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MAHARASHTRA INSTITUTE OF MEDICAL SCIENCES & RESEARCH (MIMSR)

MEDICAL COLLEGE AND YASHWANTRAO CHAVAN RURAL HOSPITAL, LATUR

Institutional Code of Ethics for Research

Vishwanathpuram, Ambajogai Road, Latur - 413512, India

Prepared By:-

Dr. Abhijeet Muglikar Member Secretary, IEC, MIMSR Medical College, Latur	

Approved by:-

Dr. N. P. Jamadar Dean, MIMSR Medical College, Latur	

FORMAL APPROVAL BY CHAIRMAN, INSTITUTIONAL ETHICS COMMITTEE

This document (standard operating procedures) after being prepared by member secretary and duly approved by all the members of Institutional Ethics Committee is hereby being released with effect from Jan.2021 for the purpose of all Institutional Ethics committee activities to be conducted henceforth.

I do hereby approve the standard operating procedures for the aforesaid purpose.

Chairman
IEC, MIMSR Medical
College, Latur

CONTENTS :

The Institutional Ethics Committee for Research in Human subjects of MIMSR Medical College, Latur would be known as IEC, MIMSR 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 Practical guidelines. This document may be amended either after 1 year or any specific requisite/regulatory requirement which might be considered relevant by the IEC.

1. DECLARATION:

The composition and working procedure of IEC, MIMSR is based on Operational Guidelines for IEC that review Biomedical Research (WHO, 2000), International Conference on Harmonization-Good Clinical Practices (ICH-GCP) Guidelines (1996), New Drugs and Clinical Trials Rules, 2019, Indian GCP guidelines (2016) and Ethical Guidelines for Biomedical Research on Human Participants by ICMR (2017).

2. ESTABLISHING AND CONSTITUTING IEC, MIMSR

Aims and Objectives or the Purpose of IEC:

IEC, MIMSR has been constituted with an aim to provide public assurance of protection, by, among other things, reviewing and approving the clinical trial protocol, the suitability ofthe investigator(s), facilities and the methods and material to conduct clinical research at MIMSR Medical College, Latur under compliance of New Drugs and Clinical Trials Rules, 2019, National Ethical Guidelines for Biomedical Research on Human Participants by ICMR and its requirements.

3. OBJECTIVE:

MIMSR Medical College, Latur has adopted these written Standard Operating procedures (SOP) to ensure the protection of the rights and welfare of human participants in biomedical and behavioral research conducted at MIMSR Medical College, Latur. The objective of these SOPs of the Institutional Ethics Committee of MIMSR Medical College (hereinafter referred to as IEC, MIMSR) for research involving human subjects is to maintain effective functioning of the IEC, MIMSR 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.

4. AUTHORITY UNDER WHICH IEC CONSTITUTED:

MIMSR Medical College and Hospital, Latur has authorized the formation of IEC MIMSR as an independent body which functions independently at our site since 2004 and is being registered under Department of Health Research, ICMR, New Delhi with respect to decision making and its working in order to provide public assurance of protection, by among other things, reviewing, etc. 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: 01-04).

5. PREPARATION OF STANDARD OPERATING PROCEDURES (SOPS) FOR IEC, MIMSR:

5.1. Purpose:

The purpose of this Standard Operating Procedure (SOP) is to define the process for writing, reviewing, distributing and amending SOPs of IEC, MIMSR, Latur. 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 (1996), Declaration of Helsinki and the prevailing amendments from time to time and Amendments from CDSCO office.

5.2. Responsibility:

5.2.1. IEC Secretariat:

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

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

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

5.2.3. Chairman of IEC:

o Chairman of IEC to appoint the SOP team to formulate the SOPs consisting of Member Secretary, one / more members of IEC and Coordinating staff
o Approve the SOPs
o Sign and date the approved SOPs

5.2.4. Coordinating staff of IEC:

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

5.2.5. IEC members:

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

5.3. 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 SOP. If the IEC members do not agree, the Chairman will inform the person/ IEC member who made the request for modification of the SOP 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.

5.4. 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 SOP writing team.

5.5. List of relevant SOPs: (SOP writing team will carry out the subsequent steps)
o Write down step by step all the procedures of the IEC o Organize, devise and name each process

5.6. 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 / bb** number will be assigned to each SOP item by the Member Secretary. "aa" will be a two-digit number assigned specifically to that SOP. "bb" will be a two-digit number identifying the version of the SOP. The number of version should be started from 01 hence for example, SOP 01/01 is the SOP number 01 with version 01. Each annex will be given unique code number with the format AX MM/NN. "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 annex form. Each page of SOP will bear the header which will the effective date i.e. date of approval and validity of the SOPs. The SOP number will be on the cover page while the bottom of page will bear the page number as Page of total pages. The first page of SOP document will be signed and dated by the author/s, the IEC members who have reviewed the SOPs and the IEC Chairman and subsequently the SOP will be implemented from that date.

5.7. 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.

5.8. Review by Consultation:
The draft SOP written by one or more members of the SOP team will be reviewed by the remaining members of the SOP team. After incorporating the suggestions put forth by the SOP 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.

5.9. Preparation and submission of final draft:
o IEC members will review the revised draft SOP in IEC meeting. o The suggestions agreed upon unanimously, by all the IEC members will be discussed and incorporated in the revised draft SOP and the final draft SOP will be formulated.

o The SOP team would stand automatically dissolved once the IEC takes final decision regarding the SOP.

5.10. Approve a new/ revised SOP:

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

5.11. Ensure implementation and file all SOPs:

o The approved SOPs will be implemented from the effective date.
o 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'.
o 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.
o Revision of approved SOPs shall occur at least once a year.

5.12. Manage current and archive superseded SOPs:

o Secretariat will manage current and archive old versions (superseded) of SOPs
o 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.

5.13. Glossary:

o Revision date: Date/year by which the SOP may be revised or reviewed.
o Recipients: Stakeholders who would receive a copy of SOP.
o 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 is 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 wellbeing of human participants involved in a clinical trial and to provide public assurance of that protection.

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

The IEC of MIMSR Medical College, Latur (IEC,MIMSR) is formed by the Dean, MIMSR Medical College, Latur in accordance with the guidelines laid down in the New Drugs and Clinical TrialsRules, 2019, National Ethical Guidelines for Biomedical Research on Human Participants by ICMR.

6.1. Appointment / relieving / acceptance of resignation of any member of the IEC, MIMSR would be the prerogative of the Dean on the recommendation of IEC, MIMSR. 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,

MIMSR Medical College, Latur will appoint co-ordinating staff for IEC. They will be supervised by the MemberSecretary.

6.2. The IEC, MIMSR will be multidisciplinary and multi-sectorial in composition and will have 7-15 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.

6.3. The Composition shall be as follows:

o Chairman (from outside the institute)

o One Member Secretary (one of the members representing the institute as designated by the Dean)

o One or more faculty members of basic medical sciences

o One or more faculty members of Dept. of Pharmacology

o One or more clinicians

o One or more legal experts

One or more independent social scientist/ representative of non-governmental agency or philosopher or ethicist or theologian

o One or more lay persons from community

o One or more woman members

6.4. 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 **(Ax: 02-04)** and declare in writing, conflicts of interest, if any prior to attending the meeting. They will attend the meeting in the capacity of 'Observer' and will not have right to vote.

6.5. Membership requirements:

o The Dean, MIMSR Medical College, Latur is responsible for appointing new committee members.

o The Chairman, Member Secretary or any member can suggest names of potential members but the final decision will remain with the Dean, MIMSR Medical College, Latur.

o 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.

o Members must disclose their interest and involvement by providing a Consent letter **(Ax: 03-04)** and in line with, the Appointment letters **(Ax: 04-04)** will be issued to members along with the Confidentiality agreement **(Ax: 05-04)** which will be required to sign for record of IEC.

o New members will be identified according to the requirement i.e. as per the composition specified in Section 6.3

o New / alternate members will be appointed if deemed necessary by Dean, MIMSR.

6.6. Tenure of Membership:

o 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.

6.7. Resignation:

o 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.
o 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.

6.8. Disqualification:
o If Dean, MIMSR, Chairman or member secretary received a communication in writing alleging misconduct by a member.
o A member can be disqualified if fails to attend more than 3 regular consecutive IEC meetings without prior intimation.
6.9. A list of members of the IEC, MIMSR, their appointment letters, bio-data and consent forms would be maintained by Member Secretary of the IEC, MIMSR. This list 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.

