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(Under New Drugs and Clinical Trials Rules, 2019)
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(Department of Health Research)

Mahatma Gandhi Institute of Medical Sciences
Sewagram 442 102, Maharashtra, India

Institutional Ethics Committee

For Research on Human Subjects

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Institutional Ethics Committee (IEC)

Standard Operating Procedures (SOPs)

VERSION: 06
Effective from: 17 November 2021
Valid up to: 16 November 2022

(As per recent regulatory requirement and requisite of accreditation: http://www.nabh.co/ct_standard.aspx)

Mahatma Gandhi Institute of Medical Sciences, Sevagram – 442102 Maharashtra, India

(Also, As recommended by DCGI holds additional responsibility of ethical aspect of research of Kasturba Nursing College)

Prepared by:

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Approved by:

Dr. Ashok Pawade, Chairman	

FORMAL APPROVAL BY THE CHAIRMAN, INSTITUTIONAL ETHICS COMMITTEE

This document (Standard Operating Procedures) after being prepared by the Member Secretary and duly approved by all the members of the Institutional Ethics Committee is hereby being released with effect from 17th November 2021 for the purpose of all Institutional Ethics Committee activities to be conducted henceforth.

I do hereby approve the SOPs for the aforesaid purpose.

Dated: 17th November 2021

Dr. Ashok Pawade
Chairman
Institutional Ethics Committee,
MGIMS

CONTENTS

The Institutional Ethics Committee for Research in Human subjects of Mahatma Gandhi Institute of Medical Sciences, Sevagram would be known as IEC, MGIMS in this document. It has been divided into different clauses and their sub clauses. It is recommended that these clauses should be referred as mentioned in this document. This Standard Operating Procedures are laid down in consensus following the regulations of New Drugs and Clinical Trials Rules, 2019, Ethical guidelines by ICMR, Declaration of Helsinki and Good Clinical Practice guidelines. This document may be amended either after 1 year or any specific requisite/regulatory requirement which might be considered relevant by the IEC.

DECLARATION

The composition and working procedure of IEC, MGIMS is based on Operational Guidelines for IEC that review Biomedical Research (WHO, 2000), International Conference on Harmonization-Good Clinical Practices (ICH-GCP) Guidelines E6(R2), New Drugs and Clinical Trials Rules, 2019, Indian GCP guidelines (2003) and National Ethical Guidelines for Biomedical Research on Human Participants by ICMR (2017) and National Guidelines for Ethics Committees Reviewing Biomedical & Health Research During Covid-19 Pandemic by ICMR (April 2020).

ESTABLISHING AND CONSTITUTING IEC, MGIMS

Aims and Objectives or the Purpose of IEC

IEC, MGIMS has been constituted with an aim to provide public assurance of protection, by, among other things, reviewing and approving the research protocol, the suitability of the investigator(s), facilities and the methods and material to conduct the research studies at Mahatma Gandhi Institute of Medical Sciences, Dr. Sushila Nayar Hospital, Melghat, Kasturba Nursing College, Kasturba Nursing School or in an around Kasturba hospital under compliance of New Drugs and Clinical Trials Rules, 2019, National Ethical Guidelines for Biomedical Research on Human Participants by ICMR and its requirements.

OBJECTIVE

Mahatma Gandhi Institute of Medical Sciences herein referred to as “MGIMS” has adopted these written Standard Operating procedures (SOP) to ensure the protection of the rights and welfare of human participants in biomedical and behavioural research conducted at MGIMS.

The objective of these SOPs of the Institutional Ethics Committee of MGIMS (hereinafter referred to as IEC, MGIMS) for research involving human subjects is to maintain effective functioning of the IEC, MGIMS and to ensure quality and technical excellence and consistent ethical review of all the submitted research proposals and the ongoing approved research projects involving human participants in accordance with the ICMR Ethical guidelines for biomedical research on human subjects.

AUTHORITY UNDER WHICH IEC CONSTITUTED

Mahatma Gandhi Institute of Medical Sciences has authorized the formation of IEC, MGIMS as an independent body which functions independently at our site since 2008 and as registered body under Drugs Controller General of India (DCGI) with effect from 20th April 2013 with respect to decision making and its working in order to provide public assurance of protection, by, among other things, reviewing and approving the clinical trial protocols, bioavailability and bioequivalence studies and Biomedical and Health Research projects, the suitability of the investigator(s), facilities and the methods and material to conduct clinical research at our site. In addition to this, the institute will provide all support to the ethics committee activities which including training, resources and infrastructure at the same time. **(Ax: 01/V06)**.

1. PREPARATION OF STANDARD OPERATING PROCEDURES (SOPS) FOR IEC, MGIMS:

1.1. Purpose:

The purpose of this Standard Operating Procedure (SOP) is to define the process for writing, reviewing, distributing and amending SOPs of IEC, MGIMS, Sevagram.
The SOPs provide clear, unambiguous instructions so that the related activities of the Committee are conducted in accordance with: New Drugs and Clinical Trials Rules (2019), National Ethical Guidelines for Biomedical Research on Human Participants by ICMR (2017), Indian GCP Guidelines (Access time 2003) http://cdsco.nic.in, WHO Operating Guidelines for Ethical Review Board that Review Biomedical Research (2000), The International Conference on Harmonization - Good Clinical Practices (ICH-GCP) Guidelines E6(R2), Declaration of Helsinki, National Guidelines for Ethics Committees Reviewing Biomedical & Health Research During Covid-19 Pandemic by ICMR (April 2020) and the prevailing amendments from time to time and Amendments from CDSCO office.

1.2. Scope:

This SOP covers the procedures of writing, reviewing, distributing and amending the SOPs of the IEC, MGIMS.

1.3. Responsibility:

It is the responsibility of the Chairman of the IEC to appoint the SOP Team to formulate the SOPs. The SOP Team will execute this by following the same procedures, format and coding system when drafting or editing any SOP of the IEC, MGIMS.

1.3.1. IEC Secretariat:

- Co-ordinate activities of writing, reviewing, distributing and amending SOPs
- Maintain on file all current SOPs and past SOPs.
- Ensure that all the IEC members and involved staff have access to the SOPs and working according to current version of SOPs.
- Chairman / Member Secretary will appoint the coordinating staff to assist IEC functions.
- Member Secretary shall vote in IEC decisions but coordinating staff of IEC can't vote in any decision making procedure of the IEC.

1.3.2. SOP team (Member Secretary and one/more members):

- Assess the requests for SOP revision in consultation with the Secretariat and Chairman.
- Propose new / modified SOPs as needed.
- Select the format and coding system for SOPs.
- Draft the SOP/modify SOP in consultation with the IEC members and involved staff.
- Review the draft SOPs.
- Submit the draft for approval to Chairman.

1.3.3. Chairman of IEC:

- Chairman of IEC to appoint the SOP team to formulate the SOPs consisting of Member Secretary, one / more members of IEC and Coordinating staff.
- Approve the SOPs with sign and date.

1.3.4. Coordinating staff of IEC:

- Maintain file of all current SOPs and the list of SOPs.
- Maintain an up-to-date distribution list for each SOP distributed.
- Maintain the SOPs with a receipt to all users.
- Maintain file of all past SOPs of Institutional Ethics Committee.
- Assist in the formulation of SOPs.
- Assist Member Secretary.

1.3.5. IEC members:

- Sign and date the acknowledgement form when they would receive approved SOP.
- Assist in all decision-making procedure of IEC.
- Assist secretariat for any help in management.

1.4. Detailed instructions:

1.4.1. Identify the need for new or amending SOP:

Any member of the IEC, Member Secretary would like a revision or notices an inconsistency/ discrepancy / has any suggestions on how to improve the existing SOPs or requests to design an entirely new SOP can put forth his request.

The Chairman will inform all the IEC members about this request in a regular full-Committee IEC meeting. If the IEC members agree to the request, an appropriate Member Secretary shall proceed with the revision process/ formulation process of the SOPs. If the IEC members do not agree, the Chairman will inform the person/ IEC member who made the request for modification of the SOPs in the same meeting.

The SOPs will be updated regularly at the interval of 1 year or if there are major changes whichever is earlier.

1.4.2. Appoint the SOP Team:

The Chairman will identify appropriate members of the IEC who have a thorough understanding of the ethical review process to constitute the SOPs writing team.

1.4.3. List of relevant SOPs: (SOPs writing team will carry out the subsequent steps)

- Write down step by step all the procedures of the IEC.
- Organize, devise and name each process.

1.4.4. Design a Format and layout:

Each SOP should be given a number and a title that is self-explanatory and is easily understood. A unique code number with the Institutional, Scientific format. **SOP aa / Vbb** number will be assigned to each SOP item by the Member Secretary. “aa” will be a two-digit number assigned specifically to that SOP. “V” refers to version of the SOP and “bb” will be a two-digit number identifying the version of the SOPs. The number of version should be started from 01 hence for example, SOPs 01/V01 is the SOP number 01 with version 01. Each annex will be given unique code number with the format AX MM/VNN. “AX” refers to Annex Form, “MM” is a two-digit number identifying the number of the annex, “NN” is a two digit number identifying the version of the SOP. Each page of SOPs will bear the header which will the effective date i.e.

date of approval and validity of the SOPs. The SOPs number will be on the cover page and on the right side corner while the bottom of page will bear the page number as Page of total pages. The first page of SOPs document will be signed and dated by the author/s, the IEC members who have reviewed the SOPs and the IEC Chairman and subsequently, SOPs will be implemented from that date.

1.4.5. New Standard Operating Procedures:

When the need for a new SOP has been identified and agreed on, a draft will be written by Member Secretary and designated IEC members of SOP team, appointed by the Chairman.

1.4.6. Review by Consultation:

The draft SOPs written by one or more members of the SOPs team will be reviewed by the remaining members of the SOPs team. After incorporating the suggestions put forth by the SOPs team members, a copy of the revised draft SOP will be sent to the Member Secretary, who will circulate it to all the IEC members to invite suggestions.

1.4.7. Preparation and submission of final draft:

- IEC members will review the revised draft SOPs in one or in IEC meeting.
- The suggestions agreed upon unanimously, by all the IEC members will be discussed and incorporated in the revised draft SOPs and the final draft SOPs will be formulated.
- The SOPs team would stand automatically dissolved once the IEC takes final decision regarding the SOPs.

1.4.8. Approve a new/ revised SOP:

- The revised SOPs will be reviewed and approved in the same manner as a new SOPs.
- The Chairman signs and dates the SOPs Approval page. The Member Secretary shall mention final effective date on SOPs, after which SOPs need to be made accessible to all stakeholders for reference through the college website or as and when requested. The Member Secretary or IEC Secretariat shall e-mail / share the approved SOPs to all members.

1.4.9. Ensure implementation and file all SOPs:

- The approved SOPs will be implemented from the effective date.
- When the revised version is distributed, old version is retrieved from all members and destroyed for except for one copy; this copy of the earlier version will be placed in the file entitled ‘Past SOPs of Institutional Ethics Committee’.
- One complete original set of current SOPs will be filed centrally in the SOP Master file, by the Member Secretary or IEC coordinating staff of the IEC in the secretariat of Institutional Ethics Committee for review and request for a revision of existing SOPs and record the dates of review on the SOP Master file.
- Revision of approved SOPs shall occur at least once a year and as and when required.

1.4.10. Manage current and archive superseded SOPs:

- Secretariat will manage current and archive old versions (superseded) of SOPs.
- Superseded SOPs should be retained and clearly marked “superseded” and archived in the file entitled ‘Past SOPs of Institutional Ethics Committee by the Member Secretary or IEC coordinating staff.

1.4.11. Glossary:

- Revision date: Date/year by which the SOP may be revised or reviewed.
- Recipients: Stakeholders who would receive a copy of SOP.
- SOP (Standard Operating Procedure): Detailed, written instructions, in a certain format, describing activities and actions undertaken by the IEC to achieve uniformity of the performance of a specific function. The aim of the SOPs and their accompanying checklists and forms are to simplify the functioning, whilst maintaining high standards of Good Clinical Practice.
- Institutional Ethics Committee (IEC): It is an independent body formally designated to review, approve and monitor clinical trials, bioavailability, bioequivalence, biomedical and behavioral research involving humans with the aim to protect the rights and welfare of the participants. It is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human participants involved in research and to provide public assurance of that protection.

2. CONSTITUTION OF THE IEC & ITS TERMS OF REFERENCES:

2.1. Purpose:

The purpose of this SOP is to define the Terms of References (TOR) which provide the framework for constitution, responsibilities and activities of IEC.

2.2. Scope:

This SOP applies to the activities performed by the IEC.

2.3. Responsibility:

It is responsibility of the IEC members and Secretariat to read, understand, follow and respect the SOP set by the IEC.

2.4. Detailed instructions:

The IEC of the Mahatma Gandhi Institute of Medical Sciences, Sevagram (IEC, MGIMS), is formed by the Dean, MGIMS in accordance with the guidelines laid down in the New Drugs and Clinical Trials Rules, 2019 and National Ethical Guidelines for Biomedical Research on Human Participants by ICMR.

2.4.1. Appointment / relieving / acceptance of resignation of any member of the IEC, MGIMS would be the prerogative of the Dean on the recommendation of IEC, MGIMS. The appointment of the IEC member will be confirmed after receipt of their consent to abide by the Good Clinical Practice (GCP) guidelines and maintenance of confidentiality. The Dean, MGIMS will appoint co-ordinating staff for IEC. They will be supervised by the Member Secretary.

The Dean will appoint the IEC members under the following circumstances:

- When a member completes his/ her tenure.
- If a member resigns before the tenure is completed.
- If a member ceases to be a member for any reason including death or disqualification.
- To fulfil the membership requirements as per Section 2.4.2. and 2.4.4.

2.4.2. Composition:

The IEC, MGIMS will be multidisciplinary and multi-sectorial in composition and will have minimum 7 and maximum 15 members from medical, non-medical, scientific and non-scientific areas. At least 50% of members will be non-affiliated to this institute. It will have representation that is varied in terms of gender, age and social background. The members representing medical scientist and clinicians should have post graduate qualification & adequate experience in their respective fields.

The Composition shall be as follows:

- Chairman (from outside the institute who will be a non-affiliated to the institute)
- One Member Secretary (one of the members representing the institute as designated by the Dean)
- One Joint Member Secretary (appointed if necessary)
- One or more faculty members of basic medical sciences
- One or more faculty members of Dept. of Pharmacology
- One or more clinicians
- One or more legal experts
- One or more independent social scientist/ representative of non-governmental

agency or philosopher or ethicist or theologian
- One or more lay persons from community
- One or more woman members

2.4.3. The IEC may appoint alternate members who can take part in the IEC activities in absence of regular members to maintain the quorum.

The IEC may invite member(s) of specific patient groups or other special interest groups for an IEC meeting (if required, based on the requirement of research area, e.g. HIV AIDS, genetic disorders, stem cell research etc.) for eliciting their views. Such individuals will have to sign confidentiality agreement and declare in writing, conflicts of interest **(Ax: 14/V06)**, if any prior to attending the meeting. They will attend the meeting in the capacity of 'Observer' and will not have right to vote.

2.4.4. Membership requirements:

- The Dean, MGIMS is responsible for appointing new committee members.
- The Chairman, Member Secretary or any member can suggest names of potential members but the final decision will remain with the Dean, MGIMS.

  Members will be designated in their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, experience as well as their commitment and willingness to volunteer the necessary time and effort for IEC. Members must disclose their interest and involvement to have a membership of IEC by providing a consent **(Ax: 02/V06)**.
- All members will be appointed based on the basis that they are willing to publicize full name, profession and affiliation. The members should actively participate in the IEC meeting to review and give their unbiased opinion regarding the ethical issues. The appointment letter will be issued to the members along with their responsibilities towards IEC **(Ax: 03/V06)**.

  All members shall sign a confidentiality agreement **(Ax: 04/V06)** at the time of appointment, the terms of which shall be binding on them even after the termination of the contract and also all IEC members shall sign a declaration to the effect that there is no conflict of interest **(Ax: 12/V06)**. In case a member breaches the confidentiality, his/her membership can be terminated and legal proceedings may be initiated by the institution. Any member who has direct involvement or self-affirmed Conflict of Interest (COI) with a proposal being considered shall declare so at the time of meeting and will voluntarily withdraw from the reviewing and decision making process, by expressing the same in writing to the Chairman. This should be recorded in the minutes of the meeting. All members must maintain confidentiality and declare a conflict of interest when applicable.
- New members will be identified according to the requirement i.e. as per the composition specified in Section 2.4.2. If the potential member fulfils the conditions of appointment as defined in 2.4.8. of this SOP, he/she will be appointed on IEC.
- New / alternate members will be appointed if deemed necessary by Dean, MGIMS.

2.4.5. Tenure of Membership:

- The appointment of the members would be for a period of three years, after which they may be either replaced or reappointed with a fresh appointment letter

prior to the end of tenure of members by the IEC secretariat. The retiring member will be eligible to be appointed for the new tenure any number of times.

2.4.6. Resignation:

- A member can resign by submitting a letter of resignation addressed to the Chairman and delivered to the Member Secretary the same will be informed by the Secretary to the appointing authority for formal acceptance and to initiate necessary replacement/recruitment procedure for filling up the vacancy.
- The members if opts to step down due to any genuine cause may do so with prior notice and proper information to the appointing authority.

2.4.7. Disqualification:

For misconduct:

- If Dean, MGIMS, Chairman or member secretary received a communication in writing alleging misconduct by a member.
- If the matter is of grave significance where integrity of IEC could be questioned, the Chairman may suspend the membership of such IEC members till final decision is taken by IEC. During the period of suspension, the concerned individuals will not have any rights, privileges or responsibilities of an IEC member and will not perform any duties of IEC member.
- The Chairman may call a meeting of the IEC specifically to discuss this issue or matter will be taken up for discussion. The meeting convened will follow the usual rules of quorum. The allegation will be discussed in the IEC meeting and the member alleged of misconduct will be provided adequate opportunity to defend himself / herself.
- The alleged member would stand disqualified if members present approve of disqualification by voting of majority of members present in the meeting. The Chairman will convey the disqualification to the concerned member in writing.

For non attendance:

- A member can be disqualified if fails to attend more than 3 regular consecutive IEC meetings without prior intimation.
- The Chairman will call a meeting of the IEC specifically to discuss this issue. The meeting convened will follow the usual rules of quorum. The allegation will be discussed in the IEC meeting and the alleged member will be provided adequate opportunity to represent his/her case with a letter to the Chairman in writing regarding unauthorised absence.
- After discussion, the Chairman / Member Secretary will inform the cessation of membership to other members of IEC through written communication or in the next meeting of IEC.

2.4.8. Conditions of appointment:

Members and subject expert will be appointed to the IEC if they accept the following conditions:

- Members will be designated in their personal capacities, based on their interest, ethical and/or scientific knowledge and expertise, experience as well as their commitment and willingness to volunteer the necessary time and effort for IEC.
- Members must disclose their name, profession, Affiliation.
- Members should provide their Curriculum Vitaes to IEC.

- Members must disclose their interest and involvement to have a membership of IEC.
- Members should actively participate in the IEC meeting to review and give their unbiased opinion regarding the ethical issues.
- Members will have to sign confidentiality statement and declare the conflict of interest.
- Members should conform the SOPs of IEC, MGIMS.

2.4.9. A list of members of the IEC, MGIMS, their appointment letters, bio-data and consent forms would be maintained by Member Secretary of the IEC, MGIMS. This list of members and the copy of the working procedures would be made available to any investigator, for the purpose of filing of research projects, upon written request for the same to the Chairman / Member Secretary.

2.4.10. Policy for updating/training of IEC members:

- All individual selected as a new member of the IEC will be required to undergo Good clinical practice (GCP) training initially.
- All IEC members shall be required to undergo refresher course in Good clinical practice (GCP) annually.
- All training including GCP, SOP, New Regulatory guidelines / updates will be conducted by the IEC, MGIMS.
- All relevant information on ethics will be brought to the attention of the members of IEC, MGIMS by the Member Secretary.
- The Chairman, Member Secretary and members will be encouraged by the appointing authority to attend national and international training programs/conferences/workshops/seminars/courses at least once in a year in the field of research ethics (over and above his own discipline) to help in improving the quality of review of research protocols/ethics committee submissions and other related activities.
- IEC Secretariat will maintain the record of training in the minutes. IEC Secretariat will provide the feedback form to the members for any suggestions.
- The IEC may sponsor or reimburse the expenses of an IEC member or prospective members for attending conference, continuing education session workshop and/ or training program etc.

2.4.11. Hierarchy:

- The Chairman will be head of the committee.
- The Member Secretary and the Joint Member Secretary (if appointed) will be the guardian of all documents, record and funds in the possession of the committee.
- Other IEC members will be regular committee members with equal ranking.
- A Joint Member Secretary will be appointed amongst the members, if necessary.

2.4.12. Roles of committee members:

Chairman:

- The Chairman will be appointed by the Dean, MGIMS.
- The Chairman will be responsible for conducting committee meetings and will lead all discussions and deliberations pertinent to the review of research proposals.
- The Chairman will sign documents and communications related to IEC functioning.
- In case of anticipated absence, the Chairman will nominate a committee member

as Acting Chairman and he will have all the powers of the Chairman for that meeting.

Member Secretary:

- To accept research study / project proposals.
- To prepare, maintain and distribute of study files.
- To schedule and organize IEC meetings after consultation with Chairman
- To prepare and maintain meeting agenda and minutes.
- To maintain IEC record and to archive them.
- To sign documents and communications related to IEC functioning.
- To communicate with the IEC members and applicants/ investigators.
- To notify the Principal Investigator regarding IEC decisions related to the submitted research proposal.
- To arrange for training of personnel and IEC members.
- To organize the preparations, review, revision and distribution of SOPs and guidelines.
- To provide necessary administrative support for IEC related activities to the Chairman.
- To provide updates on relevant and contemporary issues to ethics in health research as well as relevant contemporary literature to the committee members.
- To receive fees and issue official receipts for the same.
- To delegate various responsibilities to appropriate and authorized persons.
- To ensure adherence of IEC functioning as per SOPs.

Joint Member Secretary (whenever appointed):

The Joint Member Secretary will perform the same functions of Member Secretary.

Secretariat:

- The IEC Secretariat will be composed of the Member Secretary, Joint Member Secretary (if appointed), members, coordinator and supporting staff will follow the work delegation log as per **(Ax: 05/V06)**.
- The Member Secretary / Joint member Secretary (whenever needed) will supervise the coordinating staff of the Secretariat who will work as per **(Ax: 06/V06)**

Coordinating staff:

- To support the Member Secretary in executing functions of the IEC.
- Correspondence with the IEC members and investigators.
- Arranging IEC meetings.
- Receiving all research proposals.
- Assisting in preparing agenda and minutes of the meetings.
- Maintaining and archiving study documents.
- To perform any other functions as instructed by Member Secretary/ Chairman.

2.5. Roles and Responsibilities of IEC members:

- To attend IEC meetings and participate in discussions and deliberations for appropriate decisions.
- To review, discuss and consider research proposals submitted for evaluation.
- To monitor Serious Adverse Event reports and recommend appropriate action(s)
- To review the progress reports and monitor ongoing studies.
- To maintain confidentiality of the documents and deliberations of IEC meetings.

- To declare any conflict of interest, if any.
- To participate in continuing education activities in biomedical ethics and biomedical research.
- To provide information and documents related to training obtained in biomedical ethics and biomedical research or any related activities to the IEC secretariat.
- To provide an updated CV when requested for by the IEC secretariat.
- To carry out the work delegated by Chairman and Member Secretary / Joint Member Secretary.
- To assist the Chairman and Member Secretary in carrying out IEC work as per SOP.

However, following members should be held responsible for specific activities:

Clinician:

- To provide medical inputs on protocol: Informed consent forms and other aspects like standard of care, Placebo use, Sample size, dosing, Concomitant medications, Prohibited medications, risk & benefit to patients, Age group, Me too trial and Inclusion / exclusion criteria
- To take clinical judgement for the trial

Basic Medical Scientist:

- To provide scientist aspects of the study: Investigator's brochure, safety of drug, Pharmacodynamics and pharmacokinetics of drug, lab procedures, study design, sample size, use of biological samples,
- To see: preclinical data and whether protocol adequately addresses issue of all this matter or not, Qualification of PI and GCP training certificate**,** Details of SAEs and reporting time limit from PI, all ethics issues and other procedures involved in the study

Legal Expert:

- To review Clinical Trial Agreement (CTA): Parties involved, scope of agreement, responsibilities of parties, contract budget allocation and payment details
- To review Seven incidence of SAE included or not, Adequacy of amount
- To see whether any clause is violating the norm, Confidentiality, dispute resolution, Updated with regulatory requirements and interpretation of the same, Insurance policy: it should cover the participants for injury due to all clauses mentioned in the regulatory guidelines, validity, countries for which the policy provides cover and Liability limit – per person and total
- Indemnity**:** it should covers the liability of investigator and sponsor and could be part of CTA or separate document
- To see informed consent document

Social Scientist / NGO representative / Philosopher / Ethicist:

- To see Community perspective, Informed consent process, Compensation, Design of trial whether it is discomfort to subjects, Number of blood samples, Post-trial access to involved community, Confidentiality, Vulnerable population, Recruitment process.

Layperson:

- To see informed consent process, trial procedures, post-trial access, compensation, confidentiality, think from the subject's perspective, no exploitation of subject, subject diary simple or not.

2.6. Quorum requirements:

The requisite quorum of five members consisting at least one Medical scientist (preferably a pharmacologist), Clinician, Legal expert, Social scientist or representative of a nongovernmental voluntary agency or a philosopher or an ethicist or a theologian or a similar person and one Layperson from the community besides the Chairman and member Secretary are must for discussion on any research proposal.

- For clinical trial, the five members of quorum must be from Medical scientist (preferably a pharmacologist), Clinician, Legal expert, Social scientist or representative of a nongovernmental voluntary agency or a philosopher or an ethicist or a theologian or a similar person and one Layperson from the community as per New Drugs and Clinical Trials Rules, 2019. The quorum for reviewing regulatory clinical trials should be in accordance with current CDSCO requirements.
- For Biomedical and Health Research, a minimum of five members present in the meeting room. The quorum should include both medical, non-medical or technical or/and non-technical members.* Minimum one non-affiliated member should be part of the quorum. Preferably, the layperson should be part of the quorum. No decision is valid without fulfilment of the quorum.

  **Medical members are clinicians with appropriate medical qualifications. Technical members are persons with qualifications related to a particular branch in which the study is conducted, for example social sciences.*

2.7. Responsibilities of the Ethics Committee:

2.7.1. The IEC, MGIMS is to ensure that the research projects carried out or supported by MGIMS are sound in scientific design, have statistical validity and are carried according to its established Standard Operating Procedures based on the operational guidelines as prescribed by New Drugs and Clinical Trials Rules (2019), National Ethical Guidelines for Biomedical Research on Human Participants by ICMR (2017), Indian GCP Guidelines (Access time 2003) http://cdsco.nic.in, WHO Operating Guidelines for Ethical Review Board that Review Biomedical Research (2000), The International Conference on Harmonization - Good Clinical Practices (ICH-GCP) Guidelines E6(R2), Declaration of Helsinki and the prevailing amendments from time to time and Amendments from CDSCO office and any guidelines issued by Government of India / ICMR/ DCI during epidemics/pandemics.

The responsibilities of IEC, MGIMS are:

- To protect the safety, dignity, rights, wellbeing and confidentiality of the potential research participants.
- To keep all information submitted to IEC confidential specially the proprietary.
- To include solely those patients who have given informed consent for participation in the research.
- To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs.
- To ensure equitable recruitment of subjects in the study.
- To ensure that the research is conducted under the supervision of the

medical persons or scientists with required experience and expertise.
- To assist in the development and the education of a research community responsive to local health care requirements and training community members, members of the public, investigators, IEC members in ethical research.
- To participate in activities that promote ethical research in the institution and community.

2.7.2. The IEC, MGIMS would review all new research projects and if approval is given it would be for a maximum period of one year (for projects ≥ 1 year). After completion of a year, the progress of the project would be reviewed and further extension may be provided. Status of any project can be retrieved by tracking the record document. The IEC, MGIMS would maintain a list of all projects submitted, approved, disapproved and outcome of each project with confidentiality. **(Ax: 07/V06)**

2.7.3. The IEC, MGIMS should ensure that patients' rights are not compromised regarding any payments proposed to be made in the study to the patients towards reimbursement of incidental expenses.

2.7.4. The IEC will review only those projects which are carried out in this institution by the staff members and students of the institution. IEC may accept the responsibility for any study in which either any investigator or student or guide should be involved from this institute.

2.8. Process of conduction of IEC, MGIMS meetings:

2.8.1. The committee would meet once in every month or whenever it is necessary. If needed where the situation is justified the meeting may be called more than once in a month.

2.8.2. The meetings would be called by the Member Secretary and the notice for the meetings would be sent usually 7 working days prior to the scheduled date.

2.8.3. The member-secretary will record the minutes of the meeting and circulate the same to the members within a month of the meeting.

2.9. Preparation of Annual Report:

IEC Secretariat will prepare a yearly activity report of the IEC for submission to the Dean which will include the following elements:
- A quantitative evaluation of the activities of the committee in a year
- The list of the proposals reviewed in a year
- Status of each study proposal

3. EVALUATION OF IEC:

3.1. Purpose:

The purpose of this SOP is to provide the guidance to address and develop plans for existing or potential problems identified during self-evaluation of ethics committee members.

3.2. Scope:

It covers the Corrective and Preventive Action (CAPA) concerning information and procedures followed by the IEC.

3.3. Responsibility:

The committee will conduct periodic self-assessment annually through internal meeting of the members using the Self-Assessment Tool **(http://www.fercap-sidcer.org/selftool.php).** The Chairman may designate a team of one/more members. IEC members will collect information and identify a problem, determine root cause, identify and implement a corrective and/or preventive action to prevent further recurrence.

- Self Evaluation of Chairman will be done. **(Ax: 08/V06)**
- The Chairman will do evaluation of the IEC members, Member Secretary and Joint Secretary. **(Ax: 09/V06)**
- Evaluation of IEC staff will be done by Member Secretary. **(Ax: 10/V06)**
- The individual feedback will be provided to all members by Member Secretary.

3.4. Detailed instructions:

The corrective and preventive actions and root cause analysis (as required) will be discussed in the full board meeting and will be implemented accordingly. **(Ax: 11/V06)**

4. POLICY FOR CONFIDENTIALITY AND RESOLUTION OF CONFLICT:

4.1. Purpose:

The purpose of this SOP is to describe the process to identify and manage Confidentiality / Conflict of Interest (COI) among IEC members, guest attendees, observers and subject expert.

4.2. Scope:

It covers the agreement on Confidentiality and Conflict of Interest concerning information and procedures followed by the IEC.

4.3. Responsibility:

The IEC, MGIMS would refer to the GCP guidelines, ICMR guidelines and New Drugs and Clinical Trials Rules, 2019 and their modifications. It is responsibility of each and every newly appointed members to read, understand, accept and sign the confidentiality agreement. In case of any conflict as mentioned below for which the following format will be used to take undertaking from the concerned member of IEC.

No members having a conflict of interest will be involved in the oversight of the clinical trial or bioavailability or bioequivalence or biomedical or any human research study being reviewed by his/her and it is responsibility of each members to withdraw voluntarily, by expressing to the Chairman in writing that there is no conflict of interest with a sign. If one of the members has her/his own proposal for review, then the member should not participate when the project is discussed.

It is the responsibility of the guest/observers intending to attend a meeting to read, understand, accept and sign the agreement contained in the Confidentiality / Conflict of Interest form prior to attending an IEC meeting and/or before ethical review tasks with the Institutional Ethics Committee are commenced.

It is the responsibility of the Subject Expert to read, understand, accept and sign the agreement contained in the Confidentiality/Conflict of Interest form before beginning their ethical review tasks with the IEC and/or attending a meeting of IEC.

The Secretariat will ensure that the Confidentiality /Conflict of Interest Agreement Forms are duly signed and dated by the IEC members, Guests or observers for IEC meetings or Subject Expert prior to attending IEC meetings, accessing ethics committee documents or undertaking review processes (as applicable) and notify to the IEC, Chairman. The Secretariat will file signed Confidentiality/ Conflict of Interest Agreement forms. There should be no conflict of interest.

The details in respect of the conflict of interest of the members will be recorded in the minutes of the meetings.

4.4. Detailed instructions:

4.4.1. Every member at beginning of the tenure and before he/she commences to review research projects submitted to IEC and before he/she starts to function as an IEC member and before he/she starts attending IEC meeting will read the Confidentiality Agreement **(Ax: 04/V06)** and Conflict of Interest Agreement **(Ax: 12/V06)** carefully and thoroughly and will accept by signing it. No members

having a conflict of interest will be involved in the oversight of the clinical trial or bioavailability or bioequivalence or biomedical or any human research study being reviewed by his/her and each member is responsible to withdraw voluntarily, by expressing to the Chairman in writing that there is no conflict of interest with a sign **(Ax: 13/V06)**. He/she will sign and date the document and hand over the document to the secretariat.

