include appropriate counseling, medical treatment and financial relief. The contractor furthermore undertakes to protect the confidentiality of the information relating to the possible identification of subjects involved in the research.

7. **Recherches impliquant des êtres humains.** Si et dans la mesure où les travaux à effectuer dans le cadre du présent accord incluent des études ou interviews impliquant des êtres humains (ci-après dénommés "recherches" ou "étude de sujets humains"), les points suivants sont applicables:
7.1 Aspects éthiques
Il incombe au contractant de s'assurer qu'au cours des travaux effectués dans le cadre de cet accord et impliquant l'étude de sujets humains, les droits et la santé de ces derniers soient protégés conformément au code d'éthique ou à la législation du pays, ou, à défaut, à la Déclaration d'Helsinki et aux amendements qui pourraient lui être ultérieurement apportés. Avant de commencer toute recherche, le contractant doit s'assurer que: a. les droits et le bien-être des sujets impliqués sont suffisamment protégés; b. le consentement libre et éclairé a été obtenu pour tous les participants; c. des experts indépendants désignés par le contractant ont évalué les risques et les avantages potentiels et ont jugé qu'ils s'équilibrent de manière acceptable et; d. toute exigence particulière de la réglementation nationale a été satisfaite.
7.2 Exigences réglementaires
Il incombe au contractant de respecter la réglementation nationale relative aux recherches impliquant l'étude de sujets humains.
7.3 Protection des sujets humains
Sans préjudice des obligations lui incombant aux termes des lois en vigueur, le contractant prendra des mesures appropriées en vue d'éliminer ou d'atténuer toute conséquence négative pour les sujets ou leur famille résultant de la conduite des recherches dans le cadre de cet accord. Ces mesures comprendront, dans la mesure du possible, des conseils appropriés, un traitement médical et un dédommagement financier. Le contractant s'engage en outre à protéger le caractère confidentiel des informations qui pourraient permettre d'identifier les sujets impliqués dans les études.

8. **Compliance with WHO Policies.** By entering into this agreement, the contractor acknowledges that it has read, and hereby accepts and agrees to comply with, the WHO Policies (as defined below). In connection with the foregoing:
- Company Contractors shall take appropriate measures to prevent and respond to any violations of the standards of conduct, as described in the WHO Policies, by their employees and any other persons engaged by them to perform the work under the agreement; and
- Individual Contractors shall not engage in any conduct that would constitute a violation of the standards of conduct, as described in the WHO Policies.
Without limiting the foregoing, the contractor shall promptly report to WHO, in accordance with the terms of the applicable WHO Policies, any actual or suspected violations of any WHO Policies of which the contractor becomes aware. For purposes of this agreement, the term "WHO Policies" means collectively: (i) the WHO Code of Ethics and Professional Conduct; (ii) the WHO Policy on Sexual Exploitation and Abuse Prevention and Response; (iii) the WHO Code of Conduct for responsible Research, (iv) the WHO Policy on Whistleblowing and Protection Against Retaliation; and (v) the UN Supplier Code of Conduct, in each case, as amended from time to time and which are publicly available on the WHO website at the following links:

8 **Respect des politiques de l'OMS.** En concluant cet accord, le contractant reconnaît qu'il a lu les Politiques de l'OMS (telles que définies ci-dessous), et qu'il les accepte et convient de s'y conformer. En lien avec ce qui précède :
- les Personnes Morales doivent prendre des mesures appropriées afin de prévenir et répondre à toute violation des normes de conduite, telles que décrites dans les Politiques de l'OMS, par leurs employés et par toute autre personne qu'elles ont engagées pour exécuter les travaux en vertu de cet accord; et
- les Personnes Physiques ne doivent pas adopter un comportement pouvant constituer une violation des normes de conduite, telles que décrites dans les Politiques de l'OMS.
Sans limiter la portée de ce qui précède, le contractant doit immédiatement signaler à l'OMS, conformément aux dispositions des Politiques de l'OMS applicables, toute violation réelle ou présumée dont il a connaissance concernant toute Politique de l'OMS. Aux fins du présent accord, l'expression « Politiques de l'OMS » signifie collectivement : (i) le Code d'éthique et de déontologie de l'OMS, (ii) la Politique de l'OMS relative à la prévention et à la lutte contre l'exploitation et les abus sexuels, (iii) le Code de conduite pour une recherche responsable, (iv) la Politique de l'OMS sur le signalement des actes répréhensibles et la protection contre les représailles, et (v) le Code de conduite des fournisseurs des Nations Unies, y compris leurs modifications éventuelles et qui sont publiquement accessibles sur le site internet de l'OMS aux liens suivants : http://www.who.int/about/finances-accountability/procurement/en/ pour ce

World Health Organization

AGREEMENT FOR PERFORMANCE OF WORK
ACCORD POUR EXECUTION DE TRAVAUX

GLOBAL PROCUREMENT AND LOGISTICS
Global Service Centre
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Registration	2021/1101610-0
Purchase Order	202652451
Unit Reference	SRH/MCA/SEARO

http://www.who.int/about/finances-accountability/procurement/en/ for the UN Supplier Code of Conduct and at http://www.who.int/about/ethics/en/ for the other WHO Policies.

qui est du Code de conduite des fournisseurs des Nations Unies, et http://www.who.int/about/ethics/en/ pour ce qui est des autres Politiques de l'OMS.

9. **Zero tolerance for sexual exploitation and abuse.** WHO has zero tolerance towards sexual exploitation and abuse. In this regard, and without limiting any other provisions contained herein:

- each Company Contractor warrants that it will: (i) take all reasonable and appropriate measures to prevent sexual exploitation or abuse as described in the WHO Policy on Sexual Exploitation and Abuse Prevention and Response by any of its employees and any other persons engaged by it to perform the work under the agreement; and (ii) promptly report to WHO and respond to, in accordance with the terms of the Policy, any actual or suspected violations of the Policy of which the Company Contractor becomes aware; and
- each Individual Contractor warrants that he/she will: (i) not engage in any conduct that would constitute sexual exploitation or abuse as described in the WHO Policy on Sexual Exploitation and Abuse Prevention and Response; and (ii) promptly report to WHO, in accordance with the terms of the Policy, any actual or suspected violations of the Policy of which the Individual Contractor becomes aware.

9. **Tolérance zéro pour l'exploitation et les abus sexuels.** L'OMS applique la tolérance zéro en matière d'exploitation et d'abus sexuels. À cet égard, et sans limiter la portée de toute autre disposition du présent accord :

- chaque Personne Morale garantit: i) qu'elle prendra toutes les mesures raisonnables et appropriées pour prévenir tout acte d'exploitation ou d'abus sexuels tels que décrits dans la Politique de l'OMS relative à la prévention et à la lutte contre l'exploitation et les abus sexuels, par l'un quelconque de ses employés et toute autre personne engagée par elle pour exécuter les travaux prévus au titre du présent accord; et (ii) qu'elle signalera immédiatement à l'OMS et donnera suite à toute violation réelle ou présumée de cette Politique dont elle a connaissance, conformément aux dispositions de la Politique; et
- chaque Personne Physique garantit: i) qu'elle n'adoptera aucun comportement qui relèverait de l'exploitation ou l'abus sexuels tels que décrits dans la Politique de l'OMS relative à la prévention et à la lutte contre l'exploitation et les abus sexuels; et ii) qu'elle signalera immédiatement à l'OMS toute violation réelle ou présumée de la Politique dont elle a connaissance, conformément aux dispositions de la Politique.

10. **Tobacco/Arms Related Disclosure Statement.** Company Contractors may be required to disclose relationships they may have with the tobacco and/or arms industry through completion of the WHO Tobacco/Arms Disclosure Statement. In the event WHO requires completion of this Statement, the Company Contractor undertakes not to permit work on the agreement to commence, until WHO has assessed the disclosed information and confirmed to the Company Contractor in writing that the work can commence.

10. **Déclaration relative à l'industrie du tabac/de l'armement.** Il peut être demandé aux Personnes Morales de déclarer leurs éventuelles relations avec l'industrie du tabac et/ou de l'armement en remplissant la déclaration requise par l'OMS relative à l'industrie du tabac/de l'armement. Dans les cas où l'OMS demande une telle déclaration, la Personne Morale s'engage à ne pas autoriser le commencement des travaux au titre de l'accord tant que l'OMS n'a pas évalué les informations communiquées et confirmé par écrit à la Personne Morale que ces travaux peuvent commencer.

11. **Anti-terrorism and UN sanctions; Fraud and Corruption.** The contractor warrants for the entire duration of the agreement that:

(i) it is not and will not be involved in, or associated with, any person or entity associated with terrorism, as designated by any UN Security Council sanctions regime, that it will not make any payment or provide any other support to any such person or entity and that it will not enter into any employment or subcontracting relationship with any such person or entity;

(ii) it shall not engage in any illegal, corrupt, fraudulent, collusive or coercive practices (including bribery, theft and other misuse of funds) in connection with the execution of the agreement; and

(iii) the contractor shall take all necessary precautions to prevent the financing of terrorism and/or any illegal corrupt, fraudulent, collusive or coercive practices (including bribery, theft and other misuse of funds) in connection with the execution of the agreement.

Any payments used by the contractor for the promotion of any terrorist activity or any illegal, corrupt, fraudulent, collusive or coercive practice shall be repaid to WHO without delay.

11. **Anti-terrorisme et sanctions de l'ONU; fraude et corruption.** Le contractant garantit, pour toute la durée de l'accord :

(i) qu'il n'est ni ne sera impliqué à l'égard de, ni associé à, aucune personne ou entité que le régime de sanctions du Conseil de sécurité de l'ONU a désignée comme étant associée au terrorisme, qu'il ne fera aucun paiement à, ou ne soutiendra d'aucune autre manière, une telle personne ou entité, et qu'il ne conclura aucune relation d'emploi ni de sous-traitance avec une telle personne ou entité ;

(ii) qu'il ne prendra part à aucune pratique illégale, de corruption, de fraude, de collusion ou de coercition (y compris, pots de vin, vol ou autre utilisation abusive de fonds) en lien avec l'exécution de l'accord ; et

(iii) le contractant prendra toutes les précautions nécessaires pour empêcher le financement du terrorisme et/ou toute pratique illégale, de corruption, de fraude, de collusion ou de coercition (y compris, pots de vin, vol ou autre utilisation abusive de fonds) en lien avec l'exécution de l'accord.

Tout paiement utilisé par le contractant pour la promotion de toute activité terroriste ou de toute pratique illégale, de corruption, de fraude, de collusion ou de coercition doit être immédiatement remboursé à l'OMS.

12. **Breach of essential terms.** The contractor acknowledges and agrees that each of the provisions of general conditions 8, 9, 10 and 11 above constitutes an essential term of this agreement, and that in case of breach of any of these provisions, WHO may, in its sole discretion, decide to:

(i) terminate this agreement, and/or any other contract concluded by WHO with the contractor, immediately upon written notice to the contractor, without any liability for termination charges or any other liability of any kind; and/or

(ii) exclude the contractor from participating in any ongoing or future tenders and/or entering into any future contractual or collaborative relationships with WHO.

WHO shall be entitled to report any violation of such provisions to WHO's governing bodies, other UN agencies, and/or donors.

12. **Violation de clauses essentielles.** Le contractant reconnaît et accepte que chacune des dispositions des conditions générales 8, 9, 10 et 11 ci-dessus constitue une clause essentielle du présent accord, et qu'en cas de manquement à l'une quelconque de ces dispositions, l'OMS peut, à sa seule discrétion, décider :

(i) de résilier immédiatement cet accord, et/ou tout autre contrat conclu par l'OMS avec le contractant, moyennant une notification écrite adressée au contractant, sans être redevable d'aucune pénalité au titre d'une telle résiliation et sans que sa responsabilité ne soit engagée d'une quelconque manière que ce soit; et/ou

(ii) d'exclure le contractant de toute participation à des appels d'offres en cours ou à venir et/ou de toute relation contractuelle ou de collaboration future avec l'OMS.

L'OMS sera en droit de rapporter toute violation de ces dispositions aux organes directeurs de l'OMS, aux autres organismes des Nations Unies et/ou aux donateurs.

13. **Termination.** WHO may terminate this agreement or any part thereof with immediate effect (in addition to any other rights or remedies to which WHO may be entitled, including the right to claim damages), on written notice to the contractor if the contractor is:

(i) in breach of any material obligation(s) under this agreement and, to the extent such breach is capable of being remedied, fails to correct such breach within a period of thirty (30) days after having received a written notification to that effect from WHO; or

(ii) adjudicated bankrupt or formally seeks relief of its financial obligations.

13. **Résiliation.** L'OMS peut résilier avec effet immédiat le présent accord ou toute partie de celui-ci (en plus de tous les autres droits ou recours dont l'OMS peut se prévaloir, y compris celui de réclamer des dommages-intérêts), moyennant une notification écrite adressée au contractant, si ce dernier :

(i) est en violation d'une (ou plusieurs) obligation(s) importante(s) du présent accord et, dans le cas d'une violation susceptible d'être réparée, manque de remédier à une telle violation dans les trente (30) jours suivant la réception d'une notification écrite de l'OMS envoyée à cet effet ; ou

(ii) s'est déclaré en faillite ou a demandé officiellement à être exonéré de ses obligations financières.

14. **Use of WHO name and emblem.** Without WHO's prior written approval, the contractor shall not, in any statement or material of an advertising or promotional nature,

World Health Organization

AGREEMENT FOR PERFORMANCE OF WORK
ACCORD POUR EXECUTION DE TRAVAUX

GLOBAL PROCUREMENT AND LOGISTICS
Global Service Centre
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Registration	2021/1101610-0
Purchase Order	202652451
Unit Reference	SRH/MCA/SEARO

refer to this agreement or the contractor's relationship with WHO, or otherwise use the name (or any abbreviation thereof) and/or emblem of the World Health Organization.

15. **Publication of agreement.** Subject to considerations of confidentiality, WHO may acknowledge the existence of this agreement to the public and publish and/or otherwise publicly disclose the contractor's name and for Company Contractors, the country of incorporation, general information with respect to the work described herein and the agreement's value. Such disclosure will be made in accordance with WHO's Information Disclosure Policy and shall be consistent with the terms of this agreement.

16. **Audit.** WHO may request a financial and operational review or audit of the work performed by Company Contractors under this agreement, to be conducted by WHO and/or parties authorized by WHO, and the Company Contractor undertakes to facilitate such review or audit. This review or audit may be carried out at any time during the implementation of the work performed under this agreement, or within five years of completion of the work. In order to facilitate such financial and operational review or audit, the Company Contractor shall keep accurate and systematic accounts and records in respect of the work performed under this agreement.
The Company Contractor shall make available, without restriction, to WHO and/or parties authorized by WHO:

(i) the Company Contractor's books, records and systems (including all relevant financial and operational information) relating to this agreement; and

(ii)reasonable access to the Company Contractor's premises and personnel.

The Company Contractor shall provide satisfactory explanations to all queries arising in connection with the aforementioned audit and access rights.

WHO may request the Company Contractor to provide complementary information about the work performed under this agreement that is reasonably available, including the findings and results of an audit (internal or external) conducted by the Company Contractor and related to the work performed under this agreement.

17. **Surviving provisions.** Those provisions of this agreement that are intended by their nature to survive its expiration or earlier termination shall continue to apply.

18. **Settlement of disputes.** Any matter relating to the interpretation or application of this agreement which is not covered by its terms shall be resolved by reference to Swiss law. Any dispute relating to the interpretation or application of this agreement shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties or, in the absence of agreement, with the Rules of Arbitration of the International Chamber of Commerce. The parties shall accept the arbitral award as final.

19. **Privileges and immunities.** Nothing contained in or relating to this agreement shall be deemed to constitute a waiver of any of the privileges and immunities enjoyed by WHO and/or as submitting WHO to any national court jurisdiction.

14. **Utilisation du nom et de l'emblème de l'OMS.** Le contractant n'a pas le droit, dans aucune déclaration ni aucun support à caractère publicitaire ou promotionnel, de faire référence au présent accord ou à sa relation avec l'OMS, ni d'utiliser d'une autre manière le nom (ou toute abréviation de celui-ci) et/ou l'emblème de l'Organisation mondiale de la Santé, sans l'autorisation écrite préalable de l'OMS.

15. **Publication de l'accord.** Sous réserve de considérations relatives à la confidentialité, l'OMS a le droit de divulguer l'existence de cet accord et de publier, et/ou rendre public d'une autre manière, le nom du contractant ainsi que, le pays d'enregistrement si le contractant est une Personne Morale, des informations générales concernant les travaux décrits dans le présent accord et la valeur de l'accord. Cette divulgation se fera conformément à la politique de l'OMS sur la divulgation des informations et aux dispositions du présent accord.

16. **Vérification.** L'OMS peut demander qu'un examen ou une vérification de type financier et opérationnel des travaux effectués par les Personnes Morales en vertu du présent accord soit effectué(e) par l'OMS et/ou par des parties autorisées par l'OMS, et la Personne Morale s'engage à faciliter cet examen ou cette vérification. Cet examen ou cette vérification peut être effectué(e) à tout moment pendant l'exécution des travaux effectués au titre du présent accord, ou dans les cinq ans suivant l'achèvement des travaux. Afin de faciliter cet examen ou cette vérification de type financier et opérationnel, la Personne Morale doit tenir des comptes et des registres précis et systématiques sur les travaux effectués en vertu du présent accord.
La Personne Morale doit mettre à la disposition de l'OMS et/ou des parties autorisées par l'OMS, sans restriction:

(i) les livres, les archives et les systèmes de la Personne Morale concernant le présent accord (y compris l'ensemble des informations financières et opérationnelles pertinentes); et

(ii) un accès raisonnable aux locaux et au personnel de la Personne Morale.

La Personne Morale doit fournir des explications satisfaisantes en réponse à toutes les questions découlant de la vérification et des droits d'accès susmentionnés.

L'OMS peut demander à la Personne Morale de lui communiquer des informations complémentaires concernant les travaux exécutés au titre du présent accord qui sont raisonnablement à sa disposition, y compris les conclusions et les résultats d'une vérification (interne ou externe) effectuée par la Personne Morale au sujet des travaux exécutés au titre du présent accord.

17. **Dispositions restant en vigueur après la fin du contrat.** Les dispositions du présent accord qui sont, de par leur nature, destinées à survivre à l'expiration ou à la résiliation anticipée dudit accord continueront de s'appliquer.

18. **Règlement des différends.** Toute question concernant l'interprétation ou l'application du présent accord que les dispositions de ce dernier ne permettent pas de résoudre doit être résolue par référence au droit suisse. Tout différend relatif à l'application ou à l'interprétation du présent accord qui n'aurait pu être résolu à l'amiable fera l'objet d'une conciliation. En cas d'échec de celle-ci, le différend sera réglé par arbitrage. Les modalités de l'arbitrage seront convenues entre les parties ou, en l'absence d'accord, déterminées selon le Règlement d'arbitrage de la Chambre de Commerce internationale. Les parties reconnaissent que la sentence arbitrale sera finale.

19. **Privilèges et immunités.** Aucun des termes du présent accord ne sera considéré comme constituant une renonciation à quelque privilège ou immunité que ce soit dont jouit l'OMS en vertu du droit national ou international et/ou interprété comme une soumission de l'OMS à la compétence d'une quelconque juridiction nationale.

Sensitivity: Internal & Restricted

Agreement for Performance of Work (APW) between WHO Regional Office for South-East Asia and Sushila Nayar Public Health Institution for developing and piloting of training tools for pre-service comprehensive abortion care with special reference to second trimester abortions amongst post graduate medical students

16 July – 16 October 2021

BACKGROUND

Between 2015 and 2019, on an average, 73.3 million induced (safe and unsafe) abortions occurred worldwide each year. There were 39 induced abortions per 1000 women aged between 15–49 years. (1) 3 out of 10 (29%) of all pregnancies, and 6 out of 10 (61%) of all unintended pregnancies, ended in an induced abortion. (1) Among these, 1 out of 3 were carried out in the least safe or dangerous conditions. (2) Over half, of all estimated unsafe abortions globally, were in Asia, most of them in South and Central Asia. (2) Each year between 4.7% – 13.2% of maternal deaths can be attributed to unsafe abortion (3). Abortions are safe when they are carried out by a person with the necessary skills, using a WHO recommended method appropriate to the pregnancy duration. Almost every abortion death and disability could be prevented through sexuality education, use of effective contraception, provision of safe, legal induced abortion, and timely care for complications. (4)

Awareness, access, resources, availability matters a lot in seeking services for abortions. The 1971 Medical Termination of Pregnancy Act made abortion legal for women under a wide range of conditions and medication abortion has been available in India since 2002. (5) In late January 2020, the Union Cabinet amended the 1971 Medical Termination of Pregnancy (MTP) Act allowing women to seek abortions as part of reproductive rights and gender justice. Jha reported that an estimated 10 million female fetuses were illegally aborted in India and around 500,000 girls were being lost through sex-selective abortions annually (Jha et al. 2006). (6) It was reported that for estimated four post-natal deaths, there was one prenatal death among girls, which suggested that about one million fetuses or unreported infanticides, occurred between 1981 and 1991(Gupta 1997). (7)

However, information from many studies has indicated that unintended pregnancy, rather than sex of the child underlies demand for most abortions. Analysis of National Family Health Survey-2(NFHS-2) recordings of 90000 women in India revealed that between women who had all boys and those who had all girls, there was no significant difference in the probability of their having an abortion. Only in one (Haryana), of 26 states from where information, women whose previous child was a girl, were about two times (1.8) more likely to terminate the current pregnancy than other women (Pallikadavath et al. 2006).(8) Saha reported that Maharashtra had a higher incidence of sex-selective abortions and unwanted sex of the fetus was the reason stated by 12.5% of abortion seekers, 19% rural and 5.8% urban respondents (Saha 2004) (9) Still not much is known of real scenario of rural masses, specially community based. Second trimester abortions are real issues as due to PCPNDT act many obstetrician refuse with the fear of sex selection but many women who conceive in lactational amenorrhea, unmarried girls who hide their pregnancy, failure of contraceptive where women is not aware , women in whom fetal anomalies are there , they really suffer. For second trimester abortions different skills are needed and expertise is required. The 2020 amendment says that now one RMP can decide for second trimester abortion instead of two which was recommended before.

DSN

WHO South East Asia Regional office, MCA has been taking initiative to start preservice training to capacitate MBBS graduates with skills of providing standard comprehensive abortion care till first trimester. But there are many abortions which are conducted in second trimester. As per ACOG, in 2008, 1.2 million abortions occurred in the United States, of which 6.2% took place between 13 weeks of gestation and 15 weeks of gestation, and 4.0% took place at 16 weeks of gestation or later (10). The second trimester abortions done medically or surgically need expertise as complications during this period post termination may be life threatening and may need urgent interventions.

It is also important to train the postgraduate students in preservice itself regarding the second trimester abortions, specially pre intervention and post intervention assessments. In the second trimester abortions, the various recommended methods need special training and skills and this trained and skilled doctor can provide the best outcomes. There have been some amendments in the MTP Law 2020 by the policy and program makers and now the terminations can be done until 24 weeks and, in some cases, even beyond where we have gross fetal anomalies. It is strongly recommended that the postgraduates should come out with good knowledge, attitude and skills to perform WHO recommended second trimester medical and surgical abortions and as recommended by MTP LAW in India safely and efficiently when they start their service in private or Governmental sector.

OBJECTIVE

To develop and conduct pilot testing of pre-service competency-based training tools for postgraduate medical students for second trimester medical and surgical abortion and provide feed loop on the content, duration and training methods.

SPECIFIC OBJECTIVES

- In collaboration with WHO SEARO to draft a module with the course outline, training curriculum, schedule and training materials for preservice training of second trimester abortions for postgraduates.
- To develop & piloting the training module by conducting the training using the facilitator's guide.
- To use various competency-based training methods such as illustrated lectures, case studies, drills, group discussions, demonstration in model, demonstration in clients and other innovative approaches for the training.
- Demonstrations on counseling, and other CAC procedures will be tested using provided animated videos.
- Review and comment on the training tool based on the experience of the training.
- Provide feed-back loop on content, training methods, training duration, use of appropriate training tools as planned in the draft training tool.

METHODOLOGY

The team at MGIMS, Sevagram will first review global and regional documents related to second trimester abortion. After the review of literature, the WHO recommended methods will be reviewed in depth. The updated review of other literature will also be done. The existing pre-service training tools in different countries and the regions will be seen in detail. Study of the WHO guidelines on evidence-based practices for second trimester abortion will be used as base. Based on that the various sessions & power points presentation on different sessions will be developed as counselling, consent, documentation, prerequisites, methodology, procedures, complications and their management, facilitators guide and learner's handbook including question banks, assessment method etc.

- The tool so developed will be shared to the WHO Officials for preliminary review and for approval.

- Training of Postgraduate students in the Department of OBGYN will be conducted with the permission from the administration receive this training.
- The permission to conduct the training will also be obtained by institutional ethical committee prior to the training.
- There will be an orientation meeting of OBGY faculties for conducting CAC training.
- The feedbacks of the facilitators & participants will be obtained to finalize a comprehensive abortion care guideline for second trimester abortions.

Following topic will be covered during the training;

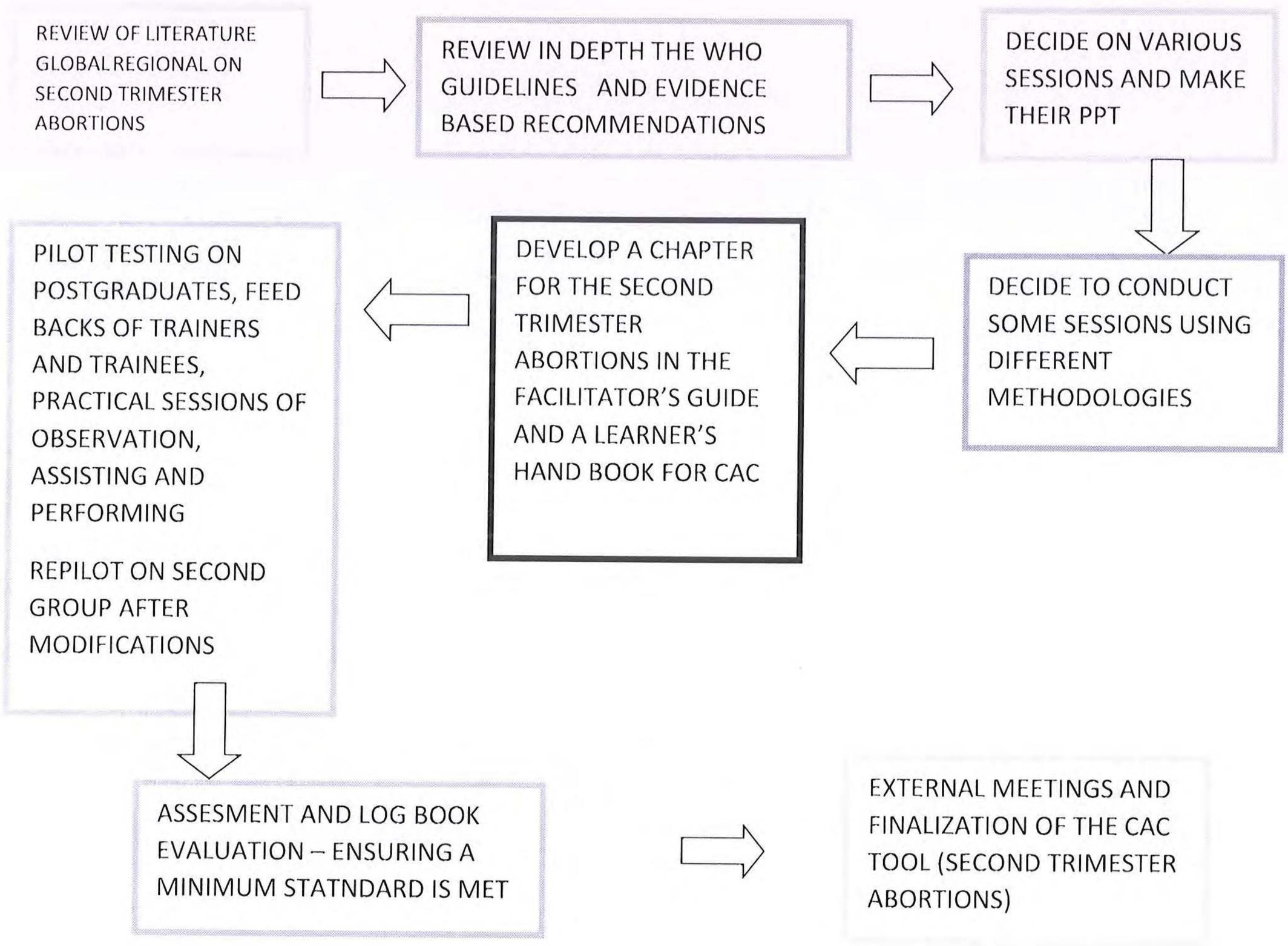
- Indian abortion law, procedural process and policy.
- key elements of SAS.
- women's rights for abortion and post abortion care in all the health facilities
- clinical assessment for abortion care in second trimester.
- counseling and offer choice regarding medical abortion (MA) or surgical abortion in second trimester and obtain informed consent.
- post-abortion family counseling and contraceptive services including long term methods.
- SAS to young women.
- elements of infection prevention.
- all recommended methods of second trimester abortions
- individualized pain management plan.
- all medical and surgical methods of second trimester abortions.
- steps to diagnose and mange complications during and after abortions.
- post-procedure and follow-up care after second trimester abortion.

During the training period the learners will be introduced to the key elements of safe abortion services (SAS) in second trimester. Classroom and clinical sessions will focus on key aspects of service delivery. For the skilled competency learners will practice on the anatomic models using checklist that lists the key steps. This humanistic approach will help learners to build skills needed to perform SAS.

- The evaluation will include all three domain Knowledge, Skills and Attitude.
- The post training test will be conducted to see the knowledge update and skills will be tested using check list when they are performing procedure (model/ clients).
- The feedbacks of trainers and trainees will be shared with WHO Team
- Meetings of different medical colleges who have conducted the similar trainings from different places/countries will be arranged in collaboration with WHO India office
- Final comprehensive guidelines for CAC for first and second trimester abortions.