6.10. Hierarchy:
o The Chairman will be head of the committee.
o The Member Secretary will be the guardian of all documents, record and funds in the possession of the committee.
o Other IEC members will be regular committee members with equal ranking.
6.11. Chairman:
o The Chairman will be appointed by the Dean, MIMSR
o The Chairman will be responsible for conducting committee meetings and will lead all discussions and deliberations pertinent to the review of research proposals.
o The Chairman will sign documents and communications related to IEC functioning.
o In case of anticipated absence, the Chairman will nominate a committee member as Acting Chairman.

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

o To perform any other functions as instructed by Member Secretary/ Chairman.

6.14. Responsibilities of IEC members:

o To attend IEC meetings and participate in discussions and deliberations for appropriate decisions.
o To review, discuss and consider research proposals submitted for evaluation.
o To monitor Serious Adverse Event reports and recommend appropriate action(s)
o To review the progress reports and monitor ongoing studies.
o To maintain confidentiality of the documents and deliberations of IEC meetings.
o To declare any conflict of interest, if any.
o To participate in continuing education activities in biomedical ethics and biomedical research.
o To provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat
o To carry out the work delegated by Chairman and Member Secretary
o 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:
o 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
o To take clinical judgement for the trial

Basic Medical Scientist:
o 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,
o 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:
o To review Clinical Trial Agreement (CTA): Parties involved, scope of agreement, responsibilities of parties and payment details
o To review Seven incidence of SAE included or not, Adequacy of amount
o 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 Rule 122DAB, Validity, Countries for which the policy provides cover and Liability limit – per person and total
o Indemnity**:** it should Covers the liability of investigator and sponsor and Could be part of CTA or separate document
o To see informed consent document

Social Scientist / NGO representative / Philosopher / Ethicist:
o 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:
o 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.

7. 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.

8. RESPONSIBILITIES OF THE ETHICS COMMITTEE:

8.1. The IEC, MIMSR is to ensure that the research projects carried out or supported by MIMSR are sound in scientific design, have statistical validity and are carried according to the standard guidelines as prescribed by Good Clinical Practice (GCP), Indian council of Medical Research (ICMR) guidelines and New Drugs and Clinical Trials Rules, 2019. The responsibilities of IEC, MIMSR are:

o To protect the safety, dignity, rights and wellbeing of the potential research participants.
o To include solely those patients who have given informed consent for participation in the research.
o To ensure that universal ethical values and international scientific standards are expressed in terms of local community values and customs.
o To ensure equitable recruitment of subjects in the study.
o To ensure that the research is conducted under the supervision of the medical persons or scientists with required experience and expertise.
o To assist in the development and the education of a research community responsive to local health care requirements.

8.2. The IEC, MIMSR 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, MIMSR would maintain a list of all projects submitted, approved, disapproved and outcome of each project with confidentiality. **(Ax: 06-04)**

8.3. The IEC, MIMSR 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.

9. POLICY FOR UPDATING/TRAINING OF IEC MEMBERS:

9.1. All relevant information on ethics will be brought to the attention of the members of IEC, MIMSR by the Member Secretary.

9.2. All IEC members shall be required to undergo refresher course in Good clinical practice (GCP) annually.

9.3. 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.

9.4. Evaluation of IEC:

The committee will conduct periodic self-assessment annually through internal meeting of the members using the Self-Assessment Tool **(Ax: 07-04).** The individual feedback will be provided to all members by Member Secretary.

10. SELECTION AND RESPONSIBILITIES OF SUBJECT EXPERT:

10.1. Purpose:

For Obtaining the expertise of a professional as a subject expert either affiliated or non-affiliated, to the Institutional Ethics Committee.

10.2. 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.

10.3. 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.

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

10.5. Co-ordination with subject expert:
Subjects experts will participate after they agree to the confidentiality clause **(Ax: 08- 04)** 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, MIMSR
o Investigator or Co-investigator/ Study coordinator of the project under review.
o Any expert in the field of study as and when invited by the IEC, MIMSR. 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.

11. SUBMISSION PROCESS OF RESEARCH PROPOSALS:
All research proposals are to be submitted to the Member Secretary of the IEC, MIMSRin the prescribed Application format **(Ax: 09-04)** along with check list in the prescribed format **(Ax: 10-04)** and detailed study protocol at least three weeks in advance, especially for all clinical trials. Covering letter addressed to the Chairman / Member Secretary, IEC, MIMSR through the Dean, MIMSR
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
iv. Summary / Synopsis
v. Clear research objectives and rationale for undertaking the investigation in human subjects in the light of existing knowledge.
vi. Recent curriculum vitae of the investigators indicating qualification and experience.
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 and vernacular languages and the validity of the translation and back translation (certificate).
xiii. Safety of proposed intervention and any drug or vaccine to be tested, including results of relevant laboratory and animal research. *
xiv. 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.
xv. Case Record Form / Proforma / Questionnaire
xvi. Proposed compensation for participation and reimbursement of incidental expenses/ serious adverse events occurring during the study participation. *
xvii. Plans for storage and maintenance of all data collected during the trial.
xviii. Plans for publication of results – positive or negative – while maintaining the privacy and confidentiality of the study participants.
xix. A statement on probable ethical issues and steps taken to tackle the same.
Activity plan / Timeline
xxi. Amendments to protocol (if any)
xxii. Protocol signature page
xxiii. All other relevant documents related to the study protocol including regulatory clearances and insurance documents as applicable. *
xxiv. Investigator's agreement with the sponsor / Clinical Trial Agreement (CTA) / Agreement to comply with national and international GCP protocols for clinical trials. *
xxv. GCP training certificate (< 3 yrs.) of Principle investigator and study team members
xxvi. Details of Funding agency / Sponsors and fund allocation for the proposed work. *
xxvii. Insurance policy of the study. *
xxviii. Investigator's Brochure. *
xxix. Undertaking by the Investigator*
xxx. Memorandum of Understanding (MOU) between collaborative institutions
xxxi. CTRI registration*
xxxii. DCGI Approval letter. *
xxxiii. FDA marketing/manufacturing license for herbal drugs*
xxxiv. Health Ministry Screening Committee (HMSC) approval*
xxxv. Bhabha Atomic Research Centre (BARC) approval*
xxxvi. Genetic Engineering Advisory Committee (GEAC) approval*
xxxvii. Ethics Committee clearance of other centers (if applicable)
xxxviii. Any additional document(s), as required by IEC
Note: Thirteen copies of the research proposals for clinical trial and checklist filled in by PI along with soft copy on CD need to be submitted, one for the records of the IEC, MIMSR 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.
(*Applicable for Clinical trials)

12. CONSENT REVIEW PROCESS:

Informed Consent:

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. Any changes in Informed Consent Document (ICD) should be approved before implementation and submitted to CLA. As per the new requirements, Table 3 of Third Schedule in New Drugs and Clinical Trials Rules, 2019 **(Ax: 11-04)**, 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 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, MIMSR periodically review the following (by the way of performing random inspection visits).

12.1. 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.

12.2. 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.

12.3. 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.

12.4. 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. 12.5. 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:

12.5.1. Written informed consent should be obtained from the parent or legal guardian. However, all paediatric participants should be informed to the fullest extent possible about the study in a language and in terms that they are able to understand.

12.5.2. Where appropriate, paediatric participants should additionally assent to enroll in the study. Mature minors and adolescents should personally sign and date a separately designed written assent form.

12.5.3. 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 paediatric 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.

12.6. 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.

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

12.8. 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).

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

12.9.1. 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.

12.9.2. 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.

13. PROCESS OF CONDUCTION OF IEC, MIMSR MEETINGS:

13.1. The committee would meet once in every 3 months or whenever it is necessary. If neededwhere the situation is justified the meeting may be called more than once in a month.

13.2. 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.

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

14. REVIEW PROCEDURE:

14.1. The IEC, MIMSR should review every research proposal involving human subjects as per checklist **(Ax: 12-04).** It would ensure that a scientific evaluation has been completed before ethics review is taken up.

14.2. The ethics review of a new project would be done through formal meetings and would not resort to decisions on them through circulation of proposals. 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 MIMSR 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.

14.3. 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, MIMSR for reviewing the proposals of academic research submitted by Postgraduate students as part of their thesis work & UG students.

14.4. 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.

14.5. 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.