4.4.2. Every observer or guest for IEC, committee meeting: before initiating ethical review and / or before commencement of the meeting will read the Confidentiality /Conflict of Interest Agreement Form **(Ax: 14/V06)** carefully and thoroughly and will accept by signing it. The Secretariat will obtain the document for record.

4.4.3. Every Subject Expert before initiating ethical review and / or before commencement of IEC meeting will read the Confidentiality /Conflict of Interest Agreement Form **(Ax: 15/V06)** carefully and thoroughly and will accept by signing it. The Secretariat will obtain the document for record.

4.5. Clarification of doubts, if any:

If any of the IEC members, Guests /observers, Subject Experts have any doubt and they will seek clarifications or additional information from the Secretariat, the Member Secretary will provide explanations, additional information and/ or clarifications.

5. SELECTION AND RESPONSIBILITIES OF SUBJECT EXPERT:

5.1. Purpose:

The purpose of this SOP is to provide procedures for obtaining the expertise of a professional as a subject expert either affiliated or non-affiliated, to the Institutional Ethics Committee.

5.2. Scope:

If the IEC determine that a study involves procedures or information that is not within the collective expertise of the IEC members, the Chairman/ Member Secretary on behalf of the IEC will invite individual(s) with competence in special area(s) to assist in the review of issues that require expertise beyond or in addition to that/ those available with the IEC.

5.3. Responsibility:

Upon the advice or recommendation of the secretariat or any IEC member, it is the responsibility of the IEC to nominate the name of one or more special subject experts and be endorsed by the Chairman for the given project.

5.4. Detailed instructions:

5.4.1. Recommendation:

The IEC will designate subject experts from the different specialties and the Chairman / Member Secretary on behalf of the IEC will invite subject expert selected by the IEC in writing to assist in the review of the project and provide his/ her independent opinion.

Depending upon the complexity of the issue(s) are not within the collective expertise of all members, the Chairman/ Member Secretary on behalf of the IEC will invite one or more experts which may or may not be affiliated with the institution.

5.4.2. Selection:

The final approval from the IEC Chairman to refer the project to the specified subject expert will be taken by the Secretariat.

5.4.3. Co-ordination with subject expert:

Subjects experts will participate after they agree to the confidentiality clause and declare in writing, conflicts of interest, if any **(Ax: 15/V06)** and abide by the rules and regulations of IEC whose opinion would be valuable but they would not be involved in the decision making process of the Ethics committee. The expert would be requested to provide an opinion in writing within 30 working days, depending upon the gravity and seriousness of the matter. The following would be designated as Subject expert during the meetings of the IEC, MGIMS.

- Investigator or Co-investigator/ Study coordinator of the project under review.
- Any expert in the field of study as and when invited by the IEC, MGIMS.

The Member Secretary will provide explanations/ clarifications (telephonically or in writing) to the subject experts if any doubts or questions are raised. The Chairman / Legal expert / IEC members can provide any further explanations. If

deemed necessary, subject expert may be reimbursed for expenses on travel, time spent, documents referred to in library/ internet, incidental expenses, etc.

5.4.4. Reviewing procedure:

IEC Secretariat will provide study protocol documents along with the Study Assessment Form to the subject experts **(Ax: 16/V06)**, after signing confidentiality statement and conflict of interest declaration by the subject expert. The subject expert will be requested to complete and provide the Assessment Form (duly signed and dated) to the Secretariat within a stipulated time.

If deemed necessary, the Chairman / Member Secretary may request for additional information or clarifications from the subject expert in writing. Additional Information provided by the subject expert will be considered as a part of the Assessment Report.

If deemed necessary, the Chairman / Member Secretary may invite to attend IEC meeting. However, the subject expert will not participate in the decision making process.

5.4.5. Termination of services:

As the subject expert is appointed for a particular task or project and the services of subject expert get automatically terminated once the final decision regarding the project is taken by the IEC. The IEC will approach the subject expert again in future for his/her expert advice, as he/she is a member included in the list of experts.

6. POLICY FOR INITIAL SUBMISSION OF RESEARCH PROPOSALS:

6.1. Purpose:

The purpose of this SOP is to describe the process that how the IEC secretariat manages protocol submissions.

6.2. Scope:

Initial submission will include submission of research protocol for Initial Review of the Protocol and related documents.

- Clinical trial and academic clinical trial.
- Biomedical and Health Research.
- All research proposals of funded and non-funded studies involving human subjects i.e. PG dissertation or research, UG research, ICMR STS, MUHS STRG/LTRG and any other research studies.

6.3. Responsibility:

It is the responsibility of the IEC secretariat to verify eligibility of PI, receive the submission packages, ensure complete documentation, record receipt of the package and forward to the member secretary.

6.4. Detailed instructions:

- **Initial Submission:**

  All clinical trials, academic trials, bioequivalence, bioavailability, biomedical and health research and other academic research (UG, PG, DNB, PhD, Nursing) study proposals will be submitted to the Member Secretary of the IEC, MGIMS in the prescribed Application format along with checklist and detailed study protocol at least three weeks in advance (especially for all clinical trials). The investigators shall submit their research study proposals for ethical review as per the checklist **(Ax: 17/V06) along with** application form **(Ax: 18/V06).** Additionally, the investigator shall submit separate application forms according to specific projects as given below:

  6.4.1. For clinical trials, bioequivalence, bioavailability research **(Ax: 19/V06)**

  6.4.2. For Human Genetics Testing Research **(Ax: 20/V06)**

  6.4.3. For Socio-behavioral and Public Health research **(Ax: 21/V06)**

  Covering letter addressed to the Chairman / Member Secretary, IEC, MGIMS through the Dean, MGIMS and forwarded by Head of the department and guide (if any) to be submitted by Principal Investigator (PI) along with the list of identifying documents. The Secretariat will verify eligibility of PI / research staff involving in the study along with delegation of responsibilities of study team **(Ax: 22/V06)** before accepting the protocol of regulatory studies / non-regulatory studies (if needed) and will perform the actions against the submission.

  The protocol would include the following:

  i. Title of the Protocol
  ii. Name and contact details of Principal Investigator
  iii. Name and contact details of Sponsor/CRO

iv. Recent curriculum vitae of the investigators indicating qualification and experience and medical registration certificates
v. Summary / Synopsis
vi. Clear research objectives and rationale for undertaking the investigation in human subjects in the light of existing knowledge
vii. Subject recruitment procedures or proposed methods / advertisement / notices
viii. Inclusion and exclusion criteria for entry of subjects in the study
ix. Precise description of methodology of the proposed research, including intended dosages of drugs, planned duration of treatment and details of invasive procedures if any
x. A description of plans to withdraw or withhold standard therapies in the course of research
xi. The details of statistical analysis of the study
xii. Procedure for seeking and obtaining informed consent with sample of patient information sheet and informed consent forms in English as per **(Ax: 23/V06)** and vernacular languages and the validity of the translation and back translation (certificate) or amendments to the Informed consent document (if any)
xiii. Assent form, if applicable **(Ax: 24/V06)**
xiv. Safety of proposed intervention and any drug or vaccine to be tested, including results of relevant laboratory and animal research*
xv. For research carrying more than minimal risk, an account of plans to provide medical therapy for such risk or injury or toxicity due to over-dosage should be included.
xvi. Case Record Form / Proforma / Questionnaire
xvii. Patient instruction card, identity card, diary etc., if any
xviii. Proposed compensation for participation and reimbursement of incidental expenses/ serious adverse events occurring during the study participation*
xix. Plans for storage and maintenance of all data collected during the trial
xx. Plans for publication of results – positive or negative – while maintaining the privacy and confidentiality of the study participants
xxi. A statement on probable ethical issues and steps taken to tackle the same.
xxii. Activity plan / Timeline
xxiii. Amendments to protocol (if any)
xxiv. Protocol signature page
xxv. All other relevant documents related to the study protocol including regulatory clearances and insurance documents as applicable*
xxvi. Investigator's agreement with the sponsor / Clinical Trial Agreement (CTA) / Agreement to comply with national and international GCP protocols for clinical trials*
xxvii. Clinical trial budget
xxviii. GCP training certificate (< 3 yrs.) of Principal investigator and study team members
xxix. Details of Funding agency / Sponsors and fund allocation for the proposed work*
xxx. Insurance policy of the study*

xxxi. Investigator's Brochure*
xxxii. Undertaking by the Investigator*
xxxiii. Memorandum of Understanding (MOU) between collaborative institutions
xxxiv. CTRI registration*
xxxv. DCGI Approval letter*
xxxvi. FDA marketing/manufacturing license for herbal drugs*
xxxvii. Health Ministry Screening Committee (HMSC) approval*
xxxviii. Bhabha Atomic Research Centre (BARC) approval*
xxxix. Genetic Engineering Advisory Committee (GEAC) approval*
xl. Stem cell committee (ICSCR) approval*
xli. Ethics Committee clearance of other centers (if applicable)
xlii. Any additional document(s), as required by IEC

Note: The copies of the research proposals for clinical trial and checklist filled in by PI along with soft copy in CD or in any storage media device need to be submitted, one for the records of the IEC, MGIMS and one each for every member. IEC may constraint the need for hard-copy based submission of research projects to practice eco-friendly paperless system of operation. For this purpose, IEC would review for a brief PowerPoint Presentation (PPT) to be presented by PI covering all the key topics which shall have equal importance as documentation.

(*Applicable for Clinical trials)

- Upon submission of study proposal, IEC secretariat will verify and record the details in the inward register and mention the inward no. along with EC reference no. on the first page of covering letter of the protocol. The secretariat will keep one original set of all documents for IEC record. After verifying documents, if IEC found incomplete submission, IEC will return to respective investigator with stating the reason for the same that will depend upon the completeness of the content of the protocol as mentioned above. However, it is necessary for PI to submit the remaining documents before reviewing the same.
- Member Secretary / Joint Secretary will review the protocol and related documents and will take the decision regarding the type of the review required for the particular protocol as follows:
  - Full Board Review
  - Expedited Review
  - Exempt from Review

7. FULL BOARD REVIEW PROCEDURE:

7.1. Purpose:

The IEC, MGIMS shall review every research proposal involving human subjects and other forms of studies (except in-vitro and animal experiments), before the research is initiated. IEC shall ensure that a scientific rationale, scope, methodology and the ethical aspects of the study before review is taken up. The committee shall evaluate the possible risks and benefits to the participants with proper justification as well as the expected benefits to the community. The adequacy of documentation for ensuring privacy & confidentiality shall also be reviewed.

7.2. Scope:

It covers the procedure applies to the review of all protocols submitted for initial review and decisions thereof by the IEC.

7.3. Responsibility:

The ethics review of a new project would be done through formal meetings by the IEC members and would not resort to decisions on them through circulation of proposals. All the IEC members shall review all the protocols. The Chairman/Member Secretary can identify the primary reviewer as per expertise and allocate the projects.

7.4. Detailed instructions:

7.4.1. The research proposals presenting more than minimal risk that are not covered under exempt or expedited review shall be subjected to full committee review. The members will review every research proposal as per checklist **(Ax: 25/V06).**

7.4.2. The following decisions may be provisionally taken by the Member Secretary in communication with the Chairman, without a formal meeting, subject to the approval of the IEC, MGIMS at the next scheduled meeting:

a) Extension of the study beyond the approved period.
b) Amendment to the study related document not involving the study design.
c) Restarting a previously discontinued research project.
d) All notifications related to adverse events.

7.4.3. Reviewing of Academic Research proposals submitted by Post graduate and undergraduate students:

A separate Ethics committee with identified members may be constituted by the Chairman, IEC, MGIMS for reviewing the proposals of academic research submitted by Postgraduate students as part of their thesis work & UG students.

7.4.4. The IEC will not allow the use of trainees/employees working within the organization to be used as trial participants unless students and staff have the same rights as any other potential subject to participate in the research project, irrespective of the degree of risk, provided all of the following conditions exist.

7.4.5. The research must not bestow upon participating Institutional subjects any competitive academic or occupational advantage over other Institutional students or staff who does not volunteer and the researchers must not impose any

academic or occupational penalty on those Institutional trainees or staff who does not volunteer.

7.4.6. Institutional students and staff must not be systematically treated differently from non-Institutional subjects as part of the project. Due to the potential for perceived or real coercion to participate, Institutional students and staff who desire to participate in the research (especially those under the direct supervision of the PI or listed research collaborators) must be reviewed by Dean of the Institution.

7.4.7. Where the protocol indicates that the prior consent of the trial subject or the subject's legally acceptable representative is not possible, the IEC will determine that the proposed protocol and/or other document (s) adequately address the relevant ethical concerns and meet applicable regulatory requirements for such trials (i.e., in emergency situations). This shall be communicated to the investigator in writing while approving the protocol.

7.4.8. It will also take note of the adverse events of the ongoing projects from the concerned investigators time to time and if considered may take up onsite monitoring with the help of the suitable sub-committee (formed with the formal permission from the Dean, MGIMS) who will submit report to the IEC for reviewing. It will also report the same to regulatory authority within the specified time.

7.4.9. The committee will also take up the issue of compensation following standard guidelines in case of any adverse events deemed to be caused by the direct association of the concerned clinical trial (Guidelines for determining quantum of financial compensation to be paid in a case of clinical trial related injury or death; as per scope and provisions made in the New Drugs and Clinical Trials Rules, 2019 and ICMR guidelines).

7.4.10. The following types of research are considered to involve more than **minimal risk** and require ethical approval:

Research involving those who lack normal physical / mental capacity. All research involving those who lack normal capacity, or those who during the research project has become lacking in capacity.

Research involving sensitive topics – for example participants' sexual behavior, their illegal or political behavior, their experience of violence, their abuse or exploitation, their mental health, or their gender or ethnic status.

Research involving groups where permission of a guardian is normally required for initial access to members. This includes research involving guardians such as adult professionals (e.g. those working with children or the elderly), or research in where access to research participants is not possible without the permission of another adult, such as another family member (e.g. the parent or husband of the participant) or a community.

Research involving access to records of personal or confidential information, including genetic or other biological information, concerning identifiable individuals.

Research which could induce psychological stress, anxiety or humiliation or cause more than minimal pain.

Research involving intrusive interventions or data collection methods – for example, the administration of substances, vigorous physical exercise, or

techniques such as hypnotism. In particular, where participants are persuaded to reveal information which they would not otherwise disclose in the course of everyday life.

The Committee would evaluate the possible risks to the subjects, the expected benefits and adequacy of documentation for ensuring privacy, confidentiality and justice issues.

7.5. Informed Consent review process:

The principal investigator must be obtained subject's consent in writing using Informed Consent Form (ICF). Patient information sheet and Informed consent form should be approved before initiation of study and furnished to Central Licensing Authority (CLA). Any changes in Informed Consent Document (ICD) should be approved before implementation and submitted to CLA. As per the requirements, Table 3 of Third Schedule in New Drugs and Clinical Trials Rules, 2019, IEC shall review the ICD using checklist **(Ax: 26/V06)**. The ICD should clearly state that the subject is entitled to free medical management as long as required in case of injury, and financial compensation in case of clinical trial related injury or death. The investigator will have to clearly inform the subject about his right to claim compensation in case of trial related injury or death and to contact the sponsor / representative directly for any claim related queries. The contact details of sponsor and ethics committee representative should be provided in the ICD. In order to aid the calculation of compensation amount, the ICD now should have further details about the subject like qualification, occupation, annual income, address and contact details of the nominee and his/her relation with the subject. A copy of ICD should be provided to subject and same should be mentioned in the ICD document. IEC, MGIMS periodically review the following (by the way of performing random inspection visits). If deemed necessary, the Member Secretary in consultation with Chairman may directly communicate with the research participant and ask for the feedback **(Ax: 27/V06)**.

7.5.1. The investigator shall provide information about the study verbally as well as using a patient information sheet, in a language that is nontechnical and understandable by the subject.

7.5.2. The PI shall describe procedures for obtaining informed consent including the procedure of Audio Video recording from the research participant prior to enrolling into a research study, especially vulnerable subjects.

7.5.3. If the subject is unable to give consent (unconscious or minor or suffering from severe mental illness or disability), the same should be obtained from a legally acceptable representative a Legally Acceptable Representative (LAR) who is able to give consent for or authorise and intervention in the patient as provided by law of India.

7.5.4. If the LAR is unable to read or write, an impartial witness should be included in the consent process who will sign in the consent on behalf of his / her.

7.5.5. If subject is from paediatrics age group, the subjects are legally unable to provide written informed consent and are dependent on their parent or legal guardian to assume responsibility for their participation in clinical studies. In such case:

- Written informed consent should be obtained from the parent or legal guardian. However, all pediatric participants should be informed to the fullest extent possible about the study in a language and in terms that they are able to understand.
- Where appropriate, pediatric participants should additionally assent to enrol in the study. Mature minors and adolescents should personally sign and date a separately designed written assent form.
- Although a participant's wish to withdraw from a study must be respected, there may be circumstances in therapeutic studies for serious or life-threatening diseases in which, in the opinion of the Investigator and parent or legal guardian, the welfare of a pediatric patient would be jeopardized by his or her failing to participate in the study. In this situation, continued parental or legal guardian consent should be sufficient to allow participation in the study.

7.5.6. Assurance that the research participants shall receive information that becomes available during the course of the research relevant to their participation including their rights, safety and wellbeing is documented.

7.5.7. The provisions made for receiving and responding to queries and complaints from research participants or their representatives during the course of a research project.

7.5.8. Any payments proposed to be made to subjects/patients has to be documented and notified to IEC and included on the ICD (Informed Consent Document)/ICF (Informed Consent Form).

7.5.9. Audio Visual (AV) Recording of Informed Consent process shall follow as following:

- According to ICMR guidelines, when a participant is willing to participate but not willing to sign or give a thumb impression or cannot do so, then verbal/oral consent may be taken on approval by the EC, in the presence of an impartial witness who should sign and date the consent document. This process can be documented through audio or video recording of the participant, the PI and the impartial witness, all of whom should be seen in the frame. However, verbal/oral consent should only be taken in exceptional circumstances and for specific, justifiable reasons with the approval of the EC. It should not to be practiced routinely.
- In case of vulnerable subjects in clinical trials of New Chemical Entity (NCE) or New Molecular Entity (NME) including procedure of providing information to the subject and his understanding on such consent, should be maintained by investigator for record:

  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 should be maintained by the investigator for record.

7.6. Clinical Trial Agreement (CTA) review process:

As per regulatory requirement, the PI must provide a legal agreement or contract with the head of the institute and sponsor where trial is to be conducted. The investigator should sign the same to conduct the trial in accordance with the

protocol, good clinical practice guidelines, and all applicable requirements, among other things. EC should review the agreement and contract budget with the following mentioned terms using checklist as per **(Ax: 28/V06)** before giving approval:

- Roles and responsibilities of the various stakeholders involved (sponsor, investigator, Contract Research Organization, any laboratory, etc.)
- Conduct of study in compliance with Good Clinical Practices (GCP), applicable regulatory and ethical guidelines, and the approved protocol
- Compliance with procedures for data recording and reporting
- Terms of confidentiality and non-disclosure
- Details of insurance and indemnity (compensation details)
- Permission for monitoring, audit and inspection of the trial site. The contract should explicitly state that the CRO or monitor should be given access to the trial sites, source data and documents, and reports. The agreement should also state that the institution or site should allow access to the regulatory authorities (if needed) for an inspection.
- Agreement to retain all essential documents (related to the trial), until the Sponsor informs the site that the documents are not required (archiving)
- Proposed communication plan
- Details of the financial support, payments, honorariums and fees, etc.
- Grounds for termination of contract
- Publication policy

The allocation of roles and responsibilities can be mentioned:

- Data processing
- Breaking of the code
- Statistical analysis
- Preparation of the study report
- Preparation and submission of materials to the Ethics Committee, regulatory authorities and other oversight committees
- Reporting of Adverse Drug Reactions, Adverse Events, Serious Adverse Events
- Quality Control and Quality Assurance systems with written Standard Operating Procedures (SOPs).

8. EXPEDITED REVIEW POLICY:

8.1. Purpose:

The purpose of this SOP is to determine if a study protocol qualifies for expedited review and provide instructions on management, review and approval of a project through the expedited review.

8.2. Scope:

It covers the procedure applies to the review and approval of research studies and documents, which qualify for expedited review by the IEC.

8.3. Responsibility:

It is responsibility of the Chairman / Member Secretary to determine if a project / protocol qualifies for an expedited review. All the IEC members shall review all the protocols. IEC may appoint a separate ethics committee of identified members or designate one / more primary reviewers to expedite the review of proposals that require expedited decision.

8.4. Detailed instructions:

8.4.1. Determine protocols for expedited review & designate the primary reviewers:

The proposal submitted for initial review or where investigator should be requested for the expedited review stating the reasons in the covering letter to the IEC. The ICMR Ethical guidelines will be followed in deciding on the need of such review. Expedited review may also be taken up in cases of nationally relevant proposals requiring urgent review. The IEC Chairman / Member Secretary will take the final decision regarding whether a study with **'not more than minimal risk'** qualifies for an expedited review **(Ax: 29/V06)**.

IEC may do expedited review only if the protocols involve -

- Proposals that pose no more than minimal risk may undergo expedited review, for example;
  - Research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and leftover clinical samples.
  - Research involving clinical documentation materials that are non-identifiable (data, documents, records).
- Modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s).
- Revised proposals previously approved through expedited review, full review or continuing review of approved proposals.
- Minor deviations from originally approved research causing no risk or minimal risk.
- Progress reports where there is no additional risk, for example activity limited to data analysis. Expert committee will conduct expedited review of SAEs.
- Research during emergency situation (e.g. COVID-19 pandemic) and disaster. However, the final decision on whether an expedited review process may be used will be decided by the IEC.

8.4.2. Review protocol & give comments and recommendations:

The protocol shall review in the full board meeting. However, the designated members / primary reviewers may review the protocol and give their comments and recommendations to the member secretary within seven days from date of receipt of the protocol. The designated members / primary reviewers, after reviewing each study protocol will lead the discussion on the relevant protocol in the subsequent meeting.

8.4.3. Decision of IEC:

- After reviewing the protocol by the designated members / primary reviewers, the Member Secretary will discuss about the comments with the Chairman and decision will be taken in consultation with Chairman. The decision will be ratified in the regular meeting of IEC.
- If deemed necessary, the proposal will be discussed in the forthcoming meeting.
- The expedited review process should be completed within 14 working days.
- The decision will be conveyed to the principal investigator.
- If project is disapproved or requires resubmission after certain modifications, this will be informed to the Principal Investigator. The reasons for disapproval of a project will be specified in the letter sent to Principal Investigator.

9. POLICY FOR EXEMPTION FROM ETHICS REVIEW:

9.1. Purpose:

The purpose of this SOP is to describe which research projects proposals can be exempted from ethics review and do not require the approval of IEC.

9.2. Scope:

It covers the procedure applies to the all protocols submitted for exemption from review by the IEC.

9.3. Responsibility:

The Member Secretary will determine in consultation with the Chairman whether the protocol qualifies for exemption from review. The Member Secretary will record the decision in the exemption form with reasons forwarded by PI and will inform members in the next meeting of IEC.

9.4. Detailed instructions:

9.4.1. Determine for exemption from review:

The proposals submitted for initial review or requested for the exemption from review stating the reason in the application form for exemption from review **(Ax: 30/V06)** to the IEC will be evaluated for the exemption from review.

Proposals with less than minimal risk where there are no linked identifiers, e.g.

- Research conducted on data available in the public domain for systematic reviews or meta-analysis.
- Observation of public behaviour when information is recorded without any linked identifiers and disclosure would not harm the interests of the observed person.
- Quality control and quality assurance audits in the institution.
- Comparison of instructional techniques, curricula, or classroom management methods.
- Consumer acceptance studies related to taste and food quality.
- Public health programs by government agencies such as program evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers).

The research proposals which do not involve live human participants or data derived from them are exempt from ethics review. e.g.

- Audits of educational practices.
- Research on microbes cultured in the laboratory.
- Research on immortalized cell lines.

In some circumstances research which appears to meet low risk criteria may need to be reviewed by the IEC. This might be because of requirements of:

- The publisher of the research.
- An organization which is providing funding resources, existing data, access to participants etc.
- Ethical issues involved in data.

9.4.2 Decision of IEC:

The secretariat will communicate the decision to the Principal Investigator within 14 days after the decision regarding the exemption is taken. The Member Secretary will inform the IEC members about the decision in the next full board meeting and will record in the minutes. The Chairman / Member Secretary may keep the application for review and decision regarding exemption in the next full board meeting.

The PI must bring any changes to the protocol to the notice of the IEC prior to implementation.

The IEC will determine if requested protocol changes alter the risks: benefits analysis of the study, thereby requiring a change in review or exemption category. In such cases investigator will have to resubmit the study protocol and related documents for change review process.

10. POLICY FOR REVIEW OF RESUBMITTED PROTOCOLS:

10.1. Purpose:

The purpose of this SOP is to describe how IEC manages study protocols and related documents resubmitted after initial review.

10.2. Scope:

It covers the procedures applies to study protocols that have been resubmitted to the IEC with the Principal Investigator responding to clarifications and modifications sought and comments made by the IEC during initial review.

10.3. Responsibility:

It is the responsibility of the IEC Secretariat to ensure the completeness of the documents submitted to the IEC for reconsideration. Either the Member Secretary / Joint Secretary or designated members by the Chairman / Member secretary or all the IEC members may review a resubmitted protocol as per IEC decision determined by the IEC at the time of the initial review of the project during the full board IEC meeting.

10.4. Detailed instructions:

10.4.1. Reviewing procedure:

The secretariat will verify the resubmitted documents if the principal investigator has replied within 180 days of receipt of IEC letter or PI will be asked to submit the requisite documents and forward it to Member Secretary.

If there are minor modifications, the protocol and related documents will be reviewed by the Member Secretary / Joint Secretary or designated members or all the IEC members will be discussed as per decision taken during initial review.

If there are major modifications, the protocol and related documents will be reviewed by the Member Secretary / Joint Secretary or designated members or all the IEC members will be discussed in the next full board meeting as per decision taken during initial review. In case the decision is to discuss, the Primary reviewer(s) / Member Secretary will present a brief oral summary of the study design and the comments of the IEC members/Chairman in the IEC full board meeting.

The IEC members/ Member Secretary/ Chairman will refer to the query letter/ comments as guidance for the review and check whether the recommendations of the IEC have been followed or adequately responded to and will also check for completeness of protocol and related documents as per requirements. The review process should be completed within 7-10 days.

10.4.2. Decision of IEC:

The final decision regarding the query reply shall include one of the following:

- If the IEC decision is ‘Approved’, it implies the approval of the study as it is presented with no modifications and the letter of permission can be issued to the Principal Investigator.
- If the IEC decision is ‘Approved with minor modification, the IEC Chairman may authorize the Member Secretary / Primary reviewer + Member Secretary

to determine if the response and changes are satisfactory and decide if letter of permission can be issued to the Principal Investigator.

- If the IEC decision is 'Approved with major modification, the IEC Chairman may authorize the Primary reviewer + Member Secretary to review the responses which may or may not be discussed in next full board meeting depending on the comments of the reviewers. If the response and changes are approved in the full board, letter of permission can be issued to the Principal Investigator.

The decision will be communicated to the PI within 14 days. For the projects which will be discussed in the full board meeting, the decision will be communicated within 14 days of the meeting. Response from the PI to the IEC communication is expected within 180 days of date of receipt of the letter and in the absence of any response, the project will be declared closed for the IEC office records. Reply to subsequent queries should be sent in 60 days. The Secretariat will record the decision reached on the response in the minutes of the meeting.

11. POLICY FOR REVIEW OF AMENDED PROTOCOLS / RELATED DOCUMENTS:

11.1. Purpose:

The purpose of this SOP is to describe how amended protocol/ protocol related documents are managed and reviewed by the IEC.

11.2. Scope:

It covers the procedures applies to previously approved study protocols but later being amended and submitted for approval to the IEC. Amendments made to protocols will not be implemented until reviewed and approved by the IEC.

11.3. Responsibility:

It is the responsibility of the IEC Secretariat to manage protocol amendments in any occasion to the already approved protocol by the IEC. The Member Secretary/ Chairman will determine whether the proposed protocol amendment(s) is minor or major in nature following submission. Minor amendments would undergo review by the Member Secretary / Chairman / IEC members in expedited manner and will be informed in full board. If the amendments are major, it will undergo review by IEC members and will be discussed in full board.

11.4. Detailed instructions:

11.4.1. Reviewing procedure:

IEC Secretariat will accept the amended protocol submitted by the PI and ensure completeness of content of the protocol amendment (the details of amendment including the summary of changes from previous version to present version and mention the reason for amendment) and will forward it to the Member Secretary / Chairman with the protocol amendments request form **(Ax: 31/V06)**. If any of the documents or information are missing / incomplete, the Secretariat will inform the Principal Investigator to submit the required documents. The Member Secretary or Chairman will categorize the amendments as minor or major amendment.

The minor amendments of the protocol and related documents will be reviewed Member Secretary / Chairman / IEC members. The major amendments of the protocol and related documents will be reviewed by IEC members and will be discussed in the upcoming full board meeting. The committee members will review the amended documents and assess the change in risk / benefit ratio and impact of the amendment (modifications in the ICD, re-consent of research participants, untoward effects likely to occur because of the amendment or any other).

11.4.2. Following aspects of the Protocol amendment which may include but is not limited to:

- Change in study design
- Additional treatments or the deletion of treatments
- Changes in inclusion/exclusion criteria.
- Change in method of dosage formulation, such as, oral changed to intravenous
- A significant change in the number of research participants (if the decrease/increase in the number of research participants alters the

fundamental characteristics of the study, it is significant)

- A significant decrease or increase in dosage amount
- Change in risk/benefit ratio

11.4.3. Decision of IEC:

The IEC shall critically review the content of amendment with justification in ethics point of view following Good Clinical Practice (GCP) guidelines. If the proposed amendment are minor and found satisfactory and the decision is approved, the approval letter can be issued to the PI. The decision will be communicated to the PI within 14 days. For the major amendments which are discussed in the full board meeting found satisfactory and approved, the decision will be communicated within 14 days of the meeting. If the decision is disapproved, the same will be informed PI in the meeting with the reason for disapproval. The Secretariat will record the decision reached on the proposed amendment in the minutes of the meeting.

12. POLICY FOR PERIODIC REVIEW OF PROTOCOLS:

12.1. Purpose:

The purpose of this SOP is to describe how periodic reviews of previously approved protocols are managed by the IEC. The purpose of the periodic review is to monitor the progress of the entire study, not just the changes in it, to ensure continuous protection of the rights and welfare of research participants.

12.2. Scope:

It covers the procedures applies to conducting any periodic review of study protocols involving research participants at intervals appropriate to the degree of risk. All the regulatory projects **(clinical trials or bioavailability or bioequivalence studies)** approved by the IEC will be reviewed **twice in a year** and **non-regulatory or academic trials** will be reviewed at least once a year. Depending upon the degree of risk to the participants, the nature of the studies, the vulnerability of the study participants and duration of the study, the IEC may choose to review or monitor the protocols more frequently.

12.3. Responsibility:

It is the responsibility of the Secretariat to remind the IEC that should be continuously reviewed. The Member Secretary will determine the date of periodic review of the study in consultation with Chairman. The IEC is responsible for reviewing the progress made in the protocol, assessment of risk / benefit, the rate of accrual of participants and the occurrence of unexpected events or problems.

12.4. Detailed instructions:

12.4.1. Reviewing procedure:

The Member Secretary will plan for periodic review of protocol in consultation with the Chairman in the full board meeting. The progress of clinical trial research proposals will be followed (via periodic reports from PI) at regular intervals of 6 months for long duration studies i.e. studies more than 1 year and at regular intervals of 3 months for short duration studies i.e. studies less than 1 year as per format **(Ax:32/V06)**. But, in special situations IEC, MGIMS will ask for follow up report from PI at shorter intervals based on the need, nature and events of research project. IEC members will review the progress of the entire study, protocol/Informed consent Document amendments, not just the changes in it, to ensure continuous protection of the rights and welfare of research participants. If the Principal Investigator fails to submit the periodic update report within one month of the due date unless specified otherwise, the IEC secretariat will send a reminder. If there is no response within 15 days after the date of reminder, the IEC secretariat will put up the matter for discussion in the next full board meeting for appropriate action which may consist of but not limited to:

- A letter of reprimanding the Investigator
- Suspending review of projects for a specified time.
- A letter asking the Investigator to put recruitment of new participants on hold.

If deemed necessary, principal investigators may be called for the discussion.

12.4.2. Decision of IEC:

The committee will ensure research are conducted in accordance with the ICH GCP, New Drugs & Clinical Trial Rules 2019, National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017 and current regulatory guidelines/ requirements. If IEC found there is no need of any modifications, the IEC shall approve the study to continue as it is. The protocol that have been suggested modifications by the IEC may not approve until the conditions have been met by the PI. The research may be discontinued with reason if the established procedure found to be not satisfactory or any significant findings that have arisen during the review process by the IEC. The decision of IEC will be communicated to the PI within 14 days. The Secretariat will record the decision reached on the proposed periodic review report in the minutes of the meeting.

