No.V.25011/318-HRD/2016-HR
Government of India
Ministry of Health and Family Welfare
(Department of Health Research)

2nd Floor IRCS Building
Red Cross Road, New Delhi
Date: 31st Oct., 2016

To,

The Dean,
Mahatma Gandhi Institute of Medical Sciences,
Sevagrma – 442102,
Wardha, Maharashtra.

Subject: HRD Scheme of the Department of Health Research for Young Scientist - project entitled **"Genetic study of mutation and polymorphism in X-linked specific hTAF7L gene related to idiopathic human male infertility cases"** under **Dr. Prafulla S. Ambulkar.**

Dear Sir/Madam,

I am directed to refer to your letter dated 21.04.2016 forwarding of acceptance of the terms and conditions of the fellowship by **Dr. Prafulla S. Ambulkar** and to convey the approval of the Competent Authority for the above mentioned research project initially for a period of one year from **15.11.2016** subject to extension upto the total duration as specified in para 4 below.

2. The budget allotment of first year **Rs.15,04,000/- (Rupees Fifteen Lakh Four Thousand Only)** is sanctioned as detailed in the attached statement (Annexure-I).

3. The component – wise break – up of the total budget for whole duration as sanctioned is given in the enclosed statement (Annexure-II).

4. The approved total duration of the research scheme is **3 Years.**

5. The project is covered under the component **"Young Scientist in newer areas of research".**

6. The payment of grant-in-aid will be further subject to the Rule 206 to 215 and provisions of GFR-2005/DFPR-1978/Receipt and Payment Rules 1983 (as amended from time to time) and also subject to the following terms and conditions:

a. The grant of the project will be released in favour of **"Mahatma Gandhi Institute of Medical Sciences, Sevagram – 442102, Wardha, Maharashtra".**

Other Terms & Conditions of the Grant:

I. The payment of the grant will be made by the Electronic transfer/ Demand Draft/ Cheque and the receipt of the same shall be duly acknowledged by the Institute.

II. After completion of the project/activity the ownership of the physical and intellectual assets created or acquired out of the funds granted shall vest with the Department.

III. Expenditure should on no account exceed the budget sanctioned for the project. Re-appropriation of savings to meet excess expenditure under various sub heads shall not be made without the approval of the DHR. No expenditure shall be incurred on items not sanctioned under the scheme.

IV. Extension beyond the approved duration would not be entertained. If interesting/ important leads emerge that need to be followed-up, a separate proposal may be submitted. Only in exceptional cases, where a valid justification exists, and recommended by the Technical Evaluation Committee and Project Approval Committee an extension can be considered to complete the project.

V. The host Institute would be required to submit an annual progress report and also give audited statement of expenditure by the Auditor of the research Organization/Institute etc. However, the first progress report should be submitted at least three months prior to the completion of the annual report.

VI. At the completion of the project, the final report should be sent in the prescribed format. The report should be submitted not later three months from the date of completion of the project. Failure to submit the Annual/Final report in time may lead to termination of the project without any notice.

The receipt of the letter may kindly be acknowledged.

Yours faithfully

31/10/16

(Om Parkash)
Under Secretary to the Govt. of India
Tel. No. 23736090

Copy to:

1. Dr. Prafulla S. Ambulkar, Senior Research Fellow, Human Genetic Division, Department of Anatomy, Mahatma Gandhi Institute of Medical Sciences, Sevagrma – 442102, Wardha, Maharashtra
2. The Secretary, DHR & DG, ICMR – For information please.

महाराष्ट्र आरोग्य विज्ञान विद्यापीठ, नाशिक
MAHARASHTRA UNIVERSITY OF HEALTH SCIENCES, NASHIK
दिंडोरी रोड, म्हसरुळ, नाशिक - ४२२००४ Dindori Road, Mhasrul, Nashik - 422004
Tel: (0253) 2539206/2539196, Fax: (0253) 2539197
Website: http://www.muhs.ac.in, E-mail: udc@muhs.ac.in

राजेंद्र च. शहाणे
सहा. कुलसचिव

Rajendra C. Shahane
Asstt. Registrar

O.No.: MUHS/UDC/GFL/05/2016-17/ E-1/ 998/2017 Date: 09.08.2017

By e-mail and Speed Post

To,

Dr. Jawalant Waghmare
Asso. Proferssor, Dept. of Anotomy
Mahatma Gandhi Institute of Medical Sciences,
Post Sewagram,
Dist. Wardha – 442 102
jewaghmare@mgims.ac.in

Subject : Sanction of Long Term Research Grant (AY 2016 -17)

Reference: 1) Your LTRG application
2) University Notification no. 25/2014, available on www.muhs.ac.in

Sir / Madam

With reference to the above-cited subject, I am directed to inform you that, on the recommendations of the Research Grant Scrutiny Committee, your research proposal, submitted vide your application referred at sr.no. 2 above, has been accepted and accordingly, Hon'ble Vice-Chancellor is pleased to accord **sanction of Rs. 95,000/-** for **1)**Chemicals for tissue DNA extraction Rs.15,000/-, **2)** DNTP for PCR amplification, make applied bio system Rs.20,000/-, **3)** DNA polymerase & 100 bp ladder; make Agilent Rs.30,000, **4)**Two pairs of primer (SRY & DAX) construction; each primer 24 bp; make IDT tech Rs.5,000/-, **5)**Plastic wares for DNA extraction & PCR Rs.15,000/- ,Contingencies /Sequencing of samples Rs.10,000/- as Long Term Research Grant for teachers.

Kindly note that this sanction of grant accorded to the said student shall always be subject to the rules and regulation as laid down in the University Notification no. 25/2014, as amended from time to time and also any such rules and regulations prescribed by the University from time to time.

You are required to follow and implement the ibid University Notification meticulously.

Yours,

Asst. Registrar
University Department Cell

Copy for Information:

The Dean
Mahatma Gandhi Institute of Medical Sciences,
Post Sewagram,
Dist. Wardha – 442 102

महाराष्ट्र आरोग्य विज्ञान विद्यापीठ
Maharashtra University of Health Sciences
म्हसरुळ, वणी-दिंडोरी रोड, नाशिक ४२२ ००४
Mhasrul, Vani-Dindori Road, Nashik 422 004
Phone: 0253-2539196, Fax: 0253-2539197
website: www.muhs.ac.in, e-mail: udc@muhs.ac.in

University Department Cell

Long Term Research Grant (LTRG) for teachers and MUHS Employees

Terms and Conditions

The sanction of LTRG is subject to,

(i) the terms and conditions as mentioned below,

(ii) the rules and regulations as laid down in the University Notification no. 25/2014 and

(iii) any such rules and regulations prescribed by the University from time to time.

1. A 'Certificate of Acceptance' in the prescribed format (enclosed with the Sanction Letter) of the conditions governing the LTRG project should be sent IMMEDIATELY to this Office, by e-mail, followed by hard copy of the same by SPEED POST.

2. The grant shall not be used for self-finance and for any other purpose, whatsoever, other than the purpose for which it is sanctioned for.

3. Audited Utilisation Certificate of the full allocated amount, audited Statement of Expenditure and final progress report shall be submitted IMMEDIATELY after completion of the project.

4. The grantee College/Institute shall ensure the utilization of grants-in-aid for which it is being sanctioned/paid. In case of non-utilisation/part-utilisation, **simple interest** @ 10% per annum, as amended from time-to-time, on the unutilized amount from the dated of draw to the date of refund as per provisions contained in General Financial Rules of Government of India will be charged.

To be issued on the College Letter-Head of the Institute

Specimen Format
Acceptance Certificate for Long Term Research Grant (LTRG) project for Teachers and MUHS Employees

For Office Use Only

Reference: Sanction Letter no.: MUHS/UDC/GFL/04/2015-16/E-1/ , dated . .2017

Name: Dr. _____, Designation:

College:

Title of the project: .....

.....

.....

1. The research project is not being supported by any other funding agency.

2. The terms and conditions related to LTRG are acceptable to the Principal Investigator and College/Institute.

3. At present, I have no research project approved by MUHS, Nashik and the accounts for the previous project, if any, have been settled.

4. The College/Institute is affiliated to/recognized by MUHS, Nashik, vide letter no. (attach copy) ..... dated .....

5. Date of birth: .....

6. The date of implementation of project is . .201
   (Date of implementation will be the date of sanction of first instalment)

Principal Investigator : Name ..... Sign .....Date: .....

Co-investigator, if any: Name ..... Sign .....Date: .....

Head of Institute : Name ..... Sign with Stamp and date. .....

College/Institute Round Seal

Telephone : 23715217, 23711303
Telefax : 23711303

Secretary-General : SH. TEJINDER AHLUWALIA

E-mail : tbassnindia@yahoo.co.in
Website : www.tbassnindia.org

16/10/2017

SPEED POST

Sub: Short Term Research Project

Madam,

It is further to our letter dated 31.8.2017 informing that your project "Mitochondrial DNA Deletions Mapping in Pulmonary Tuberculosis Patients- A pilot study" has been approved for financial assistance of Rs. 30000/- and your agreement for the same.

Please find enclosed Bank of India cheque No.159496 dated 13/10/2017 for Rs.15,000/-being the first instalment of the financial assistance sanctioned for the short term research project. Kindly acknowledge receipt.

You are requested to kindly proceed with your work and let us have a progress of the same. The second and final instalment will be released on receipt of the satisfactory progress.

Wishing you all the best,

Yours faithfully,

(Tejinder Ahluwalia)
SECRETARY GENERAL

Dr Shweta S. Talhar
Assistant Professor,
Medical Genetics Division,
Department of Anatomy,
Mahatma Gandhi Institute of Medical Sciences,
Sevagram, Wardha, Maharashtra
Pin Code-442102

(no subject)

5 messages

tbassnindia@yahoo.co.in <tbassnindia@yahoo.co.in> Thu, Aug 31, 2017 at 4:21 AM
Reply-To: "tbassnindia@yahoo.co.in" <tbassnindia@yahoo.co.in>
To: "shweta@mgims.ac.in" <shweta@mgims.ac.in>

THE TUBERULOSIS ASOCIATION OF INDIA

Short term research projects: Financial assistance

Sir/Madam,

We feel pleasure to inform you that your research project titled "Mitochondrial DNA Deletions Mapping in Pulmonary Tuberculosis Patients- A pilot study " has been approved for grant of financial assistance of up to Rs.30000/- . This approval is subject to sending (before release of funds) a consent of the researcher that he or she will be able to do this research project within the amount sanctioned.

- The amount approved will be disbursed to you in two equal instalments. The cheques will be issued in favour of the Principal Investigator.
- The first instalment will be released on receipt of your consent/agreement to undertake the project. Second and the final will be disbursed on your submitting the satisfactory progress of the project and the Association being satisfied with the same.
- The results/findings of the research may also be used by the TAI for publication in its Indian Journal of Tuberculosis. So it may not be given/disclosed by the researcher to any one without the prior permission of TAI.
- It is imperative for you or the sponsors of your research project to take care of the statutory requirements such as ethical clearance for the project.

You are advised to start the research project and conclude it within the period as envisaged in your proposal.

The next National Conference (NATCON) is scheduled to be held from 15th to 17th December, 2017 at Amalapuram/Rajahmundry (Andhra Pradesh). We propose to have one or two scientific sessions for TAI-assisted short term research projects in this conference. So if your research outcome is ready by 15th of November, 2017, it may be considered for

Telephone : 23715217, 23711303
Telefax : 23711303

Secretary-General : SH. TEJINDER AHLUWALIA

E-mail : tbassnindia@yahoo.co.in
Website : www.tbassnindia.org

16/10/2017

SPEED POST

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It is further to our letter dated 31.8.2017 informing that your project "Mitochondrial DNA Deletions Mapping in Pulmonary Tuberculosis Patients- A pilot study" has been approved for financial assistance of Rs. 30000/- and your agreement for the same.

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Wishing you all the best,

Yours faithfully,

(Tejinder Ahluwalia)
SECRETARY GENERAL

Dr Shweta S. Talhar
Assistant Professor,
Medical Genetics Division,
Department of Anatomy,
Mahatma Gandhi Institute of Medical Sciences,
Sevagram, Wardha, Maharashtra
Pin Code-442102

NO. BT/BI/04/034/2002 Vol. II

GOVERNMENT OF INDIA
MINISTRY OF SCIENCE AND TECHNOLOGYS
DEPARTMENT OF BIOTECHNOLOGY
BIOINFORMATICS DIVISION

Block No. 2, 6th - 8th Floor
C.G.O. Complex, Lodhi Road.
New Delhi 110 003
Date: 30/11/2017

ORDER

In continuation of this department's sanction order of even number dated: 26th August. 2015, Sanction of the President of India is hereby accorded under Rule 18 of the Delegation of Financial Powers Rules 1978 for the release of a sum of Rs. 8, 33,977/- (Rs. Eight Lakhs Thirty Three Thousand and Nine Hundred Seventy Seven) Being the release for Sub-DIC Project/Bioinformatics Centre; Principal Investigator/Coordinator: Dr. Satish Kumar, Professor & Head, Department of Biochemistry, Mahatma Gandhi Institute of Medical Sciences, Sevagram (Wardha) - 442 102, Maharashtra as per detail given below:

S. No	Item	Amount
Recurring Grant:		
1.	Manpower	5,50,000
2.	Contingency	1,00,000
3.	Travel	25,000
4.	Other Cost:	
	(a). Database/journal	75,000
	(b). Training/workshop in BI	25,000
	(c). Studentship In Bioinformatics	18,256
	(b). Traineeship In Bioinformatics	48,000
3.	Interest Earned	(-)7,279
	Total	8,33,977

(Rs. Eight Lakhs Thirty Three Thousand and Nine Hundred Seventy Seven)

2. The other terms and conditions governing the financial sanction will remain unaltered.

3. The amount of Rs.8,33,977/- (Rs. Eight Lakhs Thirty Three Thousand and Nine Hundred Seventy Seven) will be directly credited by the Pay & Accounts Officer, DBT in the account as detailed below:
Dean, Mahatma Gandhi Institute of Medical Sciences, Sevagram (Wardha) - 442 102, Maharashtra as per detail given below.

Name of the Bank	State Bank of India, Sevagram
Bank Account No	30309119301
IFSC Code	SBIN0012756
MICR Code	442002516

4. The expenditure is Debitable to:

Demand No. 85	:	Department of Biotechnology
3425	:	Other Scientific Research (Major Head)
60	:	Other (Sub Major Head)
60.200	:	Assistance to Other Scientific Bodies (Minor Head)
29	:	Biotechnology Research and Development, Human Resource
29.17	:	Assistance for Research and Development
29.17.31	:	Grant In aid for 2017-18 (Plan)

Contd..../

5. This issue under the power delegated to this department and with the concurrence of IF Division vide their Dy.No.102/IFD/SAN/2697/2017- 2018 dated: 06.10.2017.

6. As per Rule 236 (1) of GFR 2017, the accounts of all Grantee Institutions or Organizations shall be open to inspection by the sanctioning authority and audit, both by the Controller and Auditor General of India under the provision of CAG (DPC) Act 1971 and internal audit by the Principal Accounts Office of the Ministry or Department, whenever the Institution or Organization is called upon to do so.

7. The Competent Authority has allowed a sum of Rs. (-) 3,61,093/- shown as balance to be carried forward from financial year 2016-17 to the financial year 2017-18.

8. The Institute/Agency will keep the whole of the grant in a Bank Account earning interest, and the interest so earned should be reported to DBT in the Utilization Certificate and Statement of Expenditure. The Interest so earned will be treated as created to the institute/Agency and shall be adjusted towards further installment of the grant and or at the time of Final Settlement of Accounts.

9. The Principal Investigator/Coordinator, Sub-DIC Project/Bioinformatics Centre, Mahatma Gandhi Institute of Medical Sciences, Sevagram (Wardha) - 442 102, Maharashtra will submit audited Utilization Certificate and Expenditure Statement in respect of above mentioned amount.

10. A copy of Utilization certificate for the year 2016-17 is enclosed.

11. No UC is pending to this program.

12. This sanction order has been noted at Serial No. 104 in the Register of Grants.

13. All the Official Travel related to this program should be made only through Air India. No International Travel will be undertaken from the sanctioned project grant unless specified otherwise.

(Dr. T. Madhan Mohan)
Adviser

To

The Pay & Account officer
Department of Biotechnology,
New Delhi – 110003

Copy to:

1. Principal Director of Audit (Scientific Deptt.)., AGCR Building, New Delhi
2. Cash section, DBT (2copies)
3. Sanction Folder
4. IFD, DBT
5. Dean, Mahatma Gandhi Institute of Medical Sciences, Sevagram (Wardha) - 442 102, Maharashtra
6. Dr. Satish Kumar, Principal Investigator/Coordinator, Sub-DIC Project/Bioinformatics Centre, Mahatma Gandhi Institute of Medical Sciences, Sevagram (Wardha) - 442 102, Maharashtra
7. Concerned file.

(Dr T. Madhan Mohan)
Adviser

FILE NO. EMR/2016/006466

SCIENCE & ENGINEERING RESEARCH BOARD

5 & 5A, Lower Ground Floor
Vasant Square Mall
Plot No. A, Community Centre
Sector-B, Pocket-5, Vasant Kunj
New Delhi-110070

Dated: 14-Aug-2017

ORDER

Subject: Financial Sanction of the research project titled **"Study of interaction between platelet and human lymphatic filarial parasite with focus on eicosanoid metabolism and its pathophysiological implication"** under the guidance of Dr. Kalyan ' Goswami, Biochemistry, Mahatma Gandhi Institute of Medical Sciences , Sevagram, wardha, Wardha, Maharashtra-442102 and by Prof. D. Dash, Professor, Biochemistry, Institute Of Medical Sciences, Banaras Hindu University and by Dr. Maryada Venkatarami Reddy, Director Professor & Head Of Dept, Biochemistry, Mahatma Gandhi Institute Of Medical Sciences - Release of 1st grant.

Sanction of **Science and Engineering Research Board (SERB**) is hereby accorded to the above mentioned project at a total cost of **Rs. 3840600/- (Rs.** Thirty Eight Lakh Forty Thousand Six Hundred **Only)** with break-up of **Rs. 310000/- under Capital (Non-recurring) head** and **Rs.3530600/- under General (Recurring) head** for a duration of 36 months. The items of expenditure for which the total allocation of **Rs. 3840600/-** has been approved are given below:

The following budget may be considered for **Mahatma Gandhi Institute Of Medical Sciences, Sevagram, Wardha**

S. No	Head	Total (in Rs.)
A	**Non-recurring**	
1	Equipment -> Biosafety Cabinet Type II	310000
A'	Total (Non-Recurring)	**310000**
B	**Recurring Items**	
1	Recurring - A : (Manpower, Consumables, Travel, Contingencies)	2531600
2	Recurring - B : (Overhead Charges)	284000
B'	Total (Recurring)	**2815600**
C	**Total cost of the project (A' + B')**	**3125600**

The following budget may be considered for **Banaras Hindu University, Pandit Madan Mohan Malviya Road, Varanasi**

S. No	Head	Total (in Rs.)
A	**Non-recurring**	
1	Equipment	0
A'	Total (Non-Recurring)	**0**
B	**Recurring Items**	
1	Recurring - A :	650000
2	Recurring - B : (Overhead Charges)	65000
B'	Total (Recurring)	**715000**
C	**Total cost of the project (A' + B')**	**715000**

2. Sanction of the **SERB** is also accorded to the payment of
Rs. 310000/- (Rupees Three Lakh Ten Thousand only) under 'Grants for creation of capital assets' and **Rs. 938500/-** (Rupees Nine Lakh Thirty Eight Thousand Five Hundred only) under 'Grants-in-aid General' to **Dean, Mahatma Gandhi Institute Of Medical Sciences, Sevagram, Wardha**
and **Rs. 238000/-** (Rupees Two Lakh Thirty Eight Thousand only) under 'Grants-in-aid General' to **Registrar, Banaras Hindu University, Pandit Madan Mohan Malviya Road, Varanasi**
being the first installment of the grant for the year 2017-2018 for implementation of the said research project.

3. Sanction of the grant is subject to the conditions as detailed in Terms & Conditions available at website (www.serb.gov.in).

4. Overhead expenses are meant for the host Institute towards the cost for providing infrastructural facilities and general administrative support etc. including benefits to the staff employed in the project.

5. While providing operational flexibility among various subheads under head Recurring-A, it should be ensured that not more than Rs. 1.5 lakh each should be spent for travel and contingency.

6. As per rule 211 of GFR, the accounts of project shall be open to inspection by sanctioning authority/audit whenever the institute is called upon to do so.

7. The institute will furnish to the SERB, New Delhi, separate Utilization certificate(UCs) financial year wise to the SERB for Recurring (Grants-in-aid General) & Non-Recurring (Grants for creation of capital assets) and an audited statement of accounts pertaining to the grant immediately after the end of each financial year.

8. The manpower sanctioned in the project, if any is co-terminus with the duration of the project and SERB will have no liability to meet the fellowship and salary of supporting staff if any. beyond the duration of the project

9. The institute will maintain separate audited accounts for the project. A part or whole of the grant must be kept in an interest earning bank account which is to be reported to SERB. The interest thus earned will be treated as credit to the institute to be adjusted towards further installment of the grant.

10. The sanctioned equipments and consumables would be produced as per GFR 2005 and its disposal would be done with prior approval of SERB.

11. The institute may refund any unspent balance to SERB by means of a Demand Draft favoring "FUND FOR SCIENCE AND ENGINEERING RESEARCH" payable at New Delhi.

(Dr. Balachandar Venkatesan)
Scientist E
ms_hs@serbonline.in

To,
Finance & Budget Officer
SERB, New Delhi
Copy forwarded for information and necessary action to: -

1.	The Principal Director of Audit, A.G.C.R.Building, IIIrd Floor I.P. Estate, Delhi-110002
2.	Sanction Folder, SERB , New Delhi.
3.	File Copy
4.	**Dr. Kalyan ' Goswami** **Biochemistry** **Mahatma Gandhi Institute of Medical Sciences , Sevagram, wardha, Wardha, Maharashtra-442102** **Email: goswamikln@gmail.com** **Mobile: 919970030441** **Prof. D. Dash** **Biochemistry, Institute Of Medical Sciences** **Banaras Hindu University** **Dr. Maryada Venkatarami Reddy** **Biochemistry** **Mahatma Gandhi Institute Of Medical Sciences** (Start date of the project may be intimated by name to the undersigned. For guidance, terms & Conditions etc. Please visit www.serb.gov.in.)
5.	**Dean,** **Mahatma Gandhi Institute Of Medical Sciences, Sevagram, Wardha** **Registrar,** **Banaras Hindu University, Pandit Madan Mohan Malviya Road, Varanasi** (Receipt of Grant may be intimated by name to the undersigned)

(Dr. Balachandar Venkatesan)
Scientist E
ms_hs@serbonline.in

FILE NO. EMR/2016/006466
SCIENCE & ENGINEERING RESEARCH BOARD(SERB)
(a statutory body of the Department of Science & Technology, government of India)

5 & 5A, Lower Ground Floor
Vasant Square Mall
Plot No. A, Community Centre
Sector-B, Pocket-5, Vasant Kunj
New Delhi-110070

Dated: 14-Aug-2017

ORDER

Subject: Financial Sanction of the research project titled **"Study of interaction between platelet and human lymphatic filarial parasite with focus on eicosanoid metabolism and its pathophysiological implication"** under the guidance of Dr. Kalyan ' Goswami, Biochemistry, Mahatma Gandhi Institute of Medical Sciences , Sevagram, wardha, Wardha, Maharashtra-442102 and by Dr. Maryada Venkatarami Reddy, Director Professor & Head Of Dept, Biochemistry, Mahatma Gandhi Institute Of Medical Sciences - Release of 1st grant.

Sanction of **Science and Engineering Research Board (SERB)** is hereby accorded to the above mentioned project at a total cost of **Rs. 3125600/- (Rs.** Thirty One Lakh Twenty Five Thousand Six Hundred **Only)** with break-up of **Rs. 310000/- under Capital (Non-recurring) head** and **Rs.2815600/- under General (Recurring) head** for a duration of 36 months. The items of expenditure for which the total allocation of **Rs. 3125600/-** has been approved are given below:

The following budget may be considered for **Mahatma Gandhi Institute Of Medical Sciences, Sevagram, Wardha**

S. No	Head	Total (in Rs.)

A	**Non-recurring**	
1	Equipment -> Biosafety Cabinet Type II	310000
A'	Total (Non-Recurring)	**310000**
B	**Recurring Items**	
1	Recurring - A : (Manpower, Consumables, Travel, Contingencies)	2531600
2	Recurring - B : (Overhead Charges)	284000
B'	Total (Recurring)	**2815600**
C	**Total cost of the project (A' + B')**	**3125600**

2. Sanction of the **SERB** is also accorded to the payment of

Rs. 310000/- (Rupees Three Lakh Ten Thousand only) under 'Grants for creation of capital assets' and **Rs. 938500/-** (Rupees Nine Lakh Thirty Eight Thousand Five Hundred only) under 'Grants-in-aid General' to **Dean, Mahatma Gandhi Institute Of Medical Sciences, Sevagram, Wardha**

being the first installment of the grant for the year 2017-2018 for implementation of the said research project.

3. The expenditure involved is debitable to **Fund for Science & Engineering Research (FSER)**

This release is being made under Extra Mural Research Funding (Individual Centric). (PAC Health Sciences)

4. The Sanction has been issued to Mahatma Gandhi Institute Of Medical Sciences, Sevagram, Wardha with the approval of the competent authority under delegated powers on **12 August, 2017** and vide Diary No. **SERB/F/4823/2017-2018** dated **14 August, 2017**

5. Sanction of the grant is subject to the conditions as detailed in Terms & Conditions available at website (www.serb.gov.in).

6. Overhead expenses are meant for the host Institute towards the cost for providing infrastructural facilities and general administrative support etc. including benefits to the staff employed in the project.

7. While providing operational flexibility among various subheads under head Recurring-A, it should be ensured that not more than Rs. 1.5 lakh each should be spent for travel and contingency.

8. As per rule 211 of GFR, the accounts of project shall be open to inspection by sanctioning authority/audit whenever the institute is called upon to do so.

9. The sanctioned equipment would be procured as per GFR and its disposal of the same would be done with prior approval of SERB.

10. The release amount of **Rs. 1248500/-** (Rupees Twelve Lakh Forty Eight Thousand Five Hundred only) will be drawn by the Under Secretary of the SERB and will be disbursed by means of RTGS transaction as per their Bank details given below:

Account Name	**Mahatma Gandhi Institute of Medical Sciences**
Account Number	**1784800213**
Bank Name & Branch	**Central Bank Of India Central Bank of India, Sevagram, Wardha 442 102**
IFSC/RTGS Code	**CBIN0280697**
Email id of A/C Holder	**dean@mgims.ac.in**
Email id of PI	**goswamikln@gmail.com**

11.The institute will furnish to the SERB, New Delhi, separate Utilization certificate(UCs) financial year wise to the SERB for Recurring (Grants-in-aid General) & Non-Recurring (Grants for creation of capital assets) and an audited statement of accounts pertaining to the grant immediately after the end of each financial year.

12. The institute will maintain separate audited accounts for the project. A part or whole of the grant must be kept in an interest earning bank account which is to be reported to SERB. The interest thus earned will be treated as credit to the institute to be adjusted towards further installment of the grant.

13. The project File no. EMR/2016/006466 may also be mentioned in all research communications arising from the above project with due acknowledgement of SERB.

14. The manpower sanctioned in the project, if any is co-terminus with the duration of the project and SERB will have no liability to meet the fellowship and salary of supporting staff if any. beyond the duration of the project

15. As this is the first grant being released for the project, no previous U/C is required.

16. The institute may refund any unspent balance to SERB by means of a Demand Draft favoring "FUND FOR SCIENCE AND ENGINEERING RESEARCH" payable at New Delhi.

17. The organization/institute/university should ensure that the technical support/financial assistance provided to them by the Science & Engineering Research Board, a statutory body of the Department of Science & Technology (DST), Government of India should invariably be highlighted/ acknowledged in their media releases as well as in bold letters in the opening paragraphs of their Annual Report.

18. In addition, the investigator/host institute must also acknowledge the support provided to them in all publications, patents and any other output emanating out of the project/program funded by the Science & Engineering Research Board, a statutory body of Department of Science & Technology (DST), Government of India.

(Dr. Balachandar Venkatesan)
Scientist E
ms_hs@serbonline.in

To,
Under Secretary
SERB, New Delhi
Copy forwarded for information and necessary action to: -

1.	The Principal Director of Audit, A.G.C.R.Building, IIIrd Floor I.P. Estate, Delhi-110002
2.	Sanction Folder, SERB , New Delhi.
3.	File Copy
4.	**Dr. Kalyan ' Goswami** **Biochemistry** **Mahatma Gandhi Institute of Medical Sciences , Sevagram, wardha, Wardha, Maharashtra-442102** **Email: goswamikln@gmail.com** **Mobile: 919970030441** **Dr. Maryada Venkatarami Reddy** **Biochemistry** **Mahatma Gandhi Institute Of Medical Sciences** (Start date of the project may be intimated by name to the undersigned. For guidance, terms & Conditions etc. Please visit www.serb.gov.in.)
5.	**Dean,** **Mahatma Gandhi Institute Of Medical Sciences, Sevagram, Wardha** (Receipt of Grant may be intimated by name to the undersigned)

(Dr. Balachandar Venkatesan)
Scientist E
ms_hs@serbonline.in

FILE NO. EMR/2016/006466
SCIENCE & ENGINEERING RESEARCH BOARD(SERB)
(a statutory body of the Department of Science & Technology, government of India)
5 & 5A, Lower Ground Floor
Vasant Square Mall
Plot No. A, Community Centre
Sector-B, Pocket-5, Vasant Kunj
New Delhi-110070

Dated: 14-Aug-2017

ORDER

Subject: Financial Sanction of the research project titled **"Study of interaction between platelet and human lymphatic filarial parasite with focus on eicosanoid metabolism and its pathophysiological implication"** under the guidance of Prof. D. Dash, Biochemistry, Institute of Medical Sciences, Banaras Hindu University , Banaras Hindu University - Release of 1st grant.

Sanction of **Science and Engineering Research Board (SERB**) is hereby accorded to the above mentioned project at a total cost of **Rs. 715000/- (Rs.** Seven Lakh Fifteen Thousand **Only)** with break-up of **Rs. 0/- under Capital (Non-recurring) head** and **Rs.715000/- under General (Recurring) head** for a duration of 36 months. The items of expenditure for which the total allocation of **Rs. 715000/-** has been approved are given below:
The following budget may be considered for **Banaras Hindu University, Pandit Madan Mohan Malviya Road, Varanasi**

S. No	**Head**	**Total (in Rs.)**
A	**Non-recurring**	
1	Equipment	0
A'	Total (Non-Recurring)	**0**
B	**Recurring Items**	
1	Recurring - A :	650000
2	Recurring - B : (Overhead Charges)	65000
B'	Total (Recurring)	**715000**
C	**Total cost of the project (A' + B')**	**715000**

2. Sanction of the **SERB** is also accorded to the payment of
and **Rs. 238000/-** (Rupees Two Lakh Thirty Eight Thousand only) under 'Grants-in-aid General' to **Registrar, Banaras Hindu University, Pandit Madan Mohan Malviya Road, Varanasi**
being the first installment of the grant for the year 2017-2018 for implementation of the said research project.
3. The expenditure involved is debitable to **Fund for Science & Engineering Research (FSER)**
This release is being made under Extra Mural Research Funding (Individual Centric). (PAC Health Sciences)

4. The Sanction has been issued to Banaras Hindu University, Pandit Madan Mohan Malviya Road, Varanasi with the approval of the competent authority under delegated powers on **12 August, 2017** and vide Diary No. **SERB/F/4824/2017-2018** dated **14 August, 2017**

5. Sanction of the grant is subject to the conditions as detailed in Terms & Conditions available at website (www.serb.gov.in).

6. Overhead expenses are meant for the host Institute towards the cost for providing infrastructural facilities and general administrative support etc. including benefits to the staff employed in the project.

7. While providing operational flexibility among various subheads under head Recurring-A, it should be ensured that not more than Rs. 1.5 lakh each should be spent for travel and contingency.

8. As per rule 211 of GFR, the accounts of project shall be open to inspection by sanctioning authority/audit whenever the institute is called upon to do so.

9. The sanctioned equipment would be procured as per GFR and its disposal of the same would be done with prior approval of SERB.

10. The release amount of **Rs. 238000/-** (Rupees Two Lakh Thirty Eight Thousand only) will be drawn by the Under Secretary of the SERB and will be disbursed by means of RTGS transaction as per their Bank details given below:

Account Name	**Project Account**
Account Number	**27790200000003**
Bank Name & Branch	**Bank of Baroda Bank of Baroda, BHU Campus, Varanasi-221005**
IFSC/RTGS Code	**BARB0BHUVAR**
Email id of A/C Holder	**registrar@bhu.ac.in**
Email id of PI	**goswamikln@gmail.com**

11.The institute will furnish to the SERB, New Delhi, separate Utilization certificate(UCs) financial year wise to the SERB for Recurring (Grants-in-aid General) & Non-Recurring (Grants for creation of capital assets) and an audited statement of accounts pertaining to the grant immediately after the end of each financial year.

12. The institute will maintain separate audited accounts for the project. A part or whole of the grant must be kept in an interest earning bank account which is to be reported to SERB. The interest thus earned will be treated as credit to the institute to be adjusted towards further installment of the grant.

13. The project File no. EMR/2016/006466 may also be mentioned in all research communications arising from the above project with due acknowledgement of SERB.

14. The manpower sanctioned in the project, if any is co-terminus with the duration of the project and SERB will have no liability to meet the fellowship and salary of supporting staff if any. beyond the duration of the project

15. As this is the first grant being released for the project, no previous U/C is required.

16. The institute may refund any unspent balance to SERB by means of a Demand Draft favoring "FUND FOR SCIENCE AND ENGINEERING RESEARCH" payable at New Delhi.

17. The organization/institute/university should ensure that the technical support/financial assistance provided to them by the Science & Engineering Research Board, a statutory body of the Department of Science & Technology (DST), Government of India should invariably be highlighted/ acknowledged in their media releases as well as in bold letters in the opening paragraphs of their Annual Report.

18. In addition, the investigator/host institute must also acknowledge the support provided to them in all publications, patents and any other output emanating out of the project/program funded by the Science & Engineering Research Board, a statutory body of Department of Science & Technology (DST), Government of India.