14.6. 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.

14.7. 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.

14.8. 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 on site monitoring with the help of the suitable sub-committee (formed with the formal permission from the Dean, MIMSR) who will submit report to the IEC for reviewing. It will also report the same to DCGI within the specified time.

14.9. 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.

14.10. 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.

14.11. Research involving potentially vulnerable groups:

It describes 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. IEC members are responsible for receiving, verifying, and reviewing the research protocols pertaining to vulnerable populations using the Risk benefit assessment tool **(Ax: 13-04).** Such protocols should be reviewed keeping in mind the following points when it concerns research that involves groups that could be potentially vulnerable to coercion:

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

Member of the IEC who would be reviewing such protocols should be well versed with the potential harm or risk of such population participating in the study. For example, children and young people, those with a learning disability or cognitive impairment, or individuals in a dependent or unequal relationship. Committee will review the safety and the rights of justice issues involving vulnerable population if applicable for any particular study involving such populace. Vulnerable Subjects will be defined as per the standard guidelines by ICMR

(http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf) A vulnerable category of subjects are those who are relatively (or absolutely) incapable of protecting their own interests which includes children, prisoners, pregnant women, handicapped or mentally disabled persons, refugees, displaced persons and economically or educationally disadvantaged persons, who are likely to be vulnerable to coercion or undue influence. When a trial is to be carried out in the vulnerable populations like the paediatric, geriatric population, pregnant women, etc., the consent of the trial subject and subject's Legally Acceptable Representative (LAR) is to be mandatorily taken and 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. Where required assent of the participant will also be taken and this will be ensured during review and approval of the ICF.

14.12 Protocol deviation/ non-compliance/ violation: IEC will responsible to review deviation / non-compliance/ violation. The member secretary / Chairman will categorize the protocol deviation as minor and major or may designate members (one/more) to 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. Following the procedures mentioned in protocol in accordance with statutory provisions, National /International ethical guidelines and procedures mandated by IEC, protocol deviation/non-compliance/violation will be detected accordingly.

14.12.1. 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 should submit the protocol deviation report as per the format. **(Ax: 14-04)**

14.12.2. 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 should submit the protocol violation report as per the format. **(Ax: 15-04)**

*** Review of Protocol Amendments:**
In any occasion of amendments to the already approved protocol by the IEC, the said amendment is reviewed by the IEC in the next meeting following submission. The content of amendment is critically reviewed with justification in ethics point of view following Good Clinical Practice (GCP) guidelines. The consensus approval from the committee members regarding this is recorded and communicated to the Principal Investigator.

15. POLICY FOR RESOLUTION OF CONFLICT:
The IEC, MGIMS would refer to the GCP guidelines, ICMR guidelines and New Drugs and Clinical Trials Rules, 2019 and their modifications 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. **(Ax: 16-04)** 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 health 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. The details in respect of the conflict of interest of the members will be recorded in the minutes of the meetings.

16. DECISION MAKING PROCESS:

a) Only those IEC, MIMSR 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 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, MIMSR 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 **(Ax: 16-04)** and should be recorded so in the minutes.

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

c) The decision of the IEC, MIMSR would be by consensus after the quorum requirements are fulfilled to recommend / reject /suggest modifications for a repeat review. If any experts are invited, they would not participate in decision making on a proposal. The decision of the IEC, MIMSR would be one of the following ways:

o 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.

o Approved with modifications: This is a conditional approval. The revisions are required. If revisions are found satisfactory, approval will be granted.

o 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.

o 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.

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

16.1. Communicating the decision: The IEC, MIMSR would issue an opinion letter to communicate the decision taken on any project following prescribed format of approval letter as per recommendation of New Drugs and Clinical Trials Rules, 2019 **(Ax: 17-04)**. This opinion letter would be issued by the Member Secretary to convey the decision of the IEC, MIMSR to the Principal Investigator and must include the following information mentioned with turnaround time of 21 days:

16.1.1. The name of the Project (Same as the Project title).

16.1.2. List of documents reviewed by the IEC, MIMSR including the revised version of documents if any.

16.1.3. List of members present at the meeting.

16.1.4. Members who did not participate in the decision making process.

16.1.5. The date and time of meeting.

16.1.6. The decision of the IEC, MIMSR.

16.1.7. A note to PI to strictly adhere to SOP of IEC, MIMSR Version 04/2020, GCP and latest regulatory requirements plus submission progress updates/deviations as and when it occurs while implementing the sanctioned project.

16.1.8. 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.

16.2. 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.

16.3. In case of premature termination of study, notification should include the reasons for termination along with the summary of results conducted till date.
16.4. IEC, MIMSR may also ratify the provisional decision of the Member Secretary, taken in situations mentioned in clause 14.2, and such ratification if any would be recorded in the minutes of the meeting.
16.5. All correspondence between the IEC, MIMSR 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, MIMSR for a minimum period of five years after the completion of the research.

17. EXPEDITED REVIEW POLICY:

17.1. Purpose:

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.

17.2. Responsibility:

It is responsibility of the Chairman / Member Secretary to determine if a project / protocol qualifies for an expedited review. They 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.

17.3. 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. IEC may do expedited review only if the protocols involve -
17.3.1. Proposals that pose no more than minimal risk may undergo expedited review, for example;
o Research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and leftover clinical samples.
o Research involving clinical documentation materials that are non identifiable (data, documents, records).
17.3.2. Modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s).
17.3.3. Revised proposals previously approved through expedited review, full review or continuing review of approved proposals.
17.3.4. Minor deviations from originally approved research causing no risk or minimal risk.
17.3.5. Progress reports where there is no additional risk, for example activity limited to data analysis. Expert committee will conduct expedited review of SAEs.

17.4. Review protocol & give comments and recommendations:

The designated members / primary reviewers will review the protocol and give their comments and recommendations to the member secretary within seven days from date of receipt of the protocol.

17.5. Decision of IEC:

17.5.1. The Member Secretary will discuss about the comments with the Chairman and decision will be taken in consultation with Chairman.
17.5.2. The decision will be ratified in the regular meeting of IEC.
17.5.3. If deemed necessary, the proposal will be discussed in the forthcoming meeting.

17.5.4. The expedited review process should be completed within 14 working days.
17.5.5. The decision will be conveyed to the principal investigator.

18. POLICY FOR FEES RELATED TO ETHICS COMMITTEE ACTIVITIES:
As a policy of the appointing authority IEC, MIMSR 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 trial may be charged in consultation with the institute authority.

19. 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.

19.1. 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
a) It should declare that the study will be conducted in adherence to relevant national / international guidelines.
b) Policy regarding autonomy (right to withdraw)
c) Confidentiality
d) Selection of participants should be equitable as per the format **(Ax: 18-04)**.
e) Process of obtaining informed consent
f) Protection of vulnerable subjects
g) Policy regarding treatment of study related injury, compensation for study related injury and participation.
h) 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.
19.2. It is mandatory for the investigators to submit the following documents to the IEC, MIMSR
a) A report on the performance of the research on an annual basis and a copy of final report.
b) Each serious adverse event in MIMSR 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).
c) All amendments or revisions in the study protocol.
d) Protocol deviation / non-compliance**(Ax: 14-04)**/ violation **(Ax: 15-04)**
e) Study completion or discontinuation reports.
f) Justification to restart a study discontinued earlier.

19.3. 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:19-04)**. But, in special situations IEC, MIMSR 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, MIMSR by the PI. The final closure report should be received by the PI as per format **(Ax: 20-04)**.

19.4. 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.

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

IEC reviews the SAEs the following the standard protocol **(Ax: 21-04) –** As per format mentioned in the New Drugs and Clinical Trials Rules, 2019 (Third Schedule Table 5)

20.1. 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. In addition, the committee is authorized to offer mediation under appropriate circumstances. IEC should also 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 prepare their report using **Annexure** and based on the report from expert committee (reviewers) IEC will send the same with its opinion on 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. Notifying the IEC does not relieve the PI from his/her responsibility to notify the sponsor, head of institute and regulatory authorities.

20.2. Detailed instructions about on site SAEs:

SAE related activities before IEC meeting:

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. The IEC office should receive the initial reports of SAEs occurred for IEC approved studies within 24 hrs. of the occurrence of the SAE. 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. Follow up reports shall be received within 14 calendar 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.