13. POLICY FOR REVIEW OF STUDY COMPLETION (CLOSURE) REPORT:

13.1. Purpose:

The purpose of this SOP is to provide instructions on the review of study completion (closure) report for every study previously approved by the IEC.

13.2. Scope:

It covers the procedures applies to the review of the study completion (closure) report which is an obligatory review of each investigators' activities presented to the IEC as a written report of study completed.

13.3. Responsibility:

It is the responsibility of the IEC Secretariat to review the report for completeness. It is the responsibility of the Chairman/ Member secretary to review the study report and notify it or request for further information, if necessary.

13.4. Detailed instructions:

13.4.1. The study completion (closure) report is expected from the investigator within one month of completion of the study at the site as per **(Ax: 33/V06)**. A brief study report containing data analysis from all centres can be submitted by the investigator once available from the sponsor.

The Chairman and Member Secretary will review the report and notify it to the IEC members in the forthcoming full board meeting or the Chairman / member secretary can designate two other IEC members to review the study completion report and related documents. If deemed necessary, the Chairman/member secretary may keep the report for discussion at the forthcoming IEC meeting.

In case, there is a significant finding during the review process, this will be communicated to PI. It is the responsibility of PI to provide the required information to the IEC. If PI fails to submit the report for academic research (Thesis, STS, STRG, Short term observational research) within 1 year from date of completion, then IEC will dispose the master file once the archival period over.

If necessary, the IEC secretariat will retrieve the master file from the archiving with permission of the Member Secretary.

13.4.2. Decision of IEC:

The secretariat will note the decision in the meeting minutes and the study shall be considered as closed if decision by IEC is noted and the same will be recorded.

If required, IEC would request PI for additional information / clarification. The decision will be communicated to the PI within 14 days of the date of the full board meeting.

14. POLICY OF DECISION MAKING PROCESS:

14.1. Purpose:

The purpose of this SOP is to describe the decision making process of the approval for study proposals and other activities performed by the IEC.

14.2. Scope:

It covers the procedures applies to the decision making process performed by the IEC.

14.3. Responsibility:

It is the responsibility of the IEC members and Secretariat to ensure that the research are conducted in accordance with the ethical principles and quorum requirement are fulfilled to recommend / reject /suggest modifications by consensus.

14.4. Detailed instructions:

14.4.1. Only those IEC, MGIMS members who are independent of the investigator and the sponsor of the proposal would vote/provide opinion on the proposal. If a member is also an investigator for a proposal, he/she would not be involved in the decision making process when the said proposal is being discussed, and would not chair the session. Such a member must voluntarily withdraw from the IEC, MGIMS while making a decision on an application which evokes such a conflict of interest, which should be indicated in writing in the above mentioned format for undertaking and should be recorded so in the minutes.

14.4.2. The study team member (Investigator / Co-investigator / Study coordinator's) non-participation in the decision making process would be recorded in the minutes and also in the opinion letter issued for the project.

14.4.3. The decision of the IEC, MGIMS would be by consensus after the quorum requirements are fulfilled to recommend / reject /suggest modifications for a repeat review in accordance with ICH GCP, New Drugs & Clinical Trial Rules 2019, National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017 and current regulatory guidelines/ requirements.

If any experts are invited, they would not participate in decision making on a proposal.

The decision of the IEC, MGIMS would be one of the following ways:

- **Approved**: The study is approved in its present form. When committee approves the study, the certificate will be issued within a period of 15 days.
- **Approved with modifications**: The study is approved but the revisions are required. It can be minor or major. If revisions are found satisfactory, the approval will be granted.
- **Resubmit**: Extensive revisions are necessary. Principal Investigator has to comply with the changes suggested by IEC during the meeting. The revised project will then be reviewed in the next meeting.
- **Not approved:** The study is not approved in its current form. The required modifications will be suggested during the meeting with reasons. If the

investigator wishes to appeal to the decision, he/she may do so by contacting the IEC Secretariat. The IEC may decide to accept or deny the appeal. If the appeal is denied, the IEC decision is final and the study may not be approved or resumed.

- **Defer**: The decision cannot be arrived at present and therefore postpone to next meeting. Grounds for this: lack of quorum, lack of expertise etc.

14.4.4. Communicating the decision: The IEC, MGIMS would issue the opinion letter to communicate the decision taken on any clinical trial, bioavailability and bioequivalence proposals following prescribed format of approval letter as per recommendation of New Drugs and Clinical Trials Rules, 2019 **(Ax: 34/V06)** and for any biomedical and health research or any other research as per **(Ax: 35/V06).** IEC shall customize this letter according to requirement for amendment, expedited review or exemption from review. This opinion letter would be issued by the Member Secretary to convey the decision of the IEC, MGIMS to the Principal Investigator and must include the following information mentioned with turnaround time of 21 days:

- The name of the Project (Same as the Project title).
- List of documents reviewed by the IEC, MGIMS including the revised version of documents if any.
- List of members present at the meeting.
- Members who did not participate in the decision making process.
- The date and time of meeting.
- The decision of the IEC, MGIMS.
- A note to PI to strictly adhere to SOP of IEC, MGIMS Version 06/2021-22, GCP and latest regulatory requirements plus submission progress updates/deviations as and when it occurs while implementing the sanctioned project.
- An IEC may decide to reverse its positive decision on a study in the event of receiving information that may adversely affect the benefit / risk ratio.

14.4.5. The discontinuation of a research should be ordered if the IEC finds that the goals of the trial have already been achieved midway or unequivocal results are obtained.

14.4.6. In case of premature termination of study, notification should include the reasons for termination along with the summary of results conducted till date.

14.4.7. IEC, MGIMS may also ratify the provisional decision of the Member Secretary, taken in situations mentioned in clause 7.4.2., and such ratification if any would be recorded in the minutes of the meeting.

14.4.8. All correspondence between the IEC, MGIMS and the Investigator/ Co-investigator/ Study coordinator and all other relevant records (Proposal, opinion letter, minutes of the meeting etc.) would be retained by the IEC, MGIMS for a minimum period of five years after the completion of the research.

15. POLICY FOR FEES RELATED TO ETHICS COMMITTEE ACTIVITIES:

15.1. Purpose:

The purpose of this SOP is to describe the finances related policies for the IEC activities and functioning.

15.2. Scope:

It covers the finances related policies applies to the review of research projects.

15.3. Responsibility:

It is the responsibility of the IEC to charge the processing fees for review of research projects.

15.4. Detailed instructions:

As a policy of the appointing authority IEC, MGIMS does not charge any fees for processing any project proposals, review of SAE and inviting Subject expert as well as for any other of its activities. However, reasonable processing fees for clinical / academic trials may be charged in consultation with the institute authority.

15.4.1. Fee structure:

- Funded research (Non-interventional study) with funding amount below ₹1,00,000 need not pay.
- Funded research (Non-interventional study) with funding amount upto ₹10,00,000 = ₹3,000 as entry fees and ₹500 per year thereafter till the termination of the project.
- Funded research (Non-interventional study) with funding amount more than ₹10,00,000 upto ₹50,00,000 = ₹5,000 as entry fees and ₹700 per year thereafter till the termination of the project.
- Funded research (Non-interventional study) with funding amount more than 50,00,000 = ₹7,000 as entry fees and ₹1000 per year thereafter till the termination of the project.
- Funded research (Clinical Trial) having single centre operation ₹10,000 as entry fees and ₹5,000 /- per year thereafter till the termination of the project.
- Funded research (Clinical Trial) having multicentric operation ₹10,000 as entry fees and ₹7,000 /- per year thereafter till the termination of the project.

15.4.2. Method of payment:

All such processing charges should be deposited in the bank account of IEC, MGIMS at Central Bank of India, Sevagram branch.

15.4.3. Budget Preparation:

The committee review fee should be incorporated in budgets or payment of funded research studies.

15.4.4. Memorandum of Understanding:

The details of bank account are mentioned in MoU between the IEC and Dean, MGIMS.

15.4.5. Expenditure:

The expenditure will be made from the IEC account towards following:

- Paying honorarium to external members (₹ 1000 to Chairman and ₹500 to other members) for each meeting attended and invited experts.

- GCP training programme organized by IEC.
- IEC members who present papers on research ethics and representing institute IEC in national/international conference.

Note: The processing fees from the funded research will be charged. However, the reasonable fees for such research will be charged in consultation with the members of IEC.

16. MANAGEMENT OF PREMATURE TERMINATION /SUSPENSION / DISCONTINUATION OF THE STUDY /WITHDRAWAL OF STUDY BEFORE INITIATION:

16.1. Purpose:

The purpose of this SOP is to proceed and manage the premature termination/ suspension / discontinuation of the study / withdrawal of study before site initiation of a research study. Protocols may be terminated at the recommendation of the IEC, Data Safety Monitoring Board (DSMB), Principal Investigator, sponsor, Regulator or other authorized bodies wherein subject enrolment and subject follow-up are discontinued before the scheduled end of the study.

16.2. Scope:

This SOP applies to any study approved by IEC that is being recommended for termination before its scheduled completion.

16.3. Responsibility:

It is responsibility of IEC secretariat to receive premature termination/ Suspension / Discontinuation of the study / Withdrawal of study before site initiation of a research study report submitted by PI as per **(Ax: 36/V06).** It is the responsibility of the Chairman to terminate any study that the IEC has previously approved when the safety or benefit of the study participants is doubtful or at risk, also to review the termination suggested by IEC members, PI, Sponsor or other authorized bodies. The secretariat is responsible for management of the premature termination/ suspension/discontinuation documents/Withdrawal of study.

16.4. Detailed instructions:

16.4.1. Review the report:

- The member secretary / Chairman shall review the results, reasons and accrual data and discuss the report **(Ax: 36/V06)** at the full board meeting.
- If the Premature termination/ suspension/discontinuation report is unclear or more information is required from the PI, the Chairman shall instruct the Secretariat to seek clarifications/ additional information from the Principal Investigator.
- The Chairman/Member Secretary / IEC members will review the information available and take a decision depending on the seriousness of the termination. The decision will be taken to ensure that the safety and rights of the research participants are safeguarded. The decision will be taken by consensus / voting.

16.4.2. Record and communication:

- The decision will be communicated to the PI within 14 days and Secretariat will record of the Premature Termination / Suspension / Discontinuation of the study / Withdrawal of study in the minutes of the meeting.
- In case of termination of any such study prematurely, the detailed reasons for such termination shall be communicated to the Central Licencing Authority immediately by the PI.
- In case of termination of any clinical trial the detailed reasons for such termination shall be communicated to the Central Licencing Authority within thirty working days of such termination by the PI

17. POLICY FOR PROTOCOL DEVIATION/ NON-COMPLIANCE/ VIOLATION:

17.1. Purpose:

The purpose of this SOP is to provide the instructions for taking action(s) when investigators / trial sites fails to:

- Follow the procedures written in the approved protocol.
- Comply with national and/ or international guidelines, statutory provisions, institutional guidelines or rules or procedures mandated by the Institutional Ethics Committee (IEC) for the conduct of human research.
- Respond to the IEC requests regarding statutory, ethical, scientific or administrative matters.

17.2. Scope:

It covers the policies applied to all research involving human research participants.

17.3. Responsibility:

The IEC shall be responsible to receive the deviation / non-compliance/ violation reports. Protocol deviation/ non-compliance/ violation will be reported by the Investigator/ study site/sponsor/ Contract-Research Organization to the IEC in the prescribed format **(Ax: 37/V06)**. The Member Secretary / Chairman will categorize the protocol deviation as major or minor. The IEC members or designated member(s) (if any), will review and take a decision depending on the seriousness of the deviation/non-compliance/violation. The decision will be taken to ensure that the safety and rights of the research participants are safeguarded.

17.4. Detailed instructions:

The procedures mentioned in protocol in accordance with statutory provisions, National /International ethical guidelines and procedures mandated by IEC, protocol deviation/non-compliance/violation may be detected in following ways (but not limited to)**:**

- The IEC members performing monitoring of the project at trial site may detect protocol deviation/non-compliance/violation if the project is not been conducted as per protocol/national/international regulations.
- The Secretariat may detect protocol deviation/non-compliance/violation from failure to comply with statutory requirements/failure to respond to requests from IEC within reasonable time limit/failure to respond to communication made by IEC.
- The IEC members may detect protocol deviation/non-compliance/violation when scrutinizing annual/ periodic reports/ SAE reports/ any other communication received from the Investigator/ trial site/ sponsor/ study monitor/ contract research organization/ethics committee monitor.
- The IEC secretariat and/ or IEC members may become aware of a protocol deviation/ non-compliance/ violation while reviewing study-related documents including reports filed in by the Principal Investigator.
- Communication/ complaint/ information received from research participant who has been enrolled or any individual who has been approached for enrolment.
- Any report/ communication brought to the notice of Member, Secretary/ Joint Secretary/Chairman of IEC by an independent person.

- Communication received from the Dean informing IEC about an alleged protocol violation/ non-compliance/ protocol deviation.

17.4.1. Definitions with examples:

Protocol deviation/s: Any change, divergence or departure from the study design or procedures of protocol which does not have a major impact on the subject's rights, safety or well-being or completeness, accuracy, study outcome and reliability of study data and has not been approved by IEC will be considered **minor deviation**.

On the content of a deviation, the protocol has approved by IEC that may affect the subject's rights, safety or wellbeing and/or the completeness accuracy, study outcome and reliability of study data will be considered **major deviation**. The PI shall submit the protocol deviation report to the IEC in the prescribed format **(Ax: 37/V06)**.

Protocol violation/s: A protocol violation is a deviation from the IEC approved protocol that may affect the subject's rights, safety, or wellbeing and/or the completeness, accuracy, study outcome and reliability of the study data will be considered a **protocol violation**. The PI shall submit the protocol violation report to the IEC in the prescribed format **(Ax: 37/V06)**.

Examples list is not exhaustive:

I. The deviation has harmed or posed a significant or substantive risk of harm to the research subject. For example:

- A research participant has received the wrong treatment
- A research participant had met withdrawal criteria during the study but was not withdrawn.
- A research participant received an excluded concomitant medication.

II. The deviation compromises the scientific integrity of the data collected for the study. For example:

- A research participant was enrolled but does not meet the protocol's eligibility criteria.
- Failure to treat research participants per protocol procedures that specifically relate to primary efficacy outcomes. (if it involves patient safety it meets the first category above)
- Changing the protocol without prior IEC approval.
- Inadvertent loss of samples or data.

III. The deviation is a willful or knowing breach of human participant protection regulations, policies, or procedures on the part of the investigator(s). For example:

- Failure to obtain informed consent prior to initiation of study-related procedures.
- Falsifying research or medical records.
- Performing tests or procedures beyond the individual's professional scope or privilege Status (credentialing).

IV. The deviation involves a serious or continuing noncompliance with federal, state, local or Institutional human participant protection regulations, policies, or procedures. For example:

- Working under an expired professional license or certification

- Failure to follow federal and/or local regulations, and intramural research policies
- Repeated minor deviations

V. The deviation is inconsistent with the NIH Human Research Protection Program's research, Medical and Ethical principles. For example:

- A breach of confidentiality.
- Inadequate or improper informed consent procedure.

17.4.2. Reviewing procedure:

- The Chairman / Member Secretary / primary reviewers will review the submitted protocol deviations/ non-compliances/ violations and assess the impact on the safety wellbeing of the participants and data integrity of the study along with risk benefit analysis.
- Primary reviewers (if appointed) will send the comments to the Member Secretary with the decision.
- The Chairman / Member Secretary / IEC members will review the information available and take a decision depending on the seriousness of the deviation / non-compliance/ violation. The decision will be taken to ensure that the safety and rights of the research participants are safeguarded. The decision will be taken by consensus / voting. The actions taken by IEC could include one or more of the following:
  - Inform the Principal Investigator that IEC has noted the deviation /violation
  - Direct the PI to ensure that deviations/violations do not occur in future and follow IEC recommendations.
  - Enlist measures that the PI would undertake to ensure that deviations/violations do not occur in future
  - Reprimand the PI.
  - Call for additional information.
  - Suspend the study till additional information is made available and is scrutinized.
  - Suspend the study till recommendations made by the IEC are implemented by the PI and found to be satisfactory by the IEC.
  - Suspend the study for a fixed duration of time.
  - Inform the Dean.
  - Revoke approval of the current study.
  - Inform DCGI or Other relevant regulatory authorities.
  - Keep other research proposals from the PI/ Co-I under abeyance.
  - Review and/ or inspect other studies undertaken by PI/Co-I.
  - Refuse to review subsequent applications from an investigator cited for non-compliance for a specified duration of time.
  - Any other action considered appropriate by the IEC for safeguarding the interests of the research participants participating in the current trial or in future trials.

17.4.3. The action will be taken by the IEC based on:

- The nature and seriousness of the deviation /violation.
- Frequency of deviation / violation in the study in the past.
- Frequency of deviation / violation in previous studies conducted by the same PI/ Co-I or in the same department.

17.4.4. Communicating the decision and record:

- The decision will be communicated to the PI within 14 days after the meeting except if the decision is project suspension/termination, which will be communicated to the Principal Investigator within 1 working day of the meeting.
- The Secretariat will record the decision reached on the protocol deviation / violation in the minutes of the meeting.

18. REVIEW OF SERIOUS ADVERSE EVENTS (SAE) AND UNEXPECTED ADVERSE EVENTS (UAE) REPORTS:

18.1. Purpose:

The purpose of this SOP is to describe how Serious Adverse Events (SAE) and Unexpected Adverse Events (UAE) reports are managed and reviewed by the IEC.

18.2. Scope:

It covers the procedures applies to the review of SAE and UAE reports submitted to the IEC.

18.3. Responsibility for review of SAE & UAE:

The primary responsibility of the IEC is to review and address SAE and unexpected events involving risks to research participants with protection of safety, rights and confidentiality of the research participants. In addition, the committee is authorized to offer mediation under appropriate circumstances.

IEC should make sure that researchers are made aware of the policies and procedures concerning reporting and continuing review requirements.

The Member Secretary is responsible for receiving the complete SAE / unexpected events reports and directing them to the members/designated expert reviewers for detailed review. The expert reviewers will be selected in their personal capacities based on their interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the expert committee work. The designated expert reviewers (Subject expert) will sign the Confidentiality and Conflict of Interest agreements regarding meeting, deliberations, applications, information on research participation and related matters in the specified format of **(Ax: 15/V06)**. The expert reviewers will prepare their report using **Annexure** and based on the report from expert committee (reviewers) IEC will send the same with its opinion with a special focus on relatedness to the clinical trial, medical management and the financial compensation (if any, determined in accordance with the formula specified) to the DCGI expert committee for review of SAEs and ratification in the IEC meeting. The IEC may invite Legal Expert member of the IEC to provide opinion on the legal implication of adverse event.

The IEC shall review the serious adverse events, unexpected adverse events and other site SAE reports (CIOMS, SUSARs) of each research at appropriate and specified intervals and will maintain the record.

Notifying the IEC does not relieve the PI from his/her responsibility to notify the sponsor, head of institute and regulatory authorities.

The IEC will follow all applicable guidelines released by the regulatory authorities and revised from time to time.

18.4. Detailed instructions about onsite SAEs:

18.4.1. SAE related activities for clinical trials or bioavailability or bioequivalence study:

The IEC secretariat shall receive the initial reports of SAEs occurred for IEC approved studies within 24 hrs. of the occurrence of the SAEs of a clinical trials or bioavailability or bioequivalence study as per format **(Ax: 38/V06)** mentioned in the New Drugs and Clinical Trials Rules, 2019 (Third Schedule Table 5). The Member Secretary/ Secretariat will verify that the SAE reports in the prescribed format are complete, signed and dated by the PI. In case he/she notes that the report is incomplete, it will be forwarded to PI, to revert with adequate data.

If the investigator fails to report any serious adverse event within the stipulated period, he/she will have to furnish the reasons for delay to the satisfaction of the regulatory authority along with the report of the serious adverse event. This will be considered as a violation. Follow up reports shall be received within 14 calendar days. Expert committee will review the SAE reports and arrange a meeting depending on the timelines. The IEC Secretariat will receive the report of the Expert committee and recommendation taken on the onsite SAE report. The IEC will receive the review report by the expert committee and will communicate the decision on the SAE report along with the opinion on financial compensation to the licensing authority within 30 days of occurrence of SAE. IEC shall inform the concerned Principal Investigator about the decision. If decision is that the research participant is entitled for financial compensation an emergency IEC meeting will be scheduled immediately for the same. In case of SAE, the report with due analysis will be submitted also by the sponsor within 14 days. If the PI has not adhered to the above stipulated time period, the IEC office will notify the discrepancies in the reporting time and time of occurrence of SAE to the PI.

If deemed necessary the licensing authority will be informed about the UAEs.

The deliberations and communication will be presented in the subsequent full board meeting.

18.4.2. SAE related activities for academic or other than clinical trials:

The IEC secretariat shall receive the initial reports of SAEs occurred for IEC approved studies within 24 hrs. of the occurrence of the SAEs as per format **(Ax: 38/V06)** and SAEs of biomedical and health research as per **(Ax: 39/V06)**. Such trials will be conducted in accordance with the approved clinical trial protocol, ethical principles specified in National Ethical Guidelines for Biomedical and Health Research Involving Human Participants by ICMR with a view to ensuring protection of rights, safety and wellbeing of trial subject during conduct of trials.

The SAEs reported under the trials will be reviewed by the IEC members / designated reviewers through the expedited review or in the next meeting of IEC. The Secretariat will record the final review opinion or decision in the minutes of the meeting.

18.4.3. Actions to be taken by Member Secretary:

- The Member Secretary after receipt of the SAE Report will forward it to the designated reviewer within 2 working days for review through email or in writing a letter.

- Designated reviewers will review the SAE and communicated the opinion by e-mail or telephone/written report to inform the Chairman/ Member Secretary, IEC.
- He may ask PI for further follow up information and/ or additional details on causality of the event, provision of medical treatment till SAE is resolved and financial compensation.
- The Member Secretary will ratify the designated reviewer's report along with relevant documents from PI at the next IEC meeting.
- The final review opinion of IEC will be communicated to DCGI within 30 days from the SAE report. The IEC decision will also be communicated to the PI through email.
- Compensation if applicable will be calculated as per formula specified in the New Drugs and Clinical Trial Rules, 2019 and ICMR guidelines and appropriate compensation will be given to the subject according to regulatory guidelines.

18.4.4. Actions to be taken by Chairman:

- The Chairman may suspend the membership of the concerned expert committee member, if the matter is of grave significance where integrity of IEC could be questioned about the SAE.
- The Chairman may call for a meeting of the IEC specifically to discuss this issue or the matter will be taken up for discussion.

19. POLICY OF MONITORING AND OVERSIGHT:

19.1. Purpose:

The purpose of this SOP is to provide the procedures to select a site for monitoring and how the site will be monitored.

19.2. Scope:

It covers the procedure applies to any visit and/or monitoring of any study sites as stated in the Institutional Ethics Committee (IEC) approved study protocols.

19.3. Responsibility:

The Member Secretary in consultation with Chairman will identify and designate one or more IEC members/independent monitor (along with EC members) from IEC to conduct site monitoring of the study sites of relevant projects. The Secretariat will inform the Principal Investigator in writing about the date/time of monitoring visit and request for confirmation from the Principal Investigator or Co-investigator to be available for the monitoring visit. The Identified members of IEC will declare in writing conflict of interest, if any prior to visit the site. The independent monitor (if designated) will sign a Confidentiality/ Conflict of Interest Agreement form **(Ax: 15/V06)** prior to accessing documents related to study and visiting the study site. The report should be submitted by them to IEC by 7 days in the specified visit report format **(Ax: 40/V06).**

19.4. Detailed instructions:

The monitoring will be done either as routine process (annually) at the time of approval of study depending upon the reason by the IEC members or during the ongoing approved project or for specific causes as follows –

- Large number of protocol deviations reported with repetition or unclear action taken after the Root cause analysis highlighted by the IEC secretariat.
- Serious and large number violations reported
- Large number of studies carried out at the study site or by the investigator
- Repeated SAEs
- Non-compliance of progress report by the investigator
- Higher than the proposed recruitment of subjects in the study
- Suspicious conduct
- Complaints received from participants or any other study related person
- Frequent failure by investigators to submit the required documents
- Any other cause as decided by IEC

Especially, the monitoring for vulnerable subjects will carry out twice a year.

19.4.1. Before the visit:

The Chairman / Member Secretary will designate an IEC members or appoint an Independent monitor who along with IEC members will perform the task of monitoring. The selected members or independent monitor will be provided the information with an appointment letter in this regard. The identified monitors in consultation with the Member Secretary and the Chairman will decide the agenda (as mentioned in the section no. 19.4.2.). The Secretariat will intimate in writing

about the date/time of monitoring visit and request for confirmation from the Principal Investigator or Co-investigator to be available for the monitoring visit. The secretariat will provide relevant reference material/ documents related to the project for review. The monitoring board will review the project related documents and make appropriate notes.

19.4.2. During the visit:

IEC, MGIMS will inspect the study site. Key focus areas during oversight are listed below:

- Delegation log of responsibilities of study team.
- Protocol understanding of the site team.
- Approved protocols, Informed consent, Audio-Visual recording of consent, case record forms and subject diaries and make sure that the site is using the most recent version.
- Informed consent process or audio-visual consent or audio consent process, if possible. The process of audio-visual recording of consent will be observed as per specified checklist format and guidance document **(Ax: 41/V06).**
- Randomly selected participants' files to ensure that participants are signing the correct informed consent.
- Investigational Drug accountability is adequately controlled and documented throughout the product flow at the study site (arrival, dispensing, use, return from the subject and return/destruction after the study.
- Laboratory and other facilities necessary for the study at the site.
- Source documents.
- Verify the investigator is enrolling only eligible subjects.
- Investigator's oversight adequacy.
- Availability of study specific logs and forms.
- Protocol deviation/violation (if any).
- Views of the study participants, if possible.
- SAEs are appropriately reported within the time as per the applicable regulatory requirement(s). Case record forms would be checked to review the safety data i.e. Adverse Events (AEs) and SAEs for the volume or severity of adverse events.

19.4.3. After the visit:

The IEC member/ Independent monitor will submit the completed Site Monitoring Visit Report **(Ax: 40/V06)** *to* the IEC secretariat within *7 days* of conducting a site monitoring visit.

The report should describe the findings of the monitoring visit.

On basis of the information and comments received from the IEC members/ Independent monitor, IEC will take appropriate action by voting or combination of actions, some of which are listed below, but are not limited to:

- Continuation of the project with or without changes
- Restrictions on enrolment
- Recommendations for additional training
- Recruiting additional members in the study team
- Revising the protocol or ICD or CRF / providing qualifications/ experience criteria for members of the study team, termination of the study,

- Suspending enrolment of new research participants till further review by the IEC
- Suspending all trial related procedures (except those intended for safety and wellbeing of the participant) till further review by the IEC
- Call a meeting for emergency review. (This review should be initiated within 48 working hours (2 working days) of receipt of information). This review could be done through a meeting, teleconference, email or telephonic conversation. The Member secretary will take appropriate steps to ensure that IEC members are informed about this full board meeting.
- Depending upon the complexity of the issue(s) are not within the collective expertise of all members, the Chairman/ Member Secretary on behalf of IEC will invite one or more experts. These experts could participate after they agree to the confidentiality clause and abide by the rules and regulations of IEC whose opinion would be valuable but they would not be involved in the decision making process of the Ethics committee. The expert would be requested to provide an opinion in writing within 30 working days, depending upon the gravity and seriousness of the matter. They would be designated as Subject expert during the meetings of the IEC, MGIMS.
- The Member Secretary / Secretariat will share the outcome of the visit / issues raised by the monitoring board with the concerned investigator in form of a report within 14 working days. The PI should reply within 14 working days to IEC.
- If the PI fails to comply to the requirements, IEC can take punitive action as Protocol deviation / non-compliance/violation.

20. AGENDA PREPARATION, MEETING PROCEDURES AND RECORDING OF MINUTES:

20.1. Purpose:

The purpose of this SOP is to describe the administrative process and provide instructions for the preparation agenda, invitation, distribution, review, approval, minutes and action to be taken by the IEC.

20.2. Scope:

It covers the procedures applies to administrative processes concerning the preparation of the agenda and meeting procedures for all full Board IEC meetings.

20.3. Responsibility:

It is the responsibility of the Secretariat to prepare the agenda for the IEC meeting and to ensure proper recording and dissemination of the minutes after the meeting is over. The Chairman and Member Secretary will review and approve the agenda and the minutes sent to him/her.

20.4. Detailed instructions:

20.4.1. Agenda:

It is responsibility of the IEC secretariat to prepare the agenda for IEC meeting and to ensure proper recording and dissemination of minutes after the meeting is over.

No limit is placed on the number of items on the agenda. The number of items is based on available expertise (members and consultants), urgency, order of submission to the IEC and IEC workload. In agenda will include date, venue, time and list of programme/issues to be discussed. Members interested in posting some agenda for the forthcoming meeting may send it to the office of Member Secretary one day prior to scheduled period.

Meeting venue:

Seminar Room, Department of Biochemistry, MGIMS, Sevagram is reserved for IEC meeting, unless otherwise specified. It is responsibility of coordinator to ensure the meeting room, equipment (Projector) and facilities are available in good working conditions.

20.4.2. List of proposals/notifications:

It is responsibility of IEC secretariat to prepare list of proposals/notifications for disbursement along with the study documents/protocols among the members.

20.4.3. Conduct of Meeting:

The committee would meet once in every month or whenever it is necessary. If needed where the situation is justified the meeting may be called more than once in a month. The meetings may not be held in the months of April/ May and October/ November during the vacation period.

The meeting will be held as scheduled provided. The members will gather in IEC meeting room on scheduled time. The meeting shall start with welcoming members by Chairman. The Chairman / Member Secretary shall determine the quorum is maintained. The Member Secretary will discuss the minutes of the previous meeting of IEC as well as major issues/policies discussed in minutes of the other IEC and present the agenda for the current meeting. The Secretariat will obtain the signatures of all the IEC members on the attendance register. The Member Secretary will present the agenda of the meeting for discussion. If an

IEC member has conflict of interest involving a project then he/she should declare the same, before the meeting commences and leave the meeting room before the discussion on the same. This will be recorded in the minutes. The investigator will present the study through a presentation. Those investigators who have been asked by the IEC secretariat to provide additional information or clarifications related to their project may do so in the meeting. The IEC members will discuss and clarify the comments and suggestions. The Member secretary shall record the discussions.

20.4.4. Decision Making Process:

IEC member will withdraw from the meeting for the decision procedure concerning the study where conflict of interest exists. If any IEC member has her/his own proposal for IEC review he/she will not participate in the IEC discussion or vote on that particular project. Decisions will only be made at meetings where a quorum is present. Neither PI nor any of proposed study team members participated during the decision making of the IEC. Only IEC members who attend the meeting will participate in the decision.

Types of decision:

- **Approved:** The study is approved in its present form. When committee approves the study, the certificate will be issued within a period of 15 days.
- **Approved with modifications:** This is a conditional approval. The revisions are required. If revisions are found satisfactory, approval will be granted.
- **Resubmit:** Extensive revisions are necessary. Principal Investigator has to comply with the changes suggested by IEC during the meeting. The revised project will then be reviewed in the next meeting.
- **Not approved:** The study is not approved in its current form. The required modifications will be suggested during the meeting with reasons. If the investigator wishes to appeal to the decision, he/she may do so by contacting the IEC Secretariat. The IEC may decide to accept or deny the appeal. If the appeal is denied, the IEC decision is final and the study may not be approved or resumed.
- **Defer:** The decision cannot be arrived at present and therefore postpone to next meeting. Grounds for this: lack of quorum, lack of expertise etc.

20.4.5. Preparing and recording the minutes:

- The Member Secretary will record the minutes of the meeting and disseminate the same to the members within a month of the meeting for their signed approval.
- The minutes of the IEC meeting will be ratified in the subsequent IEC meeting.
- In the record section of IEC secretariat, approved minutes will be maintained by the coordinating staff with confidentiality for a minimum period of five years both as soft and hard copies.
- The records will be maintained in such a way that it can be retrieved by tracking the records maintained in the tracking records of the minutes of the meeting.
- IEC Secretariat shall share the minutes of meeting with the authorized person when a request is made in the specified format **(Ax: 43/V06)** that is approved by the Chairman / Member Secretary.

21. CONDUCTION OF EMERGENCY MEETINGS:

21.1. Purpose:

The purpose of this SOP is to identify the administrative process for preparing for an emergency meeting and to provide instructions on the review and approval of study activities using the emergency meeting procedures.

21.2. Scope:

It covers the policies applies to emergency IEC meetings. Emergency meetings may be scheduled to approve safety / life threatening issues, SAE and other study activities that require Full Board review.