(Dr. Balachandar Venkatesan)
Scientist E
ms_hs@serbonline.in

To,
Under Secretary
SERB, New Delhi
Copy forwarded for information and necessary action to: -

1.	The Principal Director of Audit, A.G.C.R.Building, IIIrd Floor I.P. Estate, Delhi-110002
2.	Sanction Folder, SERB , New Delhi.
3.	File Copy
4.	**Prof. D. Dash** **Biochemistry, Institute of Medical Sciences** **Banaras Hindu University , Banaras Hindu University** **Email: ddash.biochem@gmail.com** **Mobile: 919336910665** (Start date of the project may be intimated by name to the undersigned. For guidance, terms & Conditions etc. Please visit www.serb.gov.in.)
5.	**Registrar,** **Banaras Hindu University, Pandit Madan Mohan Malviya Road, Varanasi** (Receipt of Grant may be intimated by name to the undersigned)

(Dr. Balachandar Venkatesan)
Scientist E
ms_hs@serbonline.in

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

File Number: EMR/2016/006466

Dated: 13-Oct-2017

Subject: Start date for the project titled "Study of interaction between platelet and human lymphatic filarial parasite with focus on eicosanoid metabolism and its pathophysiological implication".
Dear Dr. Kalyan ' Goswami,

The start date of your file number **EMR/2016/006466** is **9 October, 2017, 9 October, 2017**

You are now requested to upload the Statement of Expenditure and Utilization Certificate after each financial year so as to enable us release next installments.

To upload SE/UC , Kindly go to Submitted Proposals --> **View** --> **Select the File Number** --> **Upload SE/UC** --> **Upload New SE**

Yours sincerely,
(Dr. Under Secretary)
DDO
Email: finance@serb.gov.in

Dr. Kalyan ' Goswami
Biochemistry
Mahatma Gandhi Institute Of Medical Sciences , Sevagram, Wardha, Wardha, Maharashtra-442102

[illegible]

SCIENCE & ENGINEERING RESEARCH BOARD (SERB)

(A statutory body of the Department of Science & Technology, Government of India)

5 & 5A, Lower Ground Floor
Vasant Square Mall
Plot No. A, Community Centre
Sector-B, Pocket-5, Vasant Kunj
New Delhi-110070

Dated: [illegible] 2017

ORDER

Subject: [illegible] Mahatma Gandhi Institute of Medical Sciences, Sevagram [illegible]

Sanction of Science and Engineering Research Board (SERB) is hereby accorded [illegible] project [illegible] total cost of Rs. [illegible] under Capital (Non-Recurring) [illegible] under [illegible] (Recurring) head for a duration of three years. The details of expenditure [illegible] approved are given below:

The following budget [illegible] for Mahatma Gandhi Institute of Medical Sciences, Sevagram, Wardha

S. No	Head	Total (in Rs.)
A	Non-recurring	
1	Equipment [illegible]	[illegible]
A'	Budget (Non-Recurring)	[illegible]
B	Recurring Grants	
1	Recurring - [illegible]	[illegible]
2	Recurring - [illegible] (Overhead Charges)	[illegible]
D	Total Recurring	[illegible]
C	Total cost of the project (A + B)	[illegible]

2. Sanction of the SERB is also accorded to the payment of:
   - Rs. [illegible] towards [illegible] capital assets [illegible] to Mahatma Gandhi Institute of Medical Sciences, Sevagram, Wardha

being the first installment of the grant for the year 2016-17 [illegible]

3. The expenditure [illegible] is debitable to Fund for Science & Engineering Research (FSER)
The [illegible] made under Empowerment and Equity Opportunities for Excellence in Science [illegible] (SC)

4. The Sanction [illegible] Mahatma Gandhi Institute of Medical Sciences, Sevagram [illegible] 2017 [illegible] 22 February 2017

5. Sanction of the grant is subject to the conditions as detailed in Terms & Conditions [illegible]

6. Overhead expenses [illegible] infrastructure [illegible] project.

7. [illegible]

8. [illegible]

9. [illegible]

10. [illegible]

Account Name	Mahatma Gandhi Institute of Medical Sciences, Sevagram
Account Number	[illegible]
Bank Name & Branch	Central Bank of India, Sevagram Branch
IFSC/MICR Code	[illegible]
Email Id of Agency	[illegible]

CLINICAL TRIAL AGREEMENT

THIS CLINICAL TRIAL AGREEMENT ("Agreement") is made and entered into as of 12th day of October 2017 (hereinafter "Effective Date") by and between:

DiagnoSearch Life Sciences Pvt. Ltd. an Indian company with a principal office at 702, Dosti Pinnacle, Plot No. E-7, Road No. 22, Wagle Industrial Estate, Thane- 400604, Maharashtra, India (hereinafter "CRO"), acting on behalf of Serum Institute of India Pvt. Ltd. with office located 212/2, Off Soli Poonawalla Road, Hadapsar, Pune 411028, India. (hereinafter "Sponsor");

Dr. Abhishek Vijay Raut in his personal capacity and with an office located at Department of Community Medicine, Dr. Sushila Nayar School of Public Health, Mahatma Gandhi Institute of Medical Sciences, Sewagram, Wardha, Maharashtra, India – 442 102 (hereinafter "Investigator"); AND

Dr. Sushila Nayar School of Public Health, Mahatma Gandhi Institute of Medical Sciences, Sewagram, Wardha, Maharashtra, India – 442 102 (hereinafter "Institution")

WHEREAS CRO is engaged in the business of managing and providing clinical research services and related activities and has been appointed by Sponsor to arrange and administer a clinical study entitled: ROTA: 06: A Phase II/III, Multicenter, OPEN-LABEL, Randomized Study of Liquid Bovine Rotavirus Pentavalent Vaccine (LBRV-PV) to Evaluate Lot-to-Lot Consistency and to Compare Non-inferiority with ROTASIIL (Lyophilized BRV-PV) in Healthy Infants in India (" the Protocol") and has entered into an agreement with Sponsor or one of its affiliates concerning the management, funding and administration of the Study;

AND WHEREAS Sponsor intends to appoint Investigator relating to the said ROTA: 06 clinical study and requires CRO to supervise the services / activities to be undertaken by Investigator along with the services provided by CRO to Sponsor.

AND WHEREAS Institution and Investigator have each reviewed sufficient information regarding Sponsor's vaccine (the "Study Vaccine"), the Protocol for the Study and the Investigator Brochure to evaluate their interest in participating in the Study and each desires to participate in the Study as more particularly described in this Agreement.

NOW, THEREFORE, subject to the terms, conditions and covenants hereinafter set forth CRO, Investigator and Institution agree as follows.

CRO, Investigator and Institution are sometimes hereinafter individually referred to as a Party and collectively as Parties.

For The Deccan Merchants Co-op. Bank Ltd.
Authorised Signatories

भारत 57329 SPECIAL ADHESIVE महाराष्ट्र
124719 OCT 12 2017 16:54
INDIA Rs.0000100/-PB7019
STAMP DUTY MAHARASHTRA

Article 1 – The Study

1.1 The Institution and the Investigator undertake to conduct the Study in strict accordance with various guidelines and applicable regulatory requirements including but not limited to (a) the current World Medical Association Declaration of Helsinki titled, "Ethical Principles for Medical Research Involving Human Subjects;" (b) the current ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95); (c) the current Indian Ministry of Health and Family Welfare guideline for good clinical practice titled, "Good Clinical Practices for Clinical Research in India;" (d) the current Indian Council of Medical Research ethical guideline for clinical research titled, "Ethical Guidelines for Biomedical Research on Human Subjects;" (e) the written requirements of all reviewing Institutional Ethics Committees and institutional review boards (collectively, the Institutional Ethics Committees) and subsequent amendments if any, to the above guidelines and such other regulations that may be pronounced by a competent authority from time to time. It is understood and agreed that, in the event of a conflict among any of the Standards, the most stringent Standard shall apply.

1.2 The Institution and the Investigator will perform the Study in an efficient and professional manner and will use their best efforts to complete the Study within the time period estimated as mentioned in Schedule B.

1.3 CRO will act as a contact point for the Investigator, Institution and Sponsor, regarding any issue which may arise in the implementation of the study.

1.4 The Study shall be carried out at the Institution under the review of its Institutional Review Board or an appropriate independent review committee of scientists and other qualified individuals as set forth in the Declaration of Helsinki (any such Board, body or committee to be referred to hereinafter as "IRB"), in compliance with the applicable local regulation, Sponsor's Standard Operating Procedure (SOP)s, if required; Institution's own SOP, the Protocol which is approved by Sponsor, Investigator and the IRB and a copy of which is attached hereto as Schedule A (and any subsequently approved Protocol amendments), and the terms of this Agreement and under the supervision of the Investigator.

1.5 Before commencing the Study, the Investigator will seek approval to conduct the study from the IRB and shall obtain consent as per applicable local regulations of all Study Subjects (or, if permitted their legal representative) who participate in the Study, including consent to allow Sponsor and its Affiliates (hereinafter defined) to access personal and medical information as necessary to monitor the Study or to receive and use Study data. Investigator must deliver to the Sponsor/CRO the written approval for the conduct of the Study, the approved informed consent form and the terms of the Protocol from the IRB. In this Agreement "Affiliate" means any entity that controls, is controlled by, or is under common control with the Sponsor. In this context, "control" shall mean (1) ownership by one entity, directly or indirectly, of at least fifty percent (50%) of the voting stock of another entity; or (2) power of one entity to direct the management or policies of another entity, by contract or otherwise;

1.6 The Sponsor/CRO is under no obligation to release Study Vaccine or any other related supplies as defined in Protocol to the Investigator unless and until satisfactory proof of IRB approval is submitted to the CRO.

1.7 Institution and Investigator shall use Study Vaccine only to conduct the Study in accordance with the Protocol; shall not chemically, physically or otherwise modify Study Vaccine, unless specifically required to do so by the Protocol; and shall handle, store, ship and dispose of Study Vaccine with appropriate care and in compliance with manufacturer's instructions and all applicable local, state and federal laws, rules and regulations, including, but not limited to, those governing hazardous substances.

1.8 Institution and Investigator shall not charge any Study subject or third-party payer for Study procedures required by the Protocol that are paid for by CRO/Sponsor under this Agreement or for any Study Vaccine that is provided or paid for by CRO/Sponsor.

1.9 The Investigator hereby warrants that he/she has received a copy of the Investigator Brochure and has read and understood its contents.

1.10 Any change, amendment or modification to this Agreement or any Schedule hereto must be authorized in witting by all Parties. Provided however those changes to the Protocol may be made (i) in accordance with procedures outlined in the Protocol, or (ii) with the agreement of the Investigator, Institution and Sponsor. Any changes to the Protocol shall be accompanied by such notification, review and/or approval of the IRB as may be required by applicable law and/or the Protocol. The Institution and the Investigator shall not consent to any change in the Protocol requested by the relevant IRB without the prior written consent of CRO or SPONSOR.

1.11 The Investigator may appoint such other individuals as she/he, in accordance with applicable law and/or the Protocol, may deem appropriate as sub-investigators to assist in the conduct of the Study (such other individuals are collectively referred to hereinafter as "Sub-investigators"). All such Sub-investigators must be approved by CRO / Sponsor and copies of their curriculum vitae and other regulatory documentation as required (such as financial disclosure forms) forwarded to CRO/ Sponsor. The Investigator shall be responsible for leading any such team of Sub-investigators, and shall ensure that such Sub-investigators are properly qualified and licensed.

1.12 The Investigator hereby certifies and undertakes that s/he is not and has not been debarred under the Drugs and Cosmetics Acts 1940, Drugs and Cosmetics Rules, 1945, and any legislation in connection with any of the services or work provided hereunder as amended, or any other similar legislation, or excluded by a regulatory authority from participating in the development or approval of a drug or biological or disqualified by a regulatory authority as a clinical investigator, and that this certification may be relied upon in any applications to the Federal Food and Drug Administration for drug approval. Furthermore, the Institution and Investigator hereby certify and undertake that they will not use the services of a person so debarred, and that such certification can be similarly

relied upon. It is understood and agreed that this certification imposes a continuing obligation upon the Institution and Investigator to notify the CRO/Sponsor of any change in the truth of this certification.

1.13 The Investigator acknowledges and agrees that its obligations set forth herein are of a personal nature and that the character, competence and reputation of the Investigator were instrumental in the Sponsor's / CRO's selection of the Investigator for the conduct of the Study. Consequently, it is agreed that the Investigator may not in any way transfer, cede or assign, directly or indirectly, the rights granted herein without the express written authorization of the CRO. If Investigator should become unwilling or unable to conduct the Study, the Institution shall consult with the CRO regarding the appointment of a new principal investigator. In such an event, CRO shall supervise the services / activities undertaken by new principal investigator relating to the Study along with the services provided by CRO to Sponsor. If both Parties cannot agree on a substitute, all further enrolment of subjects into the Study shall immediately cease and decision on the continuation of subjects already recruited in the study will be taken jointly by CRO & Sponsor on a case to case basis.

1.14 The Institution and the Investigator shall comply with ICH/GCP, the Protocol and all applicable laws, rules, regulations and documentation of the Study (hereinafter "Regulatory Requirements") in the performance and documentation of the Study. Without in any way limiting the foregoing, these obligations shall include the following:

(a) The Institution and the Investigator shall, as the same may be required of them by Regulatory Requirements, or specific instruction of CRO prepare, document and maintain records and case histories on the case report form supplied by the CRO, retain such data and records after completion of the Study, and obtain advance informed consent from each of the subjects, or their duly authorized representatives, as defined in the Protocol participating in the Study (hereinafter "Subjects").

(b) The Institution and Investigator shall administer the preparation of laboratory tests for shipment (e.g., centrifuge, freezing, packing, labeling) and arrange for courier services with respect to the shipment of biological samples (e.g., completion of shipment forms, ensure the relevant shipment procedure);

(c)The Institution and Investigator shall report adverse events and serious adverse events as required by the regulation in force and amended from time to time. The definition of adverse events and serious adverse events and the reporting procedure are included in the Protocol.

(d) Upon reasonable notice and at reasonable times during the term of this Agreement, Institution and the Investigator shall permit representatives of the CRO and/or the Sponsor to examine their representative facilities, to validate case reports against original data in their files, to make copies of relevant records and monitor the work performed hereunder, and to determine the adequacy of the facilities and whether the Study is being conducted in compliance with this Agreement, and Regulatory Requirements.

CRO/Sponsor representative should also be permitted to review the relevant financial documents related to the Study including but not limited to quotations, invoices, employee agreement, salary slips, attendance records, subject compensation logs, annual maintenance contract (applicable for instruments, equipments being used in the Study) agreements, physical verification of assets.

(e) The Investigator will keep appropriate records of Study Vaccine received, dispensed, used, and returned to pharmacy/storage (and returned to CRO/Sponsor) in accordance with Regulatory Requirements.

1.15 Institution and Investigator agree to inform Sponsor / CRO promptly if they become aware of material non-compliance with the Protocol, ICH Good Clinical Practices, or any applicable laws, rules or regulations; incomplete or inaccurate recording of data; or any significant misconduct or other matters of concern relating to the performance of the Study at Institution.

1.16 Institution and Investigator agree that Sponsor / CRO may make public the names of the Investigator and the Institution as part of a list of Investigators and Institutions conducting the Study when making either protocol or results summary register postings. Institution and Investigator agree that Sponsor may make public the amount of funding provided to Institution by Sponsor for the conduct of the Study and may identify Institution and Investigator as part of this disclosure. Investigator agrees that, if Investigator, consistent with the terms of this Agreement, speaks publicly or publishes any article or letter about a matter related to the Study or Study Vaccine or that otherwise relates to Sponsor, Investigator will disclose that he/she was an investigator for the Study.

1.17 The CRO/ Sponsor shall provide, without cost, sufficient amounts of the Study Vaccine to conduct the Study. The Institution and Investigator may not use or dispose of the Study Vaccine in any way other than as specified in the Protocol.

1.18 Institution agrees that any nationally-licensed medicinal products that are not the subject of the Study but are required for the routine care of a Study subject during and after the Study for the disease or condition to which the Study relates are expected to be available to the Study subject and funded through the usual operations of the local healthcare system independently from the Study and without expectation of support from CRO and/or Sponsor.

1.19 Institution/Investigator agree to record all side effects including laboratory abnormalities, whether serious or not, of which they may become aware in the appropriate Case Report Forms (CRFs) and in medical files of the subjects in accordance with the requirement set out in the Protocol.

Article 2 – Compensation

2.1 Institution and Investigator may enroll up to 200 subjects. Recruitment for this Study will be through competitive enrolment, and Institution and Investigator may enroll more

(but only after receiving written confirmation from Sponsor) or less depending on the enrolment at other sites. Investigator agrees that enrolment in the Study will be restricted pursuant to the Protocol based on the Inclusion / Exclusion criteria. CRO/Sponsor retain the right, to be exercised at CRO's/Sponsor's sole discretion, to terminate this Agreement for any reason, including poor enrolment.

2.2 The Investigator /Institution shall complete and deliver the work to CRO/Sponsor (including any technical report and financial statement that may be required) by the date fixed in this Agreement or any additional period that may be granted by CRO/Sponsor. 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.

2.3 In full and complete consideration of Investigator's and Institution's participation in the Study and of their covenants and obligations hereunder, and to cover their respective costs connected with the conduct of the Study, CRO shall pay amount as set forth in Schedule B hereto. Said amount is based on Subjects completing the Study in full compliance with the Protocol for whom completed case report forms have been delivered by Investigator to CRO/Sponsor or CRO's/Sponsor's designee and all queries have been resolved. The Parties agree that these payment terms are consistent with the principles of fair market value payments for the performance of Study-related activities.

2.4 Subject is said to be enrolled if s/he completed all visit study procedures. If a subject does not complete the Study, the amount payable will be pro-rated according to the number of visits attended by said Subject; provided that, prior to any payment by CRO completed case report forms for such Subjects have been accepted by CRO/Sponsor.

2.5 For all subjects who fail to enroll, the amount payable will be Rs. 2000 per subject. Notwithstanding the foregoing, the maximum number of screen failures for which Investigator shall be compensated shall not exceed 8 % of randomized subjects at site.

2.6 There is no payment for Subjects who are chart screened, but who do not have a informed consent as required by the regulation for the research project and do not complete any of the Screening Visit procedures.

2.7 All payment obligations are conditioned upon Institution's and Investigator's compliance with the standards identified in this Agreement. CRO will not make payments for or, if payment has been made, Institution/Investigator will repay to CRO any payments for study visits, procedures, or other work associated with a Study subject if CRO/Sponsor determine that the Study visits, procedures or other work associated with the subject was not conducted by Investigator, sub investigator or Study staff in compliance with the Protocol, applicable law or regulation, or ICH/ GCP Guidelines.

2.8 Investigator and Institution are responsible for all applicable direct taxes including but not limited to State, Central and municipal taxes presently or hereafter imposed

upon any and all such amounts, including but not limited to professional and incomes taxes, Wealth Tax, Transaction tax. However CRO agrees to pay any indirect tax that may be introduced by any local, state, Central Government / authority including but not limited to service tax, excise, Goods and service tax (GST) based on the revenue and /or out of pocket expenses that are paid/payable by CRO to the Investigator/Institution under this agreement.

2.9 The payments represent all Study costs, and no other money will be payable by CRO.

2.10 The Parties hereby agree and covenant that Investigator / Institution will directly issue invoices to Sponsor which will be certified by CRO. The Parties agree that CRO shall act as a pure agent of Sponsor and facilitate payments to be made to the Investigator / Institution.

2.11 All amounts payable to the Investigator / Institution will be subject to Tax Deduction at source as required by the relevant tax provisions

2.12 Further, as per Rule 96A of Central Goods and Service Tax Act, 2017 Parties agree that:

(i) If invoices issued by CRO, Investigator and Institution are without levying GST, then such invoices shall specifically mention - "**Supply to SEZ Unit or SEZ Developer for Authorised Operations under Bond or Legal Undertaking without payment of Integrated Tax.**" Every such invoice must also mention the GSTIN No. 27AABCS4225M2Z6 of our SEZ unit.

(ii) However, if CRO, Investigator and Institution opt to levy GST, then such invoices shall specifically mention - "**Supply to SEZ Unit or SEZ Developer for Authorised 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 our SEZ unit.

(iii) It is understood that Sponsor enjoys exemption from GST by claiming status of Special Economic Zone (SEZ) unit and accordingly invoices will be raised without levying GST. However, Client shall reimburse the amount including but not limited to tax liability, interest and penalty thereon imposed on CRO/Investigator/Institution by any competent authorities arising out of breach, action, inaction or failure to comply with provisions of Central Goods and Service Tax Act by Sponsor.

2.13 Cheques should be made payable to Dean MGIMS and delivered to the following address:

Mahatma Gandhi Institute of Medical Sciences Sewagram
Mahatma Gandhi Institute of Medical Sciences Sewagram, Wardha, Maharashtra, India-442102

Article 3 – Institution Staff and Facilities

3.1 The Institution acknowledges that all payments for all necessary laboratory and other facilities, equipment, supplies (other than the Study Vaccine), and physicians and clinical support staff required to discharge its obligations under this Agreement are provided for in the compensation schedule as provided in Schedule B. Institution shall ensure that all such facilities and staff are arranged to support the Study.

3.2 All matters, terms and payment of compensation, benefits and other conditions of engagement of any nature for the Investigator, any Sub-investigators and any support staff used in the Study shall be solely a matter between the Institution and such individuals, regardless of whether such individuals are considered employees, agents or independent contractors of the Institution and no amounts payable by CRO under this Agreement shall be considered to be a salary payment by CRO or Sponsor to Investigator , sub-investigator or support staff. All Institution/Investigator staff performing Services under this Agreement shall at all times be employed or engaged by Institution/Investigator and shall not be employees or subcontractors of CRO or Sponsor. Accordingly Institution/Investigator shall deal with all issues relating to the employment or engagement of the Institution/Investigator staff including without limitation: payment of salary and any employment-related benefits; deduction of all Pay As You Earn, National Insurance and any other employee-related taxes and contributions; disciplinary and performance issues; grievances; issues relating to a member of staff's ill health; and issues relating to a member of staff's terms and conditions of employment or engagement

3.3 The Investigator and the Institution will take appropriate steps to inform each Sub-investigator, physician, clinical support staff and any support staff of the terms of this Agreement, obtain their agreement to abide by the terms and conditions of this Agreement and ensure that those persons comply with the terms and conditions of this Agreement.

3.4 During the term of the Agreement, Institution and Investigator agree to permit representatives of the CRO and the Sponsor to examine at any reasonable time during normal business hours the facilities where the Study is being conducted, the Study data including original patient records and any other relevant information necessary to confirm that the Study is being conducted in conformance with the protocol and in compliance with applicable laws and regulations. Institution and / or Investigator shall notify Sponsor / CRO in writing within three (3) business days of becoming aware of any FDA or other government inspection or inquiry concerning the Study or within twenty

four (24) hours of any surprise government inspection or inquiry concerning the Study. Investigator and Institution agrees to promptly take any reasonable actions requested by CRO/Sponsor to cure deficiencies noted during an inspection or audit.

Article 4 – Reports

4.1 The Investigator will maintain accurate and complete records in accordance with Regulatory Requirements and the Investigator will comply with all reporting requirements contained in the Protocol/SOPs/any other Sponsor's specification. The Investigator will provide the CRO/Sponsor with copies of all reports provided to the Investigator's IRB.

4.2 The Investigator shall keep the CRO advised of the status of the Study via periodic reports, which are to be transmitted via electronic means or other mutually agreeable method. The frequency of reports shall be mutually agreed to by both Parties. If required by the Sponsor, there shall also be a final report of the Study presented to the CRO/Sponsor.

4.3 All case report forms and other reports submitted to the CRO and all data generated hereunder shall become the property of the Sponsor and may be used by the Sponsor for any purpose without further obligation or liability to the Institution and/or the Investigator.

4.4 The Institution and the Investigator shall provide such financial disclosures to Sponsor as CRO /Sponsor may request, on such forms as Sponsor may supply or as Sponsor may approve. During the time the Study is being conducted and for one (1) year thereafter, Investigator and each Sub-investigator shall update such forms promptly and provide same to CRO /Sponsor as may be requested by Sponsor or whenever any material change occurs in the information disclosed by a previous form.

4.5 A Subject's individual medical records shall remain the property of the Investigator / Institution. The Investigator will, where duly authorized or where allowed by law, provide or make such medical records and individual Subject data available to the CRO / Sponsor and governmental agencies.

4.6 Institution shall make and retain records regarding the Study as required by the Protocol, applicable law or regulation, or ICH/GCP Guidelines, and in accordance with Institution's standard archiving procedures. Institution will retain such records for a minimum of ten (10) years. Thereafter, Institution will contact Sponsor prior to any destroying such records and will retain the records if requested by Sponsor.

4.7 All Study data and reports and any other information provided to and created by Investigator or Institution in the performance of their duties hereunder remain the property and confidential information of Sponsor at all times.

4.8 The Investigator agrees not to provide the Study data to any third party or to use the Study data in any way without the Sponsor's prior written consent. The Investigator also agrees to not identify, Subjects in order to benefit research conducted or sponsored by any third party, without the Sponsor's prior written consent.

Article 5 – Inventions

5.1 The Institution and Investigator hereby acknowledge and agree that Sponsor shall own all right, title and interest in and to the Protocol, all intellectual property rights arising from the Study including but not limited to reports, discoveries, data, inventions, developments, structures, designs, protocols, biochemical strategies, biological materials, formulations, compositions, analytic methodology, chemical and quality control procedures, devices, know-how, technologies, techniques, systems methods, products, processes, algorithms, concepts, formulas, processes, ideas, writings, trade names, business names, logos, design marks or other proprietary marks, technical research, development and manufacturing data, trade secrets or utility models in any stage of development, whether or not patentable and whether or not reduced to practice, and all improvements, modifications, derivative works from, other rights in and claims related to, any of the foregoing and whether or not made, discovered, conceived, invented, originated, devised or improved by the Institution, Investigator , Sub investigator and Study staff in the performance of the Study or relating to the Study Vaccine or which incorporate Sponsor's confidential Information (collectively, the "Inventions"), and the Institution and Investigator hereby expressly and irrevocably assign, and will cause Sub-investigators and Study staff to assign, to the Sponsor, all right, title and interests that they may have in any such Inventions without payment of additional consideration.

5.2 The Investigator shall promptly disclose to the CRO/Sponsor in writing any and all Inventions generated pursuant to this Agreement and undertake not to use such Inventions than for the purposes of this Agreement without the prior written consent of the Sponsor.

5.3 If CRO/Sponsor requests, Institution and Investigator shall execute, and will cause the Sub investigators and Study staff to execute, any instruments or testify as Sponsor deems necessary for Sponsor and/or Sponsor's Affiliates to draft, file, and prosecute patent applications, defend patents, or to otherwise protect Sponsor 's interest in the Inventions . CRO/Sponsor will reasonably compensate Institution and/or Investigator (as applicable) for the time devoted to such activities and will reimburse Institution and or Investigator (as applicable) for reasonable and necessary expenses incurred. The Institution and the Investigator hereby grant to Sponsor an exclusive, worldwide, irrevocable, non-restrictive and full royalty free license under such Inventions to exploit the same for any purpose whatsoever.

5.4 The obligations of this Section shall survive termination of this Agreement.

Article 6 – Publication; Publicity

6.1 Sponsor will seek to publish the Study results in the searchable, peer reviewed scientific literature in the form of a publication or presentation of Study results from all Study sites (a "Multicenter Publication"). Any participation of the Investigator or other representatives of Institution as a named author of this Multicentre Publication will be determined in accordance with the International Committee of Medical Journal Editors Uniform Requirements for Manuscripts, and Institution and Investigator acknowledge that the enrollment of Study subjects alone is not a qualification for authorship.

6.2 Institution and Investigator, consistent with scientific standards and in a scientific forum, may publish or present the Study results from Institution's Study data (an "Institution Publication"), provided that the Institution Publication does not also disclose any Confidential Information of Sponsor other than the Study results from Institution's Study data. Institution shall submit to Sponsor for review and comment any proposed Institution Publication at least thirty (30) days prior to submitting the Institution Publication to any third party. If Sponsor requests a delay in order to file patent applications relating to any Inventions, Institution and Investigator agree to delay submitting the Institution Publication to any third party for up to one hundred twenty (120) days after Sponsor's request. Institution and Investigator also agree that any Institutional Publication shall only be made after the Multicenter Publication, provided that the Multicenter Publication is submitted within twelve (12) months after conclusion of the Study at all sites.

6.3 The Institution and the Investigator shall not, without the prior written consent of the Sponsor, make or give any public announcements, press releases or statements to the public or the press regarding the Study, this Agreement or use the Sponsor's trademarks, logos, name, or a variant thereof for advertising or promotional purposes.

6.4 The Institution and the Investigator will not use the name of CRO nor Sponsor nor Sponsor's Affiliates nor of any of their employees, in any publicity without the prior written approval of CRO and Sponsor.

Article 7 - Confidential Information

7.1 In connection with the performance of Study services, CRO and/or Sponsor may provide, or have provided, certain Confidential Information (hereinafter defined) to Institution and Investigator solely for the purpose of enabling the Institution and Investigator to conduct the Study. Institution and Investigator agree not to use, or permit the use of Confidential Information except for the performance of this Agreement and not to disclose Confidential Information to third parties except as necessary to conduct the Study and under an agreement by the third party to be bound by the obligations of this Section. Institution shall safeguard Sponsor / CRO Confidential Information with the same standard of care that is used with Institution's confidential information, but in no event less than reasonable care.

7.2 In this Agreement "Confidential Information" means all information (including, without limitation, study protocols, case report forms, clinical data, other data, reports,

specifications, computer programs or models and related documentation, know-how, trade secrets, or business or research plans, processes, procedures) of Sponsor / CRO or their Affiliates that are: (1) provided to Institution and Investigator in connection with this Agreement or the Study; (2) Study data, results, or reports created by Institution, Investigators, Sub-investigators or Study Staff in connection with the Study (except for a Study subject's medical records); and (3) cumulative Study data, results, and reports from all sites conducting the Study.

7.3 The obligations of confidentiality and limited use under this Section shall not extend to:

(i) any information that is or becomes publicly available, except through breach of this Agreement;

(ii) any information that Institution/ Investigator can demonstrate that it possessed prior to, or developed independently from, disclosure or development under this Agreement;

(iii) any information that Institution/ Investigator receives from a third party (other than Sponsor or its Affiliates) which is not legally prohibited from disclosing such information;

(iv) any disclosure of information that Institution/Investigator is required by law to make, provided that CRO/ Sponsor is notified of any such requirement with sufficient time to seek a protective order or other modifications to the requirement;

(v) any information that is appropriate to include in an Institution Publication made in accordance with this Agreement or

(vi) a Study subject's specific medical information, as necessary for the appropriate medical care of the subject.

7.4 Notwithstanding any termination of this Agreement the provisions of confidentiality will apply for a period of ten (10) years from the date hereof.

Article 8 – Independent Contractor

The relationship of Sponsor, CRO, Institution and Investigator under the Agreement is that of independent contractors. The Parties do not intend to create a partnership or joint venture between themselves. Institution and/or Investigator are not an agent of CRO / Sponsor and have no right or authority to bind CRO and/or Sponsor in any manner to any agreement or obligation whatsoever.

Article 9 – Term and Termination; Effect of Termination

9.1 This Agreement shall commence on the Effective Date and shall, unless sooner terminated as herein expressly provided, continue until completion of the Study.

9.2 This Agreement may be terminated by CRO/Sponsor, at any time, with or without cause, immediately upon notice to Investigator to this effect; a notice by CRO and/or Sponsor that the Study is terminated shall also constitute effective notice of termination of this Agreement.

9.3 Upon termination or expiry of this Agreement:

(a) Institution and Investigator will not enroll additional Study Subjects, and will cooperate with CRO and Sponsor in the orderly discontinuation of the Study;

(b) the Parties will meet and confer promptly to determine an appropriate phase-out for Subjects already enrolled in the Study;

(c) Institution and Investigator shall use reasonable efforts to revoke any financial obligations incurred and shall avoid incurring any additional costs in connection with the Study;

(d) Investigator [and Institution] shall be entitled to receive payment by CRO of any amounts accrued as of the date of termination for Study- related work actually performed and expenses actually and reasonably incurred; in the event CRO has pre-paid Investigator and/or Institution for Study services not yet performed as of the date of termination, Investigator shall promptly refund to CRO all such pre-payments;

(e)Investigator and Institution shall deliver to CRO/Sponsor all case report forms and any other reports or documentation prepared during the course of the Study, whether completed or not, in their possession or under their control; and

(f) Investigator and Institution shall either return to CRO / Sponsor or destroy, in accordance with CRO / Sponsor's instructions and / or the terms of the Protocol, all unused or partially used Study Vaccine in their possession or under their control.

(g) All Confidential Information of Sponsor (except for such records that the Institution and Investigator are required by law or regulation to retain) which in the Institution's and/or Investigator's possession shall be promptly delivered to Sponsor, or at Sponsor's discretion destroyed with destruction certified in writing.

(h) Institution represents that medical care for the disease or condition to which the Study relates is available to Study subjects following the Study in accordance with local standard of care through the usual operations of the local healthcare system, and that upon completion of the Study, Institution will appropriate transition Study subjects from the Study to such medical care or refer Study subjects to a health care provider for such medical care.

(i) No termination hereunder shall constitute a waiver of any rights or causes of action that either Party may have based upon events occurring prior to the termination date Articles 5, 6, 7, 10, and 11 shall survive any termination or expiration of this Agreement, as well as any other terms which by their intent or meaning are intended to so survive.

Article 10 – Indemnification

10.1 Sponsor shall defend, indemnify, save and hold harmless the Institution, its directors, officers, employees, agents, assigns and the Investigator (each, an "Institution Indemnitee") from any and all liabilities, claims, actions or suits by third parties for bodily injury or death, that arise out of Institution's administration of the Study Vaccine or procedures provided for by the Protocol ("Institution Claim"), provided that Sponsor shall not indemnify any Institution Indemnitee for any Institution Claim to the extent the Institution Claim arose out of:

(a) failure by Institution Indemnitees to conduct the Study in accordance with (i) this Agreement and the Protocol, (ii) all written instructions delivered by CRO/Sponsor concerning administration of the Study, (iii) all applicable government laws, rules and regulations and (iv) the manner required of a reasonable and prudent clinical investigator or physician; and

(b) the negligence or willful malfeasance of any Institution Indemnitee, or any other person on the Institution's property or under its control, exclusive of CRO / Sponsor employees.

10.2 Sponsor's obligations under this Section with respect to an Institution Claim are conditioned on:

(a) Prompt written notification to Sponsor of the Institution Claim so that Sponsor's ability to defend or settle the Institution Claim is not prejudiced; and

(b) Institution Indemnitees' agreement that CRO/Sponsor has full control over the defense or settlement of the Institution Claim and to fully cooperate with CRO/Sponsor in the defense or settlement of the Institution Claim; provided, that CRO/Sponsor will not settle any such Institution Claim under terms that include an admission of fault or wrongdoing by any Indemnitee or which requires an Indemnitee to undertake a future course of action without that Indemnitee's written consent to such components.