20.3. Actions to be taken by Member Secretary:

The Member Secretary after receipt of the SAE Report will forward it to the designated reviewer within 1 working day for review. Designated reviewer will review the SAE and communicated the opinion by e-mail or telephone/written report to inform the Chairman/

Member Secretary, IEC. 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. Compensation if applicable will be calculated as per formula specified in the New Drugs and Clinical Trial Rules, 2019 and ICMR guidelines.

20.3.1. Appropriate compensation will be given to the subject according to New Drugs and Clinical Trials Rules, 2019.

21. POLICY OF MONITORING AND OVERSIGHT:

The Chairman/Member Secretary will identify and designate one or more IEC members/independent monitor from IEC to conduct site monitoring of the study. 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 Coinvestigator to be available for the monitoring visit. The report should be submitted by them to IEC by 5 days in the specified visit report format **(Ax: 22-04).** The monitoring will be done either as routine process (annually) during the ongoing approved project or for specific causes as follows –

o Serious deviations reported
o Repeated SAEs
o Non-compliance of progress report by the investigator
o Higher than the proposed recruitment of subjects in the study
o Complaints received from participants
o Any other cause as decided by IEC

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

21.1. Inspection of Site:

IEC, MIMSR will inspect the study site at any time with prior intimation to site & to Investigator about the same. Key focus areas during oversight are listed below:

Delegation log of responsibilities of study team.
o Protocol understanding of the site team.
o Approved protocols, Informed consent and Audio-Visual recording of consent and make sure that the site is using the most recent version.
o Drug accountability.
o Laboratory and other facilities necessary for the study at the site
o Source documents
o Investigator's oversight adequacy
o Availability of study specific logs and forms
o Protocol deviation/violation (if any)
o SAE reporting

Outcome of the visit will be shared by the Member Secretary with the concerned investigator in form of a report within 14 working days.

21.2. Actions to be taken by Chairman:

The Chairman, IEC on basis of the information and comments received from the Member Secretary, IEC and applying his/ her judgment will direct the IEC to any one or more actions listed below, but are not limited to.

o Suspending enrolment of new research participants till further review by the IEC
o Suspending all trial related procedures (except those intended for safety and wellbeing of the participant) till further review by the IEC
o Suspend some trial-related procedures.
o 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.
o 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. The following would be designated as Subject expert during the meetings of the IEC, MIMSR.

22. POLICY FOR WAIVER OF WRITTEN INFORMED CONSENT:

The IEC may grant waiver for requirement of obtaining written informed consent for requesting waiver of consent by the investigators. The Chairman / Member Secretary / IEC members will review the request taking into consideration the types of studies for which waiver of consent may be granted. 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.

23. MANAGEMENT OF PREMATURE TERMINATION /SUSPENSION / DISCONTINUATION OF THE STUDY /WITHDRAWAL OF STUDY:

23.1. Purpose:

To proceeds and manages 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.

23.2. Responsibility:

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.

23.3. Detailed instructions:

Receive premature termination/ Suspension / Discontinuation of the study / Withdrawal of study before site initiation of a research study:

23.3.1. The member secretary / Chairman shall review the results, reasons and accrual data and discuss the report at the regular Full Board meeting.

23.3.2. 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.

23.3.3. 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.

23.4. Record and communication:

23.4.1. 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. 23.4.2. 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. 23.4.3. 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.

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 Institutional Ethics Committee (IEC).

24.2. Scope:

This SOP applies to handling of requests for information/ complaints made by participants concerning the rights and wellbeing of the research participants participating in research studies 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:

o 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: 23-04)**

o 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.

o 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).

o The Secretariat will inform the Chairman about the request, query or complaint received from the research participant.

o 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:

o Right to voluntary participation in research study.

o 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.

o To ask any questions you may have.

o 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 o Right to information about Research Study in an understandable language.

o Right to informed consent and if necessary audio-video consenting before participation in

any Research Study.
o 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. o Right to be treated with dignity, respect and courtesy in a non-judgmental and non-threatening manner.
o 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.
o Right to be informed of the risks, benefits and alternatives of proposed treatment.
o Right to privacy and confidentiality.
o Right to be informed on how to voice a complaint to express concerns, violation of your rights and/or grievance and seek redressal.
o Right to participation in research and innovative therapies.
o Right to consent for diagnostic and therapeutic procedures.
o Right to access clinical records.
o Right to get 24 hours emergency contact details of Research doctor.
o Right to get contact details of Chairperson and Member Secretary of Institutional Ethics Committee.

Responsibilities of Research Participant:

o To provide correct and complete demographic information including full name, age, address, telephone number and e-mail ID (if available).
o To be compliant with research protocol and procedures.
o 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.
o Carefully weigh the risks and benefits when deciding whether to participate in the study.
o To inform your research study doctor and research study team, immediately in case of any injury or development of any new medical conditions.
o 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.
o 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.
o To follow instructions, advice and restrictions regarding treatment plan and visit schedules.
o To treat hospital staff and study team with courtesy.

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

o 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:
o Appoint a subcommittee of two or more IEC members for enquiry in order to resolve the matter.
o Call an emergency meeting of two or more IEC members for discussion or
o Consider the matter for discussion at the next full board meeting
o 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.
o The IEC will insist on factual details to determine gap, if any, between truth and individual

perception.

o 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.

o 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.

o 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.

o The Secretariat will place all documents in the relevant study file.

25. POLICY OF COMMUNICATIONS WITH DIFFERENT STAKE HOLDERS:

25.1. Purpose:

This SOP defines IEC communication with different stakeholder as per regulatory mandate and specifications. IEC communicates with following mentioned stakeholders as per regulatory mandate and specifications:

o Principal Investigator /study team designee
o DCGI
o Dean of the Institute
o Sponsor
o Study Participants

IEC receives letters from different stakeholder submitted or sent to IEC Secretariat and maintain them in record. IEC may mention outward number for letters sent to all concerned stakeholders and records of the same also are kept.

25.2. Principal Investigator:

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

o Study Project Initial Dossier and Amendments, Approval/Dis-Approval letter*/ Query Letters
o Reply to Serious Adverse Event notification
o Opinion on EC analysis and compensation of Study injury/Death
o Response to Protocol deviation/Violation/Waiver
o Response to Continue review/study completion report
o Study termination letter.

*** Communicating the decision:** The IEC, MIMSR would issue an opinion letter to communicate the decision taken on any project following prescribed format of approval letter as per recommendation of New Drugs and Clinical Trials Rules, 2019. This opinion letter would be issued by the Member Secretary to convey the decision of the IEC, MIMSR to the Principal Investigator and must include the following information mention turnaround time 21 days:

o The name of the Project (Same as the Project title)
o List of documents reviewed by the IEC, MIMSR including the revised version of documents if any. List of members present at the meeting.
o Members who did not participate in the decision making process.
o The date and time of meeting.
o The decision of the IEC, MIMSR.
o A note to PI to strictly adhere to SOP of IEC, MIMSR Version 04/2020, GCP and latest regulatory requirements plus submission progress updates/deviations as and when it occurs while implementing the sanctioned project.
o 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.

25.3. DCGI:

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

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

25.4. Dean of the Institute:
IEC writes to Dean or emails regarding following mentioned communications but not limited to, whenever deemed necessary.
o Annual reports of IEC.
o Sharing amended SOP for final acceptance.
o Any issues in IEC functioning
o IEC Requirements

25.5. Sponsor:
IEC writes to Sponsor or emails regarding following mentioned communications but not limited to, whenever deemed necessary.
o Response to any queries raised.
o Confirmation of free medical management and compensation in applicable cases (If deemed necessary).

25.6. Study Participants:
IEC writes to study participants or emails regarding following mentioned communications but not limited to, whenever deemed necessary.
o Reply for complaints
o Reply if any information requested to IEC Office

26. PROCEDURE FOR MEETING PROCEDURES AND RECORDING OF MINUTES:
26.1. 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. Meeting venue: Pharmacology Lecture Hall, Department of Pharmacology, MIMSR, Latur 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.
26.2. 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.
26.3. Conduct of Meeting: The members should gather in IEC meeting room on scheduled time. The Member Secretary should 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. 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 should be recorded in the minutes.
26.4. 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.
o Approved with modifications: This is a conditional approval. The revisions are required. If revisions are found satisfactory, approval will be granted.

o 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.
o 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.
o Defer: The decision cannot be arrived at present and therefore postpone to next meeting. Grounds for this: lack of quorum, lack of expertise etc.
26.5. Preparing and recording the minutes:
o 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.
o The minutes of the IEC meeting will be ratified in the subsequent IEC meeting.
o 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.
o 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.