21.3. Responsibility:

It is responsibility of the Member Secretary in consultation with Chairman to call an emergency meeting. It is responsibility of the IEC secretariat to arrangement of an emergency meeting. It is responsibility of the Chairman/ Member Secretary to conduct the meeting and discuss the matter with the IEC members for the decision making.

21.4. Detailed instructions:

21.4.1. The Chairman/ Member Secretary will decide to call an emergency meeting for any one or more of the following reasons:

- Urgent issues (which, if not decided upon early could adversely affect or have adverse impact on patient safety, public safety or national economy etc.
- Occurrence of unexpected serious adverse event(s).
- A matter of life and death for the patients continuing in the trial.
- Other reasons, as deemed appropriate by the Chairman.

21.4.2. Arrangement of an emergency meeting:

- The Secretariat will endeavor to contact each and every IEC member and inform about the date, time and venue of the meeting as well as the reason for calling for the meeting. For the purpose of calling an emergency meeting, contact by telephone or email to the email address provided by the member would be considered as sufficient.
- The Secretariat will ensure the distribution of all relevant documents for which emergency meeting is scheduled. The relevant details can be sent via email.
- Emergency meetings may be arranged through teleconference or any virtual platform.
- The emails received from the members will be considered for the attendance.

21.4.3. Discussion and decision-making process:

- The Chairman / Member Secretary / Secretariat will determine the quorum is maintained as per requirement.
- The IEC members will act according to the relevant IEC SOPs (Expedited Review, SAE review, Review of Protocol deviations/violations etc.) for discussion and decision-making on the matter under consideration. The minutes of the emergency meeting would be prepared, distributed, approved and filed as described in the steps above for regular full board meeting.

22. POLICY FOR MAINTAINING OF ACTIVE PROJECTS RECORD:

22.1. Purpose:

The purpose of this SOP is to provide instructions for preparation, circulation and maintenance of active study files and other related documents approved by the IEC.

22.2. Scope:

It covers the policies applies to all active study files and their related documents that are maintained in the IEC office.

22.3. Responsibility:

It is the responsibility of IEC Secretariat to ensure that all study files are prepared, maintained, circulated and kept securely for the specified period of time under a proper system that ensures confidentiality and facilitates retrieval at any time.

22.4. Detailed instructions:

22.4.1. Organize the active study files (IEC Secretariat):

- IEC secretariat will organize the contents of the active study files and maintain the active study files.
- IEC Secretariat will maintain one original set of hard copy and soft copies (for regulatory studies and if needed non regulatory studies) in the IEC office.
- The study files will comprise all essential documents and correspondence related to the study/protocol. The study files should be established at the time of initial submission and should be assigned unique identifiers.
- IEC Secretariat shall ensure all documents related to the study file are gathered, classified and combined together appropriately.
- The Coordinator will save the submissions which will be stored separately and in the external hard disk of the office.
- The submitted hard copy protocols and the related documents will be labeled and stored in cupboard with lock and key in separate cupboard.

22.4.2. Maintain the study files (Coordinator):

- Collect and file related documents of the approved study appropriately.
- Attach an identity Label to the set of documents.
- Keep all active study documents in a secure place.
- Maintain the study files in an easily accessible, but secure place until the final report is received, reviewed and accepted by the IEC or the matter will be discussed at Full Board by IEC.
- The soft copies of active study files stored on computer which are password protected and will be accessible only to the IEC secretariat.
- The cupboard where hard copies of the active study files are kept will be kept in a lock and key and will have controlled access only to the secretariat.
- If any IEC member/non-members (auditor or other authorized person) of IEC wants to have access, they can access the project file with the help of secretariat after the permission of Chairman / Member Secretary.
- Annual subscription of appropriate anti-virus and malware protector will be availed for the soft copy submissions.

- Annual maintenance of fire proof service provider and paste control provider will be availed for the protection of hard copies.
- Send all closed study files to the archive.

23. POLICY FOR ARCHIVING AND RETRIEVING:

23.1. Purpose:

The purpose of this SOP is to define the process for Storage/archival / disposal of closed files and retrieval of documents in a secure manner while maintaining access for review by auditors, inspectors or any authorized persons.

23.2. Scope:

It covers the policies applies to archiving the study files and administrative documents that are retained for at least five years or for longer duration if specifically mandated after completion of the research/ termination of research so that the records are accessible to auditors, inspectors and other authorized persons.

23.3. Responsibility:

It is the responsibility of the IEC Secretariat to maintain closed study files and administrative documents.

23.4. Detailed instructions:

23.4.1. After receiving final or completion report and termination report of the studies (IEC Secretariat):

- Remove the contents (hard and soft copies) of the entire files from the active study cupboard to the archived study cupboard.
- All correspondence between the IEC, MGIMS and the Investigator/ Co-investigator/ Study coordinator and all other relevant records (Proposals, opinion letter, minutes of the meeting etc.) would be retained by the IEC, MGIMS for a minimum period of five years after the completion of the research so that the records will be accessible to the authorized persons.
- The cupboard where hard copies of the archived study files are kept will be kept in a lock and key and will have controlled access only to the secretariat.
- The coordinating staff will maintain the confidentiality for control and archiving of the records by signing the Confidentiality agreement. **(Ax: 42/V06)**

23.4.2. Retrieving Documents:

- The written request for retrieval can only be made request by IEC members, auditors or any authorized person in the specified format **(Ax: 43/V06)**.
- Retrieval of documents can only be done when a request is made in the request form that is approved (signed and dated) by the Chairman / Member Secretary.
- For administrative purpose, the Member Secretary can retrieve archived file(s) without having to require IEC Chairman's approval or can authorize Secretariat to retrieve any file physically. In such a situation, the register will be maintained by the IEC secretariat.
- IEC Secretariat will maintain a movement register with following information related to retrieval: File number, Name and designation of individual making a request for retrieval with his/her signature, Date of approval of request by IEC Chairman, Date and time of retrieval, Name and signature of IEC staff/ Secretariat retrieving the file, Date and time of returning the file. **(Ax: 44/V06)**

23.4.3. Disposal of documents:

- After completion of the archival period, the closed files will be shredded and disposed. However, all copies of the research projects and documents submitted to IEC review will be shredded by the authorized personnel of IEC after the IEC meeting without any notification to the Principal Investigator.

24. POLICY FOR COMPLAINT OF NEGLIGENCE BY RESEARCH PARTICIPANTS: Dealing with Participants' Requests and/or Complaints to Institutional Ethics Committee

24.1. Purpose:

The purpose of this SOP is to describe procedures for dealing with requests for information by research participants regarding their rights as a participant or to resolve their complaint/s that is/are related to their participation in research approved by the IEC.

24.2. Scope:

This SOP applies to handling of requests for information/ complaints made by participants concerning the rights and well-being of the research participants participating in research studies approved by the IEC.

24.3. Responsibility:

It is the responsibility of the IEC Secretariat and Chairman/ Member Secretary to initiate the process of giving information asked by research participants or to address any injustice that has occurred, if any complaints are received.

24.4. Detailed instructions:

- A request, complaint or query from a research participant will be accepted by the Secretariat and forwarded to the IEC Member Secretary after entering into the request record form - **Request/ Complaint Form (Ax: 45/V06).** The request / complaint form will be available at all clinical trials' sites.
- The Member Secretary may receive a request, complaint or query directly from the participant. He/she will record it in the request record form and notify the Secretariat.
- The Member Secretary will additionally ascertain details of the request/ complaint by examining any relevant documents and by interviewing the participant, if necessary. If required, the Member Secretary will call for additional relevant information and documents from the Principal Investigator (PI).
- The Secretariat will inform the Chairman about the request, query or complaint received from the research participant.
- In case of a request for additional information or clarification, the Member Secretary in consultation with the Chairman will provide the information himself / herself or will designate one or more IEC member(s) to provide such information.

24.4.1. In receiving and responding to complaints, the following guiding rights and responsibilities will shape the participants' actions:

Rights of Research Participant:

- Right to voluntary participation in research study.
- Right to have enough time to decide whether or not to be in the research study, and to make that decision without any pressure from the people who are conducting the research.
- To ask any questions you may have.

- Right to know about Institutional Ethics Committee and its responsibilities towards protecting patients' rights, safety and well-being involved in a research project and to provide public assurance of that protection
- Right to information about Research Study in an understandable language.
- Right to informed consent and if necessary audio-video consenting before participation in any Research Study.
- Right to refusal of participation or withdrawal of participation at any point in the study without disclosing any reason.
- Right to receive quality healthcare in a safe, clean environment without discrimination because of race, age, color, religion, nationality, culture, ethnicity, language, disability, sex or manner of payment.
- Right to be treated with dignity, respect and courtesy in a non-judgmental and non-threatening manner.
- Right to information regarding investigational product, duration of study, treatment option available as per standard of care, anticipated expenditure, information on medical management of any injury and compensation in case of any study related injury or death or any compensation provided for participation in an understandable language.
- Right to be informed of the risks, benefits and alternatives of proposed treatment.
- Right to privacy and confidentiality.
- Right to be informed on how to voice a complaint to express concerns, violation of your rights and/or grievance and seek redressal.
- Right to participation in research and innovative therapies.
- Right to consent for diagnostic and therapeutic procedures.
- Right to access clinical records.
- Right to get 24 hours emergency contact details of Research doctor.
- Right to get contact details of Chairman and Member Secretary of Institutional Ethics Committee.

Responsibilities of Research Participant:

- To provide correct and complete demographic information including full name, age, address, telephone number and e-mail ID (if available).
- To be compliant with research protocol and procedures.
- To ask question when he/she does not understand what the doctors, research study team, or other healthcare team members tells about diagnosis or treatment.
- Carefully weigh the risks and benefits when deciding whether to participate in the study.
- To inform your research study doctor and research study team, immediately in case of any injury or development of any new medical conditions.
- Not to take any medications without the knowledge of research doctor and research study team.
- To disclose to doctors and research study team if currently part of any other Clinical Trial or had participated in any other Clinical Trial in last one year.
- Provide complete and accurate information about your health including your previous medical history, and all the medications that you are presently taking including alternative treatments like Ayurveda, Homoeopathy, Unani or herbal

medications, all records of previous investigations and treatment and of allergic reactions, especially sensitivity to any drug.

- To follow instructions, advice and restrictions regarding treatment plan and visit schedules.
- To treat hospital staff and study team with courtesy.

24.4.2. In case of a complaint received from a research participant:

- The Member Secretary, in consultation with the Chairman will initiate a process to address any injustice that may have occurred. Depending on the seriousness of the matter, the Chairman will direct the Member Secretary to:
- Appoint a subcommittee of two or more IEC members for enquiry in order to resolve the matter.
- Call an emergency meeting of two or more IEC members for discussion or
- Consider the matter for discussion at the next full board meeting
- The Chairman/ Member Secretary/ designated IEC members will assess the situation and mediate a dialogue between the research participant and PI in an attempt to resolve the matter.
- The IEC will insist on factual details to determine gap, if any, between truth and individual perception.
- The final decision will be taken by the Member Secretary in consultation with the Chairman based on the recommendation of any one of the above and it will be informed to the research participant and the PI by the Secretariat.
- The information including any action taken or follow-up and final decision will be recorded in the form and the form is signed and dated.
- The IEC members will be informed about the action taken and the outcomes in the forthcoming IEC meeting (in case of requests/ complaints not discussed in full board meeting) and minuted.
- The Secretariat will place all documents in the relevant study file.

25. POLICY FOR WAIVER OF WRITTEN INFORMED CONSENT:

25.1. Purpose:

The purpose of this SOP is to describe the type of research projects for which the IEC may grant waiver for requirement of obtaining written informed consent.

25.2. Scope:

It covers the policies applies to all protocols with a request of granting consent waiver submitted for review by the IEC.

25.3. Responsibility:

It is the responsibility of the IEC Secretariat to manage waiver of consent application form **(Ax: 46/V06)**. The Member Secretary/ Chairman/ IEC members will review and take a decision regarding the waiver of consent application. It is responsibility of the secretariat to communicate the decision to the investigator.

25.4. Detailed instructions:

- The IEC may grant waiver for requirement of obtaining written informed consent for requesting waiver of consent by the investigators through expedited review or in full board meeting.
- When a request for waiver of consent is submitted by the Principal Investigator to the IEC secretariat, the Secretariat will verify the application and the relevant documents and forward the package to the Member Secretary / Chairman.
- The IEC will review the request taking into consideration the types of studies for which waiver of consent may be granted as mentioned in the criteria.
- The IEC will ensure that there are adequate mechanisms described in the protocol for protection of the identity of the research participants and maintaining confidentiality of the study data. This is necessary as the participant cannot be assured directly about confidentiality of health data through a formal informed consent process, when consent waiver is granted.
- The IEC will convey the decision regarding approval/disapproval of waiver to the principal investigator in writing. If the waiver is not granted, the IEC will provide reasons for the same.
- The decision whether to grant the waiver is taken and will be inform in the upcoming full board meeting.

26. RESEARCH INVOLVING POTENTIALLY VULNERABLE GROUPS:

26.1. Purpose:

The purpose of this SOP is to describe the requirements concerning review of research that involves groups that could be potentially vulnerable to coercion in regard to autonomy and present conditions that may affect risk/benefit determinations or bearing unequal burden in research.

26.2. Scope:

It covers the policies and procedures applies to all research dealing with vulnerable population.

26.3. Responsibility:

IEC members are responsible for receiving, verifying and reviewing the research protocols pertaining to vulnerable populations. The Chairman/ Member Secretary may assign appropriate primary reviewers who have thorough understanding of the ethical review process with appropriate expertise to conduct the reviews of such research as per Risk benefit assessment tool and checklist **(Ax: 47/V06).**

26.4. Detailed instructions:

26.4.1. Policies for reviewing the protocol with vulnerable population:

Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests. Individuals whose willingness to volunteer in a research study may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate may also be considered vulnerable. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable persons include patients with incurable diseases, people in nursing homes, unemployed or impoverished people, patients in emergency situations, ethnic minority groups, homeless people, nomads, refugees, minors, and those incapable of giving consent. This list may not be exhaustive as there may be circumstances in which other groups are considered vulnerable, women for example, in an orthodox patriarchal society.

The protocol should be reviewed keeping in mind the following points when it concerns research that involves groups that could be potentially vulnerable to coercion

- Measure to protect autonomy,
- Risk/benefit determinations with respect to the vulnerability
- Bearing unequal burden in research.

Any member of the IEC or Secretariat who would be dealing with such protocols should be well versed with the potential harm or risk of such population

participating in the study. The checklist for different vulnerable population is being provided in **(Ax: 48/V06 to Ax: 55/V06)**. Special justification is required for inviting vulnerable individuals to serve as research participants and, if they are selected, the means of protecting their rights and welfare must be strictly applied.

26.4.2. The Chairman / Member Secretary may appoint two or more members of the IEC who have a thorough understanding of the ethical review process and experience in the field of research to review such type of protocols. The reviewers should be familiar in the concept of vulnerability and protections for participants with diminished autonomy.

IEC Secretariat will:

- IEC Secretariat will provide a suitable checklist according to the participants to be recruited in study to the investigator. Inform the investigator to download the appropriate application form and informed consent document/ assent form. If the checklists are not available (for e.g. critically/terminally ill or socially/economically disadvantaged/HIV/Leprosy patients/marginalized population) the investigators want to include the above-mentioned population in the study. They have to mention in the protocol details regarding justification of including the vulnerable population for the study, risk and benefits to the study participants along with mechanism of minimizing risks, measures to protect their autonomy, measures for recruitment of such participants along with measures taken for protection of privacy and confidentiality.
- IEC can recommend for written / verbal Informed consent /audio–visual consent /audio consent (leprosy patients) in the vulnerable population. All the protocol dealing with vulnerable population will be considered for full board review.
- IEC Secretariat will provide appropriate reference material or help reviewer to locate such material related to vulnerable populations when specifically requested for, by a reviewing member.

26.4.3. Review the protocol:

- IEC Members will review the protocol and the informed consent document or assent form.
- The Member Secretary will confirm that the IEC recommendations have been incorporated in the revised protocol and in the final draft of informed consent document or assent form.

26.4.4. Approval:

- The protocol will be approved by the IEC with the appropriate checklist as given in **(Ax: 48/V06 to Ax: 55/V06)**.
- Wherever necessary the IEC approval should state that if in future the vulnerability status of the participants changes for e.g.; unconscious patient gaining consciousness, then the protocol and ICD should be amended and resubmitted to the IEC for reconsideration and approval following which the participant should be re-consented and reconsidered for the same.

27. POLICY OF COMMUNICATIONS WITH DIFFERENT STAKEHOLDERS:

27.1. Purpose:

This SOP defines IEC communication with different stakeholder as per regulatory mandate and specifications.

27.2. Scope:

It covers the policies applies to all different stakeholders regarding the IEC activities and functioning.

27.3. Responsibility:

The Chairman, Member Secretary, IEC Secretariat and all stakeholders are responsible for IEC activities and functioning as per regulatory mandate**.**

27.4. Detailed instructions:

IEC communicates with following mentioned stakeholders as per regulatory mandate and specifications:

27.4.1. Principal Investigator or Co-investigator /Study team designee:

IEC writes or e-mails to Principal Investigator regarding following mentioned communications but not limited to, whenever deemed necessary.

- Study Project Initial Dossier and Amendments, Approval/Dis-Approval letter/ Query Letters
- Reply to Serious Adverse Event notification
- Opinion on EC analysis and compensation of Study injury/Death
- Response to Protocol deviation/Violation/Waiver
- Response to Continue review/study completion report
- Study termination letter.
- Dealing with appeal / complaint made by investigators against IEC members.

However, Investigators will be held responsible for specific activities:

Responsibilities of Investigators:

The investigators need to be submitted all proposals of funded and non-funded studies i.e. Clinical research, research projects involving human subjects, PG dissertation or research, UG research, ICMR STS, MUHS STRG and any other research studies to IEC for the review before commencing the study.

Investigators should follow documented procedure i.e. Standard Operating Procedures (SOPs) of IEC in compliance with the regulation and the approved protocol or informed consent, safety reporting management, delegation of responsibilities and training, investigational product, clinical trial documentation, record retention, archival and destruction.

- The investigator should ensure the ethical concerns in the protocol in compliance with regulatory rules and regulations, wherein following aspects can be included in the section of ethical consideration
  - It should declare that the study will be conducted in adherence to relevant national / international guidelines.
  - Policy regarding autonomy (right to withdraw)
  - Confidentiality
  - Recruitment and Selection of participants must be equitable (fair or just)

within the confines of the study. Researchers may not exclude participants on the basis of gender, race, national origin, religion, creed, education, or socioeconomic status. The benefits and burdens of research must be fairly distributed. The Principal Investigator shall submit the details of participants to the IEC in the format **(Ax: 56/V06).**

- Process of obtaining informed consent
- Protection of vulnerable subjects
- Policy regarding treatment of study related injury, compensation for study related injury and participation.
- Dissemination of data and Publication

An investigator may be invited telephonically/ through written communication in the IEC meeting to discuss for amended protocol, SAEs, serious deviations/violations or any study related issues.

- It is mandatory for the investigators to submit the following documents to the IEC, MGIMS
  - A report on the performance of the research on an annual basis and a copy of final report.
  - Each serious adverse event in MGIMS and in other centers, where the study is being implemented along with DSMB report and also if there is report received from CRO/ Audit reports from concerned authorities in case so as to ensure the reporting of the same to DCGI within stipulated time frame prescribed in the notification (vide Indian Gazette).
  - All amendments or revisions in the study protocol.
  - Protocol deviation / non-compliance/ violation
  - Study completion or discontinuation reports.
  - Justification to restart a study discontinued earlier.
- **Good Clinical Practice (GCP)**:
  Investigators should have knowledge about clinical trial process, ethical issue and applicable rules and regulation ensuring data integrity and protection of subject rights, safety and wellbeing. Investigators should be GCP trained regularly at the interval of three years and GCP training certificate should be provided to the IEC at the time of initial submission.
- **SOPs of IECs:**
  Investigators should follow documented procedure i.e. Standard Operating Procedures (SOPs) of IEC in compliance with the regulation and the approved protocol or informed consent, safety reporting management, delegation of responsibilities and training, investigational product, clinical trial documentation, record retention, archival and destruction.
- **Investigators site specific SOPs:**
  Investigator should prepare site specific for the regulatory studies which should cover the following elements related to the conduct of the clinical trial.
  - Updated investigators Brochure and clinical trial oversight plan
  - Work delegation log signed by the PI
  - SOP/Policy document to ensure continuity of trial in case of staff and investigator attrition
  - Clinical trial site shall have a policy of investigators handling over the trial where the Principal investigator and study team members will be

responsible for the trial related activities. In case of absence of PI, another investigator shall take over the charge of trial until such time who shall be authorized person from the site shall communicate with the sponsor and ethics committee, if needed. There should be eligible and adequate research staff to ensure that recruited subjects' rights safety and wellbeing is not compromised.

- If any Principal Investigator is retired / promoted / transferred / suspended / intended to leave the institute then, either he/she should authorize any eligible study team member, or Co-PI or Co-I can take responsibility of PI with permission from IEC in advance. If Co-PI or Co-I is not there or not eligible, then institutional head in consultation with concerned departmental head can appoint any eligible member as a PI.
- **Periodic Update report by the PI:**
  Progress of all the CT research proposals will be followed (via periodic reports from PI) at regular intervals of 6 months for long duration studies i.e. studies more than 1 year and at regular intervals of 3 months for short duration studies i.e. studies less than 1 year as per format **(Ax: 32/V06)**. But, in special situations IEC, MGIMS will ask for follow up report from PI at shorter intervals based on the need, nature and events of research project. Approval, therefore for long term studies will be valid for 1 year. Renewed approval will be issued on yearly basis after the progress of the study is submitted to IEC, MGIMS by the PI. If the Principal Investigator fails to submit the periodic update report within one month of the due date unless specified otherwise, the IEC secretariat will send a reminder. If there is no response within 15 days after the date of reminder, the IEC secretariat will put up the matter for discussion in the next full board meeting for appropriate action which may consist of but not limited to:
  - A letter of reprimanding the Investigator
  - Suspending review of projects for a specified time.
  - A letter asking the Investigator to put recruitment of new participants on hold.

  The final closure report should be received by the PI as per format **(Ax: 33/V06)**.
- **It is mandatory for the PI to constitute Data safety management board (DSMB) to monitor any adverse events in the course of the study and to get clearance form DSMB for continuation of the study, which must be submitted along with adverse event report.** The DSMB should have multidisciplinary representation, including physicians from relevant medical specialties, biostatistician and may also include other experts such as epidemiologists, pharmacologist. The DSMB should have membership limited to individuals free of apparent significant conflicts of interest, whether they are financial, intellectual, professional, or regulatory in nature. The appropriate size depends on the type of study and types of expertise needed.
- **Management of complaints by investigators:**
  For dealing the complaints from investigators against IEC members, it is the responsibility of the IEC to adhere to the principals of fairness, confidentiality, integrity and prevention of detriment while addressing appeal/ investigating

the complaints by investigators. The Member Secretary in consultation with the Chairman to initiate a process to give information to the participants or to identify and address any injustice that has occurred if complaints are received from investigators. The Chairman/ Member Secretary may decide to provide the information himself/herself or may designate one or more IEC member to provide such information. They will assess the situation and mediate a dialogue between the investigator and members against whom complaint is lodged in an attempt to reach the amicable solution. The IEC will insist on factual details to determine gap, if any, between truth and individual perception. If the mutual agreement regarding workable solution is reached, the matter will be considered as resolved. If there is no mutual agreement and matter is not resolved, a meeting will be called as soon as possible of Head of the institution (if necessary) / Chairman / Member secretary and / or IEC member and the concerned investigator/s to resolve the matter.

27.4.2. DCGI:

IEC writes to DCGI or emails regarding following mentioned communications but not limited to, whenever deemed necessary

- Opinion on SAE Analysis and Compensation of Study injury/death if applicable
- Study Termination letter
- Issues with Investigators or different stake holders involved
- Recommendations on DCGI Approved and other studies (If necessary)
- Ethics Committee Registration Communications

27.4.3. Dean of the Institute:

IEC writes to Dean or emails regarding following mentioned communications but not limited to, whenever deemed necessary.

- Annual reports of IEC.
- Sharing amended SOP for final acceptance.
- Any issues in IEC functioning
- IEC Requirements

27.4.4. Sponsor:

IEC writes to Sponsor or emails regarding following mentioned communications but not limited to, whenever deemed necessary.

- Response to any queries raised.
- Confirmation of free medical management and compensation in applicable cases (If deemed necessary).

27.4.5. Study Participants:

IEC writes to study participants or emails regarding following mentioned communications but not limited to, whenever deemed necessary.

- Reply for complaints
- Reply if any information requested to IEC Office

28. POLICY FOR REVIEW OF STUDY PROPOSALS DURING THE EPIDEMICS / LOCKDOWN:

28.1. Purpose:

The purpose of this SOP is to describe how the EC will function and conduct ethics review in an emergency situation with restrictions as imposed by social distancing requirements during the epidemics or lockdown.

28.2. Scope:

It covers the procedures applies to review of all protocols submitted during the epidemics or lockdown.

28.3. Responsibility:

IEC Chairman / Member Secretary is responsible to ascertain epidemics/ periods of lockdown and is follow the procedure of submission, review and decision conveying according to the conditions. It is responsibility of the IEC Secretariat or Member Secretary to receive the submission package (hard and soft copies), ensure complete documentation and record receipt of the package. The Member Secretary shall categorize the research into full review, expedited review or exemption from review and identify need for review by experts/ independent consultants/ patient /others, designate reviewers or in the full board meeting.

28.4. Detailed instructions:

Any announcement by college, hospital or government Authorities restricting movements of individuals for certain duration. Emergency virtual (online) IEC meetings will be conducted during epidemics / lockdown period. IEC Secretariat shall manage the protocol submissions to the IEC during periods of lockdown/ epidemics.

28.4.1. Meeting procedures:

- The IEC Secretariat and Member Secretary in consultation with Chairman will schedule a virtual meeting and decide the agenda.
- The Secretariat will intimate in writing about the date/time of meeting and invite the members and investigators / researchers for the meeting.
- The Chairman shall open the meeting and determine the quorum. The members of IEC will declare in writing conflict of interest, if any prior to discussion.
- The investigator or representative shall present the research virtually through a brief PowerPoint Presentation (PPT). The designated Subject expert (if any) would be requested to provide opinion on the proposal.
- The IEC members and Primary reviewers (if designated) will discuss and reach consensus to decision-making.
- In case, if Chairman deemed necessary, the secretariat will share entire documents with the IEC members through email for review. The IEC members / subject experts (if appointed) will share their decision or queries (if any), on the research proposals. If any queries raised by the members, IEC secretariat will convey the same to the investigators for rectification / revised submission. The concerned investigator will replied with rectification / revised submission through email similarly. IEC will not come to the decision unless the reviewer ratify the revised submission. IEC Secretariat will preserve the emails for record in the files.

- The Member Secretary / Secretariat will record the decision in the minutes of the meeting.

28.4.2. Post meeting activities:

- The secretariat will communicate the decision to the Principal Investigator within 14 days and maintain the record.
- The decision about the follow-up / Monitoring / Analysis of SAE/ handling of issues related to non-compliance, violation, complaints will be taken by the Member Secretary in consultation with Chairman.

REFERENCES:

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2. Indian Council of Medical Research. *National Ethical Guidelines for Biomedical and Health Research Involving Human Participants.* New Delhi; 2017. https://icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf. Accessed 19 July 2019.
3. Good Clinical Practices for Clinical Research in India, CDSCO, http://cdsco.nic.in
4. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), INTEGRATED ADDENDUM TO ICH E6 (R1): GUIDELINE FOR GOOD CLINICAL PRACTICE E6 (R2) [updated 2016 Nov 9; cited 2019 June5] Available from https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4_2016_1109.pdf.
5. New Drugs and Clinical Trials Rules 2019: Changes in responsibilities of the ethics committee http://www.picronline.org Accessed on Saturday, December 28, 2020, IP: 14.139.127.194)
6. Forum for ethical review committees in the Asian and Western Pacific Region http://www.fercap-sidcer.org/selftool.php
7. R4-RA Clinical trial - http://www.r4ra-nihr.whri.qmul.ac.uk/feedback.php
8. National Institute of Allergy and Infectious Diseases https://clinregs.niaid.nih.gov/country/india#ethics_committee
9. Clinical Trials Toolkit India https://cdsatoolkit.thsti.in/route-map-2/
10. ICMR Bioethics unit https://ethics.ncdirindia.org/Tools_and_Instruments.aspx
11. WHO Operating Guidelines for Ethical Review Board that Review Biomedical Research (2000), https://www.who.int/tdr/publications/documents/ethics.pdf
12. Declaration of Helsinki and the prevailing amendments from time to time (https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/)
13. Amendments from CDSCO office https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/clinical-trials/
14. National Guidelines for Ethics Committees Reviewing Biomedical & Health Research During Covid-19 Pandemic from https://ethics.ncdirindia.org//asset/pdf/EC_Guidance_COVID19.pdf

LIST OF ANNEXURES:

1. Authorization letter by the Head of Institute - **Ax:01/V06**
2. Consent letter for membership - **Ax:02/V06**
3. Appointment letter - **Ax:03/V06**
4. Confidentiality agreement for IEC members - **Ax:04/V06**
5. Work delegation log of EC - **Ax:05/V06**
6. Working rules for the Coordinating staff of IEC secretariat - **Ax:06/V06**
7. Tracking record format for retrieval of project status - **Ax:07/V06**
8. Self evaluation form of Chairman - **Ax:08/V06**
9. Self evaluation form of Members - **Ax:09/V06**
10. Self evaluation form of Coordinator - **Ax:10/V06**
11. Corrective Action and Preventive Action - **Ax:11/V06**
12. Conflict of Interest Agreement for IEC members - **Ax:12/V06**
13. Conflict of Interest form for declaring conflicts during IEC meetings - **Ax:13/V06**
14. Confidentiality /Conflict of Interest Agreement for guest or observer - **Ax:14/V06**
15. Confidentiality /Conflict of Interest Agreement for subject expert - **Ax:15/V06**
16. Study Assessment Form for subject experts - **Ax:16/V06**
17. IEC Checklist for all research studies - **Ax:17/V06**
18. IEC application for Initial review - **Ax:18/V06**
19. IEC application for clinical trials, bioequivalence, bioavailability studies - **Ax:19/V06**
20. IEC application for Human Genetics Testing Research study proposals - **Ax:20/V06**
21. IEC application for Socio-behavioral and Public Health research study proposals - **Ax:21/V06**
22. Delegation of responsibilities of study team - **Ax:22/V06**
23. Patient Information Sheet & Informed Consent Document - **Ax:23/V06**
24. Assent Form - **Ax:24/V06**
25. Checklist for reviewing protocol by EC members - **Ax:25/V06**
26. Checklist for reviewing ICD by EC members - **Ax:26/V06**
27. Patient feedback form - **Ax:27/V06**
28. Checklist for CTA and clinical trial budget - **Ax:28/V06**
29. Application for Expedited review - **Ax:29/V06**
30. Application for Exemption from review - **Ax:30/V06**
31. Protocol / related amendment request form - **Ax:31/V06**
32. Periodic review report / study progress report - **Ax:32/V06**
33. Study completion/closure report - **Ax:33/V06**
34. IEC approval letter for clinical trials, bioequivalence, bioavailability - **Ax:34/V06**
35. IEC approval letter for biomedical and health research or any other research - **Ax:35/V06**
36. Premature termination report - **Ax:36/V06**
37. Protocol deviation / violation report - **Ax:37/V06**
38. SAE submission report for clinical trials or bioavailability or bioequivalence study - **Ax:38/V06**
39. SAE submission report for biomedical and health research - **Ax:39/V06**
40. Site monitoring report - **Ax:40/V06**
41. Checklist for Monitoring of Audiovisual recording of AV consent Process and Guidance document - **Ax:41/V06**
42. Confidentiality agreement by EC coordinator - **Ax:42/V06**
43. Document retrieval request form - **Ax:43/V06**

44. Movement register for retrieval of documents - **Ax:44/V06**
45. Request complaint form by participant - **Ax:45/V06**
46. Application for waiver of consent - **Ax:46/V06**
47. Risk and benefit assessment tool and checklist - **Ax:47/V06**
48. Checklist- Requirements for Research Involving Children - **Ax:48/V06**
49. Checklist- Requirements for Research Involving Pregnant Women & Fetuses - **Ax:49/V06**
50. Checklist- Research Involving Cognitively Impaired Adults - **Ax:50/V06**
51. Checklist- Research Involving Students, Employees or Residents - **Ax:51/V06**
52. Checklist- Considerations for Genetic Research - **Ax:52/V06**
53. Checklist- Requirements for Research involving terminally ill patients - **Ax:53/V06**
54. Checklist- Considerations for Research in HIV participant - **Ax:54/V06**
55. Checklist- Requirements for Research involving economically/socially backward/illiterate patients - **Ax:55/V06**
56. Selection of equitable participants - **Ax:56/V06**

Dr. Nitin M. Gangane
MD, DNB, FUICC, FICP, FAMS, PhD
DEAN

MAHATMA GANDHI INSTITUTE OF MEDICAL SCIENCES

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Ax: 01/V06

TO WHOM SO EVER IT MAY CONCERN

This is to confirm that I have authorized the reformation of an **Institutional Ethics Committee (IEC)** for three years **from 11/07/2019 to 10/07/2022** which will function independently at Mahatma Gandhi Institute of Medical Sciences with respect to decision making and its working in order to provide public assurance of protection, by, among other things, reviewing and approving the clinical trial protocols, bioavailability and bioequivalence studies, Biomedical and Health Research projects and academic research, the suitability of the investigator(s), facilities and the methods and material to conduct clinical research at our site.