Dscy

Following will be the flow in the training –



TRAINING SITE

Department of OBS/GYNAE, Mahatma Gandhi Institute Of Medical Sciences, Sewagram Wardha

TRAINING SITE

First, second- and third-year residents working in the Department of OBS/GYNAE, will be included in two batches with 8 in each.

DURATION

16 July – 16 October 2021.

Two weeks for each batch.

TRAINERS

Minimum Four Trainers (1: 4 trainee)

ETHICAL CONSIDERATION

Ethical approval from the ethical committee of MGIMS, Sewagram.

SRHR PTAEO details

- Project: SEFGL2016871
- Award: 3.1
- Task: 68540

ACTIVITY PLAN

S. NO.	ACTIVITY	TIMELINE
1.	Development of draft of second trimester CAC module	45 days
2.	Conduct the first preservice training of PGs using the same module – first group	46 – 59 days
3.	Feedback trainers and trainees and discussion with WHO team	60 to 63 days
4.	Modifications	64 – 65 days
5.	Conduct the preservice training of PGs using the same module – second group	66 – 79 days
6.	Meeting with stake holders and other colleges for finalization of CAC tool and certification	Between 80 – 85 days

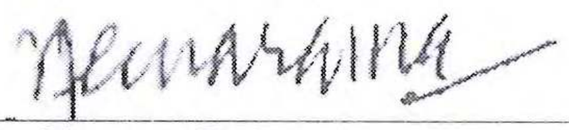
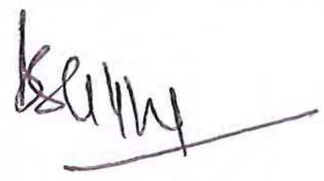
DSW

BUDGET

Details	Total amount in INR
Training coordinator (1)	467,397
Trainers (4)	333,855
IT technologist	200,313
Training materials Printing of the tools (Learner's guide, Facilitator's manual,) Training models, instruments, & drugs	222,570
Training Venue hiring charges	111,285
Tea/ Snacks	222,570
Miscellaneous (stationary/Laptop/ internet/communication etc.)	140,961
Total	**1,698,951**

PAYMENT SCHEDULE

First instalment: 25% Upon signature of Agreement by 16 July 2021	25%	INR 424,737.75
Second installment: 65% upon submission of training plans in detail to SEARO Team by 16 August 2021	65%	INR 1,104,318.15
Final instalment: 10% or actuals, whichever is less, upon submission of all deliverables and certified financial statement by 16 October 2021	10%	INR 169,895.1
Total		**INR 1,698,951**

For the **WORLD HEALTH ORGANIZATION**		For the **CONTRACTUAL PARTNER**	
Signature:		Signature:	
Name and Title	**Dr Neena Raina** Senior Adviser Reproductive, Maternal, Newborn, Child & Adolescent Health and Ageing WHO-SEARO, New Delhi	Name and Title:	**Dr B S Garg** Sushila Nayar Public Health Institution Mahatma Gandhi Institute of Medical Sciences

Prevention of maternal and neonatal death/infections with a single oral dose of azithromycin in women in labor (in low- and middle-income countries): a randomized controlled trial

ClinicalTrials.gov number: NCT###(when available)

Lead Study Investigator(s): Alan T.N. Tita, MD, PhD, Center for Women's Reproductive Health and Maternal-Fetal Medicine Division, UAB
Wally Carlo, MD, Neonatology Division, UAB
Elwyn Chomba, MBChB, DCH, MRCP, University Teaching Hospital

Subcommittee Members: Marian Knox-Thomas, MD, NICHD
Menachem Miodovnik, MD, NICHD
Tracy Nolen, DrPH, RTI International
Elizabeth McClure, PhD, RTI International
Jennifer J. Hemingway-Foday, MPH, RTI International
Emily MacGuire, MPH, RTI International

Version Number: Version 1.1

Version Date: December 20, 2018

Funding: Eunice Kennedy Shriver National Institute of Child Health and Human Development and The Bill & Melinda Gates Foundation

Version Tracking

Version	Date	Authors	Comments
1.2	Dec 20, 2018	AZ WG and GN Investigators	This version will be used for IRB/ERC submissions after December 20, 2018.

Table of Contents

AZITHROMYCIN INVESTIGATORS

Central Team: Global Network Site 03 (Zambia)

Waldemar A. Carlo, MD
Principal Investigator
University of Alabama at Birmingham
Birmingham, Alabama
wcarlo@peds.uab.edu

Alan T.N. Tita, MD, PhD
Azithromycin Protocol Lead Investigator
University of Alabama at Birmingham
Birmingham, Alabama
atita@uabmc.edu

Elwyn Chomba, MBChB, DCH, MRCP
Senior Foreign Investigator
University Teaching Hospital
Lusaka, Zambia
echomba@zamnet.zm

Site Investigators

Global Network Site 02 (Democratic Republic of Congo)

Carl Bose, M.D.
Principal Investigator
University of North Carolina School of Medicine
Chapel Hill, North Carolina
cbose@med.unc.edu

Antoinette Tshefu, MD, PhD, MPH
Senior Foreign Investigator
Kinshasa School of Public Health
antotshe@yahoo.com

Global Network Site 03 (Zambia)

Wally Carlo, MD
Principal Investigator
University of Alabama at Birmingham
Birmingham, Alabama
Wcarlo@PEDS.UAB.EDU

Elwyn Chomba, MBChB, DCH, MRCP
Senior Foreign Investigator
University Teaching Hospital
Lusaka, Zambia
echomba@zamnet.zm

Global Network Site 06 (Guatemala)

Nancy Krebs, MD
Principal Investigator
UCHSC
Denver, Colorado
Nancy.krebs@ucdenver.edu

Ana Garces, MD, MPH
Senior Foreign Investigator
INCAP
Guatemala City, Guatemala
agarces@incap.org

Global Network Site 07 (Bangladesh)

William Petri, MD
Principal Investigator
University of Virginia
Charlottesville, Virginia
wap3g@virginia.edu

Rashidul Haque, MD
Senior Foreign Investigator
ICDDR,B
Dhaka, Bangladesh
rhaque@icddrb.org

Global Network Site 08 (Belagavi, India)

Richard Derman, MD, MPH
Principal Investigator
Thomas Jefferson University
Philadelphia, PA
Richard.Derman@jefferson.edu

Shivaprasad S. Goudar MD, MHPE
Senior Foreign Investigator
KLE University's J N Medical College
Belgaum, India
sgoudar@jnmc.edu

Global Network Site 09 (Pakistan)

Robert L. Goldenberg, MD
Principal Investigator
Columbia University
New York, New York
rlg88@columbia.edu

Sarah Saleem, MD
Senior Foreign Investigator
Aga Khan University
Karachi, Pakistan
sarah.saleem@aku.edu

Global Network Site 11 (Nagpur, India)

Patricia L. Hibberd, MD, PhD
Principal Investigator
Boston University
Boston, Massachusetts
[redacted]

Archana Patel, MD, DNB, MSCF, PhD
Senior Foreign Investigator
Kasturba Medical Research Foundation
Nagpur, India
[redacted]

Global Network Site 12 (Kenya)

Ed Liechty, MD
Principal Investigator
Indiana University School of Medicine
Indianapolis, Indiana
[redacted]

Fabian Esamai, MBChB, MMed, MPH, PhD
Senior Foreign Investigator
Moi University School of Medicine
Eldoret, Kenya
[redacted]

National Institute of Child Health and Human Development (NICHD)

Marion Koso-Thomas, MD, MPH
Medical Officer, Global Network for Women's and Children's Health
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
[redacted]

Menachem Miodovnik, MD
Medical Officer, Global Network for Women's and Children's Health
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
[redacted]

RTI International

Elizabeth Mcclure, PhD
Principal Investigator, Data Coordinating Center
RTI International, Durham, NC
[redacted]

Tracy Nolan, DrPH
Senior Statistician, Data Coordinating Center
[redacted]

Jay Hemingway-Foday, MPH, MSW
Protocol Manager for Azithromycin Protocol, Data Coordinating Center
[redacted]

Emily MacGuire, MPH, MSW
Protocol Manager for Azithromycin Protocol, Data Coordinating Center
[redacted]

ACRONYMS

AC	Alzheimers
ACOG	American Congress of Obstetricians and Gynecologists
ANC	Antenatal Care
BP	Blood pressure
DCC	Data Coordinating Center
DMC	Data monitoring committee
DMS	Data Management System
DRC	Democratic Republic of Congo
ERC	Ethical review Committee
FIGO	International Federation of Gynecology and Obstetrics
FDA	Food and Drug Administration
GA	Gestational age
GI	Gastrointestinal
GN	Global Network for Women's and Children's Health Research
HR	High risk
IRB	Institutional Review Board
JAMA	Journal of the American Medical Association
ITT	Intention to treat
LIC	Low income country
LMIC	Low- and middle-income countries
LMP	Last menstrual period
MNH	Maternal and Newborn Health
NEJM	New England Journal of Medicine
NICHD	Eunice Kennedy Shriver National Institute of Child Health and Human Development
NIH	National Institutes of Health
NNT	Number needed to treat
OHRP	U.S. Office of Research Protections
PI	Principal Investigator
pSBI	possible serious bacterial infection
RCT	Randomized controlled trial
RTI	Research Triangle Institute International
SAE	Serious adverse event
SC	Steering Committee
SFI	Senior Foreign Investigator
SMFM	Society for Maternal-Fetal Medicine
UAB	University of Alabama at Birmingham
WHO	World Health Organization

ABSTRACT

Background: Maternal and neonatal infections are among the most frequent causes of maternal and neonatal deaths, and current prophylactic strategies have not been effective in preventing many of these deaths. Recently, a randomized clinical trial conducted in a single site in The Gambia showed that treatment with a oral dose of 2 g azithromycin vs. placebo for all women in labor reduced certain maternal and neonatal infections. However, it is unknown if this therapy reduces maternal and neonatal sepsis and mortality.

Hypotheses: The trial includes two primary hypotheses, a maternal hypothesis and a neonatal hypothesis. First, a single, prophylactic intrapartum oral dose of 2 g azithromycin given to women in labor will reduce maternal death or sepsis. Second, a single, prophylactic intrapartum oral dose of 2 g azithromycin given to women in labor will reduce intrapartum/neonatal death or sepsis.

Study Design Type: Randomized, placebo-controlled, parallel multicenter clinical trial. Women in labor will be randomized with one-to-one ratio to intervention/placebo.

Population: Pregnant women in labor at ≥ 28 weeks gestational age with a live fetus pregnancy who plan to deliver vaginally in a facility. Women with evidence of chorioamnionitis or other infection requiring antibiotic therapy (not prophylaxis) at time of eligibility, allergy to azithromycin, use of azithromycin, erythromycin or other macrolide within 3 days of enrollment, known arrhythmia or cardiomyopathy, or plan for cesarean section delivery prior to enrollment will be excluded.

Intervention: A single, prophylactic intrapartum oral dose of 2 g azithromycin.

Comparison: A single intrapartum oral dose of an identical appearing placebo

Outcomes:
Primary outcomes: 1) Incidence of maternal death or sepsis and 2) Incidence of intrapartum/neonatal death or sepsis.

Secondary outcomes: Individual components of the primary outcomes (maternal death, maternal sepsis, intrapartum/neonatal death, neonatal sepsis), neonatal death/sepsis, neonatal deaths due to sepsis, and all cause neonatal death; the primary maternal outcome in a high risk for infection population; specific maternal infections; use of subsequent maternal antibiotic therapy; pyloric stenosis; health care resource utilization; culture positive infections and resistance, in an ancillary surveillance study, incidence of antimicrobial resistance and microbiome diversity.

1 STATEMENT OF PROBLEM

1.1 Primary Hypotheses

This study will have two primary hypotheses, one with a maternal focus and one with a neonatal focus. First, a single, prophylactic intrapartum oral dose of 2 g azithromycin given to women in labor in low and middle-income settings will reduce maternal death or sepsis. Second, a single, prophylactic intrapartum oral dose of 2 g azithromycin given to women in labor in low and middle-income settings will reduce intrapartum/neonatal death or sepsis.

1.2 Primary Specific Aims

To test the effectiveness of a single dose of prophylactic intrapartum azithromycin compared to placebo in reducing the risk of the composite outcome of maternal death or sepsis. To separately test the effectiveness of a single oral dose of intrapartum azithromycin prophylaxis (2 g) compared to placebo in reducing the risk of the composite outcome of intrapartum/neonatal death or sepsis. Both groups will receive the routine or usual care provided at the facility during and after labor.

1.3 Secondary Specific Aims

The single dose of intrapartum azithromycin prophylaxis (2 g) will be compared to placebo to accomplish the following secondary aims:

- Main Secondary Aim for Women at High Risk for Infection Cohort:
  - a. To evaluate whether the risk of maternal death or sepsis differs among laboring women with and without high-risk for infection (high risk is defined as women with prolonged labor (≥12 hours) and/or prolonged membrane rupture (≥18 hours)).
- Other secondary specific Aims:
  - b. To evaluate the effectiveness in reducing the risk of individual components of the primary composite endpoints (i.e., maternal death, maternal sepsis, intrapartum/neonatal death, neonatal sepsis including specifically all-cause neonatal deaths and neonatal deaths due to sepsis).
  - c. To evaluate the effectiveness on the risk of intrapartum/neonatal death or sepsis in infants of laboring women at high-risk for infection because of prolonged labor (≥18hours) and/or prolonged membrane rupture (≥18 hours).
  - d. To evaluate the effectiveness on the risk of maternal infections including clinical chorioamnionitis, endometritis, wound infections (perineal or subsequent cesarean), abdominal or pelvic abscess, mastitis/breast abscess, pyelonephritis and pneumonia in all laboring women as well as in those at high-risk for infection.
  - e. To evaluate the effectiveness in reducing the use of subsequent maternal antibiotic therapy from randomization to 6 weeks for any reason in all laboring women as well as in those at high-risk for infection.
  - f. To compare the use of health care resources. Use of health care resources will be measured in terms of maternal and neonatal duration of hospital stay, unscheduled clinic or ER visits, readmissions, and admission to special care units/intensive care units in all laboring women and newborns as well as in those at high-risk for infection.
  - g. To assess maternal GI symptoms (e.g., nausea, vomiting, and diarrhea) and other reported side effects, as well as infant pyloric stenosis and type of culture positive infections.

[antimicrobial resistance and maternal and infant microbiome diversity are measured in an ancillary study].

h. To determine whether the effect on each of the primary outcomes differs by region [Africa, Latin America or Asia], any other antibiotic use during labor, and mode of delivery [cesarean or vaginal]. Note that antibiotic use will not include use to treat any infections diagnosed after randomization as those will be outcomes.

1.4 Background

Maternal and neonatal infections are among the most frequent causes of maternal and neonatal death. Maternal infection during pregnancy and the puerperium account for approximately 10% of the global burden of maternal deaths. This places maternal infection among the top five causes of maternal mortality worldwide.[1] Neonatal infection is the third most common cause of neonatal mortality and accounts for about 16% of neonatal mortality worldwide.[2] Furthermore, maternal and neonatal deaths from infections are not decreasing compared with deaths from other frequent causes of mortality.[3,4] There is a need for innovative simple effective interventions that can be scaled up to reduce the burden of both maternal and neonatal mortality due to infections.

1.4.1 Prevention of Maternal and Neonatal Deaths from Infections

Current strategies to prevent maternal and neonatal deaths from infections are insufficient. Current approaches to prevention, identification, and treatment of neonatal sepsis have had limited impact. According to the WHO, maternal deaths from infection have remained unchanged or increased in some instances, whereas deaths from other causes have reduced. The evidence backing current WHO guidelines for prevention and treatment of peripartum infections is generally graded as low or very low quality.[1] Efforts for early identification and treatment of neonatal infection are important but neonatal deaths due to infection continue to be very prevalent. Recent studies of alternative antibiotic regimens that do not require a full course of intravenous antimicrobial therapy have shown comparable effectiveness but have not reduced deaths from infections.[3,4] Among research priorities, a WHO guideline panel identified the evaluation of the role of routine prophylactic antibiotics in women who undergo a normal vaginal birth as well as in those at high risk for infection due to prolonged labor or membrane rupture.[5]

1.4.2 Risks for Maternal and Neonatal Infections

Maternal and neonatal infections by maternal risk including cesarean delivery. While the role of antibiotic prophylaxis for cesarean delivery is well-established, in many low-resource settings, many maternal infections occur after vaginal deliveries with high-risk for infections. Cesarean delivery especially after labor or membrane rupture is the strongest risk factor for maternal peripartum infection including endometritis, wound infection and sepsis (increasing risk by up to 5 to 20 times compared to vaginal delivery).[6] The fraction of maternal infection attributable to cesarean delivery is rather low because of the low cesarean delivery rate of 5-10% or lower, especially in the Africa region, compared with 20-30% or higher in the US and many high income countries.[6] Therefore, strategies that address maternal peripartum infection and sepsis in the developing world should focus as well on identifying and preventing (as well as treating) infection in women who have a vaginal birth, particularly those who are at high risk. There is an increased risk of infection in women who undergo prolonged labor ≥18 hours (at least 2 fold) or membrane rupture ≥6 hours (at least 2-3 fold) compared to women who do not experience these risk factors.[4] These risk factors identify a large group of women who are at the highest

risk for maternal peripartum infections (including chorioamnionitis, endometritis, perineal wound infection and post-cesarean surgical site infections) and sepsis after a vaginal or cesarean delivery and also place newborns at increased risk for sepsis. However, even though 80-90% of pregnancies in labor are not at this highest-risk for infection (depending on criteria used), they may account for about 50% of maternal and neonatal infections in LMICs. Thus, testing antibiotic strategies during labor in LMICs should include both the high-risk and lower risk women as highlighted in research priorities from the WHO guideline panel.[7]

Antibiotic Prophylaxis for Women who deliver by Cesarean section. The appropriate use of antibiotic prophylaxis for cesarean delivery and antiseptic agents are among the most effective preventive interventions as highlighted by the WHO guidelines for maternal peripartum infections.[1] Antibiotic prophylaxis, preferably prior to incision, in particular, among several strategies, effectively reduces the risk of infection and the associated high health care and personal costs.[1,8-11] However, the prevalence of cesarean sections is low in many low-resource settings, particularly in sub-Saharan Africa, and thus, do not account for the large burden of the maternal and neonatal infections worldwide.

1.4.3 Intrapartum Azithromycin to Prevent Maternal and Neonatal Infection

Azithromycin: a novel approach to maternal and neonatal infections. A novel approach to maternal and neonatal infection is to target organisms that may be very frequent pathogens but that historically have not been the target of antimicrobial treatment.[12] A multicenter randomized clinical trial (RCT) of azithromycin prophylaxis added to the standard prophylactic regimen (cephalosporin) in women who underwent cesarean delivery following labor or membrane rupture for at least 4 hours in the US showed that maternal infection was reduced by about 30%.[13] A single center RCT in a low income country (LIC) setting suggested that azithromycin prophylaxis may improve maternal and neonatal outcomes. In an RCT in The Gambia that included all women in labor, treatment with 2g of azithromycin vs. placebo before delivery reduced maternal and neonatal infections.[14] Therefore, we propose to evaluate the effectiveness of a single oral dose of azithromycin as an intrapartum prophylactic agent for maternal and neonatal infection and death. We will also monitor the potential side effects of this intervention.

1.5 Rationale/Justification

Maternal infection and sepsis is a priority to reduce maternal and neonatal deaths. Compared to peripartum hemorrhage and pre-eclampsia/eclampsia, maternal infection has received less attention as a major cause of maternal death; proportionally it accounts for increasing deaths.[1] The WHO and other global health action has identified maternal infection/sepsis as a priority problem to reduce maternal deaths. In addition, maternal infection significantly increases the risk of neonatal sepsis which is one of the leading causes of neonatal death in LICs.[15] Most recently, a NEJM perspective article highlighted the WHO resolution issuing a clarion call recognizing "sepsis" as a global health priority.[16] Drawing from our findings on azithromycin prophylaxis for cesarean delivery in the US[13] and data from another preliminary trial in The Gambia, Africa,[14] we propose to evaluate the role of a single oral dose of azithromycin (plus usual care) to prevent maternal death or postpartum sepsis and intrapartum/neonatal death or sepsis in laboring women as well as the targeted sub-population of those at the highest risk for infection because they have prolonged labor (≥18hours) and/or prolonged membrane rupture (≥8 hours).

Azithromycin is available as a generic agent with easy storage requirements. It has a bimodal half-life of up to 70 hours in the non-pregnant population. Although its pharmacokinetic characteristics are not as

well studied in the pregnant population, it is commonly used during pregnancy for treatment of chlamydia and other infections. Azithromycin covers a broad spectrum of bacteria (including gram-positive cocci, genital anaerobes and mycoplasmas, and certain gram-negative bacilli and anaerobes) that are associated with maternal infections which are often polymicrobial (chorioamnionitis, endometritis, and perineal/cesarean wound infection) and sepsis. In addition to the aforementioned organisms which may play a role in neonatal infection, azithromycin also has activity against Group B streptococcus which is a major cause of neonatal sepsis in developed countries and may be implicated in LICs and low-resources settings as well. Therefore, a successful prophylaxis intervention is likely to reduce infections and death and may also reduce health care costs and need for prolonged antibiotic therapy to treat infections which may be associated with resistance. Indeed, the recent WHO Guidelines on peripartum infection articulated the following among research priorities: what are the benefits of initiating prophylactic antibiotics among women undergoing uncomplicated vaginal birth and among those at high risk such as after prolonged rupture of membranes? A JHPIEGO consultative meeting on enhancing the focus on maternal infections suggested that "Attention to identification and prompt management of prolonged labor and prolonged rupture of membranes is critical to reduce disease and death due to maternal sepsis."[15,16,17]

1.6 Previous Studies

1.6.1 The Gambian Trial

Data from a single center trial in a LIC setting suggest the potential for azithromycin prophylaxis to improve maternal and neonatal outcomes. Among 929 Gambian mothers (randomized to 2 g of azithromycin vs. placebo before delivery) and their 930 newborns, maternal infections were lower in the azithromycin group (3.6% vs 9.2%; relative risk [RR], 0.40; 95% confidence interval [CI], 0.22-0.71; P = 0.002).[12] Among newborns, the overall prevalence of infections was also lower in the azithromycin group (18.1% vs 23.8%; RR, 0.76; 95% CI, 0.58-0.99; P = 0.052).[14] Maternal and neonatal carriage of infectious organisms was lower in the azithromycin group.[13]

1.6.2 The US Trial and Cost Analysis

In a multicenter US RCT, it was demonstrated a further 50% reduction in the risk of maternal peripartum infection by adding a single 500 mg intravenous dose of azithromycin to the standard prophylactic regimen (a single intravenous dose of cefazolin 1-2 g or ampicillin) in the highest-risk group of women who undergo cesarean delivery following labour or membrane rupture for at least 4 hours.[18] These results were observed despite universal use of either oral cephalosporin or clindamycin in the arms of the trial. Specifically, the 95% without penicillin allergy had cephalosporin (mainly cefazolin) for usual cesarean prophylaxis; the remainder had gentamicin and clindamycin. In addition, 25-30% received a penicillin for GBS prophylaxis. Infection was significantly lower in the azithromycin group compared to the placebo group: 6.1% vs. 12%; RR=0.51 (95 % CI 0.39 to 0.68); p<0.0001. Specifically, adjunctive azithromycin use was associated with significant reductions in the risks of endometritis (3.8% vs. 6.1%, RR=0.62, 95% CI: 0.42-0.92; p=0.02) and wound infection (2.4% vs. 6.6%, RR=0.35, 95% CI: 0.22-0.56; p<0.0001. The number needed to treat (NNT) to prevent one infection was 17 for any infection, 43 for endometritis and 24 for wound infection. Other maternal outcomes including need for readmission or unscheduled visits for any reason or specifically for infection (decreased by up to 50%), serious adverse events, postpartum fever, or subsequent treatment with antibiotics were also significantly less common with azithromycin prophylaxis. Short term perinatal/infant outcomes including deaths, sepsis, and other serious neonatal

morbidities were rare in this developed country population and did not differ between groups.[2] In a related cost-analysis report, it was estimated that use of adjunctive azithromycin saves approximately $360 for each use in unscheduled (high-risk) cesarean deliveries such as those studied in the RCT and $143 per use in scheduled or pre-labor cesarean delivery.[74] The results suggesting cost-savings were robust across wide ranges of baseline risk of infection and treatment effect size.[74] Thus, in the US alone, adjunctive azithromycin prophylaxis for cesarean delivery could lead to $350M in cost-savings/year due to avoided infection. These works built upon, and are supported by, over 20 years of research on maternal infections at UAB and elsewhere.[4][75] Azithromycin provides coverage against the most common pathogens identified in association with peripartum infections including genital mycoplasmas and ureaplasmas (when specific methods are utilized to identify them).

1.6.3 Other Important Considerations

A recurrent concern regarding the potential routine use of azithromycin in a large population is antibiotic resistance. Monitoring for characteristics suggestive of resistant infection will be important to incorporate in the protocol. However, a number of factors mitigate concerns about antibiotic resistance: (a) the design of the trial using a single prophylactic dose (as opposed to recurrent treatment doses) of antibiotic, (b) surveillance of maternal clinical cultures up to 6 weeks in the trial in cesareans in the US revealed that positive wound cultures overall and those positive for resistant organisms were significantly less frequent in the azithromycin group;[2] (c) if successful, prophylaxis will reduce the risk of infection and actually reduce the overall frequency of use of antibiotics to treat infection (a result in the US trial as noted above). It is estimated that women in the high-risk for infection group as defined will account for about 10-20% of laboring women. In principle, the use of single prophylactic dose (as opposed to multiple) minimizes the likelihood of antimicrobial resistance but samples will be taken to determine antimicrobial resistance.[45]

Azithromycin is currently recommended to treat or prevent several infections in pregnancy including gonorrhea (1g po), chlamydia (1 g po), and Mycobacterium avium complex prophylaxis (600mg twice/week or 1.2g weekly po). Azithromycin is sometimes used for perioperative prophylaxis in patients at risk for endocarditis (500mg po). Considering the success with a single dose of 2 g in the Gambian trial, our success with 500mg IV for cesarean prophylaxis, and the 40% bioavailability of oral azithromycin, we propose to use 2g po of azithromycin for the proposed intervention. The best approach to this evaluation in order to influence future uptake into clinical practice is an RCT. The primary maternal outcome will be maternal death or sepsis within 6 weeks after delivery. The primary neonatal outcome will be intrapartum/neonatal death or sepsis within 28 days after birth (defined by WHO criteria).[76]

Azithromycin is pregnancy category B – animal studies using maternally toxic doses showed no fetal harm. Limited studies suggest azithromycin is excreted in human milk in a sustained fashion.[24] There are no specific drug-drug interactions warranting dose adjustments when given with other medications. Elimination is by both hepatic and renal route, and no specific adjustments are mandated for patients with renal or hepatic insufficiency. The long elimination 1/2-life of 68 hours is due to extensive uptake and subsequent release of drugs from tissues. The only absolute contraindications are rare: known hypersensitivity reaction to azithromycin, erythromycin or other macrolide antibiotic or history of cholestatic jaundice due to azithromycin. Potential adverse events include very rare (<<1%) allergic hypersensitivity (mild and severe skin reactions – Stevens Johnson Syndrome and toxic epidermal

necrolysis, angioedema and anaphylaxis) and clostridium difficile-associated diarrhea. With multi-day azithromycin therapy, 0.6% of patients discontinued within myanmar due to side effects. With single 1-2 gram doses, gastrointestinal symptoms (nausea 5-16%, diarrhea/loose stools 7-14%, abdominal pain 5-7%, vomiting 3-7%, and dyspepsia 1%) as well as vaginitis 2% and dizziness (1%) were the most commonly reported side effects. No other side effects occurred with a frequency greater than 1%.

Azithromycin has been associated with hypertrophic pyloric stenosis in some observational studies. In a retrospective study, oral azithromycin exposure during the first 14 days after birth was associated with an increased incidence of pyloric stenosis.[14] However, an increased risk of pyloric stenosis was not reported in infants following a single dose of azithromycin to women in labor in randomized trials in the US and Gambia.[2,3,15] The much larger sample size of the proposed study affords the opportunity to further explore this question.

The FDA in 2013 issued an advisory regarding concerns about potential for rare life-threatening arrhythmias with azithromycin use particularly among those with preexisting cardiovascular risk. The information was based on an observational study of older, ill patients who received multiple courses of oral azithromycin over 5 days.[16] The findings are not applicable to our current study population for several reasons: the population is much younger, generally without cardiac co-morbidities, a single dose rather than cumulative doses of oral azithromycin over 5 days is being studied, additional studies of younger, healthy patients did not suggest an increased cardiovascular risk[17]; and patients with arrhythmia or known history of cardiomyopathy will be excluded. In addition, the prior study of 2015 women in the US did not suggest a cardiovascular safety signal, and the potential reduction in severe infection may exceed the excess risk of severe arrhythmia with a single dose of azithromycin.[17]

2 METHODS

Pregnant women in labor at study health facilities who appear to be ≥28 weeks gestational age by best clinical estimate with a live fetus pregnancy will be screened for eligibility (see **Section 2.2**) by research staff starting at the time of admission and continuously during the hospitalization. Gestational age will be determined using the "best estimate" algorithm that is currently used in the GN MNH registry. Those eligible will be consented. Those consented will be randomized to receive a single dose of azithromycin 2 g or identical placebo to be given and directly observed during labor. Because of the ease of storage of azithromycin, sequentially prepared medications in identical packages following the randomization sequence will be available and dispensed by the study staff. The rest of the care will be provided according to the local standard of care. Women will be followed up until discharge and surveillance maintained prospectively, with visits at 3 days for those discharged at <72 hours, as well as one week and six weeks after delivery as has generally been done in the Global Network to ascertain study outcomes.

We will apply the recently recommended "simple and actionable" WHO definition of sepsis in a 2017 statement endorsed by multiple international organizations. The definition of sepsis includes a suspicion of infection and the presence of organ dysfunction based on clinical findings.[18]

To further ensure more objective ascertainment of the sepsis outcome, we propose that the DCC will prospectively define a process for defining criteria for a masked centralized review and adjudication of all cases of infection to ensure conformity with the proposed definition. This approach of adjudication is applied to validate infection in many trials including our recently completed ASPIRIN trial.[19] This approach

to adjudication has some similarities to the near-miss classification for adjudication in women delivering in the Global Network sites that was done recently.[42]

2.1 Study Design

This study is a masked, placebo-controlled RCT. The investigational regimen is 2 g of azithromycin and the comparison arm is an identical placebo which is given orally. Both groups will also receive the standard of care during labor, delivery and post-partum per local standards.