10.3 Additionally, Sponsor also agrees to compensate as required by the current compensation guidelines notified vide:
Gazette dated 30th January 2013, G.S.R 53 (E), rule 122 DAB, 12th December 2014, G.S.R. 889 (E), and any amendment or new pronouncement notified by the Competent Authority

Notwithstanding clause 10.3 above, Sponsor shall not stand to pay any medical expenses of any human subject in the Study in the event of any adverse reaction arising out of or resulting from:

(i) A failure to adhere to the terms of this Agreement, Sponsor's written instructions relating to the Study (including the Clinical Trial Protocol) and/or ICH-GCP guidelines and / or all applicable Standards. All the deviation from the Protocol need to be notified to Sponsor and CRO.

(ii) Institute shall be responsible for all the medical management expenses for the injury caused by negligent acts or omissions or intentional, reckless or willful malfeasance by Investigator, the Institution, or the Institution's staff and employees.

10.4 The Investigator, jointly and severally with Institution, will indemnify and hold the CRO, the Sponsor and their affiliated corporations, successors, directors, trustees, officers, employees and agents harmless from any and all Liabilities suffered by same as a result of a claim asserted against same, arising, or are alleged to arise, from;

(a) negligence or intentional or gross fault on the part of the Institution, Investigator, or any other study personnel involved in the performance of the Study;

(b) activities contrary to the provisions of this Agreement, including a failure to use the Study Vaccine in compliance with the Protocol or to adhere to the terms of the Protocol;

(c) the Investigator's failure to obtain IRB review and approval;

(d) the Investigator's failure to obtain proper written informed consent from the Subjects; or

(e) a breach of any applicable laws by the Institution, Investigator, or any other Study personnel involved in the performance of the Study.

In the event a claim or action is or may be asserted, an Institution Indemnitee shall have the right to select and to obtain representation by separate legal counsel. If an Institution Indemnitee exercises such right, all costs and expenses incurred by such Institution Indemnitee for such separate counsel shall be fully borne by the Institution Indemnitee; provided, that without CRO/Sponsor prior written consent, the Institution Indemnitee shall make no admission to, or any settlement or agreement with, any person or party who is in any manner related to the Liabilities for which indemnification may be sought.

The obligation of this section shall survive termination of this Agreement.

Article 11 – Limitation of Liability

Except for as provided in 10.1 and 10.3, whether attributable to contract, tort, warranty, negligence, strict liability or otherwise, Sponsor/CRO's liability for any claims, damages, losses or liabilities arising out of or related to this Agreement or the Services performed hereunder shall not exceed the amounts paid by CRO to Investigator and/or Institution for Services under this Agreement.

IN NO EVENT SHALL EITHER PARTY BE LIABLE HEREUNDER FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, PUNITIVE OR SPECIAL DAMAGES (INCLUDING BUT NOT LIMITED TO LOST PROFITS AND LOSS OF USE OF FACILITIES) SUSTAINED BY THE OTHER PARTY OR ANY OTHER INDIVIDUAL, THIRD PARTY OR OTHER ENTITY FOR ANY MATTER ARISING OUT OF OR PERTAINING TO THE SUBJECT MATTER OF THIS AGREEMENT. THE PARTIES EXPRESSLY ACKNOWLEDGE THAT THE FOREGOING LIMITATIONS HAVE BEEN NEGOTIATED BY THE PARTIES AND REFLECT A FAIR ALLOCATION OF RISK.

Article 12- Insurance

Institution shall maintain medical professional liability insurance with limits in accordance with local standards for each medical professional involved in the Study, or require that each medical professional maintain such insurance. Upon CRO's /Sponsor's request, Institution shall have its insurance carrier (or shall cause the medical professional to have his or her insurance carrier) furnish to CRO/Sponsor certificates that all insurance required under this Agreement is in force.

Article 13 - Human Rights

Institution represents that, with respect to employment and conducting the Study under this Agreement, Institution will:

(a) not use child labor in circumstances that could cause physical or emotional impairment to the child;

(b) not use forced labor (prison, indentured, bonded or otherwise);

(c) provide a safe and healthy workplace; safe housing (if housing is provided by Institution to its employees); and access to clean water, food, and emergency healthcare in the event of accidents in the workplace;

(d) not discriminate against employees on any grounds (including race, religion, disability or gender);

(e) not use corporal punishment or cruel or abusive disciplinary practices;

(f) pay at least the minimum wage and provide any legally mandated benefits;

(g) comply with laws on working hours and employment rights;

(h) respect employees' right to join and form independent trade unions;

(i) encourage subcontractors under this Agreement to comply with these standards;

(j) maintain a complaints process to address any breach of these standards.

Article 14 - Anti-Bribery and Anti-Corruption

14.1 The Institution and Investigator represent and warrant that they shall not, directly or indirectly, take any action which would cause them, or their employees and sub-investigators to be in violation of any anticorruption or anti-bribery law or regulations applicable to the Investigator ("Anticorruption Laws"), including but not limited to the United States Foreign Corrupt Practices Act of 1977, as amended, or the regulations issued there under ("FCPA").

14.2 The Institution and its affiliates has established and continues to maintain reasonable internal controls and procedures intended to ensure compliance with the Anticorruption Laws and the FCPA, including controls and procedures designed to ensure that the Investigator or its employees or Sub-investigators do not make payments in violation of the Anticorruption Laws and the FCPA

Article 15-EQUIPMENT

(a) With respect to any equipment ("Loaned Equipment") provided to Institution by CRO or Sponsor exclusively to perform the Services pursuant to this Agreement Institution agrees that no title to nor any proprietary rights related to the Loaned Equipment is transferred to Institution, that the Loaned Equipment will be used only for the Study and only as described in the Protocol and any other written directions provided by CRO/Sponsor, that the Loaned Equipment will not be transferred by Institution to the possession of any third party without the written consent of CRO/Sponsor, and that, at the completion of the Study or at CRO's/Sponsor's request, Institution will return the Loaned Equipment and all related training materials and documentation to CRO /Sponsor.

(b) Investigator and Study Staff will attend scheduled training to use the Loaned Equipment following reasonable advance notice of scheduling. The Loaned Equipment will be kept in a safe and secure location and Institution will be responsible for any theft, damage, or loss to the Loaned Equipment other than normal wear and tear. Institution will be responsible for arranging and paying for any required electricity supply, backup power supply, internet connection, telephone line, and/or facsimile line as necessary to use the Loaned Equipment. Institution shall also be responsible for maintenance cost and annual calibration cost which is required to

keep the loaned equipment in a working condition. If the Institution fails to return the Loaned Equipment within the timeframe specified by CRO/Sponsor, the Institution will be responsible for reimbursing CRO/Sponsor for any penalties, late fees, and/or replacement costs.

(c) Institution acknowledges that the Loaned Equipment may involve valuable patent, trademark, trade name, trade secret, and other proprietary rights of the Loaned Equipment manufacturer. Institution will not violate and will take appropriate steps and precautions to ensure that those with access to the Loaned Equipment do not violate these proprietary rights, including, without limitation:
(i) not removing any label or notice of Loaned Equipment ownership or other rights,
(ii) not making any copy, reproduction, changes, modification, or alteration of any software or firmware included with the Loaned Equipment or
(iii) not disassembling or decompiling any such software or firmware or otherwise attempting to discover any source code or trade secret related to such software or firmware.

Article 16– Force Majeure and Delays

In the event either Party shall be delayed or hindered or prevented from the performance of any act required hereunder by reasons of strike, lockouts, labor troubles, failure of power, restrictive government or judicial orders, or decrees, riots, insurrection, war, Acts of God, inclement weather or other similar reason or cause beyond that Party's control, then performance of such act (except for the payment of money owed) shall be excused for the period of such delay; provided the Party provides notice of the existence of and reason for such nonperformance or delay in specific detail. In the event of a delay for a consecutive of 90 days, the non-affected Party will have right to terminate this Agreement by serving written notice to the other Party.

Article 17 – Applicable Law

This Agreement shall be construed, governed, interpreted, and applied in accordance with the laws of India and dispute under this Agreement
and shall be subjected to the exclusive jurisdiction of courts of the City of Pune without regard to its conflict of laws provisions.

Article 18 - Regulatory Inspection:

The Investigator/Institution shall notify the Sponsor/CRO immediately by telephone or facsimile in case they receive any communication from Food and drug Administration or any other governmental or regulatory body with regard to Inspection/Audit of the Institution's facility relating to the Study during the term of this Agreement and shall allow CRO/Sponsor to be present at the inspection or participate in any response to the

action, and provide to Sponsor/CRO copies of all materials correspondence, statements forms and records which the site receives, obtains or generate pursuant to any such Inspection.

Article 19 – Electronic Record and Electronic Signature

Investigator/ Institution acknowledges that Electronic Records (defined hereinafter), Electronic Signatures (defined hereinafter), and handwritten signatures executed to Electronic Records, utilized for capturing study related data and for performing services under this Agreement, will be trustworthy, reliable, and are equivalent to paper records and handwritten signatures executed on paper.

As defined in 21 CFR Part 11 "Electronic record" shall mean any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system. "Electronic signature" shall mean a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

Investigator/ Institution shall remain accountable and responsible for actions initiated under its Electronic Signature.

Article 20 – Miscellaneous

20.1 Institution will obtain written consent from personnel involved in the study that allows Sponsor, Sponsor affiliates, and third party suppliers working for Sponsor or its affiliates to hold and process personal data provided with respect to study staff anywhere in the world, both manually and electronically, for all purposes relating to the performance of this Agreement, for the purposes of administering and managing the business activities of any company in the SPONSOR group of companies, and for compliance with applicable procedures, laws, and regulations.
Investigator consents to the use, storage and processing of his/her personal data as set out above.

20.2 This Agreement, including the annexed Schedules and Appendices , sets forth the entire understanding between the Parties herein, and there are no other understandings or promises, written or verbal, not set forth herein, relating to the subject matter hereof and supersedes all other prior agreements, discussions whether oral or in writing. This Agreement may not be changed or supplemented, except by a writing executed by all Parties.

20.3 The Institution and Investigator understand and agree that SPONSOR is a third party beneficiary to this Agreement and, in this capacity, can enforce any terms as if it were a Party hereto.

20.4 If any provision(s) of this Agreement should be illegal or unenforceable in any respect, the legality and enforceability of the remaining provisions of this Agreement shall not be affected.

20.5 Failure by either Party to enforce any rights under this Agreement shall not be construed as a waiver of such rights nor shall a waiver by either Party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances.

20.6 All legal notices to be given by either Party to the other shall be made in writing by hand delivery or by registered or certified mail, return receipt requested or by other method reasonably capable of proof of receipt thereof and addressed to the Parties at their respective addresses first set forth above to the attention of:

If to the Institution, to:	Dr. Sushila Nayar School of Public Health, Mahatma Gandhi Institute of Medical Sciences, Sewagram, Wardha, Maharashtra, India – 442 102
If to the Investigator, to:	Dr. Abhishek Vijay Raut Department of Community Medicine Dr. Sushila Nayar School of Public Health, Mahatma Gandhi Institute of Medical Sciences, Sewagram, Wardha, Maharashtra, India – 442 102
If to the CRO, to:	DiagnoSearch Life Sciences Pvt. Ltd 702, Dosti Pinnacle, Plot No. E-7, Road No. 22, Wagle Industrial Estate, Thane- 400604, Maharashtra, India
If to the Sponsor, to:	Serum Institute of India Pvt. Ltd. 212/2, Off Soli Poonawalla Road, Hadapsar, Pune 411028, India.

Or to such other address and any Party may designate in writing from time to time to the other. Any notice shall be effective as of its date of receipt.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed in multiple counterparts by their duly authorized representatives.

By: Abhishek 24/OCT/2017
Name: Dr. Abhishek Raut
Title: Principal Investigator

Associate Professor
Community Medicine
MGIMS, Sevagram

FOR AND ON BEHALF OF:
Mahatma Gandhi Institute of Medical Sciences

By: _____
Name: Dr K R Patond
Title: Dean MGIMS

24.x.17

DEAN
Mahatma Gandhi Institute of
Medical Sciences, SEVAGRAM.

FOR AND ON BEHALF OF:
DiagnoSearch Life Sciences Pvt Ltd

By: _____ 12/oct/2017
Name: Mandar Vaidya
Title: Director-Operations

SCHEDULE A
PROTOCOL NUMBER: ROTA: 06

SCHEDULE B

STUDY BUDGET

Headings	V1 (Screening/ Randomization/ Dose 1)	V2 (Dose 2)	V3 (Dose 3)	V4	Total (Rs.)
Part A : Site Grant/ completed subject					
Visit Activities (Investigator/Co-Inv/SP, Study coordinator, phlebotomist, nurse, FW)	6000	3550	3550	1900	15,000
Visit Scheduling & subject follow up					
Source completion, eCRF compeletion & query closure, maintenance of trackers & CRA communication					
ISF maintenance					
Monthly invoice preparation					
Total Grant (per subject)					15,000
Institutional Overheads (@10%)					1,500
Part B: Travel Charges for subject	**500**	**500**	**500**	**500**	**2,000**
Grand Total (per subject)					**18,500**
Total Site Budget (200 subjects)					**3,700,000**
Part C - One Time Costs					
SAEs Payments & Compensation	On Actuals				0
EC Submission	On Actuals				0

Note: An amount of Rs. 2000 will be paid for each screen failed subject. The maximum number of screen failures for which Investigator shall be compensated shall not exceed 8% of total randomized subjects at the site.

ROTA: 06

PAYMENTT SCHEDULE

In connection with the Study, DLS will pay in accordance with the terms set forth in the Budget (schedule B):

1. The first invoice will be at the time of the site initiation visit and will include 25% of the "Total Site Budget (200 subjects)' (INR 925,000/-). This amount will be adjusted in subsequent invoices (15% in every invoice).

2. Subsequent payments (Investigator Grant, Institutional overheads and Patient Compensation) will be made on monthly basis for the amount proportional to the no. of subject visits completed in the preceding month. Site should submit the invoice for the completed subject visit at the end of each month. Sponsor/ designee will arrange to remit the funds to site within 30 days of receipt of correct invoice from the site. If for any reason, site is unable to randomize even one patient in the study, the advance payment will be returned to the Sponsor/ designee within a reasonable period (not exceeding 30 calendar days) on receipt of written communication from Sponsor/ designee to refund this amount.

3. Monthly invoices will be cleared by the Sponsor/ designee within 30 days of submission irrespective of the data being source verified by the monitors. However, site needs to ensure that source data is updated real time and electronic Case Report Form is filled within 05 working days of subject visit. While clearing the invoices at Sponsor/ designee end, in-house monitors will remotely review the compliance to the data entered vs. actual patient visit in the period of invoicing

4. Payment will be pro-rata based on the actual no. of visits completed by the subject.

5. Screen failures would be paid at 2000 INR per subject and payment would be made at end of study.

6. Reimbursement for any investigation performed for safety evaluation will be on actuals on submission of bills.

<u>Other Terms and conditions:</u>

1. Investigator acknowledges that the Study is a multicenter study and the recruitment for this Study will be through competitive enrolment, and investigator may enroll more or less depending on the enrolment at other sites. Investigator agrees that enrolment in the Study will be restricted pursuant to the Protocol based on the inclusion / exclusion criteria. CRO / Sponsor retain the right, to be exercised at Sponsor's sole discretion, to terminate this Agreement for any reason, including poor enrolment.

2. Payment for drop outs or early terminated subjects would be pro-rated depending on the number of completed study visits. Invoice for completed visit will be raised at the end of each month.

3. If the payment towards the Institutional grant and subject compensation is paid to the investigator/institute directly by DiagnoSearch then it will be sole responsibility of the investigator/institute to pay the same to the concerned parties / individual (as applicable)

PAYMENT INSTRUCTIONS

1. All payments except subject compensation will be released after deduction of applicable taxes.

2. Payments will be made through cheque / bank transfer as per the payee details provided below.

Beneficiary Name	Dean MGIMS
Bank Name:	Central Bank of India
Bank Address	Sewagram
Branch	Sewagram
Beneficiary Account No.	1784800213
PAN of the Institute	AAATK2046G

File No: BIO/CT/17/000006
Directorate General of Health Services
Central Drugs Standard Control Organization
FDA Bhawan, Kotla Road New Delhi - 110002
(Biological Division)

Dated: 10-OCT-2017

To,

M/s. Serum Institute of India Pvt. Ltd.
212/2, Off. Soli Poonawalla Road
Hadapsar, Pune Maharashtra (India) - 411028

Subject: Permission for conducting a clinical trial titled "A PHASE II/III, MULTICENTER, OPEN-LABEL, RANDOMIZED STUDY OF LIQUID BOVINE ROTAVIRUS PENTAVALENT VACCINE (LBRV-PV) TO EVALUATE LOT-TO-LOT CONSISTENCY AND TO COMPARE NON-INFERIORITY WITH ROTASIIL (LYOPHILIZED BRV-PV) IN HEALTHY INFANTS IN INDIA".

CT No. CT- 21 /2017

Reference:- Your Application No. BIO/Form44/FF/2017/3815 dated 19-JUN-2017 on the subject mentioned above.

Sir,

This Directorate has no objection to your conducting the subject mentioned clinical trial as per the provisions of Drugs and Cosmetics Rules under the supervision of the following investigators mentioned in your letter and as per **Protocol No.: ROTA-06, Version No. 2.0 Dated: 14-07-2017** submitted to this Directorate.

1. Dr Abhishek Vijay Raut, MBBS,MD, DNB, Department of community Medicine, Dr Sushila Nayar School of Public Health, Mahatma Gandhi Institute of Medical Sciences, Sewagram, District – Wardha (Maharashtra),Pin-442102.
2. Dr. Dinesh Kumar, MBBS,MD, Department of Community Medicine, Government Medical College, Bakshi Nagar, Jammu – 180001
3. Dr Veena G Kamath, MBBS,MD, Centre for vaccine studies, Prasanna School of Public Health, Manipal University, Manipal, Karnataka, PIN-576 104
4. Dr. Anand Kawade, MBBS, MD, Vadu Rural Health Program, Shirdi Sai Baba Rural Hospital. A division of KEM Hospital, Pune. Vadu, Budruk, Shirur Block Pune District, Pune – 412216
5. Dr. Sanjay K. Lalwani, MBBS,MD, ,DNB, Bharati Vidyapeeth Medical College and Hospital, Katraj, Dhankawadi, Pune,Maharashtra-411043
6. Dr. Ritabrata Kundu, MBBS,MD, Institute of Child Health 11 Dr. Biresh Guha Street, Kolkata, West Bengal- 700017
7. Dr. Padmasani Venkat Raman, MD, MRCPCH (UK), Department of pediatrics, Sri Ramachandra Medical Centre, No. 1, Ramachandra Nagar, Porur, Chennai, Tamil Nadu -600116
8. Dr. Madhu Gupta MBBS,MD, Ph.D, Department of Community Medicine, Post Graduate Institute of Medical Education & Research (PGIMER), Chandigarh - 160012

The clinical trial permission is subject to the following conditions:

a. Clinical trial shall be conducted in compliance with the approved protocols, requirements of Schedule Y, Good Clinical Practice Guidelines issued by this Directorate and other applicable regulations.
b. Approval of the Ethics Committee duly registered with the office of DCG (I) shall be obtained before initiating the clinical trial.
c. Clinical trials shall be registered at Clinical trials Registry of India before enrolling the first patient for the study.
d. Annual status report of each clinical trial, as to whether it is ongoing, completed or terminated, shall be submitted to the Licensing Authority, and in case of termination of any clinical trial the detailed reasons for the same shall be communicated to the said Licensing Authority.
e. Any report of serious adverse event occurring during clinical trial study to the subject, after due analysis, shall be forwarded within fourteen days of its occurrence as per Appendix XI and in compliance with the procedures prescribed in Schedule Y.
f. In case of an injury or death during the study to the subjects, the applicant shall provide complete medical management and compensation in the case of trial related injury or death in accordance with rule 122 DAB and the procedures prescribed under Schedule Y, and the details of compensation provided in such cases shall be intimated to the Licensing Authority within thirty days of the receipt of the order of the said authority.
g. The premises of Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial study sites shall be open to inspection by the officers authorized by the Central Drugs Standard Control Organization, who may be accompanied by an officer of the State Drug Control Authority

concerned, to verify compliance to the requirements of Schedule Y, Good Clinical Practices guidelines for conduct of clinical trial in India and other applicable regulations.

h. The Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial study sites and the Investigator shall allow officers authorized by the Central Drugs Standard Control Organization, who may be accompanied by an officer of the State Drug Control Authority concerned, to enter with or without prior notice, any premises of Sponsor including their employees, subsidiaries and branches, their agents, contractors and sub-contractors and clinical trial sites to inspect, search and seize any record, data, document, books, investigational drugs, etc. related to clinical trial and provide adequate replies to any queries raised by the inspecting authority in relation to the conduct of clinical trial.

i. Clinical trial shall be conducted only at those sites which are institutes/hospitals having adequate emergency facilities and duly registered Institutional Ethics committees.

j. The details of payment/honorarium/financial support/fees paid by the Sponsor to the investigator (s) for conducting the study shall be made available to this Directorate before initiation of each of the trial sites.

k. An audio - video recording of the informed consent process in case of vulnerable subjects in clinical trials of New Chemical Entity or New Molecular Entity including procedure of providing information to the subject and his understanding on such consent, shall be maintained by the investigator for record; Provided that in case of clinical trial of anti-HIV and anti-Leprosy drugs, only audio recording of the informed consent process of individual subject including the procedure of providing information to the subject and his understanding on such consent shall be maintained by the investigator for record.

l. It may kindly be noted that merely granting permission to conduct clinical trials with the drug does not convey or imply that based on the clinical trial data generated with the drug, permission to market this drug in the country will automatically be granted to you.

m. 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.

n. Only CDL, Kasauli Certified batches shall be used in the clinical trial.

Yours faithfully,

GYANENDRA NATH SINGH

Digitally signed by GYANENDRA NATH SINGH
Date: 2017.10.12 11:18:08 +05'30'

(Dr. G. N. Singh)
Drugs Controller General (India)

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

No. IEC/78/2017.

Reg. No. ECR/47/Inst/MH/2013
(Under Rule 122 DD. Drug & Cosmetics Rules 1945)

Mahatma Gandhi Institute of Medical Sciences
SEVAGRAM 442 102, Maharashtra, India
Institutional Ethics Committee
For Research on Human Subjects
Tel : 91 7152 284341 Extn. 262, Fax : 91 7152 284333 E mail : iec@mgims.ac.in

Date: 18/08/2017

To,

Dr. B S Garg
Dr. Sushila Nayar School of Public Health,
Department of Community Medicine,
Mahatma Gandhi Institute of Medical Sciences,
Sewagram, Wardha-442102
Maharshtra, India

Protocol ID: VPM1002-IN-3.01TBR

Title of the 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

Date of EC Meeting: 18/08/2017

Time of EC meeting: 10.30 am

Place of EC Meeting: Department of Biochemistry, Institutional Ethics committee for Research on Human Subjects Mahatma Gandhi Institute of Medical Sciences, Sewagram-442102, Maharashtra, India

Members of IEC for Research on Human Subjects, MGIMS have reviewed the following documents submitted vide letters dated 8th Feb 2017, 6 Apr 2017, 4 May 2017, 18 May 2017, 20 Jun 2017, 1 Aug 2017 and 7 Aug 2017 for the clinical study with total 2000 subjects to be enrolled in the study.

Sr. No.	Document	Version date / identifier
Submission dated 8 Feb 2017		
1	Protocol	Version 2.0 dated 10/Dec/2016
2	Protocol signature Page for Version 2.0 Protocol	PI signature dated 23/Dec/2016
3	Investigator Brochure	Version 1.0 dated 22/Jul/2016
4	eCRF	Version 1.0 dated 25/Oct/2016
5	Source Document Draft	Version 1.0 28/Oct/2016

6	Informed Consent Document (English)	Version 2.0 dated 10/Dec/2016
7	Informed Consent Document (Hindi)	Version 2.0 dated 10/Dec/2016
8	Translation Certificate (Hindi)	Dated 12/Jan/2017
9	Informed Consent Document (Hindi to English)	Version 2.0 dated 10/Dec/2016/Hindi to English
10	Back translation Certificate (Hindi to English)	Dated 12/Jan/2017
11	Informed Consent Document (Marathi)	Version 2.0 dated 10/Dec/2016
12	Translation Certificate (Marathi)	Dated 12/Jan/2017
13	Informed Consent Document (Marathi to English)	Version 2.0 dated 10/Dec/2016/Marathi to English
14	Back translation Certificate (Marathi to English)	Dated 12/Jan/2017
15	HIV Consent Document (English)	Version 2.0 dated 10/Dec/2016
16	HIV Consent Document (Hindi)	Version 2.0 dated 10/Dec/2016
17	Translation Certificate (Hindi)	Dated 12/Jan/2017
18	HIV Consent Document (Hindi to English)	Version 2.0 dated 10/Dec/2016/Hindi to English
19	Back translation Certificate (Hindi to English)	Dated 12/Jan/2017
20	HIV Consent Document (Marathi)	Version 2.0 dated 10/Dec/2016
21	Translation Certificate (Marathi)	Dated 12/Jan/2017
22	HIV Consent Document (Marathi to English)	Version 2.0 dated 10/Dec/2016/Marathi to English
23	Back translation Certificate (Marathi to English)	Dated 12/Jan/2017
24	Participant Diary (English)	Version 2.0 dated 03/Jan/2017
25	Participant Diary (Hindi)	Version 2.0 dated 03/Jan/2017
26	Translation Certificate (Hindi)	Dated 16/Jan/2017
27	Participant Diary (Hindi to English)	Version 2.0 dated 03/Jan/2017
28	Back translation Certificate (Hindi to English)	Dated 16/Jan/2017
29	Participant Diary (Marathi)	Version 2.0 dated 03/Jan/2017
30	Translation Certificate (Marathi)	Dated 16/Jan/2017
31	Participant Diary (Marathi to English)	Version 2.0 dated 03/Jan/2017
32	Back translation Certificate (Marathi to English)	Dated 16/Jan/2017
33	PI CV and Medical License	Signed dated 26/Aug/2016
34	Co-I CV and Medical License	
	Dr.Subodh Sharan Gupta	04/Feb/2017

	Dr. Abhishek Vijay Raut	04/Feb/2017
35	Investigator Undertaking	Dated 23/Dec/2016
36	Insurance	Policy No- 152500361510500000001 Period 01/Mar/2016 to 28/Feb/2017
37	DCGI Submission and acknowledgement letter	Dated 23/Sept/2016
Submission dated 6 Apr 2017		
38	DCGI approval	Dated 20/Mar/2017
39	Informed consent documents updated with the travel amount (No change in Version/Identifier)	
	Informed Consent Document (English)	Version 2.0 dated 10/Dec/2016
	Informed Consent Document (Hindi)	Version 2.0 dated 10/Dec/2016
	Informed Consent Document (Hindi to English)	Version 2.0 dated 10/Dec/2016/Hindi to English
	Informed Consent Document (Marathi)	Version 2.0 dated 10/Dec/2016
	Informed Consent Document (Marathi to English)	Version 2.0 dated 10/Dec/2016/Marathi to English
40	Insurance updated	Policy No- 15250036150500000001 Period 01/Mar/2017 to 28/Feb/2018
Submission dated 4 May 2017		
41	CTRI No.: CTRI/2017/03/008266	Registered on 30/03/2017
42	Clarification to conditions of Clinical Trial Permission letter dated 18 Apr 2017	Dated 18 Apr 2017
Submission dated 18 May 2017		
43	Site Organisational Plan	Dated 24/Apr/2017
Submission dated 20 Jun 2017		
44	Source Document	Version 2.0 dated 07/June/2017
45	Consent form for Audio-Visual Recording of Informed Consent (English)	Version 1.0 dated 15/May/2017
46	Consent form for Audio-Visual Recording of Informed Consent (Hindi)	Version 1.0 dated 15/May/2017
47	Translation Certificate (Hindi)	Dated 02/Jun/2017
48	Consent form for Audio-Visual Recording of Informed Consent (Hindi to English)	Version 1.0 dated 15/May/2017/Hindi to English
49	Back translation Certificate (Hindi to English)	Dated 02/Jun/2017
50	Consent form for Audio-Visual Recording of Informed Consent (Marathi)	Version 1.0 dated 15/May/2017

51	Translation Certificate (Marathi)	Dated 02/Jun/2017
52	Consent form for Audio-Visual Recording of Informed Consent (Marathi to English)	Version 1.0 dated 15/May/2017/Marathi to English
53	Back translation Certificate (Marathi to English)	Dated 02/Jun/2017
Submission dated 1 Aug 2017		
54	Clinical Trial Agreement (fully executed CSA)	Dated 29/Jul/2017
Submission dated 7 Aug 2017		
55	Study Organisation plan with summary of changes	Version 2.0 dated 25/Jul/2017

The quorum was met during the meeting. Out of 13 members, 9 members were present as listed below and out of them two members namely Dr. Subodh Gupta and Dr. Rahul Narang being directly involved in the study, volunteered to withdraw from the decision making process based on all the documents received as per requisite mentioned above for approval of this study. It is hereby confirmed that neither PI nor any of the study team members participated in the voting decision making procedures of the committee.

Members present during the meeting are listed below:

Member name	Degree (Qualification)	Gender	Scientific / Non-scientific (Background)	Affiliation with institution(s) (yes/no)
Dr. Ashok Pawade, Chairperson	B.Com, LLB & LLM (Administrative law & Constitutional law) and Ph.D. (Constitutional law)	Male	Non-scientific	NO Ex-Principal, Law College, Wardha (Retired) Not affiliated to any organization at present
Dr. K. Goswami, Member Secretary	MD (Biochemistry)	Male	Scientific	Yes Professor, Department of Biochemistry, MGIMS, Sevagram.
Dr. O. P. Gupta, Member Clinician	MD (Medicine)	Male	Scientific	Yes Senior consultant and emeritus professor, Department of Medicine, MGIMS, Sevagram.
Dr. Manish Jain, Member Clinician	MD (Paediatrics)	Male	Scientific	Yes Professor & Head, Department of Paediatrics, MGIMS, Sevagram
Dr. Rahul Narang Basic Scientist	MD (Microbiology)	Male	Scientific	Yes Professor, Department of Microbiology, MGIMS, Sevagram.
Adv. Harish Chandak, Legal Expert	B.Com, LLB, LLM & Adv. Dip. in Cyber law	Male	Non-scientific	Yes Professional lawyer and Panel advocate for various organizations

Dr. Tarak Kate, Social Scientist / Representative of NGO	MSc. PhD. Botany	Male	Scientific	Yes Founder – Chairman, Dharamitra (NGO committed to sustainable rural development)
Dr. Subodh Gupta, Epidemiologist	MD (Pediatrics), DNB (Social & Preventive Medicine)	Male	Scientific	Yes Professor, Department of Community Medicine, MGIMS, Sevagram.
Mr. V. N. Sable, Layperson from Community	BA Part – II	Male	Non-scientific	No Not affiliated to any organization (Retired Person)

We approve the trial to be conducted in its presented form.

The MGIMS-IEC as a registered body under DCGI is formed and functions in accordance with the ICMR, ICH-GCP and Schedule Y requirements/guidelines.

We expect to be informed about the following

1. Safety information: All SAE occurring during the course of the study, reports of unexpected severe adverse drug reactions, any new information which may adversely affect the safety of the subjects or the conduct of the trial, revised version of IB
2. No deviations from or changes of, the protocol should be initiated without prior written approval / favourable opinion of the IRB/IEC except when necessary to eliminate immediate hazards to the subject, or when changes involve only logistic or administrative changes.
3. Any amendment to the protocol, Informed consent or any other information given to the subjects.
4. Progress of the study quarterly or at the end of the study whichever is earliest.

Dr. Kalyan Goswami
Member Secretary
Member Secretary
Institutional Ethics Committee
Mahatma Gandhi Inst. of Medical Sciences
SEVAGRAM - 442102 Maharashtra India

United Nations Children's Fund
'B' wing, R - 2,
Technopolis building,
Ground floor, Marakab Caves road,
Near MIDC, Opp: Holy Family School,
Andheri (East),
Mumbai - 400093.
INDIA

Telephone: 91 22 26875172/73/74
91 22 66740098
Fax 91 22 26875171
www.unicef.org

SSFA Reference: MAH/SSFA/17/CDN-EDN/019

21 November 2017
Dr. B.S. Garg
Secretary
secretary@mgims.ac.in
The Kasturba Health Society
Seva Gram Wardha
Maharashtra-India

Re: Empowering Family and Communities for responsive care giving: Preparatory phase-22 Nov 2017- 31 Dec 2017

Dear Dr.Garg,

1. I am writing on behalf of the United Nations Children's Fund ("UNICEF") to confirm UNICEF's agreement to make available cash assistance to The Kasturba Health Society,Sevagram Wardha in an amount not exceeding [Ten lakhs thirteen thousand only for period of 22 Nov 2017 to 31 Dec 2017. [INR] (1013000) and supplies as outlined in the Terms of Reference (the "Resources"). The Resources are to strengthen the Organisation's capacity to implement the activity (the "Activity") detailed in the Terms of Reference attached to this letter agreement as Annex I. The Resources are governed by this letter agreement, the Terms of Reference attached as Annex I, and the General Conditions that are found on the public internet at http://www.unicef.org/about/partnerships/files/General_Terms_and_Conditions.docx (hereinafter "Small-Scale Funding Agreement" or "SSFA").

2. Transfer of Resources. UNICEF will transfer the amount of the cash assistance as soon as possible after it receives a copy of this SSFA signed by both Parties and the FACE form as per terms agreed in the Terms of Reference. The Implementing Partner understands that the amount of the cash assistance will not be increased by UNICEF under any circumstances, including in cases of currency fluctuations or price increase. UNICEF will transfer the cash assistance to Organisation by cheque or wire transfer to the following bank account:

Bank name: Central Bank of India
Bank address: The Kasturba Health Soceity Complex. 1st floor, Sewagram
Account title: The Kasturba Health Society, Sewagram
Account No.: 1784800213
Account Currency: INR
Routing No.: CBIN0280697
Bank contact person.

United Nations Children's Fund
B Wing, R - 2
Technopolis building
Ground floor, Mahakali Caves road,
Near MIDC, Opp. Holy Family School,
Andheri (East),
Mumbai - 400093.
INDIA

Telephone 91 22 66751772/73/74
91 22 65740063

Fax 91 22 26870171

www.unicef.org

SSFA Reference: MAH/SSFA/17/CDN-EDN/020

Very truly yours,

United Nations Children's Fund

By Swati Mishra for Date: 21/11/2017

Rajeshwari Chandrasekar

Chief, UNICEF Field office for Maharashtra

AGREED ON BEHALF OF [The Implementing Partner].