The IEC shall adhere to existing applicable rules & regulation for its formation and functioning which includes the registration of IECs, criteria for selection, tenure, resignation, schedule of meeting, reporting to regulatory authority and other administrative process. The IEC at present follow International Conference on Harmonisation – Good Clinical Practices (ICH-GCP) Guidelines E6 (R2), Indian GCP guidelines (Access time 2003), New Drugs and Clinical Trials Rules, 2019 (NDCTR-2019), Declaration of Helsinki, Ethical Guidelines for Biomedical Research on Human Participants by ICMR (2017), National Guidelines for Ethics Committees Reviewing Biomedical & Health Research During Covid-19 Pandemic by ICMR (April 2020) and the prevailing amendments from time to time. The Committees will consist of members who collectively have the qualifications and experience to review and evaluate the scientific, medical and ethical aspects of a proposed research project.

In addition to this, the institute will provide all support to the ethics committee activities which including training, resources and infrastructure at the same time.

Date of formation of Ethics Committee:	20th April 2013
Name of Ethics Committee:	Institutional Ethics Committee
Address of office of Ethics Committee:	Mahatma Gandhi Institute of Medical Sciences, Sevagram - 442102, District-Wardha, Maharashtra, India. Telephone – +91 7152 - 284341-355 Ext. 266 Fax - +91 7152 - 284333 E-mail – iec@mgims.ac.in
Details of Registration:	Reg. No. ECR/47/Inst/MH/2013/RR-19 (Under New Drugs and Clinical Trials Rules, 2019) File. No. EC/NEW/INST/2020/490 (Prov.) (Department of Health Research)
NABH Accreditation:	Certificate no. EC-CT-2021-0168

Signature:
Name: **Dr. Nitin M. Gangane**
Designation: **Dean**
Seal: DEAN Mahatma Gandhi Institute of Medical Sciences, SEVAGRAM
Date: **17 November 2021**

CONSENT LETTER FOR EC MEMBERSHIP

From,

…….

…….

…….

To

The Dean
MGIMS,
Sevagram

Subject: Consent to be a member of Institutional Ethics Committee (IEC), MGIMS

Ref: Your Letter No: ……dated: ……

Respected Sir,

In response to your letter stated above, I give my consent to become a member of IEC, MGIMS.
I shall regularly participate in the IEC meeting to review and give my unbiased opinion regarding the ethical issues.
I shall not keep any literature or study related document with me after the discussion and final review.
I shall maintain all the research project related information confidential and shall not reveal the same to anyone other than project related personnel.
I herewith enclose my CV.

Thanking you,

Yours sincerely,

Date:

(Name of the Member & Signature)

Address, E-mail & Contact details:

…….

…….

…….

…….

APPOINTMENT LETTER

Date:

To

……..
……..
……..
……..

Subject: Letter of Appointment

Dear ……..,

I am pleased to appoint you as …….. of the Institutional Ethics Committee (IEC) for research on human subjects, Mahatma Gandhi Institute of Medical Sciences, Sevagram. for a term of three years from …… to …… following Standard Operating Procedures (SOPs) of IEC, MGIMS, after which renewal of your appointment will be by consensus. Terms & Conditions regarding the resignation and replacement procedures may be found in the SOPs.

During this tenure, you should be aware of the role as a member of the IEC and follow significant responsibility as given (PTO).

In accordance with the declaration confidentiality agreement, you are requested to sign the agreement between you and the IEC regarding meeting deliberations, information on research participants & related matters.

We look forward for your active participation in functioning of this Committee as per the guidelines of National Regulatory Body DCG(I), ICMR and as well MUHS, Nashik.

I appreciate your kind acknowledgement at the earliest.

With best regards,

Dr. ……..
Dean

Enclosure: Responsibilities of member

RESPONSIBILITY OF CHAIRPERSON:

- Conduct committee meetings and will lead all discussions and deliberations pertinent to the review of research proposals.
- Supervise conduct of all meetings
- Sign documents and communications related to IEC functioning.
- Appoint the SOP team to formulate the SOPs of IEC
- Help to reach consensus in decision-making process.
- The chairperson can take final call for any protocol
- The Chairperson can terminate any study that the IEC has previously approved when the safety or benefit of the study participants is doubtful or at risk, also to review the termination suggested by IEC members, PI, Sponsor or other authorized bodies.
- Endorse the subject experts nominated by IEC and appoint them.
- Monitor Serious Adverse Event reports and recommend appropriate action(s)
- Review the progress reports and monitor ongoing studies.
- Maintain confidentiality of the documents and deliberations of IEC meetings.
- Declare any conflict of interest, if any.
- Participate in continuing education activities in biomedical ethics and biomedical research.
- Provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat
- Provide an updated CV when requested for by the IEC secretariat
- In case of anticipated absence, the Chairperson will nominate a committee member as Acting Chairperson.

RESPONSIBILITY OF MEMBER SECRETARY:

- Coordinate all meetings after consultation with Chairperson
- Identify the need for new or amended SOP and formulate the SOPs of IEC
- Organize the preparations, review, revision and distribution of SOPs and guidelines.
- Ensure adherence of IEC functioning as per SOPs.
- Prepare agenda of the meeting and minutes of the meeting
- Accept research study / project proposals.
- Usually delegated signatory by Chairperson
- Overall administration of Ethics Committee and IEC secretariat
- From within the institute for better facilitation
- Sign documents and communications related to IEC functioning.
- Communicate with the IEC members and applicants/ investigators.
- Notify the Principal Investigator regarding IEC decisions related to the submitted research proposal.
- Arrange for training of personnel and IEC members.
- Provide necessary administrative support for IEC related activities to the Chairperson.
- Provide updates on relevant and contemporary issues to ethics in health research as well as relevant contemporary literature to the committee members.
- The Member Secretary will be the guardian of all documents, record and funds in the possession of the committee.
- Monitor Serious Adverse Event reports and recommend appropriate action(s)
- Review the progress reports and monitor ongoing studies.
- Maintain confidentiality of the documents and deliberations of IEC meetings.
- Declare any conflict of interest, if any.
- Participate in continuing education activities in biomedical ethics and biomedical research.
- Provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat
- Provide an updated CV when requested for by the IEC secretariat

RESPONSIBILITY OF JOINT SECRETARY:

- Coordinate all meetings after consultation with Chairperson
- Identify the need for new or amended SOP and formulate the SOPs of IEC
- Organize the preparations, review, revision and distribution of SOPs and guidelines.
- Ensure adherence of IEC functioning as per SOPs.
- Prepare agenda of the meeting and minutes of the meeting
- Accept research study / project proposals.
- Usually delegated signatory by Chairperson
- Overall administration of Ethics Committee and IEC secretariat
- From within the institute for better facilitation
- Sign documents and communications related to IEC functioning.
- Communicate with the IEC members and applicants/ investigators.
- Notify the Principal Investigator regarding IEC decisions related to the submitted research proposal.
- Arrange for training of personnel and IEC members.
- Provide necessary administrative support for IEC related activities to the Chairperson.
- Provide updates on relevant and contemporary issues to ethics in health research as well as relevant contemporary literature to the committee members.
- The Member Secretary will be the guardian of all documents, record and funds in the possession of the committee.
- Monitor Serious Adverse Event reports and recommend appropriate action(s)
- Review the progress reports and monitor ongoing studies.
- Maintain confidentiality of the documents and deliberations of IEC meetings.
- Declare any conflict of interest, if any.
- Participate in continuing education activities in biomedical ethics and biomedical research.
- Provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat
- Provide an updated CV when requested for by the IEC secretariat

Note: The Joint Secretary will aforementioned work in absence of Member Secretary in consultation with the Chairperson and prior intimation to Member Secretary.

RESPONSIBILITY OF CLINICIAN:

- Attend IEC meetings and participate in discussions and deliberations for appropriate decisions.
- Help to maintain quorum
- Review, discuss and consider research proposals submitted for evaluation.
- Provide medical inputs on protocol, Informed consent forms and other aspects like:
  - standard of care,
  - Placebo use,
  - Sample size,
  - Dosing,
  - Concomitant medications,
  - Prohibited medications,
  - risk & benefit to patients,
  - Age group,
  - Me too trial
  - Inclusion / exclusion criteria
- Take clinical judgement for the trial
- Monitor Serious Adverse Event reports and recommend appropriate action(s)
- Review the progress reports and monitor ongoing studies.
- Maintain confidentiality of the documents and deliberations of IEC meetings.
- Declare any conflict of interest, if any.
- Participate in continuing education activities in biomedical ethics and biomedical research.
- Provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat
- Provide an updated CV when requested for by the IEC secretariat
- Carry out the work delegated by Chairperson and Member Secretary
- Assist the Chairperson and Member Secretary in carrying out IEC work as per SOP

RESPONSIBILITY OF BASIC MEDICAL SCIENTIST:

- Attend IEC meetings and participate in discussions and deliberations for appropriate decisions.
- Help to maintain quorum
- Review, discuss and consider research proposals submitted for evaluation.
- To provide scientist aspects of the study:
  - Investigator's brochure,
  - Safety of drug,
  - Pharmacodynamics and pharmacokinetics of drug,
  - Lab procedures,
  - Study design,
  - Sample size,
  - Use of biological samples,
- To see:
  - Preclinical data and whether protocol adequately addresses issue of all this matter or not,
  - Qualification of PI and GCP training certificate,
  - Details of SAEs and reporting time limit from PI,
  - All ethics issues and other procedures involved in the study
- Review the progress reports and monitor ongoing studies.
- Maintain confidentiality of the documents and deliberations of IEC meetings.
- Declare any conflict of interest, if any.
- Participate in continuing education activities in biomedical ethics and biomedical research.
- Provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat
- Provide an updated CV when requested for by the IEC secretariat
- Carry out the work delegated by Chairperson and Member Secretary
- Assist the Chairperson and Member Secretary in carrying out IEC work as per SOP

RESPONSIBILITY OF LEGAL EXPERT:

- Attend IEC meetings and participate in discussions and deliberations for appropriate decisions.
- Help to maintain quorum
- Review, discuss and consider research proposals submitted for evaluation
- Review Clinical Trial Agreement (CTA): Parties involved, Scope of agreement, Responsibilities of parties and payment details
- Review Seven incidence of SAE included or not, Adequacy of amount
- See whether any clause is violating the norm, Confidentiality, dispute resolution, Updated with regulatory requirements and interpretation of the same,
- Insurance policy: It should cover the participants for injury due to all clauses mentioned in Rule 122DAB, Validity, Countries for which the policy provides cover and Liability limit – per person and total
- Indemnity: It should Covers the liability of investigator and sponsor and Could be part of CTA or separate document
- See informed consent document
- Review the progress reports and monitor ongoing studies.
- Maintain confidentiality of the documents and deliberations of IEC meetings.
- Declare any conflict of interest, if any.
- Participate in continuing education activities in biomedical ethics and biomedical research.
- Provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat
- Provide an updated CV when requested for by the IEC secretariat
- Carry out the work delegated by Chairperson and Member Secretary
- Assist the Chairperson and Member Secretary in carrying out IEC work as per SOP

RESPONSIBILITY OF SOCIAL SCIENTIST / NGO REPRESENTATIVE:

- Attend IEC meetings and participate in discussions and deliberations for appropriate decisions.
- Help to maintain quorum
- Review, discuss and consider research proposals submitted for evaluation
- To see:
  - Community perspective,
  - Informed consent process,
  - Compensation,
  - Design of trial whether it is discomfort to subjects,
  - Number of blood samples,
  - Post-trial access to involved community,
  - Confidentiality,
  - Vulnerable population,
  - Recruitment process.
- Review the progress reports and monitor ongoing studies.
- Maintain confidentiality of the documents and deliberations of IEC meetings.
- Declare any conflict of interest, if any.
- Participate in continuing education activities in biomedical ethics and biomedical research.
- Provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat
- Provide an updated CV when requested for by the IEC secretariat
- Carry out the work delegated by Chairperson and Member Secretary
- Assist the Chairperson and Member Secretary in carrying out IEC work as per SOP

RESPONSIBILITY OF SCIENTIFIC MEMBER:

- Attend IEC meetings and participate in discussions and deliberations for appropriate decisions.
- Help to maintain quorum
- Review, discuss and consider research proposals submitted for evaluation
- To see:
  - Community perspective,
  - Informed consent process,
  - Compensation,
  - Design of trial whether it is discomfort to subjects,
  - Number of blood samples,
  - Post-trial access to involved community,
  - Confidentiality,
  - Vulnerable population,
  - Recruitment process.
- Review the progress reports and monitor ongoing studies.
- Maintain confidentiality of the documents and deliberations of IEC meetings.
- Declare any conflict of interest, if any.
- Participate in continuing education activities in biomedical ethics and biomedical research.
- Provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat
- Provide an updated CV when requested for by the IEC secretariat
- Carry out the work delegated by Chairperson and Member Secretary
- Assist the Chairperson and Member Secretary in carrying out IEC work as per SOP

RESPONSIBILITY OF LAYPERSON:

- Attend IEC meetings and participate in discussions and deliberations for appropriate decisions.
- Help to maintain quorum
- Review, discuss and consider research proposals submitted for evaluation
- To see:
  - Informed Consent Process,
  - Trial procedures,
  - Post-trial access,
  - Compensation,
  - Confidentiality,
  - Think from the subject's perspective,
  - No exploitation of subject,
  - Subject diary simple or not.
- Review the progress reports and monitor ongoing studies.
- Maintain confidentiality of the documents and deliberations of IEC meetings.
- Declare any conflict of interest, if any.
- Participate in continuing education activities in biomedical ethics and biomedical research.
- Provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat
- Provide an updated CV when requested for by the IEC secretariat
- Carry out the work delegated by Chairperson and Member Secretary
- Assist the Chairperson and Member Secretary in carrying out IEC work as per SOP

CONFIDENTIALITY AGREEMENT

I agree to take reasonable measures to protect the confidential Information; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to destroy all Confidential Information (including any minutes or notes I have made as part of my duties) to the Chairperson upon termination of my functions as a Committee member.

I hereby do confirm that to maintain the integrity and sanctity in the best interests of the committee. I also do hereby declare that I will not breach the confidentiality and all the information that is accessible to me as a member of IEC, especially during the reviewing, decision making and any discussion, shall not be disclosed by me to anyone other than the members of the committee or concerned study related personnel, as approved by the regulatory body.

Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as confidential.

Signature:

Name & Designation: _____

_____

Date: _____

WORK DELEGATION LOG OF EC SECRETARIAT

Job description	**Delegated to**	**Delegated by (Chairperson / Member Secretary)**
Receipt of documents for initial submission to MGIMS		
Processing of submitted documents to MGIMS members prior to Meetings		
Recording of Minutes of the Meeting for MGIMS meetings		
Review of the Minutes of meeting		
Taking the Signature of the MGIMS chairperson on the finalized minutes		
Receipt of SAE/SUSAR and other adverse event reports from the MGIMS site as well as other sites recruiting on the same protocol. Ensuring timely review and documentation, in accordance with the SOP		
Review of the SAE/SUSAR and other AE reports		
Receipt of Protocol deviation reporting from the MGIMS site and ensuring timely review and documentation in accordance with the SOP		
Review of protocol deviations at the MGIMS		
Receipt of any additional documents /modification/amendments to the protocol. Ensuring timely review and documentation, in accordance with the SOP		

WORKING RULES FOR THE COORDINATING STAFF OF IEC SECRETARIAT

1. The hierarchy of the coordinating staff will be as follows:

EC Coordinator who will overall look after the management of IEC and under him/her will be one attendant. The Member Secretary / Joint Secretary will supervise the coordinating staff and Secretariat. All these coordinating staff will help the IEC Chairperson and Member Secretary/ Joint Secretary in executing functions of the IEC. Additional staff may be appointed and duties assigned; as and when deemed necessary by the IEC. The coordinating staff will be regular employees.

2. The terms and conditions of the appointment shall be as follows:

The appointment will be on regular basis. A monthly salary will be given by the institute. Since the posts are of MGIMS, Sevagram posts, the KHS Services rules will be applied to them. The appointed staff will get benefit of MGIMS, Sevagram.

3. Duties of the Coordinator:
   - Overall management of the IEC
   - Assisting in formulating the SOPs of IEC
   - Managing the financial expenditure of the IEC and maintaining the details of the account and communication regarding the same.
   - All communication to the members and external experts instructed by the Chairperson / Member Secretary.
   - All communication to the investigators in case of change in any policy of IEC with prior information to the Chairperson / Member Secretary.
   - All correspondence (as per regulatory requirements) to the regulatory authorities in regards to protocol review, SAE/ compensation issue, registration / re-registration process etc.
   - Assisting the Chairperson/Member Secretary to reply any inquiry put forth by the regulatory authority/investigator/any person.
   - Arranging and attending the IEC meetings.
   - Receiving all research proposals
   - Assisting in preparing agenda and minutes of the IEC meetings
   - Overall co-ordination of the activities related to audits/registrations /accreditations /recognitions with national and international bodies.
   - Confirmation that all the data (hard copy and soft copy) are maintained and are up to date.
   - Managing the SOPs of the IEC, its revision as well as uploading the recent approved

SOP on the institutional website as and when needed.

- Confirming about the completion of the archival procedures.
- Retrieving of archived documents permitted by Chairperson / Member Secretary.
- Conducting self-assessment of IECs periodically with the member secretary and/or member/s of IEC
- Coordinating staff of IEC will not vote in any decision making procedure of the IEC.
- Maintaining the all record of IEC with the confidentiality for control and archiving

A yearly activity report for submission to the Dean which includes:

- A quantitative evaluation of the activities of the committee's in a year
- The list of the proposals reviewed in a year with status of each study proposal
- Any other duties assigned by the IEC as per SOPs.

4. Duties of the office assistant / attendant:
   - Assisting the secretariat in arranging the IEC meetings
   - Dispatching sets of study documents to IEC members and external experts
   - Filing study related documents
   - Assisting in archiving and maintaining the study files
   - Performance of other duties assigned by the Chairperson/Member Secretary/Joint Secretary/Coordinator.
5. The coordinating staff will report to the Chairperson and/or Member Secretary.

TRACKING RECORD FORMAT FOR RETRIEVAL OF PROJECT STATUS

Details of Clinical Trials / Research study proposals reviewed by Institutional Ethics Committee (Year: ……)									
Sr. No.	**Project Title**	**Type of Study**	**Principal Investigator**	**Qualifications of the PI**	**Sponsor**	**Date of Meeting**	**Status of Project (Approved/ Rejected)**	**Proposed Study closeout date**	**Remarks by IEC**

SELF EVALUATION FORM OF CHAIRMAN

1. Mention (√) the individual who is performing the evaluation:
   Self – evaluation : ☐

   Supervisor or other administrator : ☐

   Member Secretary IEC: ☐

   IEC members or other chairs: ☐
2. Name of the person who is evaluated :
3. Number of Meeting attended out of total meetings :
4. Average number of exempt determination made :
5. Average number of protocol reviewed by the expedited procedure :
6. Average number of protocol reviewed that went to the convened IEC:
7. Average number of amendments reviewed:
8. Average number of SAEs reported and communicated to regulatory authority:
9. When did you update the IEC SOPs last time?:
10. When did you review the IEC SOPs last time?:
11. Completion of educational requirements: Yes ☐ No ☐
12. Attendance at educational sessions (Make tick (√) in the column)
    Regular : ☐ Irregular : ☐
13. Number of educational sessions conducted :

Evaluation of Chairs

Person performing the evaluation – _____

Preparedness for meetings Scale

Poor	Fair	Average	Good	Excellent
1	2	3	4	5

i) Contribution to IEC meetings Scale

Poor	Fair	Average	Good	Excellent
1	2	3	4	5

ii) Quality of reviews Scale

Poor	Fair	Average	Good	Excellent
1	2	3	4	5

iii) Communication with IEC staff Scale

Poor	Fair	Average	Good	Excellent
1	2	3	4	5

Feedback:

Signature: **Date:**

SELF EVALUATION FORM OF MEMBER SECRETARY/MEMBERS

1. Mention (√) the individual who is performing the evaluation: Self – evaluation: ☐
   Chairman or Supervisor or other administrator: ☐
   Member secretary IEC: ☐
   IEC members or other chairs: ☐
2. Name of the person who is evaluated: _____
3. Number of Meeting attended out of total meetings : ☐ / ☐
4. Number of exempt determination made:
5. Average number of protocol reviewed by the expedited procedure :
6. Average number of protocol reviewed that went to the convened IEC :
7. Average number of reviews completed as the primary reviewer:
8. Average number of amendments reviewed:
9. Average number of continuing review protocols reviewed:
10. Average number of protocols disapproved:
11. Average number of SAEs reviewed as Expert Committee member:
12. When did you review the IEC SOPs last time?:
13. Completion of required checklist : (Make tick (√) in the column)
    Yes: ☐ No: ☐
14. Completion of educational requirement : (Make tick (√) in the column)
    Yes: ☐ No: ☐
15. Attendance at educational sessions : (Make tick (√) in the column)
    Regular: ☐ Irregular: ☐
16. Number of educational sessions conducted:
17. Preparedness for meetings : (Make tick (√) in the column)
    Good: ☐ Average: ☐ Poor: ☐
18. Contribution to IEC meetings: (Make tick (√) in the column) Good: ☐ Average: ☐ Poor: ☐
19. Quality of Reviews : (Make tick (√) in the column)
    Good: ☐ Average: ☐ Poor: ☐
20. Communication with IEC staff : (Make tick (√) in the column)
    Good: ☐ Average: ☐ Poor: ☐

Feedback:

Signature: **Date:**

SELF EVALUATION FORM OF COORDINATOR

1. Mention (√) the individual who is performing the evaluation:
   Self – evaluation: ☐
   Chairman or Supervisor or other administrator: ☐
   Member secretary: ☐
   Name of the person who is evaluated:
   _____
2. Handles workload efficiently : (Make tick (√) in the column)
   Yes: ☐ No: ☐
3. Number of protocol processed that were reviewed by the expedited procedure : ☐
4. Number of protocols processed that went to the convened IEC : ☐
5. Completion of required checklists and documentation : (Make tick (√) in the column)
   Yes: ☐ No: ☐
6. Maintains paper files efficiently and correctly : (Make tick (√) in the column)
   Yes: ☐ No: ☐
7. Prepares agenda and minutes in timely manner : (Make tick (√) in the column)
   Yes: ☐ No: ☐
8. Prepare IEC records efficiently and correctly : (Make tick (√) in the column):
   Yes: ☐ No: ☐
9. Maintain IEC rosters efficiently and correctly: (Make tick (√) in the column):
   Yes: ☐ No: ☐
10. Completion of educational requirement : (Make tick (√) in the column):
    Yes: ☐ No: ☐
11. Attendance at educational sessions: (Make tick (√) in the column):
    Yes: ☐ No: ☐
12. Number of educational sessions conducted : ☐
13. Preparedness for meetings : (Make tick (√) in the column)
    Good: ☐ Average: ☐ Poor: ☐
14. Communication with IEC chair and members : (Make tick (√) in the column)
    Good: ☐ Average: ☐ Poor: ☐
    Communication Good: ☐ Average: ☐ Poor: ☐
15. Ability to help investigator : Good: ☐ Average: ☐ Poor: ☐

Feedback:

Signature: **Date:**

CORRECTIVE ACTION AND PREVENTIVE ACTION

1. The purpose of this SOP is to provide guidance to address and develop plans for existing or potential problems identified during self-evaluation of ethics committee members.

2. This SOP covers the corrective and preventive action concerning information and procedures followed by the Institutional Ethics Committee (IEC).

3. The committee will conduct periodic self-assessment annually through internal meeting of the members using the Self-Assessment Tools.

4. Definitions:
   - Corrective and Preventive Action (CAPA) Plan: actions taken to collect information and identify a problem, determine root cause, identify and implement a corrective and/or preventive action to prevent further recurrence.
   - Root Cause: factor that caused a nonconformance and should be permanently eliminated through process improvement.
   - Root Cause Analysis: is a class of problem solving methods used to identify the root causes of problems or events.
   - Corrective Action: Immediate action to a problem that has already occurred or has been identified.
   - Preventive Action: Taken to eliminate the root cause of a potential problem including the detection/identification of problems.
   - Policy statement:
   - A CAPA is written to identify a discrepancy or problem in the self-evaluation of ethics committee members, note the root cause of the identified problem, identify the corrective action taken to prevent recurrence of the problem, and document that the corrective action has resolved the problem.

5. Procedure:
   - The problems related to evaluation of members must be bought to the notice by member secretary/chairperson.
   - The Chairperson may designate a team of one/more members.
   - The team designated will evaluate the magnitude of the problem and potential impact of the issue on the overall functioning of Ethics Committee.
   - Describe the reason for the issue and identify the root cause of the problem.
   - Describe the procedures implemented to resolve the problem. Mention the time period required for its resolution.
   - Describe the preventive actions taken or planned.
   - After the corrective procedures are implemented, evaluation of the procedures must be made after due course and submitted by one/more membered team to Chairperson.
   - The problems related to evaluation of members, procedures implemented to resolve the problem and the corrective and preventive action will be discussed with permission of chairperson in full board.
   - The documentation with respect to problems related to evaluation of members, procedures implemented to resolve the problem and the corrective and preventive action will be maintained in separate administrative file named ‘Corrective and Preventive Action’.

CONFLICT OF INTEREST AGREEMENT FOR IEC MEMBERS

In the course of my activities as a member of the IEC, I rnay be provided with confidential Information and documentation (which we will refer to as the "Confidential information"). I agree to take reasonable measures to protect the Confidential information; subject to applicable legislation including the access to it, as per the Right to Information Act, not to disclose the Confidential Information to any person; not to use the confidential information for any purpose outside the IEC's mandate, and in particular, in a manner which would result in a benefit to myself or any third party.

I undersigned will immediately disclose to the Chairperson/Member Secretary of the IEC any actual or potential conflict of interest that I may have in relation to any particular proposal submitted for review by the committee and to abstain from any participation in discussions or recommendations or decision making in respect of such proposals.

I, ……. have read and I accept the aforementioned terms and conditions as explained in this agreement.

Signature:
Name:

Date:

CONFLICT OF INTEREST FORM FOR DECLARING CONFLICT DURING IEC MEETING

IEC Meeting date:

Following study projects are going to be discussed in the IEC meeting:

Sr. No	Protocol No / Title	Name of Sponsor	Name of PI

I hereby declare the conflict of Interest for projects to be discussed / reviewed during meeting dated:

SN	Name	Designation/ Role of member in Ethics Committee	Conflict of Interest			
			Yes	No	Signature	If Yes, write the protocol No.
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						

CONFIDENTIALITY AGREEMENT

For Guest / Observer Attendees to IEC Meetings

I, _____ (name), understand that I am being allowed to attend the Institutional Ethics meeting scheduled on _____ at _____am/ pm as a guest / observer. The meeting will be conducted in the _____, MGIMS. In the course of the meeting of Institutional Ethics Committee some confidential information may be disclosed or discussed. Upon signing this form, I ensure to take reasonable measures to keep the information as confidential.

I must volunteer to inform the Chairman, Secretary and other members to withdraw myself from participating in any process that might lead to possible personal benefit owing to my presence as an opining and decision making member of the IEC during any of the meeting of the IEC in order to avoid the conflict of interest involved.

Signature of the Guest / Observer_____

Date _____

Chairperson of IEC,_____

Date _____

I, _____ (name) acknowledge that I have

received a copy of this Agreement signed by the IEC Chairperson and me.

Signature of the Guest/ observer _____

Date _____

CONFIDENTIALITY AGREEMENT

For Subject Experts

I,_____

_____ (Name and Designation) as a non-member of Institutional Ethics Committee (IEC), understand that the copy/ copies given to me by the IEC, is/are confidential. I shall use the information only for the indicated purpose as described by the IEC and shall not duplicate, give or distribute these documents to any person(s) without prior permission from the IEC. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

I must volunteer to inform the Chairman, Secretary and other members to withdraw myself from participating in any process that might lead to possible personal benefit owing to my presence as an opining and decision making member of the IEC during any of the meeting of the IEC in order to avoid the conflict of interest involved.

_____ **Signature of the recipient**	_____ **Date**
_____ **Chairperson of IEC**	_____ **Date**

I,_____(name) acknowledge that I have received a copy of this Agreement signed by the Chairperson of the IEC and me.

_____ _____

Signature **Date**

STUDY ASSESSMENT FORM FOR SUBJECT EXPERT

IEC Ref. Number:	
Protocol Title:	
Comments on the protocol:	
Comments on the Informed Consent Document:	
Comments on any other issues/ aspects:	
Remarks:	Recommend approval:
	Recommend approval after incorporation of changes suggested:
	Recommend disapproval (Please state Reasons):
	Any other (Please specify with reasons)
Name of the Subject Expert:	
Signature with Date:	

PROJECT SUBMISSION CHECKLIST

For projects involving research in human subjects for submission to **IEC, MGIMS**

Project Title: _____

_____

_____

Protocol submission for initial review (Tick accordingly)

Sr. No.	Document	Yes	No	Date of submission, if pending	NA	Remarks
1	Letter to Member Secretary/ Chairperson	☐	☐		☐	
2	Project submission application form duly filled up	☐	☐		☐	
3	Summary of protocol (in not more than 500 words)	☐	☐		☐	
4	Protocol	☐	☐		☐	
5	Amendments to protocol	☐	☐		☐	
6	Informed consent in English	☐	☐		☐	
7	Informed consent in regional languages (Total No:-)	☐	☐		☐	
8	Assent form	☐	☐		☐	
9	Back translations of Informed consent	☐	☐		☐	
10	Translation certificate	☐	☐		☐	
11	Back translation certificate	☐	☐		☐	
12	Amendments to the informed consent, if any	☐	☐		☐	
13	Application for waiver of consent	☐	☐		☐	
14	Case Record Form	☐	☐		☐	
15	Subject recruitment procedures: (Proofs: advertisement, notices etc.)	☐	☐		☐	
16	Patient instruction card, identity card, diary etc.	☐	☐		☐	
17	Patient/Subject Questionnaire/s (No. -)	☐	☐		☐	
18	Investigator’s Brochure	☐	☐		☐	
19	Insurance policy (Single copy is needed for submission)	☐	☐		☐	
20	Investigator’s undertaking to DCG(I)	☐	☐		☐	

21	Memorandum of Understanding (MOU) between collaborative institutions	☐	☐		☐	
22	DCG(I) approval	☐	☐		☐	
23	Investigator's agreement with sponsor (Copy of the Final Signed Document) / CTA	☐	☐		☐	
24	Budget	☐	☐		☐	
25	FDA marketing/manufacturing license for herbal formulations/ nutraceutics(Single copy)	☐	☐		☐	
26	Health Ministry Screening Committee (HMSC) approval in case the study involves collaboration with any foreign laboratory/clinic/institution(Single copy)	☐	☐		☐	
27	Bhabha Atomic Research Centre (BARC) approval in case study involves use of radioisotopes/ ionizing radiations(Single copy)	☐	☐		☐	
28	Genetic Engineering Advisory Committee (GEAC) approval in case study involves use of gene therapy (Single copy)	☐	☐		☐	
29	Director General of Foreign Trade (DGFT) approval in case study samples are to be sent abroad for analysis(Single copy)	☐	☐		☐	
30	Stem cell committee (ICSCR) approval	☐	☐		☐	
31	Any other approval from regulatory authority	☐	☐		☐	
32	Administrative sanction from the Head of the Institution in case of collaborative studies with other institutions (Single copy)	☐	☐		☐	
33	Signed and dated brief current curriculum vitae of the study team members (principal investigator, co-investigator, study coordinator)	☐	☐		☐	
34	Ethics Committee clearance of other centers, if any (Total No _____)	☐	☐		☐	
35	Log of delegation of responsibility of the study team members	☐	☐		☐	
36	Document Receipt Form (one copy only)	☐	☐		☐	
37	Current Status of Ongoing Studies conducted by Principal Investigator	☐	☐		☐	
38	Documentation of CTRI registration/ any other WHO platform registry (whenever applicable; one copy only)	☐	☐		☐	

39	GCP training certificates of principal investigator and co investigators (one copy only)	☐	☐		☐	
40	Any other Documents submitted	☐	☐		☐	

Date: Name & Signature of PI

EC Ref. No.*(for office use):*

General Instructions: a) Tick one or more as applicable. Mark NA if not applicable
b) Attach additional sheets if required

SECTION A - BASIC INFORMATION

1. ADMINISTRATIVE DETAILS

(a) Name of Organization:

(b) Name of the Ethics Committee:

(c) Name of Principal Investigator:

(d) Department/Division: (e) Date of Submission: Click here to enter a date.