2.2 Study Population/Location

Pregnant women laboring in health facilities of the eight Global Network sites/other health facilities will be eligible. The Global Network sites are described in **Appendix 1**. Health facilities may include any hospitals and health centers where women routinely deliver within the study sites.

2.2.1 Inclusion Criteria

- Pregnant women in labor ≥28 weeks GA(by best estimate) with a pregnancy with one or more live fetuses who plan to deliver vaginally in a facility.
- Admitted to health facility with clear plan for spontaneous or induced delivery
- Live fetus must be confirmed via a fetal heartrate by Doptone prior to randomization.
- ≥18 years of age or minors 14-17 years of age in countries where married or pregnant minors (or their authorized representatives) are legally permitted to give consent.
- Have provided written informed consent (Note: written informed consent may be obtained during antenatal care, but verbal re-confirmation may be needed(per local regulations) at the time of randomization).

2.2.2 Exclusion Criteria

- Non-emancipated minors (as per local regulations)
- Evidence of chorioamnionitis or other infection requiring antibiotic therapy at time of eligibility (however, women given single prophylactic antibiotics with no plans to continue after delivery should not be excluded).
- Arrhythmia or known history of cardiomyopathy
- Allergy to azithromycin or other macrolides that is self-reported or documented in the medical record.
- Any use of azithromycin, erythromycin, or other macrolide in the 3 days or less prior to randomization.Plan for cesarean delivery prior to randomization.
- Preterm labor undergoing management with no immediate plan to proceed to delivery.
- Advanced stage of labor (≥8 cm or ≥3 cm cervical dilation per local standards) and pushing or too distressed to understand, confirm, or give informed consent regardless of cervical dilation.
- Are not capable of giving consent due to other health problems such as obstetric emergencies (for example, antepartum haemorrhage) or mental disorder.
- Any other medical conditions that may be considered a contraindication per the judgment of the site investigator.
- Previous randomization in the trial.

Sites may choose to obtain written consent during antenatal care from pregnant women of the age of consent who plan to deliver vaginally in a facility and have no known medical exclusions. In this case,

study staff must fully assess and confirm eligibility at the time of randomization. It may also be necessary to verbally reaffirm consent at the time of randomization, if required by local regulations.

2.3 Study Intervention and Comparison

The study intervention is a single 2 g dose of directly observed oral azithromycin, to be administered as four 500 mg pills or tablets directly after randomization. By random allocation, participants will receive 2 g of oral azithromycin vs. placebo. We will design the placebo with the assistance of a reputable pharmacy/pharmaceutical company, using identical capsules or pills containing azithromycin in 2 g or a matching placebo (non-antimicrobial agent) to accomplish masking. All of the participants' obstetric care will be similar for all both arms and consist of the routinely available care at each center.

2.4 Detailed Study Procedures

2.4.1 Community Sensitization

Local health providers will receive sensitization about the study to foster communication and collaboration at the facilities where enrollment will take place. In addition, pregnant women and their families in the enrollment area will receive information about the study during antenatal care (ANC) visits to facilitate recruitment and comprehension during the consenting process. Sites may choose to consent women during these sensitization sessions, prior to labor; however, confirmation of eligibility and consent will be required during the screening process described in **Sections 2.4.2 and 2.4.3**.

2.4.2 Screening

Women in labor in defined health facilities (both hospitals and health centers) will be identified by research staff. A brief review of eligibility will be made to determine whether the patient is in labor and does not meet any of the exclusion criteria. If a contraindication to participation in the trial is found, the woman will be excluded from the trial at this point.

2.4.3 Consent

Before a woman participates in the trial, the research staff must obtain her informed consent to voluntarily take part in the study. Consent will be obtained from women ≥18 years of age or minors 14-17 years of age in countries where married or pregnant minors (or their authorized representatives) are legally permitted to give consent. When enrolling minors, we will follow the in-country policies for human research protection and the guidelines approved by the local ethical review committees (ERCs). In the case of pregnant minors, this may require that written consent is obtained from her parents/guardians or husband, with written assent from the minor.

Potential participants will be screened and enrolled in the study upon admission for delivery; therefore, consent will be obtained during labor. Consent should be obtained as early as possible during the intrapartum period and must be obtained prior to the cervical dilation limit approved by local authorities (e.g. either < 6 cm or 10 cm) and/or pushing, as assessed from clinical exam by health facility staff. It is not feasible to wait because the intervention must be given before delivery. Research sites may choose to obtain initial consent during ANC; however, in this situation, confirmation of consent will be required during the screening and enrollment process.

If consent is obtained during labor, study staff will make necessary accommodations to ensure that the laboring women can comprehend the information presented during the consent process. Potential

participants were present in labor can take as much time as needed to consider participation while in labor and will be able to discuss the study with family/friends if desired before deciding on participation. If the participant cannot read, the form will be read aloud to her by a person unaffiliated with the study. Alternatively, the Research Coordinator or a designate may read the consent, but in the presence of a witness who is unaffiliated with the research study. Potential participants will be given an opportunity to discuss the study procedures and ask questions. Additional details are provided in the study Manual of Procedures.

Their balance will be maintained while describing the risks and benefits of participation in the study. No undue pressure will be placed on the potential participant to enroll in the trial. It will further be explained that lack of participation will not affect the usual and anticipated standard of care. As the literacy levels will vary and may be a challenge, the consent process will include a verbal review of the consent form.

After the potential participant has read the consent form, but before she signs, the research staff will show her a sample study pill and confirm that she is willing and able to take the study pill as prescribed. Only if she is willing to commit to taking the pill will she be enrolled; otherwise, this will be recorded as a refusal of consent. Following review of the consent, the potential participant (or parent/guardian) will be asked to sign the form. If the potential participant (or parent/guardian) is unable to sign her name, she will be asked to use her thumbprint to indicate written approval. In both cases, the unaffiliated person will also sign the consent form. Both the research staff and the study participant retain signed copies of the form.

An eligible woman may refuse to participate in the trial at the time of recruitment. This will be recorded in the Screening and Recruitment Form. She may also choose to withdraw from the study at any time after enrolment. This will be recorded on the Withdrawal/Termination Form.

All research staff responsible for obtaining consent will be trained and certified in the protection of human subjects and the study-specific consent procedures. A model written informed consent form, developed according to the requirements of the U.S. Office of Research Protections (OHRP), is found in **appendix 2**. Each site may modify the model consent to conform to local standards, but the OHRP required elements must be maintained. The research sites will also be responsible for translating the consent form into the appropriate language(s) for their local context.

Global Network countries with legislation regarding the need to videotape consents will comply with the country regulations; however, this is not part of the consent form requirements. This will not be required by protocol but rather decided by each site so as to comply with local rules and regulations.

2.4.4 Masking

Both the azithromycin and placebo will be procured from the same manufacturer. The packaging will be standardized across sites and will be labeled as "Azithromycin 2 gm Placebo", with the expiration date and a unique identifier. A certificate of authenticity will likewise be provided.

Clinical and research staff as well as the women will be masked to treatment status unless there is a serious adverse event potentially related to the treatment modality that requires unmasking for safety reasons. There will be one pharmacist at each site who will monitor randomization, drug supply, and

safety. Under the instruction of the DCC, the study pharmacist will be trained and authorized to apply unmasking procedures, if concerns about randomization or participant safety are identified.

2.4.5 Randomization Procedures

Randomization of participants will be carried out to obtain a 1:1 allocation ratio between the treatment and placebo arms. Randomization will be stratified by site. A computer algorithm generated by the data coordinating center (DCC) will create the random assignment to one of the treatment arms based on randomly permuted block design with randomly varied block sizes. The block sizes will be known only by the DCC personnel. Each site will receive a lot of the study drug to be distributed sequentially at the participating health facilities which are randomizing women for the study site.

2.4.6 Monitoring before Discharge

Routine post-delivery care will be provided to participants by their clinical providers who will be masked to the study interventions. Research staff (also masked to study medications) trained in obstetric and perinatal outcomes abstraction will be responsible for collecting research data from participant medical records or directly from participants, as relevant, before discharge. Data needed to determine sepsis will include temperature (fever or hypothermia) essentially, plus one or more of heart rate (tachycardia), blood pressure (hypotension), respiratory rate (or hypoxia or distress), clinical exam (jaundice or altered mental status) and urine output (low) and a suspicion of infection by the clinical provider or research team. Maternal and neonatal outcomes will be evaluated in the hospital following the delivery (on an ongoing basis until discharge). All participants will be asked to agree to maternal/infant medical record release to abstract information for outcome assessments as part of the consent form. In addition, participants will be educated about the signs and symptoms of infection and other study outcomes and encouraged to call the research team with any concerns.

2.4.7 Monitoring after Discharge

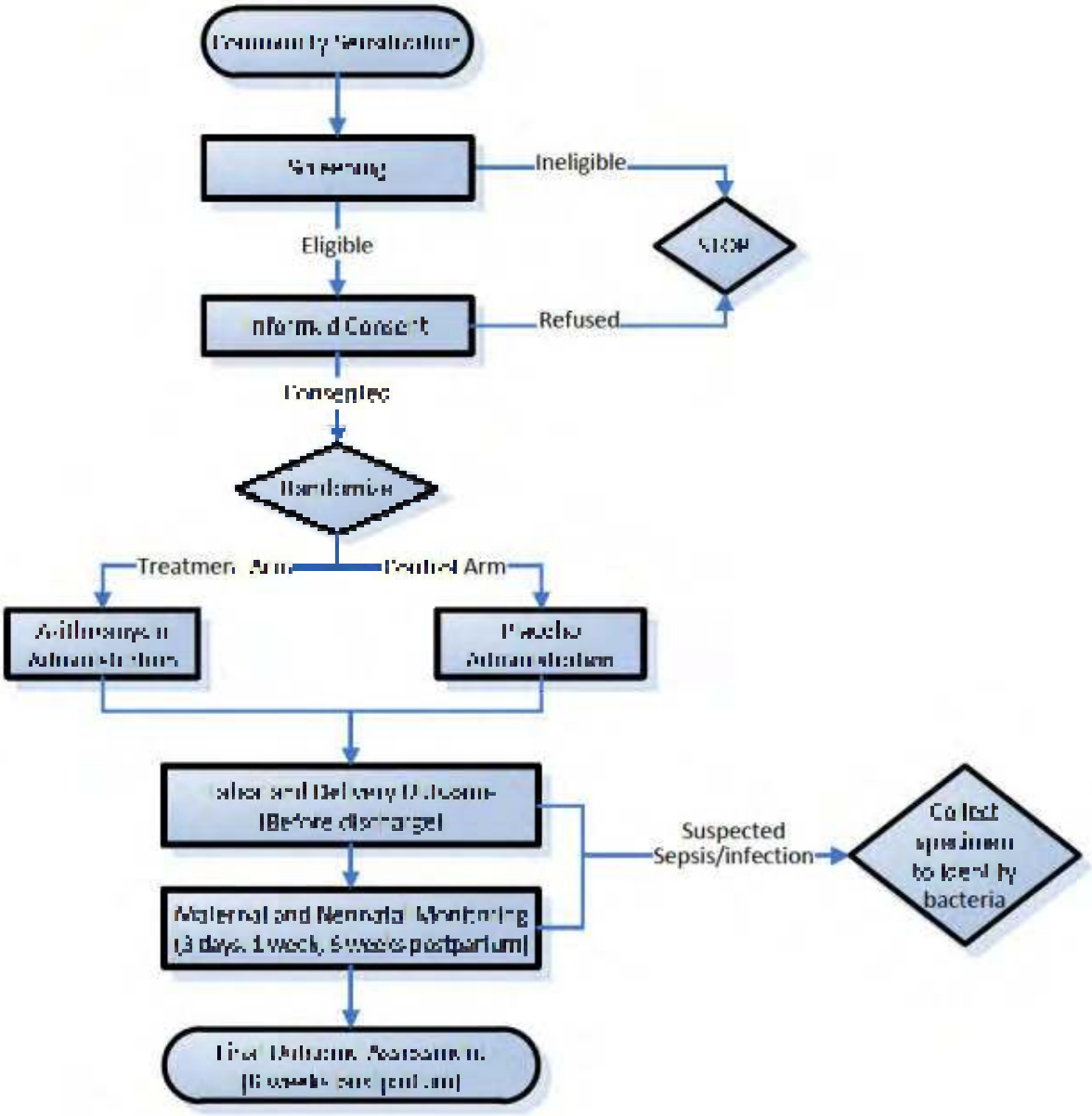
After discharge, participants will be followed at 1 and 6 weeks after birth. For participants discharged at <72 hours, a 3-day post-partum visit will also be scheduled. These study visits will be used to assess for symptoms and signs of maternal and infant infection or diagnosis and treatment of infection, as well as other study outcomes, prior to each visit. WHO criteria for infections will be used and included in the data collection forms. In the case of suspected infection, research staff will collect specimens for culture and sensitivity as feasible from relevant infections such as blood, urine, and pus from wound or skin infections or drained abscesses in order to identify individual infectious agents.

If indicated, records of unscheduled visits to any health facility prior to the routine study visits will be obtained and reviewed to assess trial study outcomes. Treating providers may also be called if clarification is needed. Based on the scheduled visits, study staff will identify any unscheduled visits or readmissions that occurred in the interim. Readmissions and related diagnoses identified during follow-up visits will be then be validated through medical record review.

2.4.8 Sequence of Study Activities

The sequence of study activities is described in **Figure 1**. A detailed schedule of study procedures is found in **Appendix 3**.

Figure 1. Flowchart of Study Activities



2.5 Primary Outcomes

The primary outcomes are

- Maternal: Incidence of maternal death or sepsis within 6 weeks [42 days] post-delivery in intervention vs. placebo group.
- Neonatal: Incidence of intrapartum/neonatal death or sepsis within 4 weeks [28 days] post-delivery in intervention vs. placebo group.

Maternal sepsis is defined per WHO as a life-threatening condition defined as organ dysfunction resulting from suspected or confirmed infection during pregnancy, childbirth, post-abortion, or postpartum period.[5] This WHO definition, endorsed by multiple global health organizations, will be

operationalized as suspected or confirmed infection based on the presence of fever (>38 C) or hypothermia (<36 C) plus one or more signs of mild to moderate organ dysfunction including tachycardia (>110bpm), low BP (<90/50mm Hg), tachypnea (>24 breaths/min), altered mental status, and reduced urinary output (<500ml/24 hours or <20 cc/hr over several hours).[9] Components of peripartum infection which will be considered in making the diagnosis of suspected or confirmed infection include clinical chorioamnionitis, endometritis, wound infections (perineal or subsequent cesarean), abdominal or pelvic abscess, mastitis/breast abscess, pyelonephritis and pneumonia as defined in Section 2.6 below.

Neonatal infection is defined as a febrile newborn with proven or possible serious bacterial infection (sBI) or pneumonia, meningitis, or urinary infection; omphalitis. Possible serious bacterial infection will be determined using WHO criteria of possible serious bacterial infection defined as fast breathing (respiratory rate ≥ 60 breaths/minute), severe chest in-drawing, fever (temperature ≥ 38 °C), hypothermia (temperature < 35.5 °C), no movement at all or movement only on stimulation, feeding poorly or not feeding at all, and/or convulsions.[10]

Centralized masked adjudication of key infection outcomes will be implemented by the DCC and investigators during the trial to standardize and enhance the reproducibility of trial results. Local site investigators will review and validate the diagnosis for all participants identified to have the primary outcomes applying pre-specified criteria. These reviews will be conducted masked to treatment group. A second investigator from a different site will review the participant's information and make a final outcome determination. If this does not agree with the determination of the local site investigator, then the adjudicating investigator will discuss with the local investigator to reach a consensus, failing which the study PIs will make the final call. This process will be coordinated by the DCC.

The individual components of these primary outcomes are also of interest and will be analyzed.

2.6 Other Maternal Outcomes

a. Chorioamnionitis: Fever (≥100.4°F/38°C on two occasions at least 30minutes apart or ≥102°F/39°C on one occasion) in addition to one or more of the following: fetal tachycardia >160bpm, maternal tachycardia>100bpm, uterine tenderness, or purulent lochia prior to delivery.
b. Endometritis: Fever (≥100.4°F/38°C on two occasions at least 30 minutes apart or ≥102°F/39°C on one occasion) in addition to one or more of uterine tenderness or purulent lochia after delivery.
c. Other infections: Wound infection refers to purulent infection (superficial or deep infection including necrotizing fasciitis) of a perineal wound or wound at a subsequent cesarean with or without fever and leading to prescription of antibiotics; abdominopelvic abscess is evidence of pus noted during open surgery, interventional aspiration or imaging; pneumonia refers to fever and clinical symptoms suggestive of lung infection including cough and tachypnea with or without radiological confirmation; pyelonephritis refers to fever, urinalysis/dip suggestive of infection and costovertebral angle tenderness with or without confirmatory urine culture).
d. Use of subsequent maternal antibiotic therapy after randomization to 6 weeks for any reason.
e. Maternal initial hospital length of stay, defined as the time of admission until initial discharge (time may vary by site).
f. Maternal readmissions within 6 weeks of delivery.
g. Maternal admission to special care units.
h. Maternal GI symptoms including nausea, vomiting, and diarrhea and other reported side effects.

2.7 Other Neonatal Outcomes

a. Neonatal initial hospital length of stay, defined as time of delivery until initial discharge (time may vary by site).
b. Neonatal readmissions within 6 weeks of delivery.
c. Neonatal admission to special care units.
d. Neonatal death due to sepsis using the Global Network algorithm for causes of death.
e. Pyloric stenosis within 6 weeks of delivery, defined as clinical suspicion based on severe vomiting leading to death or surgical intervention (pyloromyotomy) as verified from medical records with or without radiological confirmation.

2.8 Safety Monitoring

Surveillance of maternal side effects including nausea, vomiting, and diarrhea/loose stools, abdominal pain, vaginitis, and dizziness potentially associated with azithromycin will be conducted during labor and postpartum. Risks also include anaphylaxis, allergic reactions (rash), liver failure, and arrhythmias which are rare with azithromycin. Surveillance of maternal side effects potentially associated with azithromycin will be conducted during labor and postpartum. Finding suggestive of pyloric stenosis will be assessed during the follow up visits. Surveillance will also include assessment of unintended medical visits, maternal deaths, and fetal and neonatal deaths. These outcomes will be reviewed at least twice a year by the Data Monitoring Committee (DMC) appointed by NICHD.

2.9 Site Preparation

In preparation for study implementation, the site investigators will meet with local health authorities and conduct community sensitization activities to ensure that study procedures are appropriate for the local context and to encourage commitment and engagement at the facility and community level. Site preparation activities will focus on:

- Disseminating study objectives to local health authorities and other stakeholders
- Identifying and hiring study staff;
- Developing site-specific procedures for safety monitoring procedures;
- Exploring locally-acceptable methods to monitor and improve follow-up visit compliance;
- Identifying potential implementation challenges and developing culturally appropriate solutions;
- Training research staff in the implementation of the study procedures, follow-up and ascertainment of infections.

2.10 Potential Risks and Benefits to Participants

There are several potential direct and indirect benefits of this trial. In developing countries, including those of GN partners, fetal and neonatal deaths due to infections and maternal and neonatal infections are common. If intrapartum azithromycin reduces maternal and fetal/neonatal mortality or infections, many deaths could be reduced in the GN sites as well as worldwide.

Emerging data suggest that intrapartum azithromycin reduces maternal and neonatal infection. It is not known if deaths could be prevented but as infections are one of the most frequent causes of maternal and neonatal deaths, there is a possibility that mortality could be reduced.

An ongoing concern for peripartum and perinatal antibiotic prophylaxis is the selection of resistant organisms including azithromycin-resistant organisms leading to resistant infections, and there is

concern that disruption of gut and other flora (microbiome) in women and particularly in neonates may lead adverse events including increased allergic reactions, rash and childhood asthma.[32 to 36] In the trial from Gambia of a single oral dose of azithromycin during labor, higher prevalence of colonization with S. aureus azithromycin resistance observed among women and their babies four weeks after treatment had waned 12 months later and azithromycin did not induce other antibiotic resistance in S. pneumoniae or S. aureus; resistance data from actual infections were not available. There was a 7% vs. 22% prevalence of any bacteria in breast milk in those receiving azithromycin vs. placebo [4-5]. In the US trial of 2013 of adjunctive azithromycin in 2013 women who underwent unscheduled cesarean delivery, culture positive maternal infections (1.4% vs. 3.0%) and infections with at least one resistant bacterial species (1% vs. 2.4%) were significantly less frequent in the azithromycin group. Azithromycin-resistant organisms were identified in only 7 (3 vs. 4) participants. There is a paucity of data to address theoretical concerns that disturbances in the establishment of the indigenous intestinal microbiome caused by antibiotic exposure in early life or cesarean delivery, either directly or through modifications of breast microbiome, may increase risk of immune mediated and inflammatory conditions such as atopic disorders, inflammatory bowel disease and obesity later in life.[26-32] While the potential for important benefits in both the mother and infant likely outweighs the likelihood and effects of antibiotic resistance and microbiome changes, these should be monitored. In addition to monitoring resistance patterns in isolates from clinical infections, antimicrobial and microbiome surveillance of a subset of enrolled participants are included in an ancillary protocol.

3 ANALYTICAL PLAN

Baseline demographic characteristics and key clinical measures will be compared between the women in the two treatment arms using contingency table approaches for categorical variables and analysis of variance models for continuous variables.

For summaries of study data, categorical measures will be summarized in tables listing the frequency and the percentage of participants; continuous data will be summarized by presenting mean, standard deviation, median and range; and ordinal data will be summarized by only presenting median and range. P-values presented will be based on two-sided tests unless otherwise specified and generally adjusted for randomization factor of site. For most analyses, the interaction between treatment and site will be assessed and if significant, results will also be presented by site. For continuous outcomes, distributional properties will be evaluated and if required, transformations or non-parametric tests will be employed. Additional details for potential covariate adjustments in secondary analyses or handling violations of analytic method assumptions will be detailed in the statistical analysis plan.

Three key populations are of interest for study analyses:

1. The Intention to Treat (ITT) population will include all women randomized and their infants. Analyses of this cohort will be conducted based on randomized treatment.
2. The High Risk for Infection (HRI) sub-group will include all women in the ITT and their infants meeting criteria for being high risk (i.e., prolonged labor (≥18 hours) and/or rupture of membranes (≥24 hours)) at the time of randomization. Analyses of this cohort will be conducted based on randomized treatment.

3. The As Treated population will include all randomized participants that receive any study drug during the study and their infants. Analyses of this cohort will be conducted based on treatment received.

The final determination of analysis population membership will be via a masked data review prior to final study analyses in order to address any potential anomalous cases that may arise in this large efficacy study population (e.g. randomization/treatment of a woman who is discharged prior to delivery due to false labor or unresponsiveness to induction).

3.1 Statistical Analysis Plan

3.1.1 Primary Analyses

Incidence of maternal death or sepsis and intrapartum/neonatal death or sepsis will be compared between the two treatment arms using generalized linear models. These generalized linear models will be fit with each binary outcome separately as the outcome measure. Estimates of relative risk and associated 95% confidence intervals will be reported. The model will include terms for treatment and site. As randomization occurs at the pregnancy level and approximately 1-2% of pregnancies are anticipated to be multiple gestations, models for neonatal outcomes will account for correlation among multiples assuming an exchangeable covariance structure. For the two primary outcomes, these analyses will be conducted using the ITT population and the p-values associated with the treatment term will be used to formally test each of the two primary hypotheses at the alpha = 0.05 level.

As secondary analyses of the primary outcomes, assuming an overall treatment effect is observed, the models will be run including region (Africa, Latin America, or Asia) and a treatment by region interaction term. If the interaction term has a p<0.1, then effects will be reported by region with treatment effect within region tested at the 0.025 level.

Additional exploratory models will also be run including individually: 1) a treatment by site interaction term, 2) any other antibiotic use during labor (yes or no) and its interaction with treatment, and 3) mode of delivery (cesarean or vaginal) and its interaction with treatment. If the interaction term for any of these models has a p<0.1, then effects will also be reported by the relevant subgroups. These exploratory secondary models will also include any demographic or clinical variables found to differ significantly between the treatment arms in the preliminary analyses described above.

From each final model, estimates of relative risk associated with treatment will be obtained including unadjusted estimates of risk from the primary models as well as estimates of risk adjusted for potential confounders from the secondary analyses.

3.1.2 Secondary Analyses – Women at High Risk for Infection Cohort

The major secondary aim is assessing the two primary outcomes (i.e. incidence of maternal death or sepsis and incidence of intrapartum/neonatal death or sepsis) in the women at high risk for infection cohort. These analyses will be contingent on an analysis assessing if the treatment effect differs between the HR cohort vs. non high risk women where non high risk women comprise all women and their infants in the ITT population that delivered prior to meeting criteria for high risk (i.e. they delivered after <13 hours of labor and <8 hours post-rupture of membranes). Specifically, the model for the primary analysis of both the maternal and neonatal primary outcomes will be run including a treatment by risk status interaction term and excluding any data from individuals that meet high risk criteria after

randomization. If the p-value for that interaction is ≤ 0.10 for either the maternal or neonatal outcome, then the HR cohort analyses will be presented.

The exclusion of data from individuals meeting high risk criteria between randomization and delivery is intended to provide the most distinct groups regarding the HR risk cohort to non-high risk women comparison. As this exclusion is based on a post randomization event, sensitivity analyses will be conducted to examine any treatment group differences in meeting high risk criteria post randomization and if there is a difference, to determine the potential magnitude of impact this difference has on treatment effect. An exploratory analysis will also be completed that assesses if there is a difference in treatment effect between women randomized prior to high risk classification vs. those randomized after high risk classification.

3.1.3 Secondary Analyses – Other Secondary Outcomes

Other maternal and neonatal binary outcomes including: the individual components of the primary outcomes, neonatal deaths due to sepsis, maternal infections (clinical chorioamnionitis, endometritis, wound infections (perineal or subsequent cesarean), pyelonephritis and pneumonia), use of subsequent maternal antibiotic therapy, pyloric stenosis and occurrences of maternal or neonatal readmission or admission into special care unit will be analyzed using the approaches detailed in **Section 3.1.1** for the ITT population and approaches detailed in **Section 3.1.2** for the HR cohort. A similar process with generalized linear models employing an appropriate link function will be used to analyze the outcomes of maternal and neonatal initial hospital length of stay.

Binary safety outcomes, e.g. nausea, vomiting, and diarrhea, will also be analyzed using the approaches detailed in **Section 3.1.1**. These analyses will be conducted using the As Treated population.

3.2 Sample Size

3.2.1 Sample Size for Primary Outcome

Sample size estimates were generated to evaluate the potential benefits of peripartum prophylactic azithromycin to reduce the risk of adverse maternal and neonatal outcomes in two population cohorts of women in low and low-middle income settings. The first population of interest comprises all women delivering in facilities (overall).

Power calculations for the study in the overall study population were generated for two primary outcome measures, one being the risk of maternal death or sepsis among women in the target population and the other being intrapartum/neonatal death or sepsis in infants delivered by women in the target population. For each of these outcome measures estimates of the required sample size needed to detect a risk reduction of 20%, 25%, and 30% were generated for power of 0.8, 0.85, and 0.9. The risk of sepsis or maternal death was assumed to be 3%. That number is slightly higher than the current risk in the Global Network's population, which is slightly less than 3%. However, we anticipate that with active surveillance rather than passive reporting based on the new WHO definition of maternal sepsis (designed to capture more cases of sepsis), the risk will be at least 3%. For the neonatal outcome, the underlying risk of the combined outcome of intrapartum stillbirth, neonatal death, or sepsis was assumed to be 3%. This estimate was based on recent data from the Global Network indicating that the risk of intrapartum stillbirth is approximately 1.5% and the risk of neonatal death during the first 28 days

after delivery is 2.3% we assumed that the risk of sepsis not resulting in death is approximately 4%. The resulting required evaluable sample sizes are shown in Table 1 below:

Table 1. Sample Sizes for the OverallPopulation, Alpha=0.05

		Evaluable Sample Size per Arm		
Baseline Risk	Risk Reduction	Power=0.80	Power=0.85	Power=0.90
3%	20%	11455	13103	15334
3%	25%	7123	8259	9648
3%	30%	4815	5508	6446
8%	20%	4066	4685	5483
8%	25%	2564	2921	3419
8%	30%	1727	1975	2311

The sample sizes shown above assume that the hypothesis test of interest is for the overall population and that the Type 1 error is controlled at the neonatal and maternal hypothesis level via testing each arm at an alpha = 0.05 level. Interest has been expressed for the overall study for being able to test the neonatal risk separately in south Asia and sub-Saharan Africa. Controlling the Type I error rate at the 0.025 level for each of those two areas within this sub-analysis of neonatal risk will be conducted to avoid multiple comparison concerns. The resulting sample sizes for that comparison are shown in Table 2 below. Note that this sample size would be the size required separately for the African and Asian sites. It is planned that each site will enrol approximately equal number of participants. As such, approximately 97.3% of randomized mothers will be from sub-Saharan Africa and 97% will be from Asia. This planned enrollment distribution is approximately equivalent to the rates of in-facility deliveries observed in the Global Network registry database. Specifically, approximately a third of the facility deliveries are conducted in sub-Saharan Africa and between 45% and 50% of the facility deliveries are conducted in Asia. These estimates are also consistent with the enrollment rates for the ASPIRIN study that is currently being conducted at these sites. Therefore, to get the total study sample size required, the numbers in the table would need to be multiplied by 3 to achieve reasonable power for the African site.

Table 2. Sample Sizes Within Region, Alpha=0.025

		Evaluable Sample Size per Arm		
Baseline Risk	Risk Reduction	Power=0.80	Power=0.85	Power=0.90
3%	20%	4961	5607	6477
3%	25%	3099	3496	4038
8%	30%	2091	2363	2729

Given the above information, we propose a sample size of 34,000 participants for the overall study. For the primary neonatal outcome of interest of intrapartum/neonatal sepsis or death, assuming that the loss to follow up will be in the 2% to 3% range (consistent with the current ASPIRIN trial and the Global Network Maternal and Newborn Health registry), this sample size will be sufficient to provide 90% power to detect a 25% reduction in neonatal mortality and sepsis in the sub Saharan African region and will provide 80% power to detect a 20% reduction in Asia. For the primary maternal outcome of maternal death or sepsis, the sample size will provide 90% power to detect a 20% reduction from 8% in the combination aggregated across all study sites.