By _____

Date: 21/11/2017

Dr. B. S. Garg

Secretary , Kasturba Health Society Seva Gram Wardha

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

unite for children

unicef

United Nations Children's Fund
'B' wing, R - 2,
Technopolis building,
Ground floor, Mahakali Caves road,
Near MIDC, Opp. Holy Family School,
Andheri (East)
Mumbai - 400093
INDIA

Telephone 91 22 26875172/73/74
91 22 66740098

Fax 91 22 26875171

www.unicef.org

SSFA Reference: MAH/SSFA/17/CDN-EDN/019

3. Subject to availability, UNICEF will transfer any supplies as outlined in the Terms of Reference. The Implementing Partner will become owner of the supplies when it receives them. If UNICEF agrees to store the supplies for the Implementing Partner or hold them on the Partner's behalf, the Implementing Partner will become owner of those supplies as agreed between UNICEF and the Implementing Partner. Exceptionally, UNICEF may decide in writing that UNICEF shall remain the owner of the supplies transferred to the Implementing Partner.

4. Implementation and Monitoring of the Activity. Implementing Partner will implement the Activity in conformity with the terms of this SSFA, in particular, Implementing Partner will: (a) undertake the Activity in accordance with the budget, schedule and other details set out in the Terms of Reference; (b) make any designated contribution listed in the Terms of Reference; (c) undertake the Activity with diligence and efficiency; (d) procure any goods or services using the Funding with due consideration to "best value for money" and in agreement with UNICEF; (e) exercise the highest standard of care when administering the Resources. UNICEF will monitor the implementation of the Activity, in accordance with UNICEF's standard procedures for monitoring and evaluating activities it funds. Implementing Partner will provide full cooperation to UNICEF for such monitoring and evaluation, and will require to its employees and personnel to fully cooperate with UNICEF in connection with such monitoring and evaluation.

5. Managing the Resources. Implementing Partner will maintain clear, accurate, complete and up-to-date books and records showing the funds received from UNICEF under this SSFA, as well as disbursements made by the Implementing Partner, including any unspent balance. Implementing Partner will cooperate with UNICEF with any review of the way the cash assistance was administered and spent and how supplies were stored and utilized, and will require its employees and personnel to fully cooperate with UNICEF with such a review.

6. Reports; Returning Unspent Balance. Implementing Partner will provide UNICEF with reports, and frequency of such reporting will be done, in accordance with the requirements in the Terms of Reference. Implementing Partner will return to UNICEF any unspent balance of the cash assistance at the expiration or early termination of this SSFA.

7. Other Matters. This SSFA becomes effective when UNICEF receives a copy duly signed by both Parties. It will be valid until the end date detailed in Annex I. If the Parties have disagreements about the project or the implementation of this SSFA, they will use their best efforts to settle those disagreements amicably. If a disagreement cannot be settled amicably it will be decided finally by the UNICEF respective Regional Director and the Organisation will respect and implement that decision. UNICEF's privileges and immunities are not waived.

8. Please confirm your agreement with the foregoing, on behalf of Organisation, by signing, dating, and returning to us the enclosed copy of this Letter Agreement.

United Nations Children's Fund
[illegible]
Ground floor, Maharshi Karve road,
Near MMC, Opp. Holy Family School,
Andheri (East)
Mumbai - 400069
INDIA

Telephone: 91 22 26575172/73/74
91 22 66140069
Fax 91 22 26575171
www.unicef.org

SSFA Reference: MAH/SSFA/17/CDN-FDN/019

Very truly yours,

United Nations Children's Fund

By Swati Mohapatra Date: 21/11/2017

for Rajeshwari Chandrasekar

Chief, UNICEF Field office for Maharashtra

AGREED ON BEHALF OF [The Implementing Partner]:

By _____

Date: 21/11/2017

Dr. B. S. Garg

Secretary , Kasturba Health Society Seva Gram Wardha

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

unite for children

unicef

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Telephone: 91 22 26875172/73/74
91 22 66740069
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SSFA Reference:

UNICEF Country/Regional Office Letterhead

SSFA Reference: MAH/SSFA/17/CDN-EDN/020

Dr. B.S. Garg
Secretary
secretary@mgims.ac.in
The Kasturba Health Society
Seva Gram Wardha
Maharashtra-India

Re: Empowering Family and Communities for responsive care giving: Preparatory phase: Jan - Apr 18

Dear Dr.Garg:

1. I am writing on behalf of the United Nations Children's Fund ("UNICEF") to confirm UNICEF's agreement to make available cash assistance to Click here to enter text. ([The Kasturba Health Society,Sevagram Wardha) in an amount not exceeding [Fifteen lakhs fifty thousand only for period 01 Jan to 30 Apr 18] [INR] ([15,50,000) and supplies as outlined in the Terms of Reference (the "Resources"). The Resources are to strengthen the Organisation's capacity to implement the activity (the "Activity") detailed in the Terms of Reference attached to this letter agreement as Annex I. The Resources are governed by this letter agreement, the Terms of Reference attached as Annex I, and the General Conditions that are found on the public internet at http://www.unicef.org/about/partnerships/files/General_Terms_and_Conditions.docx (hereinafter "Small-Scale Funding Agreement" or "SSFA").

2. Transfer of Resources. UNICEF will transfer the amount of the cash assistance as soon as possible after it receives a copy of this SSFA signed by both Parties and the FACE form as per terms agreed in the Terms of Reference. The Implementing Partner understands that the amount of the cash assistance will not be increased by UNICEF under any circumstances, including in cases of currency fluctuations or price increase. UNICEF will transfer the cash assistance to Organisation by cheque or wire transfer to the following bank account:

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Account title: The Kasturba Health Society, Sewagram
Account No.: 1784800213
Account Currency: INR
Routing No.: CBIN0280697
Bank contact person:

3. Subject to availability, UNICEF will transfer any supplies as outlined in the Terms of Reference. The Implementing Partner will become owner of the supplies when it receives them. If UNICEF agrees to store the supplies for the Implementing Partner or hold them on the Partner's behalf, the Implementing Partner will become owner of those supplies as agreed between UNICEF and the Implementing Partner. Exceptionally, UNICEF may decide in writing that UNICEF shall remain the owner of the supplies transferred to the Implementing Partner.

4. Implementation and Monitoring of the Activity. Implementing Partner will implement the Activity in conformity with the terms of this SSFA, in particular, Implementing Partner will: (a) undertake the Activity in accordance with the budget, schedule and other details set out in the Terms of Reference; (b) make any designated contribution listed in the Terms of Reference; (c) undertake the Activity with diligence and efficiency; (d) procure any goods or services using the Funding with due consideration to "best value for money" and in agreement with UNICEF; (e) exercise the highest standard of care when administering the Resources. UNICEF will monitor the implementation of the Activity, in accordance with UNICEF's standard procedures for monitoring and evaluating activities it funds. Implementing Partner will provide full cooperation to UNICEF for such monitoring and evaluation, and will require to its employees and personnel to fully cooperate with UNICEF in connection with such monitoring and evaluation.

5. Managing the Resources. Implementing Partner will maintain clear, accurate, complete and up-to-date books and records showing the funds received from UNICEF under this SSFA, as well as disbursements made by the Implementing Partner, including any unspent balance. Implementing Partner will cooperate with UNICEF with any review of the way the cash assistance was administered and spent and how supplies were stored and utilized, and will require its employees and personnel to fully cooperate with UNICEF with such a review.

6. Reports; Returning Unspent Balance. Implementing Partner will provide UNICEF with reports, and frequency of such reporting will be done, in accordance with the requirements in the Terms of Reference. Implementing Partner will return to UNICEF any unspent balance of the cash assistance at the expiration or early termination of this SSFA.

7. Other Matters. This SSFA becomes effective when UNICEF receives a copy duly signed by both Parties. It will be valid until the end date detailed in Annex I. If the Parties have disagreements about the project or the implementation of this SSFA, they will use their best efforts to settle those disagreements amicably. If a disagreement cannot be settled amicably it will be decided finally by the UNICEF respective Regional Director and the Organisation will respect and implement that decision. UNICEF's privileges and immunities are not waived.

8. Please confirm your agreement with the foregoing, on behalf of Organisation, by signing, dating, and returning to us the enclosed copy of this Letter Agreement.

Very truly yours,

SSFA Reference: _____

United Nations Children's Fund

By _____ Date:

[Rajeshwari Chandrasekar]

[Chief, UNICEF Field office for Maharashtra]

AGREED ON BEHALF OF [The Implementing Partner]:

By _____ Date:

Dr. B. S. Garg

[Secretary , Kasturba Health Society Seva Gram Wardha

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

दूरभाष/PABX : 26588980, 26588707, 26589336, 26589745,
26589873, 26589414
फैक्स/FAX : 011-26588662, 011-26589791, 011-26589258

तार / GRAM : वैज्ञानी / SCIENTIFIC
Web-site : www.icmr.nic.in
E-mail : icmrhqds@sansad.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

File No.5/7/1061/13-RCH
Dated: 13.11.2017

The Dean
Mahatma Gandhi Institute of Medical Sciences
Sewagram 442 102 Wardha District
Maharashtra – INDIA..

Subject: Sanction of Budget allotment for the ICMR NTF New Scheme entitled, "Usage of Solar powered Portable culture Incubator in District Hospital(DC), Primary Health Centre(PHC), Community Health Centre (CHC) ---Feasibility Study in MGIMS, Wardha

Sir,

The Director General of the ICMR sanctions the above mentioned project with total budget allotment of Rs.7,94,300/-(Rupees Seven lakh ninety four thousand three hundred only) for duration of **TWO Years** w.e.f **01.01.2018 as per details** provided in Annexure-I.

First & final Installment of grant-in-aid of Rs.7,94,300/-for the First Year will be released out of the first year budget of Rs.7,94,300/- through RTGS.

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

1 The payment of the grant will be made in two installments in the name of Head of the Institute. The first installment of the grant will be paid generally as soon as report regarding the commencement of the project and appointment of the staff is received by the Council. The demand for payment of the subsequent installment of the grant should be placed with the Council in advance.

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

3. The approved duration of the research scheme is **Two Years.** The annual extension will be given after review of the work done on the research scheme during the previous year.

4. Five copies of the annual progress report of work done be submitted to the Council every year after completion of ten months of the project. Failure to submit the report in time may lead to termination of the project.

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

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

The receipt of this letter may please be acknowledged.

Yours faithfull

(Harjeet Kaur
Admn. Office
for Director Genera

Copy together with a copy of the budget statement forwarded for information to:

1. **Dr. Chetna Maliye,** Deptt. of Community Medicine, Mahatma Gandhi Insrtitute of Medical Sciences, Sewagram 442 102 Wardha District, Maharashtra – INDIA.

2.Copy together with two copies of the budget statement forwarded to **Accounts Section-**V, ICMR for information and necessary action. The expenditure on the account may be met from the provision made under head **Task Force** scheme on grant-in-aid basis in the budget of the Council for the financial year 2017-2018

3.Copy together with two copies of the budget statement forwarded to budget section (Finance) ICMR for completion of the Council's budget.

4.IRIS cell, ICMR, **ID.No.** 2007-0683 A-I

5. Main File

RFC No:RCH/NTF/3/2017-18 dated 20.11.2017

For Director General

INDIAN COUNCIL OF MEDICAL RESEARCH
V. Ramalingaswami Bhawan, Ansari Nagar, New Delhi – 110 029
Phone : 26588980, 26588707, 26589336, 26589745, 26589873,
FAX: 011-26588662, 26589791, GRAM : SCIENTIFIC,
Web-site: www.icmr.nic.in, e-mail: icmrhqds@sansad.nin.in

No. GIA/1/2014-DHR Dated: .01.2017

Subject: Grant-in-aid Scheme of the Department of Health Research for 'Inter-Sectoral Convergence & Coordination for Promotion and Guidance on Health Research - Approval to the Project entitled **"Community based studies on maternal health, newborn and infants care through health systems in rural Wardha"** under **Dr. B.S. Garg.**

OFFICE MEMORANDUM

The competent authority sanctioned the payment of **Rs. 87,62,610/- (Rupees Eighty Seven Lakh Sixty Two Thousand Six Hundred Ten only)** as 2nd instalment of 1st year grant for the above stated project.

Rs.3,01,388/- (an interest & Participants Registration Fee is Rs.) is already available with PI from last year grant.

A formal bill for **Rs. 87,62,610/- (Rupees Eighty Seven Lakh Sixty Two Thousand Six Hundred Ten only)** is sent herewith after adjustment of unspent balance/interest accrued for **Rs. 3,01,388/-** and net payment by NEFT/**RTGS/Electronic Transfer** for **Rs. 84,61,222/-** in the favour of **"The Dean, Mahatma Gandhi Institute of Medical Sciences, Sewagram, Wardha-442102(Maharashtra)". (Mandate form enclosed)**

(Dr. V.P. Singh)
Scientist-D

Accounts Section-V : -

Copy to:

1) **"The Dean, Mahatma Gandhi Institute of Medical Sciences, Sewagram, Wardha-442102(Maharashtra)"** Electronic Transfer/Bank Draft for the amount of **Rs. 84,61,222/-** as 2nd instalment of 1st year will be sent to you by Electronic Transfer in due course.The grant has been sanctioned on the conditions laid down in our letter referred to above.

2) **Dr. B.S. Garg, Director, Dr. Sushila Nayar School of Public Health, Mahatma Gandhi Institute of Medical Sciences, Sewagram, Wardha-442102 (Maharashtra).**

for Director-General

O/C

INDIAN COUNCIL OF MEDICAL RESEARCH
V. Ramalingaswami Bhawan, Ansari Nagar, New Delhi – 110 029
Phone : 26588980, 26588707, 26589336, 26589745, 26589873,
FAX: 011-26588662, 26589791, GRAM : SCIENTIFIC,
Web-site: www.icmr.nic.in, e-mail: icmrhqds@sansad.nin.in

FORMAL BILL

Formal bill for **Rs. 87,62,610/- (Rupees Eighty Seven Lakh Sixty Two Thousand Six Hundred Ten only)** is sent herewith after adjustment of Rs 3,01,388/- as (an interest & Participants Registration Fee) and net payment is **Rs. 84,61,222/- (Rs. Eighty Four Lakh Sixty One Thousand Two Hundred Twenty Two Only)** as the 2nd instalment of 1st year grant to meet expenditure for the project entitled **"Community based studies on maternal health, newborn and infants care through health systems in rural Wardha"** under **Dr. B.S. Garg** for payment to **"The Dean, Mahatma Gandhi Institute of Medical Sciences, Sewagram, Wardha-442102(Maharashtra)". (Mandate form enclosed)**

The amount may be debited to the Special grant of Rs.21,83,61,106/- under head "GIA-DHR" research scheme received from Department of Health Research for the year 2016-17.

Received contents

6/2/17

(Dr. V.P. Singh)
Scientist-D

आरोग्य सेवा

जाक्र/जिआअ/जिपव/आयडीएसपी/ /२०१८
कार्यालय, जिल्हा आरोग्य अधिकारी,
जि.प.वर्धा. दि. ०४/०५/२०१८

प्रति,

विभाग प्रमुख,
सुक्ष्मजीवशास्त्र,
एमजीआयएमएस, सेवाग्राम, वर्धा

विषयः एसओई/युसी(SOE/UC) एकात्मिक रोग सर्व्हेक्षण कार्यक्रम, वर्धा कार्यालयास सादर करण्याबाबत.

उपरोक्त विषयान्वये सन २०१७-१८ चे मंजूर कृती आराखडयानुसार संदर्भ प्रयोगशाळेकरि रु. २.०० लाख मंजूर करण्यात आलेले आहे. तथापि राज्यस्तरावरुन प्राप्त सुचनेनुसार एकात्मि रोग सर्व्हेक्षण कार्यक्रमा अंतर्गत मंजूर निधीमधून झालेल्या खर्चामधून उर्वरित रु. २.०० लाख संद प्रयोगशाळेकरिता आपणाकडे वळते करण्यात आलेले असून वर्ग करण्यात आलेल्या निधीच एसओई/युसी (SOE/UC) एकात्मिक रोग सर्व्हेक्षण कार्यक्रम, वर्धा कार्यालयास त्वरीत सादर करण्य याव्यात.

जिल्हा आरोग्य अधिकारी
जिल्हा परिषद, वर्धा

प्रतिलिपी माहितीस्तव सविनय सादर
- मा. अधिष्ठाता, एमजीआयएमएस, सेवाग्राम.

जिल्हा आरोग्य अधिकारी
जिल्हा परिषद, वर्धा

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

तार का पता - "मेडिनस्ट"
TELEGRAM - "MEDINST"
दूरभाष : २६१०८०००, २६१०९०००, २६१८८०००
Telephone : 26108000, 26109000, 26188000

जय प्रकाश नारायण एपेक्स ट्रॉमा सेन्टर
JAI PRAKASH NARAYAN APEX TRAUMA CENTRE
अ.भा.आ.सं., राज नगर, नई दिल्ली-110029 (भारत)
A.I.I.M.S., RAJ NAGAR, NEW DELHI-110029 (INDIA)

संदर्भ सं./ Ref. No. 75/CDC/TC/2020

दिनांक / Dated : 30.09.2020

BUDGET STATEMENT

MAHATMA GANDHI INSTITUTE OF MEDICAL SCIENCES, SEVAGRAM

CDC funded project entitled "Capacity Building and Strengthening of Hospital Infection Control to detect and prevent antimicrobial resistance in India".

Approved Budget	30.09.2020 – 29.09.2021
1. **Salaries and Wages**	
One: Senior Research Fellow (SRF) @ Rs. 28,000/- + HRA 30% (Rs. 8400/-)	Rs. 4,36,800.00
One: Junior Nurse @ Rs. 18,000/-	Rs. 2,16,000.00
One: Laboratory Technician @ Rs. 18,000/-	Rs. 2,16,000.00
One: Data Entry Operator @ Rs. 18,000/-	Rs. 2,16,000.00
One: Laboratory Attendant @ Rs. 15,800/-	Rs. 1,89,600.00
2. Supplies	Rs. 20,000.00
Total	**Rs. 12,94,400.00**
Remaining unspent balance as on 30.09.2020	**Rs. 1,60,764.00**
Total Budget	**Rs. 11,33,636.00/-**

Dr. Purva Mathur
Professor & PI
JPNATC, AIIMS, New Delhi

तार का पता - "मेडिनस्ट"
TELEGRAM - "MEDINST"
दूरभाष : २६१०८०००, २६१०९०००, २६१८८०००
Telephone : 26108000, 26109000, 26188000

जय प्रकाश नारायण एपेक्स ट्रॉमा सेन्टर
JAI PRAKASH NARAYAN APEX TRAUMA CENTRE
अ.भा.आ.सं., राज नगर, नई दिल्ली-110029 (भारत)
A.I.I.M.S., RAJ NAGAR, NEW DELHI-110029 (INDIA)

संदर्भ सं./ Ref. No. 75/CDC/TC/2020/Revised

दिनांक / Dated : ...01.01.2021.....

BUDGET STATEMENT

MAHATMA GANDHI INSTITUTE OF MEDICAL SCIENCES, SEVAGRAM

CDC funded project entitled "Capacity Building and Strengthening of Hospital Infection Control to detect and prevent antimicrobial resistance in India".

Approved Budget	01.08.2021 – 30.11.2021
1. **Salaries and Wages**	
One: Junior Nurse @ Rs. 17040/-	Rs. 68,160.00
Two: Laboratory Technician @ Rs. 17040/-	Rs. 1,36,320.00
One: Data Entry Operator @ Rs. 17040/-	Rs. 68,160.00
One: Laboratory Attendant @ Rs. 14,910/-	Rs. 59,640.00
One: Junior Nurse (For SSI) @ Rs. 18,000/-	Rs. 72,000.00
2. Supplies (Till September 2021*)	Rs. 6,00,983.00
Total	**Rs. 10,05,263.00**
Remaining unspent balance as on 31.07.2021	**Rs. 2,05,263.00**
Total Budget	**Rs. 8,00,000.00/-**

* After 30.09.2021 Supply expenditure will not be allowed.

Dr. Purva Mathur
Professor & PI
JPNATC, AIIMS, New Delhi

INDIAN COUNCIL OF MEDICAL RESEARCH

अन्सारी नगर, पोस्ट बॉक्स 4911, नई दिल्ली - 110 029

ANSARI NAGAR, POST BOX 4911, NEW DELHI - 110029

File No. AMR/RC/62/2014-ECD-II

Dated: 15/2/17

IRIS Id : 2014-26710

Subject: - Payment of 1st and final Installment of grant-in-aid for the research scheme entitled, **"Mahatma Gandhi Institute of Medical Sciences, Sevagram Regional Center for Antimicrobial Resistance Surveillance Network"**

MEMORANDUM

Reference this office letter No.AMR/RC/62/2014-ECD-II

The Director-General, ICMR sanctions the payment of **Rs.16,77,600/- (Rupees Sixteen Lakh Seventy Seven Thousand Six Hundred only)** as the 1st and final installment of the 1st year grant in connection with the above mentioned research scheme. The amount **Rs.16,77,600/-** may be debited in the provision of **Rs.16,77,600/-** made for the above mentioned research scheme for the current financial year.

A formal bill for **Rs.16,77,600/-** is sent herewith for payment by RTGS/Cheque for **Rs.16,77,600/-** to The Dean, Mahatma Gandhi Institute of Medical Science, Sevagram, Wardha (M.S.) 442 102.

(Anita Madan)
Administrative Officer
For Director General

Accounts Section, ICMR.

Copy to: -

1. The Dean, Mahatma Gandhi Institute of Medical Science, Sevagram, Wardha (M.S.) 442 102.
2. Dr. Vijayshri Deotale, Prof. & Head, Deptt. Of Microbiology, M.G.I.M.S, Sevagram, Wardha (M.S.)-442 102. A bank draft/cheque for the amount of **Rs.16,77,600/-** installment will be sent to you in due course. The grant has been sanctioned on the conditions laid down in our letter referred to above. It is requested that an audited statement of accounts together with utilization certificate for the grant received and utilized may be sent to this office in due course.
3. IRIS Cell (P & I) Section, ICMR.
4. DEO 'B'

Anita

(Anita Madan)
Administrative Officer
For Director General

July 9, 2013

Dr. Poonam Varma Shivkumar
Professor & Head of OBGYN
Mahatma Gandhi Institute of Medical Sciences
Sevagram, Warda
Maharashtra

RE: Memorandum of Understanding

Dear Dr. Shivkumar,

Jiv Daya Foundation is pleased to present the enclosed Memorandum of Understanding ("MOU") in connection with the proposed collaboration between Jiv Daya Foundation and your organization regarding the partograph research study project with MGIMS, Wardha. As described in detail in the MOU, the proposed Project Grant Program will provide the following support on the terms and conditions outlined in the MOU:

Rs. 2,36,000 for the initial 6 month grant period for supplemental salary support for 2 Auxiliary Nurse Midwives, 1 Data Entry Operator, 1 Attendant, computer, scanner, copy machine, and contingency costs.

The initial Project Grant Program will be for a term of 6 months. The initial term can be renewed based on successful outcomes of the project and if it is determined that the support provided has a measurable and positive impact on outcomes. Renewal of the MOU will be subject to proper documentation, accurate data entry and reporting, staff performance and reporting of how the funds are spent. Please note that Jiv Daya Foundation will need to be kept closely informed throughout the project. We will be working with you, as the collaborator on this project, to closely monitor and oversee all aspects of the project through regular conference calls and collection of weekly progress reports.

Please review the enclosed Memorandum of Understanding and let us know if there are any modifications to be made. If you are in agreement with the terms listed, please sign and return to Jiv Daya Foundation at the address set forth in this letter.

Sincerely,

Jennifer Lowe
Grants Coordinator

Encl.

cc: Dr. Vinay K. Jain

Jiv Daya Foundation – Dallas - Texas -75251 – USA
Phone: +001 214 593 0530 – Fax: +001 214 593 1902 – E-mail: team@jivdayafound.org
Website: www.jivdayafound.org

MEMORANDUM OF UNDERSTANDING

BY AND BETWEEN
JIV DAYA FOUNDATION AND
MAHATMA GANDHI INSTITUTE OF MEDICAL SCIENCES, SEVAGRAM, WARDHA

This Memorandum of Understanding ("MOU") describes the terms and conditions under which Jiv Daya Foundation ("Jiv Daya" or the "Foundation") will provide funding and assistance under its grant program to MGIMS, Wardha (the "Recipient") in connection with the project described in Appendix 1 (the "Project Grant Program"). Details regarding the Project Grant Program, including the Project, responsible personnel and the scope of financial and other support to be provided under this MOU, are set forth in Appendix 1, which is incorporated in this MOU and forms a part of it. Appendix 2 (wire transfer instructions) and Appendix 3 (staff information) should be completed by Recipient and returned to Jiv Daya. Recipient's project proposal is attached as Appendix 4.

BACKGROUND REGARDING JIV DAYA FOUNDATION

Jiv Daya is a private not-for-profit, non-governmental foundation founded in 2002 by Dr. Vinay Jain and his family. Simply stated, Jiv Daya's mission is to improve quality of life around the world. To that end, Jiv Daya seeks to establish long-term collaborative partnerships with medical institutions and physicians and to promote alliances between cancer centers, hospitals and health professionals across the globe to help ensure that available expertise is maximally used.

The Foundation's primary focus areas for giving include pediatric oncology, pathology, palliative care, disability assistance, maternal health, Kala-Azar alleviation, and Jain heritage preservation. In these areas, Jiv Daya works with partnering institutions and organizations to create capacity-building projects that will improve the infrastructure of care in developing countries such as India. Depending on need, Jiv Daya may provide equipment, salary support and/or training for physicians, nurses, social workers, counselors and data managers. The Foundation also seeks to expand and improve data collection methods for follow-up purposes by developing online databases for use by partnering institutions. In addition, Jiv Daya provides support in forming alliances and consortia of organizations to facilitate access to knowledge and technology transfer. Further information about Jiv Daya Foundation is available on its website at http://www.jivdayafound.org.

GENERAL TERMS AND CONDITIONS

Recipient agrees to conduct all project activities in compliance with the Foundation's standards and principles for grant awards, including the following:

1. **Purpose:** Project Grant Program support will be provided only for the purposes stated in this MOU, and grant funds shall be used for such purposes substantially in accordance with the budget set forth in Appendix 1. No substantial changes shall be made from the approved budget without prior written approval by the Foundation. Recipient acknowledges and

understands that, under United States law, Foundation grant funds, and income earned on those funds, may be spent only for charitable, religious, scientific, literary or educational purposes.

5. Inspection of Documents: Recipient agrees to provide Jiv Daya will all relevant information and documentation relating to the Project that may reasonably be requested by Jiv Daya relating to the use of grant funds. Such information and documents include, but are not limited to, background and qualifications of personnel, staff compensation, written information given to staff and patients, data collection and analysis reports, periodic progress reports, development updates, expenditure reports and other appropriate reports and documentation. Jiv Daya Foundation will review such documentation to ensure the validity of the project and proper use of funds.

3. Reports: Recipient will timely submit periodic progress reports, as detailed below.

4. Acknowledgements: Recipient will acknowledge Jiv Daya support in all printed publications and the like discussing data collection or the progress made possible by the Project Grant Program.

5. Use of Photographs and Information: Recipient will give permission for Jiv Daya to use photographs taken during site visits and hospital information on the Jiv Daya website and in Jiv Daya publications and materials.

6. Confidentiality: Jiv Daya will protect the confidentiality of information and data provided by Recipient. Recipient and Jiv Daya each agree to treat all information and data disclosed to the other party in connection with the Project Grant Program in furtherance of their common goals.

7. Payments: Jiv Daya will make all payments under the Project Grant Program to Recipient in quarterly installments throughout the year, contingent on receipt and approval of proper reporting documentation for project goals and a detailed breakdown of expenditures.

8. Bank Accounts: Recipient should arrange for Jiv Daya grant funds to be kept in a separate bank account whenever possible. If a separate account is not possible due to institutional regulations, the recipient should record and maintain the grant funds in a separate bookkeeping account limited to charitable purposes in the grantee's financial records. An institutional director or financial director must sign and have notarized an affidavit stating that grant funds are used solely for the purposes outlined in the MOU and that Jiv Daya is the sole funder of all staff salaries and items provided by the MOU.

9. Returns of Unused Funds. Any grant funds, and any income earned on grant funds, that are not spent or committed for approved purposes in connection with the Project Grant Program, as described in Appendix 1 must be returned to the Foundation.

10. Compliance. The Foundation reserves the right, in its sole discretion, to discontinue the Project Grant Program and all funding under it if the Foundation is not satisfied with the progress of the grant or the information reported by Recipient.

GRANTEE REQUIREMENTS

REPORTS

Recipient agrees to participate in such conference calls and to submit such reports and data as may be requested by Jiv Daya from time to time during the Project Grant Program. Records of receipts and expenditures as well as copies of the report furnished to us should be kept available for our inspection until four years after the completion of the grant.

Format

Each written report, including the final written report, must contain two parts: (1) a narrative account, and (2) a financial account of what was accomplished by the expenditure of the grant (with receipts). Formal reports should be sent quarterly and must be received and approved by the foundation prior to the release of the next installment of funding.

1. *Narrative Account*: The narrative account should provide a detailed description of what was accomplished by the grant, including a description of the progress made toward achieving the goals of the grant and the assurance that the activities under the grant have been conducted in conformity with the terms of the grant.

2. *Financial Account*: The financial account should provide a financial statement reporting, in U.S. dollars, all expenditures of Foundation grant funds. The financial statement should include only Foundation funds received and expended under this grant during the period covered by the report. Records should be maintained of such expenditures adequate to enable the use of such funds to be checked readily. Documentation of grant funding received and expended, certified by an accountant, financial director, or independent notary must be included with every report. This should include pay stubs or copies of checks to staff, bank statements reporting the amount of grant funding received in the local currency, individual salary records for each staff member, receipts for items purchased, and other relevant materials.

Reports should be submitted through email at team@jivdayafound.org or by hard-copy to the following address:

Maternal Health Program Manager
Jiv Daya Foundation
12400 Coit Road, Suite 570
Dallas, TX 75251

Required Reports

- **Completed Partograph.** All completed partographs must be submitted to Jiv Daya at the end of each day.

- **Weekly Progress Reports**. Weekly progress reports must be submitted to Jiv Daya by the Foundation-supported data manager or attendant which must include the total number of deliveries performed, the total number of partograph collected, and details of any complications that occurred.

- **Quarterly Progress Reports**. A written progress report signed by an appropriate officer of Recipient detailing what has been achieved and how Foundation funds have been used must be furnished to the Foundation every 3 months.

- **Final Report.** Upon completion of the initial research project grant period, Recipient must timely prepare and submit a Final Report detailing the use of grant funds and the results and achievements of the Project including final data analysis and results.

STAFF

- **Information.** Recipient must provide the following information for all Foundation supported employees: name, address, position, terms of employment and compensation.

- **Prompt Payment to Staff.** Under no circumstances may the payment of compensation be delayed to cover other expenditures. Ensuring staff salary payments should be given the highest priority.

- **Salary Increments.** Request for staff member salary increases may be made to Jiv Daya Foundation at any time; however, regular or annual pay increases are not sanctioned by the Foundation without prior express written consent. The Foundation reserves the right to make all decisions regarding a staff member's salary based solely on Jiv Daya's assessment of the staff member's job performance.

PROHIBITED ACTIVITIES

So that the Foundation may comply with the tax laws of the United States, it is understood that the Foundation grant funds will not be used for any of the following purposes:

1. to carry on propaganda, or otherwise to attempt to influence any legislation (within the meaning of Section 4945(d)(1) of the United States Internal Revenue Code);

2. to influence the outcome of any specific public election or to carry on, directly or indirectly, any voter registration drive (within the meaning of Section 4945(d)(2) of the United States Internal Revenue Code); or

3. to make any grant to an individual or organization or

4. to undertake any activity for any purpose other than the charitable purposes specified in Section 170 (c)(2)(B) of the United States Internal Revenue Code.

Please contact the Foundation should you have any question regarding permitted activities.

PROJECT COMMENCEMENT AND TERMINATION

This MOU will become effective on the date that it is fully executed by both Jiv Daya and Recipient. The term of the Project Grant Program will be as described in Appendix I. The Project Grant Program may be terminated by Jiv Daya at any time before expiration of its term if Jiv Daya determines, in its sole discretion, that reasonable cause for termination exists. In the event of such termination, Jiv Daya will provide Recipient with written notice of termination, documenting the reason for termination. Circumstances that may warrant termination include, but are not limited to:

- Determination of unexpected, significant or unacceptable risk to persons;
- Failure to spend funds solely for the purposes of the grant program;
- Failure to submit documentation, reports, and status updates with the Foundation;
- Failure to submit information or inaction to provide adequate information or progress;
- Insufficient adherence to Jiv Daya Foundation requirements.

- Non-compliance with monitoring processes or procedures;
- Insufficient or incomplete data, or data that otherwise cannot be evaluated.

In the event of discontinuation of the Project Grant Program prior to the end of the term, Recipient must return to the Foundation all unexpended grant funds, in an amount to be agreed between the parties.

OTHER REQUIREMENTS OF THIS AGREEMENT

Any notice required by this MOU shall be sufficiently given if sent in writing by prepaid, first class, certified or registered mail, addressed in the case of Jiv Daya Foundation to:

Jiv Daya Foundation
Attn: Dr. Vinay Jain
12400 Coit Road, Suite 570
Dallas, TX 75251

and in the case of Recipient, to the address that we file with Jiv Daya.

This MOU, including its attachments, represents the complete agreement between the parties regarding its subject matter and supersedes all prior written or oral promises, representations and agreements regarding the same subject matter. This MOU may be amended or modified only in a written document signed by duly authorized representatives of Jiv Daya and Recipient. This MOU may be executed in two or more counterparts, each of which will be deemed an original. If any provision of this MOU is held to be unenforceable for any reason, that unenforceability shall not affect the enforceability of any other provision of this MOU, and the parties will negotiate in good faith to substitute an enforceable provision with similar terms.

Executed by the parties hereto as of the date set forth below:

JIV DAYA FOUNDATION:

Vinay K. Jain, President

Date

RECIPIENT:

Title: _____

Date

APPENDIX I – DESCRIPTION OF PROJECT AND GRANT PROGRAM

SUMMARY DESCRIPTION OF PROJECT

Tiv Days Foundation agrees to collaborate with MGIMS, Wardha on the Partograph Research Study Project. This will be accomplished through the provision of additional support staff for the labor and delivery ward, namely supplemental salary support for 1 Data Entry Operator, 1 attendant, and 2 Auxiliary Nurse Midwives. The goal of the project will be to ensure the complete and accurate plotting of modified WHO partograph in 100% of laboring women and assess the reduction in maternal and fetal complication rates". Expected sample size will be 1,900 within the initial 6 month grant period. The Auxiliary Nurse Midwives (ANMs) will be responsible for collecting all required measurements and ensuring the accurate filling of the partograph as well as monitoring of laboring women, and coordinating with all Doctors and para-medical assistants. The Data Entry Operator will be responsible for entering all data collected by ANM's in new paper partograph and conducting all computer based data entry. The Attendant will be responsible for collecting and sending completed partograph's to IDF staff as well as all other minor duties related to the project such as photocopying, sending reports, etc. Additional support may be given based on the successful outcomes of this project. Additional support may include the provision of e-partograph devices in association with Zhejiang.