27. POLICY FOR ARCHIVING AND RETRIEVING:

27.1. Purpose:

The purpose of this Standard Operating Procedure (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.

27.2. Responsibility:

It is the responsibility of the IEC Secretariat to maintain closed study files and administrative documents.
27.3. All correspondence between the IEC, MIMSR 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, MIMSR for a minimum period of five years after the completion of the research so that the records will be accessible to the authorized persons.
27.4. The coordinating staff will maintain the confidentiality for control and archiving of the records by signing the Confidentiality agreement. **(Ax: 24-04)**
27.5. The written request for retrieval can only be made request by IEC members, auditors or any authorized person.
27.6. 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.
27.7. 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.

28. REFERENCES:

1. New Drugs and Clinical Trials Rules, 2019 – CDSCO [Internet] 2019 June. [Updated 2019 March; cited 2019 June 5]Available from https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdfdocuments/NewDrugs_CTRules_2019.pdf.

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. WHO Operating Guidelines for Ethical Review Board that Review Biomedical Research (2000), https://www.who.int/tdr/publications/documents/ethics.pdf
7. 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/)
8. Amendments from CDSCO office https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/clinical-trials/

29. LIST OF ANNEXURES:

1. Authorization letter by the Head of Institute **(Ax: 01-04)**
2. Confidential agreement for guest/observer **(Ax: 02-04)**
3. Consent letter for membership **(Ax: 03-04)**
4. Appointment letter for joining **(Ax: 04-04)**
5. Confidentiality agreement by joining members **(Ax: 05-04)**
6. Tracking record format for retrieval of project Status **(Ax: 06-04)**
7. Self-assessment tool (Evaluation) **(Ax: 07-04)**
8. Confidentiality agreement by subject experts **(Ax: 08-04)**
9. IEC Standard Application Format **(Ax: 09-04)**
10. IEC Standard Checklist Format **(Ax: 10-04)**
11. Standard protocol for Informed Consent **(Ax: 11-04)**
12. Checklist for IEC members **(Ax: 12-04)**
13. Risk & benefit assessment tool **(Ax: 13-04)**
14. Protocol deviation/non-compliance **(Ax: 14-04)**
15. Protocol violation **(Ax: 15-04)**
16. Undertaking regarding conflict of interest **(Ax: 16-04)**
17. Format for Approval by IEC **(Ax: 17-04)**
18. Recruitment of equitable subjects **(Ax: 18-04)**
19. Study progress report **(Ax: 19-04)**
20. Study closure report **(Ax:20-04)**
21. Standard protocol for reviewing of SAE **(Ax: 21-04)**
22. Site monitoring visit report **(Ax: 22-04)**
23. Request/ Complaint Form **(Ax: 23-04)**
24. Confidentiality agreement by Coordinator **(Ax: 24-04)**

MIMSR Medical College, Latur
Institutional Ethics Committee
Office : Department of Pharmacology

To whomsoever it may concern

This is to confirm that I have authorized the formation of IEC which will function independently at MIMSR Medical college, Latur with respect to decision making and its working in order to provide public awareness of protection by reviewing and approving clinical trial protocols, BA/BE studies and Biomedical research projects.

In addition to this institution will provide all support to the ethics committee activities including training, resources and infrastructure.

Date of Formation of Ethics Committee :
Name of the Ethics committee : Institutional Ethics committee, MIMSR, Latur
Address of Ethics Committee : Department of Pharmacology, MIMSR Medical college, Latur.

Dean
MIMSR Medical College, Latur.

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_____, MIMSR. 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.

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

From,
……..
……..
……..

To
The Dean
MIMSR
Latur.

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

Ref: Your Letter No: ……..dated: ……..

Respected Sir,

In response to your letter stated above, I give my consent to become a member of IEC, MIMSR 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 andfinal review.

I shall maintain all the research project related information confidential and shall not revealthe 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:
……..
……..
……..
……..

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, MIMSR Medical College, Latur for a term of three years from to …… following Standard Operating Procedures (SOPs) of IEC, MIMSR, 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 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 researchproposal.
- 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 wellas relevant contemporary literature to the committee members.
- The Member Secretary will be the guardian of all documents, record and funds in thepossession 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 biomedicalresearch.
- Provide information and documents related to training obtained in biomedical ethics andbiomedical research to the IEC secretariat
- Provide an updated CV when requested for by the IEC secretariat

RESPONSIBILITY OF CLINICIAN:

o Attend IEC meetings and participate in discussions and deliberations for appropriate decisions.
o Help to maintain quorum
o Review, discuss and consider research proposals submitted for evaluation.
o 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

o Take clinical judgement for the trial
o Monitor Serious Adverse Event reports and recommend appropriate action(s)
o Review the progress reports and monitor ongoing studies.
o Maintain confidentiality of the documents and deliberations of IEC meetings.
o Declare any conflict of interest, if any.
o Participate in continuing education activities in biomedical ethics and biomedical research.
o Provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat
o Provide an updated CV when requested for by the IEC secretariat
o Carry out the work delegated by Chairperson and Member Secretary
o Assist the Chairperson and Member Secretary in carrying out IEC work as per SOP.

RESPONSIBILITY OF BASIC MEDICAL SCIENTIST:

o Attend IEC meetings and participate in discussions and deliberations for appropriate decisions.
o Help to maintain quorum
o Review, discuss and consider research proposals submitted for evaluation.
o 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,

o 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

o Review the progress reports and monitor ongoing studies.
o Maintain confidentiality of the documents and deliberations of IEC meetings.
o Declare any conflict of interest, if any.
o Participate in continuing education activities in biomedical ethics and biomedical research.
o Provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat
o Provide an updated CV when requested for by the IEC secretariat
o Carry out the work delegated by Chairperson and Member Secretary
o Assist the Chairperson and Member Secretary in carrying out IEC work as per SOP

RESPONSIBILITY OF LEGAL EXPERT:

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

RESPONSIBILITY OF SOCIAL SCIENTIST / NGO REPRESENTATIVE:

o Attend IEC meetings and participate in discussions and deliberations for appropriate decisions.
o Help to maintain quorum
o Review, discuss and consider research proposals submitted for evaluation
o 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.

o Review the progress reports and monitor ongoing studies.
o Maintain confidentiality of the documents and deliberations of IEC meetings.
o Declare any conflict of interest, if any.
o Participate in continuing education activities in biomedical ethics and biomedical research.
o Provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat
o Provide an updated CV when requested for by the IEC secretariat
o Carry out the work delegated by Chairperson and Member Secretary
o Assist the Chairperson and Member Secretary in carrying out IEC work as per SOP

RESPONSIBILITY OF SCIENTIFIC MEMBER:

o Attend IEC meetings and participate in discussions and deliberations for appropriate decisions.
o Help to maintain quorum
o Review, discuss and consider research proposals submitted for evaluation
o 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.

o Review the progress reports and monitor ongoing studies.
o Maintain confidentiality of the documents and deliberations of IEC meetings.
o Declare any conflict of interest, if any.
o Participate in continuing education activities in biomedical ethics and biomedical research.
o Provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat
o Provide an updated CV when requested for by the IEC secretariat
o Carry out the work delegated by Chairperson and Member Secretary
o Assist the Chairperson and Member Secretary in carrying out IEC work as per SOP

RESPONSIBILITY OF LAYPERSON:

o Attend IEC meetings and participate in discussions and deliberations for appropriate decisions.
o Help to maintain quorum
o Review, discuss and consider research proposals submitted for evaluation
o 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.

o Review the progress reports and monitor ongoing studies.
o Maintain confidentiality of the documents and deliberations of IEC meetings.
o Declare any conflict of interest, if any.
o Participate in continuing education activities in biomedical ethics and biomedical research.
o Provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat
o Provide an updated CV when requested for by the IEC secretariat
o Carry out the work delegated by Chairperson and Member Secretary
o Assist the Chairperson and Member Secretary in carrying out IEC work as per SOP

CONFIDENTIALITY AGREEMENT

I hereby do confirm that to maintain the integrity and sanctity in the best interests of the committee. I must volunteer to inform the chairperson/ 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 meetings of the IEC in order to avoid the conflict of interest involved. 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.