3.2.2 Sample Size for High-Risk Women

The second population of interest comprises the cohort of high-risk population of women delivering in facilities with high risk being defined as term and preterm pregnant women who experience prolonged labor or prolonged membrane rupture. As the analysis of the high-risk cohort is contingent upon observing a difference in treatment effect for maternal outcomes in high risk women compared to low risk women (i.e. interaction term p-value < 0.1), additional sample size estimates were generated separately for the high-risk cohort.

The primary objective of the higher risk component of the study is to test the effectiveness of a single oral dose of intrapartum azithromycin prophylaxis compared to placebo (all receive usual care) in reducing the risk of maternal sepsis or death in high risk laboring women. To estimate the sample size required for this component of the study, we assumed conservatively that the underlying risk of the combined outcome in the target population is 6%. Comparable to the other study estimates of the required sample size needed to detect a risk reduction of 20%, 25%, and 30% were generated for power of 0.8, 0.85, and 0.9. Because the interest for this study is in testing the hypothesis overall rather than by region, the estimates were generated using an alpha of 0.05. The results of these calculations are shown in Table 3 below.

Table 3. Sample Sizes for the High-Risk Cohort, Alpha=0.05

Baseline risk	Risk Reduction	Evaluable Sample Size per Arm		
		Power=0.80	Power=0.85	Power=0.90
6%	20%	5268	6369	7852
6%	25%	3470	3967	4644
6%	30%	2344	2681	3138

Because a risk reduction of at least 30% is expected in this population, we propose a sample size for this HR cohort of 5,500 women. That sample size will be sufficient to detect a 30% risk reduction with a power of 0.85 with an assumed 2% to 3% loss to follow-up. Assuming that 20% of the women are at high risk, the overall study sample size of 34,000 should allow for sufficient enrollment into the HR cohort.

3.3 Available Population

There are no competing protocols ongoing in the GN. Assuming conservatively that 50% of women in labor (90,000 facility births per year) meet eligibility criteria for entry and are enrolled in the trial, approximately 15,000 women/infant dyad will be enrolled per year.

To reach the enrollment target of 34,000, each study site will aim to recruit an equal number of study participants (n=4,250 per site); however, recruitment will be monitored and if a site does not meet targets, adjustments may be made. No site will be permitted to recruit more than 20% of the overall study sample size.

Based on study data in GN data, we anticipate that the target of 5,500 higher risk women will be enrolled during the trial. However, through ongoing monitoring, the DCC will assess the number of women enrolled in the "high-risk" group and may modify target enrollment as needed to ensure at least 5,500 higher risk women are enrolled.

3.4 Projected Recruitment Time

The projected study timeline is 36 months or less. This includes the following:

- 0-6 months: Finalize protocol, forms. Obtain approvals, train staff, and obtain/ship study drug/placebo to sites.
- 7-31 months: Enroll participants (exact period of enrollment may vary by site)
- 32-36 months: Complete follow-up; data cleaning and primary analyses.

3.5 Study Monitoring Plan

3.5.1 Reporting Serious Adverse Events

Serious Adverse events (SAEs) will be monitored continuously using a special form that will be required for any event that meets the following criteria:

- Results in neonatal/fetal or maternal death;
- Is life-threatening;
- Requires hospitalization or prolongs existing hospitalization;
- Results in persistent or significant disability or incapacity;
- Suspicion of pyloric stenosis within 6 weeks (prolonged vomiting leading to death or surgery)
- Any other serious or unexpected adverse event that the study investigator(s) feels should be reported.

The occurrence of any of these events will trigger completion of the Serious Adverse Events Form.

3.5.2 Method and Timing for Reporting Serious Adverse Events

The Senior Foreign Investigator (SFI) must report the following SAEs by emailing or faxing a copy of the form to RTI as follows:

Within 48 hours of SFI's notification of the event:

- All deaths (maternal, intrapartum stillbirths, neonatal)
- All SAEs with a definite or suspected/probable relationship to the intervention

Within 7 days of SFI's notification of the event:

- All life threatening events;
- All SAEs considered to have a probable or possible relationship to the intervention;
- All emailed or faxed forms should also be entered into the DMS and transmitted within 7 days as a back up to ensure no SAE is missed.

Additional reporting procedures include:

- RTI will forward all SAEs to the US based Principal Investigator (PI) and NIH for further assessment of relationship to study intervention. The PI and SFI will be responsible for reporting to their respective IRB and other regulatory authorities per their institutional policy.
- RTI will be responsible for reporting SAEs to the DMC biannually at a minimum. The frequency of reporting to the DMC may be increased if the reported events or interim data reviews by the DMC indicate that more frequent safety monitoring is needed.

- Any SAE considered unrelated to the intervention is not required to be reported in an expedited manner. These events should be entered into the data management system and transmitted per routine procedures.

3.5.3 Data Monitoring Plan and Stopping Rules

All the Global Network sites will report data to the Global Network Data Coordinating Center, located at RTI International. The data will be used to evaluate protocol adherence and site performance (e.g., recruitment, loss to follow-up, data quality). The DCC will provide standardized progress reports to NICHD and the site investigators on a monthly basis to monitor outcome variables and adverse events.

Oversight of the trial will be handled by two principal groups with different focuses:

1. **Protocol-focused Steering Committee (SC):** The SC is comprised of the Central Study Team from the University of Alabama at Birmingham and the University of Zambia, NICHD, the DCC, and investigators from each of the participating sites (see Azithromycin Investigators on page 8). The Central Study Team, with assistance from NICHD and the DCC, will have primary responsibility for overall study design, development of study materials and procedures, and oversight of study implementation. They will review via conference call bi-weekly to monitor study progress and ensure proper implementation of the trial. The Site Investigators will be responsible for providing guidance on study design, developing site-specific implementation plans, ensuring study staff are properly trained, and providing oversight of the study at the site level. The SC will convene via conference call at least once per quarter and will meet in person twice a year to discuss study design and implementation issues. Members of the Central Study team, NICHD, and RTI will also conduct site visits, as the budget allows, to bolster enthusiasm, provide hands-on training and education to the participating staff, and address site-specific issues, if any.
2. **Data Monitoring Committee (DMC):** The DMC, a standing group that monitors all NICHD-funded Global Network studies, will be responsible for ensuring safe and ethical treatment of study participants through monitoring of the study. The membership will include, at a minimum, a statistician, obstetrician, pediatrician, and an expert in international health. The DMC designated by NICHD will review the data collected at approximate 6-month intervals throughout the course of the study. The DMC reports, which are prepared by the Data coordinating center, will include information on study enrollment rates and participant progress through the study, participant compliance with protocol-specified treatment regimens, protocol violations, adverse events, and efficacy outcomes. The focus of the DMC review will be on monitoring participant safety and study progress/futility. Data on treatment effectiveness will also be presented to frame the DMC discussions on safety and futility. Additionally, one formal interim analyses of efficacy is planned as detailed in **Section 3.5.4**. The DMC will be charged with monitoring adverse events and side effects from azithromycin. All known associated side effects and specific obstetric, fetal, or neonatal concerns will be considered reportable to the DMC. The study will be reviewed by the DMC bi-annually at a minimum but may be reviewed more frequently if concerns are raised about participant safety or about adequate process of the study.

3.5.4 Interim/Adverse Event Monitoring Plan

The DMC designated by NICHD will complete safety reviews of the data bi-annually at minimum during the intervention phase or as often as they decide. Safety reports will be reviewed internally by the DCC quarterly and the DMC chair will be notified if any potential safety signals are identified to allow for

more frequent DMC monitoring if needed. Adverse events will be recorded and submitted to the DCC (and IRBs) who will report these cumulative masked data to the DMC in the safety reviews. The DMC recommendations about study continuation will be distributed to the IRBs. The DMC will forward their monitoring activities to the project officer representing the NICHD.

Additionally, one formal interim analysis of efficacy and futility will be conducted during the study. Interim analyses will be conducted assessing both the primary maternal and neonatal outcomes use the primary analytic approach detailed in **Section 3.1.1 and 3.1.2**. As the maternal and neonatal hypotheses are both of equal importance as well as the treatment effect within the high-risk cohort, the DMC will not be able to recommend early termination for efficacy unless significance is observed for both outcomes in all comers and the direction and magnitude of effect in the high-risk cohort is consistent with the effect observed in all comers. Cut-off p-values for testing for efficacy at this interim analysis will be determined based on a correction for multiple comparisons to ensure an overall alpha of 0.05. The futility assessment will be based on an analysis of conditional power. The details of the timing of the interim analysis as well as the approaches for correcting for multiplicity and analyzing conditional power will be determined in collaboration with the DMC prior to initiation of study enrollment. Safety and efficacy of the azithromycin will be reviewed and compared with data from the placebo group according to a data center plan. The primary outcome rate will be calculated, and the data center will develop guidelines for interim analysis decision making (e.g. the O'Brien-Fleming boundary table).

3.5.5 Risks/Benefits

Based on the preliminary data, there are few risks to this intervention especially given the single oral dose. Severe risks include anaphylaxis and allergic reactions (rash) and liver failure which are rare with azithromycin based on the product insert and our long history of use of prophylactic azithromycin at UAB since 2003. In 2013, the FDA issued an advisory regarding concerns about potential for rare life-threatening arrhythmias with azithromycin use particularly among those with prevailing cardiovascular risk. To minimize the risk of life-threatening side effects, those with arrythmia, known history of cardiomyopathy, or are known allergy to azithromycin will be excluded. With single 1-2gram doses, gastrointestinal symptoms (nausea 5-18%, diarrhea/loose stools 7-14%, abdominal pain 5-7%, vomiting 2-7%, and dyspepsia 3%) as well as vaginitis 2% and dizziness (1%) were the most commonly reported side effects. These side effects will be monitored.

3.6 Quality Control

3.6.1 Training

All study personnel must participate in training on the proper implementation of study procedures and the ethics of conducting research with human subjects before beginning any research activity. The SPI and project coordinator will ensure that all study personnel receive the appropriate training and obtain the required certification. RTI will be responsible for developing a certification test. The SPI and project manager will be responsible for overseeing the certification process.

3.6.2 Study Monitoring

Major monitoring responsibilities of the PI/SPI, assisted by the country coordinator, are (1) performing proper IRB approval; (2) monitoring delivery of the study intervention; (3) assessing and evaluating quality of study implementation; (4) ensuring compliance with the intervention, including proper randomization; (5) evaluating accuracy, precision, and completeness of data collected, entered, and

represented, along with the DCC; (6) ensuring that all personnel are fulfilling their obligations; (7) maintaining staff morale and enthusiasm; (8) maintaining communication and handling ad hoc problems; (9) ensuring interim consistency; and (10) proposing improvements to monitoring activities.

NICHD and the DCC staff will conduct site visits as needed. These visits will include review of individual participant records, including supporting data, to ensure protection of study participants, compliance with the protocol, and accuracy and completeness of records. The SPI/PI will make study documents (e.g., logbooks, data forms, staff training certificates) and pertinent hospital/clinic records readily available for inspection by the local IRB, site monitors, and the NICHD for confirmation of the study data.

3.6.3 Drug Quality Assurance and Monitoring

The study drug manufacturer will have a Good Manufacturing Practices designation verified by the FDA and a certificate of authenticity will be provided. Each site will adapt best practice guidelines for drug shipment and storage to the needs and infrastructure of their local environment. Study staff will be trained in on the drug shipment and storage plan to ensure that best practices are maintained at all time. Additionally, participants will receive detailed instruction on proper storage of the study drug at home. Drug stability information will be maintained throughout the study. For quality assurance, a sample of pills from each site will be randomly selected and tested for bioavailability at multiple time points during the study period. A sample from each batch will be tested.

3.6.4 Plan for Sustaining Intervention

We will plan to present abstracts to reputable international obstetric meetings (e.g. SMFM, ACOG or FIGO) and manuscripts within 3-6 months of completion of the primary data collection to high impact journals such as the New England Journal of Medicine, JAMA, or the Lancet. If the results are positive, we will facilitate the change in practice at participating sites and also approach the WHO to instigate guideline updates to reflect the study findings.

4 Data Management Procedures

Data will be collected both prospectively and from existing medical records, using hard copy forms or Android Tablets. Regardless of data capture methodology, all data will be kept confidential. Each participant will be assigned a unique study ID which will be used to identify the participant. Only the screening log will contain the name (which is not transmitted). If hard copy forms are used, they will be retained in a secure location for possible editing or queries at the central data entry site. Data will be entered into computers using the Data Management System (DMS) developed by RTI and the assigned study number. The DMS will also allow site staff to produce project reports and backup the study database. Electronic data will be transferred from each data management computer to a single Research Unit Data Center in near-real-time, creating a cumulative data repository. At least once a week, data will be transmitted from the Research Unit Data Center to the DCC at RTI, where the central database will be located. The DCC will conduct training on data collection procedures and the DMS system, as needed.

Precision and accuracy of actual data collected will be checked by chart review (random 5%) and internal procedures using the computer program. Monthly audits and incomplete data reports will be performed by a review team consisting of at least the SPI and country coordinator. Data editing and error resolution will be performed monthly. In addition, a sample of participants will be visited to confirm participation,

with procedures determined per site. These activities will be shared between the site and the DCC. The timing of data collection is found in the schedule of study procedures (**Appendix 9**).

4.1 Data Forms

The following forms will be used for this study:

Form Name	Purpose	Key Data Elements	Data Source
Screening Log	To track screening and enrollment	Contact information, screening and enrollment date, status	Participant interview/report
Screening and Enrollment	To determine eligibility and record consent status	Screening date, review and confirmation of inclusion/exclusion criteria, consent status/date.	Participant interview/report, clinical assessment, provider report, medical records
Randomization Form	To confirm eligibility and track randomization	Eligibility confirmation, randomization date/time, drug administration date/time, any problems with drug administration (e.g., vomiting, dropped med, etc.).	Study records, participant interview and observation
Maternal Data Form	To collect additional maternal information	• Demographic and baseline clinical data: admission date/time, EDD, GA, age, height, weight, pregnancy and medical history, etc. • Events during labor: timing of onset of labor, prolonged labor, premature rupture of membranes, date/time/type of membrane rupture, type of labor, indication for induction (if applicable), vital signs during labor (temp, HR, RR, BP), complications, antibiotic use after randomization, etc. • Delivery information: delivery date/time, delivery type, cesarean birth information (if applicable), general complications during/after delivery, wound complications, antibiotic treatment during/after delivery, other infections diagnosed post-randomization, discharge information, etc.	Participant interview/report, provider report, medical records
Neonatal Data Form	To collect information about the infant directly after delivery	• Sex • Birthweight • Delivery outcome (live or stillbirth) • Complications: sepsis/infection, apnea, meconium stained amniotic fluid, tachypnea, feeding difficulties, hepatomegaly, splenomegaly, petechiae, jaundice, allergic reaction. • Type of feeding • Discharge information: date/time, status (discharged, transferred, died)	Participant interview/report, provider report, medical records
Follow-up	To collect maternal and infant health status during follow-up visits at 3 days, 1 week, and 6 weeks after delivery.	• Timing follow up • Maternal and infant status since discharge: general status, symptoms, indication of infection, clinic visits, hospitalizations, antibiotic use	Participant interview/report, provider report, clinical exam, medical records
Unscheduled	To collect information	Reason for medical visit, details about medical	Participant interview/report,

Form Name	Purpose	Key Data Elements	Data Source
Medical Visit	about clinical events reported during follow up visits	visit	provider report, medical records
Specimen Collection and Result Form	To track specimen collection when there is indication of maternal or infant infection	Date/time of specimen collection, reason for collection, location of wound/infection; tracking information for shipping/storing specimen, results	Study documentation if collected and/or tested by study, medical records if collected and/or tested by health facility
Serious Adverse Events	To record fatal, life-threatening, or any other serious, unexpected adverse event	Date/time of event, date/time of resolution, nature of adverse event, management of adverse event, attribution to study (yes/no).	Participant interview/report, provider report, medical records
Final Study Status	To document final study status	Final study status (e.g., completion, withdrawal, lost-to-follow-up), Date of final study status. If withdrawal, provide reason.	Participant report, medical records
Protocol Deviation	To record protocol deviations and corrective actions	Date and nature of deviation/violation, corrective action	Participant report, study records, medical records
Outcome Adjudication	To validate cases of infection using standard study definitions	Primary and secondary outcomes	Study documentation, provider reports/interviews, medical records

5 REFERENCES

1. World Health Organization. (2015). WHO recommendations for the prevention and treatment of maternal peripartum infections. Retrieved August 22, 2018, from http://www.who.int/reproductivehealth/publications/maternal_perinatal_health/peripartum-infections-guidelines
2. Liu, L., Oza, S., Hogan, D., Perin, J., Rudan, I., Lawn, J. E., ... Black, R. E. (2015). Global, regional, and national causes of child mortality in 2000-13, with projections to inform post-2015 priorities: an updated systematic review. *The Lancet*, *385*(9966), 430-440.
3. Tshefu, A., Lokangaka, A., Ngaima, S., Engmann, C., Esamai, F., Gisore, P., ... African Neonatal Sepsis Trial (ANISTAT) group. (2015). Simplified antibiotic regimens compared with injectable procaine benzylpenicillin plus gentamicin for treatment of neonates and young infants with clinical signs of possible serious bacterial infection when referral is not possible: a randomised, non-blind, equivalence trial. *Lancet*, *385*(9979), 1767-1776.
4. Saha, S. K., Schrag, S. J., Ahmed, A. S., Shahrin, L., Islam, M., Quasem, I., Katz, D. E., ... Projahnmo Study Group in Bangladesh. (2015). Safety and efficacy of alternative antibiotic regimens compared with 7 day injectable procaine benzylpenicillin and gentamicin for outpatient treatment of neonates and young infants with clinical signs of severe infection when referral is not possible: a randomised, open-label, equivalence trial. *Lancet Global Health*, *3*(5), e279-287.
5. Ali, F., Nisar, I., Tikmani, S. S., Rahim, R., Shahzad, S., Jehan, F., ... Zaidi, A. K. (2017). Simplified antibiotic regimens for treatment of clinical severe infection in the outpatient setting when

referral is not possible for young infants in Pakistan (Simplified Antibiotic Therapy Trial [SATT]): a randomised, open-label, equivalence trial. *Lancet Global Health, 5*(2), e177-e188.

6. Zaidi, A. K., Tikmani, S. S., Sultana, S., Baloch, B., Kazi, M., Rehman, H., . . . Coutsoudis, S. (2013). Simplified antibiotic regimens for the management of clinically diagnosed severe infections in newborns and young infants in first-level facilities in Karachi, Pakistan: study design for an outpatient randomized controlled equivalence trial. *Pediatric Infectious Disease Journal, 32* Suppl 2(Suppl 1), S19-25. https://doi.org/10.1097/INF.0b013e31829f7aa
7. Gibbs, R. S. (1980). Clinical risk factors for puerperal infection. *Obstetrics and Gynecology, 55*(5 Suppl), 178S-184S.
8. World Health Organization. (2015). WHO Statement on Caesarean Section Rates. Retrieved August 22, 2018, from http://www.who.int/reproductivehealth/publications/maternal_perinatal_health/cs-statement.html
9. Mackeen, A. D., Packard, R. E., Ota, E., Berghella, V., & Baxter, J. K. (2014). Timing of intravenous prophylactic antibiotics for preventing postpartum infectious morbidity in women undergoing cesarean delivery. *Cochrane Database of Systematic Reviews, 12*(12), CD009516. https://doi.org/10.1002/14651858.CD009516.pub2
10. Smaill, F. M., & Grivell, R. M. (2014). Antibiotic prophylaxis versus no prophylaxis for preventing infection after cesarean section. *Cochrane Database of Systematic Reviews, 10*, CD007482. https://doi.org/10.1002/14651858.CD007482.pub3
11. Gyte, G. M. L., Dou, L. X., & Vazquez, J. C. (2014). Different classes of antibiotics given to women routinely for preventing infection at caesarean section. *Cochrane Database of Systematic Reviews, 7*(11). https://doi.org/10.1002/14651858.CD006726.pub2
12. Tita, A. T. N., Rouse, D. J., Blackwell, S., Sacco, G. R., Spong, C. Y., & Andrews, W. W. (2008). Evolving concepts in antibiotic prophylaxis for cesarean delivery: a systematic review. *Obstetrics and Gynecology, 113*(3), 675-682.
13. Tita ATN, S. J., Roggess K, et al. (2016). Adjunctive azithromycin prophylaxis for cesarean delivery. *New England Journal of Medicine, 375*, 1231-1241.
14. Oluwalana, C., Camara, B., Bottomley, C., Goodier, S., Bojang, A., Kampmann, B., . . . Roca, A. (2017). Azithromycin in labor lowers clinical infections in mothers and newborns: a double-blind trial. *Pediatrics, 139*(2). https://doi.org/10.1542/peds.2016-2281
15. World Health Organization. (2017). Statement on maternal sepsis. Retrieved August 22, 2018, from http://www.who.int/reproductivehealth/publications/maternal_perinatal_health/maternal-sepsis-statement.html
16. Reinhart K, D. R., Kissoon N, Machado FR, Schachter RD, Finfer S, . . . (2017). Recognizing sepsis as a global health priority - a WHO resolution. *New England Journal of Medicine, 377*(5), 414-417.
17. van Dillen, J., Zwart, J., Schutte, J., & van Roosmalen, J. (2010). Maternal sepsis: epidemiology, etiology and outcome. *Current Opinion in Infectious Diseases, 23*(3), 249-254. https://doi.org/10.1097/QCO.0b013e328339e25c
18. Tita A, O. C., Bojang A, Camara B, Kampmann B, Bailey R, Dierdan A, Bottomley C, D'Alessandro U. (2016). Oral azithromycin given during labour decreases bacterial carriage in the mothers and their offspring: a double blind randomised trial. *Clin Microbiol Infect., 22*(6), e1-9.
19. Hansen, T. M., Kilgore, M., Seydewitz, J. M., Andrews, W. W., & Tita, A. T. N. (2017). Economic evaluation of adjunctive azithromycin prophylaxis for cesarean delivery. *Obstetrics and Gynecology, 130*(2), 328-334. https://doi.org/10.1097/AOG.0000000000002125
20. Andrews, W. W., Hauth, J. C., Cliver, S. P., Savage, K., & Goldenberg, R. L. (2003). Randomized clinical trial of extended spectrum antibiotic prophylaxis with coverage for Ureaplasma

urealyticum to reduce post-cesarean delivery endometritis. *Obstetrics and Gynecology, 107*(6), 1283-1289.

21. Tita AT, Hall J, Grimes A, Owen J, Stamm AM, Andrews WW. . (2008). Decreasing incidence of postcesarean endometritis with expanded-spectrum antibiotic prophylaxis. *Obstetrics and Gynecology, 111*(1), 51-56.
22. Tita, A. T., Owen, J., Stamm, A., Hauth, J. C., & Andrews, W. W. (2009). Impact of extended-spectrum antibiotic prophylaxis on incidence of post cesarean surgical wound infection. *American Journal of Obstetrics and Gynecology, 199*(3), 303.
23. Watts, D. H., Eschenbach, D. A., & Kenny, G. E. (1989). Early postpartum endometritis: the role of bacteria, genital mycoplasmas, and Chlamydia trachomatis. *Obstetrics and Gynecology, 73*(1), 52-60.
24. Hoyme, U. B., Kviat, N., & Eschenbach, D. A. (1986). Microbiology and treatment of late postpartum endometritis. *Obstetrics and Gynecology, 68*(2), 226-232.
25. Emmons, S. L., Krohn, M., Jackson, M., & Eschenbach, D. A. (1988). Development of wound infections among women undergoing cesarean-section. *Obstetrics and Gynecology, 72*(4), 559-564.
26. Roberts, S., Maccato, M., Faro, S., & Pinell, P. (1993). The microbiology of post-cesarean wound morbidity. *Obstetrics and Gynecology, 82*(3), 389-396.
27. Rosene, K., Eschenbach, D. A., Tompkins, L. S., Kenny, G. E., & Watkins, H. (1986). Polymicrobial early postpartum endometritis with facultative and anaerobic bacteria, genital mycoplasmas, and Chlamydia trachomatis: treatment with piperacillin or cefoxitin. *Journal of Infectious Diseases, 153*(6), 1028-1037.
28. Andrews, W. W., Sheri, S. R., Goldenberg, R. L., Cliver, S. P., Hauth, J. C., & Cassell, G. H. (1995). Association of post-cesarean delivery endometritis with colonization of the chorion by Ureaplasma urealyticum. *Obstetrics and Gynecology, 85*(4), 509-514. https://doi.org/10.1016/0029-7844(94)00436-H
29. Keski-Nisula, L., Kirkinen, P., Katila, M. L., Ollikainen, M., Suonio, S., & Saarikoski, S. (1997). Amniotic fluid U. urealyticum colonization: significance for maternal peripartal infections at term. *American Journal of Perinatology, 14*(3), 151-156.
30. Yoon, B. H., Romero, R., Park, J. S., Chang, J. W., Kim, Y. A., Kim, J. C., & Kim, K. S. (1998). Microbial invasion of the amniotic cavity with Ureaplasma urealyticum is associated with a robust host response in fetal, amniotic, and maternal compartments. *American Journal of Obstetrics and Gynecology, 179*(5), 1254-1260. https://doi.org/10.1016/S0002-9378(98)70142-5
31. Swedyn, W. I. (2005). Prophylactic antibiotics in obstetrics-gynecology: a current asset, a future liability? *Expert Review of Anti-Infective Therapy, 4*(6), 957-964. https://doi.org/10.1586/14787210.4.6.957
32. World Health Organization. (2015). Guideline: Managing Possible Serious Bacterial Infection in Young Infants When Referral is not Feasible. Retrieved August 22, 2018, from https://apps.who.int/iris/bitstream/handle/10665/181426/9789241508268_eng.pdf;jsessionid=F7181176B6D1C896CF2544DDF53F55A7?sequence=1
33. Sutton, A. L., Acosta, E. P., Larson, K. B., Kerstner-Wood, C. D., Tita, A. T., & Biggio, J. R. (2015). Perinatal pharmacokinetics of azithromycin for cesarean prophylaxis. *American Journal of Obstetrics and Gynecology, 212*(6), 812.
34. Eberly, M. D., Eide, M. B., Thompson, J. L., & Nylund, C. M. (2015). Azithromycin in Early Infancy and Pyloric Stenosis. *Pediatrics, 135*(3), 483. https://doi.org/10.1542/peds.2014-2026
35. Ray, W. A., Murray, K. T., Hall, K., Arbogast, P. G., & Stein, C. M. (2012). Azithromycin and the risk of cardiovascular death. *New England Journal of Medicine, 366*(20), 1881-1890.

36. Svanström, H., Pasternak, B., & Hviid, A. (2013). Use of azithromycin and death from cardiovascular causes. *New England Journal of Medicine, 368*(18), 1704-1701. https://doi.org/10.1056/NEJMoa1300799
37. Hoffman, M. K., Goudar, S. S., Kodkany, B. S., Goco, N., Koso-Thomas, M., Miodovnik, M., . . . Derman, R. J. (2017). A description of the methods of the aspirin supplementation for pregnancy indicated risk reduction in nulliparas (ASPIRIN) study. *BMC Pregnancy and Childbirth, 17*(1), 131. https://doi.org/10.1186/s12884-017-1312-x
38. Goldenberg, R. L., Saleem, S., Ali, S., Moore, J. L., Lokangako, A., Tshefu, A., . . . McClure, E. M. (2017). Maternal near miss in low-resource areas. *International Journal of Gynaecology and Obstetrics, 138*(3), 347-355. https://doi.org/10.1002/ijgo.12219
39. Bonet, M., Souza, J. P., Abalos, E., Fawole, B., Knight, M., Kouanda, S., . . . Metin Gulmezoglu, A. (2018). The global maternal sepsis study and awareness campaign (GLOSS): study protocol. *Reprod Health, 15*(1), 16. https://doi.org/10.1186/s12978-017-0437-8

APPENDIX 1. DESCRIPTION OF PARTICIPATING GLOBAL NETWORK SITES

The Global Network for Women's and Children's Health Research (GN) was created as a private-public partnership between the U.S. National Institutes of Health (NIH) and the Bill and Melinda Gates Foundation in response to the alarming rates of morbidity and mortality in women and children and the lack of research expertise and infrastructure in the developing world. Its mission is to expand scientific knowledge, develop research infrastructures, and improve health outcomes by building research partnerships to conduct research on feasible, cost-effective, sustainable interventions to address the major causes of perinatal morbidity and mortality of women and children in the developing world. It is currently funded only by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD).

The current configuration of the GN is comprised of eight multidisciplinary research sites in seven developing countries (Bangladesh, Democratic Republic of Congo, Guatemala, India, Kenya, Pakistan, and Zambia), each with an established collaboration between an institution in the United States and one or more in the developing country. Each site has a U.S.-based senior principal investigator (PI) and a senior foreign investigator (SFI) based in the developing world, who lead a team of in-country research staff.

In 2005, the GN implemented its first multicountry protocol, the First Breath (FB) study, a community-based cluster trial to determine whether education and training in the American Academy of Pediatrics Neonatal Resuscitation Program (NRP) and the Essential Newborn Care Program (ENC) of the World Health Organization (WHO) reduced neonatal mortality (7 days) more than education and training in ENC alone. More than 3,700 birth attendants from 100 GN communities with > 150,000 deliveries were taught the appropriate procedures and provided with the necessary equipment to resuscitate infants at birth. Communities were randomized to ENC plus NRP or continued ENC.

The GN has continued to build on the capacity developed in the FB trial through the implementation of more than 10 additional multicountry protocols to address priority research needs to improve maternal and child health in low-resource settings. Current projects include:

- The Maternal Newborn Health Registry: a prospective, population-based study of pregnancies and their outcomes in low-middle income countries (India, Guatemala, India, Pakistan, Bangladesh, Zambia and Kenya). All pregnant women in participating clusters are registered and their outcomes tracked for 6 weeks post-delivery. The primary purpose of this prospective, population-based observational study of approximately 60,000 women per year is to quantify and understand the trends in pregnancy services and outcomes over time in defined, low-resource geographic clusters. The goal is to provide population based statistics on stillbirths, neonatal and maternal mortality as the basis of health care policy. The data from the registry also provide the mortality and morbidity outcomes for Global Network trials and help investigators plan future studies for the Global Network.