(f) Type of review requested[1]**:**

Exemption from Review ☐ Expedited Review ☐ Full Committee Review ☐

(g) Title of the study:

Acronym/ Short title, (If any):

(h) Protocol number(If any): Version number:

(i) Details of Investigators:

Name	Designation and Qualification	Department and Institution	Address for communication[2]
Principal Investigator/Guide			
Co-investigator/student/fellow			

(j) Number of studies where applicant is a:

i) Principal Investigator at time of submission: ii) Co-Investigator at time of submission:

(k) Duration of the study:

[1] *Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017on Page 36 Table 4.2. for the types of review*

[2] *Include telephone/mobile, fax numbers and email id*

2. FUNDING DETAILS AND BUDGET

(a) Total estimated budget for site:

At site | In India | Globally

(b) Self-funding ☐ Institutional funding ☐ Funding agency ☐ *(Specify)*

SECTION B - RESEARCH RELATED INFORMATION

3. OVERVIEW OF RESEARCH

(a) Lay Summary of study[3] (within 300 words)

(b) Type of study:

Basic Sciences	☐	Clinical	☐	Cross Sectional	☐
Retrospective	☐	Epidemiological/ Public Health	☐	Case Control	☐
Prospective	☐	Socio-behavioural	☐	Cohort	☐
Qualitative	☐			Systematic Review	☐
Quantitative	☐	Biological samples/Data	☐		
Mixed Method	☐	Any others *(Specify)*	☐		

4. METHODOLOGY

(a) Sample size/ No. of Participants (*as applicable)*

At site | In India | Globally

Control group | Study Group

Justification for the sample size chosen (*100 words*); In case of qualitative study, mention the criteria used for saturation

(b) Is there an external laboratory/ outsourcing involved for investigations?[4] Yes ☐ No ☐ NA ☐

(c) How was the scientific quality of the study assessed?

Independent external review	☐	Review by Sponsor/Funder	☐	Review within PI's institution	☐
Review within multi-centre research group	☐	No Review	☐		

Date of review: Click here to enter a date.

Comments of Scientific Committee, if any(100 words)

[3] *Summarize in the simplest possible way such that a person with no prior knowledge of the subject can easily understand it.*

[4] *If participant samples are sent outside for investigations, provide details of the same and attach relevant documentation such as an MTA/ MoU etc.*

SECTION C - PARTICIPANT RELATED INFORMATION

5. RECRUITMENT AND RESEARCH PARTICIPANTS

(a) Type of participants in the study:

Healthy volunteer ☐ Patient ☐ Vulnerable person/ Special groups ☐ Others *(Specify)* ☐

Who will do the recruitment?

Participant recruitment methods used:

Posters/ leaflets/Letters ☐ TV/Radio ads/Social media/Institution website ☐ Patients / Family/Friends visiting hospitals ☐ Telephone ☐

Others*(Specify)* ☐

(b) i. Will there be vulnerable person/special groups involved? Yes ☐ No ☐ NA ☐

ii. If yes, type of vulnerable person /special groups

Children under 18 yrs ☐ Pregnant or lactating women ☐

Differently abled (Mental/Physical) ☐ Employees/Students/Nurses/ Staff ☐

Elderly ☐ Institutionalized ☐

Economically and socially disadvantaged ☐ Refugees/Migrants/Homeless ☐

Terminally Ill (stigmatized or rare diseases) ☐

Any other *(Specify)*: ☐

iii. Provide justification for inclusion/exclusion

iv. Are there any additional safeguards to protect research participants?

(c) Is there any reimbursement to the participant? Yes ☐ No ☐

If yes, Monetary ☐ Non-monetary ☐ Provide details

(d) Are there any incentives to the participant? Yes ☐ No ☐

If yes, Monetary ☐ Non-monetary ☐ Provide details

(e) Are there any participant recruitment fees/ incentives for the study provided to the PI/ Institution?

If yes, Monetary ☐ Non-monetary ☐ Provide details Yes ☐ No ☐

6. BENEFITS AND RISKS

(a) i. Are there any anticipated physical/social/psychological discomforts/ risk to participants? Yes ☐ No ☐

If yes, categorize the level of risk[5]:

Less than Minimal risk ☐ Minimal risk ☐

Minor increase over minimal risk or Low Risk ☐ More than Minimal Risk or High Risk ☐

ii. Describe the risk management strategy:

(b) What are the potential benefits from the study?	Yes	No	If yes, Direct	Indirect
For the participant	☐	☐	☐	☐
For the society/community	☐	☐	☐	☐
For improvement in science	☐	☐	☐	☐

Please describe how the benefits justify the risks

(c) Are Adverse Events expected in the study[6]? Yes ☐ No ☐ NA ☐

Are reporting procedures and management strategies described in the study? Yes ☐ No ☐

If Yes, Specify

7. INFORMED CONSENT

(a) Are you seeking waiver of consent? If yes, please specify reasons and skip to question 8. Yes ☐ No ☐

(b) Version number and date of Participant Information Sheet (PIS):

Version number and date of Informed Consent Form (ICF):

(c) Type of consent planned for :

Signed consent	☐	Verbal/ oral consent	☐	Witnessed consent	☐	Audio-Video (A/V) consent	☐
Consent from LAR (If so, specify from whom)	☐	For children<7 yrs parental/LAR consent	☐	Verbal assent from minor (7-12 yrs) along with parental consent	☐	Written Assent from Minor (13-18 yrs) along with parental consent	☐

Other *(specify)* ☐

(d) Who will obtain the informed consent?

PI/Co-I ☐ Nurse/Counselor ☐ Research Staff ☐ Other*(Specify)* ☐

Any tools to be used

[5]*For categories of risk refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017. Page 6 in Table 2.1*

[6]*The term adverse events in this regard encompass both serious and non-serious adverse events.*

(e) Participant Information Sheet(PIS) and Informed Consent Form (ICF)

English ☐ Local language ☐ other ☐ (*specify*)

List the languages in which translations were done

If translation has not been done, please justify

(f) Provide details of Consent requirement for previously stored samples if used in the study[7]

(g) Elements contained in the Participant Information Sheet(PIS) and Informed Consent Form (ICF)

Simple language	☐	Data/ Sample sharing	☐	Compensation for study related injury	☐
Risks and discomforts	☐	Need to recontact		Statement that consent is voluntary	
Alternatives to participation	☐	Confidentiality	☐	Commercialization/benefit sharing	☐
Right to withdraw	☐	Storage of samples	☐	Statement that study involves research	☐
Benefits	☐	return of research results	☐	Use of photographs/ identifying data	☐
Purpose and procedure	☐	Payment for participation	☐	Contact information of PI and Member Secretary of EC	☐
Others*(Specify)* ☐					

8. PAYMENT/COMPENSATION

(a) Who will bear the costs related to participation and procedures[8]?

PI ☐ Institution ☐ Sponsor ☐ Other agencies*(specify)* ☐

(b) Is there a provision for free treatment of research related injuries? Yes ☐ No ☐ NA ☐

If yes, then who will provide the treatment?

(c) Is there a provision for compensation of research related SAE? If yes, specify. Yes ☐ No ☐ NA ☐

Sponsor ☐ Institution/ Corpus funds ☐ Project grants ☐ Insurance ☐

(d) Is there any provision for medical treatment or management till the relatedness is determined for injury to the participants during the study period? If yes, specify. Yes ☐ No ☐ NA ☐

(e) Is there a provision for ancillary care for unrelated illness during the study period? If yes, please specify. Yes ☐ No ☐ NA ☐

[7] *Information on re-consent requirements can be found at National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017,Page 54 in Section 5.8*

[8] *Enclose undertaking from PI confirming the same*

9. STORAGE AND CONFIDENTIALITY

(a) Identifying Information: Study Involves samples/data. If Yes, Specify Yes ☐ No ☐ NA ☐

Anonymous/unidentified ☐ Anonymized: reversibly coded ☐ Irreversibly coded ☐ Identifiable ☐

If identifiers must be retained, what additional precautions will be taken to ensure that access is limited / data is safeguarded? (e.g. data stored in a cabinet, password protected computer etc.)

(b) Who will be maintaining the data pertaining to the study?

(c) Where will the data be analyzed[9] and by whom?

(d) For how long will the data be stored?

(e) Do you propose to use stored samples/data in future studies? Yes ☐ No ☐ Maybe ☐
If yes, explain how you might use stored material/data in the future?

SECTION D: OTHER ISSUES

10. PUBLICATION, BENEFIT SHARING AND IPR ISSUES

(a) Will the results of the study be reported and disseminated? If yes, specify. Yes ☐ No ☐ NA ☐

(b) Will you inform participants about the results of the study? Yes ☐ No ☐ NA ☐

(c) Are there any arrangements for continued provision of the intervention for participants, if effective, once the study has finished? If yes describe in brief *(Max 50 words)* Yes ☐ No ☐ NA ☐

(d) Is there any plan for post research benefit sharing with participants? If yes, specify
Yes ☐ No ☐ NA ☐

(e) Is there is any commercial value or a plan to patent/IPR issues. If yes, Please provide details
Yes ☐ No ☐ NA ☐

(f) Do you have any additional information to add in support of theapplication, which is not included elsewhere in the form? If yes, provide the details. Yes ☐ No ☐

[9] *For example, a data entry room, a protected computer etc.*

SECTION E: DECLARATION AND CHECKLIST

11. DECLARATION (Please tick as applicable)

☐	I/We certify that the information provided in this application is complete and correct.
☐	I/We confirm that all investigators have approved the submitted version of proposal/related documents.
☐	I/We confirm that this study will be conducted in accordance with the latest ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants and other applicable regulations and guidelines including responsible.
☐	I/We confirm that this study will be conducted in accordance with the Drugs and Cosmetics Act 1940 and its Rules 1945 as amended from time to time, GCP guidelines and other applicable regulations and guidelines.
☐	I/We will comply with all policies and guidelines of the institute and affiliated/collaborating institutions where this study will be conducted.
☐	I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol.
☐	I/We declare that the expenditure in case of injury related to the study will be taken care of.
☐	If applicable, I/We confirm that an undertaking of what will be done with the leftover samples is provided, if applicable.
☐	I/We confirm that we shall submit any protocol amendments, adverse events report, significant deviations from protocols, progress reports (if required) and a final report and also participate in any audit of the study if needed.
☐	I/We confirm that we will maintain accurate and complete records of all aspects of the study.
☐	I/We will protect the privacy of participants and assure safety and confidentiality of study data and biological samples.
☐	I/We hereby declare that I/any of the investigators, researchers and/or close relative(s), have no conflict of interest (Financial/Non-Financial) with the sponsor(s) and outcome of study.
☐	I/We have the following conflict of interest (PI/Co-PI): 1. 2.
☐	I/We declare/confirm that all necessary government approvals will be obtained as per requirements wherever applicable.

Name of PI: Signature: Click here to enter a date.

Name of Co-PI: Signature: Click here to enter a date.

Name of Guide: Signature: Click here to enter a date.

Name of HOD: Signature: Click here to enter a date.

12. CHECKLIST

S.No	Items	Yes	No	NA	Enclosure No.	EC Remarks(If applicable)
ADMINISTRATIVE REQUIREMENTS						
1.	Cover letter	☐	☐	☐		
2.	Brief CV of all Investigators	☐	☐	☐		
3.	Good Clinical Practice (GCP) training of investigators in last 3 years	☐	☐	☐		
4.	Approval of Scientific Committee	☐	☐	☐		
5.	EC clearance of other centers*	☐	☐	☐		
6.	Agreement between collaborating partners*	☐	☐	☐		
7.	MTA between collaborating partners*	☐	☐	☐		
8.	Insurance policy/certificate	☐	☐	☐		
9.	Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification	☐	☐	☐		
10.	Copy of contract or agreement signed with the sponsor or donor agency	☐	☐	☐		
11.	Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs/Regulatory authorities for proposed study (whether in same location or elsewhere) and modification(s) to protocol	☐	☐	☐		
PROPOSAL RELATED						
12.	Copy of the detailed protocol[11]	☐	☐	☐		
13.	Investigators Brochure (If applicable for drug/biologicals/device trials)	☐	☐	☐		
14.	Participant Information Sheet(PIS) and Informed Consent Form (ICF)(English and translated)	☐	☐	☐		

15.	Assent form for minors (12-18 years) (English and Translated)	☐	☐	☐		
16.	Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated)	☐	☐	☐		
17.	Advertisement/material to recruit participants (fliers, posters etc)	☐	☐	☐		

PERMISSION FROM GOVERNING AUTHORITIES

	Other Registration/ permissions	**Required**	**Not required**	**Received**	**Applied dd/mm/yy**	**EC Remarks**
18.	CTRI	☐	☐	☐	Enter date	
19.	DCGI	☐	☐	☐	Enter date	
20.	HMSC	☐	☐	☐	Enter date	
21.	NAC-SCRT	☐	☐	☐	Enter date	
22.	ICSCR	☐	☐	☐	Enter date	
23.	RCGM	☐	☐	☐	Enter date	
24.	GEAC	☐	☐	☐	Enter date	
25.	BARC	☐	☐	☐	Enter date	
26.	Tribal Board	☐	☐	☐	Enter date	
27.	Others (Specify)	☐	☐	☐	Enter date	

ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY

	Item	**YES**	**NO**	**NA**	**Enclosure no.**	**EC remarks**
28.		☐	☐	☐		
29.		☐	☐	☐		

[10]These formats are adaptable and can be modified by the Ethics Committee members depending on their needs and requirements Acknowledgement for Receipt of Application (Copy to be provided to PI)

**For multicentric research. MTA-Material transfer agreement; CTRI-Clinical Trial Registry-India; DCGI-Drug Controller General of India;HMSC-Health Ministry's Screening Committee;NAC-SCRT- National Apex Committee for Stem Cell Research and Therapy;IC-SCR-Institutional committee for Stem Cell Research;RCGM- Review Committee on Genetic Manipulation;GEAC- Genetic Engineering Approval Committee;BARC- Bhabha Atomic Research Centre*

[11]Refer to National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017, section 4 page no. 35Box 4.4(b)

APPLICATION FORM FOR CLINICAL TRIALS

Institutional Ethics Committee, MGIMS

EC Ref. No.*(for office use):*

Title of study:

Principal Investigator and Co-investigator (Name, Designation and Affiliation) :

1. Type of clinical trial Regulatory trial ☐ Academic trial ☐

   CTRI registration number: NABH accreditation number EC registration number:

2. If regulatory trial, provide status of CDSCO permission letter

   Approved and letter attached ☐

   Applied, under process ☐

   Not applied (State reason)

3. Tick all categories that apply to your trial

Phase - I	☐	Phase II	☐
Phase III	☐	Phase IV or Post Marketing Surveillance	☐
Investigational medicinal products	☐	Investigational New drug	☐
Medical devices	☐	New innovative procedure	☐
Drug/device combination	☐	Bioavailability/Bioequivalence studies	☐
Non-drug intervention	☐	Repurposing an existing intervention	☐
Indian system of medicine (AYUSH)	☐	Stem cells	☐
Phytopharmaceutical drug	☐	Approved drug for any new indication or new route of administration	☐
Others (specify)	☐		

4. Trial design of the study (May choose more than one)

   I.

Randomized	☐	Factorial	☐
Non randomized	☐	Stratified	☐
Parallel	☐	Adaptive	☐
Cross-over	☐	Comparison trial	☐
Cluster	☐	Superiority trial	☐

Matched-pair	☐	Non-inferiority trial	☐
Others (specify)	☐	Equivalence trial	☐

II. If there is randomization, how will the participants be allocated to the control and study group(s)?

III. Describe the method of allocation concealment (blinding / masking), if applicable

5. List the primary / secondary outcomes of the trial.

6. Is there a Contract Research Organization (CRO) /Site Management Organisation (SMO) / Any Other Agency such as public relation/Human resource? Yes ☐ No ☐

If yes, Name and Contact details:

State how the CRO/SMO/agency will be involved in the conduct of the trial (tick all that apply)

Project management	☐	Clinical and medical monitoring	☐
Regulatory affairs	☐	Data management	☐
Statistical support	☐	Medical writing	☐
Site management	☐	Audits, quality control, quality assurance	☐
Finance management	☐	Recruitment and training	☐
Administrative support	☐	Others (specify)	☐

7. Please provide the following details about the intervention being used in the protocol

I. Drug/s, device/s and/or biologics; If yes, provide regulatory approval details Yes ☐ No ☐ NA ☐

II. Already approved drugs or a combination of two or more drugs with new indications / change in dosage form / route of administration. If yes, provide details Yes ☐ No ☐ NA ☐

III. Provide contact details of who prepared and /or is manufacturing the drug/s, device/s and biologics

IV. Provide details of patent of the drug/s, device/s and biologics.

8. Describe in brief any preparatory work or site preparedness for the protocol? Yes ☐ No ☐ NA ☐

If yes, (100words)

9. Is there an initial screening/ use of existing database for participant selection? Yes ☐ No ☐ NA ☐

If Yes, provide details[22]

10. Are there any anticipated incidence, frequency and duration of adverse events related to the intervention? If yes, provide details of arrangements made to address them. Yes ☐ No ☐ NA ☐

11. Does the study use a placebo?
If yes, justify the use of the placebo and risks entailed to participants. Yes ☐ No ☐ NA ☐

12. Will current standard of care be provided to the control arm in the study? Yes ☐ No ☐ NA ☐
If no, please justify.

13. Are there any plans to withdraw standard therapy during the study ?If yes, please justify.
Yes ☐ No ☐ NA ☐

14. Are there any rules to stop the protocol in case of any adverse events? If yes, please specify.
Yes ☐ No ☐ NA ☐

15. Does the study have a Data and Safety Monitoring Plan? If no, please justify. Yes ☐ No ☐

16. Participant Information Sheet(PIS) and Informed Consent Form (ICF)

English	☐	Local language (Certified that local version (s) is/are a true translation of the English version and can be easily understood by the participants)	☐	Other*(Specify)*	☐

List the languages in which translations were done

Justify if translation not done

[22]*In order to select participants for your protcol does the protocol require you to screen an initial population or refer to an existing database before shortlisting participants. If yes, provide details on the same*

17. Involvement/consultation of statistician in the study design Yes ☐ No ☐ NA ☐

18. Is there any insurance coverage of the trial? If yes, provide details. Yes ☐ No ☐

i. Is the PI registered with Medical Council of India (MCI) or the State Medical Council registration? Please provide details. Yes ☐ No ☐

ii. Is the PI trained in GCP in last 3 years?. If yes, Please enclose certificate Yes ☐ No ☐

Signature of PI: Click here to enter a date.

APPLICATION FORM FOR HUMAN GENETICS TESTING RESEARCH

Institutional Ethics Committee, MGIMS

EC Ref. No.*(for office use):*

Title of study:

Principal Investigator (Name, Designation and Affiliation)

1. Describe the nature of genetic testing research being conducted.

   (e.g.- screening/gene therapy/newer technologies/human embryos/foetal autopsy)

2. Does the study involve pretest and post-test counselling? If yes, please describe. Yes ☐ No ☐ NA ☐

3. Explain the additional safeguards provided to maintain confidentiality of data generated.

4. If there is a need to share the participants' information/investigations with family/community, is it addressed in the informed consent? Yes ☐ No ☐ NA ☐

   If findings are to be disclosed, describe the disclosure procedures (e.g. genetic counseling)

5. Is there involvement of secondary participants? Yes ☐ No ☐ NA ☐

   If yes, will informed consent be obtained? State reasons if not. Yes ☐ No ☐ NA ☐

6. What measures are taken to minimize/ mitigate/eliminate conflict of interest?

7. Is there plan for future use of stored sample for research? Yes ☐ No ☐

   If yes, has this been addressed in the informed consent. Yes ☐ No ☐

Signature of PI: Click here to enter a date.

APPLICATION FORM FOR SOCIO-BEHAVIOURAL AND PUBLIC HEALTH RESEARCH

Institutional Ethics Committee, MGIMS

EC Ref. No.*(for office use):*

Title of study:
Principal Investigator (Name, Designation and Affiliation)

1. Data collection method used in the study

Focus group	☐	Questionnaire/survey	☐	Observation	☐
Interviews	☐	Documents and records	☐	Ethnographies/oral history/case studies	☐
Others(Specify)	☐				

If it is an interview, will there be audio-video recording of participants' interview? If yes, justify the reasons and storage strategies. Yes ☐ No ☐

2. Type of informed consent is used in the study?

Individual consent	☐	Gate-keeper consent	☐	Community consent	☐
Others (specify)	☐				

3. Provide details of safeguards to ensure privacy and confidentiality of participants in the event of data sharing? Yes ☐ No ☐

4. Describe strategies to manage if any patterns of behavior of self-harm or harm to the society are identified.(e.g.: Suicide or infanticide) Yes ☐ No ☐ NA ☐

5. Are cultural norms and/or social considerations/sensitivities taken into account while designing the study and participant recruitment? Yes ☐ No ☐

6. Is there a use of an interpreter? If yes, describe the selection process. Yes ☐ No ☐ NA ☐

7. Describe any preparatory work or site preparedness for the study Yes ☐ No ☐ NA ☐

8. I. Type of risk related to procedures involved in the study

Invasive ☐ Potentially harmful ☐ Emotionally disturbing ☐ Involving disclosure ☐

Describe the risk minimization strategies.

II. Justify reasons if individual harm is overriding societal benefit. Yes ☐ No ☐ NA ☐

III. Describe how do societal benefits outweigh individual harm.

9. Does the study use incomplete disclosure or active deception or authorized deception? If yes, provide details and rationale for deception. Yes ☐ No ☐

10. Describe the debriefing process that will be used to make participants aware of the incomplete disclosure or deception, including their right to withdraw any record of their participation.

Signature of PI:

Click here to enter a date.

DELEGATION OF RESPONSIBILITIES OF STUDY TEAM

Date:

Study Title:

No.	Role	Name
1	Principal Investigator	
2	Co-Principal Investigator	
3	Co-Principal Investigator	
4	Co-Investigator	
5	Co-Investigator	
6	Co-investigator	
7	Co-Investigator	
7	Co-investigator	
8	Study Coordinator *	
9	Study Coordinator *	
10	Laboratory Technician	
11	Social worker	
12	(Any other staff)	

* Study coordinator may preferably be a person specifically appointed for coordinating the clinical trial activities.

(Please place tick against assigned duties for each member in the following table)

Code	TASKS	Role 1	Role 2	Role 3	Role 4	Role 5	Role 6	Role 7	Role 8	Role 9	Role 10
A	All relevant documents pertaining to protect blinding										
B	Research participants selection/ Screening										
C	Obtain informed consent										
D	Evaluate inclusion/ exclusion criteria										
E	Conduct the visit assessments										
F	Physical examination										
G	Complete the source documents										
H	Complete Case Record Form										
I	Final review and sign Case Record Form										
J	Collect laboratory safety test samples										

K	Processing of blood samples										
L	Preparing aliquots & keeping a track of the samples sent										
M	Review & sign of the lab reports										
N	Receive the study drug, document drug dispensing, storage & accountability										
O	Person to whom research participants should contact in case of adverse event										
P	Report all serious adverse events										
Q	Follow up of Serious Adverse Event										
R	Maintaining study site master file										
S	In-charge of inventory & supplies										
T	Archiving of study documents										
U	Resolution of queries										
V	Overall coordination and supervision										

Signature with date of Principal Investigator: _____

FORMAT OF INFORMED CONSENT

1. Project title:

2. Checklist of informed consent documents for clinical trial subject:

2.1 *Essential Elements:*

(i) Statement that the study involves research and explanation of the purpose of the research.

(ii) Expected duration of the participation of subject.

(iii) Description of the procedures to be followed, including all invasive procedures.

(iv) Description of any reasonably foreseeable risks or discomforts to the Subject.

(v) Description of any benefits to the Subject or others reasonably expected from research. If no benefit is expected Subject should be made aware of this.

(vi) Disclosure of specific appropriate alternative procedures or therapies available to the Subject.

(vii) Statement describing the extent to which confidentiality of records identifying the Subject will be maintained and who will have access to Subject's medical records.

(viii) Trial treatment schedule and the probability for random assignment to each treatment (for randomized trials).

(ix) Statement describing the financial compensation and the medical management as under:

(a) In case of an injury occurring to the subject during the clinical trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.

(b) In the event of a trial related injury or death, the sponsor or his representative or the investigator or centre, as the case may be, in accordance with the rule 39, as the case may be, shall provide financial compensation for the injury or death.

(x) An explanation about whom to contact for trial related queries, rights of Subjects and in the event of any injury.

(xi) The anticipated prorated payment, if any, to the subject for participating in the trial.

(xii) Responsibilities of subject on participation in the trial.

(xiii) Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the subject is otherwise entitled.

(xiv) Statement that there is a possibility of failure of investigational product to provide intended therapeutic effect.

(xv) Statement that in the case of placebo controlled trial, the placebo administered to the subjects shall not have any therapeutic effect.

(xvi) Any other pertinent information.

2.2 Additional elements, which may be required:

(a) Statement of foreseeable circumstances under which the participation of the subject may be terminated by the Investigator without his or her consent.

(b) Additional costs to the subject that may result from participation in the study.

(c) The consequences of a Subject's decision to withdraw from the research and procedures for orderly termination of participation by Subject.

(d) Statement that the Subject or Subject's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the Subject's willingness to continue participation will be provided.

(e) A statement that the particular treatment or procedure may involve risks to the Subject (or to the embryo or foetus, if the Subject is or may become pregnant), which are currently unforeseeable.

(f) Approximate number of Subjects enrolled in the study.

3. Format of informed consent form for Subjects participating in a clinical trial –

Informed Consent form to participate in a clinical trial

Study Title:

Study Number:

Subject's Initials: _____ Subject's Name: _____

Date of Birth/Age: _____

Address of the Subject _____

Qualification _____

Occupation: Student or Self-Employed or Service or Housewife or Others

(Please click as appropriate)

Annual Income of the subject:

Name and address of the nominees and his relation to the subject (for the purpose of compensation in case of trial related death).

Place Initial box (Subject)

(i) I confirm that I have read and understood the information [ ] Sheet dated _____ for the above study and have had the opportunity to ask questions. [ ]

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]

(iii) I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial.
I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purposes [ ]

(v) I agree to take part in the above study. [ ]

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:

Date: _____/ ____ /

Signatory's Name: _____

Signature of the Investigator: _____ Date: ____ / ____ /

Study Investigator's Name: ___ _____

Signature of the Witness _____ Date: ____ / ____ /

Name of the Witness:_____

Copy of the Patient Information Sheet and duly filled Informed Consent Form shall be handed over to the subject his or her attendant.

CHILD ASSENT FORM (Age 7-18)

In order for minors (younger than 18 years of age) to participate in a research study, parental or guardian permission must be obtained. For minors younger than 7 years of age, only a parental permission form is required. For minors age 7-18, a child assent form, written in the following format is required.

The child assent form must be brief and contain extremely simplistic language written at the appropriate age level. The **Child Assent Form** should be include a version number and date page in the footer. The following elements should be covered in the child assent form:

1. Project title:
2. A statement of the purpose of the research
3. A description of the procedures to be applied to the minor;
4. A description of the potential risks and discomforts associated with the research;
5. A description of any direct benefits to the minor;
6. A statement that the minor does not have to participate if he/she does not want to;
7. A statement that the minor is free to withdraw at any time;
8. A statement that the minor should discuss whether or not to participate with his/her parents prior to signing the form;
9. A statement that the parent(s)/guardian(s) of the minor will be asked for their permission on behalf of the minor;
10. An offer to answer all questions.

Only the minor and the investigator obtaining consent should sign the child assent form with date. The parent or legal guardian of the minor should be given a copy of the assent form.

CHECKLIST FOR REVIEW OF RESEARCH PROTOCOL

Study Protocol Title:	
Principal Investigator:	
Date Protocol Received by Reviewer:	

Mandatory for: *Clinician, **Lay person, Social Scientist, ***Basic Medical Scientist and ****Legal Expert

Sr No	Details	State (Y) for 'Yes', (N) for 'No', (NR) if not relevant, (NS) if not sure, (NC) if not complete	Comments
1.	GENERAL INFORMATION		
	Is study title appropriate?		
	Is there a protocol identifying number and date?		
	Is the name and address of sponsor stated?		
	Is the name and institution of investigator/s stated?		
	Is the study site appropriate in terms of facilities, expertise, patient populations etc?		
	Is there sufficient and appropriate expertise and experience in the study team?		
	Is there any conflict of interest among members of the study team? If there is, how is it managed?		
2.	***BACKGROUND/LITERATURE REVIEW		
	Is the literature review complete with sufficient information on the disease or medical condition studied, the investigational product/process, preclinical and early clinical findings, etc.		
	Is there an acceptable review of the known risks and potential benefits of the investigational product/process?		
	Is the risk acceptable for the expected benefit?		

3.	OBJECTIVES AND PURPOSE		
	Does the study have acceptable societal value or beneficial outcome?		
	Is the objective(s) clear and acceptable?		
4.	***STATEMENT ON ETHICAL ISSUES		
	Is there an acceptable statement on what are the ethical issues in study and how are the issues addressed?		
5.	*TRIAL DESIGN		
	Is the study endpoint(s) clearly stated and acceptable?		
	Is the study design including all procedures appropriate and acceptable?		
	Is the use of placebo, washout, withholding treatment, cross-over, etc, acceptable?		
	Is there acceptable measure taken to minimize bias such as randomization, blinding, maintenance of randomization codes, and procedures for breaking codes, etc?		
	Is there acceptable rationale, description and justification for (a) route of administration, dosage, and treatment p (b) device/process specifications?		
	Is the study intervention(s) groups and distribution of subjects in the groups acceptable?		
	Is the expected duration of subject participation acceptable?		
	Is the sequence and duration of all study periods including follow-up, acceptable and necessary?		
	Is there acceptable accountability procedure for investigational products acceptable and monitoring of compliance of subjects?		
	Are there appropriate collection,		

	storage and use of biospecimens as well as personal information?		
	Is there collection of specimens for pharmacogenomic analysis?		
	Is the specimen optional?		
	Is the specimen necessary and appropriate?		
	Is stored specimen used for future research?		
	Is the future research related to the medical condition and investigational product/process of this study?		
	Is the dignity and privacy of the subject protected in the future research?		
	Is there appropriate criteria for suspending or terminating the study?		
6.	*, **SELECTION AND WITHDRAWAL OF SUBJECTS		
	Is the study population appropriate and clearly described?		
	Is there acceptable number of subjects to be enrolled including reason and calculation for sample size?		
	Are there acceptable inclusion and exclusion criteria?		
	Are there acceptable process, place and timing for obtaining informed consent / assent?		
	Is there acceptable subject withdrawal criteria?		
	Is it clear when and how are subjects withdrawn, what are the follow-up processes, and whether withdrawn subjects are replaced?		
7.	*TREATMENT AND PROCEDURES		
	Are the permitted and not permitted medications / treatments during trial clearly stated and acceptable?		

	Is there appropriate rescue medication / procedure?		
8.	*ASSESSMENT OF EFFICACY		
	Is there acceptable specification of efficacy parameters, methods and timing for assessment, recording and analysis?		
9.	*ASSESSMENT OF SAFETY		
	Is there acceptable procedure and timing for getting reports of adverse events and inter-current illnesses?		
	Is the process and duration of follow-up of adverse events acceptable?		
10.	*STATISTICS		
	Is there an acceptable statistical plan and methods for data analysis?		
	Is there sufficient information on the selection of subjects to be included in analysis?		
11.	**CONFIDENTIALITY AND SECURITY OF SOURCE DOCUMENTS AND STUDY DATA		
	Is there acceptable means for protecting privacy and confidentiality of personal information?		
	Are subjects given access to the Personal information and study data?		
	Is there acceptable duration and means of storage and archival of medical records and study data?		
	Is study data destroyed after period of storage?		
12.	****FINANCE AND INSURANCE		
	Is the insurance or indemnity letter from sponsor acceptable?		
13.	*PUBLICATION POLICY		
	Is the publication policy suitable for protecting the confidentiality of subjects' personal information?		

14.	**INVOLVEMENT OF VULNERABLE SUBJECTS		
	Are minors involved as subjects?		
	If minors are involved, is there appropriate assent and parental agreement form?		
	Is there any involvement of other vulnerable subjects?		
	Is there appropriate protection for the vulnerable subjects?		
15.	MISCELLANEOUS		
	Is the grammar and language acceptable?		