Signature:

Name & Designation: _____

_____

Date: _____

Ax: 06-04

TRACKING RECORD FORMAT FOR RETRIEVAL OF PROJECT STATUS

Details of NCE Trials reviewed by ONP Institutional Ethics Committee (IEC Formation: .....)									
Sr. No.	**Date of Meeting**	**Type of Study**	**Project Title**	**Sponsor**	**Principal Investigator**	**Qualifications of the PI**	**Status of Project (Approved/ Rejected)**	**SAE Occurred**	**Informed Consent followed as per rules**

IEC 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. Number of exempt determination made : ☐
5. Number of protocol reviewed by the expedited procedure : ☐
6. Number of protocol reviewed that went to the convened IEC: ☐
7. Number of reviews completed as the primary reviewer : ☐
8. Completion of educational requirements : ☐ Yes ☐ No
9. Attendance at educational sessions (Make tick (√) in the column)
Regular : ☐ Irregular : ☐
10. Number of educational sessions conducted : ☐

Evaluation of Chairs

Person performing the evaluation –

Name of the person who is evaluated-
Period –
i) Preparedness for meetings Scale

Poor	Fair	Average	Good	Excellent
1	2	3	4	5

ii) Contribution to IEC meetings Scale

Poor	Fair	Average	Good	Excellent
1	2	3	4	5

iii) Quality of reviews Scale

Poor	Fair	Average	Good	Excellent
1	2	3	4	5

iv) Communication with IEC staff Scale

Poor	Fair	Average	Good	Excellent
1	2	3	4	5

IEC EVALUATION FORM FOR MEMBER SECRETARY/MEMBERS

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. Number of exempt determination made : ☐
5. Number of protocol reviewed by the expedited procedure : ☐
6. Number of protocol reviewed that went to the convened IEC : ☐
7. Number of reviews completed as the primary reviewer : ☐
8. Completion of required checklist : (Make tick (√) in the column)
Yes: ☐ No: ☐
9. Completion of educational requirement : (Make tick (√) in the column)
Yes: ☐ No : ☐
10. Attendance at educational sessions : (Make tick (√) in the column)
Regular: ☐ Irregular: ☐
11. Number of educational sessions conducted: ☐
12. Preparedness for meetings : (Make tick (√) in the column)
Good: ☐ Average: ☐ Poor: ☐
13. Contribution to IEC meetings: (Make tick (√) in the column) Good: ☐ Average: ☐ Poor: ☐
14. Quality of Reviews : (Make tick (√) in the column)
Good: ☐ Average: ☐ Poor: ☐
15. Communication with IEC staff : (Make tick (√) in the column)
Good: ☐ Average: ☐ Poor: ☐

Feedback-

Signature:

Date:

IEC EVALUATION FORM OF COORDINATOR

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

CONFIDENTIALITY AGREEMENT FORM 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.

_____ **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**

Institutional Ethics Committee
MIMSR, Medical College, Latur

Application form for projects Involving research in human subjects

- Please fill in the details in legible hand writing
- Tick √ in the box for the appropriate answer
- Tick/ Write NA if question is not applicable

IEC, MIMSR Reference No:

Title of the protocol

_____
_____
_____

	Name	**Designation & Qualifications**	**Department & Institution**	**Signature**
Principal Investigator				
Co-Investigator				
Co-Investigator				
Co-Investigator				
Co-Investigator				

(If additional collaborators attach details and letter of Consent by the collaborator (s) on a Separate page.)

Please attach brief curriculum vitae of the study team members (principal investigator, co-investigator,
Study coordinator) Attached ☐
Non-sponsored **(Investigator Initiated)** study ☐ Sponsored study ☐

1. Sponsor Information:

1. Indian a) Government ☐ Central ☐ State ☐
b) Private ☐

2. International Government ☐ Private ☐ UN Agencies ☐

3. Industry National ☐ Multinational ☐

Contact Address of Sponsor:

_____
_____

2.Total Budget : Rs._____
Research Fund will be deposited in: DJST ☐ DDF ☐ Research Society ☐ Other ☐
If other, please specify_____
Please give details of allocation of budget in an attachment. Attached ☐

Type of Study : Epidemiological ☐ Basic Sciences ☐ Animal studies ☐
Any Other ☐ please specify _____
Clinical: Single center ----- Multicentric ---------
If multicentric, how many centres _____

3. Clinical Trials:
Medicine /Vaccines/Device/Herbal Remedies :
i. Does the study involve use of :
Medicine ☐ Devices ☐ Vaccines ☐
Indian Systems of Medicine ☐ Any other ☐ NA ☐
If other, specify----------

ii. Is it approved and marketed
In India ☐ UK & Europe ☐ USA ☐ NA ☐
Other countries, specify----------

iii. Does it involve a change in use, dosage, route of administration? **If yes**, whether DCGI's /Any other Regulatory authority's Permission is obtained? **If yes,** Date of permission :---------- If No, whether DCGI's /Any other Regulatory Authority's Permission applied for?	Yes Yes	No No	NA NA
iv. Is it an Investigational New Drug (IND)? **If yes,** IND No:	Yes	No	NA
a) Investigator's Brochure submitted	Yes	No	NA
b) In vitro studies data	Yes	No	NA
c) Preclinical Studies done	Yes	No	NA
d) Clinical Study is : Phase I ☐ Phase II ☐ Phase III ☐ Phase IV			
e) To submit package insert in case test drug is already marketed in India Attached			
f) Are you aware if this study/similar study are being done elsewhere? **If Yes**, Specify details ---------- ----------	Yes	No	
g). Whether DCGI's permission for testing IND obtained? If yes, Date of permission :---------- Whether DCGI's permission for testing IND applied for?	Yes	No	NA
h) For Ayurvedic or herbal formulation, a copy of the marketing/manufacturing license issued by the FDA to the company to be submitted	Yes	No	NA

4. **Protocol of the proposal** (Submit as attachment)–
Introduction, literature review, aim(s) & objectives, justification for study, methodology describing the potential risks & benefits, outcome measures, statistical analysis and whether it has any national significance

5. Subject selection:
i. Number of Subjects at this centre :
Number of Subjects at all sites in India :
Total number of Subjects at all sites :

ii. Duration of study :

iii. Will subjects from both sexes be recruited
Yes ☐
No ☐
NA ☐

iv. Inclusion / exclusion criteria given Yes ☐ No ☐

v. Type of subjects Volunteers ☐ Patients ☐ NA ☐

vi. Vulnerable subjects Yes No NA
If yes, mention category
pregnant women ☐ children ☐ elderly ☐
fetus ☐ illiterate ☐ handicapped ☐
terminally ill seriously ill ☐ mentally challenged ☐
economically or socially backward employees ☐ captives institutionalized
dependent staff ☐ students ☐

Any other To specify --------- ---------- ----------

6. Privacy and confidentiality
i. Study involves - Direct Identifiers ☐
Indirect Identifiers/coded ☐
Completely anonymised/ delinked ☐

ii. Confidential handling of data by staff Yes ☐ No ☐

7. Use of biological/ hazardous materials i. Use of fetal tissue or	Yes	No	NA
ii. Use of organs or body fluids	Yes	No	NA
iii. Use of recombinant/gene therapy	Yes	No	NA
If yes, has Department of Biotechnology (DBT) approval for DNA products been obtained?	Yes	No	NA
Iv. Use of pre-existing/stored/left over samples	Yes	No	NA
v. Collection for banking/future research	Yes	No	NA
vi. Use of ionizing radiation/radioisotopes	Yes	No	NA
If yes, has Bhaba Atomic Research Centre (BARC) approval for radioactive isotopes been obtained?	Yes	No	NA
Vii. Use of Infectious/bio-hazardous specimens	Yes	No	NA
Viii. Proper disposal of material			
8. Will any sample collected from the patients be sent abroad? **If Yes, specify details of collaborators**	Yes	No	NA

a) Sample will be sent abroad because (Tick appropriate box):
Facility not available in India ☐
Facility in India inaccessible ☐

Facility available but not being accessed. ☐

If so, reasons……..

b) Has permission from Director General of Foreign Trade (DGFT) been obtained?

Yes ☐ No ☐ NA ☐

c) Has permission from Director General of Foreign Trade (DGFT) been applied for?