- Preterm birth remains the leading cause of neonatal mortality and long-term disability throughout the developed and developing world. A growing body of evidence suggests that 1st trimester administration of low dose aspirin can reduce the rate of PTB substantially. The **ASPIRIN Study** is a prospective, randomized, placebo-controlled, double-masked, multi-center clinical trial to examine whether low dose aspirin initiated between 6 0/7 weeks- 12 6/7 weeks gestation reduces the risk of preterm birth. The study has enrolled 11,920 women across seven sites in Africa, Asia, and Latin America.

- Attention is increasingly directed to the role of maternal nutrition during the 1st trimester for normal growth and development during the first thousand days, from conception to the child's second birthday. The primary hypothesis of the **Women First: Preconception Maternal Nutrition study** is that for women in poor communities, a comprehensive maternal nutrition intervention commencing at least 3 months prior to conception and continuing throughout pregnancy, will be associated with a significantly greater newborn length than for offspring whose mothers start to receive the same intervention at 12 weeks gestation or who do not receive the intervention at all. The results of this trial will make a major contribution to refining evidence-based strategies for maternal nutrition supplementation and evaluating the cost-benefits of extending such strategies beyond pregnancy to virtually all women of child-bearing age, including adolescent girls.

APPENDIX 2. SAMPLE INFORMED CONSENT

Global Network for Women's & Children's Health Research

Single oral dose of azithromycin 2 gm in laboring women to prevent neonatal infection/death and maternal peripartum infection/death

INVESTIGATORS:
[LIST SITE INVESTIGATORS]

SPONSOR:
The Eunice Kennedy Shriver National Institutes of Child Health and Human Development (NICHD)

You are being asked to participate in a research study for pregnant mothers. This study is funded by the U.S. National Institutes of Health and the Bill and Melinda Gates Foundation. This form provides you with information about the study so that you can decide whether you would like to participate. A member of the research team will describe the study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part. You may also request that the research staff read the form to you.

What is the purpose of the study?
The purpose of the study is to learn whether an antibiotic, called azithromycin, given orally (by mouth) to pregnant women during labor can reduce the risk of infection for the woman and her baby.

Who will be in the study?
A total of 34,000 women will be enrolled in this study from eight sites in sub-Saharan Africa, South Asia, and Latin America. In [insert site name], no more than [insert max sample size] will be enrolled.

You qualify for this study if you are a pregnant woman of the legal age of consent who is in labor with one or more live fetuses and a pregnancy ≥28 weeks, plan to deliver vaginally in a health facility, have no known infections that require antibiotics, have no known problems taking azithromycin or similar antibiotics (penicillin), and have not used azithromycin, erythromycin, or similar antibiotic in the past 7 days. We will ask you some questions about your pregnancy and health status to make sure you qualify to participate.

What will happen if I join this study?
Before participating, you will be provided with information about the study procedures and given an opportunity to ask questions. If you qualify and agree to participate, you will be asked to sign this form to indicate your consent.

If you agree to participate, you will be assigned to either the treatment group or the control group. The assignment is made randomly, like flipping a coin or choosing a grain of rice from a bag. The women in the treatment group will take four 500 mg azithromycin pills. For comparison, the women in the control group will take four pills that look identical to azithromycin but do not contain any medication. This will

allow the researchers to compare how well azithromycin works to prevent infection in babies and mothers. Neither you nor the study staff will know whether you are assigned to the treatment or control group.

After you have been assigned to a treatment group, you will be given 4 small 500 mg pills to take by mouth. A member of the study team will watch you take the pills. After you take the pills, you will receive care during your labor, delivery, and recovery from the health facility staff, according to the local standard of care.

While you are at the health facility to deliver your baby, the study team will also collect:

- information about your labor and delivery;
- information about your baby, such as birthweight and health status at the time of delivery;
- if you or your baby develop an infection before you are discharged from the health facility, a sample will also be taken from the site of the infection. You may also be asked to provide a blood sample.

It will take no more than 30 minutes to complete the consent form, take the pill, and provide information about you and your baby.

After delivery, a member of the study team will visit you and your baby a total of three times. These visits will be scheduled to take place at your home at 3 days, 1 week and 6 weeks after delivery; however, if you or your baby are hospitalized at the scheduled time, the study team may visit you in the hospital. During the visit, you will be asked questions to assess for signs of infection in you or your baby. If you or your baby develop an infection, we will collect a specimen to help identify the bacteria involved. This may be a sample of pus, urine, or blood. The visits will take approximately 30 minutes.

To ensure that we have accurate and complete information about the health of you and your baby, we will access and collect information from the medical records at the health facilities where you and your baby have received care. By agreeing to participate in this study, you are also agreeing to give permission for the study staff to access your medical records. We will take precautions to protect the information that is collected from your medical records. Only study staff will have access to this information. To further protect you and your baby, all of your information will be coded with a number in place of your name.

The local research staff have been selected because of their skills, knowledge, and familiarity with your community. The research staff are here to support you during the study and should be contacted between visits if you have any questions or concerns.

<u>What are the risks and discomforts</u>

Azithromycin is sometimes used to treat infections in pregnant women and children. Research shows that the risks of taking azithromycin are minimal. A commonly reported side effect is gastric discomfort (nausea, stomach pain, diarrhea, vomiting); however, you will be given pills with a special coating which will help prevent stomach discomfort. There is also a small but rare risk that azithromycin could cause arrythmia (irregular or abnormal heartbeat) or an allergic reaction; therefore, you will not be able to participate if you have a known history of heart problems or have had a bad reaction to azithromycin or a similar drug in the past.

If it is necessary to take a sample because of infection, you or your baby may feel temporary discomfort, but this will only last a few seconds. To minimize this, we will ensure research staff are well trained in the procedure.

Another possible risk of participating in this study is that your name and personal information may be seen by persons who are not part of the project. To prevent this, you will be given an identification number that will be used in place of your name on all study documents.

Information from this research study will be retained by [local institution] and RTI International in the United States (U.S.) and in the future may be included in a de-identified public use database managed by NICHD Data and Specimen Hub (DASH) in compliance with the U.S. National Institutes of Health (NIH) Public Access Policy. De-identified means that you and your baby will not be individually identified by name or other personal identifiers in the database. Your full name or any address data is will not be included. Information released will not identify you or your baby's participation in this research study.

What are the benefits of participating?

You will not receive any money from participating in the study, but your participation may provide important information that can be used in the future to prevent infection in mothers and babies. Also, there is preliminary information suggesting that the use of azithromycin in pregnancy can reduce the risk of maternal and infant infection.

If new information about the benefits or risks of azithromycin use in pregnancy becomes available during this study, this information will be given to you by [insert name of Senior Investigator] or his/her staff.

Will I have to pay for anything?

It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to refuse to participate or to withdraw your participation at any time. If you refuse or decide to withdraw, you will not lose any benefits or rights to which you are entitled. These actions will not have any negative effect on the health care you receive from your local health providers. You will still receive your normal medical care.

Can I be removed from this study?

You will be withdrawn from the study if the research staff thinks that your participation may cause harm to you or your baby. The research staff may also remove you from the study for other reasons at their discretion. Also, the sponsor may stop the study at any time.

What will happen if you are injured by this research?

Although the risk of injury is expected to be very low, all research involves a chance that something bad might happen to you. Despite all safety measures, your participation could result in a medical problem or injury. If you or your infant is injured as a result of your participation, you will be provided with emergency care by the study and referred to a doctor for ongoing care, if needed. Ongoing care will not be paid for by the study. [Insert name of Research Institution] and NICHD have not set aside funds to pay you for any

such reactions, injuries or related medical care. However, by signing this form, you do not give up any of your legal rights.

What should you do if you have additional questions?

If you have questions about this study or a project-related injury, you should contact [investigator contact]. If you have questions about your or your baby's rights as a project participant, please contact [insert ethics committee contact].

If you have any questions about the study, please call [insert senior investigator].

Agreement to be in this study

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I know that being in this study is voluntary and I choose to be in this study. I understand I will get a copy of this consent form.

Signature (or thumbprint):_____ Date:_____
(Mother)

Print Name:_____
(Mother)

Signature (or thumbprint):_____ Date:_____
(Father/Guardian/Partner)

Print Name:_____
(Father/Guardian/Partner)

APPENDIX 3. SCHEDULE OF STUDY PROCEDURES

Community Sensitization	ANC Visits x	During Labor/ Before Delivery	After Delivery/ Before Discharge	3 days after Delivery	1 Week after Delivery	6 Weeks after Delivery	As Needed
Screening							
• Eligibility confirmation		X					
• Clinical assessment		X					
Consent		X					
Randomization		X					
Drug Administration		X					
Baseline Data Collection							
• Sociodemographic information		X	X				
• Medical history		X	X				
• Labor and delivery information			X				
Monitoring							
• Drug side effects		X	X				
• Maternal vitals during labor/delivery		X	X				
• Neonatal events during labor/delivery			X				
• Fetal death			X				
• Assessment of maternal infection			X	X	X	X	X
• Assessment of neonatal sepsis			X	X	X	X	X
• Maternal death			X	X	X	X	X
• Neonatal death			X	X	X	X	X
• Fetal anemia			X	X	X	X	X
• Other maternal outcomes			X	X	X	X	X
• Other fetal outcomes			X	X	X	X	X
• Unscheduled medical visits			X	X	X	X	X
Serious Adverse Events			X	X	X	X	X

Effects of a Single Oral Dose of Azithromycin 2 gram in Laboring Women and Antimicrobial Resistance (AMR) Monitoring

A Sub-study to the A-PLUS Trial

Lead Study Investigator(s):
Alan T.N. Tita, MD, PhD, Center for Women's Reproductive Health and Maternal-Fetal Medicine Division, UAB
Wally Carlo, MD, Neonatology Division, UAB
Elwyn Chomba, MBChB, DCH, MRCP, University Teaching Hospital, Zambia

Subcommittee Members:
Patricia Hibberd, MD, PhD, Boston University School of Public Health
Marion Koso-Thomas, MD, NICHD
Menachem Miodovnik, MD, NICHD
Akila Subramaniam, MD, UAB
Charitharth V. Lal, MD, UAB
Ana Garces, MD, MPH, INCAP, Guatemala
William Petri, MD, University of Virginia
Tracy Nolen, DrPh, RTI International
Elizabeth McClure, PhD, RTI International
Jean Kim, PhD, RTI International
Jennifer J. Hemingway-Foday, MPH, RTI International
Emily MacGuire, MPH, RTI International
Chris McClure, MPH, RTI International

Version Number: Version 1.1

Version Date: March 5, 2019

Funding: Eunice Kennedy Shriver National Institute of Child Health and Human Development and The Bill & Melinda Gates Foundation

Table of Contents

Acronyms:

AMR	Antimicrobial resistance
A-PLUS	Azithromycin-Prevention in Labor Use Study
AZM	Azithromycin
CI	Confidence interval
CLSI	Clinical and Laboratory Standard Institute
CSF	Cerebrospinal fluid
Etest	Epsilometer test
GAS	Group A streptococcus
GBS	Group B streptococcus
GN	Global Network
MB	Microbiome
MIC	Minimal inhibitory concentration
MRSA	Methicillin-resistant *Staphylococcus aureus*
N-P	Nasopharyngeal swab
OTU	Operational taxonomic units
PCoA	Principal coordinates analysis
VRE	Vancomycin-resistant enterococcus

1. Background

Effects of azithromycin use: Monitoring antimicrobial resistance and microbiome effects

FDA information related to azithromycin in [http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm] indicates: is a macrolide derivative of erythromycin that acts by binding to the 50S ribosomal subunit of susceptible microbes and interferes with protein synthesis. Azithromycin was initially patented as Zithromax™ but the medication is now widely available as non-proprietary (generic) preparations. Susceptible organisms include a broad spectrum of atypicals, aerobic and facultative gram-negative and gram-positive cocci and rods, and some anaerobes. Azithromycin was formerly classified as pregnancy category B—animal studies using maternally toxic doses showed no fetal harm. Studies suggest it is excreted in human milk in a sustained fashion [1]. The only absolute contraindication is known hypersensitivity reaction to azithromycin, erythromycin, or other macrolide antibiotic (quite rare). There are no specific drug-drug interactions warranting dose adjustments when given with other medications. Elimination is by both renal and hepatic route, and no specific adjustments are mandated for patients with renal or hepatic insufficiency. The long elimination, 1/2-life of 68 hours, is due to extensive uptake and subsequent release of drugs from tissues. Potential adverse events include very rare (<<1%) allergic hypersensitivity (mild and severe skin reactions – Stevens-Johnson Syndrome and toxic epidermal necrolysis, angioedema and anaphylaxis) and *Clostridium difficile*-associated diarrhea mainly in the elderly. Gastrointestinal symptoms (diarrhea 4-9%, abdominal pain 2-3%, nausea 4-6% and vomiting 1-3%) are the most commonly reported side effects though the frequencies are similar to background.

An ongoing concern for peripartum and perinatal antibiotic prophylaxis with antibiotics including azithromycin is the selection of resistant organisms including azithromycin- or erythromycin-resistant organisms, methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant enterococcus (VRE), and ampicillin-resistant *Escherichia coli* [2-3]. The most frequently encountered mechanism of resistance to azithromycin is modification of the 23S rRNA at positions corresponding to A2058 and A2059 in the Escherichia coli numbering system. In addition, there are concerns about pseudomembranous colitis and disruption of gut and other flora (microbiome) in women and in neonates leading to increased allergic reactions, rash, and childhood asthma [2-3]. These adverse events and antibiotic resistance are less likely to occur with the single dose prophylactic antibiotic strategy. In the study from Gambia of a single oral dose of azithromycin during labor, the higher prevalence of *S. aureus* azithromycin resistance observed among women and their babies four weeks after treatment had waned 12 months later, and azithromycin did not induce other antibiotic resistance to *Streptococcus pneumoniae* or *S. aureus*. There was a 7% vs. 21% prevalence of any bacteria in breast milk in those receiving azithromycin vs. placebo [4-5]. This requires further evaluation, including the effects on other organisms as well as the microbiome.

Given the clinical benefits of intrapartum azithromycin so far reported in two trials and the likelihood that it may become the usual practice if our large trial (The A-PLUS Trial: Azithromycin Prevention in Labor: the Study) confirms the reported benefits, it is important to monitor antibiotic resistance to determine the safety of azithromycin prophylaxis. Therefore, the goal of this ancillary protocol to the A-PLUS Trial will be to monitor antimicrobial resistance and maternal and newborn microbiome effects of the single dose of prophylactic azithromycin. This will be accomplished in three ways:

1. Clinical monitoring with culture and sensitivity testing from suspected bacterial infections in mothers and newborns;
2. Serial susceptibility monitoring of antimicrobial resistance patterns (including azithromycin resistance) from selected maternal and newborn flora through culture and sensitivity testing;
3. Serial microbiome collection and storage of specimens for future testing to monitor maternal and newborn microbiome status at selected sites.

A summary of the methods is outlined in Section 2.

2. Methods

2.1. Clinical Monitoring of Microbes and Antimicrobial Resistance Profile of Infections

Randomized and treated mothers or their babies diagnosed with infections up to 6 weeks after delivery will have clinical culture and sensitivity testing sent, including azithromycin resistance for clinical isolates, as noted below. The clinical monitoring is included as a component of the A-PLUS protocol and consent will be obtained at the time of enrolment in the main trial. No additional consent for this activity will be required for the AMR protocol.

2.1.1. Sample size consideration

We estimate a 4% incidence of sepsis in mothers and in newborns after labor. However, *suspected* sepsis or infection requiring blood or other specimen sampling (particularly in newborns) will be more frequent and specimens will be obtained frequently from other sites in mothers. Therefore, we estimate conservatively that over 10% of mothers (6% suspected sepsis, 3% perineal wound infection, 1.5% each of breast abscess/mastitis and post-cesarean site infection, and 1% pyelonephritis) and a similar proportion of newborns (10%) may require blood or other specimen collection as indicated by suspected sepsis or other type of infection in Table 1. This corresponds to 3,400 mothers and 3000 infants with clinical sepsis with plans to collect in duplicate.

Table 1. Proposed AZ Resistance Monitoring in Cultures for All Suspected Infections through 6 Weeks Postpartum

MOTHER- Suspected Infection	Obtain Specimens from ALL Accessible Infected Sites	Example Organisms of Concern re: Azithromycin Resistance
Surgical site infection after C-section	Wound swab for culture	*S. aureus*
Perineal infection	Wound swab for culture	*S. aureus, E. coli*
Sepsis (WHO criteria)	Blood culture	GAS, GBS, Gram negatives
Mastitis / breast abscess	Breast milk/pus for culture	*S. aureus*
Pyelonephritis	Urine for culture	*E. coli*/Gram negatives

BABY- Suspected Sepsis	Obtain if possible	Example Organisms of Concern re: Azithromycin Resistance
Suspected sepsis (per study definition)	Blood, urine, and/or pus culture, CSF, stool sample	*S. aureus*, GBS, GAS, Gram negatives

2.1.2. Culture method and sensitivity testing

For the isolation and identification of dominant bacterial pathogens found in the various infection sites, clinical cultures will be performed using site-specific routine standard clinical and microbiological practices. These cultures will be prepared using various media types which may include selective and/or differential media such as blood agar, Mannitol Salt Agar, or MacConkey Agar. Following 24 – 72 hours of incubation, the dominant organisms (one or more) found on each culture plate will be selected for identification. Bacterial isolates will be identified according to the clinical routine at each center, which may include observations of bacterial growth phenotypes (e.g. colony morphology, or variant growth on differential media), microscopic observations using various staining techniques (e.g. Gram stain, India ink, Acid fast stain, etc.), performance of biochemical assay tests (e.g. catalase, indole, CAMP, etc.), and antibody-based test methods (e.g. latex agglutination test).

The dominant bacterial isolates will also be challenged for antibiotic sensitivity or resistance to azithromycin (AZM), using standardized procedures and materials. The procedures will be based on the site-specific routine clinical and microbiological practices, but supplemental support may be provided by the study to ensure standardization across sites. This may include the provision of Epsilometer test (Etest) strips (AZM to provide the minimal inhibitory concentration (MIC) for the target bacterium which is interpreted as sensitive,

intermediate or resistant to azithromycin based on the recommended values set by the Clinical and Laboratory Standard Institute (CLSI).

2.1.3. Analytic Approach

The identified pathogens will be summarized overall by treatment arm as well as separately by region, mother vs. infant and infection site. The susceptibility vs. resistance to azithromycin will also be summarized overall by treatment arm as well as by region, pathogen, infection site and by mother vs. infant. These analyses will be descriptive in nature but dependent on having sufficient data to run models, descriptive comparisons of treatment arms may be obtained; for example, via estimating relative risk estimates between treatment arms for pathogen prevalence and/or resistance. Additional details of any such comparisons will be described in a data processing and statistical analysis plan.

2.2. Serial Antimicrobial Susceptibility Monitoring

2.2.1. Serial monitoring of antimicrobial susceptibility/resistance patterns from selected maternal and newborn flora sites

A subset of maternal-infant dyads at each GN country regardless of clinical infections will be randomly selected and serially monitored (at baseline 0-1 day, 1 week, 6 weeks and 9 months) for development of antimicrobial resistance (including azithromycin) in selected flora locations. Testing for azithromycin and other antibiotic sensitivity/resistance will be implemented following collection, including for microbes such as *S. pneumoniae* and *S. aureus* (especially N-P swabs with *S. aureus* acquired from the anterior nares during N-P collection), and *E.coli* (especially from rectal swabs). Consideration will be given to stopping the monitoring if prior sample has no resistance. The sampling scheme for this is shown in Table 2 below. A similar scheme will be used for collection and storage of specimens for microbiome (MB) analysis (Section 2.3).

2.2.2. Sample size considerations

Assuming that the primary endpoint of interest is azithromycin resistance to at least one organism from any flora at each time point, samples from a total of 848 maternal-infant dyads will be needed to be monitored to be able to estimate an overall prevalence of 10% +/- 2% with 95% confidence. Furthermore, this sample size will allow over 80% power to detect at least a 2-fold increase in azithromycin microbial resistance with azithromycin (RR=2) compared to 6-7% in placebo group. We will also be able to compare the number of organisms identified with resistance to azithromycin between randomized study groups. To account for an assumed rate of 15% for individuals declining consent to store samples for future testing, the final sample size will be 1000 maternal-infant dyads total. This corresponds to approximately 125 dyads per GN country for the duration of the study. Enrollment may vary across countries, but no individual country will enroll more than 25% of the planned sample size.

Table 3. Proposed Sample Scheme to Monitor for AZM Resistance (Culture and Test *S. pneumoniae* and *S. aureus* [N-P], and *E.coli* [Rectal]) and Effect on the Microbiome (MB) Studies in Subset

	Baseline[a] (0-1 day)	1 Week (± 4 days)	6 weeks (± 2 weeks)	9 months[a] (only if previous + result)
MOTHER				
Rectal Swab	MB/Culture	MB/Culture	MB/Culture	MB/Culture
N-P Swab	MB/Culture	MB/Culture	MB/Culture	MB/Culture
BABY				
Rectal Swab	MB/Culture	MB/Culture	MB/Culture	MB/Culture

N+P Swab	MB/Culture	MB/Culture	MB/Culture	MB/Culture

* Ideally, maternal samples should be taken before drug administration, neonatal samples should be taken after delivery

** Samples taken from persons with previous positive results: may consider 6-month sample if positive results 3 months and no additional rounds of antibiotics received.

2.2.3.Culture method and susceptibilitytesting

Each site will be provided with specific standardized media plates for the culturing of nasopharyngeal (N+P) and rectal swab samples. The media plates will be selective and differential to specifically encourage the growth of *S. pneumoniae*, *S. aureus*, and *E. coli*staining for easier identification of these select organisms based on growth variability. Any presumptivebacterial candidates will be confirmed using standardized biochemical assays which will also be provided.These positive isolates will also be exposed to azithromycinusing the Etest strips to assess for MIC which will be interpreted as sensitive, intermediate, or resistant. The process for interpreting the MIC to obtain resistance status will be detailed in the data processing and statistical analysis plan.

2.2.4.Analytic Approach

The overall prevalence and associated exact binomial 95% CI will be estimated for the occurrence of azithromycin resistance from any organism at any timepoint for either the mother or infant of the dyad. The prevalence and associated 95% CI will also be calculated by treatment arm overall as well as by organism, mother vs. infant, and region. Robust Poisson regression models that allow for the attainment of relative risk estimates and associated 95% CIs of resistance for the azithromycin study treatment arm vs. placebo will be implemented [6]. This model will be run overall as well as by mother vs. infant and organism, and also including an interaction term for region. If an interaction term of treatment group by region has a p-value≤.1, then results for that model will be presented by region. Repeated measure versions of these models will also be explored to determine if there are any time trends in resistance. Sensitivity analyses will be conducted accounting for swabs that result in at least partially missing culture data. Similarly, Poisson models will be run to compare the number of organisms identified with resistance to azithromycin between study groups.

2.3. Serial Collection and Storage of Biospecimens for Future Testing to Monitor Maternal and Newborn Microbiome Status

The same subset as for antimicrobial susceptibility/resistance monitoring above will have maternal and infant specimens collected and stored for future microbiomeanalysis including 16S/metagenomics and metatranscriptomics studies. As above, this will correspond to a total of 1000 maternal-infant dyads who are randomly selected and consent to participate in the ancillary study and agree to have samples stored for future analysis.

2.3.1.Details of sample collection, processing, and storage

A general description of each method is provided below. Detailed information will be provided in the Manual of Procedures and supplemented with additional training tools, such as videos, to ensure staff are properly trained on specimen collection, labeling, transport, and storage.

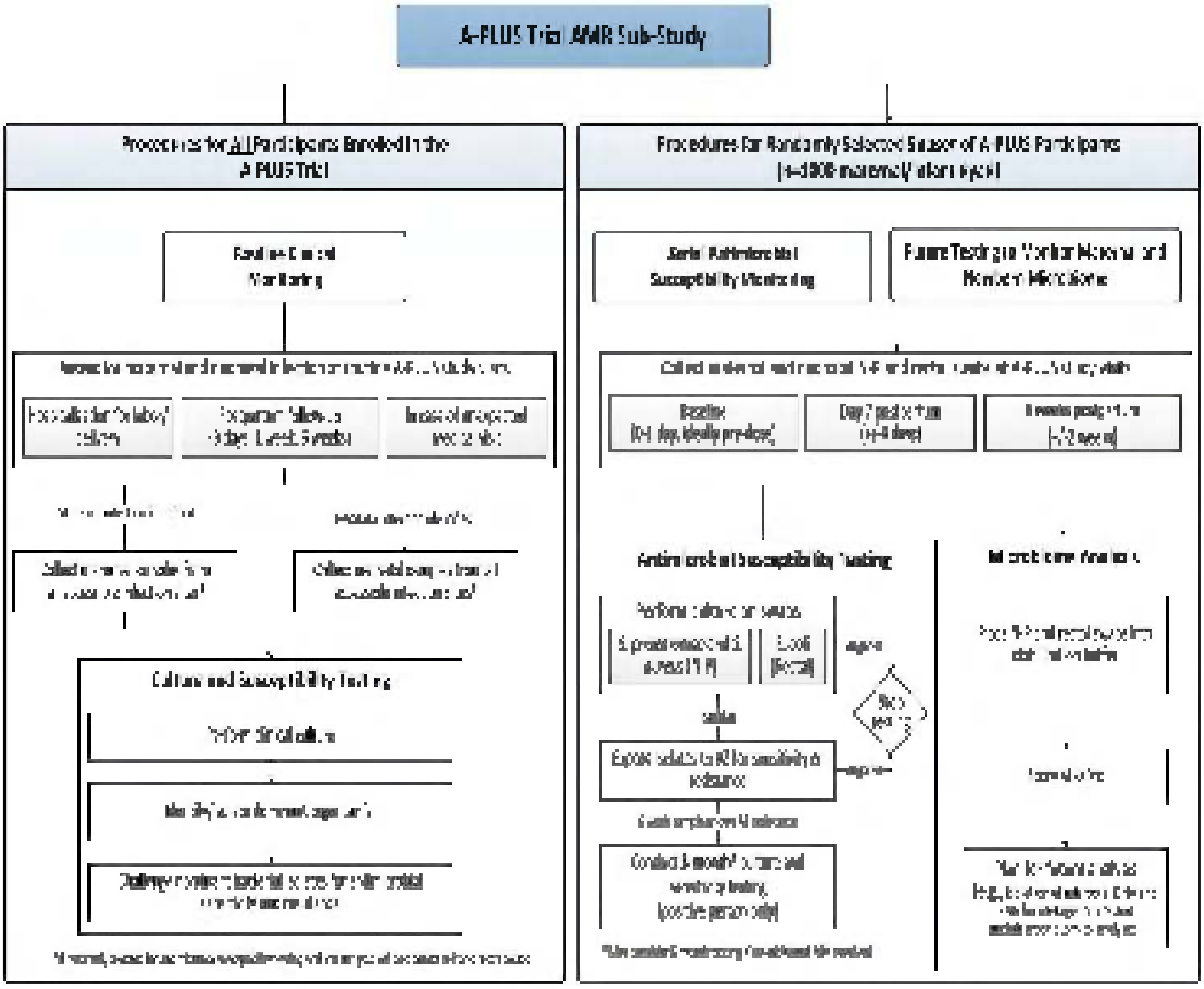
- **Rectal Swabs:** For rectal swab collection, a sterile swab will be inserted into the rectum and rotated for 2-3 seconds. The swab will be placed instabilization buffer (e.g. RNAlater solution)needed to preserve genetic material for the microbiome analysis and stored at -80°C.

- **Naso-pharyngeal swabs:**N-P swabs will be processed like rectal swabs by inserting a sterile swab into the nostril to access the nasopharyngeal cavity and rotating the swab for at least 3 seconds. The swabwill be placed into the stabilization buffer(e.g. RNAlater solution) and stored at -80°C.

2.3.2 Future isolation of microbial DNA and RNA for 16S/metagenomics and metatranscriptomics analyses

The AMR protocol will ensure the adequate collection and storage of the specimens for future analyses. Possible procedures that will be undertaken for this analysis are now outlined and will be updated at the time of actual analyses. Microbial genomic DNA and RNA transcripts will be isolated from individual samples and used to generate sequencing libraries, one for 16S/metagenomics using the isolated DNA and the other for metatranscriptomics using the total transcripts. The libraries will be sequenced using the NextGen sequencing Illumina MiSeq platform and the generated reads will be used for further analyses. These sequences will be grouped into operational taxonomic units (OTUs) and sample diversity will be calculated using a variety of diversity metrics including Shannon's, Chao1, and Simpson, as implemented in QIIME. Additionally, data relationship tools will be used including UniFrac analysis to determine relationships between different samples and principal coordinates analysis (PCoA) to visualize the dissimilarity between all samples. All of these methodologies have been published and described in detail [7, 8, 9].

2.4. Study Flow Chart



3. References

1. Sutton AL, Acosta EP, Tarwater KR, Kerstein-Wood CD, Title AT, Riggio JR. Perinatal pharmacokinetics of azithromycin for cesarean prophylaxis. Perinatal pharmacokinetics of azithromycin for cesarean prophylaxis. Am J Obstet Gynecol 2015;212(6):812.e1-6.
2. Title AT, Rouse DJ, Blackwell S, Sande CR, Spong CY, Andrews WW. Evolving Concepts in Antibiotic Prophylaxis for Cesarean Delivery: A Systematic Review. Obstet Gynecol. 2008;111(5):1179-92.
3. Ledger WJ.Prophylactic antibiotics in obstetrics gynecology: a current asset, a future liability?Expert Rev Anti Infect Ther. 2006;4(6):957-64.
4. Bojang A, Camara B, Jagne Cool I, et al. Long-term Impact of Oral Azithromycin taken by Gambian women during Labour on Prevalence and Antibiotic Susceptibility of S. pneumoniae and S. aureus in their Infants. Follow-up of a Randomized Clinical Trial.Clin Infect Dis.2018. [Epub ahead of print]
5. Roca A, Oluwalana C, Bojang A, et al. Oral azithromycin given during labour decreases pectoral carriage in the mothers and their offspring: a double blind randomized trial.Clin Microbiol Infect. 2016;22(6):555.e1-5.