SCOPE OF GRANT PROGRAM (DELIVERABLES)

Tiv Days will provide the following support in connection with the Project:

1. Incremental salary support for the Project staff identified below.
2. Computer, scanner, copy machine, phone card, and stationary for data collection and entry purposes

Data Relevant Information

1. All data collected will be the property of Recipient. The data will be entered and maintained locally in Wardha, India and backed up on a server in Dallas
2. Project success will be measured on the following:
   a. Number of partographs collected and submitted
   b. Completeness of data entered into partographs
   c. Improvements in data collection process
   d. Improvement in assessment of maternal and fetal complication rates

PROJECT DETAILS AT A GLANCE

Project Title:	Partograph Research Study at MGIMS, Wardha
Location of Project:	Wardha, India
Type of Project:	India Maternal Health Initiative
Project Objectives:	To ensure the complete and accurate plotting of modified WHO partograph in 100% of laboring women and assess the reduction in maternal and fetal complication rates.
Duration:	The Project Grant Program will commence on the date this MOU is signed, and will continue thereafter for a period of up to one year. The initial term will be for a period of six months and is renewable if it is determined that the support provided has a measurable and positive impact on outcomes.

PERSONNEL

1. Principal Collaborator

The principal investigator on the project will be:
Dr. Poonam Verma Shankumar- Professor and Head of Dept. of OBGYN
The co-investigator on this project will be:
Dr. Parmod Kumar- Assistant Professor- Dept. of OBGYN

FINANCIAL SUPPORT

Equipment/Personnel Assistance Covered by Grant

	Item	Number
1.	Salary support for Auxiliary Nurse Midwives	2
2.	Salary support for Data Entry Operator	1
3.	Salary support for Attendant	1
4.	Computer for data entry	1
5.	Scanner	1
6.	Copy Machine	1

Budget for Full Project Duration

	Item	Amount (in INR) Initial Grant Period (6-months)	Renewable Grant Period (6-months)	1-Year Total
1.	Salary Support			
	2 Auxiliary Nurse Midwives @ Rs 5,000/month	60,000	60,000	120,000
	1 Data Entry Operator @ Rs. 10,000/ month	60,000	60,000	120,000
	1 Attendant @ Rs 4000/month	24,000	24,000	48,000
	Total Salary Support	144,000	144,000	288,000
2.	Equipment			
	Computer (1) @ Rs. 40,000	40,000	0	40,000
	Scanner (1) @ Rs. 15,000	15,000	0	15,000
	Copy Machine (1) @ Rs. 19,000	19,000	0	19,000
	Monthly support for stationery, telephone bills, postage charges and contingency @ Rs. 2500/month	15,000	15,000	30,000
	Total Equipment	93,000	15,000	707,000
	Grand Total	*2,66,000*	*159,000*	*3,95,000*

APPENDIX 2 - METHOD OF PAYMENT

Payment will be made via check. Please provide your mailing instructions by answering the following questions.

Name of the Beneficiary (as check should be made out)
Beneficiary's mailing address with Pin/Zip Code

Signature Date

Title

APPENDIX 3 – SUPPORTED PROJECT STAFF INFORMATION

Please provide the information below for each employee whose salary will be supported by the Foundation:

Labor Law	Yes/No	Comments
a. Who employs personnel locally?		
(i) Name of the institution		
b. What are the local requirements?		
(ii) Registrations (with social security authorities for instance)?		
(iii) Other requirements (such as having written employment agreement, internal regulations, pension plan, etc.)		
(iii) Are there withholding/reporting/payment requirements such as social security contributions?		
(iv) Are there withholding/reporting/payment requirements such as wage tax?		

Signature Date

Title

TEL.: 265688960, 26588895

GRAM : SCIENTIFIC
FAX : 011-6868662

INDIAN COUNCIL OF MEDICAL RESEARCH
ANSARI NAGAR, POST BOX NO. 4911
NEW DELHI – 110029

File No. 5/7/1176/2014-RCH
Dated: 18.02.2015

Subject: Payment of **Ist Instt. of 1st year** as a (for one month) for the Project entitled," Community Based Study of Magnitude of Abortions, Spontaneous and Induced, Immediate and Late Complications and Care Sought by Rural Women of Two Districts of Maharashtra" under Dr.S.Chhabra.

MEMORANDUM:

Reference this office letter of even number dated 19.02.2015

The Director General, ICMR sanctions the payment of Rs. 1,31,487 (One lac Thirty One Thousand Four Hundred Eighty Seven only) as the Ist installment of the 1st year(for one month)as a incurring expenditure in connection with the above mentioned Research scheme. The amount of Rs 1,31,487/- may be debited in the provision of Rs.15,77,845/- made for the above mentioned research scheme for the financial year 2014-15 .

A formal bill for Rs 1,31,487/- is sent herewith for payment through RTGS, Bank Account No.1784800213 MICR Code of Bank 442016502 (copy enclosed)to
The Dean, Mahatma Gandhi Institute of Medical Sciences Sevargram,Wardha-442102.

RFC No. RCH/Adhoc/9/2014-15, dated:16.02.2015

Administrative Officer
for Director-General

Accounts Section - V, ICMR

1. The Dean, Mahatma Gandhi Institute of Medical Sciences,Sevargram-442102, Maharashtra,India

   A Bank/Draft/ cheque for the amount of Rs.1,31,487/- for one month installment will be sent to you in due course. The grant has been sanctioned on the condition laid down in our letter referred to above.

2. Copy together with two copies of the budget statement forwarded to budget section (Finance) ICMR for completion of the Council's budget.
3. IRIS Cell (P & I) Section, ICMR. ID No. 2013-0814
4. Dr. S. Chhabra Director Prof. MGIMS, Sewagram, Wardha, Maharashtra-442102
5. Dr. Shiv Kumar,ICMR

for Director-General

पी.ए.बी.एक्स./PABX : 26588980, 26588707, 26589336, 26589745, 26589873, 26589414
फैक्स/FAX : 011-26588662, 011-26589791, 011-26589258

तार / GRAM : विज्ञानी / SCIENTIFIC
Web-site : www.icmr.nic.in
E-mail : icmrhqds@sansad.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. 5/7/1176/2014-RCH **Dated :01.06.2015**

Subject: Payment of 2nd installment of 1st year for 5 months grant-in-aid for research scheme project entitled **"Community based study of magnitude of abortions, spontaneous and induced, immediate and late complications and care sought by rural women of two districts of Maharashtra" under Dr. S. Chhabra.**

MEMORANDUM

Reference this office letter of even number dated: 19/02/2015.

The Director General, ICMR sanctions the payment of **Rs. 6,57,436/- (Rupees Six Lakhs Fifty Seven Thousand Four Hundred Thirty Six Only)** as the 2nd installment of 1st year for 5 months. The grant for incurring expenditure in connection with the above mentioned research scheme. The amount of Rs. 6,57,436/- may be debited in the provision of Rs.15,77,845/- made for the above mentioned research scheme for the current financial year 2015-2016.

A formal bill for **Rs. 6,57,436/-** is sent herewith for payment by cheque/ Demand draft to The Dean, Mahatma Gandhi Institute of Medical Sciences Sevargram, Wardha-442102.

This is issued with the concurrence of the finance year Divn. **RFC No. RCH/Adhoc/9/2014-2015 dated: 16.02.2015.**

Yours faithfully,

(S. S. Behl)
Administrative Officer
For Director General

Accounts Sections V, ICMR

Copy to :-

1. The Dean, Mahatma Gandhi Institute of Medical Science Sevargram, Wardha-442102. A Bank Draft/ Cheque for the amount of **Rs.6,57,436/-** 2nd installment of 1st year for 5 months will be sent to you in due course. The grant has been sanctioned on the condition laid down in our letter referred to above.
2. IRIS Cell-2013-0814
3. Dr. S. Chhabra Director Prof. MGIMS, Sewagram, Wardha, Maharashtra-442102
4. Finance Section, ICMR, RFC No. RCH/Adhoc/9/2014-2015, Dated: 16.02.2015.
5. Dr. Shiv Kumar, Scientist 'F', Div. of RCH, ICMR, New Delhi – 110029.

Administrative Officer
For Director General

दूरभाष/PABX : 26588980, 26588707, 26589336, 26589745,
26589873, 26589414
फैक्स/FAX 011-26588662, 011-26589791, 011-26589258

तार/GRAM : भारुआर/SCIENTIFIC
Website : www.icmr.nic.in
E-mail : icmrhqdsc@sansad.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

File No. 5/7/1176/14-RCH Dated:31.03.2016

Subject: Payment of final installment of 1st year grant-in-aid for research scheme project entitled "**Community based study of magnitude of abortions, spontaneous and induced, immediate and late complications and care sought by rural women of two districts of Maharastra" under Dr. S. Chhabra.**

MEMORANDUM

Reference this office letter of even number dated: 19/02/2015.

The Director General, ICMR sactions the payment of **Rs.7,88,922 /- (Rupees Seven Lakhs Eighty Eight Nine Hundred Twenty Two Only)** as the final installment of 1st year for. The Grant for incurring expenditure in connection with the above mentioned research scheme. The amount of **Rs. 7,88,922 /-** may be debited in the provision of Rs.15,77,845/- made for the above mentioned research scheme for the current financial year 2015-2016.

A formal bill for **Rs. 7,88,922 /-** is sent herewith for payment by cheque/Demand draft to The Dean, Mahatma Gandhi Institute of Medical Sciences Sevargram, Wardha-442102.

This is issued with the concurrence of the finance year Divn. **RFC No. RCH/Ad-hoc/9/2014-2015 dated: 16.02.2015.**

Yours faithfully,

(Harjeet Kaur Bajaj)
Administrative Officer
for Director General

Sunil Ingal a/c no. Shabra

Accounts Section V, ICMR
Copy to:-

1. The Dean, Mahatma Gandhi Institute of Medical Sciences Sevargram, Wardha-442102. A Bank Draft/Cheque for the amount of **Rs. 7,88,922 /-** final installment of 1st year will be sent to you in due course. The Grant has been sanctioned on the condition laid down in our letter referred to above.
2. IRIS Cell-2013-0814
3. Dr. S. Chhabra Director Prof. MGIMS, Sewagram, Wardhan, Maharashtra-442102
4. Finance Section, ICMR, RFC No. RCH/Ad-hoc/9/2014-2015, Dated: 16.02.2015
5. Dr. Shiv Kumar, Scientist 'F' Div. of RCH, ICMR, New Delhi-110029

Administrative Officer
for Director General

फैक्स/FAX 26589813, 26589414
: 011-26588662, 011-26589791, 011-26589258

Web-site : www.icmr.nic.in
E-mail : icmrhqdsr.sansad.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.5/7/1176/2014-RCH

Dated:14/12/2016

The Dean,
Mahatma Gandhi Institute of Medical Sciences,
Sevagram-4402102,
Maharashtra,

Subject: Continuation of **Ad-hoc** scheme entitled "Community Based Study of Magnitude of Abortions, Spontaneous and Induced, Immediate and Late complicatios and Care Sought by Rural Women of Two Districts of Maharashtra" under Dr.S.Chhabra.

महोद्य/महोद्या,

परिषद के महानिदेशक उपर्युक्त योजना को निम्नलिखित शर्तों के अधीन दिनांक 01.07.2016 जव 30.06.2017 तक के लिए **2nd** वर्ष के बजट के लिए संलग्न विस्तृत विवरण के अनुसार **Rs.16,11,662/-(Rupees sixteen Lakhs Eleven Thousand Six Hundred Sixty Two Only)** के आवंटन के साथ जारी रखने की मंजूरी प्रदान करते है। अनुदान नीचे दर्शाए गए के अनुसार (परिशिष्ट-ए) में मांग की प्राप्ति पर वित्तीय वर्ष के दौरान संस्थान के प्रमुख को जारी किया जाएगा ।

बजट:- **16,11,662/-**रुपए ।

किश्त को जारी करने की मांग के समय यह सुनिश्चित किया जाए कि स्टाफ जो कि वास्तव मे कार्यरत है, के वेतन और भत्तों की राशि भी शामिल है ।

इस कार्यालय के दिनांक **19.2.2015** के समसंख्यक पत्र में उल्लेखित अन्य निबंधन व शर्तें वही रहेगी ।यह वित्त विभाग के दिनांक **RFC No. RCH/Adhoc/9/2014-2015,** से जारी किया जा रहा है।

कृपया इस पत्र की पावती भेजें ।

भवदीय

प्रशासन अधिकारी
कृते महानिदेसंक

प्रतिलिपि बजट विवरण की प्रति सहित सूचनार्थ अग्रेषित ।

1 लेखा विभाग 5 सूचनार्थ ।
2 Dr. S. Chhabra Director Prof Mahatma Gandhi Institute of Medical Sciences, Sevagram, Wardha, Maharashtra-442102
3 परिषद के बजट संकलन के लिए बजट अनुभाग (वित्त अनुभाग) को बजट अग्रेषित ।
4 आई.आर.आई.एस. सेल

कृते महानिदेसंक

SRIMANTA SANKARADEVA UNIVERSITY OF HEALTH SCIENCES
NARAKASUR HILL TOP, BHANGAGARH, GUWAHATI, ASSAM
Phone: 0361-2130431 E-mail: ssuhs_assam@yahoo.in Website: www.ssuhs.in

No. SSUHS/202/2014/ 1062-63 Dated: 25/2/15

From : Prof. M.K. Choudhury,
Registrar
Srimanta Sankaradeva University of Health Sciences

To,

1. Dr. Shakuntala Chhabra
Director, Professor
Department of Obstetrics & Gynaecology
Mahatma Gandhi Institute of Medical Sciences
Sewagram, Wardha, Maharashtra, PIN-442102

2. The Principal,
Fakhruddin Ali Ahmed Medical College, Barpeta.

Sub : Research project submitted by Dr. Shakuntala Chhabra, Director, Professor, Department of Obstetrics & Gynaecology, MGIMS, Wardha, Maharashtra titled "Hypertensive Disorders of Pregnancy – Prevention, Early detection and Prevention of Severity and Mortality through Cost Effective Sustainable ways in two Tertiary Care Centres in two States of India" to be undertaken in collaboration with Dr. Saswati Sanyal Choudhury, Associate Professor, Department of Obstetrics & Gynaecology, Fakhruddin Ali Ahmed Medical College, Barpeta.

Sir/Madam,

I am directed to state that the Institutional Ethics Committee for Human Research of Srimanta Sankaradeva University of Health Sciences in its meeting held on 09-12-2014 has approved the above Research Project. Accordingly, an amount of Rs.9,20,000/- (Rupees nine lakhs twenty thousand) only has been sanctioned as mentioned below:

A	Dr. Shakuntala Chhabra	Fund for 1st Year	Fund for 2nd Year
	i) Multipurpose Worker – 1	Rs.84,000/-	Rs.80,000/-
	ii) Short Phase Worker – 1	--	Rs.62,000/-
	iii) Travelling Allowance	Rs.50,000/-	--
	iv) Project Management Information System Development	Rs.1,00,000/-	Rs.1,00,000/-
	v) Communication	Rs.10,000/-	Rs.10,000/-
	vi) Laptop	Rs.40,000/-	--
	vii) Purchase of apparatus	Rs.30,000/-	--
	Total	**Rs.3,14,000/-**	**Rs.2,52,000/-**

Total (A) = Rs.5,66,000/-

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	v) Communication	Rs.10,000/-	Rs.10,000/-
	vi) Laptop	Rs.40,000/-	--
	vii) Purchase of apparatus	Rs.30,000/-	--
	Total	**Rs.3,14,000/-**	**Rs.2,52,000/-**

Total (A) = Rs.5,66,000/-

B	Principal F.A.A. Medical College, Barpeta	Fund for 1st Year	Fund for 2nd Year
	i) Multipurpose Worker – 1	Rs.84,000/-	Rs.80,000/-
	ii) Travelling Expenses	Rs.50,000/-	--
	iii) Project Management Information System Development	Rs.30,000/-	Rs.30,000/-
	iv) Communication	Rs.5,000/-	Rs.5,000/-
	v) Laptop	Rs.40,000/-	--
	vii) Purchase of apparatus	Rs.30,000/-	--
	Total (B)	**Rs.2,39,000/-**	**Rs.1,15,000/-**

Total (B) = Rs.3,54,000/-

Grand Total (A + B) = Rs.5,66,000/- + Rs.3,54,000/- = Rs.9,20,000/-

Funds for the first year shown in respect of both the Principal Investigators are hereby released.

After utilization of the fund for the 1st year the following documents duly countersigned by the Heads of the respective Medical Colleges are to be submitted to this University, so that steps may be taken to release the fund for the 2nd year in time.

1. Copies of APRs and vouchers with expenditure statement
2. Utilization Certificate
3. Annual Progress Report of the Project.

Receipt of this letter along with the Bank Draft may please be acknowledged.

Enclosures:

1. D.D. No.481727, dated 19-02-2015 for Rs.3,14,000/- in favour of Dr. Shakuntala Chhabra.
2. Cheque No. 811269, dated 16-02-2015 for Rs.2,39,000/- in favour of the Principal, FAA Medical College, Barpeta.

Yours faithfully,

25/2/15

Registrar,
Srimanta Sankaradeva University of
Health Sciences.

Memo No. SSUHS/202/2014/1064-67 Dated: 25/2/15

Copy to:

1. Dr. Saswati Sanyal Choudhury, Associate Professor, Department of Obstetrics & Gynaecology, Fakhruddin Ali Ahmed Medical College, Barpeta for information and necessary action.
2. The P.S. to the Hon'ble Vice Chancellor of Srimanta Sankaradeva University of Health Sciences for information of the Hon'ble Vice Chancellor.
3. The Finance & Accounts Officer, Srimanta Sankaradeva University of Health Sciences.
4. The Accounts Branch, Srimanta Sankaradeva University of Health Sciences.

25/2/15

Registrar,
Srimanta Sankaradeva University of
Health Sciences.

O/C

(189)

SRIMANTA SANKARADEVA UNIVERSITY OF HEALTH SCIENCES

Narakasur Hilltop, Bhangagarh, Guwahati-32, Assam, India

No. SSUHS/202/2014/ 1554 Dated: 25/4/16

From : Prof. M.K. Choudhury
Registrar,
Srimanta Sankaradeva University of Health Sciences.

To : Dr. Shakuntala Chhabra
Director, Professor,
Department of Obstetrics & Gynecology,
Mahatma Gandhi Institute of Medical Sciences,
Sewagram, Wardha, Maharashtra.
Pin-442102.

Sub : **Release of fund for the research project, "Hypertensive Disorders of Pregnancy- Prevention, Early detection and prevention of Severity and Mortality through Cost Effective Sustainable ways in Two Tertiary Care Centres in Two States of India".**

Madam,

With reference to your E- mail dated 30/03/2016, I am directed to state that the fund for the first year amounting to Rs. 3,14,000 - was released vide DD no. 481727 dated 19.02.2015. But the required documents like copies of vouchers/APRs, expenditure statement, utilization certificate have not been furnished. It is requested to furnish the same at the earliest.

However fund for the second year for Rs. 2,52,000/- is hereby released as under :

Particulars	Amount
1) Multipurpose worker-1	Rs. 80,000 -
2) Short phase worker -1	Rs. 62,000 -
3) Project Management ISD	Rs. 1,00,000 -
4) Communication	Rs. 10,000 -
Total	Rs. 2,52,000/-

SBI Cheque No. 419370 Date 20-4-16 for Rs. 2,52,000/- is enclosed herewith.

Kindly furnish the above mentioned documents showing utilization of the fund now released for the second year also.

Receipt of this letter and the Cheque may be acknowledged.

Yours faithfully,

25/4/16

Registrar
Srimanta Sankaradeva University of Health Sciences

Memo No. SSUHS/202/2014/1555 - 56 Dated. 25/4/16

Copy forwarded to:

SRIMANTA SANKARADEVA UNIVERSITY OF HEALTH SCIENCES
Narakasur Hilltop, Bhangagarh, Guwahati, Assam
Phone: 0361-2130431 (O) E-mail: ssuhs_assam@yahoo.in Website: www.ssuhs.in

No. SSUHS/202/2014/ 886 Dated: 17/3/17

From : **Prof. B.K. Bezbaruah**
Registrar,
Srimanta Sankaradeva University of Health Sciences.

To : **Dr. Shakuntala Chhabra**
Director,
Professor, Dept. of Obstetrics & Gynaecology,
Mahatma Gandhi Institute of Medical Science,
Sevagram, Wardha, Maharashtra.

Sub : **titled** **Submission of accounts, UC and project Report pertaining to the research project "Hypertensive disorders of pregnancy-prevention, early detection and prevention of severity and mortality through cost effective sustainable ways in two tertiary care centres in two states of India."**

Madam,

In inviting a reference to this University letter no. SSUHS/202/2014/1062-63 dated 25-02-2015 and SSUHS/202/2014/1554 dated 25-04-2016, I am directed to state that fund of Rs.5,66,000/- was released to you for completion of the Research Project for the first and second year.

You are requested to submit the following documents duly authenticated by the Head of the Institution to this University at the earliest.

(1) Copies of vouchers and Actual Payee's Receipt (APRs).

(2) Summery statement of expenditure.

(3) Utilization Certificate.

(4) Final Project Report combining that from FAAMC, Barpeta.

Unspent balance, if any, may please be refunded to this University on completion of the project.

Yours faithfully,

Registrar
Srimanta Sankaradeva University of Health Sciences
Dated:

Memo No. SSUHS/202/2014/
Copy to:

1. The P.S. to the Hon'ble Vice Chancellor of Srimanta Sankaradeva University of Health Sciences for kind appraisal of the Hon'ble Vice Chancellor.

Registrar
Srimanta Sankaradeva University of Health Sciences

GHETS

GLOBAL HEALTH THROUGH EDUCATION, TRAINING AND SERVICE

Local Knowledge. Global Health.

March 26, 2018

I am writing in support of my colleague, Shakuntala Chhabra, who is part of the academic staff at Mahatma Gandhi Institute of Medical Sciences, India. I am the Executive Director of Global Health through Education, Training and Service (GHETS), a U.S. based non-governmental organization dedicated to improving health systems in the developing world. GHETS works to build capacity in community-based primary care projects and assists local partners with program development, financing, and evaluation.

Based on her outstanding work and leadership on the Women and Health Task Force, we are inviting Shakuntala Chhabra to attend the Network: Towards Unity for Health conference, "Community Empowerment for Health: A Multi-Sector Approach," in Limerick, Ireland to be held August 16-20, 2018. The Network: Towards Unity for Health is an international organization of academic health professions institutions and organizations promoting equity in health through community-oriented education, research and service. GHETS will provide full funding to allow Shakuntala Chhabra to attend the pre-conference and conference events. She will arrive in Limerick, Ireland by August 13, 2018 and after completing all conference obligations will depart on August 21, 2018.

Please see our website at www.ghets.org for more information about GHETS, as well as the Network: TUFH website for specific information about the conference in Limerick, Ireland (http://thenetworktufh.org/tufh2018/). In addition, please feel free to contact me with questions or to request any supporting documentation related to GHETS or Shakuntala Chhabra's sponsorship.

Sincerely,

Sophie Flynn

Sophie Flynn
Executive Director
Global Health through Education, Training, and Service (GHETS)

8 North Main Street, Suite 401, Attleboro, MA 02703 USA
sflynn@ghets.org www.ghets.org 508.226.5091 ext. 18

Report Header

Application:	Alliance Message Management
Report type:	Message File - Message Details Report
Operator:	114526
Alliance Server Instance:	SWIFT
Date - Time:	2018/05/02 17:54:18

Messages

Message 1

Message Identifier

Message Preparation Application:	Applic. Interface
Unique Message Identifier:	I PNBPUS3NXXX 103 00695TSN18000061 (suffix 1805022630483)

Message Header

Status:	Deletable		
Format:	Swift	Sub-Format:	Input
Identifier:	fin.103	Expansion:	Single Customer Credit Transfer
Application	FIN	Nature:	Financial
Sender:	CBININBBNAG	LT:	A
Receiver:	PNBPUS3NXXX	LT:	X
Transaction Reference:	00695TSN18000061		
Priority:	Normal		
Amount: 650,	Currency: USD	Value Date: 02/05/18	
ACK/NAK Reception Date/Time (GMT):	2018/05/02 12:16:28		

Sender / Receiver

Sender Institution:	CBININBBNAG	Expansion:	CENTRAL BANK OF INDIA (NAGPUR, PUNE) NAGPUR NAGPUR IN INDIA
Receiver Institution:	PNBPUS3NXXX	Expansion:	WELLS FARGO BANK, N.A. (SPECIAL PROCESSING) NEW YORK,NY 10152 NEW YORK,NY US UNITED STATES OF AMERICA

Message Text

Block 4

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F20: Sender's Reference
          00695TSN18000061
F23B: Bank Operation Code
          CRED
F32A: Value Date/Currency/Interbank Settled Amount
          Date:          180502          2018 May 02
          Currency:         USD          US DOLLAR
          Amount:        650,00           #650,00#
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F33B: Currency/Instructed Amount
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          Amount:          650,00          #650,00#
F50K: Ordering Customer - Account - Name and Address
          Account:
                    /3059604367
          Name and Address:
                    GHETS MINI PROJECTS,OBGYN,MGIMS
                    OBGYN,MGIMS
                    SEWAGRAM
                    DIST WARDHA
F53A: Sender's Correspondent - Party Identifier - Identifier Code
          Identifier Code:
                    PNBPUS3NNYC
                              WELLS FARGO BANK, N.A.
                              (NEW YORK INTERNATIONAL BRANCH)
                              NEW YORK,NY US
F57A: Account With Institution - Party Identifier - Identifier Code
          Party Identifier:
                    /026009593
          Identifier Code:
                    BOFAUS3NXXX
                              BANK OF AMERICA, N.A.

                              NEW YORK,NY US
F59: Beneficiary Customer - Account - Name and Address
          Account:
                    /383011375027
          Name and Address:
                    THE NETWORK TOWARDS UNITY FOR HEAL
                    TH
                    3624 MARKET STREET 3RD FLOOR
F70: Remittance Information
          MAIN CONFERENCE REGISTRATION FEES O
          CHHABRA
F71A: Details of Charges
          BEN
F71F: Sender's Charges
          Currency:          USD          US DOLLAR
          Amount:          0,00          #0,00#
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Report Footer

Number of Entities: 1

End of report

THE NETWORK
TOWARDS UNITY FOR HEALTH

Certificate of Attendance

SHAKUNTALA CHHABRA

INDIA

Has attended the TUFH2018 annual conference of The Network: TUFH, co-hosted by the University of Limerick, from August 16th to 20th, 2018.

Henry Campos
Secretary General
The Network: TUFH

Khalifa Elmusharaf
Chair of Local Organizing Committee

MASSACHUSETTS GENERAL HOSPITAL

The Division of Global Health and Human Rights

Department of Emergency Medicine
125 Nashua St, Suite 910
Boston, Massachusetts 02114-2696
Tel: 617-584-0064

Thomas F. Burke, MD, FACEP, FRSM

Chief

Letter of Agreement

April 29th, 2017

Every Second Matters for Mothers-Uterine Balloon Tamponade
ESM-UBT

Dear Dr. Garg,

It was good to see you over the past few days. Thank you so very much for your remarkable leadership and partnership. We do have such a wonderful opportunity to make a difference in India, together and beyond.

With this letter of agreement I personally commit to supporting approved necessary finances for ESM-UBT across the 10 medical schools through January of 2019, or until such time that other resources are secured, from the Ujenzi Charitable Trust. Additionally, I guarantee the human resource efforts necessary from our Division to ensure high quality performance.

Over this coming two years we together will seek resources in order to secure additional support for the sustainability and scale of the ESM-UBT program, so that ultimately women across India will no longer lose their lives from postpartum hemorrhage.

It is an honor and privilege to work with you, Dr. Poonam, Dr. Jain and the entire MGIMS family. This is to confirm that Dr. Poonam is in-country lead on ESM-UBT.

Kind Regards,

Thomas F. Burke, MD, FACEP, FRSM
Chief, Division of Global Health and Human Rights, Massachusetts General Hospital
Departments of Emergency Medicine, Surgery and Pediatrics, MGH
Associate Professor of Surgery and Emergency Medicine, Harvard Medical School
Associate Professor of Global Health and Population, Harvard T.H. Chan School of Public Health

B.S. Garg MD, PhD, FAMS
Secretary, Kasturba Health Society
Mahatma Gandhi Institute for Medical Sciences, Sewagram

CC:
Dr. Poonam Shivkuma
Dr. Manish Jain
Ms. Moytrayee Guha

Cost Plus Fixed Term (CPFT) Contract for Research and Development (R&D) under the Grand Challenges Initiative India (GCI India)

Annexure 1

Complete Project document with amendments (as mutually agreed between BIRAC and MGIMS) including work program/plan shall have to be specifically mentioned.

(This document should be bound as part of the Contract and labeled as Annexure 1 and should not be submitted as a separate document.)

PROPOSAL DETAILS
1. Executive Summary (Please provide a brief executive summary that captures the core idea of the project and its potential impact):
The project aims to validate and test the feasibility, and acceptability, of introducing an innovative low-cost salivary progesterone PTB prediction test in two rural settings in India with high rates of pre term births. A validated cost effective saliva test, which has the potential for further adaptation to a point of care setting, will allow early identification of pregnant women at risk of PTB, who can then be linked to an effective pathway of care and support to reduce PTB and associated adverse consequences.
2. Project Goals and Strategic Importance Addressing PTBs is essential in order to progress on the millennium Development Goal MDG for child survival by 2015 and beyond, since 40% of under-five deaths are in newborns, and it will also give added value to maternal health MDG 5 investments. In India, among the total 27 million babies born annually, 3.6 million babies are born preterm, and over 300,000 of these preterm babies die each year because of associated complications7. India, with its highest number of PTBs and the highest number of preterm deaths worldwide4, contributes 25% of the overall global preterm related death. This is even more challenging in Indian rural setting where most women are unaware of the risk of PTB and do not readily access available care and support. This leads to increased maternal and neonatal morbidity and mortality in rural India. Currently, there is no simple test available for screening all women at risk of spontaneous PTB in any setting, although high resource settings often use cervical length measurement and cervico-vaginal fetal fibronectin9 for identification and care of women who are already deemed to be at risk due to clinical history previous PTB, previous mid-trimester miscarriage or premature rupture of membranes. These tests for predicting PTB risk are invasive, expensive, require skilled workforce and facilities and are not feasible for rural Indian setting where high end facilities are unavailable. Development of an acceptable, non-invasive point of care test for accurate prediction of women at risk of early PTB has considerable potential to reduce infant deaths in low-resource settings through improvements in antenatal and postnatal care uptake and or by referral of high risk women to higher level health facilities with experience in care of vulnerable infants. A positive test would indicate the need for heightened surveillance and targeted use, where available, of prophylactic interventions e.g. vaginal progesterone, cervical pessary or cervical stitch. The goal of the project is to undertake a large validation of this non-invasive salivary progesterone test and assess its feasibility and acceptability in a community based low resource setting in India.

Biotechnology Industry Research Assistance Council

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Mahatma Gandhi Institute of Medical Sciences, SEVAGRAM

3. Core Innovation of Proposed Project

The salivary progesterone test is based on the estimation of progesterone in saliva. The use of saliva for biomarker measurements has well known advantages, for example it can be easily collected and is non-invasive avoiding the need for vaginal examination or use of sharps to take blood. As saliva is less complex than blood, the measurement of free steroid concentrations is accurate and samples can be transported and stored without requiring freezing. Pilot studies on hospital based settings1,2,3 has shown promise on its use, but the test still requires further validation in a low resource community setting. To undertake a large-scale validation study over two years to evaluate the feasibility and accuracy of saliva progesterone test to predict PTB at less than 34 weeks and 37 weeks gestation in two rural districts of Madhya Pradesh Panna and Satna. The specific objectives of the project will include

1. To determine the association and assess the performance of a salivary progesterone test specificity, sensitivity, predictive value and ROC for prediction of PTB risk
2. To train the frontline health workers on collection, storage and transportation of salivary progesterone sample and technicians on analysis of the sample
3. To assess the feasibility, and acceptability to women and health care workers, of using this innovative test in a rural setting Interim

4. Overall Approach to Scientific Project Execution :

Study populationA prospective study will be conducted to recruit 2000 pregnant women in the two districts of Madhya Pradesh. Pregnant women will be identified and consented early in pregnancy from 12 weeks so that an accurate dating scans can be undertaken and baseline obstetric history and demographic data obtained. They will then be asked on a subsequent visit to provide a saliva sample between 24-28 weeks of pregnancy. They will be followed-up till delivery for birth outcomes. The study will be conducted in the Panna and Satna districts of Madhya Pradesh due to its high fertility Crude Birth Rate 31.7 and 28.8 respectively and high rates of PTBs with an estimated 24% of births 37 weeks. They also have high rates of neonatal mortality 63-66 per 1000 live births particularly resulting from births 34 weeks14and an infant mortality rate of 90 per 1000 live births. Major contributors to PTBneonatal mortality in these tribal dominated districts are poverty, physical stress, malnutrition, poor public health facilities and low health service utilization. Two blocks each covering more than 100,000 populations will be included from each district. Before the recruitment of participants and sample collection, training involving practical sessions will be provided for public health network staff and the laboratory teams responsible for saliva sample collection and saliva testing sample storage and immuncassay at the health facility. Semi-structured questionnaires, in-depth interviews and focus group discussion will be used to assess the practices and skills of frontline health workers and lab technicians, the acceptability and feasibility of using this innovative test in a rural setting.

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Mahatma Gandhi Institute of Medical Sciences, SEVAGRAM

5. Organizational and Team Capacity to Execute Project:

- This is a jointly coordinated project led by Dr. Poonam ShivKumar PI Head, Department of Obstetrics & Gynaecology, Mahatma Gandhi Institute of Medical Sciences MGIMS, India Dr. Rachel Tribe Co-PI, with Professor Andrew Shennan and Mr. Paul Seed, Kings College London KCL team and Dr. Sunil Mehra Project Advisor and Dr. Archana Sarkar Co-PI MAMTA Health Institute for Mother &Child MAMTA.
- Mahatma Gandhi Institute of Medical Sciences MGIMS, Department of Obstetrics & Gynaecology will provide technical support to the laboratory analysis and field implementation.
- MAMTA is present in 14 States of India. Community-based implementation, feasibility testing of research innovations for improving maternal neonatal health has been one of the strengths of MAMTA. MAMTA has significantly contributed in development, planning and implementation of research and evaluation of programs and policies on the issue of maternal, neonatal and child health HIVAIDS and TB in the context of children, adolescents, young people and women and sexual and reproductive health.
- The UK KCL team has extensive experience of undertakirg clinical scientific studies related to prediction, prevention and treatment of preterm labour and birth. . The investigators from the KCL will visit the study site for training on sample collection, storage and analysis of samples. Pre-post test will also be conducted after training to assess the effectiveness and accuracy of the staff involved. . Data analysis will be executed using SPSSSTATANVivo led by KCL statistician Mr. Paul Seed. In addition remote data quality checking will be undertaken by KCL collaborators internet based system queries raised and followed up throughout the study. The KCL team has considerable experience of sharing clinical study data with different institutions and countries and will ensure that compliance, data protection and relevant ICH-GCP principles are rigorously applied. The use of a secure internet database e.g. from MedSciNet, link-anonymised patient data only with different levels of access rights and ability for remote review of data will allow for close and accurate data monitoring throughout the study by relevant partners.

6.IP Status

Each partner brings specific strengths to the project and will contribute to all aspects of project management. The PI and Co-PIs with the addition of Professor Andrew Shennan and Mr. Paul Seed from KCL will form the basis of the project management team. They will be responsible for all aspects of study set up as described in the plan above. There are planned meetings in India and UK at specific times during the project set up and data analysis phases to enable project partners to meet face to face and for the UK team to transfer expertise to the lead partners e.g. assist in training of study staff in relevant procedures such as saliva collection, storage and analysis using ELISA and statistical analysis. A data sharing agreement will established for the project team. After publication of key findings, the project team will provide access to the database to other researchers. The project management team will ask for, and review, applications to ensure that the highest of quality of secondary analysis is undertaken by reputable and established research teams. New types of intellectual property that can be anticipated including how the identifications of these inventions will be managed. Validation of the salivary progesterone ELISA for predication of PTB in a rural Indian setting will provide novel and important data including cut off points for a positive and negative test for risk of PTB. To protect these data as intellectual property, they are likely to develop a predictive algorithm and mobile phone app that would allow input of other relevant clinical obstetric data. Additionally, for a future project, the development of a point of care test with a commercial partner may also open up other avenues for IP development. KCL with the other partners will be involved in setting up a Memorandum of Understanding and signing off grant

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28-3-16
DEAN,
Mahatma Gandhi Institute of Medical Sciences, SEVAGRAM.

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contracts that will include legal consideration of issues relating to intellectual property rights. KCL previously submitted a UK patent application with regard use of salivary progesterone for prediction of PTB. This is no longer active. The applicants are not aware of any freedom to operate issues.

7. Financial Details :

They don't have other source of funding for this proposal.

During the last five yearsMahatma Gandhi Institute of Medical Sciences1.Ensuring the complete and accurate plotting of modified WHO partograph in all laboring women 100% assessing the reduction in existing maternal and fetal complication rates at tertiary care centre.Rs. 8,00,000, Jiv Daya Foundation, Dallas, Texas, USA. October 2013-Till Date2.Previable Birth Defect, Rs.1,92,000, PGIMR, Chandigarh. November, 2014 to Till Date3.Epidemiclogical ceterminants of Hypertensive disorder of pregnancy in a cohort of rural women in Central India. Rs.3,90,006, ICMR, New Delhi, February, 2015 to till date4.Emergency Obstetric Care. Rs.1,92,000 This year grant, AVNI Foundation 2008 to Till Date5.Preventing parent to child transmission PPTCT through early identification, care and suppcrt of pregnant women for improving maternal health outcomes in two high HIV prevalent districts of India. Emoluments directly paid by Govt. International HIVAIDS Alliance 2013-20166.Amnisure Project. Rs.1,13,786, Amnisure Company 2009-20147.Maternal Death Audit. Rs.1,62,000, Govt of India, FIGO, AVNI 2010-20138.HPV Study women with Cervical Abnormality. Rs.1,04,000, Collaboration with Dr.Ambedkar Research Foundation, New Delhi 2012-20149.Near Miss Project. Rs.4,00,000, Bill Malinda Foundation 2012-201410.Anaemia Project. Rs.37,63,430, CCRS Ayush GOI 2011-2014Kings College London1.KV7 channel activators a novel treatment for preterm labor GBP 748,724, Medical Research Council MRC, UK, Nearing completion2012-20152.PARROTT trial stepped wedge trial of PLGF implementation. GBP 360,00, NIHR RFPB, UK, Ongoing 2014-20173.Implementation of the Vital Signs Alert. GBP 1,100,000, MRCNewton FundDFID, Just awarded 2015-20174.Biomarkers for the prediction and management of threatened spontaneous PTB. GBP 348,940, NIHR Clinical PhD Fellowship. Ongoing 2013-20165.Threatened preterm labor exploration of womens experiences and validation of an effective risk assessment tool to improve management and care.GBP 294,723, NIHR Clinical Research Fellowship, Ongoing 2014-20196.The CarePlan VpH Glove mer Study.GBP 42,960, Testing Services Agreement funded by Alere International, Ongoing 2015-20167.Biomarkers for the prediction of preterm birth. GBP 86,360,Rosetrees Trust, Ongoing 2013-20168.Prediction of premature labour. GBP 145,245, Sparks Charity, Ongoing 2014-20179.KV7 channels and preterm labour. GBP 90,000,

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28.3.16
DEAN
Mahatma Gandhi Institute of Medical Sciences, SEVAGRAM

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MRCKCL studentship. Tribe RM primary supervisor, Nearing completion. 2011-201510.The role of muscle repair factors in human bladder. GBP 10,000, Rosetrees Trust, Nearing completion 2013-201511.A multicentre RCT of trans-abdominal versus trans-vaginal cervical cerclage. GBP 124,682, Moulton Charitable Trust, Completed. 2008-201512.Evaluation of quantitative fFN in predicting preterm birth EQUIPP, GBP 147,500, CLRNHologic, Completed 2010-201513.Tydeman tube development . GBP 16,500, NHS innovations, Completed 2010-201414.An amniocentesis training simulator. GBP 42,355, Investment finance for technology transfer GSTT charity,Completed 2010-201515.PDE4 inhibitors a treatment for mothers and babies at risk of preterm delivery.GBP 167,600 Action Medical Research, Completed 2011-201416.Improving prediction of spontaneous preterm birth. GBP 57,000, NIHR Biomedical Research Centre. Clinical Training Fellowship, Completed2012-201317.Reproductive ageirgimpact on uterine function. GBP 77,000, BBSRC, UK18.PhD studentship, Tribe RM, Primary supervisor,Completed 2009-201319.Muscle repair factors in the human bladder implications for overactive bladder syndrome. GBP 25,000, Rosetrees Trust, Completed 201220.Prediction of preterm labour in low risk women, GBP 47,201. Action Medical Research,Completed 2010-201121.KCNG and KCNH channels novel targets for tocolytic therapy in pre-term labour, GBP 114,752, Action Medical Research, Completed 2008-201122.A longitudinal investigation of quantifiable fFN and alarm anti-proteinases in women at risk of spontaneous preterm birth, GBP 14,959, Wellbeing of Women, Completed2010-2012MAMTA Health Institute for Mother & Child1.Mainstreaming the Continuum of Care Approach into the National RMNCHA Initiatives for improved maternal health outcomes of the Young Married Women - A District Design. Rs. 35,131,847 , MacArthur Foundation & BARR Foundation , Ongoing 2014 - 172.Addressing Early Child Marriage and Delaying First Pregnancy. Rs.16,120,000, American Jewish World Service AJWS, Ongoing2015-173.Jiv Daya Foundations Project. Rs.9,691,200 ,Jiv Daya Foundations, Ongoing2014 - 164.Improving reproductive and sexual health of young people by increasing the age at marriage in India Nepal & Bangladesh. Rs.211,045,914,European Commission, Completed 2008-145.Meri Life Meri Choice. Rs.122,437,321, Elton John Aids Foundation, Ongoing 2011-166.Global Practice Centre. Rs.26,504,046 , International HIV Aids Alliance, Ongoing 2014-157.Innovation Fund - Preventing Parent to Child Transmission PPTCT through early identification, care and support of Pregnant Women for Improving Maternal Health Outcomes in two High HIV prevalence districts of India. Rs.20,880,000, International HIV Aids Alliance,Ongoing 2013-168.Vihaan Programme Global Fund Round -4 RCC Phase II. Rs. 49,776,375, India HIV AIDS Alliance

Dean
28/3/16
DEAN
Pushpawati Singhania Institute of Medical Sciences, DEVAGHAR

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EC , Ongoing 2013-169.Ensuring access to Comprehensive HIV services for MSM living with HIV/AIDS in Imphal district of Manipur. Rs. 49,776,375 , Elizabeth Taylor AIDS Foundation, Ongoing 2015-1610.Strengthening Youth Friendly Health Services through Community-based interventions in Rural India 2013-15. Rs. 12,967,470 , Physicians for Social Responsibility, PSR-Finland, Ongoing 2013-1511.Integrating Mother and Child Health Services with Prevention and Control of Diabetes and Hypertension through Engagement of ASHA. Rs. 37,470,726 , Bristol - Myers Squibb Foundation BMS, Ongoing2012-1612.Prevention and early Management of Viral Hepatitis among high risk population in India Integration program of HIV and HCV. Rs.30,039,582 , Bristol - Myers Squibb Foundation BMS, Ongoing 2014-1713.Gender Resource Centre. Rs.11,867,601 ,Department of Women & Child Development, Govt. of NCT. of Delhi, Ongoing 2007-1714.Providing Universal Access to DR TB Control Services and strengthening civil society involvement in TB care & Control in India AXSHYA. Rs.254,730,462 , International Union Against Tuberculosis & Lung Disease, Ongoing2010-1515.Composite Target Intervention F S W & M S M, Mewat District. Rs. 5,906,650 , Haryana State Aids Control Society HSACS, Ongoing 2007-1516.Community based health and development programme for carpenter community through an inclusive approach. Rs. 10,998,402 , Greenply Ltd. Ongoing2014-1717.Start Healthy Stay Health. Rs.1,233,181, Nestle India Ltd, Ongoing2014-1518.Exploring the potential to establish a centre for Adolescent Health and development in India . Rs.1,550,000 , Packard Foundation, Ongoing 201519.Garima - Training Programme. Rs. 2,637,232, Unicef, Ongoing 2014-1520.Regional Resource Centre. Rs.3,150,000, State Health Society, Punjab, Ongoing 2014-1621.Design, Monitoring and Implementation of Beneficiary feedback Mechanisms, Pilot. Rs.2,443,166, World Vision, Ongoing 2014-1622.Support for strengthening the collective response of the government to end child marriage through programme convergence and system approach in two states. Rs.13,160,000 , Ford Foundation, Ongoing 2012-1523.Operationalizing the National Plan of Action on Child marriage prevention in three districts of India through community mobilisation, state-systems activation and front-line worker mentoring. Rs. 18,512,915 , Ford Foundation, Ongoing 2013-1624.Improving Maternal and child health services and livelihood opportunities for 37,280 poor women in two districts of Uttar Pradesh, India. Rs. 23,936,502 , DFID - Department for International Development Global Poverty Action Fund, Ongoing 2012-15

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DEAN,
Mahatma Gandhi Institute of Medical Sciences, SEVAGRAM

Mahatma Gandhi Institute of Medical Sciences, Maharashtra

OBJECTIVE WISE ACTIVITIES & TIMELINES

To determine the association and assess the performance of a salivary progesterone test specificity, sensitivity, predictive value and ROC for prediction of PTB risk

Activities	Start Month	End Month	Deliverables	Name of team member/collaborator responsible for completing the activity
Project Planning Meeting	01	02	1. Roles and responsibilities of the Lead organization and the partners defined2.Finalize the project protocol and assign detailed workplan to all partner institutions	MGIMS*(With support of MAMTA & KCL)*
Institutional Ethical ReviewMeeting	02	03	Ethical approval from MGIMS Ethical Review Board	MGIMS
Recruitment of staff for lab	04	05	Lab staff in place	MGIMS
Formation of Data Safety Monitoring Board DSMB for the project	02	03	Reporting &Sharing protocol prepared, Regular Review dates finalized	MGIMS
Instruments for saliva test, setting up the lab and pre-testing	03	05	Purchase of saliva test kits, storage containers, labels, lab reagents and ELISA kit	MGIMS*(with support from MAMTA)*
Batch analysis of saliva progesterone (Monthly)	08	20	Samples will be sent to MGIMS laboratory for progesterone analysis through ELISA immunoassay	MGIMS

To train the frontline health workers on collection, storage and transportation of salivary progesterone sample and technicians on analysis of the sample

Activities	Start Month	End Month	Deliverables	Name of team member/collaborator responsible for completing the activity
Training of lab technicians	04	06	Trained lab technicians	MGIMS*(with support of KCL)*
Pre-post test to assess effectiveness of Lab Technicians training	04	06	Pre-post test to assess effectiveness of training	MGIMS*(with support of MAMTA)*
Training of Radiologists on the project protocol	03	05	Project Radiologist trained on project protocol with special focus on ultrasound and dating	MGIMS

To assess the feasibility, and acceptability to women and health care workers, of using this innovative test in a rural setting

Activities	Start Month	End Month	Deliverables	Name of team member/collaborator responsible for completing the activity
Preparation of final report (Half-Yearly)	06	24	Final report on impact of the project would be prepared	MGIMS*(with support from MAMTA & KCL)*

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Publication	12	24	One peer reviewed publication on feasibility One peer reviewed publication on test validation	MGIMS

MAMTA Health Institute for Mother and Child 3-5, Greater Kailash Enclave-II, New Delhi

OBJECTIVE WISE ACTIVITIES & TIMELINES				
To determine the association and assess the performance of a salivary progesterone test specificity, sensitivity, predictive value and ROC for prediction of PTB risk				
Activities	**Start Month**	**End Month**	**Deliverables**	**Name of team member/collaborator responsible for completing the activity**
District office set-up, Research Consultant in place, Protocol and Tool Development, Formative Research	01	03	District office set up; Baseline report to understand the skills of service providers for preterm risk identification and its management; Project Protocol an Tools	**MAMTA**
Institutional Ethical Review Meeting	02	03	Ethical approval from MERB (MAMTA Ethical Review Board)	**MAMTA**
Recruitment of field staff and Technical Consultant	02	03	Required qualified personnel -1 coordinator and 5 outreach worker per district will be recruited	**MAMTA** *(with support of KCL and MGIMS)*
Line listing and recruitment of pregnant women	04	12	Line listing of pregnant women within 12 weeks of pregnancy, saliva sample would be collected at 24-28 weeks of gestation	**MAMTA** *(with support from MGIMS)*
Data Management for project	04	22	MIS and tracking Data Management	**MAMTA**
Salivary Sample Collection, Salivary Storage at Health Worker level & Transportation (On-going)	07	20	Kits /Labels/Containers in place, Salivary Sample Collected, Stored and Transported	**MAMTA**
Follow -up Data collection	04	20	2000 pregnant women, 77 women per 4 blocks per month, pregrancy outcomes ~460 births 37 weeks and 50-189 births 34 weeks will be obtained	**MAMTA**
Data entry	06	22	1.Data entry would be done through SPSS/STATA/NVivo2	**MAMTA**
To train the frontline health workers on collection, storage and transportation of salivary progesterone sample and technicians on analysis of the sample				

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Activities	Start Month	End Month	Deliverables	Name of team member/collaborator responsible for completing the activity
Training of frontline functionaries	04	06	Frontline functionaries Trained.	**MAMTA** *(with support from KCL)*
Pre-post test of frontline functionaries.	04	06	Assessment of effectiveness of training on knowledge of salivary progesterone test., skills to collect salivary sample, storage and transport	**MAMTA**
Pre-post test to assess effectiveness of Lab Technicians training	04	06	Pre-post test to assess effectiveness of training	**MGIMS** *(with support from MAMTA)*
To assess the feasibility, and acceptability to women and health care workers, of using this innovative test in a rural setting				
Activities	**Start Month**	**End Month**	**Deliverables**	**Name of team member/collaborator responsible for completing the activity**
Quantitative and qualitative survey to assess the acceptability among health care providers and pregnant women	06	09	Assessment of acceptability among health care service providers and pregnant women	**MAMTA**
Preparation of Project Progress Report (Half- Yearly Report)	06	24	Six monthly reports and Final report at the end of study	**MAMTA** *(with support from KCL & MAMTA)*
Validation of salivary progesterone, sensitivity and specificity, ROC	12	20	Association of levels of salivary progesterone with pregnancy outcomes	**MAMTA** *(with support from KCL & MAMTA)*
Publications	12	24	One peer reviewed publication on Acceptability	**MAMTA**

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Mahatma Gandhi Institute of Medical Sciences, SEVAGRAM

NON-INDIAN COLLABORATOR

Kings College London Women's Health Academic Centre KHP 10th Floor North Wing

OBJECTIVE WISE ACTIVITIES & TIMELINES				
Activities	**Start Month**	**End Month**	**Deliverables**	**Name of team member/collaborator responsible for completing the activity**
Software Development & Pretesting	01	03	KCL preterm software for data entry, storage and analysis	**KCL**
Finalization of project protocol, tools and forms	02	03	Data management, reporting & sharing protocol prepared, regular review dates finalized	MAMTA & MGIMS **(with support from KCL)**
Software Management	06	20	Data entry, checking & management	MAMTA &MGIMS **(with support of KCL)**
Training of frontline functionaries	04	06	Frontline functionaries trained	**KCL** (with support of MAMTA)
Training of lab technicians	04	06	Trained lab technicians	**KCL** (with support of MGIMS)
Monitoring and data quality check	04	20	1. Strict to data collection protocol 2. Check on completeness, accuracy and consistency	**KCL**
Data analysis	20	24	1. Data analysis would be done through SPSS/STATA/NVivo 2. Final report on impact of the project would be prepared	KCL (with support of MGIMS and MAMTA)
Preparation of Project Progress Report (every 6th month) and Final Report	06	24	Six monthly reports and Final report at the end of study	MAMTA & MGIMS **(with support of KCL)**
Publications	12	24	One peer reviewed paper on Validation Support for two-more peer reviewed papers	**KCL** (with support of MAMTA & MGIMS)

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Mahatma Gandhi Institute of Medical Sciences, SEVAGRAM

राज्य कुटुंब कल्याण कार्यालय, पुणे
महाराष्ट्र राज्य

अतिरिक्त संचालक दूरध्वनी क्रमांक (वै) – कार्यालय दूरध्वनी क्र. –	२६०५८९९६ (वै) २६०५८७३९ (का) २६०५८१३९ (का) २६०५८४७६ (का)	अतिरिक्त संचालक, आरोग्य सेवा, कुटुंब कल्याण, मातावाल संगोपन व शालेय आरोग्य, कुटुंब कल्याण भवन, राजाबहादुर मिलरोड, रेल्वे स्टेशनच्या मागे, पुणे ४११ ००१. फॅक्स नं.- ०२० – २६०५८७६६ / २६०५८२१८ / २६०५८१०९ jssk.cell@gmail.com
आरोग्य सेवा		जा.क्र.राकुकका /कक्ष-१०(ब)/न.क्र. /२०१९, दिनांक :- 13/06/२०१९. 33869-04

प्रति,
जिल्हा शल्य चिकित्सक,
जिल्हा रुग्णालय नाशिक व रत्नागिरी.

वैदयकीय अधिक्षक,
स्त्री रुग्णालय अकोला, परभणी, नांदेड.

विषय :- Maternal Near Miss Review प्रकल्पाबाबत प्रशिक्षण....

संदर्भ :- RCH PIP 2019-20

उपरोक्त विषयान्वये केंद्र शासनामार्फत राज्यातील निवडक संस्थांमध्ये Maternal Near Miss Review प्रकल्पाची अंमलबजावणी करण्यात येणार आहे.

सदर प्रकल्पाच्या अंमलबजावणीकरिता एक दिवसीय प्रशिक्षण दि.२०/०६/२०१९ रोजी राज्य कुटुंब कल्याण कार्यालय, पुणे येथे आयोजित करण्यात येणार आहे. सदर प्रशिक्षणाकरिता वर नमूद संस्थांमधील संशोधन सहाय्यक, वर्ग १ चे / ज्येष्ठ स्त्रीरोग तज्ञ व जिल्हा निवासी वैदयकीय अधिकारी (बाहयसंपर्क) यांनी उपस्थित राहणे अपेक्षित आहे. त्यानुसार आपल्या स्तरावरुन संबंधितांना सूचित करावे.

प्रशिक्षणासाठी येताना मागील ३ वर्षामधील संस्थेतील प्रसूती, सिझेरिअन शस्त्रक्रिया, MNM Cases व MNM Software नोंदविलेल्या केसेसची संख्या याचा तपशिल घेऊन यावा. येणाऱ्या सर्व अधिकारी व कर्मचारी यांचा दैनिक भत्ता व प्रवास भत्ता मुळ आस्थापनेतून करण्यात येईल.

(डॉ. अर्चना पाटील)
अतिरीक्त संचालक, आरोग्य सेवा,
कुटुंब कल्याण मा.बा.सं. व शा. आ., पुणे-१.

प्रत माहिती व योग्य त्या कार्यवाहीस्तव,
१) उपसंचालक, आरोग्य सेवा, मंडळ नाशिक, कोल्हापूर, अकोला, औरंगाबाद, लातूर.
२) अधिष्ठाता, महात्मा गांधी इन्स्टिटयुट ऑफ मेडीकल सायन्स, सेवाग्राम, वर्धा.
३) डॉ. संजय चव्हाण, शास्त्रज्ञ व प्रमुख, Department of Operation Research NIRRH, Mumbai.

प्रत सविनय सादर,
मा. आयुक्त (आरोग्य सेवा) तथा अभियान संचालक, राष्ट्रीय आरोग्य अभियान, मुंबई.
मा. प्रधान सचिव, सार्वजनिक आरोग्य विभाग, मंत्रालय, मुंबई.
मा. संचालक, आरोग्य सेवा, आरोग्य संचालनालय, पुणे.

राज्य कुटुंब कल्याण कार्यालय, पुणे
महाराष्ट्र राज्य

अतिरिक्त संचालक दूरध्वनी क्रमांक (वे) - निवासस्थान दूरध्वनी क्र. -	२६७५८९९६ (वे) २६७५८३३९ (का) २६७५८३३९ (का) २६७५८४७६ (का)	अतिरिक्त संचालक, आरोग्य सेवा कुटुंब कल्याण माताबाल संगोपन व शालेय आरोग्य, कुटुंब कल्याण भवन, राजाबहादुर मिलरोड, रेल्वे स्टेशनच्या मागे, पुणे ४११ ००१. फॅक्स नं - ०२० - २६७५८३३६ / २६७५८३१८ / २६७५८४७९ jssk.cell@gmail.com
आरोग्य सेवा		जा.क्र.राकुकका /कक्ष-१७(ब)/न.क. / २०१९. 42380-90 दिनांक :२७/०८/२०१९.

प्रति,
जिल्हा शल्य चिकित्सक,
सामान्य रुग्णालय ठाणे, नाशिक, रत्नागिरी, परभणी, अकोला, नांदेड, वर्धा.

विषय :- FMR Code 18.2 अंतर्गत उपलब्ध अनुदान वितरणाबाबत

संदर्भ :- RCH PIP 2019-20

केंद्र शासनाच्या मार्गदर्शक सूचना व मंजूर RCH PIP 2019-20 नुसार FMR Code 18.2 मध्ये Maternal Near Miss Review या प्रकल्पाची अंमलबजावणी करण्यात येणार आहे.

राज्यातील ५ आरोग्य संस्थामध्ये NIRRH, Mumbai व MGMIS सेवाग्राम, वर्धा यांच्या तांत्रिक सहाय्याने सदर प्रकल्प राबविण्यात येणार आहे.

प्रकल्पाकरिता ५ आरोग्य संस्थामध्ये Research Assistant तसेच NIRRH Mumbai व MGMIS सेवाग्राम वर्धा येथे Consultant या पदाची भरती करण्यात आलेली आहे. FMR Code 18.2 अंतर्गत सदर पदाचे मासिक मानधनासाठी अनुदान मंजूर करण्यात आले आहे. जिल्हा निहाय निवडलेली संस्था व मंजूर अनुदानाचा तपशील खालीलप्रमाणे

अनु.क्र.	जिल्हा	आरोग्य संस्था	मंजूर (लाखामध्ये) अनुदान
१	नाशिक	जि.रु. नाशिक	२.४०
२	रत्नागिरी	जि.रु. रत्नागिरी	२.४०
३	परभणी	जि.स्त्री.रु. परभणी	२.४०
४	अकोला	जि.स्त्री.रु. अकोला	२.४०
५	नांदेड	जि.स्त्री.रु. नांदेड	२.४०
६	ठाणे	NIRRH	४.८०
७	वर्धा	MGMIS	२.४०

वर नमूद तक्त्याप्रमाणे आपणास अनुदान वर्ग करण्यात येईल. सदर अनुदान संबंधित आरोग्य संस्थेस लवकरात लवकर वर्ग करावे. जेणेकरुन प्रकल्प अंमलबजावणी योग्य पध्दतीने होईल.

(डॉ. अर्चना पाटील)
अतिरीक्त संचालक, आरोग्य सेवा,
कुटूंब कल्याण मा.बा.सं. व शा. आ., पुणे-१.

प्रत माहितीस्तव व योग्य त्या कार्यवाहीस्तव :

१) वैदयकिय अधिक्षक, स्त्री रुग्णालय, परभणी, अकोला, नांदेड.
२) डॉ. संजय चव्हाण, शास्त्रज्ञ व प्रमुख, डिपार्टमेंट ऑफ ऑपरेशन रिसर्च, NIRRH, मुंबई
३) अधिष्ठाता, महात्मा गांधी इन्स्टिटयुट ऑफ मेडीकल सायन्स, सेवाग्राम, वर्धा.

प्रत सविनय सादर,

१) मा. आयुक्त (आरोग्य सेवा) व अभियान संचालक, रा.आ.अ.आरोग्य भवन, मुंबई.
२) मा. प्रधान सचिव, सार्वजनिक आरोग्य विभाग, मंत्रालय, गो.ते.रुग्णालय संकुल, मुंबई
३) मा. संचालक, आरोग्य सेवा, आरोग्य संचालनालय, पुणे.

(2)

NATIONAL CENTRE FOR DISEASE INFORMATICS AND RESEARCH
Indian Council of Medical Research
Department of Health Research, Ministry of Health and Family Welfare, Government of India
Nirmal Bhawan-ICMR Complex (II Floor), Poojanahalli, N.H–7, B. B. Road,
Kannamangala Post, Bengaluru–562 110 (India)
Tel: +91 080 22176400, +91 080 22176300 Fax: 080 30723643, Email: ncdir@ncdirindia.org

No. NCDIR/GIA:Gen/Rural PBCR Wardha/2008/831 Date: 10 August 2017

Dr. Nitin Gangane
Principal Investigator
Population Based Cancer Registry &
Professor and Head, Department of Pathology
Mahatma Gandhi Institute of Medical Sciences
Sevagram, Wardha - 442 102
(Maharashtra)

Dear Sir,

Sub: Rural Population Based Cancer Registry at Sevagram – Wardha under Dr. Nitin Gangane, Professor and Head, Department of Pathology, Mahatma Gandhi Institute of Medical Science, Sevagram, Wardha – Maharashtra sanction for continuation for the year 2017-18.

The Director General of ICMR sanctions an allotment of Rs. 34,79,854/- (Thirty four lakhs seventy nine thousand eight hundred and fifty four only) as detailed in the attached budget statement for Rural PBCR-Wardha for the financial year 2017-18. Accordingly, please find enclosed the MoU duly signed by Director, NCDIR for the financial year 2017-18.

As requested by you, a sum of Rs.16,38,726/- (after deducting the unspent balance of available as of 31.3.2017 and funds already released for 2017-18) is being transferred to your PBCR S.B. A/c No. 31054728617, State Bank of India, Sevagram Branch, Sevagram, Wardha District (Maharashtra) to meet expenditure till 31.12.2017. This has been transferred through PFMS system vide payment advice No. C081701228098 dated 10.8.2017 from NCDIR account, Canara Bank, Kannamangala Branch, Bengaluru Rural. The receipt of the money may please be acknowledged.

The above grants have been sanctioned on the conditions laid down in our letter enclosed.

With kind regards,

Yours sincerely,

for Administrative Officer
For Director

Encl: Signed MoU.

International Agency for Research on Cancer

World Health Organization

COLLABORATIVE RESEARCH AGREEMENT – CRA No. ICB/12/05

BETWEEN **Mahatma Gandhi Institute of Medical Sciences, Sevagram, Dist. Wardha, Maharashtra 442102, India**, hereinafter '**the Institution**'

AND The International Agency for Research on Cancer, 150 cours Albert Thomas, 69372 Lyon cedex 08, France, hereinafter '**IARC**'.

IARC agrees to provide to the Institution a maximum of **€ 8,500** (**Eight thousand five hundred EUROS**), in accordance with the schedule of payments specified below;

for the period commencing: **1 February 2012** to: **31 January 2014**

for the following project: **"Role of human papillomavirus infection and other co-factors in the aetiology of head and neck cancer in Europe and India" (HPV-AHEAD);**

as more fully described in **Annex 1** of this CRA, which forms an integral part hereof and which may also include an agreed budget and specific conditions applicable to this CRA.

The 'General Conditions' overleaf also form an integral part of this CRA.

Payment will be made as follows: US$ 4,250.- on signature of this CRA,

and, where applicable, of further instalments as follows:

€ 4,250.- on satisfactory of the work

to the Institution's bank account as hereinafter specified (to be completed by the Institution):

Name of account holder: Maharma. Gandhi Institute of Medical Sciences Sevagram
Account number: 1784800213.
IBAN and BIC/SWIFT Code: CBIN. 0280697
Bank name and address: Central Bank of India, Sevagram, Post Sevagram wardha.
Currency of account: Rupees Sort code (if any):

If one of the following texts is marked with a cross ("x") in the corresponding box, the paragraph of the General Conditions referred to therein shall apply to this CRA:

☐ Paragraph 9.1 of the General Conditions overleaf. ☐ Paragraph 9.2 of the General Conditions overleaf.

IARC Responsible Technical Officer
Signature:

Name: Dr M. Tommasino
Title: Head, Infections & Cancer Biology
Date:

Institution's Principal Investigator
Signature:

Name: Dr N. Gangane
Title: Head, Dept of Pathology
Date: 16/01/2012

On behalf of the IARC
Signature:

Name: Christopher P. Wild, PhD
Title: Director
Date:

On behalf of the Institution
Signature:

Name:
Title: DEAN, Mahatma Gandhi Institute of Medical Sciences, SEVAGRAM
Date:

Allotment No.:	Obligation No.:

Collaborative Research Agreement (CRA) – General Conditions

1. The Institution and the Principal Investigator

1.1 The Institution and the Principal Investigator (PI) shall be jointly responsible for all the technical and administrative aspects of the work referred to in this CRA.

1.2 The PI must be an employee of the Institution. The Institution must notify IARC if (i) the PI ceases to be an employee of the Institution or ceases performing the responsibilities under this CRA or (ii) upon knowing that either of the aforesaid will occur during the term of this CRA. In such event, IARC shall have the right to terminate this CRA or to continue it under a new PI proposed by the Institution and approved by IARC.

2. Financial arrangements

2.1 Payments shall be made in accordance with the agreed schedule of payments into the bank account of the Institution, as specified in this CRA. The funds provided under this CRA shall be expended only in accordance with its terms. If, after the final financial report referred to in paragraph 4 below, or in the event of this CRA being cancelled under any circumstances, there remains with the Institution an unused or uncommitted balance of funds, this balance shall be payable to IARC in accordance with its instructions.

2.2 The funds provided under this CRA may not be used to meet any form of emoluments, travel costs or any other reimbursements of expenditure to any staff of IARC.

2.3 Unless otherwise provided in this CRA, the funds may not be used to cover: (a) normal administrative and overhead expenses of the Institution; (b) the cost of maintenance, repair, running or insurance of existing equipment and machinery belonging to the Institution; (c) the cost of construction of new buildings or alterations and modifications of existing buildings and premises; or (d) salary support of the PI.

3. Equipment and supplies. Except as otherwise agreed or hereinafter provided, any equipment acquired under this CRA shall be the property of the Institution. The Institution and the PI shall be jointly responsible for its proper safeguard, maintenance and care. The Institution shall nevertheless transfer ownership of any such equipment to IARC, upon the latter's request, on termination or expiry of this CRA. In such cases the Institution shall dispatch the equipment at IARC's expense to any destination chosen by IARC.

Reports. The Institution shall submit technical and financial reports to IARC on the work as required, or at least annually, as set forth in this paragraph 4. The objective of these reports is to document the collaboration between the Institution and IARC. The final technical and financial reports must be submitted within 90 days after the expiry of this CRA.

4.1 Technical reports shall be prepared by the PI and countersigned by an authorized official of the Institution. Annual reports shall summarize the results and give in sufficient detail the positive and negative findings so that the value of the work can be assessed.

4.2 Financial reports jointly certified by the Institution's chief financial officer and the PI shall be submitted to IARC in accordance with the amount of the total payments under the CRA as follows: (a) US$ 5,000 or less: a certificate confirming the funds have been expended in accordance with its terms; (b) above US$ 5,000 but not more than US$ 20,000: a financial report on form IARC CRA FR-1; or (c) above US$ 20,000: a financial report on Form IARC CRA FR-2 showing the use of the funds compared with the original budget expenditure pattern agreed between the Institution and IARC.

4.3 All financial and technical reports are subject to audit by IARC's auditors, including examination of supporting documentation and relevant accounting entries in the Institution's books. In order to facilitate such reporting and audit, the Institution shall ensure that accurate and systematic accounts and records are kept in respect of the project.

5. Relationship and responsibility of the Parties. The relationship of the Institution to IARC shall be that of an independent contractor. The Institution's employees are not entitled to describe themselves as staff of IARC. The Institution shall be solely responsible for the manner in which its – including the PI's – work on the project is carried out and accordingly shall assume full liability for any damage arising from its research or its other work under this CRA. No liability shall attach to IARC, its advisers, agents or employees.

Pre-existing information and know-how. Each party retains its intellectual perty rights over its pre-existing information and know-how disclosed under this CRA. Use of such pre-existing information and know-how by other parties, which shall be on a royalty-free basis and subject to the obligations of confidentiality specified below, shall only be for the purposes of the work funded by this CRA, unless otherwise agreed in writing.

7. Confidentiality. The Institution, the PI and IARC shall ensure for five (5) years, or such other period agreed in writing, that information designated as proprietary and confidential (by a stamp or other written notice, or when disclosed orally, has been identified as confidential at the time of disclosure and has within thirty (30) days been confirmed in writing as confidential information) is treated as confidential and only used for the purposes of the work funded by this CRA or as otherwise agreed in writing by the discloser. These obligations shall not apply to information for which the receiver can prove had a public nature prior to communication by the discloser or fell within the public domain after such communication but through no fault of its own; was already in its possession at the time of signature of this CRA and not under an obligation of confidentiality; is received from a third party without breach of any secrecy obligation; or is subsequently developed by or for the receiver independently of the confidential information received from the discloser. In addition, the confidentiality obligation shall not prevent communications to comply with national laws or regulations provided that insofar as reasonably possible the receiver has informed the discloser of the need for such communication and shall have complied with the discloser's reasonable instructions designed to protect the confidentiality of such information.

8. Results

8.1 Reporting. The results of the project funded under this CRA shall be provided by the Institution to IARC in the form of all relevant information, including know-how, and, to the extent feasible, tangible products.

8.2 Ownership. All rights in the results of the work performed under this CRA shall be vested in the Institution or, if the Institution and IARC so agree, the PI.

8.3 Transfer of ownership. To the extent the Institution and the PI do not intend to exercise their rights in the results of the work, such rights shall be promptly transferred to IARC if it so requests. Each party shall provide the other with its full cooperation to permit the effective exercise of their rights in the results of the work.

8.4 Confidentiality. In the case of results that may be eligible for protection by proprietary rights, confidentiality shall be maintained for such time as may be necessary for the submission of all appropriate patent applications or alternative forms of legal protection to be instituted, or until such other time as may be agreed by the Institution and IARC.

8.5 Publication. Subject to the confidentiality obligations specified in these general conditions, the results of the work covered by this CRA shall be disseminated jointly by the parties or – in the absence of agreement on joint publication – separately. Notwithstanding paragraph 8.2 – or, if applicable, paragraphs 9.1 or 9.2 – all parties to this CRA shall be vested with such rights as may be necessary to enable dissemination of the results of the work as provided in this paragraph 8.5. In the event that a party wishes to publish the results of the funded work and another's pre-existing confidential proprietary information has been disclosed under this CRA, the publishing party shall ensure that prior to publication the discloser consents to the publication, consent not to be unreasonably withheld and only for the purposes of, and to the extent necessary for, ensuring adequate protection of its rights in pre-existing confidential proprietary information. However, nothing herein shall prevent a party from publishing information developed by it prior to the commencement of the work or information developed by it simultaneously with, though independently of, the funded work. In any publication solely by the Institution or the PI relating to the results of the work, the responsibility for the direction thereof shall not be ascribed to IARC. Unless IARC advises otherwise, all such publications shall include a notice that the underlying investigation received support from IARC. IARC funds may not be used for publication costs unless specifically authorized.

8.6 Exploitation. The industrial or commercial exploitation of the results of the work covered by this CRA shall be exercised in accordance with an agreement to be negotiated in good faith between the Institution and IARC. The agreement shall be designed to achieve, insofar as circumstances permit, the following objectives in order of priority: (i) the general availability of products of creative activity; (ii) the availability of those products to the public health sector on preferential terms, particularly in developing countries; and (iii) the grant to the Institution – and, if so requested, IARC – of additional benefits, including royalties, account being taken of the relative value of each party's financial, intellectual and other contribution to the work.

9. Paragraphs applicable only when so provided overleaf

9.1 Paragraphs 8.2 and 8.6 shall be replaced by the following: All rights in the results of work performed under this CRA shall be vested in the Institution with IARC being automatically vested with a non-exclusive, perpetual, royalty-free, worldwide license in such rights for all uses and purposes. Such license shall be sub-licensable and assignable.

9.2 Paragraphs 8.2, 8.3 (first sentence) and 8.6 shall be replaced by the following: All rights in the results of the work performed under this CRA shall be vested in IARC.

10. Research involving human subjects

10.1 It is the responsibility of the Institution and the PI to safeguard the rights and welfare of human subjects involved in research supported in whole or in part by funds from IARC, 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. Such funds may be used only to support investigations where (a) the rights and welfare of the subjects involved in the research are adequately protected, (b) freely given informed consent has been obtained, (c) the balance between risk and potential benefits involved has been assessed and deemed acceptable by a panel of independent experts appointed by the Institution and (d) any special national requirements have been met.

10.2 It is the responsibility of the Institution and the PI to comply with the relevant national regulations pertaining to research involving human subjects.

10.3 Without prejudice to obligations under applicable laws, the Institution shall make appropriate arrangements to eliminate or mitigate the consequences to subjects or their families in the case of death, injury or illness resulting from the conduct of research referred to in paragraph 10.1. Such arrangements shall, to the extent feasible, include medical treatment and financial relief. The Institution and PI undertake to protect the confidentiality of the information relating to the possible identification of subjects involved in the research involving human subjects conducted under the auspices of this CRA.

11. Research involving the use of laboratory animals. The Institution undertakes that living vertebrate animals required for use as laboratory animals for research under this CRA shall be handled in accordance with generally accepted principles for the humane treatment of such animals and the avoidance of unnecessary suffering.

12. Research safety. The Institution shall establish and implement policies and practices providing for the safety of its employees, the public, and the environment during the conduct of the supported research. If the supported research involves the use of dangerous agents, the Institution shall establish and implement an appropriate safeguard plan which also meets all requirements of any applicable national laws or regulations.

13. Publicity. The Institution and the PI shall not refer to the relationship of IARC to the work, or to any connected products or processes, in any publicity or promotional statement or material issued for commercial purposes or with a view to financial benefit.

14. Cancellation. If this CRA is longer than one year, either IARC or the Institution may cancel it without cause on any anniversary of its entry into force on 60 days written notice to the other. Such cancellation shall be without prejudice to the application of its provisions with respect to the work performed and payments made prior to cancellation.

15. Settlement of disputes. Any matter relating to the interpretation or application of this CRA which is not covered by its terms shall be resolved by reference to the law of France. Any dispute relating to the interpretation or application of this CRA 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, in accordance with the UNCITRAL Arbitration Rules then obtaining. The parties shall accept the arbitral award as the final adjudication of the dispute.

International Agency for Research on Cancer

World Health Organization

150 cours Albert Thomas
69372 Lyon cedex 08, France

Office of the Director of
Administration and Finance
Tel.: +33 4 72 73 81 78
Fax: +33 4 72 73 83 94
E-mail: daf@iarc.fr
http://www.iarc.fr

Dr S.D. MEHTA
Director
Mahatma Gandhi Institute of Medical Sciences
Sevagram
District of Wardha
442 102 Maharashtra
INDIA

Tel. 91 7152 284341

Ref.: ICB/92/3-IND/Sevagram
ENCL.: 1

Lyon, 6 August 2014

Collaborative Research Agreement ICB/12/05 – Amendment 1

Dear Dr Mehta,

Having discussed your project needs with Dr Massimo Tommasino, and in order to enable you to complete recruitment of 500 prospective and 500 retrospective physical blocks, which is taking longer than originally expected, I am pleased to inform you that we wish to propose to increase the duration of the agreement until **31 August 2015** (18-month extension without additional funds).

Should you agree with our proposal, I would be grateful if you could reply officially to this effect. To comply with our regulations, your reply should be co-signed by you, as Director of the Institute, and Dr Nitin Gangane, the Principal Investigator. This exchange of correspondence will serve to amend the duration of the above-referenced Agreement and it will be amended on receipt of your **acceptance letter**.

The last instalment of this CRA will then be made as follows:

- **2,000.00 Euros** on **31 August 2015**, subject to receipt of satisfactory final Technical and Financial reports. For your final Financial Report, please use the attached form IARC CRA FR-1 FINAL – Amd.1.

Please note that the financial report (template to be forwarded by email) should be co-signed by Dr Nitin Gangane and the institution's chief financial officer.

Dr Tommasino and I look forward to continuing our collaboration with you.
Yours sincerely,

David Allen
Director of Administration & Finance

Approval of LTRG project

From: udc@muhs.ac.in

To: vbshivkumar@yahoo.co.in

Cc: udc.2009@rediffmail.com; dean@mgims.ac.in

Date: Saturday, 21 February, 2015 at 03:50 pm IST

Madam
Congratulations! Your LTRG (2014-15) project has been APPROVED. Recommendations/Remarks of the Research Grant Scrutiny Committee (RGSC) are appended below. You may start planning to complete you LTRG project as per the provisions of University Notification no. 25/2014, available on www.muhs.ac.in – Departments –University Department Cell – Notifications – Notification no. 25/2014.

LTRG/ E1-5/1504	Dr. Shivkumar Vitaladevuni Balasubrahmanyam MGIMS, Sewagram, Wardha (M) - 9422144855, vbshivkumar@yahoo.co.in	"Expression of ER,PR, HER2/neu, Ki67 and p53 markers in endometrial carcinoma: Clinicopathological implications and prognostic value."	**(R) Recommended** 1) Approved Rs 1,00,000/-

Further course of action in progress. Sanction Letter and financial assistance shall be released in the course of time.

You are required to follow and implement University Notification no. 25/2014, meticulously.

Dy. Registrar
HOD.

Gmail Anshu <dr.anshu@gmail.com>

Approval of LTRG project

udc@muhs.ac.in <udc@muhs.ac.in> Sat, Feb 21, 2015 at 3:52 PM
To: dr.anshu@gmail.com
Cc: dean@mgims.ac.in, udc.2009@rediffmail.com

Madam

Congratulations! Your LTRG (2014-15) project has been APPROVED. Recommendations/Remarks of the Research Grant Scrutiny Committee (RGSC) are appended below. You may start planning to complete you LTRG project as per the provisions of University Notification no. 25/2014, available on www.muhs.ac.in – Departments –University Department Cell – Notifications – Notification no. 25/2014.

LTRG/ E1-6/1504	Dr. Anshu MGIMS, Sewagram, Wardha (M) - 09822726984, dr.anshu@gmail.com	"Prognostic value of expression of cytokeratin 5/6, EGFR, e-cadherin and p53 in triple negative breast cancers in Central India. "	**(R) Recommended** 1) Approved Rs 1,00,000/-

Further course of action in progress. Sanction Letter and financial assistance shall be released in the course of time.

You are required to follow and implement University Notification no. 25/2014, meticulously.

Dy. Registrar
HOD.

NATIONAL CENTRE FOR DISEASE INFORMATICS AND RESEARCH
Indian Council of Medical Research
Department of Health Research, Ministry of Health and Family Welfare, Government of India
NirmalBhawan-ICMR Complex (II Floor), Poojanahalli, N.H–7, B. B. Road,
Kannamangala Post, Bengaluru–562 110 (India)
Tel: +91 9449067643, +91 9449033748 Fax: 080 30723643, Email: ncdir@ncdirindia.org

No. NCDIR/PBCS/14/2017/406 26 May 2017
29

Dr. Nitin Gangane
Principal Investigator, PBCR-Wardha &
Director Professor and Head,
Dept. of Pathology
Mahatma Gandhi Institute of Medical Sciences,
Sevagram Dist. Wardha
Maharashtra -442102

Dear Sir,

Sub: Project on "Population Based Cancer Survival Study on Cancers of Breast, Cervix and Head & Neck Cancers at your institute"- reg.

Thank you for sending the copy of Memorandum of Understanding (MoU) along with bank mandate form and other related documents pertaining to the above mentioned project. Please find enclosed one copy of MoU duly signed by Director, NCDIR.

I am directed to inform you that the Director, NCDIR has sanctioned the first installment grants of Rs.20,000/- towards Project on "Population Based Cancer Survival Study on Cancers of Breast, Cervix and Head & Neck Cancers" at your institute.

Accordingly, a sum of Rs.20,000/- is being transferred to your institute account No.31054728617, State Bank of India, Sevagram Branch, Wardha. This has been done through electronic transfer (NEFT / RTGS) vide cheque No. 236939 dated 31.03.2017 from NCDIR account No. 3025201000017, Canara Bank, Kannamangala Branch, Bengaluru Rural.

The receipt of the money may please be acknowledged.

With kind regards,

Yours sincerely,

(Ramesha N.M.)
Administrative Officer
For Director, NCDIR

Copy to: The Dean, Mahatma Gandhi Institute of Medical Sciences, Sevagram Dist. Wardha
Maharashtra -442102

Encl: As above.

INDIA NON JUDICIAL

Government of National Capital Territory of Delhi

e-Stamp

Certificate No.	:	IN-DL93664445094114O
Certificate Issued Date	:	27-Sep-2013 08:56 AM
Account Reference	:	[illegible]
Unique Doc. Reference	:	SUBIN-DLDL93304333000[illegible]58439240
Purchased by	:	PUBLIC HEALTH FOUNDATION OF INDIA
Description of Document	:	Article Others
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	PUBLIC HEALTH FOUNDATION OF INDIA
Second Party	:	Not Applicable
Stamp Duty Paid By	:	PUBLIC HEALTH FOUNDATION OF INDIA
Stamp Duty Amount(Rs.)	:	50 (Fifty only)

Please write or type below this line

SUB GRANT AGREEMENT

This Sub Grant Agreement (hereinafter to be referred as "Agreement") is executed on the 10th October, 2013 (hereinafter referred to as "the Execution Date")

By and between

The Public Health Foundation of India, a society registered under the Societies Registration Act, 1860 and having its registered office at ISID Complex, 4 Institutional Area, Vasant Kunj, New

For PHFI

For KHS

Delhi-110 070, India, (hereinafter referred to as "**PHFI**" which expression shall unless be repugnant to context or meaning thereof shall mean and include its successors and assigns) of the **First Party;**

And

Kasturba Health Society, a Society registered under the Indian Societies Registration act, 1860 having its registered office Sevagram Maharashtra 442 102 and also having an Institute i.e. Mahatma Gandhi Institute of Medical Sciences, Wardha (Hereinafter referred to as **"KHS"** which expression, unless repugnant to the context or meaning thereof, shall include its affiliates, successors in interest and permitted assigns) as **Second Party**.

PHFI and KHS are individually referred to as the "**Party**" and collectively as the "**Parties**".

WHEREAS:

A. **The project- Reducing blindness from diabetic retinopathy in India** Funded by the Queen Elizabeth Diamond Jubilee Trust, London, UK in partnership with the Public Health Foundation of India and the London School of Hygiene and Tropical Medicine, London, UK (Grant Number: TG018). For the purpose of this Grant a National Task force has been set-up by the Government of India. The Task force identified leading institutions working on Diabetic Retinopathy with their implementing district having functional NCD clinics. On behalf of KHS, MGIMS was asked to submit a proposal for Implement and evaluate integrated district models for the control of diabetic retinopathy that strengthen health systems. The proposal submitted was reviewed and approved by an expert group on Review programme planning and implementation in Trust supported Districts under the Trust supported program.

B. PHFI is desirous of engaging KHS/MGIMS who shall act to undertake the activities, as detailed below.

C. KHS/MGIMS has agreed to undertake this task, according to the terms and conditions set forth herein.

NOW THEREFORE, in consideration of the premises and agreements herein contained, **the receipt and sufficiency of which is hereby acknowledged,** and intending to be legally bound hereby, the Parties hereby agree as follows:

1. **Terms of Reference**

The responsibilities of the KHS/MGIMS shall be as follows:

1.1. Integration of awareness raising i.e. partners work with staff in the NPCDCS at every level (i.e. in CHC, District and State Cells) to increase awareness of the complications of diabetes, including retinopathy and the need for regular eye examinations.

1.2. Integration of screening i.e. screening is performed amongst known diabetics who are already attending services, be this at primary, secondary or tertiary level.

1.3. Set up diabetic retinopathy screening in the NCD clinics of the 4 CHCs and 1 district hospital in the proposed taluks within 3 months of project initiation (end of 3rd quarter of 2016). The screening will be done as an adjunct to physician clinics (NCD clinics) at CHC/GH on fixed days of the week.

1.4. Assess specific needs for capacity building of Ophthalmologists, Paramedic Ophthalmic Assistants (PMOA), Medical officers, Nurses and other supporting staff who are involved in Screening ,Detection, Treatment and Follow up of sight threatening Diabetic Retinopathy.

1.5. Formulate, pilot test and finalize a package of interventions consisting of educational materials on Diabetic retinopathy, quality improvement methods and raising patient awareness delivered using a multimedia/web-based platform and skill development sites.

1.6. Formulate pilot test and finalize protocols/guidelines and standard operating procedures (new or updating existing documents).

1.7. Periodically assess the progress towards identified activities and stated timelines and report to PHFI.

1.8. Meet periodically to develop the strategy and to monitor progress.

1.9. Develop advocacy tools for changing policies relevant to above said interventions.

1.10. Facilitate on-sight visit by the Trust and PHFI team.

1.11. Allow for independent evaluation by a third party identified by the Trust or PHFI

1.12. KHS/MGIMS will be the lead collaborator and is responsible for liaisoning with Department of Medicine MGIMS, Health officials of Wardha District as well as Government of Maharashtra.

1.13. Responsibilities of PHFI

- Developing IEC materials
- Liaison with the Trust and the GOI

- Facilitating various working groups
- Annual review of district DR programme
- Liaising with the funders
- Procurement of equipment needed
- Facilitating liaison between DHFW, partner in the field
- Facilitating liaison between partner and field staff for training
- Regular monitoring of activities in the field

2. Role of Collaborator

The collaborator i.e. KHS/Department of Ophthalmology & Department of Medicine MGIMS Sewagram will work in close association with the NCD physician and implementation of capacity building module. They would also conduct patient led self-care groups and in outreach activities for primary diabetes care. Department of medicine will provide technical support in training physicians from the government health facilities in Wardha district. They will also provide diabetic care services to any patients referred to them.

3. Deliverables

Deliverables to be submitted by KHS/MGIMS

KHS/MGIMS shall deliver the following by the end of this agreement.

0.1 Assess knowledge, attitude and training needs of health care personnel, before and after intervention with adequate documentation
0.2 Learning package for improving managerial and leadership skills of healthcare personnel
0.3 Package for improving awareness of patients regarding Diabetic Retinopathy, need for screening and potential therapy
0.4 Skill-labs in mentoring institutes for improving skills of healthcare personnel
0.5 Material for advocating policy changes on interventions likely to influence risk of Diabetic Retinopathy.
0.6 Establish collaborative quality-improvement and monitoring network for chosen states & voluntary institutions and integrated into the existing health system.

Programme Area	Indicator	Data to be collected	Person responsible	Frequency
Implement and evaluate district models for the control of diabetic retinopathy that strengthen and are	Number of potential screeners a) identified b) trained and c) who are actively involved in screening Number of ophthalmologists a) identified b) trained and c) who are actively involved in providing confirmatory diagnosis and treatment of DR	Implementing partner's records	Implementing partners	Annually
	Outcome • Provisional operational guidelines	Copy of the provisional	Implementing partners	Annually

integrated into health systems	for screening and management are approved by Task Force and are in use in the project districts by 2015 • Number and proportion of PHCs/CHCs with at least 50% diabetics screened for DR annually • Number and proportion of diabetics with sight threatening DR patient referred to eye care centre/mobile unit • Number and proportion of those referred who attend for confirmatory diagnosis • Number and proportion of those detected with sight threatening DR treated at eye care centre/ mobile unit by treatment modality • Number and proportion with sight threatening DR who are successfully treated (i.e. visual acuity stable or improved at 1 year) • At least 50% of the State Governments commit funds for continued implementation of the district model by 2019 • Experience from the model leads to expansion to state/national level	operational guidelines Records from NCD Clinics in districts Records from NCD/eye Clinics in districts Records from NCD/eye Clinics in districts Records from NCD/eye Clinics in districts		
	Process • Finalized clinical National guidelines for screening and management of retinopathy adopted by the NPCB by 2018 • Model pilot district programmes established in Project districts by 2016 • Number of eye care provider trained in diagnosis and management of DR • At least 10 ophthalmologists from Project districts trained in laser and/or surgical procedures for diabetic retinopathy by 2017	Copy of the final operational guidelines incorporated into NPCB Training records from implementing partners	PHFI	Annually

4. Term of Agreement

This Agreement is valid with effect from **Date of Signing** and shall remain in force till **31.12.2018** (hereinafter referred to as the **"Effective Date")**. This term may be extended for

such period and on such terms and conditions as may be mutually agreed upon by both Parties.

5. Terms of Payment

5.1 The total sub grant amount payable by PHFI to KHS is Rs.**1,05,73,611/-** (Rupees One Crore Five Lakhs Seventy Three Thousand Six Hundred and Eleven Only).

5.2 The approved detailed budget break up is attached in **Annexure -1**. PHFI will not be liable, under any circumstance, to pay any amount over and above this grant. PHFI shall pay the grant installments to MGIMS as per the schedule mentioned below as Annexure -1.

S.No.	Task	Approved Cost
1.	On Signing of the agreement (Q4 to Q6)	**47,04,225/-**
2.	Q7 to Q8 in July 2017 or 85% spent of previous grant amount	**24,95,534/-**
3.	Q9 to Q10 in Jan 2018 or 85% spent of Q7 to Q8 grant amount	**15,66,225/-**
4.	Q11 to Q12 in July 2018 or 85% spent of Q9 to Q10 grant amount	**18,07,627/-**
	Total Grant	**1,05,73,611/-**

5.3 It is hereby agreed and understood by the Parties that all amounts as due and/or payable except that payable on signing agreement, under this Clause 5.1 shall be released only after the corresponding work, as is stated herein, is completed. KHS shall submit statement of expenditure along with deliverables/utilization certificate of the amount due on PHFI for every subsequent installment on completion of relevant portion of the work along with the project report. PHFI, on being satisfied that the relevant work has been completed, shall release the funds within 15 days of approval of the work by the Project Lead at PHFI. PHFI reserves the right to direct and require KHS to make any amendments, alterations and changes to the work performed by KHS under this Agreement and the Parties hereby agree that release of any funds under Clause 5.1 shall not affect this right of PHFI, in any manner whatsoever.

5.4 The financial statements highlighting the utilization of funds under this Agreement shall be submitted by KHS in the budget format provided by PHFI. All statements should be duly authorized by the finance department of KHS. This should be reported to PHFI in 6 monthly formats. Reporting schedule is mentioned below:

Reporting Period	**Submission Date**
January to June	31st July
July to December	31st January
Audited Utilization Certificate (April to March)	30th April

5.5 Bills/ Invoices/ Receipts of expenditures from funds given by PHFI to KHS under this Agreement will be maintained separately by the latter and copies of these documents shall be submitted to the former, as and when PHFI requests, as per FCRA regulation.

5.6 KHS shall maintain complete records of all costs charged to the grant for a period of three (3) years after the expiration of the grant and make such records available to PHFI or its representatives for review at any time.

5.7 KHS to submit audited Utilization Certificate at the end of every financial year to PHFI by 30th April.

5.8 During the agreement period, if sub-grantee's registration/FCRA/PAN details are changed, cancelled or suspended, this should be immediately intimated to PHFI. Any delay in updating this change may result in retrieval of the whole sub-grant amount paid to the sub-grantee.

6. Intellectual Property Rights and Confidentiality

6.1 It is expressly agreed that all the Parties shall have joint ownership rights over all intellectual property of work and materials developed, created or produced during the term of this MoU. The Party using the IPR shall be responsible to appropriately acknowledge the other parties.

6.2 MGIMS shall not distribute, display or use in any manner whatsoever, the material prepared, produced or used in the Project and any other intellectual property generated out of this agreement except for educational and non-commercial purpose.

6.3 MGIMS shall not use any drafts, data, survey related details and extracts in any form during or after the completion of this Project except for educational and non-commercial purposes.

6.4 MGIMS shall in no way use/utilize the name "Public Health Foundation of India" or "PHFI" in any manner whatsoever, without the express written consent of PHFI.

0.5 MGIMS agrees and undertakes to not disclose any Confidential Information to any person or entity without the prior written consent of PHFI. KHS shall hold in strictest confidence and shall not use or disclose to any third party any Confidential Information or any other information that it might receive from PHFI.

0.6 The Parties declare that this Clause shall survive even after the termination of this Agreement.

7. Indemnity

KHS shall indemnify, keep indemnified and hold harmless PHFI against any or all actions, claims, proceedings, costs, damages, liabilities, penalties, fines, expenses, losses, demands and liabilities including but not limited to legal expenses and fees for legal counsel made by any third party which may be attracted/sustained on account of:

(i). Breach and/or failure/non fulfillment by KHS, of any of terms of this Agreement,

(ii). Non-compliance of KHS with the Applicable Laws including national rules and regulations or for not obtaining any necessary permissions and licenses,

(iii). Violation of any rights of third parties otherwise in connection with or incidental with the performance of this Agreement,

(iv). Any liability which may arise out of the reports provided by KHS to PHFI.

This clause shall survive the termination of this Agreement.

8. Termination & Remedy

8.1. PHFI reserves the right to immediately terminate this agreement with MGIMS without necessarily assigning reasons for such termination. PHFI shall send a written notice of such termination to KHS and this agreement shall stand terminated in 1 (one) month from the date of receipt of the said notice of termination by KHS.

8.2. In the event of termination of this Agreement by PHFI, KHS shall be reimbursed for all expenses incurred by it in accordance with the terms of this Agreement till the date of termination of this Agreement. Payment under this Clause 8.2. Shall be subject to submission of financial reports and supporting documents by KHS to PHFI. It is clarified that (a) during the notice period, KHS shall not incur any expenses unless specifically approved by PHFI in writing. In no event shall the liability of PHFI towards payments exceed the amount mentioned in Clause 5.1 of this Agreement.

8.3. Upon the expiry or termination of this Agreement in accordance with the provisions hereof, each Party shall forthwith return to the other Party any copies or extracts of documents containing any Confidential Information acquired during the course of this Agreement.

8.4. The termination, as aforesaid in Clause 8 of this Agreement, shall be without prejudice to each Party's rights and remedies under law available to it including, but not limited to the right to seek, as an alternative to termination, specific performance of obligations under this Agreement or terminate the Agreement and seek damages for a breach from the Defaulting Party, committed during the period prior to such termination.

9. Force Majeure

9.1 If at any time during the continuance of this Agreement, the performance in whole or in part by either Party of any objectives under this Agreement is prevented or delayed by reason of governmental decision, war, hostilities, act of a public enemy, civil commotion, sabotage, fire, flood, explosion, epidemics, quarantine restrictions, disturbance in supplies from normally reliable sources (including but not limited to electricity, water, fuel and the like), strike, lockout or other event beyond the reasonable control of the Party concerned (hereinafter referred to as "the Eventuality"), then notice of such Eventuality shall be given by the affected Party to the other Party within 15 days from the date of occurrence thereof.

9.2 In the event of either Party not being able to by reason of an Eventuality, meet any of its obligations under this Agreement, such obligations shall be suspended for as long as the inability continues or any date mutually agreed between the Parties. This Agreement may be terminated by either Party by providing one (1) month's written notice if the inability to undertake activities under this Agreement continues even after expiry of 90 days since the commencement of the Eventuality.

10. Dispute Resolution

10.1 In the event of any dispute relating to the interpretation or performance of this Agreement arising between the Parties, both Parties will first do their utmost to settle their dispute amicably.

10.2 In the case of failure to resolve the dispute amicably, such disputes under this Agreement shall be referred to arbitration under the Arbitration & Conciliation Act, 1996 (or any amendments thereof).The place of such arbitration shall be New Delhi. The language of arbitration shall be English. The arbitration award shall be final and binding on both parties.

11 Governing Laws

This Agreement shall be construed and enforced in accordance with the governing laws of India. The courts of New Delhi only will have the jurisdiction to decide matters pertaining to this Agreement.

12 Other Terms and Conditions

0.1 KHS may not assign or transfer any of its rights, obligations, benefit, or interest in this Agreement without the other Parties' prior approval.

0.2 All material developed/procured shall acknowledge the support by the funder Queen Elizabeth Diamond Jubilee Trust, London, UK in partnership with the Public Health Foundation of India and the London School of Hygiene and Tropical Medicine, London, UK and the following shall be carried on all such material.

0.3 This Agreement constitutes the entire agreement of the Parties with respect to the subject matter hereof and may not be modified or amended except in a written agreement signed by both Parties.

0.4 Nothing contained in this Agreement shall constitute or be deemed to constitute a partnership between the Parties, and no Party shall hold KHS out as an agent for the other Party or any of them, except with the express prior written consent of the other Parties. The rights, duties, obligations and liabilities of PHFI on the one hand and the KHS and its Affiliates on the other hand, under this Agreement shall be individual, not joint or collective, unless specifically provided for herein this Agreement.

0.5 No waiver of any breach of any provision of this Agreement shall constitute a waiver of of any prior, concurrent or subsequent breach of the same of any other provisions hereof, and no waiver shall be effective unless made in writing and signed by an authorized representative of the waiving Party. No failure or delay by a Party in exercising any right, power or remedy under this Agreement shall operate as a waiver thereof, nor shall any

single or partial exercise of the same preclude any further exercise thereof or the exercise of any other right, power or remedy.

0.6 If any provision of this Agreement is invalid, unenforceable or prohibited by law, this Agreement shall be considered divisible as to such provision and such provision shall be inoperative and shall not be part of the consideration moving from either Party hereto to the other, and the remainder of this Agreement shall be valid, binding and of like effect as though such provision was not included herein. Should any provision of this Agreement be or become ineffective for reasons beyond the control of the Parties, including because of applicable provisions of law or regulations of governmental authorities, the Parties shall use best endeavors in good faith to agree upon a new provision which shall as nearly as possible have the same effect as the ineffective provision.

0.7 Conflict Of Interest: Each party (PHFI and KHS) warrant that this Agreement is not likely to have any conflict of interest with any of their organizational, financial, contractual or other interests relating to the work under this Agreement.

13. Notices

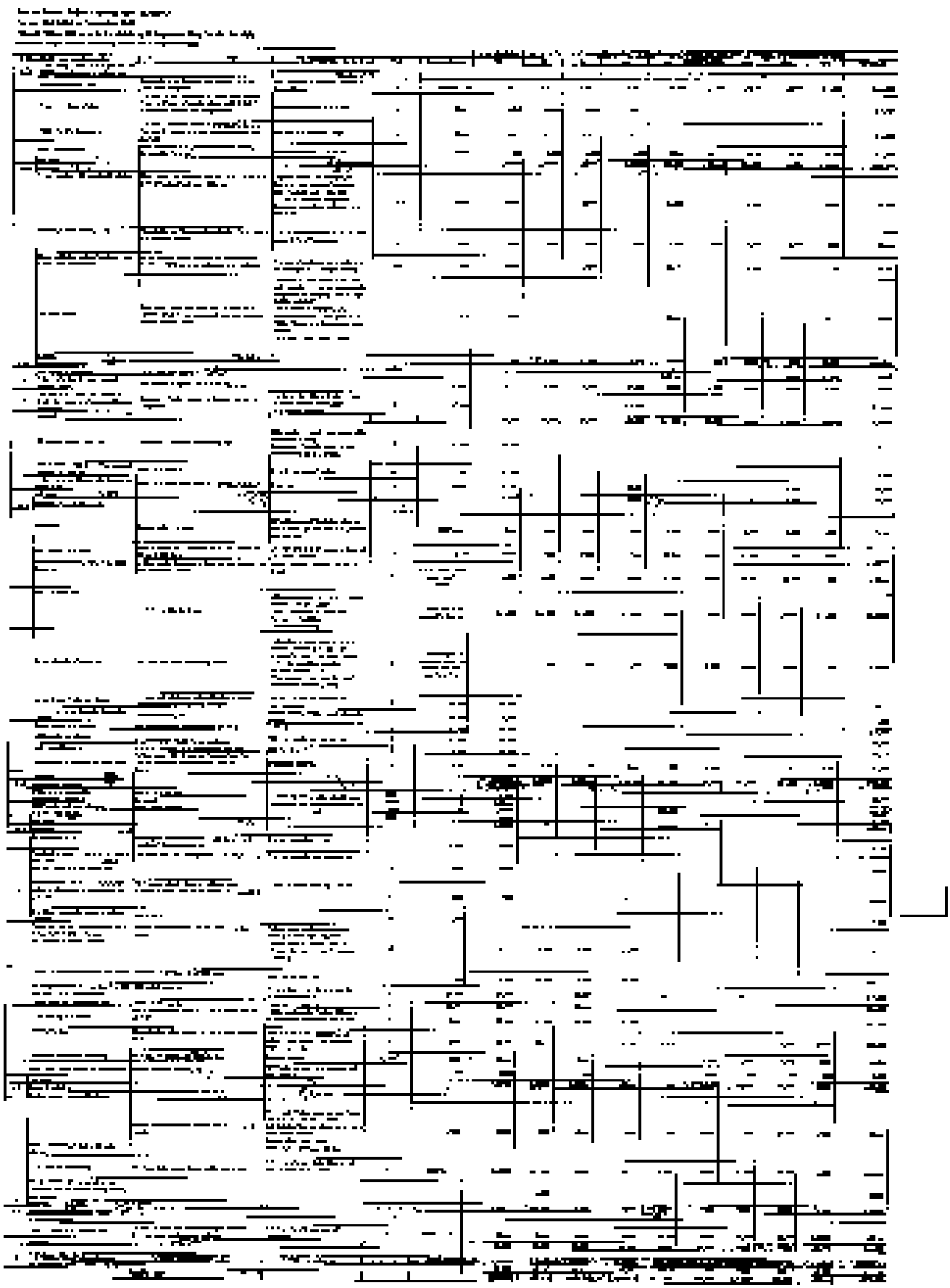
All notices under this Agreement shall be in writing and in English and either delivered by hand or sent by registered mail or courier or by email or by facsimile telex or fax, in each case to the addresses set out below. Any change of address of either party shall be immediately intimated to the other party. Failure to provide such intimation shall lead to termination of the contract and will also amount to appropriate legal recourses as mentioned in the Agreement.

For PHFI	**For KHS**
Prof: GVS Murthy **Vice President – South**	**Dr. Ajay Kumar Shukla** **Director Professor & Head** **Department Ophthalmology** **MGIMS Sewagram**
Public Health Foundation of India Plot No. 47 Sector-44, Institutional Area, Gurgaon-122002, Haryana, India	Mahatma Gandhi Institute of Medical Sciences (MGIMS) Sewagram Wardha (Maharashtra) - 442102 India
Tel: 0124-4722900 Email: murthy.gvs@iiphh.org	Telephone: (07152) 284341 – 55 Ext. 282-300 Email : eyemgims@gmail.com

SIGNED, SEALED AND EXECUTED BELOW BY THE PARTIES ON THE DATE ABOVE MENTIONED

Agreed and accepted:	Agreed and accepted:
Public Health Foundation of India (PHFI) Signature: _____ Name: **Mr. Anil Chugh** Designation: **Vice President, Finance & Resources, PHFI** **Date:** _____	**Kasturba Health Society (KHS)** Signature: _____ Name: **Dr. B. S. Garg** Designation: **Secretary Kasturba Health Society,** **Sewagram** Secretary, Kasturba Health Society P. O. Sevagram, Wardha Pin 442 102 **Date:** _____
Signature: _____ PUBLIC HEALTH FOUNDATION OF INDIA (PHFI) New Delhi 110070 Name: **Prof. GVS Murthy** Designation: **Director, IIPHH** Date:	**Mahatma Gandhi Institute of Medical Sciences** Signature: _____ Name: **Dr. Ajay Kumar Shukla** Designation: **Director Professor & Head Department Ophthalmology, MGIMS Sewagram Wardha** Date:

Annexure-1 BUDGET



PUBLIC HEALTH FOUNDATION OF INDIA

AMENDMENT TO THE AGREEMENT BETWEEN PUBLIC HEALTH FOUNDATION OF INDIA AND KASTURBA HEALTH SOCIETY

The Agreement between the **Public Health Foundation of India** and **Kasturba Health society** was first executed 10th October, 2016. And the amendment to this Agreement is now made on this 18th December, 2018 at New Delhi by and between:

Public Health Foundation of India (PHFI), a society registered under the Societies Registration Act, 1860 and having its registered office at Unit No. 316, 3rd Floor, Rectangle -1 Building, Plot No. D-4, District Centre Saket, New Delhi-110 017 (hereinafter referred to as "**PHFI**" which expression shall unless be repugnant to context or meaning thereof shall mean and include its successors and assigns) of the **First Party;**

AND

Kasturba Health society, a society registered under the Indian Societies Registration act, 1860 having its registered office sevagram Maharashtra 442 102 and also having an Institute i.e. Mahatma Gandhi Institute of Medical Sciences, Wardha (Hereinafter referred to as "**KHS**" which expression, unless repugnant to the context or meaning thereof shall include its affiliates, successors in interest and permitted assigns) as **Second Party.**

PHFI and KHS are individually referred to as the "**Party**" and collectively as the "**Parties**".

WHEREAS:

1. PHFI and KHS entered into an agreement on 10th October, 2016 (henceforth termed as '**Agreement**').
2. PHFI and KHS now desire to amend certain terms of the agreement as set forth below:

Clause 4 Term of Agreement

This Agreement is valid from **01st January, 2019** and shall remain in force till **30th June, 2019** (hereinafter referred to as 'the Effective Date').

Public Health Foundation of India (PHFI)
Plot No. 47, Sector 44, Gurugram, Haryana–122002. India Phone: +91 124 4781400 Fax: +91 124 4781601
Registered Office: 316, 3rd Floor, Rectangle -1 Building, Plot No. D-4, District Centre Saket, New Delhi-110017
Phone: +91 11 40057500 Fax: +91 11 40057515
www.phfi.org

Clause 5.4 Terms of Reporting

Reporting schedule is mentioned below:

Reporting Period	Submission Date
January'19 – March'19 (Narrative and financial reports)	7th April'19
Audited Utilization Certificate (April'19 to June'19) (Narrative and Financial Reports)	15th July'19

SIGNED, SEALED AND EXECUTED BELOW BY THE PARTIES ON THE DATE ABOVE MENTIONED

Agreed and accepted:

PUBLIC HEALTH FOUNDATION OF INDIA

Signature: _____

Name: : **Prof. D. Prabhakaran**

Designation: **Vice President,**

Research & Policy, PHFI

Date: _____

Agreed and accepted:

Kasturba Health Institute(KHS)

Signature: _____

Secretary,
Kasturba Health Society
P. O. Sevagram, Wardha

Name: Dr. B. S. Garg

Designation: Secretary, Kasturba Health Society, Sewagram

Date: _____

Signature: _____

Name: **Prof. GVS Murthy**

Designation: : **Vice President (South)-PHFI**

Director, IIPHH

Date: _____

Dr. A. K. SHUKLA
MS, DNB, FRCS
DIRECTOR, PROFESSOR & HEAD
DEPARTMENT OF OPHTHALMOLOGY
MGIMS, SEVAGRAM, WARDHA

LCIF GRANT AGREEMENT
Diabetes Pilot Project Grant

Grantee:	District 323-H1
Grant administrator:	Raje Mudhoji A. Bhonsle District Governor (2016-2017)
Grant number:	CFP15509/UND-52
Amount of grant:	US$45,000
Purpose of grant:	Screening for Diabetic Retinopathy in Diabetics
Approval date:	June 9, 2017
Project timeline:	June 2017 – November 2017
Mid-Point check in date:	September 1st, 2017
Disbursement schedule:	A single disbursement is planned.
Reporting schedule:	**A final report is due on December 1, 2017.** The district cabinet (for club and district level projects) or multiple district council (for multiple district level projects) must review and approved the final report before it is sent to LCIF. Please plan accordingly to ensure that this happens prior to the December 1, 2017 final report date.

GENERAL CONDITIONS

1. **Purpose:** The grant shall be used solely for the described purpose or purposes as approved by LCIF Chairperson Yamada and confirmed in this correspondence dated June 13, 2017.

2. **Accounting and financial review:** LCIF grant funds must be deposited in the club, district, or multiple district bank account and then disbursed to the project implementers, following the guidelines outlined below.

    - Checks, demand drafts/cashier's checks, or wires from the district account may only be issued to a certified project supplier or contractor. Such payments or checks may never be made out to "cash" or to "bearer." No project payments should be made in cash without the prior approval of LCIF.

- Lions bank accounts for LCIF grant funds shall only be established in commercial or national banks that are properly accredited and which have deposit insurance if required in that country. Use of 'cooperative banks' or community banks are prohibited. Additionally, fixed-length deposit accounts (e.g., certificates of deposit) shall not be used unless approved by LCIF.

- For LCIF projects where grant funds are made payable to the club, district or multiple district, all are prohibited from disbursing the funds to any individual, including the project chairperson or grant administrator, or otherwise release said funds to any bank account controlled solely by an individual. Unless otherwise approved by LCIF, such project disbursements received by a club, district, or multiple district should be re-issued to the implementing partner (e.g., hospital, camp, etc.) or to project suppliers and vendors, per the approved project and budget.

- In terms of financial accounting at the club, district or multiple district level, the LCIF grant should be noted in the club, district or multiple district accounts, so that the income and expenditures can be included when the accounts are audited at the end of the year.

- In situations where there is determined to be improper use or misappropriation or LCIF grant monies by a grant administrator or any person involved in an LCIF-funded project, the foundation shall pursue all necessary legal actions to retrieve said funds and to hold parties liable for any improper actions.

3. **Budget:** LCIF approved this grant based upon a detailed budget. No significant changes may be made to the budgetary allocation as approved by the LCIF Chairperson without LCIF's prior written approval.

4. **Reversion of grant funds:** This grant is intended to support a specific project as stated in the award letter and this accompanying agreement. Any portion of the grant unexpended at the completion of the project shall be immediately returned to LCIF.

5. **Additional support:** By making this grant, LCIF assumes no obligation to provide other or additional support to the grantee.

6. **Property/Equipment Ownership:** LCIF claims no ownership of and disclaims any liability for any property or equipment that may be funded by an LCIF grant. In the event there is a desire to transfer or sell any property or equipment funded by an LCIF grant, the grantee shall inform LCIF and consult with LCIF staff regarding the intended beneficiaries of such transfer or sale. Unless otherwise specifically approved in writing by LCIF, any property or equipment funded by an LCIF grant shall be transferred or sold only to an appropriate charitable entity that will continue to utilize such property or

equipment only for charitable purposes in the respective community in accordance with the intent and provisions of this grant agreement and policies of LCIF. Further, any funds derived from transfer or sale of such property or equipment shall be utilized only for charitable purposes in the respective community and shall not result in any private inurement or personal benefit to any individual or non-charitable entity.

7. **Reporting:** In accordance with the schedule listed above, the grantee shall furnish to LCIF a detailed final report on the activity associated with this grant. a) A detailed description of the project and its outcomes, as requested on the final report form; b) copies of paid receipts and supporting documentation for all items, equipment and services purchased or costs incurred consistent with the approved budget; and c) photos of work/activity and beneficiaries. The grantee shall furnish an appraisal of results achieved under the grant by December 1, 2017. Additional reporting requirements include:

    - Copies of cancelled checks, payment stubs, paid receipts, or signed letters of 'payment confirmation' from the project's vendors, suppliers or contractors.
    - Submission of detailed and itemized statements of project revenue (where applicable) and expenses with each report.
    - The final report should be reviewed and approved by the district cabinet or the multiple district council before submission to LCIF.

8. **Publicity:** Copies of any publicity received as a result of this grant must be submitted to LCIF as part of the record of grant activities. Publicity materials and media regarding this project should acknowledge the support and involvement of LCIF and Lions.

9. **Trademark Use/ Intellectual Property:** The grantee acknowledges that LCIF owns certain trademarks and trade names, including Lions Clubs International Foundation, LCIF, Lions Quest, and LCI. Grantee agrees to comply with the LCI Trademark Policies adopted by the International Board of Directors as amended from time to time. Grantee further agrees that projects receiving grant funding in accordance with this agreement shall be clearly identified as being made possible by LCIF through appropriate recognition, signage and public relations activities.

10. **Compliance:** Failure to comply with any of the terms of this agreements may result in one or more of the following: a) termination of the grant, b) suspension of future grant payments until compliance is demonstrated, c) immediate reimbursement to LCIF of the amount of any LCIF grant funds expended for purposes not previously approved, d) immediate reimbursement to LCIF of all unexpended LCIF grant funds, e) replacement of the grant administrator and/or project chairperson at the sole discretion of LCIF, f) limit Grantee's eligibility for future grants, and g) any other legal recourse available.

11. **Compliance with Local Law.** Grantee agrees that it shall not perform any actions that are prohibited by local laws, including anti-corruption laws, in carrying out the purposes of this grant.

12. **Non Discrimination.** Grantee acknowledges that it will refrain from discriminating on the bases of race, color, national origin, sex, age or disability in the performance of its services under this Grant Agreement.

13. **LCIF Privacy Policy.** Grantee agrees to comply with the LCIF Privacy Policy (attached) as amended from time to time.

The grant administrator and project coordinator accepts and agrees to comply with the above listed conditions by signing this document and agrees to comply with all reporting requirements and to provide appropriate documentation to verify those reports. Acceptance of this agreement is indicated by the grant administrator's signature below. Return this signed form to Pilotprograms@lionsclubs.org. Please retain a copy for your records.

JUNE 17, 2017
Date

JABR
Grant Administrator, Raje Mudhoji A. Bhonsle
District Governor
District 323-H1

JUNE 17, 2017
Date

Dr. Vinod Adalkhiya
Lions Project Coordinator

Date

Rebecca Daou
Executive Administrator
Lions Clubs International Foundation

No. T-12011/9/2016-Ophth.
Directorate General of Health Services
Ministry of Health & Family Welfare
Ophthalmology Section

Nirman Bhawan, New Delhi-110011
Date 26.9.2017

To

Dr. Sadhna Tayade,
Joint Director Health Services
(Ncd) & State Programe Officer
(Npcb) 06th Floor, Arogya Bhavan,
Directorate Of Health Services,
St George Hospital Compound,
P.D Mello Road
Mumbai 01

Subject: Nomination for Two days training workshop of District Ophthalmologists in early diagnosis and treatment of Glaucoma under NPCB&VI.

Sir,

I am to refer to your mail dated 17 Sept, 2017 on the above subject and to ENCLOSE HEREWITH a schedule for training of District Ophthalmologists from your State for two days training workshop in early diagnosis and treatment of Glaucoma under National Programme for Control of Blindness (NPCB&VI).

It is requested that the selected candidates may please be relieved and informed well in advance for attending the training on the allotted dates. The concerned CMOs/DPMs may also be informed for timely relieving of the candidates. The candidates may be advised to report to the key faculty at the allotted training centre for stay and other details of the training. The candidates would be provided a manual and poster for SOPs on Glaucoma diagnosis and management by the training centre.

The TA/DA to the trainees for attending the training will be paid by the training institutes as per the approved GoI norms for the said training.

A line in confirmation about the action taken in the matter may also send to the undersigned on priority.

Yours faithfully

26/9/17

(Dr. Promila Gupta)
Deputy Director General (O)
Ph.No.011-23061594
Email:ddgnpcb2016@gmail.com

Copy to:

1 The Director, Mahatma Gandhi Institute of Medical Sciences Wardha, Maharashtra. (Email - dean@mgims.ac.in eyemgims@gmail.com Phone: 0712-234345, 222556) It is requested that necessary arrangements may please be made for conducting the training workshops as per the training schedule given above.

2 Dr. Smita Singh Professor Ophthalmology Deptt. Of Ophthalmology MGIMS Sewagram Wardha Maharashtra 442102 Mobile 9439750945 drsumita2010@gmail.com for necessary follow-up action please.

Schedule for training of District Ophthalmologist in Two days training workshop of District Ophthalmologists in early diagnosis and treatment of Glaucoma under NPCB&VI

SNo.	Name of Ophthalmologist	Place of posting	Period of training	Name of allotted training centres	Name of key faculty at training centre
1	Dr. Rajesh Pawar	G.H.Akola	2 days14to15 Nov, 2017)	Mahatma Gandhi Institute of Medical Sciences Wardha, Maharashtra. dean@mgims.ac.in eyemgims@gmail.com Phone: 0712-234345, 222556	Dr. Smita Singh Professor Ophthalmology Deptt. Of Ophthalmology MGIMS Sewagram Wardha Maharashtra 442102 Mobile 9439750945 drsumita2010@gmail.com
2	Dr. Birbal Pawar	G.H.Akola			
3	Dr. N.Sonwane	DH Amaravati			
4	Dr. Virabhadra Kotalwad	DH Amaravati			
5	Dr. N. R. Jiwane	DH Bulhana			
1	Dr. Buibhar	DH Bulhana	2 days(12 to13Dec., 2017)	Mahatma Gandhi Institute of Medical Sciences Wardha, Maharashtra. dean@mgims.ac.in eyemgims@gmail.com Phone: 0712-234345, 222556	Dr. Smita Singh Professor Ophthalmology Deptt. Of Ophthalmology MGIMS Sewagram Wardha Maharashtra 442102 Mobile 9439750945 drsumita2010@gmail.com
2	Dr. C handodkar	DH Washim			
3	Dr. Darehkar	DH Washim			
4	Dr. Manoj Saketpar	Yavatmal			
5	Dr. Manoj Tagadpalliwar	SDH Pusad			
1	Dr Birbal Pawar	SDH Darwha	2 days (16 to 17Jan , 2018)	Mahatma Gandhi Institute of Medical Sciences Wardha, Maharashtra. dean@mgims.ac.in eyemgims@gmail.com Phone: 0712-234345, 222556	Dr. Smita Singh Professor Ophthalmology Deptt. Of Ophthalmology MGIMS Sewagram Wardha Maharashtra 442102 Mobile 9439750945 drsumita2010@gmail.com
2	Dr. Rekha Chate	DH Aurangabad			
3	Dr. Santosh Kale	DH Aurangabad			
4	Dr. Apangire	DH Hingoli			
5	Dr.R.R.Tawdi	DH Hingoli			

1	Dr.U.L. Paritkar	DH Jalna	2days(13 to 14Feb,2018)	Mahatma Gandhi Institute of Medical Sciences Wardha, Maharashtra. dean@mgims.ac.in eyemgims@gmail.com Phone: 0712-234345, 222556	Dr. Smita Singh Professor Ophthalmology Deptt. Of Ophthalmology MGIMS Sewagram Wardha Maharashtra 442102 Mobile 9439750945 drsumita2010@gmail.com
2	Dr. Y.R. Bwhite	DH jalna			
3	Dr. Sudhir Yadav	DH Prabhani			
4	Dr. Gore Archana	DH Prabhani			
5	Dr.S.K. Ajetrao	DH Kolhapur			

भारत सरकार
स्वास्थ्य सेवा [illegible]
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
केन्द्रीय औषध मानक नियन्त्रण संगठन
पश्चिम खण्ड
उप औषध नियंत्रक [illegible] का कार्यालय
[illegible]
जी.एम.एसडी.कम्पाउंड, बिलासीस रोड,
मुम्बई सेन्ट्रल, मुम्बई-४०० ००८.

CDSCO

GOVERNMENT OF INDIA
Ministry of Health and Family Welfare
Directorate General of Health Services
[illegible]
Office of the Deputy Drugs Controller (India)
[illegible], Zonal FDA Bhawan, GMSD Compound, Kalina,
Mumbai Central, Mumbai-400 008.
Tel: [illegible]
Fax: [illegible]
Email: [illegible]

[illegible] January [illegible]

To,
The Secretary-cum-Scientific Director
[illegible]
[illegible]
[illegible]
UTTAR PRADESH

Subject: **Forwarding of List of Proposed Medical Colleges for enrolling their institute as ADR Monitoring Centre under PvPI – reg.**

Directorate's Order Order No. [illegible]/MISC/2011-56
dated 19th April'2011

Sir,

As informed by the Directorate all the activities of PvPI will be coordinated through the National Coordinating Centre (NCC) i.e. IPC, Ghaziabad, this office would like to forward the list of proposed Medical Colleges [illegible] for enrolling as PvPI - ATIR Monitoring Centres in West Zone.

I am forwarding herewith the List of Medical Colleges who are willing to be a part of the Pharmacovigilance Programme of India along with the copies of the Letter of Intent (LOI) requesting for approval of their Pharmacovigilance Centre [illegible] ADR monitoring Centre for information and necessary action.

Yours faithfully,

[illegible]
DR. K.RAMAKRISHNAN
DY. DRUGS CONTROLLER (INDIA)
CDSCO, WEST ZONE, MUMBAI

Encl: List of Medical Colleges [illegible] LOI

Copy for information to:
1. The Deputy Controller [illegible] Drugs, New Delhi
2. Dr.S.B.Patel , Professor & Head, Department of PharmacologyGrant Medical College & Sir JJ Group Of Hospital, Byculla, Mumbai-400008

[illegible] Dr. [illegible] R. Pawar, Professor & Head, Department of Pharmacology, [illegible] Municipal Medical College & General Hospital, Mumbai [illegible]

[illegible] Dr. [illegible] Prof & Head, Deptt of Pharmacology, [illegible] Medical College & [illegible] General Hospital, Near Pune Railway Station, Pune 411 001

[illegible] Dr.R.K.Dikshit Prof. & Head, Department of Pharmacology, [illegible] Medical College, Ahmedabad [illegible]

6. Dr [illegible] Professor & Head, Department of Pharmacology, [illegible] Municipal Medical College, Ahmedabad, Gujarat-380006 [illegible]

7. Dr [illegible] Tripathi, Professor & Head Department of Pharmacology [illegible] Medical College, Near ST Bus Stand, Jail Road, Bhavnagar-364001, Gujarat

8. Dr. [illegible] dar, Proposed Co-ordinator, Professor & Head – Deptt Of Pharmacology Indira Gandhi Government Medical College, Central Avenue Road, Nagpur-440018

9. Dr. [illegible] Prof. & Head, Deptt of Pharmacology, Mahatma Gandhi Institute of Medical Sciences, Sevagram, [illegible]

10. Dr. [illegible]

11. Dr. [illegible] Medical Sciences, New Delhi [illegible]

Dr. Sushil Kumar Varma
Director - Professor & Head
Department Of Pharmacology
M.G.I.M.S, Sewagram

INDIAN PHARMACOPOEIA COMMISSION
[illegible] Coordination Centre Pharmacovigilance Programme [illegible]
MINISTRY OF HEALTH & FAMILY WELFARE, GOVERNMENT OF [illegible]
SECTOR-23, RAJ NAGAR, GHAZIABAD- 201 002.
Tel No: 0120- 2783392, 2783400, 2783401; Fax: 2783311
Mail: ipclab@vsnl.net, Web: www.ipc.gov.in

File No.- IPC/NCC-PvPI/AMC/2015-16/02

Date:- 27-04-2015

OFFICE ORDER

[illegible] Assessment [illegible] Drugs [illegible]

- [illegible] - [illegible]
- [illegible] - [illegible]
- One Pharmacologist/Pharmacist - [illegible]

This committee shall be constituted within one month from the date of office [illegible] committee shall be approved by the Di[illegible]/D[illegible] [illegible]

Terms of reference for CAC:

- [illegible] responsible [illegible] Reported [illegible]
- [illegible] twi[illegible] Even[illegible]
- After the [illegible] 15 days.
- [illegible] CAC [illegible]

[illegible] G.N. Singh

[illegible]

[illegible]

[illegible]

Dr. [illegible] Professor & Head
[illegible] Of Pharmacology
[illegible] M.G.I.M.S. Sewagram

MAHATMA GANDHI INSTITUTE OF MEDICAL SCIENCES

Appendix'C'

Sevagram : Wardha (Dist.) -442 102. MAHARASHTRA STATE

Dr. K.R. Patond
Dean

Phone : (07152) 284341 to 284355
Fax : 07152-284333, 284677

Email : dean@mgims.ac.in
Website : www.mgims.ac.in

Acceptance Certificate for Long Term Research Grant (LTRG) project

for Teachers and MUHS Employees

For Office Use Only

Reference: Sanction Letter no: MUHS/UDC/GFL/05/2015-16/E-2/693/2016 dated 25/07/2016

Name: Dr Shende Vinod Suryabhan, Designation: Assistant Professor.

College: MGIMS Sevagram

Title of the project: "Diagnostic utility of electroneuromyography and late responses in cervical radiculopathy"

1. The research project is not being supported by any other funding agency.

2. The terms and conditions related to LTRG are acceptable to the Principal Investigator and College/Institute.

3. At present, I have no research project approved by MUHS, Nashik and the accounts for the previous projects, if any, have been settled.

4. The College/ Institute is affiliated to/recognized by MUHS, Nashik, vide letter no MUHS/E-1/UG/1504/34/4003/2015 dated 30/09/2015 (Copy attached)

5. Date of birth: 17/09/1980

6. The date of implementation of project is: 25/07/2016

(Date of implementation will be date of sanction of first installement)

Principal Investigator: Name: Dr Vinod Suryabhan Shende Sign. VShende Date. 10/08/2016

Co- Investigator, if any: Name: Dr Sachin M Pawar Sign. Date. 10/08/2016

Head of Institute: Name: Dr K R Patond Sign with stamp and date ..... 11.8.16.

College/ Institute Round Seal:

DEAN,
Mahatma Gandhi Institute of
Medical Sciences, SEVAGRAM

MUHS
Tel: (0253) 2539206/2539196, Fax: (0253) 2539197
Website: http://www.muhs.ac.in, E-mail: udc@muhs.ac.in

राजेंद्र च. शहाणे
सहा. कुलसचिव

Rajendra C. Shahane
Asstt. Registrar

O.No.: MUHS/UDC/GFL/05/2015-16/ E-1/997/2017 Date: 09.08.2017

By e-mail and Speed Post

To,

Dr. Ruchi Kothari.
Assistant Proferssor, Dept. of Physiology
Mahatma Gandhi Institute of Medical Sciences,
Post Sewagram,
Dist. Wardha – 442 102
ruchi@mgims.ac.in

Subject : Sanction of Long Term Research Grant (AY 2015 -16)

Reference: 1) Your LTRG application
2) University Notification no. 25/2014, available on www.muhs.ac.in

Sir / Madam

With reference to the above-cited subject, I am directed to inform you that, on the recommendations of the Research Grant Scrutiny Committee, your research proposal, submitted vide your application referred at sr.no. 2 above, has been accepted and accordingly, Hon'ble Vice-Chancellor is pleased to accord sanction of Rs 1,00,000/- as Long Term Research Grant for teachers.

Kindly note that this sanction of grant accorded to the said student shall always be subject to the rules and regulation as laid down in the University Notification no. 25/2014, as amended from time to time and also any such rules and regulations prescribed by the University from time to time.

You are required to follow and implement the ibid University Notification meticulously.

Yours,

Asst. Registrar
University Department Cell

Copy for Information:

The Dean
Mahatma Gandhi Institute of Medical Sciences,
Post Sewagram,
Dist. Wardha – 442 102

E-72873

INDIAN COUNCIL OF MEDICAL RESEARCH
V. Ramalingaswami Bhawan, Ansari Nagar, New Delhi – 110 029
Phone : 26588980, 26588707, 26589336, 26589745, 26589873,
FAX: 011-26588662, 26589791, GRAM : SCIENTIFIC,
Web-site: www.icmr.nic.in, e-mail: icmrhqds@sansad.nin.in

No.ZON/15/11/2014-ECD-II Dated: 28/12/17

Subject: Payment of 1st installment of grant in aid for the research scheme entitled, "Surveillance of select zoonotic diseases in central India" under Dr.Rahul Narang

MEMORANDUM

Reference this office letter of even number dated NIL

The Director General, ICMR sanction the payment **Ra.11,61,170/- (Rupees Eleven Lakh Sixty One Thousand One Hundred and Seventy only)** as the 1st installment of the grant during 3rd year for incurring expenditure in connection with the above mentioned research scheme. The amount of **Ra.11,61,170/-** may be debited from the provision of **Ra.21,61,170/-** made for the above research scheme for the current financial year.

A sum of **Ra.1,45,264/-**is already available as unspent balance of last year grant. A formal bill for **Ra.11,61,170/-** is sent herewith for (i) adjustment of **Ra.1,45,264/-**(ii) for payment of **Ra.10,15,906/-**by RTGS to the Dean, Mahatma Gandhi Institute of Medical Sciences, Post –Sevagram, Wardha-442102. (Mandate Form enclosed).

(Bal Ugrin Sah)
Administrative Officer
For Director General

Accounts Section- V, ICMR

Copy to: The Dean, Central Mahatma Gandhi Institute of Medical Sciences, Post – Sevagram, Wardha-442102. An amount of **Ra.11,61,170/-** as the 1st installment will be released by RTGS after adjustment of **Rs.1,45,264/-** to you in due course.

2. IRIS Section : 2014-26070
3. Dr.Rahul Narang, Professor, Dept. of Microbiology, Mahatma Gandhi Institute of Medical Sciences, Post –Sevagram, Wardha-442102.
4. Mrs.Vandana, DEO

(Bal Ugrin Sah)
Administrative Officer
For Director General

INDIAN COUNCIL OF MEDICAL RESEARCH
V. Ramalingaswami Bhawan, Ansari Nagar, New Delhi – 110 029
Phone : 26588980, 26588707, 26589336, 26589745, 26589873,
FAX: 011-26588662, 26589791, GRAM : SCIENTIFIC,
Web-site: www.icmr.nic.in, e-mail: icmrhqds@sansad.nin.in

No. ZON/16/12/2014-ECD-II

Dated: 28/8/17

To

The Dean,
Mahatma Gandhi Institute of Medical Sciences,
Post –Sevagram, Wardha-442102.

Subject: Sanction of continuation of the project entitled, "Surveillance of select zoonotic diseases in central India" under Dr.Rahul Narang

Dear Sir,

The Director-General of the ICMR accords sanction for continuation with an allotment for **Ra.21,61,170/-(Rupees Twenty One Lakh Sixty One Thousand One Hundred and Seventy only)** as detailed in the attached budget statement for the above mentioned project for a period w.e.f. **1.3.202017 to 28.2.2018** during the year 3rd year subject to the following conditions :-

1. The grant will be released to the head of the Institute in three instalments during the financial year on receipt of the demand in the prescribed form as indicated below :-

1st instalment	**Rs.11,61,170/-**
2nd instalment	**Rs. 7,00,000/-**
3rd instalment	**Rs. 3,00,000/- (Final instalment will only be released after submission of final report/final audited statement/final SOE**
Total	**Ra.21,61,170/-**

While asking for the release of the instalment, 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 28.02.2017 out of the funds paid during the year 2016-2017 should be intimated. This will be adjusted against the current year's grant.

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 alongwith a list of non-expendable articles purchased out of the grant during the year. Any unspent balance would be refunded to the ICMR on termination of the scheme.

Further grants will be stopped unless audited statements of accounts and utilization certificates are received within a period of the year after the end of the financial year for which grant was sanctioned.

3. The last instalment of the grant will be paid on receipt of the audited certificate which should include all the liabilities of last year, expenditure incurred before but the defrayed after termination of the scheme. The prior to which the expenditure pertains should be shown clearly.

4. The grant will not be regarded as a subvention, towards the normal work of the Institution but should be exclusively utilized for the research activity for which it has been sanctioned.

5. Expenditure should on no account exceed the allotment sanctioned for the enquiry. Expenditure incurred over and above the sanctioned amount against one or more subheads of expenditure such as pay, allowances, contingencies etc. shall be met without reference to the ICMR by re-appropriation of savings under remaining sub-heads provided that the total expenditure incurred during the financial year.

No expenditure shall however, be incurred by re-appropriation of savings on items not sanctioned by the Council i.e. non-consumable equipment, stores not sanctioned by the Council savings shall also not be re-appropriated for meeting on incurring expenditure on staff that has not been sanctioned by the Council.

6. The grant paid by the Council shall be refunded in full by the institute if and when the grantee concerned discontinuous a scheme midway or does not follow the detailed technical programme laid down and approved.

7. Receipt, released by the Project Officer on behalf of ICMR project, if any, will be remitted to the Council as miscellaneous receipt and not utilized for meeting expenditure of the project.

8. All facilities for conduct of the research scheme basic equipment and ordinary laboratory chemicals, glassware, furniture and other assistance, as may be required for the smooth working of the research scheme, shall be provided by the Institute.

9. The stores purchased out of the grant of the Council shall be entered in the property/stock register and presented auditors for check and endorsement. The usual forms used for these registers and all purchases made in accordance with the procedure in vogue in your institution.

10. Only such equipment for which provision has been made in the budget shall be purchased.

11. All the non-expendable articles purchased out of the funds of the Council will be the property of the Council and will not be disposed of without their concurrence.

Staff:

12. The staff employed on the research schemes will not be the Council's employee

but for all purposes be treated as employees of the Institute and will be subject to the rules and administrative control of the Institute.

The scales of pay, allowances etc. applicable to the staff of the schemes will be the same as admissible under the rules of the grantee Institution.

Prior approval of the Council will however, be necessary if any higher than that admissible under the rules of the Institution is sought to be given e.g. by grant of advances increments or ad-hoc increase.

13. The council will not be liable to bear any expenditure pension/provident fund contribution and or leave salary contribution incurred or committed by the grantee for persons appointed on deputation from any other organization.

Report of Work Done

14. The grant is being sanctioned on the condition that reports on the progress of work done on the research scheme will be submitted by you to the Council as and when called for. Normally a progress report of work done on the enquiry is to be submitted to the Council as and when required, the enquiry may be discontinued immediately unless there is sufficient justification for non-submission of the report of work done on the research scheme.

Publication

15. The financial assistance rendered by the Council will be acknowledge in any published account of work for which the grant is given.

16. A list of papers published based on the work carried out on enquiry under the auspices of the ICMR shall be submitted annually alongwith reprints of the papers. Prior permission of the Council shall be obtained before publication of any such paper in a foreign journal.

Patents

17. The Council shall have the right to take out patent in respect of invention/discoveries made under schemes project financed by the Council. The Officer-in-Charge or the staff employed on ICMR scheme shall not apply or obtain patents for any invention/ discovery made by them without prior approval of the Council.

18. All the patents will be registered in the name of the Indian Council of Medical Research Termination of Research Scheme

19. Prior permission of the Council shall be obtained if the investigator desires to discontinue the research scheme. The reasons for discontinuing the scheme should invariably be stated.

20. A final report is required to be submitted within one month from the date of termination of the research.

21. A list(in duplicate) of non-expendable and expendable article together with property registers and suggestions for disposal of the articles should be sent to the Council within a month from the date of termination of the research scheme.

The receipt of this letter may kindly be acknowledged.

Yours faithfully,

(Bal Ugrin Sah)
Administrative Officer
For Director General

1. Copy together with a copy of the budget statement forwarded for information to : Dr.Rahul Narang, Professor, Dept. of Microbiology, Mahatma Gandhi Institute of Medical Sciences, Post –Sevagram, Wardha-442102.
2. Copy together with a copy of the budget statement forwarded to the Account Section – V for information and necessary action.
3. Copy together with copy of the budget forwarded to budget section (Fin.) ICMR for Compilation of the Council's Budget. The **RFC No. ECD/NTF/3/2014-15 Dated:6.2.2015**
4. IRIS Cell No. 2014-26070
5. Mrs.Vandana,Sr.Tech. Officer-II

(Bal Ugrin Sah)
Administrative Officer
For Director General

ZONOSIS/ADHOC

"Surveillance of select zoonotic diseases in central India" under Dr.Rahul Narang

BUDGET STATEMENT
1.3.202017 to 28.2.2018
(2017-18)

Sl.No.	Name of Head	3rd Year
I.	Staff	Amt. in Rs.
1.	SRF(Non-Med) @Rs.28000/- +Rs.2800/- (10%HRA) =Rs.30800x12x1	369600
2.	Lab. Technician @17840/-x2x12	428160
	Lab. Assistant @ Rs.16,948/-x12x1	203376
II.	Contingencies/Recurring	
a.	Contingency(Hiring of vehicles, Stationary, incidental expense etc) Glassware, plastic ware, media, Enzyme, Chemicals, molecular biology consumables/kits, primers PCR master mix, sequencing, software, stationary, cartages, internet charges, telephone charges, computer, consumables etc.	1000000
	Sub-Total	2001136
	Overhead charges 3%	**60034**
b.	Non-Recurring	
1.	Travel	100000
	Total	**2161170**
2.	Equipment(*)	
1.	Laminar AIR Flow	300000
2.	CO_2Incubator	350000
3.	Liquid Nitrogen Can-47 L Capacity	100000
4.	Liquid Nitrogen Can-33 L Capacity	50000
5.	RT-PCR Machine	1500000
6.	ICE Maker	100000
7.	Miscellaneous equipment	150000
	Total	**2550000**

Note: * The expenditure of Rs.25,50,000/- on account of equipment will be met from the unspent balance of Rs. 26,95,264/- left with the PI.
RFC No. ECD/NTF/3/2014-15
Dated:6.2.2015

No. ZON/16/12/2014-ECD-II

E-72873

INDIAN COUNCIL OF MEDICAL RESEARCH
V. Ramalingaswami Bhawan, Ansari Nagar, New Delhi – 110 029
Phone : 26588980, 26588707, 26589336, 26589745, 26589873,
FAX: 011-26588662, 26589791, GRAM : SCIENTIFIC,
Web-site: www.icmr.nic.in, e-mail: icmrhqds@sansad.nin.in

No.ZON/15/11/2014-ECD-II Dated: 21/12/17

Subject: Payment of 2nd installment of grant in aid for the research scheme entitled, "Surveillance of select zoonotic diseases in central India" under Dr.Rahul Narang

MEMORANDUM

Reference this office letter of even number dated 28/8/2017.

The Director General, ICMR sanction the payment **Rs.7,00,000/- (Rupees Seven Lakh only)** as the 2nd installment of the grant during 3rd year for incurring expenditure in connection with the above mentioned research scheme. The amount of **Rs.7,00,000/-** may be debited from the provision of **Rs.21,61,170/-** made for the above research scheme for the current financial year.

A formal bill for **Rs.7,00,000/-** is sent herewith for payment by RTGS to the Dean, Mahatma Gandhi Institute of Medical Sciences, Post –Sevagram, Wardha-442102. (Mandate Form enclosed).

(Arti Chawla)
Administrative Officer
For Director General

Accounts Section- V, ICMR

Copy to: The Dean, Central Mahatma Gandhi Institute of Medical Sciences, Post – Sevagram, Wardha-442102. An amount of **Rs.7,00,000/-** as the 2nd installment will be released by RTGS to you in due course.

2. IRIS Section : 2014-26070
3. Dr.Rahul Narang, Professor, Dept. of Microbiology, Mahatma Gandhi Institute of Medical Sciences, Post –Sevagram, Wardha-442102.
4. Mrs.Vandana, SR TO-I

(Arti Chawla)
Administrative Officer
For Director General