Yes ☐ No ☐ NA ☐

9. Is the proposal being submitted for clearance from Health Ministry's Screening Committee (HMSC) for International collaboration? (required in case of studies involving collaborations with foreign Laboratory/ Clinic/Institution)

Yes ☐ No ☐ NA ☐

10. In case of studies involving collaborations with other Indian or foreign Laboratory/Clinic/Institution has administrative sanction from the Dean obtained/ applied for? ----------

Yes ☐ No ☐ NA ☐

11. Consent : *Written ☐ Oral ☐ NA ☐

i. Consent form : (tick the included elements)

Understandable language ☐ Alternatives to participation ☐

Statement that study involves research Confidentiality of records ☐

Sponsor of study ☐ Contact information ☐

Purpose and procedures ☐ Statement that consent is voluntary ☐

Risks & Discomforts ☐ Right to withdraw ☐

Benefits ☐ Consent for future use of biological material ☐ NA ☐

Compensation for participation Benefits if any on future commercialization NA

Compensation for study related injury ☐

*If written consent will not be obtained, give reasons:----------

Whether applied for waiver of Consent: _____

ii. Who will obtain consent?

PI/Co-PI ☐ Nurse/Counselor ☐

Research staff ☐ Any other ☐

12. Will any advertising be done for recruitment of Subjects? (posters, flyers, brochure, websites – if so kindly attach a copy)	Yes	No	NA
13. Risks & Benefits: i. Is the risk reasonable compared to the anticipated benefits to subjects/ community / country?	Yes	No	NA
ii. Is there physical / social / psychological risk / discomfort? **If Yes,** Minimal or no risk ☐ More than minimum risk ☐ High risk ☐	Yes	No	NA

iii. Is there a benefit

a) To the subject? Direct ☐ Indirect ☐

b) Benefit to society ☐

14. Data Monitoring i. Is there a data & safety monitoring committee/ Board (DSMB)?	Yes	No	NA
ii. Is there a plan for reporting of adverse events? **If Yes,** reporting is done to : Sponsor ☐ Ethics Committee ☐ DSMB ☐	Yes	No	

iii. Is there a plan for interim analysis of data?	Yes	No	NA
iv. Are there plans for storage and maintenance of all trial database? **If Yes,** for how long? ----------	Yes	No	NA
15. Is there compensation for participation **If Yes,** Monetary In kind Specify amount and type: ----------	Yes	No	NA
16. Is there compensation for injury? **If Yes,** by Sponsor ☐ by Investigator ☐ by insurance ☐ by any other company ☐	Yes	No	NA
17. Do you have any conflict of interest in the present study?(financial/non financial) **If Yes, specify :**---------- ----------	Yes	No	
18. Number of protocols handled by the PI at present including current Status of ongoing studies approved by ECRHS or CARE carried out by the Principal Investigator. (Information to be given: whether study is initiated, no. of approved subjects, no. of subjects enrolled, no. of active subjects, no. of subjects who have completed the study and total duration of the study? Describe briefly in a separate sheet, if required)	☐ _____ _____ _____ _____ _____		
19. Current Brief Curriculum Vitae (signed and dated copy) of the study team members- principal investigator, co-investigator and study coordinator (Information required -age, designation and department, educational qualification, previous research experience in last five years) (Information about GCP training of PI and co-investigator)	(To be enclosed along with the form)		
20. GCP training certificates of principal investigator and co-investigators _____	(To be enclosed along with the form)		
21. Is the trial registered with Clinical Trial Registry? Clinical Trial Registry of India (CTRI)/ any other WHO platform registry **Registration number:** **_____** **If not registered, state the reason** **_____**	Yes	No	NA

Statement of Compliance:

We hereby declare that the information given above is true and that we will comply with the guidelines mentioned in the New Drugs and Clinical Trials Rules, 2019, National Ethical Guidelines for Biomedical Research on Human Participants by Indian Council of Medical Research (2017), Indian GCP Guidelines (2016) and the International Conference on Harmonization - Good Clinical Practices (ICHGCP) Guidelines (1996) and IEC, MIMSR SOPs – 2020 while conducting the research study. Signature of Principal Investigator with date: _____

Signature/s with date of Co-investigators:

1._____2._____3._____4._____

5._____

Forwarded by Head of the Department(s)

Signature/s with date of Heads of Department(s):

_____,_____,_____, _____

_____,_____,_____,_____Stamp/Seal of the Department(s)

Project submission check-list for projects involving research in human subjects
for submission to **IEC, MIMSR Medical College, Latur**

Project Title: _____

_____

Protocol submission for initial review (Tick accordingly)

Sr. No.	Document	Yes	No	Date of submission, if pending	NA
1	Project submission application form duly filled up				
2	Letter to Member Secretary/ Chairperson				
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	Back translations of Informed consent				
9	Back translation certificate				
10	Amendments to the informed consent, if any				
11	Case Record Form				
12	Subject recruitment procedures: (Proofs: advertisement, notices etc.)				
13	Patient instruction card, identity card, diary etc.				
14	Patient/Subject Questionnaire/s (No. -)				
15	Investigator Brochure				
16	Insurance policy (Single copy is needed for submission)				
17	Investigator's undertaking to DCG(I) (Single copy)				
18	DCG(I) approval (Single copy)				
19	Investigator's agreement with sponsor (Copy of the Final Signed Document)				
20	FDA marketing/manufacturing license for herbal formulations/ nutraceutics (Single copy)				
21	Health Ministry Screening Committee (HMSC) approval in case the study involves collaboration with any foreign				
22	Bhabha Atomic Research Centre (BARC) approval in case study involves use of radioisotopes/ ionizing radiations(Single copy)				
23	Genetic Engineering Advisory Committee				

	(GEAC) approval in case study involves use of gene therapy (Single copy)				
24	Director General of Foreign Trade (DGFT) approval in case study samples are to be sent abroad for analysis(Single copy)				
25	Administrative sanction from the Head of the Institution in case of collaborative studies with other institutions (Single copy)				
26	Signed and dated brief current curriculum vitae of the study team members (principal investigator, coinvestigator, study coordinator)				
27	Ethics Committee clearance of other centers, if any (Total No_____)				
28	Log of delegation of responsibility of the study team members				
29	Document Receipt Form (one copy only)				
30	Current Status of Ongoing Studies conducted by Principal Investigator				
31	Documentation of CTRI registration/ any other WHO platform registry (whenever applicable; one copy only)				
32	GCP training certificates of principal investigator and co investigators (one copy only)				
33	Any other Documents submitted Date: Name & Signature of PI				

Date :- Name & Signature of PI

INFORMED CONSENT

1. Checklist of informed consent documents for clinical trial subject,–

1.1 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.

1.2 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.

2. 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 theSponsor'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 inrelation 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.

CHECKLIST FOR IEC MEMBERS

Sr No.	**Contents Tick Remarks**	**Tick**	**Remarks**
1	Contact Address of Sponsor		
2	Total Budget		
3	Information on Clinical Trials		
4	Information on Protocol of the proposal		
5	Subject selection		
6	Privacy and confidentiality		
7	Use of biological/ hazardous materials		
8	Consent		
9	Risks & Benefits		
10	Data Monitoring		
11	Compensation for participation		
12	Compensation for injury		
13	Statement on conflict of interest		

Date: Name & Signature

RISK BENEFIT ASSESSMENT TOOL

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 wiseor 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

PROTOCOL DEVIATION LOG

Deviation: Any departure from the approved protocol, trial documents or any other information relating to the conduct of the trial that does not result in harm to the trial participants and does not significantly affect the scientific value of the trial data.

Sponsor Name	**Protocol ID**	**Site ID**
Investigator Name:		

Event date	**Date of Identification**	**Subject ID /Non subject**	**specific Description of Deviation** Describe the issue	**Could this occurrence have an impact on Patient safety**	**Could this occurrence have an impact on study outcomes**	**Site Corrective and Preventive Actions** Mention where the issue is documented and what action taken or suggested. e.g. Training given
				If "Yes" to either, then do not complete this log, instead complete a "Violation Form"		
				Yes ☐ **No** ☐	**Yes** ☐ **No** ☐	
				Yes ☐ **No** ☐	**Yes** ☐ **No** ☐	
				Yes ☐ **No** ☐	**Yes** ☐ **No** ☐	
				Yes ☐ **No** ☐	**Yes** ☐ **No** ☐	
				Yes ☐ **No** ☐	**Yes** ☐ **No** ☐	

PROTOCOL VIOLATION FORM

Sponsor Name:	Protocol ID :	Site ID:
Trial Title:		
Investigator Name:		
Subject Specific: Subject ID:	**Non-Subject Specific:**	
Date of Occurrence:	Date Reported:	
Description of the Violation		
Action Taken (Corrective &/or Preventive action)		
Corrective Action:		
Preventive Action:		
Responsibility:	Signature & Date:	
For Use by Sponsor/ designee Only:		
Comments:		
Confirmation/ reclassification of reported protocol non-adherence as Protocol Violation (PV) by Sponsor/ Designee		
☐ PV confirmed ☐ PV reclassified as Deviation		
Reasons for reclassification (if any):		
Outcome/ Decision:		
Action Authorised by: Name, Designation - Organisation	**Signature & Date**	
1.		
2.		