ADDITIONAL DOCUMENTS REQUIRED FROM INVESTIGATOR (if any):
OTHER COMMENTS (if any):

RECOMMENDATIONS:

1) **Risk assessment:** (tick mark what is appropriate)

	Study involves no more than minimal risk	
	Study involves more than minimal risk *(tick below)*	
		Risk represents minor increase over minimal risk
		Risk represents more than a minor increase over minimal risk

2) **Benefit assessment**: (tick mark what is appropriate)

	No prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant' disorder or condition
	No prospect of direct benefit to individual participants, but likely to yield generalizable knowledge to further society's understanding or the disorder or condition under study
	The research involves the prospect of direct benefit to individual participants

3) **Decision**: (tick mark what is appropriate)

Approved	
Approved with modifications	
Minor modifications/explanations required	
Major modifications/explanations required	
Resubmit	
Not approved	
Defer	

Signature with date

Primary Reviewer: Yes/ No

CHECKLIST FOR REVIEWING INFORMED CONSENT DOCUMENT

Study Title:
Name of Principal Investigator:
Date of Submission for ICD review:

S. No.	Essential Elements	Yes/ No	Remarks
1.	Language: English/ Hindi/ Other:_____		
2.	Translation & Translation Certificate		
3.	Back Translation/ Certificate		
4.	Title of Study, Study Number, Sponsor Name		
5.	Statement that the study involves research and explanation of the purpose of the research.		
6.	Expected duration of the participation of subject.		
7.	Description of the procedures to be followed, including all invasive procedures.		
8.	Description of any reasonably foreseeable risks or discomforts to the Subject.		
9.	Description of any benefits to the Subject or others reasonably expected from research. If no benefit is expected Subject should be made aware of this.		
10.	Disclosure of specific appropriate alternative procedures or therapies available to the Subject.		
11.	Statement describing the extent to which confidentiality of records identifying the Subject will be maintained and who will have access to Subject's		

	medical records.		
12.	Trial treatment schedule and the probability for random assignment to each treatment (for randomized trials).		
13.	Statement describing the financial compensation and the medical management as under: (a) In case of an injury occurring to the subject during the clinical trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier. (b) In the event of a trial related injury or death, the sponsor or his representative or the investigator or centre, as the case may be, in accordance with the rule 39, as the case may be, shall provide financial compensation for the injury or death.		
14.	An explanation about whom to contact for trial related queries, rights of Subjects and in the event of any injury.		
15.	The anticipated prorated payment, if any, to the subject for participating in the trial.		
16.	Responsibilities of subject on participation in the trial.		
17.	Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the subject is otherwise entitled.		
18.	Statement that there is a possibility of failure of investigational product to provide intended therapeutic effect.		
19.	Statement that in the case of placebo controlled trial, the placebo administered to the subjects shall not have any therapeutic effect.		

20.	Does the study consist of vulnerable Population like: ☐ Prisoners armed forces personnel ☐ Staff and students of medical ☐ Nursing and pharmacy academic institutions) ☐ Patients with incurable diseases ☐ Unemployed or impoverished persons ☐ Patients in emergency situation ☐ Ethnic minority groups ☐ Homeless persons ☐ Nomads ☐ Refugees ☐ Pregnant Women ☐ Infant/ Young Children ☐ Handicapped or mentally disabled persons ☐ Minors or other incapable of personally giving consent If "YES" please specify and fill this section further:		
20.1	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.		
20.2	Scientific justification for including the specific vulnerable group.		
20.3	Inclusion and exclusion criteria specific to the vulnerable population and their rationale.		
20.4	Research on vulnerable populations that pose more than minimal risk to studies that hold out the prospect of direct benefit to the participants. Explain the risks and potential for direct benefits to participants.		
20.5	Is the targeted group of subjects already burdened by poverty, illness, institutionalization or age.		
20.6	If so, are there procedures in place to ease those		

	burdens by providing housing or medical care		
20.7	Measures to be taken to minimize risks for vulnerable subjects.		
20.8	Measures for protecting rights and interests of vulnerable population are described.		
21.	Additional elements, which may be required:		
21.1	Statement of foreseeable circumstances under which the participation of the subject may be terminated by the Investigator without his or her consent.		
21.2	Additional costs to the subject that may result from participation in the study.		
21.3	The consequences of a Subject's decision to withdraw from the research and procedures for orderly termination of participation by Subject.		
21.4	Statement that the Subject or Subject's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the Subject's willingness to continue participation will be provided.		
21.5	A statement that the particular treatment or procedure may involve risks to the Subject (or to the embryo or foetus, if the Subject is or may become pregnant), which are currently unforeseeable.		
21.6	Approximate number of Subjects enrolled in the study.		
21.7	Travel Reimbursement Details		
22.	Patient & Nominee Details Initials Name Date of Birth/Age Address of the Subject Qualification Occupation: Student or Self-Employed or Service or		

	Housewife or Others Annual Income of the subject Name and address of the nominees and his relation to the subject (for the purpose of compensation in case of trial related death).		
23.	Declaration by volunteer (As per New Drugs & Clinical Trial Rules 2019)		
23.1	I confirm that I have read and understood the information Sheet dated _____ for the above study and have had the opportunity to ask questions.		
23.2	I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.		
23.3	I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.		
23.4	I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purposes		
23.5	I agree to take part in the above study.		
24.	Copy of Consent document will be given to volunteer.		
25.	Volunteer Name, Signature & Date Section		
26.	LAR Name, Signature & Date Section		
27.	Witness Name, Signature & Date Section		
28.	Investigator Name, Signature & Date Section		
29.	Other Volunteer Information (e.g. AV Consent, PK/PG study, any restrictions etc.)		

30.	Additional Comments, if any		

Reviewed By:	
Date:	

PARTICIPANT'S FEEDBACK FORM

Subject ID:

Project title:

Date of enrollment:

1. Patient information sheet & Main Consent Form.	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
The information about the trial was clear, concise and understandable	○	○	○	○	○
You had time to discuss your doubts about the study with the study team.	○	○	○	○	○

2. The Consent Form for optional biopsy	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
The information was presented in a clear and comprehensive manner	○	○	○	○	○

3. The patient diary card if applicable	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
Was helpful and suitable for recording the required information	○	○	○	○	○

4. Study procedures	Excellent	Very good	Good	Fair	Poor
The length of the study visits	○	○	○	○	○
The frequency of the study visits	○	○	○	○	○
The numbers of patient questionnaires	○	○	○	○	○
The number of sample blood collected	○	○	○	○	○
The biopsy procedure(s)	○	○	○	○	○
The Ultrasound procedures	○	○	○	○	○

5. We would love to hear any additional comments on your experience in the clinical trial and any suggestions on things that we could improve on?

_____

_____

_____

Date:

Signature of Patient: **Name & Signature of IEC representative:**

CHECKLIST FOR REVIEWING CLINICAL TRIAL AGREEMENT (CTA)

No.	Information	Answer
1	Name of the Study:	
2	Name of the Principal Investigator:	
3	Name of the Sponsor:	
4	Is Sponsor a party to the CTA?	☐ Yes ☐ No
5	If no, please provide a letter of undertaking and an indemnity letter (from Sponsor in favour of Institution and Investigator).	☐ Provided to SITE ☐ To be provided
6	Name of the CRO	
7	Type of Study (Interventional/ Observational)	☐ Interventional ☐ Observational
8	Investigational Product (Drug/Device/Therapy/Others)	☐ Drug ☐ Device ☐ Diagnostic ☐ Therapy ☐ NA
9	If post market, provide the date of marketing approval from DCGI.	☐☐-☐☐-☐☐☐☐
10	If it is a multi-centric trial, list the centers in India.	☐ Provided to SITE ☐ To be provided
11	Total no. of subjects to be enrolled from India?	☐☐☐☐

12	Minimum Subjects to be enrolled at Site?	☐☐☐
13	Expected Close-out date	☐☐-☐☐-☐☐☐☐
14	Will this Protocol use a Central Lab?	☐ Yes ☐ No ☐ NA
15	Name and Address of the Central Lab:	
16	Will the samples be exported outside India? If **YES**, provide a copy of the license to export the samples?	☐ Yes ☐ No ☐ Provided to SITE ☐ To be provided
17	Will these samples be used for any future research other than the Study?	☐ Yes ☐ No
18	Will genetic analysis be conducted on these samples? If **YES** provide a copy of the approval.	☐ Yes ☐ No ☐ Provided to SITE ☐ To be provided
19	Is the Sponsor providing any equipment (like laptop, refrigerator, deep freezer, etc) for the Study, except the Investigational Product?	☐ Yes ☐ No
20	If **YES**, will the equipment be retained at the site after the Study close out?	☐ Yes ☐ No
21	Is the Sponsor providing Insurance and annual maintenance for the equipment?	☐ Yes ☐ No
22	Archival period for the Study Data at the Site?	☐☐ Years

CHECKLIST FOR REVIEWING CLINICAL TRIAL BUDGET

Principal Investigator:		Date:	
Study Title:			

Sponsor	☐ Investigator ☐ Institute ☐ Academic ☐ Industry ☐ Other,				
Type of TRIAL	☐ Drug ☐ Device ☐ Stem Cell ☐ Diagnostic ☐ Observ. ☐ Other,				
Target # of Patients		Trial Duration (years)		Enrolment Period	
Number of Clinic Visits					
Number of Telephonic Visits					

Cost to Institute –

a. Check the box for the number of Clinic visits

b. DO NOT include tests that are sent to a Central Lab

c. Find COST of all investigations & charges done at Institute *at each visit*

d. Write down the TOTAL COST of tests being done at each visit

☐ Visit 1 _____	☐ Visit 2 _____	☐ Visit 3 _____	☐ Visit 4 _____
☐ Visit 5 _____	☐ Visit 6 _____	☐ Visit 7 _____	☐ Visit 8 _____
☐ Visit 9 _____	☐ Visit 10 _____	☐ Visit 11 _____	☐ Visit 12 _____
☐ Visit 13 _____	☐ Visit 14 _____	☐ Visit 15 _____	☐ Visit 16 _____
☐ Visit 17 _____	☐ Visit 18 _____	☐ Visit 19 _____	☐ Visit 20 _____
☐ Visit 21 _____	☐ Visit 22 _____	☐ Visit 23 _____	☐ Visit 24 _____
☐ Visit 25 _____	☐ Visit 26 _____	☐ Visit 27 _____	☐ Visit 28 _____
☐ Visit 29 _____	☐ Visit 30 _____	☐ Visit 31 _____	☐ Visit 32 _____
☐ Visit 33 _____	☐ Visit 34 _____	☐ Visit 35 _____	☐ Visit 36 _____
☐ Visit 37 _____	☐ Visit 38 _____	☐ Visit 39 _____	☐ Visit 40 _____
Visit 41 _____	Visit 42 _____	Visit 43 _____	☐ Visit 44 _____
Visit 45 _____	Visit 46 _____	Visit 47	☐ Visit 48 _____
☐ Visit 49 _____	☐ Visit 50 _____		

Estimated time the PI/Co-I would spend per patient (in hours) –	

CRC: ☐ Institute CRC ☐ External CRC ☐ Institute CRN ☐ Study ☐ Pharmacist ☐ Other, _____

Estimated time the CRC would spend per patient	
Patient Travel Reimbursement amount	

APPLICATION FORM FOR EXPEDITED REVIEW

Institutional Ethics Committee, MGIMS

**EC Ref. No. *(*for office use):*

Title of study:
Principal Investigator (Name, Designation and Affiliation):

1. Choose reasons why expedited review from EC is requested[12]?
   i. Involve non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples ☐
   ii. Involve clinical documentation materials that are non-identifiable (data, documents, records). ☐
   iii. Modification or amendment to approved protocol (administrative changes/correction of typographical errors and change in researcher(s)) ☐
   iv. Revised proposals previously approved through expedited review, full review or continuing review of approved proposals ☐
   v. Minor deviations from originally approved research causing no risk or minimal risk ☐
   vi. Progress/annual reports where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee. ☐
   vii. For multicentre research where a designated EC has approved the proposal, a participating EC may review participating centre specific information and modification in the study proposal through full committee meeting/ expedited review depending on the importance of local consent related issues involved specific to the centre. ☐
   viii. Research during emergencies and disasters (See Section 12 of ICMR Ethical Guidelines, 2017). ☐
   ix. Any other (please specify) ☐
2. Is waiver of consent being requested ? Yes ☐ No ☐
3. Does the research involve vulnerable person[13]? Yes ☐ No ☐
   If Yes give details:

Signature of PI: Click here to enter a date.

Comments of EC Secretariat:

Signature of Member Secretary: Click here to enter a date.

[12] *Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2*
[13] *For details, refer to application for initial review, Section-C, 5(b)*
* *In case this is first submission, leave it blank*

APPLICATION FORM FOR EXEMPTION FROM REVIEW

Institutional Ethics Committee, MGIMS

EC Ref. No.*(for office use):*

Title of study:

Principal Investigator (Name, Designation and Affiliation)

1. Choose reasons why exemption from ethics review is requested [14]?
   - i. Research on data in the public domain/ systematic reviews or meta-analyses; ☐
   - ii. Observation of public behavior/ information recorded without linked identifiers and disclosure would not harm the interests of the observed person ☐
   - iii. Quality control and quality assurance audits in the institution ☐
   - iv. Comparison among instructional techniques, curricula, or classroom management methods ☐
   - v. Consumer acceptance studies related to taste and food quality ☐
   - vi. Public health programmes by government agencies[15] ☐
   - vii. Any other (please specify in 100 words): ☐

Signature of PI: Click here to enter a date.

Comments of EC Secretariat:

Signature of Member Secretary: Click here to enter a date.

[14]*Select the category that applies best to your study and justify why you feel it should be exempted from review. For a detailed understanding of the type of studies that are exempt from review, refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, Page 51 Table 4.2.*

[15]*Such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers)*

APPLICATION/ NOTIFICATION FORM FOR AMENDMENTS

Institutional Ethics Committee, MGIMS

EC Ref. No.*(for office use):*

Title of study:
Principal Investigator (Name, Designation and Affiliation)

1. Date of EC approval: Click here to enter a date. Date of start of study: Click here to enter a date.
2. Details of amendment(s)

S.No	Existing Provision	Proposed Amendment	Reason	Location in the protocol/ICD[18]

3. Impact on benefit-risk analysis Yes ☐ No ☐
   If yes, describe in brief:
4. Is any re-consent necessary? Yes ☐ No ☐
   If yes, have necessary changes been made in the informed consent? Yes ☐ No ☐
5. Type of review requested for amendment:
   Expedited review (No alteration in risk to participants) ☐
   Full review by EC (There is an increased alteration in the risk to participants) ☐
6. Version number of amended Protocol/Investigator's brochure/ICD:

Signature of PI:

Click here to enter a date.

[18]*Location implies page number in the ICD/protocol where the amendment is proposed.*

CONTINUING REVIEW/ PERIODIC REVIEW REPORT FORMAT

Institutional Ethics Committee, MGIMS

EC Ref. No.*(for office use):*

Title of study:

Principal Investigator (Name, Designation and Affiliation)

1. Date of EC Approval: Click here to enter a date. Validity of approval: Click here to enter a date.

2. Date of Start of study: Click here to enter a date. Proposed date of Completion: Click here to enter a date.

   Period of Continuing Report Click here to enter a date. ---- to ------ Click here to enter a date.

3. Does the study involve recruitment of participants? Yes ☐ No ☐
   (a) If yes, Total number expected No. Screened: No. Enrolled:

   Number Completed: No. on followup: .

   (b) Enrolment status – ongoing / completed/ stopped

   (c) Report of DSMB[16] Yes ☐ No ☐ NA ☐

   (d) Any other remark

   (e) Have any participants withdrawn from this study since the last approval? Yes ☐ No ☐ NA ☐
   If yes, total number withdrawn and reasons:

4. Is the study likely to extend beyond the stated period[17]? Yes ☐ No ☐
   If yes, please provide reasons for the extension

5. Have there been any amendments in the research protocol/informed consent document (ICD) during the past approval period?
   If No, skip to item no.6 Yes ☐ No ☐
   (a) If yes, date of approval for protocol and ICD : Click here to enter a date.

   (b) In case of amendments in the research protocol/ICD, was re-consent sought from participants?
   If yes, when / how: Yes ☐ No ☐

[16] *In case there is a Data Safety Monitoring Board (DSMB) for the study provide a copy of the report from the DSMB. If not write NA.*
[17] *Problems encountered since the last continuing review application with respect to implementation of the protocol as cleared by the EC*

6. Is any new information available that changes the benefit -risk analysis of human participants involved in this study? Yes ☐ No ☐
   If yes, discuss in detail:

7. Have any ethical concerns occurred during this period? Yes ☐ No ☐
   If yes, give details

8. (a) Have any adverse events been noted since the last review? Yes ☐ No ☐

   Describe in brief:

   (b) Have any SAE's occurred since last review? Yes ☐ No ☐
   If yes, number of SAE's : Type of SAE's:

   (c) Is the SAE related to the study? Yes ☐ No ☐

   Have you reported the SAE to EC? If no, state reasons Yes ☐ No ☐

9. Has there been any protocol deviations/violations that occurred during this period?
   If yes, number of deviations
   Have you reported the deviations to EC? If no, state reasons Yes ☐ No ☐

10. In case of multicentric trials, whether reports of off-site SAEs have been submitted to the EC
    Yes ☐ No ☐ NA ☐

11. Are there any publications or presentations during this period? If yes give details Yes ☐ No ☐

Any other comments:

Signature of PI:

Click here to enter a date.

STUDY COMPLETION/ FINAL REPORT FORMAT

Institutional Ethics Committee, MGIMS

EC Ref. No.*(for office use):*

Title of study: Principal Investigator (Name, Designation and Affiliation)

1. Date of EC Approval: Click here to enter a date.

2. Date of Start of Study: Click here to enter a date. Date of study completion: Click here to enter a date.

3. Provide details of:
   a) Total no. of study participants approved by the EC for recruitment:
   b) Total no. of study participants recruited:
   c) Total number of participants withdrawn from the study (if any):
   Provide the reasons for withdrawal of participants[23]:

4. Describe in brief the publication/ presentation/dissemination plans of the study findings. (Also, mention if both positive and negative results will be shared)

5. Describe the main Ethical issues encountered in the study (if any)

6. State the number (if any) of Deviations/Violations/ Amendments made to the study protocol during the study period

   Deviations: Violation: Amendments:

7. Describe in brief Plans for archival of records / Record Retention:

8. Is there a plan for post study follow-up Yes ☐ No ☐

   If yes, describe in brief:

9. Do you have plans for ensuring that the data from the study can be shared/ accessed easily?

   If yes, describe in brief: Yes ☐ No ☐

10. Is there a plan for post study benefit sharing with the study participants? Yes ☐ No ☐

    If yes, describe in brief:

11. Describe results (summary) with Conclusion[24]:

[23] *Explanation for the withdrawal of participants whether by self or by the PI*
[24] *For sponsored studies, if the final report is not available from sponsor, it may be submitted later to the EC once it is ready.*

12. Number of SAEs that occurred in the study:

13. Have all SAEs been intimated to the EC: Yes ☐ No ☐

14. Is medical management or compensation for SAE provided to the participants? Yes ☐ No ☐

If yes, provide details

Signature of PI:

Click here to enter a date.

FORMAT FOR APPROVAL BY IEC

(CLINICAL TRIALS BIOEQUIVALENCE, BIOAVAILABILITY STUDY)

Ref. No. Date:

To

Dr.

Dear Dr._____

The Institutional ethics committee or independent ethics committee (state name of the committee, as appropriate) reviewed and discussed your application to conduct the clinical trial entitled "…….. "on…….(date).

The following documents were reviewed:

(a) Trial protocol (including protocol amendments), dated…….version No.(s) ……

(b) Patient information sheet and informed consent form (including updates, if any) in English or vernacular language.

(c) Investigator's brochure, dated ..... , Version no…… Proposed methods for patient accrual including advertisements etc. proposed to be used for the purpose.

(d) Principal investigator's current Curriculum Vitae.

(e) Insurance policy or compensation for participation and for serious adverse events occurring during the study participation.

(f) Investigator's agreement with the sponsor.

(g) Investigator's undertaking (Table 4).

The following members of the ethics committee were present at the meeting held on (date, time, place).

……Chairperson of the ethics committee;

…….Member-Secretary of the ethics committee

…….Name of each member with designation;

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

The ethics committee to be informed about the progress of the study, any Serious Adverse Events (SAE) occurring in the course of the study, any changes in the protocol and patient information or informed consent and to be provided with a copy of the final report.

Yours sincerely,

Member Secretary / Chairman, Ethics Committee

FORMAT FOR APPROVAL BY IEC

(BIOMEDICAL & HEALTH RESEARCH AND OTHER ACADEMIC RESEARCH)

Ref. No. Date:

To

……..
……..

Dear Dr. ……..,

The Institutional Ethics Committee reviewed and discussed your application to conduct the proposed study entitled "" on (**Date & Year)**.

The following documents were reviewed:

The following members of the IEC were present at the meeting held on **(Day, Date, Year)** at (**Time)** in the (**Place)**.

We approve the study to be conducted in MGIMS, Sevagram in the ethics point of view according to its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and any changes in the protocol should be intimated to the IEC time to time. Kindly submit the copy of the final report on completion of the study.

With kind regards,

Member Secretary / Chairman, IEC.

PREMATURE TERMINATION/ SUSPENSION/ DISCONTINUATION REPORT FORMAT

Institutional Ethics Committee, MGIMS

EC Ref. No.*(for office use):*

Title of study:

Principal Investigator (Name, Designation and Affiliation)

1. Date of EC Approval: Click here to enter a date. Date of start of study: Click here to enter a date.

2. Date of Last Progress Report Submitted to EC: Click here to enter a date.
3. Date of Termination/suspension/discontinuation: Click here to enter a date.
4. Tick the appropriate
   Premature Termination ☐ Suspension ☐ Discontinuation ☐
   Reason for Termination/Suspension/Discontinuation:
   Action taken Post Termination/ Suspension/Discontinuation:

5. Plans for post study follow up/withdrawal[21] (if any):

6. Details of study participants:
   Total participants to be recruited: Screened: Screen failures:

   Enrolled: Consent Withdrawn: Reason(Give details):

   Withdrawn by PI: Reason(Give details):

   Active on treatment: Completed treatment : Participants on Follow-up:

   Participants lost to follow up: Any other: No. of drop outs:

   Reasons for each drop-out:

7. Total Number of SAEs reported till date in the study:
   Have any unexpected adverse events or outcomes observed in the study been reported to the EC?
   Yes ☐ No ☐

8. Have there been participant complaints or feedback about the study? Yes ☐ No ☐
   If yes, provide details

[21] *Describe post-termination/suspension/ discontinuation follow up plans if any. Also describe any withdrawal plans for the study.*

9. Have there been any suggestions from the SAE Sub Committee? Yes ☐ No ☐
   If yes, have you implemented that suggestion? Yes ☐ No ☐

10. Do the procedures for withdrawal of enrolled participants take into account their rights and welfare? (e.g., making arrangements for medical care of research participants): If yes, provide details
    Yes ☐ No ☐

    Summary of Results (if any):

Signature of PI:

Click here to enter a date.

PROTOCOL VIOLATION/ DEVIATION REPORTING FORM (REPORTING BY CASE)

Institutional Ethics Committee, MGIMS

EC Ref. No.*(for office use):*

Title of study:
Principal Investigator (Name, Designation and Affiliation)

1. Date of EC approval: Click here to enter a date. Date of start of study: Click here to enter a date.
2. Participant ID: Date of occurrence: Click here to enter a date.
3. Total number of deviations /violations reported till date in the study:
4. Deviation/Violation identified by: Principal Investigator/study team ☐ Sponsor/Monitor ☐
   SAE Sub Committee/EC ☐
5. Is the deviation related to (Tick the appropriate box) :

Consenting	☐	Source documentation	☐
Enrollment	☐	Staff	☐
Laboratory assessment	☐	Participant non-compliance	☐
Investigational Product	☐	Others (*specify*)	☐
Safety Reporting	☐		

6. Provide details of Deviation/Violation:
7. Corrective action taken by PI/Co-PI:
8. Impact on (if any): Study participant ☐ Quality of data ☐
9. Are any changes to the study/protocol required? Yes ☐ No ☐

   If yes, give details

Signature of PI: Click here to enter a date.

SERIOUS ADVERSE EVENT REPORTING FORMAT (CLINICAL TRIALS)

Institutional Ethics Committee, MGIMS

EC Ref. No.*(for office use):*

Title of study:

Principal Investigator (Name, Designation and Affiliation)

1. Participant details :

Initials and Case No./Subject ID	Age at the time of event	Gender	Weight: (Kgs)
		Male ☐ Female ☐	Height: (cms)

2. Report type: Initial ☐ Follow-up ☐ Final ☐

If Follow-up report, state date of Initial report Click here to enter a date.

What was the assessment of relatedness to the trial in the initial report?

By PI- Related ☐	By sponsor - Related ☐	By EC - Related ☐
Unrelated ☐	Unrelated ☐	Unrelated ☐

3. Describe the event and specify suspected SAE diagnosis:

4. Date of onset of SAE: Click here to enter a date. Date of reporting: Click here to enter a date.

5. Onset lag time after administration of intervention: Location of SAE (Clinic/Ward/Home/Other)

6. Details of suspected study drug/device/investigational procedure causing SAE:

   I. Suspect study drug (include generic name) device/intervention:
   II. Indication(s) for which suspect study drug was prescribed or tested:
   III. Route(s) of administration, daily dose and regimen, dosage form and strength:
   IV. Therapy start date: Click here to enter a date. Stop date: Click here to enter a date.

7. Was study intervention discontinued due to event? Yes ☐ No ☐

8. Did the reaction decline after stopping or reducing the dosage of the study drug / procedure?
Yes ☐ No ☐

If yes, provide details about the reduced dose.

9. Did the reaction reappear after reintroducing the study drug / procedure? Yes ☐ No ☐ NA ☐

If yes, provide details about the dose.

10. Concomitant study drugs history and lab investigations:

I. Concomitant study drug (s) and date of administration: Click here to enter a date.

II. Relevant test/laboratory data with dates:Click here to enter a date.

III. Patient relevant history including pre-existing medical conditions (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/ renal dysfunction etc)

11. Have any similar SAE occurred previously in this study? If yes, please provide details. Yes ☐ No ☐

12. Seriousness of the SAE:

Death	☐	Congenital anomaly	☐
Life threatening	☐	Required intervention to prevent permanent impairment / damage	☐
Hospitalization-initial or prolonged	☐		
Disability		Others (specify)	☐

13. Describe the medical management provided for adverse reaction (if any) to the research participant. (Include information on who paid, how much was paid and to whom).

14. Outcome of SAE:

Fatal	☐	Recovered	☐
Continuing	☐	Unknown	☐
Recovering	☐	Other (specify)	☐

15. Was the research subject continued on the trial? Yes ☐ No ☐ NA ☐

16. Provide the details about PI final assessment of SAE relatedness to trial.

17. Has this information been communicated to sponsor/CRO/regulatory agencies? Yes ☐ No ☐

Provide details if communicated (including date)

18. Does this report require any alteration in trial protocol? Yes ☐ No ☐

19. Provide details of compensation provided/ to be provided the participants (include information on who pays, how much, and to whom)

Signature of PI: Click here to enter a date.

SERIOUS ADVERSE EVENT REPORTING FORMAT (BIOMEDICAL HEALTH RESEARCH)

Institutional Ethics Committee, MGIMS

EC Ref. No.*(for office use):*

Title of study:
Principal Investigator (Name, Designation and Affiliation)

1. Participant details :
   Initials and ID | Age at the time of event | Gender Male ☐ Female ☐ | Weight: (Kgs) Height: (cms)
2. Suspected SAE diagnosis:
3. Date of onset of SAE: Click here to enter a date. Describe the event[19]:

   Date of reporting SAE: Click here to enter a date.
4. Details of suspected intervention causing SAE[20]
5. Report type: Initial ☐ Follow-up ☐ Final ☐
   If Follow-up report, state date of Initial report Click here to enter a date.
6. Have any similar SAE occurred previously in this study? If yes, please provide details. Yes ☐ No ☐
7. In case of a multi-centric study, have any of the other study sites reported similar SAEs (Please list number of cases with details if available).
8. Tick whichever is applicable for the SAE: *(Kindly note that this refers to the Intervention being evaluated and NOT disease process)*
   A. Expected event ☐ Unexpected event ☐

[19]*Duration, setting, site, signs, symptoms, severity, criteria for regarding the event serious*
[20]*Refers to research intervention including basic, applied and operational research or clinical research, except for investigational new drugs. If it is an academic clinical trial, mention name, indications, dosage, form and strength of the drug(s)*

B.

Hopitalization	☐	Increased Hospital Stay	☐	Death	☐	Congenital anomaly/birth defect	☐
Persistent or significant disability/incapacity	☐	Event requiring intervention (surgical or medical) to prevent SAE	☐	Event which poses threat to life	☐	Others	☐

In case of death, state probable cause of death:

C. No permanent/significant functional/cosmetic impairment ☐
Permanent/significant functional/cosmetic impairment ☐
Not Applicable ☐

9. Describe the medical management provided for adverse reaction (if any) to the research participants. (include the information on who paid, how much was paid and to whom)

10. Proide details of compensation provided/ to be provided to participants (include the information on who paid, how much was paid and to whom)

11. Outcome of SAE

Fatal	☐	Recovered	☐
Continuing	☐	Unknown	☐
Recovering	☐	others(*specify*)	☐

12. Provide any other relevant information to that can facilitate assessment of the case such as medical history

13. Provide details about PI's final assessment of SAE relatedness to trial.

Signature of PI:

Click here to enter a date.

SITE MONITORING VISIT REPORT

1	Protocol ID:
2	Title:
3	Principal Investigator
4	Site:
5	Type of Study:
6	Source of funding:
7	Date of IEC approval:
8	Duration of study:
9	Start date of study:
10	Reason for monitoring: (Tick) Routine: ☐ For cause (State reason): ☐ Protocol deviations/violations: ☐ SAE reporting: ☐ Non-compliance/ Suspicious conduct: ☐ Recruitment rate: ☐ Complaints received from participants: ☐ Other: ☐ Reason (Details):
11	Last monitoring done: Yes ☐ No ☐ NA ☐ If yes, Date:
12	Status of the study: Ongoing: ☐ Accrual Completed: ☐ Follow-up: ☐ Completed: ☐ Suspended: ☐ Terminated: ☐ Closed: ☐ Closed Prematurely: ☐ Details (if any):
13	**Recruitment status:** No. of participants approved at site by IEC:

	Total participants recruited since protocol began:	
	No. of patients screened:	
	No. of patients to be enrolled:	
	No. of patients completed:	
	No. of patients ongoing: Follow-up:	
	No. of patient drop-outs:	
	No. of patients who withdrew consent: (State reasons)	
	No. of patients withdrawn by PI: (State reasons)	
14	Are site facilities appropriate? Yes ☐ No ☐	Comment:
15	**Protocol:** a. Are protocols of recent version used? Yes ☐ No ☐ NA ☐ If Yes, then state changes leading to amendment: _____ b. Is it approved by the IEC? Yes ☐ No ☐ c. Is the latest version of the protocol being used for the study? Yes ☐ No ☐ NA ☐	
16	**Informed Consent:** a. Are informed consents of recent version used? Yes ☐ No ☐ Is it approved by the IEC? Yes ☐ No ☐ b. Have there been any amendments to the ICF? Yes ☐ No ☐ NA ☐ If Yes, state changes leading to amendment:_____ c. Whether consent has been taken from all enrolled participants?	