6. Zou G. A Modified Poisson Regression Approach to Prospective Studies with Binary Data. American Journal of Epidemiology, Volume 159, Issue 7, 1 April 2004, Pages 702–706,https://doi.org/10.1093/aje/kwh090
7. Kumar R, Eipers P, Little RB et al. Getting started with microbiome analysis: sample acquisition to bioinformatics. Curr Protoc Hum Genet. 2014;82:18.8.1–18.8.29.
8. La CV, Travers C, Aghai ZH, Eipers P, Jilling T, Halloran B, Carlo WA, Keeley J, Rezonzew G, Kumar R, Morrow C, Bhandari V, Ambalavanan N. The Airway Microbiome at Birth. Sci Rep. 2016 Aug 4;6:31023. PMID:27488092
9. La CV, Bhandari V, Ambalavanan N.Genomics, Microbiomics, Proteomics and Metabolomics in Bronchopulmonary Dysplasia. Seminars in Perinatology. Am J Physiol Lung Cell Mol Physiol. 2018 Aug 16.

Appendix A: Sample Informed Consent- Antimicrobial Resistance Sub-Study

Global Network for Women's & Children's Health Research

Effects of Single Oral dose of Azithromycin 2 gram in Laboring Women and Antimicrobial Resistance (AMR) Monitoring

A Sub-study of the A-PLUS Trial

INVESTIGATORS:
[LIST SITE INVESTIGATORS]

SPONSOR:
The Eunice Kennedy Shriver National Institutes of Child Health and Human Development (NICHD)

You are being asked to participate in a research study for pregnant mothers. This study is funded by the U.S. National Institutes of Health and the Bill and Melinda Gates Foundation. This form provides you with information about the study so that you can decide whether you would like to participate. A member of the research team will describe the study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part. You may also ask that the research staff read the form to you.

What is the purpose of the study?
The purpose of this study is to learn whether an antibiotic, called azithromycin, when given orally (by mouth) as a single dose to pregnant women during labor can change how bacteria respond to antibiotics and the types of microorganisms naturally found in the body(microbiome). This is a sub-study of the A-PLUS Trial, which is a large study to evaluate the use of azithromycin, a common antibiotic, to reduce the risk of infection for women and their babiesduring labor and delivery. This sub-study will follow a group of women over time to identify specific microbes in the nose and rectum and determine whether these microorganisms respond to the antibiotic. We will also collect and store samples from the nose and rectum to better describe the types of microorganisms found in these areas.

Who will be in the study?
A total of 1000 women will be enrolled in this study from eight sites in sub Saharan Africa, South Asia, and Latin America. In [insert site name], no more than 250 women will be enrolled. The babies of enrolled women will also be included in the study. The women who participate in the AMR sub-study will be randomly selected (by chance) from those who are enrolled in the A-PLUS trial. You qualify for this study because you are enrolled in the A-PLUS trial and have been randomly selected to participate in the AMR sub-study.

What will happen if I join this study?
Before participating, you will be given information about the study procedures and given an opportunity to ask questions. If you qualify and agree to participate, you will be asked to sign this form to indicate your consent.

While you are at the health facility to deliver your baby, the study team will collect the following biological samples:

- A nasopharyngeal wash from you and your baby. This is a type of biological specimen that is collected by horizontally inserting a cotton swab into the upper part of the nose and rotating gently several times. This will help the study team understand the type of bacteria that grows in the nose and the effect of azithromycin on the bacteria.

- A rectal swab from you and your baby. This is a type of biological specimen that is collected by temporarily inserting a cotton swab into the rectum and rotating gently. This will allow the study team to understand the type of bacteria that are found in the rectum and the effects of azithromycin on the bacteria.

It will take no more than 30 minutes to complete the consent form and collect samples from you and your baby.

After you are discharged from the health facility, a member of the study team will visit you and your baby up to three times. All participants will be visited 1 week and 6 weeks after delivery. During the visit, nasopharyngeal and rectal swabs will be collected from you and your baby. If one of the samples collected from you or your baby shows that the bacteria growing in the nose or rectum has been affected by azithromycin, we will also visit you 3 months after delivery to collect another swab from the nose and rectum. It will take no more than 30 minutes to collect samples from you and your baby at home.

The local research staff have been selected because of their skills, knowledge, and familiarity with your community. The research staff are here to support you during the study and should be contacted between visits if you have any questions or concerns.

What are the risks and discomforts?

You or your baby may feel temporary discomfort when the swabs are taken from the nose and rectum, but this will only last a few seconds. To minimize discomfort, research staff will be well trained in the procedure.

Another possible risk of participating in this study is that your name and personal information may be seen by persons who are not part of the project. To prevent this, an identification number will be used in place of your name on all study documents.

What are the benefits of participating?

You will not receive any money from participating in this study, but your participation may provide important information that can be used in the future to prevent infection in mothers and babies.

If new information about the benefits or risks of azithromycin use in pregnancy becomes available during this study, this information will be given to you by [insert name of Senior Investigator] or his/her staff.

Analysis and storage of nasal and rectal swab samples

As explained earlier, we will collect samples from the nose and rectum of all participating women and their children in order to study the impact of azithromycin on bacteria that reside in these parts of the body. Some of these samples will be analyzed immediately after they are collected, in a local laboratory in [NAME OF CITY]. We also propose to store a part of each collected sample, for later analyses with more advanced methods. For these analyses, we might need to transfer the samples to another laboratory.

If you agree, the samples will be stored frozen at our research office in [NAME OF CITY], labelled with numbers but no name information on them. During the storage, only dedicated members of our study team will have access to the samples. You can request the discontinuation of storage and destruction of samples collected from you or your child at any time by contacting the Principal Investigator whose contact details are given at the beginning of this document. You can also decline storage or future use of your samples but still be permitted to participate in the study.

Will I have to pay for anything?

It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to refuse to participate or to withdraw your participation at any time. If you refuse or decide to withdraw, you will not lose any benefits or rights to which

you are entitled. These actions will not have any negative effect on the health care you receive from your local health providers. You will still receive your normal medical care.

Can I be removed from this study?

You will be withdrawn from the study if the research staff thinks that your participation may cause harm to you or your baby. The research staff may also remove you from the study for other reasons at their discretion. Also, the sponsor may stop the study at any time.

What will happen if you are injured by this research?

Although the risk of injury is expected to be very low, all research involves a chance that something bad might happen to you. Despite all safety measures, your participation could result in a reaction or injury. If you or your baby is injured as a result of your participation, you will be provided with emergency care by the study and referred to a doctor for ongoing care, if needed. Ongoing care will not be paid for by the study. [Insert name of Research Institution] and NICHD have not set aside funds to pay you for any such reactions, injuries or related medical care. However, by signing this form, you do not give up any of your legal rights.

What should you do if you have additional questions?

If you have questions about this study or a project related injury, you should contact [investigator contact]. If you have questions about your or your baby's rights as a project participant, please contact [insert ethics committee contact].

If you have any questions about the study, please call [insert senior investigator].

Agreement to be in this study

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I know that being in this study is voluntary and I choose to be in this study. I understand I will get a copy of this consent form.

Signature (or thumbprint):_____ Date:_____
(Mother)

Print Name:_____
(Mother)

Signature (or thumbprint): Date:
(Parent/Guardian/Husband, if required by local regulations)

Print Name:
(Parent/Guardian/Husband, if required by local regulations)

Agreement to store samples for future testing

We would like to store some of the nasal and rectal samples and health information collected from you and your baby to learn about microorganisms that live in and on your body and your baby's body. We will label the samples and health information using an ID number in place of your name and your baby's name, as described in the previous section.

Do you agree to let us store samples from you and your baby for future research to learn about microorganisms that live in and on the body?

. | YES . | NO

Initials (or thumbprint) of mother: _____ Date: _____

Initials (or thumbprint) of parent/guardian/husband, if required by local laws/regulations: _____

If later you change your mind and want your samples destroyed, please contact [insert name and contact information of senior investigator].

Study Title: Prevention of maternal and neonatal death/infection with a single oral dose of azithromycin in women in labor (in low- and middle-income countries): The A-PLUS Pilot Study on Infection

Principal Investigators:

Alan T.N. Tita, MD, PhD, Center for Women's Reproductive Health and Maternal-Fetal Medicine Division, UAB
Welly Carlo, MD, Neonatology Division, UAB
Elwyn Chomba, MBChB, DCH, MRCP, University Teaching Hospital

Site Director: <NAME>

Protocol Number: <LOCAL IRB #>

Version Date: 05 February 2013

Version No: 7

Sponsor: This pilot study is supported by the Eunice Kennedy Shriver National Institutes of Child Health and Human Development Global Network for Women's and Children's Health Research.

I. Objective

We propose to undertake a study to assess the rates of clinical infection identified based on the clinical signs and through use of standardized tools, including the WHO maternal and AAP neonatal clinical algorithms, among pregnant women in labor, 42 postpartum and their newborns to day 28 postpartum, as well as the organisms identified through routine clinical cultures.

II. Background& Significance

Maternal and neonatal infections are among the most frequent causes of maternal and neonatal deaths. Current antibiotic strategies have not been effective in preventing many of these deaths. One particular challenge among studies of maternal and neonatal infection is the accurate determination of sepsis using available clinical and microbial assessments. In preparation for a trial to evaluate the impact of azithromycin to reduce maternal and neonatal sepsis in low-resource settings (the A-PLUS Trial, Azithromycin-Prevention in Labor Use Study), we will undertake a pilot study to train health workers to identify signs of sepsis and other infections among women who have delivered in a study hospital (up to day 42 postpartum) and their newborns (up to 28 days postpartum).

III. Preliminary Studies

Previous studies have identified clinical signs that can be used to identify maternal infection. The recent ANISA study suggested that up to 70% of those with clinical signs of infection did not have any pathogen identified via PCR testing. Results of microbiology has found mixed results in terms of corresponding with results from the clinical signs of neonatal and maternal sepsis.

IV. Research Methods

A. Populations to be Enrolled

The pilot study will be undertaken in each of the eight Global Network Sites that will participate in the A-PLUS Trial (Bangladesh, DRC, Guatemala, Kenya, India [Belagavi and Nagpur], Pakistan and Zambia).

Using the planned infrastructure for enrolling women in the A-PLUS Trial, pregnant women who are delivering in a health facility should be screened for eligibility based on the inclusion and exclusion criteria below. Ideally, the health facilities that will be used for the A-PLUS Trial should be involved in the pilot

study. Those who are eligible and provide consent will be included in this pilot study. A sample consent form is found in **Appendix 1**.

Inclusion Criteria:

- Pregnant women in labor ≥28 weeks GA (by best estimate) with a pregnancy with one or more live fetuses who plan to deliver vaginally in a facility.
- Admitted to health facility with clear plan for spontaneous or induced delivery.
- Live fetus must be confirmed via fetal heart rate by Doptone prior to enrollment.
- ≥18 years of age or minors 14-17 years of age in countries where married or pregnant minors or their authorized representative(s) are legally permitted to give consent.
- Have provided written informed consent. [Note: written informed consent may be obtained during antenatal care, but verbal re-confirmation may be needed (per local regulations) at the time of screening].

Exclusion Criteria:

- Non-emancipated minors (as per local regulations)
- Plan for cesarean delivery prior to enrollment.
- Preterm labor undergoing management with no immediate plan to proceed to delivery.
- Advanced stage of labor (>6 cm or 20 cm cervical dilation per local standards) and acutely or too distressed to understand, confirm, or give informed consent, regardless of cervical dilation
- Not capable of giving consent due to other health problems such as obstetric emergencies (for example, antepartum hemorrhage) or mental disorder.

B. Study Design and Methods

Among women who are consented and enrolled at time of delivery, the study staff will collect data on the clinical signs of infection, according to the definitions used at the facility and standardized checklists developed for the 4-arm cluster-RCT trial. After data collection, an adjudication process will be used to validate cases of infection by assessing all reported cases for conformity with standardized study-specific infection criteria. Signs of infection will be assessed both for women and their newborns as follows:

- Use of study forms with standardized checklists of potential signs of illness (including hypo or hyperthermia) and existing site-specific protocols for determining clinical infection in pregnant and postpartum women and their infants from time of admission for labor and delivery until discharge.
- Follow up visits at 3 days, 1 week, and 6 weeks postpartum for identification of maternal infection up to day 42 postpartum and neonatal infection up to day 28 postpartum. Signs of infection will be assessed through participant interview and medical record review (if mother or infant visited a health facility), using a standardized checklist developed for the study.
- Phone (or alternatives) contact at 14 days, 21 days, 28 days, and 35 days postpartum (+/- 3 days) to review maternal and neonatal signs of infection, using standardized study education materials. If signs of infection are identified during the review, participants will be asked to visit a study facility for further assessment. These phone contacts will reinforce the participants' ability to self-assess for signs of maternal and neonatal infection and improve identification of infection between the 1 week and 6 week home visits. If phone contact is not feasible, home visits may be conducted.
- Application of adjudication process, using standardized definitions to validate cases of infection.

- Among those with signs of clinical infection according to current health facility protocols or study assessment, results of any maternal or infant cultures performed on blood or other sample collected from the site of infection (Note: The availability of blood cultures will be site-specific, based on the existing resources at the time of the pilot)

Research staff will use standardized data collection forms to document signs of infection, clinical course, antibiotic use, and blood culture collection and results (Appendix 2). Data collection time activities, timepoints, and locations are described in Table 1

Table 1. Data Collection Plan

	Labor/ Delivery	3 days pp	7 days pp	14 days pp	21 days pp	28 days pp	35 days pp	42 days pp	Suspected infection
Screening	F								
Consent	F								
Baseline maternal data	F								
Baseline neonatal data	F								
Infection assessment using study checklist	F	H	H	F	F	P	P	H	
Additional infection assessment using medical records									F
Sample collection									F

F= Facility; H=Home; P=Phone

C. Primary Outcome Measures

- Clinical sepsis diagnosed among pregnant/postpartum women to day 42 postpartum and their infants to day 28 postpartum
  - a. Proportion meeting WHO criteria for maternal and neonatal sepsis
- Other maternal infections (e.g., chorioamnionitis prior to delivery, endometritis after delivery, wound infections, abdominopelvic abscess, pneumonia, and pyelonephritis) up to day 42 postpartum and neonatal infections (e.g., bloodstream bacterial infection, pneumonia, meningitis, urinary tract infection, and omphalitis) up to day 28 postpartum.
- Frequency and types of pathogens identified by culture.
- Antibiotic use (types and frequency)

D. Sample Size and Data Analysis

A maximum of 5,000 women will be enrolled across all Global Network sites, with no more than 1200 women enrolled at any individual site. Each site should prospectively collect up to eight months of data using the study forms (see Appendix 2). Results will be entered into the study data management system and analyzed on a monthly basis. The focus of the analysis for the pilot study is on the precision of the estimates.

Precision of the estimates of the sepsis outcomes (maternal and neonatal) are based on estimated risk or prevalence in the underlying population. For the A-PLUS Trial, we assume a risk of sepsis or death to be 3% for maternal outcomes and 6% for intrapartum/neonatal outcomes. Thus, for the purposes of the pilot study, we assume an underlying risk of sepsis between 3% and 6%.

In determining sample size, obtaining precise estimates at the region level is of interest where we assume 37.5% of mothers will be from sub-Saharan Africa and 62% will be from Asia. We also aim to have reasonable precision at the site level. The probability of obtaining a 95% confidence interval with a margin of error (MOE) less than or equal to a specified amount for a variety of sample sizes and underlying risk assumptions is below in Table 1. With larger underlying risks, the variability of the estimate is greater and thus a slightly larger MOE is targeted.

For maternal sepsis, we assume the underlying risk is lower (3% or 2.5%). Assuming an underlying risk of 2%, a total sample size of at least 8,800 women (3,300 women in Africa) is required for the region level probability of a 95% CI with a MOE of +/-0.5% to be greater than approximately 95%. If instead the underlying risk is 2.5%, the probability of a MOE of +/-0.5% is greater than 90% with a total sample size of 8000 (3000 women in Africa).

For neonatal sepsis, we assume the underlying risk is closer to 4%. Assuming 4%, a total sample size of at least 9,533 women (3,200 women in Africa) is required for the region level probability of obtaining a 95% CI with a MOE of +/-0.7% to be greater than approximately 78%.

Therefore, an enrollment target of 9,600 women should allow for precise region level estimates of sepsis in this pilot study. Furthermore, for sites that enroll the maximum allowable sample size of 1,000, there will be at least an 80% probability that the MOE for a 95% confidence interval will be +/-1% if the underlying risk of sepsis is 4%.

A secondary objective of this pilot study is to obtain a precise estimate of intrapartum mortality. The underlying risk is assumed to be between 1 to 3%. When assuming an underlying risk of 3%, we will have a 79% probability of obtaining region level 95% CIs with a MOE +/-0.5% with a total sample size of at least 8,800 women (3,300 women in Africa). The probability increases with lower estimates of underlying risk. Therefore, the planned enrollment target should allow for obtaining precise estimates of intrapartum mortality as well as sepsis.

Table 1. Probabilities of obtaining 95% CI

	Underlying Risk of Sepsis				
Region Level Sample Size	2%	2.5%	3%	3.5%	4%
	w/ MOE +/- 5%	w/ MOE +/-.5%		w/ MOE +/-.7%	
1000	0.73	0.61	0.75	0.53	0.45
2100	0.94	0.76	0.67	0.57	0.50
3200	0.72	0.56	0.65	0.002	0.71
3300	0.78	0.69	0.79	0.92	0.83
3400	0.87	0.79	0.85	0.92	0.86
3500	0.92	0.89	0.91	0.99	0.97
3600	0.96	0.93	0.96	0.98	0.95

Prior to initiation of the A-PLUS Trial, sites will first engage in a **preparatory period**, which will include obtaining approvals, assessment of health center and laboratory facilities, translation of study materials, and staff training and certification. Upon completion of all preparatory activities, a site will be activated and may begin the pilot study period of active baseline collection.

During the pilot period, each site should screen, enroll, and obtain follow up on a minimum of 400 and maximum of 1,200 participants. During this pilot period, the data will be entered, analyzed, and reviewed on an ongoing basis. The data, in particular the signs of suspected infection, will be reviewed centrally for quality and completeness of data collection as well as ability to obtain high to low up rates. Based on available data in each region, it is anticipated that at a minimum 25% of the participants and 4% of their infants enrolled will have clinical sepsis based on study definition between delivery and 42 days (for mothers) or 28 days (for infants) post delivery.

To be eligible to transition to the full trial, the site must meet the following criteria:

1. All regulatory approvals obtained;
2. Study drug obtained;
3. Sufficient staff trained and certified to enroll and follow anticipated participants;
4. A minimum of 400 participants enrolled in the pilot period with (a) high follow up rate, (b) acceptable data quality/completeness, and (c) no concerns regarding infection identification and reporting.

E. Description of Risks & Justification of Procedures & Data Collection Tools

This is an observational study to assess clinically identified sepsis and other infections, as well as to document the results from the cultures taken at the study sites. The results from the study will help inform the A-PLUS Trial to improve assessment of maternal and newborn sepsis and the impact of azithromycin on the study population. The study will utilize the case report forms developed for the A-PLUS Trial to document the results. In cases of suspected infection, participants will be referred to health facilities for care and treatment per the local standard of care.

F. Potential Scientific Problems

It is well recognized that there are limitations to the available microbiology testing, which may have contradictory results to clinical symptoms of sepsis. This study may find similar contradictory results. There is also the potential that cultures may not be obtained for all participants with suspected infection, as it depends on the resources available at participating sites at the time of the pilot. To mitigate problems with sample collection, the pilot will include an assessment that will be used to develop laboratory capacity during the pilot, as well as training on procedures for sample collection, transport, storage, and testing (See Section G for more detail).

G. Knowledge to be gained

The objective of the pilot study is to observe and improve the current practices at the facilities that will be implementing the A-PLUS Trial protocol and to optimize identification of suspected infection in health facilities and at home. The pilot study will facilitate preparation for the A-PLUS Trial by:

- Providing an opportunity for staff to practice screening, enrollment, and follow-up procedures for the A-PLUSTrial.
- Applying findings from the pilot to refine study procedures andtools for the A-PLUS Trial, including(1)data collection forms, (2) checklists and educational materials on danger signs that may occur with maternal or neonatal sepsis; and (3) the adjudication process for validation of clinical infection.
- Training staff in the standard application of the WHO definitions for maternal and neonatal sepsis to improve identification and characterization of sepsis in the trial.
- Validating estimates of intrapartum deaths, maternal and neonatal sepsis used in sample size calculations.

In addition, the pilot study will provide an opportunity to inventory and upgrade local capacity to conduct routine cultures (blood and other specimens) for the A-PLUSTrial and the AMR sub-study. A standardized tool will be used to assessexisting local and institutional microbiology capacity and identifyadditional resources that will be needed to collect, transport, store, and perform cultures. The Azithromycin Working Group will monitor and facilitate the assessment and subsequent upgrades. During the pilot, study staff will receive training on procedures to collect specimens for routine cultures and to conduct AMR testing when indicated.

Global Network for Women's & Children's Health Research

Prevention of maternal and neonatal death/infections with a single oral dose of azithromycin in women in labor in low- and middle-income countries (The A-PLUS Trial): Infection Pilot Study

INVESTIGATORS:
[LIST SITE INVESTIGATORS]

SPONSOR:
The Eunice Kennedy Shriver National Institutes of Child Health and Human Development (NICHD)

You are being asked to participate in a research study for pregnant women and their babies. This study is funded by the U.S. National Institutes of Health and the Bill and Melinda Gates Foundation. This form provides you with information about the study so that you can decide whether you would like to participate. A member of the research team will describe the study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part. You may also ask that the research staff read the form to you.

What is the purpose of the study?
The purpose of this study is to better understand how to identify infection in women and their babies during labor, delivery, and postpartum (after the baby is born). This will help us prepare for a larger study evaluating the use of azithromycin, a common antibiotic, to reduce the risk of infection for women and their babies.

Who will be in the study?
Up to 9,900 women will be enrolled in this pilot study from eight sites in sub-Saharan Africa, South Asia, and Latin America. In [insert site name], no more than 1200 will be enrolled.

You qualify for this study if you are a pregnant woman at the legal age of consent who is in labor with one or more live fetuses, pregnant ≥28 weeks, and plan to deliver vaginally in a health facility. We will ask you some questions about your pregnancy and health status to make sure you qualify to participate.

What will happen if I join this study?
Before participating, you will be given information about the study procedures and given an opportunity to ask questions. If you qualify and agree to participate, you will be asked to sign this form to indicate your consent.

If you agree to participate, the study team will collect information about you and your baby while you are at the health facility to deliver your baby. The following will be collected:

- Information about your labor and delivery will be collected by asking you and your health provider questions and reviewing your medical records;
- Information about your baby, such as his/her birth weight and health at the time of delivery will be collected by asking you and your baby's health provider questions and reviewing your baby's medical records;
- If you or your baby develop an infection before you are discharged from the health facility, a sample will be taken from the site of the infection. You may also be asked to provide a blood sample.

It will take no more than 30 minutes to complete the consent form and answer questions about you and your baby. If you or your baby develop an infection, it will take no more than 15 minutes to collect the sample.

After you are discharged from the health facility, a member of the study team will visit you and your baby a total of three times at 3 days, 1 week and 6 weeks after delivery. During the visit, you will be asked questions about the health of you and your baby to determine if there are any signs of infection. You will also be asked about any visits you or your baby have made to a health facility. If you or your baby develop an infection, we will collect a specimen from both you and your baby to identify the bacteria involved. This may be a sample of pus, urine, or blood. The home visits will take approximately 30 minutes each, including sample collection.

A member of the study team will also contact you by phone (or alternative contact) at 14 days, 21 days, 28 days, and 35 days after delivery to review the signs and symptoms of infection. If you do not have a phone, a member of the study team will visit you at home. This will help you learn the possible signs of infection that you or your baby may experience after delivery so that you can quickly seek help from the study team if needed. If a sign of infection is identified in you or your baby, you will be asked to visit the study facility for further assessment and sample collection from the site of infection.

To ensure that we have accurate and complete information about the health of you and your baby, we will collect information from the medical records at the health facilities where you and your baby have received care. By agreeing to participate in the study, you are also giving permission for the study staff to look at your medical records. We will take precautions to protect the information that is collected. Only study staff will have access to this information. To further protect you and your baby, all of your information will be coded with a number in place of your name.

The local research staff have been selected because of their skills, knowledge, and familiarity with your community. The research staff are here to support you during the study and should be contacted between visits if you have any questions or concerns.

What are the risks and discomforts

If it is necessary to take a sample because of infection, you or your baby may feel temporary discomfort, but this will only last a few seconds. To minimize this, we will ensure research staff are well trained in the procedure.

Another possible risk of participating in this study is that your name and personal information may be seen by persons who are not part of the project. To prevent this, an identification number will be used in place of your name on all study documents.

Information from this research study will be retained by (local institution) and RTI International in the United States (U.S.) and in the future may be included in a de-identified public use database managed by NICHD Data and Specimen Hub (DASH) in compliance with the U.S. National Institutes of Health's (NIH) Public Access Policy. De-identified means that you and your baby will not be individually identified by name or other personal identifiers in the database. Your full name or any address details will not be included. Information released will not identify you or your baby's participation in this research study.

What are the benefits of participating?

You will not receive any money for participating in this study, but your participation may provide important information that can be used in the future to prevent infection in mothers and babies.

Will I have to pay for anything?

It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to refuse to participate or to withdraw your participation at any time. If you refuse or decide to withdraw, you will not lose any benefits or rights to which you are entitled. These actions will not have any negative effect on the health care you receive from your local health providers. You will still receive your normal medical care.

Can I be removed from this study?

The research staff may remove you or your baby from the study if they have any concerns about your participation. Also, the sponsor may stop the study at any time.

What will happen if you are injured by this research?

Although the risk of injury is expected to be very low, all research involves a chance that something bad might happen to you. Despite all safety measures, your participation could result in a reaction or injury. If you or your baby is injured as a result of participation, you will be provided with emergency care by the study and referred to a doctor for ongoing care, if needed. Ongoing care will not be paid for by the study. [Insert name of Research Institution] and VCHD have not set aside funds to pay you for any such injuries or related medical care. However, by signing this form, you do not give up any of your legal rights.

What should you do if you have additional questions?

If you have questions about this study or a project-related injury, you should contact [investigator contact]. If you have questions about your or your baby's rights as a project participant, please contact [insert ethics committee contact].

If you have any questions about the study, please call [insert senior investigator].

Agreement to be in this study

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I know that being in this study is voluntary and I choose to be in this study. I understand I will get a copy of this consent form.

Signature (or thumbprint):_____ Date:_____
(Mother)

Print Name:_____
(Mother)

Signature (or thumbprint):_____ Date:_____
(Parent/Guardian/Husband, if required by local regulations)

Print Name:_____
(Parent/Guardian/Husband)

APPENDIX 2. OVERVIEW OF PILOT DATA COLLECTION FORMS

Form # and Name	Purpose	Key Data Elements	Data Source
01-Screening and Enrollment	To determine eligibility and record consent status	Screening date, review and confirmation of inclusion/exclusion criteria, consent status/date	Medical records; clinical exam; participant interview
03-Maternal Data Form	To collect maternal demographic and clinical information before discharge	• Demographic and baseline clinical data: admission date/time, EDD, GA, age, pregnancy history, height, weight, medical history, etc. • Events during labor: onset of labor, prolonged labor, premature rupture of membranes, timing and type of membrane rupture, type of labor, induction, clinical signs during labor, complications, etc. • Delivery information: date/time, type, perinatal complications during/after delivery, wound complications, other infections diagnosed after enrollment, antibiotic treatment after enrollment, discharge information, etc.	Medical records; participant interview
04-Neonatal Data Form	To collect neonatal demographic and clinical information before discharge	• Delivery information: sex, birthweight, outcome (live or still birth), resuscitation status; • Complications (sepsis/infection, apnea, meconium stained amniotic fluid, red spots, feeding difficulties, hepatosplenomegaly, splenomegaly, petechiae, jaundice, allergic reaction); • Discharge information (date/time, status)	medical records; participant interview
06-Maternal and Infant Follow-up	To collect updated maternal and infant health status during follow up visits at 3 days, 1 week and five weeks after delivery.	• Timing of follow up • Maternal and infant status since discharge: general status, symptoms, indication of infection, clinic visits, hospitalizations, antibiotic use	Participant interview/report, provider report, clinical exam, medical records
06-Maternal Unscheduled Medical Visit	To collect information about maternal clinic events reported during follow up visits	• Presenting problem and final diagnosis • Details about medical visit (signs of infection, abscess, other treatments, laboratory tests, hospitalizations, referrals)	Medical records, provider interviews
07-Infant Unscheduled Medical Visit	To collect information about maternal clinical events reported during follow-up visits	• Presenting problem and final diagnosis • Details about medical visit (signs of infection, abscess, other treatments, laboratory tests, hospitalizations, referrals)	Medical records, provider interviews
08-Specimen Collection and Results Form	To track sample collection when there is indication of maternal or infant infection and to document results of lab tests	• Date/time and type of specimen collection; • Location of normal/infection; • tracking information for shipping/storage; • Results	Medical records (if collected by facility staff); Study documentation (if collected by study staff)
09-Serious	To document fatal, life-	Date/time of event, date/time of resolution, nature	Participant

Adverse Events	[illegible] or any other serious, unexpected adverse event	[illegible] adverse event, management of adverse event, attribution to study (yes/no)	[illegible] report, provider report, medical records
10-Protocol Deviation	To record protocol deviations and corrective actions	Date and nature of deviation/violation, corrective action	Participant report, study records, medical records
11-Final Status	To document final study status	Final status (completion, withdrawal, LTFU) and date.	Study documentation
12-Outcome Verification	To validate cases of infection using standard case study definitions.	Maternal and neonatal sepsis, other infections	Study documentation, medical records, provider interviews

Rediffmail

Mailbox of maruti_zade@rediffmail.com

Print Cancel

From: nitin gangane <nitingangane@rediffmail.com>

To: <maruti_zade@rediffmail.com>

Subject: **Fw: Allocation of lumpsum annual budget and release of funds under the project titled "Population Based Cancer Registry" including PBCS for the financial year 2021-22.**

Date: Fri, 28 May 2021 11:00:37 IST

Note: Forwarded message attached

-- Original Message --

From: Accounts Officer accounts@ncdirindia.org
To: nitingangane nitingangane@rediffmail.com
Cc: Ashok Arora aarora@ncdirindia.org, "C. Gopalakrishnan" gopalakrishnan@ncdirindia.org
Subject: Allocation of lumpsum annual budget and release of funds under the project titled "Population
Based Cancer Registry" including PBCS for the financial year 2021-22.

Dr. Nitin Gangane.
MD, DNB, FUICC,FICP,FAMS,PhD
Dean and Director Professor of Pathology,
Mahatma Gandhi Institute of Medical Sciences,
Sevagram. Dist. Wardha. Maharashtra 442102, INDIA
Contact:09422144856
Dr. Nitin Gangane
Principal Investigator, PBCR &
Professor and Head, Department of Pathology
Mahatma Gandhi Institute of Medical Sciences,
Sevagram Dist. Wardha - 442102
Maharashtra

Sir,

This has with reference to above cited subject, Director, ICMR-NCDIR has accorded approval and sanctioned the lumpsum annual budget of **Rs. 44,27,345/-** (Rupees Forty Four Lakhs Twenty Seven Thousand Three Hundred And Forty Five Only) (this includes an increase of 5% over last year budget) towards "Population Based Cancer Registry" including PBCS for the financial year 2021-22.

The Lumpsum Annual Budget of **Rs. 44,27,345/-** has been sanctioned under head as "Recurring" grants to meet the recurring expenditure includes emoluments to the manpower engaged, travelling expenses for data collection, stationery & consumables, postage, internet and website/computer maintenance. This lumpsum annual budget includes Rs.1,00,000/- towards meeting expenses incurred for travelling allowance (TA / DA / Accommodation for attending meetings / workshops / training / review meeting organized by NCDIR at designated places for PI, Co-PI and staff of PBCR's)

Accordingly, a sum of **Rs. 8,00,000/-** has been released to your centre as first installment for the financial year 2021-22.

The transaction details are as under

Name of the Centre	Amount	Date	PFMS transaction reference ID
PBCR, Mahatma Gandhi Institute of Medical Sciences, Wardha	8,00,000	20-05-2021	RBI1412192739996

The receipt of the money may please be acknowledged.

Regards,

Accounts Officer
ICMR-NCDIR, Bengaluru
For Director

Rediffmail

Mailbox of maruti_zade@rediffmail.com

Print Cancel

From: nitin gangane <nitingangane@rediffmail.com>

To: <maruti_zade@rediffmail.com>

Subject: **Fw: Release of fund under the project titled "Additional Hospital Based Cancer Registry in Source of Registration (SoR) of Population Based Cancer Registries (PBCRs)".**

Date: Mon, 17 May 2021 17:20:42 IST

Note: Forwarded message attached

-- Original Message --

From: Accounts Officer accounts@ncdirindia.org
To: nitingangane@rediffmail.com
Cc: Ashok Arora aarora@ncdirindia.org, "C. Gopalakrishnan" gopalakrishnan@ncdirindia.org
Subject: Release of fund under the project titled "Additional Hospital Based Cancer Registry in Source of
Registration (SoR) of Population Based Cancer Registries (PBCRs)".

Dr. Nitin Gangane.
MD, DNB, FUICC,PhD
Dean and Director Professor of Pathology,
Mahatma Gandhi Institute of Medical Sciences,
Sevagram. Dist. Wardha. Maharashtra 442102, INDIA
Contact:09422144856
No. NCDIR/HBCR-ADSoR/2020 17 May 2021

Dr. Nitin Gangane
Dean & Director Professor,
Principal Investigator of ADHBCR - SoR,
Department of Pathology,
Mahatma Gandhi Institute of Medical Science (MGIMS),
Sevagram, Wardha, (Maharastra)–442102.

Dear Sir,

Sub: This has with reference to above cited subject, a sum of **Rs.2,00,000/-** has been released as first installment to your centre under the above mentioned project for the Financial year 2021-22.

The transaction details are as under

Name of the centre	Amount	Date	PFMS Transaction ID	PPA No.
Mahatma Gandhi Institute of Medical Science, Wardha	2,00,000	30.04.2021	C042126915244	C042126915232

The annual budget for the financial year 2021-22 is **Rs. 7,35,000/-** to your centre. Principal investigator will have the liberty of allocation of this fund for functioning of registry and its requirements such as hiring of manpower, training, workshop, contingencies, etc.,

The receipt of the money may please be acknowledged.

Yours faithfully,

Accounts Officer
ICMR-NCDIR

Bengaluru

UTILISATION CERTIFICATE.

Mahatma Gandhi Institute of Medical Sciences : Sewagram, Dist. Wardha

Department of Paediatrics

Name Of Project : Congenital Rubella Syndrome Surveillance In India

Certified that out of Rs. 10,98,826/- of Grant-in-Aid Released during the Year ended as on 31st March 2020 by National Institute of Epidemiology (NIE), Chennai For Congenital Rubella Syndrome Surveillance In India and Rs.6,939/- on account of interest received from Bank during the year, a sum of Rs.7,88,348.70/- (Rs. Seven Lakhs Eighty Eight Thousand Three Hundred Forty Eight and Seventy Paisa Only.) has been utilized for the purpose for which it was sanctioned and balance of Rs. 3,17,416.30(Rs. Three Lakhs Seventeen Thousand Four Hundred Sixteen and Thirty Paisa Only) remains unutilized as on 31.03.2020.

[HEAD OF THE DEPARTMENT]

[HEAD OF THE INSTITUTION]

DEAN
Mahatma Gandhi Institute of
Medical Sciences, SEWAGRAM,

Wardha, the
11th day of
July, 2020

Rajendra Bhutada & Co. Chartered Accountants WARDHA

FOR RAJENDRA BHUTADA & CO
CHARTERED ACCOUNTANTS

[RAJENDRA BHUTADA – PROP.]
Membership No. 43283
FRN. 108359 W
UDIN : 20043283AAAAEG6016

MAHATMA GANDHI INSTITUTE OF MEDICAL SCIENCES : SEWAGRAM, DIST. WARDHA.
[DEPARTMENT OF PAEDIATRICS].
[PROJECT : CONGENITAL RUBELLA SYNDROME SURVEILLANCE IN INDIA]
RECEIPTS AND PAYMENTS ACCOUNT FOR THE PERIOD FROM 16TH APRIL 2019 TO 31ST MARCH 2020.

RECEIPTS			*PAYMENTS*		
GRANT IN AID :			**STAFFING :**		
From National Institute of Epidemiology(NIE), Chennai.			Technical Assistant(Nurse).	3,50,300.00	
Sanctioned on 27th February 2019.			Technician (Lab).	4,06,800.00	7,57,100.00
Released & Vide Letter.					
Dated 03.05.2019	5,49,413.00		**CONSUMABLES :**		
Dated 20.02.2020.	5,49,413.00	10,98,826.00	Clot-Act Tube.	1,164.00	
			Laboratory Material.	13,539.00	14,703.00
OTHER INCOME :					
Interest from Bank on Saving Account.		6,939.00	**CONTINGENCIES :**		
			Advertisement.	484.00	
RECOVERIES AND DEDUCTIONS :			Stationery and Printing.	10,399.00	
Profession Tax.		7,100.00	Audit Fees.	3,000.00	
			Bank Charges.	17.70	
LIABILITIES :			Postage and Courier.	175.00	
Audit Fees Payable.		3,000.00	Travelling Expenses.	1,250.00	
			Refreshment Expenses.	1,040.00	
			Repairs and Maintenance.	180.00	16,545.70
			PAYMENTS OF RECOVERIES AND DEDUCTIONS :		
			Profession Tax.		7,100.00
			CLOSING BALANCE :		
			With Central Bank of India, Sewagram.		
			On Saving Account No. 3746753115.	3,16,326.30	
			Cash in Hand.	4,090.00	3,20,416.30
T O T A L :	**Rs. ....**	**11,15,865.00**	**T O T A L :**	**Rs. ....**	**11,15,865.00**

[PROJECT INCHARGE]

[HEAD OF THE DEPARTMENT]

[HEAD OF THE INSTITUTION]

DEAN
Mahatma Gandhi Institute of

CERTIFIED that the figures shown in the above Receipts and Payments Account of MAHATMA GANDHI INSTITUTE OF MEDICAL SCIENCES : SEWAGRAM, DIST. WARDHA [DEPARTMENT OF PAEDIATRICS] [PROJECT : CONGENITAL RUBELLA SYNDROME SURVEILLANCE IN INDIA] for the period from 16th April 2019 to 31st March 2020 are in agreement with the Books of Account maintained and produced to us by the said Institution for our verification which have been checked by us us and are found to be correct subject to explanations given thereto.

Rajendra Bhutada & Co. * Chartered Accountants * WARDHA

FOR RAJENDRA BHUTADA & CO.
CHARTERED ACCOUNTANTS

[RAJENDRA BHUTADA - PROP.]
Membership No.43283
FRN. 108359 W

Wardha, the 11th day of July, 2020

भारतीय गैर न्यायिक

एक सौ रुपये Rs. 100

रु. 100 ONE HUNDRED RUPEES

सत्यमेव जयते

भारत INDIA

INDIA NON JUDICIAL

தமிழ்நாடு तमिलनाडु TAMILNADU

22528

10 DEC 2018

THE DIRECTOR, NIE
ICMR.

AS 780709

A. VASANTHA
STAMP VENDOR
L. No. 23834 / 83,
Madras High Court Campus
Chennai - 600 104

PART – A

MEMORANDUM OF UNDERSTANDING

This memorandum of understanding (MOU) is made on this day of Dec 2018 between:

The Director, National Institute of Epidemiology (NIE), II Main Road, TNHB, Ayapakkam, Chennai on one hand

AND

The Head /Dean, Mahatma Gandhi Institute of Medical Sciences, Sevagram, having its Registered Office Sevagram, Wardha, Maharashtra 442102 on the other hand.

1. The Ministry of Health and Family Welfare, Government of India, New Delhi has approved the **study titled "Congenital Rubella Syndrome Surveillance in India"** and has recommended to United Nations Development Program (UNDP) for funding. NIE has been identified and designated as the nodal agency/coordinating center for the conduct of the project involving fifteen partner institutions (Sentinel Sites) in the third year. The Director, NIE will enter into a separate agreement with each of these institutes; one for the implementing the study protocol and one for the financial arrangements.

2. And, whereas Mahatma Gandhi Institute of Medical Sciences, Sevagram is one of these aforementioned partner institutions and has been tasked, *inter alia,* with the following responsibilities in order to ensure smooth execution of the deliverables as follows:

   (a) The Sentinel Site / hospital will enrol all suspected Congenital Rubella Syndrome (CRS) cases as study participants as defined in the study protocol

   (b) The Sentinel Site / hospital will test the samples for serological confirmation of rubella infection at the sentinel site/hospital laboratory or at the designated laboratory. The sentinel site/hospital will also send samples to the National Institute of Virology, Pune for additional tests, as per the laboratory protocol.

   (c) The Sentinel Site will collect clinical and epidemiological data and complete the Clinical report form (CRF) appropriately.

   (d) The sentinel site will perform investigations strictly following the procedures outlined in the protocol.

   (e) The Completed CRFs will be sent to the National Institute of Epidemiology, Chennai

3. And, whereas the Director, NIE will fulfil the following obligations under this MOU to enable the Director / Head of the partner institute to carry out the responsibilities as mentioned herein above.

   (a) Will coordinate the work and provide the necessary technical input for the conduct of the study.

   (b) Make periodic site visits to ensure smooth implementation of the project at all the sites and maintain high quality in the ongoing work.

   (c) Respond immediately to problems and provide appropriate guidance.

4. No failure or delay or omission by either party to fulfil any of its obligations under this MOU (other than the obligations mentioned herein with a view to coordinate the timely execution of the deliverables) shall give rise to any claim against such party or be declared to be breach of this MOU if any, to the extent such failure, delay or omissions arise from the unplanned event not within the reasonable control of such party.

5. The progress during the period of the survey will be reviewed periodically by ICMR / Expert committee constituted by ICMR and necessary mid-course corrections will be made to resolve the problems faced by NIE, partner institutions, or related agencies in any aspect pertaining to the study.

6. And, whereas in order to enable NIE and partner institutes to effectively discharge their respective responsibilities and obligations under this MOU, the Director NIE and the Head of the Partner Institute / Director of the partner institute do hereby commit to put in place effective systems to deliver on the measurable outcomes set out in this MOU.

7. The decision regarding publications and reports will be taken by the Expert Committee of the project. For publication of national surveillance data the group will be identified as "Congenital Rubella Syndrome Surveillance in India" project and the Centres and Principal Investigators/Co-investigators identified by name. The contribution of the sites will be duly mentioned in the manuscript and authorships will be considered based on level of interest in writing the papers and contribution in the conduct of the project. If the sites are interested they can analyse and report the data related to their site, in consultation with the Expert Committee.

8. The Director NIE and the Director/ Head of the partner Institute, having accepted the respective responsibilities and obligations described in this Memorandum and having agreed to the terms and conditions contained herein, do set their hands to this MOU on this the _____ day of _____ 2019.

9. The MOU shall remain in force for a period of 2 years from the date of its signature and seal, and may be terminated by either side by giving a three months notice to that effect in writing. However, notwithstanding the notice of the intent to terminate the memorandum, all rights, obligations and corresponding duties and subsisting therein shall be respected and mandated till the finalization of the project and accomplishment thereof.

10. The parties to this MOU undertake to treat as CONFIDENTIAL AND PRIVILEGED information of the other institution, which is so classified in advance. The terms of confidentiality and mode of disclosure shall be as per mutually acceptable terms.

Dean/Head
Mahatma Gandhi Institute of Medical Sciences, Sevagram

Date:

DEAN
Mahatma Gandhi Institute of Medical Sciences, SEVAGRAM.

Director,
National Institute of Epidemiology

Date:

भारतीय आयुर्विज्ञान अनुसंधान परिषद
ICMR INDIAN COUNCIL OF MEDICAL RESEARCH
वी. रामलिंगस्वामी भवन, अन्सारी नगर, पोस्ट बॉक्स 4911, नई दिल्ली - 110 029

No. [illegible]

Date: [illegible]

31/8

To
The Dean,
[illegible]

Sub: [illegible]

Sir/Madam,

[illegible]

1. The Director General of the ICMR has sanctioned an amount of Rs. [illegible] as detailed in the Annexure-I for the project [illegible] for the period from [illegible] to [illegible]. The project will be implemented subject to the following conditions:

2. The payment of the sanctioned amount will be released in [illegible] instalments as detailed in the Annexure-I. The first instalment of Rs. [illegible] will be released by the Council after the project is started and the second instalment will be released after receipt of satisfactory progress report and utilization certificate for the first instalment. The progress report will be sent to the Council every [illegible].

3. The Principal Investigator will be responsible for the execution of the project. He/she will be assisted by the Co-Investigator(s) mentioned in the application. The College will not be responsible for any financial liability in the event of the project being wound up.

4. The Principal Investigator will be required to submit a detailed progress report of the work done on the project every [illegible] and a final report on the completion of the project. The final report should be submitted within [illegible] months of the completion of the project. The Council may withhold further payment if the progress report is not received in time.

5. The Principal Investigator will be required to maintain proper accounts of the expenditure incurred on the project. A statement showing how the amount released by the Council has been utilized should be submitted to the Council along with the progress report. The Principal Investigator should also maintain a stock register for the equipment purchased out of the grant.

6. The Principal Investigator will be required to publish the results of the work done on the project in a standard medical journal. The publication should acknowledge the financial assistance received from the Council. Two reprints of the publication should be sent to the Council.

7. The Principal Investigator will be required to refund to the Council any unspent balance of the grant or any amount found to have been misutilized.

8. The Principal Investigator will be required to abide by the terms and conditions of the grant as laid down by the Council from time to time.

9. The Principal Investigator will be required to acknowledge the financial assistance received from the Council in all publications resulting from the work done on the project.

10. The Principal Investigator will be required to submit a statement showing how the equipment purchased out of the grant has been utilized after the completion of the project.

11. The Principal Investigator will be required to return the equipment purchased out of the grant to the Council after the completion of the project.

12. The Principal Investigator will be required to acknowledge the receipt of this letter.

Yours faithfully,

(G.S.Sandhu)
Senior Officer
For Director General

Copy forwarded with compliments to the Principal Investigator for information and necessary action to:

1. Dr. Sachin Pawar, Assoc. Professor, Deptt. Of Physiology, MGIMS, Sevagram. 442102
2. Accounts Officer (Finance).
3. Guard File (for [illegible] Copy).

Section Officer

UTILISATION CERTIFICATE.

Name Of Project :"CT MRI Fision Project"

(Run Through-Department of Radiotherapy-M.G.I.M.S. ,Sevagram)

Certified that out of Grant-in-Aid of Rs. 60,000/- released during the Period From 21st December 2021 to 28th February 2022 by Cancer Research and Statistic Foundation Mumbai , for the Project entitled as" CT MRI Fision " the sum of Rs 60,878/- (Rupees Sixty Thousand Eight Hundred Seventy Eight Only) has been utilized for the purpose for which it was sanctioned and balance of Rs. NIL remains Unstilted.

[PRINCIPAL INVESTIGATOR]

[HEAD OF THE INSTITUTION]

Wardha, the
14th day of
March, 2022

Rajendra Bhutada & Co. Chartered Accountants WARDHA

FOR RAJENDRA BHUTADA & CO
CHARTERED ACCOUNTANTS

[RAJENDRA BHUTADA – PROP.]
Membership No. 43283
FRN. 108359 W
UDIN : 22043283AEVJJF2871

CT MRI FISION PROJECT.

[RUN THROUGH-DEPARTMENT OF RADIOTHERAPY, M.G.I.M.S., SEVAGRAM].

RECEIPTS AND PAYMENTS ACCOUNT FOR THE PERIOD FROM 21ST DECEMBER 2021 TO 28TH FEBRUARY 2022.

RECEIPTS		*PAYMENTS*	
GRANT-IN-AID :		**SUPPLIES :**	
From Cancer Research and Statistic Foundation Mumbai.Vide Letter No. NIL. Dated 26.10.2021.	60,000.00	Graph Pad Prism 9 Perpetual Licence.	60,500.00
		OTHER EXPENSES :	
OTHER INCOME :		Bank Charges.	378.00
Interest from Bank on Saving Account.	193.00	**CLOSING BALANCE :**	
ADVANCE :			
Dr Pallavi Kalbande.	685.00		
T O T A L : **Rs. ..**	60,878.0	**T O T A L :** **Rs. ..**	60,878.00

CERTIFIED that the figures shown in the above Receipts and Payments Account of CT MRI FISION PROJECT [RUN THROUGH-DEPARTMENT OF RADIOTHERAPY, M.G.I.M.S., SEVAGRAM]. for the Period From 21st December 2021 to 28th February 2022 are in agreement with the Books of Account maintained and produced to us by the said Institution for our verification which have been checked by us and are found to be correct subject to explanations given thereto.

[PROJECT INCHARGE]

[HEAD OF THE INSTITUTION]

Wardha. the 14th day of March, 2022

Rajendra Bhutada & Co. Chartered Accountants

FOR RAJENDRA BHUTADA & CO.
CHARTERED ACCOUNTANTS

[RAJENDRA BHUTADA - PROP.]
Membership No.43283
FRN. 108359 W

World Health Organization

COVERING LETTER
LETTRE D'ACCOMPAGNEMENT

GLOBAL PROCUREMENT AND LOGISTICS
Global Service Centre
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Registration	2021/1142104-0
Purchase Order	202710223
Unit Reference	WCO-SRHR

Dr B S Garg
MAHATMA GANDHI INSTITUTE OF MEDICAL SCIENCES
WARDHA
P.O. Sewagram
WARDHA
MAHARASHTRA
442102
India

AGREEMENT FOR PERFORMANCE OF WORK (APW)

Re: Mahatma Gandhi Institute of Medical Sciences- Strengthening Health Sector Response to Gender-Based Violence during COVID-19 Pandemic, 23 July - 30 November 2021

We are enclosing the Agreement for Performance of Work between the World Health Organization and MAHATMA GANDHI INSTITUTE OF MEDICAL SCIENCES, WARDHA, in the amount of INR 342,475.00 (Three Hundred Forty-Two Thousand Four Hundred Seventy-Five), for conducting the above-mentioned work. We also enclosed two attachment(s) referenced in the Agreement.

Kindly acknowledge your acceptance of this contract by returning the email with a copy of duly signed Purchase Order (all pages).

For any technical questions relating to this Agreement, please contact the responsible technical officer, Kiran SHARMA, 09650111233, sharmaki@who.int.

Invoicing Instructions for Contractors who are legal entities (Company Contractors):
Invoices must be sent via email to accountspayable@who.int. Other than invoices, please do not send any enquiry to this email address. You may contact the above responsible technical officer for enquiries.

In order to ensure timely and accurate payment, invoices must include:

- Invoice number
- Purchase Order number against each invoice line;
- Invoice descriptions matching with PO descriptions
- Invoice currency same as the Purchase Order Currency also corresponding with the currency of the bank account provided to WHO;
- Supplier name as in the PO

Invoices shall be clearly readable and stamps or any other additional markings should not obscure the original invoice content. Invoices shall not be handwritten.

On behalf of the World Health Organization, we would like to thank you for your collaboration.

WHO Global Service Centre

cc: WHO India

Concerne: Mahatma Gandhi Institute of Medical Sciences- Strengthening Health Sector Response to Gender-Based Violence during COVID-19 Pandemic, 23 July - 30 November 2021

Veuillez trouver ci-joint l' Accord pour Exécution de Travaux entre l'Organisation Mondiale de la Santé et MAHATMA GANDHI INSTITUTE OF MEDICAL SCIENCES, WARDHA, pour un montant de INR 342,475.00, vous permettant de mener à bien le travail susmentionné. Veuillez également trouver 2 pièce(s) jointe(s) mentionnée(s) dans l'Accord.

Merci de confirmer votre acceptation de ce contrat en nous retournant le courriel et une copie dûment signee du Bon de Commande (complet)

World Health Organization

AGREEMENT FOR PERFORMANCE OF WORK
ACCORD POUR EXECUTION DE TRAVAUX

GLOBAL PROCUREMENT AND LOGISTICS
Global Service Centre
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Registration	2021/1142104-0
Purchase Order	202710223
Unit Reference	WCO-SRHR

Pour toutes questions à caractère technique ayant trait à cet Accord, veuillez contacter le responsible Kiran SHARMA, 09650111233, sharmaki@who.int.

Instructions concernant la facturation pour les contractants qui sont des personnes morales.(Personne Morale):
Les factures doivent être envoyées par courriel à accountspayable@who.int. Outre les factures, n'envoyez aucune enquête à cette adresse de courrier électronique.Vous pouvez contacter le responsable technique responsable ci-dessus pour toute demande de renseignements.

De manière à garantir un paiement exact et ponctuel, les factures doivent impérativement comporter:

- Le Numéro de facture
- Le Numéro du bon de commande , répété à chaque ligne de facturation
- Des descriptifs des produits identiques à ceux du Bon de commande
- Une devise de facturation identique à celle du Bon de commande et à celle du compte en banque fourni à l'OMS
- Un intitulé de facture (nom de fournisseur) identique à celui du Bon de commande.

Les factures doivent être parfaitement lisibles. Le contenu de la facture ne doit en aucun cas être masqué par un tampon ou tout autre marquage. La facture ne doit pas être manuscrite.

Au nom de l'Organisation mondiale de la Santé, nous vous remercions de votre collaboration.

Centre mondial de services de l'OMS

cc: OMS India

Sensitivity: Internal & Restricted

World Health Organization

AGREEMENT FOR PERFORMANCE OF WORK
ACCORD POUR EXECUTION DE TRAVAUX

GLOBAL PROCUREMENT AND LOGISTICS
Global Service Centre
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Registration	2021/1142104-0
Purchase Order	202710223
Unit Reference	WCO-SRHR

The WORLD HEALTH ORGANIZATION hereby agrees to provide to
L'ORGANISATION MONDIALE DE LA SANTÉ s'engage par la présente à fournir à
MAHATMA GANDHI INSTITUTE OF MEDICAL SCIENCES
WARDHA

WARDHA
INDIA

The Maximum amount of/*Un montant Maximum de*: INR 342,475.00 (Three Hundred Forty-Two Thousand Four Hundred Seventy-Five) **in respect of/*en vue de:*** Mahatma Gandhi Institute of Medical Sciences- Strengthening Health Sector Response to Gender-Based Violence during COVID-19 Pandemic, 23 July - 30 November 2021

For the period financed by this Agreement — From/*De*: 23-JUL-2021
Période du projet *financée par le présent Accord* — To/*A*: 30-NOV-2021

Summary of work/ *Description sommaire des travaux:*

Description of work under this Agreement/ *Description des travaux faisant l'objet du présent Accord:*

Mahatma Gandhi Institute of Medical Sciences- Strengthening Health Sector Response to Gender-Based Violence during COVID-19 Pandemic, 23 July - 30 November 2021, as per the Terms of Reference at Annex 1 and within the approved budget at Annex 2. Both these Annexes form an integral part of this agreement.

During the course of the contract and on its conclusion, the contractual partner shall ensure to submit the stipulated deliverables mentioned under "Financial arrangements".

Financial arrangements/ *Dispositions financières:*

Payments will be made as follows/*Les versements seront effectués comme suit:*

	Deliverable/ Résultat	Due date/ *Date remise*	%	Currency amount/ *Montant en devise*
1	Upon submission of countersigned contract	23-JUL-2021	30.00	102,742.50
2	Upon submission of finalized tool and capacity building plan of action data	08-SEP-2021	40.00	136,990.00
3	Upon submission of draft Report	31-OCT-2021	20.00	68,495.00
4	Upon submission of certified financial statement of expenditure	30-NOV-2021	10.00	34,247.50

Annexes

The following annexes form an integral part of this Agreement/ *Les annexes listées ci-dessous font partie intégrante de l'Accord:*

Annex/Annexes	File Name/ *Nom du fichier*
1	2021/1142104 | Contractual - Terms of Reference |
2	2021/1142104 | Contractual - Budget Breakdown |

In the event that the annexes contain any provisions which are contrary to the terms of this Agreement, the terms of this Agreement shall take precedence/ *En cas de contradiction entre les dispositions des annexes et celles de*

Sensitivity: Internal & Restricted

World Health Organization

AGREEMENT FOR PERFORMANCE OF WORK
ACCORD POUR EXECUTION DE TRAVAUX

GLOBAL PROCUREMENT AND LOGISTICS
Global Service Centre
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Registration	2021/1142104-0
Purchase Order	202710223
Unit Reference	WCO-SRHR

l'Accord, les dispositions de l'Accord prévaudront dans tous les cas.

The undersigned parties, having read the terms and General Conditions, hereby conclude the present Agreement and confirm their agreement and acceptance thereof.
ON BEHALF OF WHO/ *POUR L'OMS*

Responsible WHO Technical Officer:
Fonctionnaire technique responsable de l'OMS:

Kiran Sharma
NPO (Adolescent Health & Gender)
SE_IND WR Office, India

Approved by:
Approuvé par:

PAYDEN
Deputy Head of WHO Country Office
SE_IND WR Office, India

Authorized Signatory:
Signataire autorisé:

Mr Prem Prakash Chopra
Team Lead, a.i.
Global Procurement, Processing and Logistics
(WHO BOS/SUP/GPL)

Processed by:
Traité par:

Noor Izreen Mustaffa
Procurement Assistant
HQ/BOS Business Operations

PO Approved Date:
PO approuvé le:
27-JUL-21

Les parties soussignées, ayant lu les modalités et les Conditions Générales, ratifient l'Accord et confirment leur acceptation.

CONTRACTOR/ CONTRACTANT

Signature : .....

Date: 28.7.2021

Name & Title/ Nom & Fonction : Dr B S Garg
Director, Sewa Bharat Medical Education & Research Institute
MGIMS Sewagram

Sensitivity: Internal & Restricted

World Health Organization

AGREEMENT FOR PERFORMANCE OF WORK
ACCORD POUR EXECUTION DE TRAVAUX

GLOBAL PROCUREMENT AND LOGISTICS
Global Service Centre
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Registration	2021/1142104-0
Purchase Order	202710223
Unit Reference	WCO-SRHR

GENERAL CONDITIONS

1. **Relationship of the Parties.** It is understood that the execution of the work does not create any employer/employee relationship. In this respect, the contractor shall be solely responsible for the manner in which the work is carried out. Thus, WHO shall not be responsible for any loss, accident, damage or injury suffered by any person whatsoever arising in or out of the execution of this work, including travel. Insurance coverage for any such loss, accident, damage or injury will be the contractor's responsibility, including where appropriate, insurance coverage for persons used by the contractor to carry out the work.

Without prejudice to the foregoing, WHO may in certain cases provide insurance coverage for the contractor for travel in WHO vehicles. WHO declines all responsibility for non-payment by the insurance company of all or part of a claim submitted by or for the contractor for any accident. In case of such non-payment, the contractor shall be obliged to immediately reimburse all or part of any advance which WHO may have paid to the contractor.

2. **Rights.** All rights in the work, including ownership of the original work and copyright thereof, shall be vested in WHO, which reserves the right (a) to revise the work, (b) to use the work in a different way from that originally envisaged, or (c) not to publish or use the work.

3. **Payment and use of funds.** If the option, on the face of this agreement, for payment of a fixed sum applies, that sum is payable in the manner provided, subject to proper performance of the work.
If the option for payment of a maximum amount applies:
(i) the funds shall be used exclusively for the work specified in this agreement and any unspent balance shall be refunded to WHO. In this latter case, any financial statement required shall reflect expenditures according to the relevant main categories of expenditure; and
(ii) to the extent the contractor is required to purchase any goods and/or services in connection with its performance of this agreement, the contractor shall ensure that such goods and/or services shall be procured in accordance with the principle of best value for money. "Best value for money" means the responsive offer that is the best combination of technical specifications, quality and price.

Contractors who are legal entities (hereinafter referred to as "Company Contractors") must submit an invoice to the contracting WHO department or the WHO Global Service Center in order to receive payment. Invoices are not required from contractors who are individuals (hereinafter referred to as "Individual Contractors"), who can be paid upon receipt by the contracting WHO department of the required deliverables (including any required technical reports and financial statements) in a satisfactory manner.

The invoice from Company Contractors shall reflect any tax exemption to which WHO may be entitled by reason of the immunity it enjoys. WHO is, as a general rule, exempt from all direct taxes, custom duties and the like, and the Company Contractor will consult with WHO so as to avoid the imposition of such charges with respect to this agreement and the work performed hereunder. As regards excise duties and other taxes imposed on the provision of goods and services (e.g. value added tax), the Company Contractor agrees to verify in consultation with WHO whether in the country where the tax would be payable, WHO is exempt from such tax at the source, or entitled to claim reimbursement thereof. If WHO is exempt from value added tax, this shall be indicated on the invoice, whereas if WHO can claim reimbursement thereof, the Company Contractor agrees to list such charges on its invoices as a separate item and, to the extent required, cooperate with WHO to enable reimbursement thereof.

WHO shall have no responsibility whatsoever for any taxes, duties or other contributions payable by contractors. Payment of any taxes, duties and other contributions which a contractor may be required to pay shall be the sole responsibility of that contractor who shall not be entitled to any reimbursement thereof by WHO.

4. **Satisfactory performance.** If the work is not satisfactorily completed (and, where applicable, delivered) by the date fixed in this agreement and/or if any financial statement required is not satisfactorily submitted to WHO in accordance with general condition 5 below, WHO may specify an additional period within which this agreement must be satisfactorily performed. Normally such additional period should be of at least one week's

CONDITIONS GENERALES

1. **Relation entre les Parties.** Il n'est pas institué de relations d'employeur à employé aux fins de l'exécution des travaux. À cet égard, le contractant est seul responsable de la manière dont les travaux sont exécutés. Ainsi, l'OMS ne saurait assumer, à l'égard de quelque personne que ce soit, aucune responsabilité pour toute perte, tout accident, tout dommage ou toute blessure subis au cours ou en raison de l'exécution des travaux ou d'un déplacement les concernant. La mise en place d'une couverture d'assurance pour toute perte, tout accident, tout dommage ou toute blessure subis au cours ou en raison de l'exécution des travaux sera de la responsabilité du contractant y compris le cas échéant, toute couverture d'assurance pour les personnes auxquelles le contractant recourt pour l'exécution des travaux.

Sans préjudice de ce qui précède, l'OMS peut, dans certains cas, fournir une couverture d'assurance au contractant en cas de déplacement dans un véhicule de l 'OMS. L'OMS décline toute responsabilité pour le non-paiement par la compagnie d'assurance de la totalité ou d'une partie d'une demande d'indemnisation soumise par ou pour le contractant suite à un accident. En cas de non-paiement, le contractant sera obligé d' immédiatement rembourser la totalité ou une partie des avances que l'OMS pourrait lui avoir versées.

2. **Droits.** Tous les droits attachés aux travaux, y compris la propriété des travaux originaux et le droit d'auteur y afférent, seront dévolus à l'OMS qui se réserve le droit a) de réviser les travaux, b) d'utiliser les travaux d'une autre manière que celle initialement envisagée, ou c) de ne pas publier ni utiliser les travaux.

3. **Paiement et utilisation des fonds.** Si l'option applicable - prévue au recto du présent accord - est celle du paiement d'une somme fixe, cette somme est payable dans les conditions prévues, sous réserve de l'exécution satisfaisante des travaux.
Si l'option applicable est celle du paiement d'un montant maximum :
(i) les fonds seront utilisés exclusivement aux fins des travaux précisés dans l'accord et tout solde non utilisé sera remboursé à l'OMS. Dans ce dernier cas, les états financiers requis devront indiquer les montants engagés pour les principaux postes de dépense ; et
(ii) dans la mesure où le contractant doit acheter des biens et/ou des services quelconques dans le cadre de l'exécution du présent accord, il devra veiller à ce que l'achat de ces biens et/ou services soit effectué sur la base du principe du meilleur rapport qualité-prix. On entend par « meilleur rapport qualité-prix » l'offre qui présente la meilleure combinaison du point de vue des spécifications techniques, de la qualité et du prix.

Afin d'être payé, les contractants qui sont des personnes morales (ci-après dénommés « Personnes Morales ») doivent présenter une facture au département contractant de l'OMS ou au centre mondial de services de l'OMS. Les contractants qui sont des personnes physiques (ci-après dénommés « Personnes Physiques ») ne sont pas tenus de présenter de facture et peuvent être payés au moment de la réception, sous une forme satisfaisante, des livrables requis (y compris tout rapport technique et état financier requis) par le département contractant de l'OMS.

La facture des Personnes Morales devra refléter toute exonération d'impôt à laquelle l'OMS pourrait avoir droit en vertu de l'immunité dont elle jouit. De manière générale, l'OMS est exonérée de tout impôt direct, de tout droit de douane et de tous droits et taxes similaires, et la Personne Morale devra se mettre en rapport avec l'OMS afin d'éviter l'application des dites charges en rapport avec le présent accord et les travaux qui en résultent. En ce qui concerne les impôts et autres charges indirects imposés sur la fourniture de biens et de services, (par ex. taxe à la valeur ajoutée), la Personne Morale accepte de vérifier en consultation avec l'OMS si, dans le pays où la charge serait exigible, l'OMS est exonérée de ladite charge à la source ou est en droit d'en réclamer le remboursement. Si l'OMS est exonérée de la taxe à la valeur ajoutée, cela devra être indiqué sur la facture, tandis que si l'OMS est en droit d'en réclamer le remboursement, la Personne Morale accepte de mentionner cette charge de façon séparée sur ses factures et, si nécessaire, de coopérer avec l'OMS afin d'en obtenir le remboursement.

L'OMS n'encourra aucune responsabilité pour quelque taxe, droit ou autre contribution dû par les contractants. Le paiement de quelque taxe, droit ou autre contribution qu'un contractant pourrait être tenu de payer sera de l'entière responsabilité de celui-ci et il n'aura droit à aucun remboursement de la part de l'OMS à ce titre.

4. **Exécution satisfaisante.** Si les travaux ne sont pas accomplis correctement (et, le cas échéant, fournis) à la date prévue par l'accord ou si tout état financier requis n'est pas soumis de façon satisfaisante à l'OMS conformément à la condition générale 5 ci-dessous, l'OMS peut accorder un délai supplémentaire à l'expiration duquel l'accord doit être exécuté de façon satisfaisante. En règle générale, ce délai supplémentaire est d'une semaine au moins, à moins

Sensitivity: Internal & Restricted

GLOBAL PROCUREMENT AND LOGISTICS
Global Service Centre
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Registration	2021/1142104-0
Purchase Order	202710223
Unit Reference	WCO-SRHR

duration, unless it is clear from the agreement that it was particularly important that the performance be completed on the date specified, in which case WHO may specify a shorter period or refuse to grant any additional period at all. In the event that the work is not satisfactorily completed and delivered on the date fixed, or any additional period granted by WHO and/or if any financial statement required is not satisfactorily submitted to WHO in accordance with general condition 5 below, WHO may immediately terminate this agreement (in addition to the other remedies), in accordance with general condition 13 below (without being held to grant the contractor an additional period of thirty (30) days to perform, complete and deliver the work).

5. **Completion and delivery.** The contractor shall complete and deliver the work to WHO (including any technical report that may be required) by the date fixed in this agreement or any additional period that may be granted by WHO under general condition 4 above. Any financial statement required shall be submitted within thirty (30) days thereafter at the latest. If the payment schedule on the face of this agreement provides for a final payment upon completion of the work, this final payment shall be made only after satisfactory receipt of all deliverables called for under this agreement, including any technical report and financial statement.

6. **Certification of status of individual contractors.** Each Individual Contractor certifies that he/she does not presently, and will not during the term of this agreement, hold any form of contractual relationship with WHO (including any WHO regional, country or project office, as well as any programme, center or other entity where staff is subject to WHO Staff Regulations and Rules) that confers upon the Individual Contractor the status of a WHO staff member. The Individual Contractor understands that a false statement may result in the cancellation of any or all contracts, and/or the withdrawal of any offer of a contract, with WHO.

7. **Research involving human participants.** If and to the extent the work to be performed under this agreement includes surveys or interviews involving human participants (hereinafter referred to as "research"), the following shall apply:
7.1 Ethical Aspects
It is the responsibility of the contractor to safeguard the rights and welfare of human subjects involved in research performed under this agreement, in accordance with the appropriate national code of ethics or legislation, if any, and in the absence thereof, the Helsinki Declaration and any subsequent amendments. Prior to commencing any such research, the contractor shall ensure that (a) the rights and welfare of the subjects involved in the research are adequately protected, (b) freely given informed consent has been obtained for all participants, (c) the balance between risk and potential benefits involved has been assessed and deemed acceptable by a panel of independent experts appointed by the contractor, and (d) any special national requirements have been met.
7.2 Regulatory Requirements
It is the responsibility of the contractor to comply with the relevant national regulations pertaining to research involving human subjects.
7.3 Protection of Subjects
Without prejudice to obligations under applicable laws, the contractor shall make appropriate arrangements to eliminate or mitigate any negative consequences to subjects or their families resulting from the conduct of the research under this agreement. Such arrangements shall to the extent feasible include appropriate counseling, medical treatment and financial relief. The contractor furthermore undertakes to protect the confidentiality of the information relating to the possible identification of subjects involved in the research.

8. **Compliance with WHO Policies.** By entering into this agreement, the contractor acknowledges that it has read, and hereby accepts and agrees to comply with, the WHO Policies (as defined below). In connection with the foregoing:
- Company Contractors shall take appropriate measures to prevent and respond to any violations of the standards of conduct, as described in the WHO Policies, by their employees and any other persons engaged by them to perform the work under the agreement; and
- Individual Contractors shall not engage in any conduct that would constitute a violation of the standards of conduct, as described in the WHO Policies.
Without limiting the foregoing, the contractor shall promptly report to WHO, in accordance with the terms of the applicable WHO Policies, any actual or suspected violations of any WHO Policies of which the contractor becomes aware. For purposes of this agreement, the term "WHO Policies" means collectively: (i) the WHO Code of Ethics and Professional Conduct; (ii) the WHO Policy on Sexual Exploitation and Abuse Prevention and Response; (iii) the WHO Code of Conduct for responsible Research; (iv) the WHO Policy on Whistleblowing and Protection Against Retaliation; and (v) the UN Supplier Code of Conduct, in each case, as amended from time to time and which are publicly available on the WHO website at the following links: http://www.who.int/about/finances-

qu'il ne ressorte clairement de l'accord qu'il était particulièrement important d'achever les travaux à la date initialement prévue, auquel cas l'OMS peut accorder un délai plus court ou refuser la moindre prorogation. Si les travaux ne sont pas achevés et livrés de façon satisfaisante à la date prévue ou à l'expiration de tout délai supplémentaire accordé par l'OMS, et/ou si tout état financier requis n'est pas soumis de façon satisfaisante à l'OMS conformément à la condition générale 5 ci-dessous, l'Organisation peut immédiatement résilier le présent accord (sans préjudice d'autres recours dont elle peut disposer), conformément à la condition générale 13 ci-dessous (sans être tenue d'accorder au contractant une période supplémentaire de trente (30) jours pour exécuter, achever et livrer les travaux).

5. **Achèvement et livraison.** Le contractant achève et livre les travaux à l'OMS (y compris tout rapport technique qui pourrait être requis) à la date prévue par l'accord ou à l'expiration de tout délai supplémentaire accordé par l'OMS en application de la condition générale 4 ci-dessus. Tout état financier requis est soumis au plus tard dans les trente (30) jours qui suivent. Si le calendrier de paiement prévu au recto de l'accord prévoit le paiement à la fin des travaux, celui-ci n'est effectué qu'après réception, sous une forme satisfaisante, de tous les livrables exigés aux termes de l'accord, y compris les rapports techniques et les états financiers.

6. **Certification du statut des personnes physiques.** Toute Personne Physique certifie qu'elle n'a pas actuellement et n'aura pas pour la durée du présent accord, de relation contractuelle avec l'OMS (y compris les bureaux régionaux de l'OMS, les bureaux de pays ou de projet, les programmes, centres ou entités où le personnel est soumis au Statut et au Règlement du Personnel de l'OMS) lui conférant le statut de membre du personnel de l'OMS. Toute Personne Physique comprend qu'une fausse déclaration de sa part peut entraîner l'annulation de tous les contrats, et/ou le retrait de toute offre de contrat, avec l'OMS.

7. **Recherches impliquant des êtres humains.** Si et dans la mesure où les travaux à effectuer dans le cadre du présent accord incluent des études ou interviews impliquant des êtres humains (ci-après dénommés "recherches" ou "étude de sujets humains"), les points suivants sont applicables:
7.1 Aspects éthiques
Il incombe au contractant de s'assurer qu'au cours des travaux effectués dans le cadre de cet accord et impliquant l'étude de sujets humains, les droits et la santé de ces derniers soient protégés conformément au code d'éthique ou à la législation du pays, ou, à défaut, à la Déclaration d'Helsinki et aux amendements qui pourraient lui être ultérieurement apportés. Avant de commencer toute recherche, le contractant doit s'assurer que: a. les droits et le bien-être des sujets impliqués sont suffisamment protégés; b. le consentement libre et éclairé a été obtenu pour tous les participants; c. des experts indépendants désignés par le contractant ont évalué les risques et les avantages potentiels et ont jugé qu'ils s'équilibrent de manière acceptable et; d. toute exigence particulière de la réglementation nationale a été satisfaite.
7.2 Exigences réglementaires
Il incombe au contractant de respecter la réglementation nationale relative aux recherches impliquant l'étude de sujets humains.
7.3 Protection des sujets humains
Sans préjudice des obligations lui incombant aux termes des lois en vigueur, le contractant prendra des mesures appropriées en vue d'éliminer ou d'atténuer toute conséquence négative pour les sujets ou leur famille résultant de la conduite des recherches dans le cadre de cet accord. Ces mesures comprendront, dans la mesure du possible, des conseils appropriés, un traitement médical et un dédommagement financier. Le contractant s'engage en outre à protéger le caractère confidentiel des informations qui pourraient permettre d'identifier les sujets impliqués dans les études.

8 **Respect des politiques de l'OMS.** En concluant cet accord, le contractant reconnaît qu'il a lu les Politiques de l'OMS (telles que définies ci-dessous), et qu'il les accepte et convient de s'y conformer. En lien avec ce qui précède :
- les Personnes Morales doivent prendre des mesures appropriées afin de prévenir et répondre à toute violation des normes de conduite, telles que décrites dans les Politiques de l'OMS, par leurs employés et par toute autre personne qu'elles ont engagées pour exécuter les travaux en vertu de cet accord; et
- les Personnes Physiques ne doivent pas adopter un comportement pouvant constituer une violation des normes de conduite, telles que décrites dans les Politiques de l'OMS.
Sans limiter la portée de ce qui précède, le contractant doit immédiatement signaler à l'OMS, conformément aux dispositions des Politiques de l'OMS applicables, toute violation réelle ou présumée dont il a connaissance concernant toute Politique de l'OMS. Aux fins du présent accord, l'**expression « Politiques de l'OMS » signifie collectivement** : (i) le Code d'éthique et de déontologie de l'OMS; (ii) la Politique de l'OMS relative à la prévention et à la lutte contre l'exploitation et les abus sexuels, (iii) le Code de conduite pour une recherche responsable, (iv) la Politique de l'OMS sur le signalement des actes répréhensibles et la protection contre les représailles, et (v) le Code de conduite des fournisseurs des Nations Unies, y compris leurs modifications éventuelles et qui sont publiquement accessibles sur le site internet de l'OMS aux liens suivants : http://www.who.int/about/finances-accountability/procurement/en/ pour ce qui est du Code de conduite des fournisseurs des Nations Unies, et

accountability/procurement/en/ for the UN Supplier Code of Conduct and at http://www.who.int/about/ethics/en/ for the other WHO Policies.

9. **Zero tolerance for sexual exploitation and abuse.** WHO has zero tolerance towards sexual exploitation and abuse. In this regard, and without limiting any other provisions contained herein:

- each Company Contractor warrants that it will: (i) take all reasonable and appropriate measures to prevent sexual exploitation or abuse as described in the WHO Policy on Sexual Exploitation and Abuse Prevention and Response by any of its employees and any other persons engaged by it to perform the work under the agreement, and (ii) promptly report to WHO and respond to, in accordance with the terms of the Policy, any actual or suspected violations of the Policy of which the Company Contractor becomes aware; and
- each Individual Contractor warrants that he/she will: (i) not engage in any conduct that would constitute sexual exploitation or abuse as described in the WHO Policy on Sexual Exploitation and Abuse Prevention and Response; and (ii) promptly report to WHO, in accordance with the terms of the Policy, any actual or suspected violations of the Policy of which the Individual Contractor becomes aware.

10. **Tobacco/Arms Related Disclosure Statement.** Company Contractors may be required to disclose relationships they may have with the tobacco and/or arms industry through completion of the WHO Tobacco/Arms Disclosure Statement. In the event WHO requires completion of this Statement, the Company Contractor undertakes not to permit work on the agreement to commence, until WHO has assessed the disclosed information and confirmed to the Company Contractor in writing that the work can commence.

11. **Anti-terrorism and UN sanctions; Fraud and Corruption.** The contractor warrants for the entire duration of the agreement that:

(i) it is not and will not be involved in, or associated with, any person or entity associated with terrorism, as designated by any UN Security Council sanctions regime, that it will not make any payment or provide any other support to any such person or entity and that it will not enter into any employment or subcontracting relationship with any such person or entity;

(ii) it shall not engage in any illegal, corrupt, fraudulent, collusive or coercive practices (including bribery, theft and other misuse of funds) in connection with the execution of the agreement; and

(iii) the contractor shall take all necessary precautions to prevent the financing of terrorism and/or any illegal, corrupt, fraudulent, collusive or coercive practices (including bribery, theft and other misuse of funds) in connection with the execution of the agreement.

Any payments used by the contractor for the promotion of any terrorist activity or any illegal, corrupt, fraudulent, collusive or coercive practice shall be repaid to WHO without delay.

12. **Breach of essential terms.** The contractor acknowledges and agrees that each of the provisions of general conditions 8, 9, 10 and 11 above constitutes an essential term of this agreement, and that in case of breach of any of these provisions, WHO may, in its sole discretion, decide to:

(i) terminate this agreement, and/or any other contract concluded by WHO with the contractor, immediately upon written notice to the contractor, without any liability for termination charges or any other liability of any kind; and/or

(ii) exclude the contractor from participating in any ongoing or future tenders and/or entering into any future contractual or collaborative relationships with WHO.

WHO shall be entitled to report any violation of such provisions to WHO's governing bodies, other UN agencies, and/or donors.

13. **Termination.** WHO may terminate this agreement or any part thereof with immediate effect (in addition to any other rights or remedies to which WHO may be entitled, including the right to claim damages), on written notice to the contractor if the contractor is:

(i) in breach of any material obligation(s) under this agreement and, to the extent such breach is capable of being remedied, fails to correct such breach within a period of thirty (30) days after having received a written notification to that effect from WHO; or

(ii) adjudicated bankrupt or formally seeks relief of its financial obligations.

14. **Use of WHO name and emblem.** Without WHO's prior written approval, the contractor shall not, in any statement or material of an advertising or promotional nature,

http://www.who.int/about/ethics/en/ pour ce qui est des autres Politiques de l'OMS.

9. **Tolérance zéro pour l'exploitation et les abus sexuels.** L'OMS applique la tolérance zéro en matière d'exploitation et d'abus sexuels. À cet égard, et sans limiter la portée de toute autre disposition du présent accord :

- chaque Personne Morale garantit : i) qu'elle prendra toutes les mesures raisonnables et appropriées pour prévenir tout acte d'exploitation ou d'abus sexuels tels que décrits dans la Politique de l'OMS relative à la prévention et à la lutte contre l'exploitation et les abus sexuels, par l'un quelconque de ses employés et toute autre personne engagée par elle pour exécuter les travaux prévus au titre du présent accord; et (ii) qu'elle signalera immédiatement à l'OMS et donnera suite à toute violation réelle ou présumée de cette Politique dont elle a connaissance, conformément aux dispositions de la Politique; et
- chaque Personne Physique garantit : i) qu'elle n'adoptera aucun comportement qui relèverait de l'exploitation ou l'abus sexuels tels que décrits dans la Politique de l'OMS relative à la prévention et à la lutte contre l'exploitation et les abus sexuels; et ii) qu'elle signalera immédiatement à l'OMS toute violation réelle ou présumée de la Politique dont elle a connaissance, conformément aux dispositions de la Politique.

10. **Déclaration relative à l'industrie du tabac/de l'armement.** Il peut être demandé aux Personnes Morales de déclarer leurs éventuelles relations avec l'industrie du tabac et/ou de l'armement en remplissant la déclaration requise par l'OMS relative à l'industrie du tabac/de l'armement. Dans les cas où l'OMS demande une telle déclaration, la Personne Morale s'engage à ne pas autoriser le commencement des travaux au titre de l'accord tant que l'OMS n'a pas évalué les informations communiquées et confirme par écrit à la Personne Morale que ces travaux peuvent commencer.

11. **Anti-terrorisme et sanctions de l'ONU; fraude et corruption.** Le contractant garantit, pour toute la durée de l'accord :

(i) qu'il n'est ni ne sera impliqué à l'égard de, ni associé à, aucune personne ou entité que le régime de sanctions du Conseil de sécurité de l'ONU a désignée comme étant associée au terrorisme, qu'il ne fera aucun paiement à, ou ne soutiendra d'aucune autre manière, une telle personne ou entité, et qu'il ne conclura aucune relation d'emploi ni de sous-traitance avec une telle personne ou entité ;

(ii) qu'il ne prendra part à aucune pratique illégale, de corruption, de fraude, de collusion ou de coercition (y compris, pots de vin, vol ou autre utilisation abusive de fonds) en lien avec l'exécution de l'accord ; et

(iii) le contractant prendra toutes les précautions nécessaires pour empêcher le financement du terrorisme et/ou toute pratique illégale, de corruption, de fraude, de collusion ou de coercition (y compris, pots de vin, vol ou autre utilisation abusive de fonds) en lien avec l'exécution de l'accord.

Tout paiement utilisé par le contractant pour la promotion de toute activité terroriste ou de toute pratique illégale, de corruption, de fraude, de collusion ou de coercition doit être immédiatement remboursé à l'OMS.

12. **Violation de clauses essentielles.** Le contractant reconnaît et accepte que chacune des dispositions des conditions générales 8, 9, 10 et 11 ci-dessus constitue une clause essentielle du présent accord, et qu'en cas de manquement à l'une quelconque de ces dispositions, l'OMS peut, à sa seule discrétion, décider :

(i) de résilier immédiatement cet accord, et/ou tout autre contrat conclu par l'OMS avec le contractant, moyennant une notification écrite adressée au contractant, sans être redevable d'aucune pénalité au titre d'une telle résiliation et sans que sa responsabilité ne soit engagée d'une quelconque manière que ce soit; et/ou

(ii) d'exclure le contractant de toute participation à des appels d'offres en cours ou à venir et/ou de toute relation contractuelle ou de collaboration future avec l'OMS.

L'OMS sera en droit de rapporter toute violation de ces dispositions aux organes directeurs de l'OMS, aux autres organismes des Nations Unies et/ou aux donateurs.

13. **Résiliation.** L'OMS peut résilier avec effet immédiat le présent accord ou toute partie de celui-ci (en plus de tous les autres droits ou recours dont l'OMS peut se prévaloir, y compris celui de réclamer des dommages-intérêts), moyennant une notification écrite adressée au contractant, si ce dernier :

(i) est en violation d'une (ou plusieurs) obligation(s) importante(s) du présent accord et, dans le cas d'une violation susceptible d'être réparée, manque de remédier à une telle violation dans les trente (30) jours suivant la réception d'une notification écrite de l'OMS envoyée à cet effet ; ou

(ii) s'est déclaré en faillite ou a demandé officiellement à être exonéré de ses obligations financières.

Sensitivity: Internal & Restricted

GLOBAL PROCUREMENT AND LOGISTICS
Global Service Centre
Block 3510
Jalan Teknokrat 6
63000 Cyberjaya
MALAYSIA
gsc-procurement@who.int

WHO Reference/ *Référence OMS*

WHO Registration	2021/1142104-0
Purchase Order	202710223
Unit Reference	WCO-SRHR

refer to this agreement or the contractor's relationship with WHO, or otherwise use the name (or any abbreviation thereof) and/or emblem of the World Health Organization.

15. **Publication of agreement.** Subject to considerations of confidentiality, WHO may acknowledge the existence of this agreement to the public and publish and/or otherwise publicly disclose the contractor's name and for Company Contractors, the country of incorporation, general information with respect to the work described herein and the agreement's value. Such disclosure will be made in accordance with WHO's Information Disclosure Policy and shall be consistent with the terms of this agreement.

16. **Audit.** WHO may request a financial and operational review or audit of the work performed by Company Contractors under this agreement, to be conducted by WHO and/or parties authorized by WHO, and the Company Contractor undertakes to facilitate such review or audit. This review or audit may be carried out at any time during the implementation of the work performed under this agreement, or within five years of completion of the work. In order to facilitate such financial and operational review or audit, the Company Contractor shall keep accurate and systematic accounts and records in respect of the work performed under this agreement.
The Company Contractor shall make available, without restriction, to WHO and/or parties authorized by WHO:

(i) the Company Contractor's books, records and systems (including all relevant financial and operational information) relating to this agreement; and

(ii)reasonable access to the Company Contractor's premises and personnel.

The Company Contractor shall provide satisfactory explanations to all queries arising in connection with the aforementioned audit and access rights.

WHO may request the Company Contractor to provide complementary information about the work performed under this agreement that is reasonably available, including the findings and results of an audit (internal or external) conducted by the Company Contractor and related to the work performed under this agreement.

17. **Surviving provisions.** Those provisions of this agreement that are intended by their nature to survive its expiration or earlier termination shall continue to apply.

18. **Settlement of disputes.** Any matter relating to the interpretation or application of this agreement which is not covered by its terms shall be resolved by reference to Swiss law. Any dispute relating to the interpretation or application of this agreement shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in accordance with the modalities to be agreed upon by the parties or, in the absence of agreement, with the Rules of Arbitration of the International Chamber of Commerce. The parties shall accept the arbitral award as final.

19. **Privileges and immunities.** Nothing contained in or relating to this agreement shall be deemed to constitute a waiver of any of the privileges and immunities enjoyed by WHO and/or as submitting WHO to any national court jurisdiction.

14. **Utilisation du nom et de l'emblème de l'OMS.** Le contractant n'a pas le droit, dans aucune déclaration ni aucun support à caractère publicitaire ou promotionnel, de faire référence au présent accord ou à sa relation avec l'OMS, ni d'utiliser d'une autre manière le nom (ou toute abréviation de celui-ci) et/ou l'emblème de l'Organisation mondiale de la Santé, sans l'autorisation écrite préalable de l'OMS.

15. **Publication de l'accord.** Sous réserve de considérations relatives à la confidentialité, l'OMS a le droit de divulguer l'existence de cet accord et de publier, et/ou rendre public d'une autre manière, le nom du contractant ainsi que, le pays d'enregistrement si le contractant est une Personne Morale, des informations générales concernant les travaux décrits dans le présent accord et la valeur de l'accord. Cette divulgation se fera conformément à la politique de l'OMS sur la divulgation des informations et aux dispositions du présent accord.

16. **Vérification.** L'OMS peut demander qu'un examen ou une vérification de type financier et opérationnel des travaux effectués par les Personnes Morales en vertu du présent accord soit effectué(e) par l'OMS et/ou par des parties autorisées par l'OMS, et la Personne Morale s'engage à faciliter cet examen ou cette vérification. Cet examen ou cette vérification peut être effectué(e) à tout moment pendant l'exécution des travaux effectués au titre du présent accord, ou dans les cinq ans suivant l'achèvement des travaux. Afin de faciliter cet examen ou cette vérification de type financier et opérationnel, la Personne Morale doit tenir des comptes et des registres précis et systématiques sur les travaux effectués en vertu du présent accord.
La Personne Morale doit mettre à la disposition de l'OMS et/ou des parties autorisées par l'OMS, sans restriction:

(i) les livres, les archives et les systèmes de la Personne Morale concernant le présent accord (y compris l'ensemble des informations financières et opérationnelles pertinentes); et

(ii) un accès raisonnable aux locaux et au personnel de la Personne Morale.

La Personne Morale doit fournir des explications satisfaisantes en réponse à toutes les questions découlant de la vérification et des droits d'accès susmentionnés.

L'OMS peut demander à la Personne Morale de lui communiquer des informations complémentaires concernant les travaux exécutés au titre du présent accord qui sont raisonnablement à sa disposition, y compris les conclusions et les résultats d'une vérification (interne ou externe) effectuée par la Personne Morale au sujet des travaux exécutés au titre du présent accord.

17. **Dispositions restant en vigueur après la fin du contrat.** Les dispositions du présent accord qui sont, de par leur nature, destinées à survivre à l'expiration ou à la résiliation anticipée dudit accord continueront de s'appliquer.

18. **Règlement des différends.** Toute question concernant l'interprétation ou l'application du présent accord que les dispositions de ce dernier ne permettent pas de résoudre doit être résolue par référence au droit suisse. Tout différend relatif à l'application ou à l'interprétation du présent accord qui n'aurait pu être résolu à l'amiable fera l'objet d'une conciliation. En cas d'échec de celle-ci, le différend sera réglé par arbitrage. Les modalités de l'arbitrage seront convenues entre les parties ou, en l'absence d'accord, déterminées selon le Règlement d'arbitrage de la Chambre de Commerce internationale. Les parties reconnaissent que la sentence arbitrale sera finale.

19. **Privilèges et immunités.** Aucun des termes du présent accord ne sera considéré comme constituant une renonciation à quelque privilège ou immunité que ce soit dont jouit l'OMS en vertu du droit national ou international et/ou interprété comme une soumission de l'OMS à la compétence d'une quelconque juridiction nationale.

Sensitivity: Internal & Restricted