Ax: 66-04

UNDERTAKING REGARDING CONFLICT OF INTEREST

Date:

To
The Chairperson,
Institutional Ethics Committee,
MIMSR, Nagpur.

I ....., hereby declare that as Principal Investigator/ Co-investigator / Author / Study team (of) / I have financial interest in the study entitled ……..... ……..... ……..... and I realize that there is a possibility of evoking a conflict of interest I will voluntarily withdraw from this meeting after informing the Chairperson in advance and in writing about it.

Sincerely,

Signature

Name:……..

Role in EC:……

Date of meeting……..

FORMAT FOR APPROVAL BY IEC (CLINICAL TRIALS)

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, Ethics Committee

FORMAT FOR APPROVAL BY IEC (OTHER RESEARCH PROJECTS)

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 MIMSR, Nagpur 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, IEC.

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

STUDY PROGRESS REPORT

Section A: Summary Information

- Site Initiation date:
- Date range for activities included in report:
- Organization name:
- Project name:
- Primary contact information(PI):

Section B: Executive Summary

Study Team

Designation	Number needed	Number available	Staff Resigned	Staff Appointed	Comment/ Remarks

Recruitment status

Sr. No.	Site ID	Total Consented / Screened	Randomized	Follow up visit details

Protocol Violations:

Section D: Scientific Report

- **List of Early terminated /Withdrawn Subjects**

Sr.No.	Subject ID	Date when withdrawn	Discontinued after visit	Reason for discontinuation

(1) Any sites added or dropped to each trial:

(2) The date of the most recent meeting of the Data Safety and Monitoring Board (or equivalent) and any interim analyses:

Principal Investigator (Name and Signature):

Site:

Ax: 71-04

STUDY CLOSEOUT REPORT

Dated:

To,

The Chairman,

Institutional Ethics Committee for Research on Human Subjects,

MIMSR Medical College, Latur

Reference (Project Name):

Subject: End of study of _____

I wish to inform you that the above-mentioned study conducted at _(Department)_, Indira Gandhi Government Medical College & Hospital (MIMSR), Nagpur is complete. This study was being conducted at_____centres. Following is the brief summary of the project.

Recruitment

Initial Ethics Committee approval to conduct the study was obtained on _____

Site Initiation visit was conducted on: _____

First patient First visit (FPFV) at site was on: _____

Last patient Last visit at site was on: _____

Overall Enrolment Study Status	**Site**	**Overall**
Total Number of Subjects screened		
No. of Screen failure subjects		
No. of subjects randomized to the treatment		
No. of early terminations		
No. of subjects completed the study		

Ax: 20-04

Serious Adverse Events occurred

Overall SAE status	Site	Overall
No. of SAEs occurred		

Compliance with Protocol
Attachment 2: Site specific Protocol Deviation Violation Tracker.
Archival of study data

Audit and inspections
As informed by the sponsor / CRO the study can be audited by members of sponsor or external audit contractors on their behalf or inspected by the regulatory authorities.

Clinical Study Report
Clinical Study Report will be submitted to you when received from the sponsor.
If you need further information, please let me know.

Sincerely,

Principal Investigator

Attachments:
Attachment 1: (Site specific protocol deviation / violation tracker)
Attachment 2: (Any other document)

STANDARD PROTOCOL FOR REVIEWING SERIOUS ADVERSE EVENT

1. **Patient Details:**
   Initials and other relevant identifier (hospital or out-patient department (OPD) record number etc)*
   Gender
   Age or date of birth
   Weight
   Height
2. **Suspected Drug(s):**
   Generic name of the drug*
   Indication(s) for which suspect drug was prescribed or tested.
   Dosage form and strength.
   Daily dose and regimen (specify units - e.g., mg, ml, mg/kg).
   Route of administration.
   Starting date and time of day.
   Stopping date and time, or duration of treatment
3. **Other Treatment(s):**
   Provide the same information for concomitant drugs (including non-prescription or Over the Counter OTC drugs) and non-drug therapies, as for the suspected drug(s).
4. **Details of Serious Adverse Event:**
   Full description of the event including body site and severity, as well as the criterion (or criteria) for considering the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the event*
   Start date (and time) of onset of event.
   Stop date (and time) or duration of event.
   Dechallenge and rechallenge information.
   Setting (e.g., hospital, outpatient clinic, home and nursing home).
5. **Outcome:**
   Information on recovery and any sequelae; results of specific tests or treatment that may have been conducted.
   For a fatal outcome, cause of death and a comment on its possible relationship to the suspected event; Any post-mortem findings.
   Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc.
6. **Details about the Investigator:***
   Name and Address
   Telephone number
   Profession (specialty)
   Date of reporting the event to Central Licencing Authority:
   Date of reporting the event to ethics committee overseeing the site:
   Signature of the Investigator or Sponsor
   Note: Information marked * must be provided.

SITE MONITORING VISIT REPORT

- ❖ No. of participants approved at site by IEC: _____
- ❖ Total participants recruited since protocol began: _____
- ❖ New participants recruited since last year:
  - No. of patients screened: ____
  - No. of patients enrolled: ____
  - No. of patients completed: ____
  - No. of patients ongoing: ____
  - No. of patient drop-outs: ____
  - No. of patients who withdrew consent:____(State reasons)
  - No. of patients withdrawn by PI:____(State reasons)

Are site facilities appropriate? Yes ☐ No ☐	Comment:
Are informed consents of recent version used? Yes ☐ No ☐	Comment:
Is it approved by the IEC? Yes ☐ No ☐	Comment:
Whether consent has been taken from all patients? Yes ☐ No ☐	Comment:
Whether appropriate vernacular consent has been taken? Yes ☐ No ☐	Comment:
Are protocols of recent version used? Yes ☐ No ☐	Comment:
Is it approved by the IEC? Yes ☐ No ☐	Comment:
Any adverse event found? Yes ☐ No ☐	Comment:
Any SAEs found? Yes ☐ No ☐	Comment:
Was the IEC informed about SAEs within 7 working days? Yes ☐ No ☐	Comment:
Has any death occurred? Yes ☐ No ☐	Comment:
Was the IEC informed about this death within 24 hrs? Yes ☐ No ☐	Comment:

Any protocol non-compliance /violation? Yes ☐ No ☐		
Are all case record forms up to date? Yes ☐ No ☐		
Are necessary life-saving equipments/drugs present at the site? Yes ☐ No ☐		
Are the site personnel adequate? Yes ☐ No ☐		
Any other relative observations :		
Comments of the monitor		
Duration of visit:……hours	Starting from:	Finish:
Name of IEC/ Independent Monitor		
Completed by:		Date:

REQUEST/ COMPLAINT FORM

Date:	
Received by :	
Request/ Complaint received through:	Telephone No. _____ Fax No. . _____ Letter / Date _____ Walk-in / Date / Time _____ Other, specify _____
Participant's Name:	
Contact details	
Address & Phone:	
IEC Project no.	
Title of the Project	
Starting date of participation :	
Information requested/ complaint/query	
Action taken:	
Reviewed by	
Final Decision	
Dated of EC meeting	

Name, Signature and Date of Member Secretary _____

Flowchart.

Sr. No.	Activity	Responsibility
1	Receiving the request/ query/complaint from research participant	IEC Member Secretary/ Member
2	Initiating process to identify the problem	IEC Chairperson/ Member Secretary
3	Deliberations to arrive at solution	IEC Chairperson/ Member Secretary/ Members
4	Communication with the research participant	IEC Secretariat
5	File the request document	IEC Secretariat

CONFIDENTIALITY AGREEMENT

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: _____

Dean
M.I.M.S.R. Medical College,
& Y.C.R. HOSPITAL,
LATUR - 413 531.