	Yes ☐ No ☐ d. Whether appropriate vernacular consent has been taken? Yes ☐ No ☐ e. Is there source documentation of the ICF process? Yes ☐ No ☐ NA ☐ f. Is ICF signed by PI /Co-Principal Investigator/Co-I? Yes ☐ No ☐ NA ☐ g. Who signed the ICF? Participant ☐ LAR ☐ Impartial Witness ☐ h. Is the correct language used for the participant? Yes ☐ No ☐ NA ☐
17	Any protocol non-compliance /violation noted? Yes ☐ No ☐ NA ☐
18	Have all the deviations/violations notified to IEC? Yes ☐ No ☐ NA ☐ Comment (if any):
19	Have the eligibility, inclusion exclusion criteria been adhered to? Yes ☐ No ☐ NA ☐
20	Are all case record forms up to date? Yes ☐ No ☐ NA ☐
21	Any adverse event found? Yes ☐ No ☐ NA ☐ If Yes No. of Adverse events: Comments (if any):
22	Any SAEs found? Yes ☐ No ☐ NA ☐ If Yes a. No. of SAEs: b. No. of deaths reported: • Deaths unrelated to participation in the trial: • Deaths possibly related to participation in the trial:

	• Deaths related to participation in the trial: c. Was the IEC informed about SAEs within 24 hrs of occurrence? Yes ☐ No ☐ NA ☐ Comment (if any):
23	Was the IEC informed about SAEs after due analysis within 14 days? Yes ☐ No ☐ NA ☐ Comment (if any):
24	Has any death occurred? Yes ☐ No ☐ NA ☐
25	Are the Investigational drugs accountability and prescription procedures performed and documented? Yes ☐ No ☐ NA ☐ If 'Yes' kindly state the issues: _____
26	Are necessary life-saving equipment/drugs present at the site? Yes ☐ No ☐ NA ☐
27	Any are there any changes to the study personnel? Yes ☐ No ☐ NA ☐ If 'Yes' kindly state the same:_____
28	How well are participants protected? Yes ☐ No ☐ NA ☐
29	Any other relative observations:
30	Comments of the monitor:

Duration of visit: ……..….hours	Starting from: Finish:
Date of monitoring visit:	
Name of IEC/ Independent Monitor:	

Completed by:	Date:

CHECKLIST FOR MONITORING OF AUDIOVISUAL RECORDING OF AV CONSENT PROCESS

1. Facility where informed consent process should be carried out - (well lit, free from noise, privacy ensured, dedicated room, camera permanently set /temporary arrangement, voice recording to be tested before hand):
   Yes_____No_____
   Remarks:

2. Whether consent for AV recording already taken before start of recording/ it is taken in front of the camera: Yes_____No_____

3. Whether elements enlisted in Appendix V of NDCTR is covered during discussion.
   Yes_____No_____
   Remarks:

4. Introduction of each person – name, age (Person conducting the informed consent discussion participant/ legally acceptable representative (LAR) wherever relevant / impartial witness wherever relevant) involved during informed consent process and information about necessity for audiovisual recording - by name, designation and his/ her role in the research, current date and time, enquiry of the language participant understands , showing the consent form in the camera which is going to be used for the study:
   Yes_____No_____
   Remarks:

5. The following minimum elements should feature in the recording of the informed consent process: (Purpose, treatment allotment, randomization, procedure, follow up, benefit/risks, compensation for Participation, Compensation for Study related Injury, nominee name and details, voluntariness and right to withdraw and contact for further information – Investigator name and EC Chair/member secretary name)
   Yes_____No_____
   Remarks:

6. If Inclusion Criteria has been administered by a designated person who is not medically qualified?
   Yes_____No_____
   Remarks:

7. Is there evidence that subject's queries of a medical nature were answered in the process or assurance was given to clarify the same later?
   Yes_____No_____
   Remarks:

8. The consent is taken in language the participant/ legally acceptable representative (LAR) understands best and is literate in.
   Yes_____No_____
   Remarks:

9. Information to the participant/ LAR and impartial witness (as applicable) that the process of taking the consent is being recorded for the purpose of documentation as required by the government rules:
   Yes_____No_____
   Remarks:

10. Information to the participant/ LAR and impartial witness (as applicable) that the confidentiality of information and privacy of participants is assured:
    Yes_____No_____
    Remarks:

11. Information to the participant/ LAR and impartial witness (as applicable) that the recording may be shown to government agencies or members from the IEC:
    Yes_____No_____
    Remarks:

12. Explanation or narration by the person conducting the informed consent discussion:
    Yes_____No_____
    Remarks:

13. Whether audio-visual recording is performed for all subjects, independently:
    Yes_____No_____
    Remarks:

14. Questions regarding participation asked by the potential participant/LAR are answered satisfactorily:
    Yes_____No_____
    Remarks:

15. Ample time was given to read and understand the consent as per the content?
    Yes_____No_____
    Remarks:

16. Opportunity to discuss the same with family members:
    Yes_____No_____
    Remarks:

17. Reading out by the participant/LAR (or having read out by impartial witness) the statements mentioned in Informed Consent:
    Yes_____No_____
    Remarks:

18. Stating whether participant agrees or not for each statement:
    Yes_____No_____
    Remarks:

19. Whether checked for participants understanding of the informed consent process:
    Yes_____No_____

Remarks:

20. Documentation of signatures of all those involved in the Informed Consent Process:
    Yes_____No_____
    Remarks:

21. Clarity and completeness of AV recording (pages vis-a- vis timing):
    Yes_____No_____
    Remarks:

22. Check whether re-consenting is done for changes in ICF/LAR inclusion in the beginning if any:
    Yes_____No_____
    Remarks:

23. Check whether re-consenting is done by the same Investigator:
    Yes_____No_____
    Remarks:

24. Whether re-consenting is done in same language:
    Yes_____No_____
    Remarks:

25. How much timing taken for the re-consent:
    Yes_____No_____
    Remarks:

26. Storage of recording in password protected laptop/ desktop computer and/ or hard drive and labelled CD:
    Yes_____No_____
    Remarks:

27. Access of AV consent recorded allowed only to the principal investigator and designated members of the study team.
    Yes_____No_____
    Remarks:

Signature and date of PI /Co-I _____

GUIDANCE DOCUMENT FOR AUDIOVISUAL RECORDING OF AV CONSENT PROCESS

Pre-recording checklist:

1. Equipment is functioning correctly - YES /NO
2. All parties (trial team personnel conducting the consent, the patient and as applicable legally acceptable representative (LAR), impartial witness and/or translator are seated comfortably and are seen within the frame of the video recording. YES /NO
3. All parties are reminded that this AV recording is in compliance with regulatory requirements YES/NO
4. All parties are informed that this AV recording will be kept confidential but can be shown to others as per legal requirements or for ensuring compliance with law. YES /NO

AV recording:

1. Reconfirm that the video recording frame includes all concerned parties. YES /NO
2. The member of the research team should state the date, time, title of the research protocol and the language of the written informed consent document. YES /NO
3. All concerned parties should identify themselves by stating their names, designation and role with respect to the consent process for this research. YES /NO
4. If LAR is involved, he/she should state relation to participant. YES /NO
5. If translator is involved, he/she should confirm that he/she is proficient in the language of the informed consent document as well as the language in which the medically qualified authorized member of the research team is proficient in for the consent process. YES /NO
6. At any point during the recording, any participant may request for a break (*e.g.* to go to the bathroom or answer a phone or if mother want to feed her baby). In such a case, the AV recording shall be stopped mentioning the time of stopping. It will be resumed/ restarted by stating the date and time of restarting the recording. YES /NO
7. The medically qualified authorized member of the research team administering the consent shall use the checklist to ask the potential participant/ LAR questions to document the authenticity of the informed consent process. Translation will be done as applicable. The answers of the participant/ LAR shall be recorded for each point. YES /NO
8. The actual signing process by all concerned parties should also be recorded. YES /NO

Post recording checklist:

1. The memory card/ storage device used in the camera for video recording will be the source document. Check the file for clarity regarding the audio and video recording. YES /NO
2. The memory card/ storage device used in the camera for video recording will be the source document. Check the file for clarity regarding the audio and video recording. YES /NO
3. Rename the file with the unique number for the patient on this research protocol. YES /NO
4. Make backup one by copying that file onto the dedicated external Hard Disk which will be used to document all consent AV recording for a specific research protocol. YES /NO
5. This external HDD should be suitably labeled and password protected. YES /NO
6. Store the external HDD in a secure location to ensure confidentiality. YES /NO
7. Make backup two by copying that file onto a remote cloud storage with encryption using the computer with internet access. YES /NO
8. This should also be suitably located, labeled and password protected. YES /NO

CONFIDENTIALITY AGREEMENT BY EC COORDINATOR

I do hereby declare to maintain confidentiality and agree to the following: -

1. I understand that my name will be recorded on official records in connection with access to any IEC information / data retained by IEC Secretariat.
2. I will maintain the privacy and confidentiality of all accessible data (electronic & printed) or spoken confidential information.
3. I will access data only for which I am authorised explicitly. On no occasion will I use this data including personal, confidential, or subject information for my personal interest or advantage or for any other purpose.
4. I will not disclose confidential or personal data or sensitive information to anyone other than those to whom I am authorised to do so.
5. All personal or confidential information will be kept secure while in my custody and no copies or notes containing such information will be retained by me on completion of the agreed duties.
6. I agree to protect the confidentiality and security of any password, resources used by me to access and utilize the computer systems.
7. I will lock away any record when I leave the office or workstation.
8. If in doubt about any aspect of handling confidential or personal information, I will inform the Member Secretary or any authorized person.
9. I understand that I will continue to be bound by this signed Confidentiality Agreement.

Signature of Coordinator: _____

Date: _____/_____/_____

Name: _____

Signature of Member Secretary: _____

Date: _____/_____/_____

Name: _____

DOCUMENT RETRIEVAL REQUEST FORM

Requested by: Name: _____

Chairperson: ☐

Member Secretary: ☐

IEC Member: ☐

Secretariat staff: ☐

Authority: ☐

Others: ☐

Name of Document requested:

Purpose of the request:

Signature of person requesting and date:

Signature of Member Secretary/ Chairperson and date:

Remarks (if any):

MOVEMENT REGISTER FOR RETRIEVAL OF DOCUMENTS

No	File Number and Document	Name and Designation of person requesting with his/her signature	Date Requested	Date of approval	Retrieved by (Name, Signature and Date)	Returned Date	Archived by (Name, Signature and Date)

PARTICIPANT REQUEST / COMPLAINT FORM

IEC R no.	
Date:	
Received by:	
Request/ Complaint received through:	• Telephone No. _____ • Fax No._____ • Letter / Date _____ • E-mail /Date _____ • Walk-in / Date / Time _____ • Other, specify _____
Participant's Name:	
Contact details Address & Phone:	
Title of the Project	
Starting date of participation :	
Information requested/ complaint/query	
Action taken:	
Reviewed by:	
Final Decision:	
Dated of EC meeting:	

Name:

Signature of Member Secretary

Date

Flowchart.

1.	**Activity**	**Responsibility**
2.	Receiving the request/ query/complaint from research participant	IEC Member Secretary/ Member
3.	Initiating process to identify the problem	IEC Chairperson/ Member Secretary
4.	Deliberations to arrive at solution	IEC Chairperson/ Member Secretary/ Members
5.	Communication with the research participant	IEC Secretariat
6.	File the request document	IEC Secretariat

APPLICATION FORM FOR REQUESTING WAIVER OF CONSENT

1. **Principal Investigator's name:**
2. **Department:**
3. **Title of project:**

_____

_____

4. **Names of other participants, staffs and students:**

_____

_____

5. **Request for waiver of informed consent:**

- Please check the reason(s) for requesting waiver (Please refer the back of this annexure for criteria that will be used by IEC to consider waiver of consent).

[1] Research involves 'not more than minimal risk'

[2] There is no direct contact between the researcher and participant

[3] Emergency situations as described in ICMR Guidelines (ICMR 2017 Guidelines), National Guidelines for Ethics Committees Reviewing Biomedical & Health Research During Covid-19 Pandemic, April 2020

[4] Any other (please specify)

_____

- Statement assuring that the rights of the participants are not violated

_____

- State the measures described in the Protocol for protecting confidentiality of data and privacy of research participant

_____

Principal Investigator's signature with date:

Final decision at full board meeting held on:

Waiver granted Yes ☐ No. ☐ If not granted, reasons

_____

_____

Signature of the Member Secretary with Date:

Type of research projects which may qualify for consent waiver:

A request to waive written informed consent must be accompanied by a detailed explanation. The investigator is also required to provide assurance regarding protection of identity of research participants and maintenance of confidentiality about the data of the research participants. The following criteria (ICMR 2017 & National Guidelines for Ethics Committees Reviewing Biomedical & Health Research During Covid-19 Pandemic, April 2020.) must be met for a research project so that it can qualify for granting a waiver of both written and verbal consent.

1. The proposed research presents no more than minimal risk to participants. (ICMR guidelines 2017*,* National Guidelines for Ethics Committees Reviewing Biomedical & Health Research During Covid-19 Pandemic, April 2020*.)* e.g. a retrospective review of patient case records to determine the incidence of disease/ recurrence of disease. [Minimal risk would be defined as that which may be anticipated as harm or discomfort not greater than that encountered in routine daily life activities of general population or during the performance of routine physical or psychological examinations or tests. However, in some cases like surgery, chemotherapy or radiation therapy, great risk would be inherent in the treatment itself, but this may be within the range of minimal risk for the research participant undergoing these interventions since it would be undertaken as part of current everyday life.
2. When it is impractical to conduct research since confidentiality of personally identifiable information has to be maintained throughout research as maybe required by the sensitivity of the research objective. *(*ICMR 2017guidelines, National Guidelines for Ethics Committees Reviewing Biomedical & Health Research During Covid-19 Pandemic, April 2020*.)*
   e.g. conducting interviews with citizens about their religious beliefs/ people with HIV and AIDS/conducting phone interviews with homosexuals.
   The only record linking the participant and the research would be the consent document and when there is a possible legal, social or economic risk to the participant entailed in signing the consent form as they might be identified as such by signing the consent form, the requirement for obtaining consent can be waived of by the IEC.
   [In case of telephonic interviews, waiver of written informed consent may be requested but this does not mean that verbal consent cannot be utilized].
   The following points need to be considered.
   a. The following documents need to be submitted for the IEC review
   - A script for verbal consent - a verbal consent script provides all of the elements of consent in a more informal style. In addition, each subject should be provided with an information sheet that describes the study and gives contact names and numbers.
   - The interview schedule (questions to be asked???) will confirm that the interview is a simple 5-minute call and that no questions are asked that compromise a person's confidentiality or position.

   b. Normally, investigators will be asked to keep a log of those who were approached about the study and offered verbal consent. A simple chart can indicate the participants as participant 1, participant 2, and participant 3. A column can indicate that verbal consent was given and a date. Since a specific number of study participants are to be recruited. It is important that investigators keep some record to indicate that they are not enrolling more participants than they originally requested.
3. Research on publicly available information, documents, records, work performances, reviews, quality assurance studies, archival materials or third-party interviews, service programs for benefit of public having a bearing on public health programs, and consumer acceptance studies. (ICMR 2017 guidelines, National Guidelines for Ethics Committees Reviewing Biomedical & Health Research during Covid-19 Pandemic, April 2020.)
4. Research on anonymized biological samples from deceased individuals, left over samples after clinical investigation, cell lines or cell free derivatives like viral isolates, DNA or RNA from recognized institutions or qualified investigators, samples or data from repositories or registries etc. (ICMR 2017guidelines, National Guidelines for Ethics Committees Reviewing

Biomedical & Health Research During Covid-19 Pandemic, April 2020.)

5. In emergency situations when no surrogate consent can be taken. (ICMR 2017 guidelines, National Guidelines for Ethics Committees Reviewing Biomedical & Health Research During Covid-19 Pandemic, April 2020.) when consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible, the IEC can allow waiver of consent for recruiting participant in a research study. However, information about the intervention should be given to the patients whenever he/she gains consciousness or to relative/ legal guardian when available later.

RISK BENEFIT ASSESSMENT TOOL AND CHECKLIST

HIGH RISK / LOW BENEFIT (CLASS – A)	HIGH RISK / HIGH BENEFIT (CLASS – B)
Risk	**Risk**
• Completely new drug / formulation • Highly Toxic substances • Safety / Effectiveness not established through earlier studies • High incidence of SAEs/ Side effects in prelim studies • Inadequate or no risk AE handling mechanisms • High data disclosure and data leakage possibilities • Affects large no. of participants • Violation legal / statutory regulations • Inadequate project documentation • Inadequate PI / Staff expertise • New / untried procedures	• Completely new drug / formulation • Highly Toxic substances • Safety / Effectiveness not established through earlier studies • High incidence of SAEs / Side effects in prelim studies • Inadequate or no risk AE handling mechanisms • High data disclosure and data leakage possibilities • Affects large no. of participants • Violation legal / statutory regulations • Inadequate project documentation • Inadequate PI / Staff expertise • New / untried procedures
Benefit	**Benefit**
• Cost of treatment / drug borne by participant • Replaces current drugs with no extra benefits either treatment wise or cost wise • Short term relief as opposed to long term action • No post-trial alternatives	• Completely new cure • Preventive for life i.e. Vaccinations • Significant improvement over existing cures / treatments • Minimal side effects vis-à-vis existing treatments • Elimination of disease rather than temporarily curative • Significant reduction in treatment costs / mode (ex. Pill vs surgery) • Extension of benefits / availability of treatment post-trial • Benefits large no. of participants

LOW RISK / LOW BENEFIT (CLASS – D)	**LOW RISK / HIGH BENEFIT (CLASS – C)**
Risk	**Risk**
• Proven / Acceptable toxicity • Proven safety and efficacy • Drug / formulation a variation of approved drug / class of drugs • SAEs indicate minor / acceptable reactions, side effects • No drug but only data analysis • Minimal data disclosure / leakage possibilities • Minimal risk to legal / statutory regulations • Standard operating / surgical procedures	• Proven / Acceptable toxicity • Proven safety and efficacy • Drug / formulation a variation of approved drug / class of drugs • SAEs indicate minor / acceptable reactions, side effects • No drug but only data analysis • Minimal data disclosure / leakage possibilities • Minimal risk to legal / statutory regulations
Benefit	**Standard operating / surgical procedures** **Benefit**
• Cost of treatment / drug borne by participant • Replaces current drugs with no extra benefits either treatment wise or cost wise • Short term relief as opposed to long term action • No post-trial alternatives	• Completely new cure • Preventive for life i.e. Vaccinations • Significant improvement over existing cures / treatments • Minimal side effects vis-à-vis existing treatments • Elimination of disease rather than temporarily curative • Significant reduction in treatment costs / mode (ex. Pill vs surgery) • Extension of benefits / availability of treatment post-trial • Benefits large no. of patients

S. No.	Elements	Yes/No	Remarks
1.	Were the risks to human research participants that are beyond minimal risk or that require specific attention.		
2.	Is there any reasonable evidence of potential benefits.		
3.	Is the clinical data supporting the risk/benefit ratio in favour of the drug in the proposed new claim is available		
4.	Were steps been taken to minimize or to mitigate risks.		
5.	Were benefits accruing to the research participants, if any? If there will be no benefits, information justifying the potential subjects to participate available.		
6.	Will the community receive any benefit from the conduct of research.		
7.	Was the benefits justified risk during the conduct of research.		

Reviewed By:	
Signature & Date:	

CHECKLIST FOR REVIEWING RESEARCH INVOLVING CHILDREN
(VULNERABLE POPULATION)

Investigator: IEC Ref:

Study Title: ……
…….

For the principal investigator		**IEC Office**
RISK DETERMINATION	**BENEFIT ASSESSMENT**	**IEC ACTION**
Minimal*	Direct benefit	Approvable
	No direct benefit	
Greater than minimal risk	Potential to child	Approvable
Greater than minimal risk	No direct benefit to individual offer general knowledge about the child's condition or disorder.	Approvable case –by-case **

* Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or occurring during the performance of routine physical or psychological examinations or tests.

** Risk may not be more than a minor increase over minimal risk, consent of both parents is required under normal circumstances.

	Yes	**No**	**NA**
Does the research pose greater than minimal risk to children?			
If yes: Are convincing scientific and ethical justifications given?			
If yes: Are adequate safeguards in place to minimize these risks?			
Does the study involve normal volunteers?			
If yes: Is the inclusion of normal volunteers justified?			
Are the studies conducted on animals and adults, appropriate and justified?			
If No: Is the lack of studies conducted on animals and adults justified?			
Will older children be enrolled before younger ones?			
Is permission of both parents necessary?			
If Yes: Are conditions under which one of the parents may be considered: “not reasonably available” described?			
If Yes: Are the conditions acceptable?			
Will efforts be made ensure that parents’ permission to involve their children in research studies is free from coercion, exploitation, and /or unrealistic promises?			
Are provisions made to obtain the assent of children over 7 and, where appropriate, honoring their dissent?			
Are provisions made to protect subjects’ privacy and the confidentially of information regarding procedures?			
Are there special problems that call for the presence of a monitor or IEC member during consent procedures?			
Are special needs of adolescents such as counseling and confidentiality accounted for in the research design?			
Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?			
Does the research involve implications for other family member ?(for example, genetic risk , HIV infection , Hepatitis C)			
If Yes: Are there adequate mechanisms in place to deal with other members of the family?			
Are parents required to be present during the conduct of the research? (Are proposed participants to be very young? Are the procedures involved painful? Must the subject stay overnight in the hospital when they otherwise would not have to?)			

- Approval to proceed with this category of research must be made by the IEC Secretariat, with input from selected experts

Signature of Principal Investigator:_____Date _____

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Comments:	
Primary Reviewer(s) Signature & Date	

CHECKLIST FOR RESEARCH INVOLVING PREGNANT WOMEN & FETUSES

(VULNERABLE POPULATION)

Investigator: **IEC Ref:**

Study Title: ……

…….

SECTION 1
THIS RESEARCH INVOLVES PREGNANT WOMEN OR FETUSES PRIOR TO DELIVERY:

	Yes	No	NA
Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;			
The risk to the fetus is not greater than minimal, or any risk to the fetus which is greater than minimal is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus;			
Any risk is the least possible for achieving the objectives of the research;			
The woman's consent or the consent of her legally authorized representative is obtained in accord with the informed consent provisions, unless altered or waived.			
The woman or her legally authorized representative, as appropriate, is fully informed regarding the reasonably foreseeable impact of the research on the fetus			
No inducements, monetary or otherwise, will be offered to terminate a pregnancy;			
Women's participation in the research will not have an effect on the decisions by investigator with respect to the timing, method or procedures used to terminate a pregnancy; and			
The decision of investigator determining the viability of a fetus will not have an effect if the women participates in the research			

If the response to any of the above is No, the research is not approvable by the IEC at this time.
See section 3

SECTION 2
THIS RESEARCH INVOLVES FETUSES AFTER DELIVERY:

	Yes	No	NA
Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to fetuses			
The individual(s) providing consent is fully informed regarding the reasonably foreseeable impact of the **research** on the fetus			
No inducements, monetary or otherwise, will be offered to terminate a pregnancy;			

Women's participation in the research will not have an effect on the decisions by investigator with respect to the timing, method or procedures used to terminate a pregnancy; and			
The decision of investigator determining the viability of a fetus will not have an effect if the women participates in the research			

AND

A. Fetuses of uncertain viability	**Yes**	**No**	**NA**
1. Does the **research** hold out the prospect of enhancing the probability of survival of the particular fetus to the point of viability, and any risk is the least possible for achieving the objectives of the **research;**			
OR			
The purpose of the **research** is the development of important biomedical knowledge which cannot be obtained by other means and there will be no risk to the fetus resulting from the **research**;			
2. The legally effective informed consent of either parent of the fetus or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained.			

And/or

B. Nonviable fetuses	**Yes**	**No**	**NA**
1. Vital functions of the fetus will not be artificially maintained;			
2. There will be no risk to the fetus resulting from the research;			
3. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and			
4. The legally effective informed consent of both parents of the fetus will be obtained except that the waiver and alteration provisions do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable fetus will suffice to meet the requirements of this paragraph. The consent of a legally authorized representative of either or both of the parents of a nonviable fetus will not suffice to meet the requirements of this paragraph.			

If the response to any of above is **No,** the research is not approvable by the IEC at this time. See section 3.

SECTION 3
THIS RESEARCH CAN BE CONDUCTED ONLY AFTER:

(a) The IEC finds that the research presents a reasonable opportunity to further the understanding, prevention or alleviation of a serious problem affecting the health or welfare of pregnant women or fetuses **and,**

(b) The secretary, after consultation with a panel of experts in pertinent disciplines (for examples: science, medicine, ethics, law) to determine either:

(1) That the research in fact satisfies the conditions set forth in NDCTR, 2019, as applicable, or

(2) The following:

(i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women or fetus;

(ii) The research will be conducted in accord in sound ethical principles; and

(iii) Informed consent will be obtained in accord with informed consent provisions of NDCTR, 2019 and other applicable subparts, unless altered or waived in accord.

Signature of Principal Investigator:_____Date _____

IEC Office use only	
Comments:	
Primary Reviewer(s) Signature & Date	

CHECKLIST FOR RESEARCH INVOLVING COGNITIVELY IMPAIRED ADULTS (VULNERABLE POPULATION)

Investigator: **IEC Ref:**

Study Title: ……

……..

- The purpose of this checklist is to provide support for IEC members or the Designated Reviewer when reviewing research involving cognitively impaired adults as subjects.
  1. For review using the expedited procedure this checklist is to be completed by the **Designated Reviewer** to document determinations required by the regulations and protocol specific findings justifying those determinations and retained.
  2. For review using the convened IEC is to document determinations required by the regulations and protocol specific findings justifying these determinations.

1. **Research Involving Cognitively Impaired Adults in which there is Anticipated Direct Benefit to the subject** (All items must be "Yes")		
Yes	No	One of the following is true (Tick - t-hat is true) • The risk to the participants is presented by an intervention or procedure that holds out prospect of direct benefit for the individual subject. • More than minimal risk to participants is presented by monitoring procedure that is likely to contribute to the participants well – being.
Yes	No	The risk is justified by the anticipated benefit to the participants.
Yes	No	The relation of anticipated benefit to the risk is at least as favourable to the participants as that presented by available alternative approaches.
Yes	No	The proposed plan for the assessment of the capacity to consent is adequate.
Yes	No	Assent is required of: (One of the following must be "**Yes**") One of the following is true (**Tick - that is true**) • All participants • All participants capable of being consulted. • None of the participants
Yes	No	The consent document includes a signature line for a legally authorized representative.
2. Research Involving Cognitively Impaired Adults in which there is No Anticipated Direct Benefit to the subject (All items must be "Yes")		
Yes	No	The proposed plan for the assessment of the capacity to consent is adequate

Yes	No	The objectives of the trial cannot be met by means of study of participants who can give consent personally.
Yes	No	The foreseeable risks to the participants are low.
Yes	No	The negative impact on the participants well-being is minimized and low.
Yes	No	The trial is not prohibited by law.
Yes	No	Participants have a disease or condition for which the procedures in the research are intended.
Yes	No	Participants will be particularly closely monitored.
Yes	No	Participants will be withdrawn if they appear to be unduly distressed.
Yes	No	The proposed plan for the assessment of the capacity to consent is adequate.
Yes	No	Assent is required of (One of the following must be **"Yes")** One of the following is true **(Tick - that is true**) • All participants • All participants capable of being consulted. • None of the participants
Yes	No	The consent document includes a signature line for a legally authorized representative.

Signature of Principal Investigator:_____Date _____

IEC Office use only	
Comments:	
Primary Reviewer(s) Signature & Date	

CHECKLIST FOR RESEARCH INVOLVING STUDENTS, EMPLOYEES OR RESIDENTS

(VULNERABLE POPULATION)

Investigator: **IEC Ref:**

Study Title: ……

……..

Participants who are students, employees or residents require special considerations:

Does the employer or supervisor of the research participant need to be aware of the research project?	No	Yes
Is there a letter of support and/ or internal services checklist?	No	Yes
Have the participants been assured that their status (education, employment, and/or promotion) will not be affected by any decision to participate or not?	No	Yes
Have the risks to participants been minimized?	No	Yes
Have participants been assured that participation is voluntary (no signs of coercion)?	No	Yes
Have participants been assured that confidentiality will be protected or maintained?	No	Yes

Signature of Principal Investigator:_____Date _____

IEC Office use only	
Comments:	
Primary Reviewer(s) Signature & Date	

CHECKLIST FOR CONSIDERATION OF GENETIC RESEARCH

(VULNERABLE POPULATION)

Investigator: **IEC Ref:**

Study Title: ……

……

	Yes	No
Will the samples be made anonymous to maintain confidentiality? If yes, stop here		
Has the investigator established clear guidelines for disclosure of information, including interim or inconclusive research result?		
Has the appropriateness of the various strategies for recruiting participants and their family members been considered?		
Does the proposed study population comprise family members?		
Will family members be implicated in the studies without consent?		
Will the samples be destroyed in the future?		
Is genetic counseling being offered?		

Signature of Principal Investigator:_____Date _____

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Comments:	
Primary Reviewer(s) Signature & Date	

CHECKLIST FOR RESEARCH INVOLVING TERMINALLY ILL PATIENTS

(VULNERABLE POPULATION)

Investigator: **IEC Ref:**

Study Title: ……

……

RISK DETERMINATION	BENEFIT ASSEMENT	IEC ACTION
Minimal	With direct benefit: Without direct benefit:	Approved: Not Approved:
	Potential benefit:	Approved: Not Approved:
	No direct benefit to individual but offer general knowledge about the child's condition or disorder and may benefit to the society or future generations are likely to benefit:	Approved case by case safeguards (with special safeguards): Not Approved:
Less than minimal risk	With direct benefit: Without direct benefit:	Approved: Not Approved:
	Potential benefit:	Approved: Not Approved:
	No direct benefit to individual but offer general knowledge about the child's condition or disorder and may benefit to the society or future generations are likely to benefit:	Approved case by case safeguards (with special safeguards): Not Approved:
Minor increase over minimal risk or Low risk	With direct benefit: Without direct benefit:	Approved: Not Approved:
	Potential benefit:	Approved: Not Approved:
	No direct benefit to individual but offer general knowledge about the child's condition or disorder and may benefit to the society or future generations are likely to benefit:	Approved case by case safeguards (with special safeguards): Not Approved:
More than minimal risk or High Risk	With direct benefit: Without direct benefit:	Approved: Not Approved:
	Potential benefit:	Approved: Not Approved:
	No direct benefit to individual but offer general knowledge about the child's condition or disorder and may benefit to the society or future generations are likely to benefit:	Approved case by case safeguards (with special safeguards): Not Approved:

Minimal risk- Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests where occurrence of serious harm or an adverse event (AE) is unlikely

	Yes	**No**	**NA**
Does the research pose greater than minimal risk to patients?			
If yes: Are convincing scientific and ethical justification given?			
If yes: Are adequate safeguard in place to minimize these risks?			
Are appropriate studies that have been conducted on animals and adults justified?			
If No: Is the lack of appropriate studies conducted on animals and adults justified?			
Do the anticipated benefits justify requiring the subjects to undertake the risks			
Is inclusion of vulnerable population warranted?			
Can the research question be answered by using a non-vulnerable population?			
Will efforts be made ensure that participants are free from coercion, exploitation, and /or unrealistic promises?			
Are provisions made to obtain the consent?			
Are provisions made to protect participant's privacy and the confidentially of information regarding procedures?			
Are there special problems that call for the presence of a monitor or IEC member during consent procedures?			
Are special needs of counseling and confidentiality accounted for in the research design?			
Are there any special problems such as confidentiality and reporting that might arise in this research			

Signature of Principal Investigator:_____Date _____

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Comments:	
Primary Reviewer(s) Signature & Date	

CHECKLIST FOR RESEARCH INVOLVING HIV PARTICIPANTS

(VULNERABLE POPULATION)

Investigator: **IEC Ref:**

Study Title: ……

…….

	Yes	No
Was the consent taken voluntarily?		
During the consent process, is the privacy maintained?		
Is the pre testing counseling provisions are in place?		
Will the samples be made anonymous to maintain confidentiality? If yes, stop here in stored sample study.		
Has the investigator established clear guidelines for disclosure of information, including interim or inconclusive research result?		
Where is the test being carried out? Is the laboratory provide high-quality testing services, and quality assurance mechanisms		
The disclosure of the test results will be done only to the study team/sponsors/regulators with the participant consent.		
Has the appropriateness of the various strategies for recruiting participants and their care takers been considered?		
Does the proposed study requires family members/caretakers permission?		
Would the confidentiality will be maintained?		
Will family members / care takers will be disclosed about the test results?		
Will the samples be destroyed in the future?		
Will the samples be stored for future?		
Is post HIV testing counseling being offered and given?		
Would the participant provided with effective referral to appropriate follow- up services as indicated, including long term prevention and treatment support?		

Signature of Principal Investigator:_____Date _____

IEC Office use only

Comments:	
Primary Reviewer(s) Signature & Date	

CHECKLIST FOR RESEARCH INVOLVING ECONOMICALLY/SOCIALLY BACKWARD/ILLITERATE PATIENTS
(VULNERABLE POPULATION)

Investigator: **IEC Ref:**

Study Title: ……

……..

	Yes	**No**	**NA**
Does the research pose greater than minimal risk to patients?			
If yes: Are convincing scientific and ethical justification given?			
If yes: Are adequate safeguard in place to minimize these risks?			
Do the anticipated benefits justify requiring the subjects to undertake the risks			
Is inclusion of vulnerable population warranted?			
Can the research question be answered by using a non-vulnerable population?			
Will efforts be made ensure that participants are free from coercion, exploitation, and /or unrealistic promises?			
Are provisions made to obtain the consent?			
Are provisions made to protect participants' privacy and the confidentially of information regarding procedures?			
Are there special problems that call for the presence of a monitor or IEC member during consent procedures?			
Are special needs of counseling and confidentiality accounted for in the research design?			
Are there any special problems such as confidentiality and reporting that might arise in this research			

Signature of Principal Investigator:_____Date _____

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Comments:	
Primary Reviewer(s) Signature & Date	

FORMAT FOR RECRUITMENT OF EQUITABLE SUBJECTS

Study Title:

Type of study:

Date of EC approval:

Date of start of study:

Period of recruitment:

Total no. of patient recruitment:

Sr. No.	Subject Initial	Gender	Age	Address	Education	Date of Consent taken	Randomized or screen failed	Details of Compensation / Travel reimbursement

Details of SAEs:

Sr. No.	Subject ID	SAEs onset date	SAE Term	SAEs stop date	Details of Compensation	Remarks

Name & Signature of PI:

Date: