KMCT
AYURVEDA MEDICAL COLLEGE
Approved by NCISM and Affiliated to Kerala University of Health Sciences

TO WHOM SO EVER IT MAY CONCERN

This is to certify that the information in the attached documents is verified by me and is true to the best of my knowledge.

PRINCIPAL
K.M.C.T. AYURVEDA
MEDICAL COLLEGE

K.M.C.T. AYURVEDA MEDICAL COLLEGE

Manassery PO, Mukkam, 673602,Kozhikode,Kerala
0495-229 4664 ayurveda@kmct.edu.in
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3.3.1
Code of ethics of research

PRINCIPAL
K.M.C.T. AYURVEDA
MEDICAL COLLEGE

KMCT
MEDICAL COLLEGE

Ref.No:693/KMCTMC/09/2019

Date: 10.09.2019

NO OBJECTION CERTIFICATE

Certified that we have No Objection to provide the service of the institutional ethics committee for KMCT Ayurveda Medical College in our institution from 10.09.2019.

KMCT MEDICAL COLLEGE
Pin - 673602
MANASSERY

Principal

Principal
KMCT Medical College
Manassery P.O
Kozhikode

Manassery P.O., Mukkam - 673 602. Kozhikode, Kerala, India
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KMCT MEDICAL COLLEGE

INSTITUTIONAL ETHICS COMMITTEE

Ref No:KMCTMC/IEC/10/2023 04.10.2023

I hereby establish and reconstitute the Institutional Ethics Committee of KMCT Medical College from 04.10.2023 to ensure a competent review of ethical aspects of the project proposals received and execute the same free from any bias or external influence.

The following members will constitute the Institutional Ethics Committee.

Dr. C.Ravindran — Chairman
Retd Principal
Govt Medical College Calicut

Dr.Jayakrishnan T — Member secretary
Professor & HOD, Community Medicine,
KMCT Medical College, Phone no: 9447953005

Dr.Mohandas P G — Member (Clinician)
Professor&HOD, General Surgery,
KMCT Medical College, Phone no:9447159084

Dr Divya G Krishnan — Member (Pharmacologist)
Professor & HOD, Pharmacology
KMCT Medical College, Phone no:9895448783

Dr.Reetha James — Member (Clinician)
Associate Professor, Internal Medicine
KMCT Medical College, Phone no:9952721044

Dr.Shamnas M — Member (Pharmaceutical Scientist)
Prof.& HOD, Dept. of Pharmacy Practice
National college of Pharmacy

Dr.ReslinA .Khader — Member (Basic Medical Scientist)
Associate Professor, Pathology
KMCT Medical College, Phone no:7025200889

Dr. Anupama A. — Member (Basic Medical Scientist)
Assistant Professor, Community Medicine.
KMCT Medical College, Phone no:9446549443

Mr.D.V.Narayanan — Member (Legal Expert)
Legal Expert
Kozhikode.PhoneNo:9447776977

Smt.Latha — Member (Social Worker)
SocialWorker.
PhoneNo:9349425399

Mr.Raman.E — Member (Representative from Community)
Representative from Community,Mukkom

Sri.ManoharNamboodiri — Member (Theologian/Philosopher)
Priest Manassery Temple,Manassery (PO) Mukkam

The tenure of this membership will be for a period of 3 years from the date of appointment. The IEC will also review the protocols & clinical trials submitted by affiliated institutions of KMCT Trust & other Hospitals & Institutions with which the IEC have signed MOU for this purpose.

Principal, KMCT Medical College

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INSTITUTIONAL ETHICS COMMITTEE

Standard Operating Procedures

Version 4

Effective from: 25 September 2023
Valid till : 24 September 2026

PREPARED BY:

NAME	SIGNATURE
Dr. Anupama A.	

REVIEWED BY:

NAME	SIGNATURE
Dr. Jayakumar. T	

APPROVED BY:

NAME	SIGNATURE
Dr. C. Ravindran	

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PREPARATION, REVIEW & REVISION OF SOP

1.1 PURPOSE

The purpose of this SOP is to define the process for writing, reviewing, distributing and amending SOPs of the Institutional Ethics Committees (IEC), KMCT Medical College. 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) and 2022 (Amendments), National Ethical Guidelines for Biomedical Research on Human Participants by ICMR (2017), Indian GCP Guidelines, WHO Operating Guidelines for Ethical Review Board that Review Biomedical Research (2000), The International Conference on Harmonization - Good Clinical Practices (ICH-GCP) Guidelines E6(R2), Declaration of Helsinki, National Guidelines for Ethics Committees Reviewing Biomedical & Health Research During Covid-19 Pandemic by ICMR (April 2020) and the prevailing amendments from time to time and Amendments from CDSCO office.

1.2. SCOPE:

This SOP covers the procedure of writing, reviewing, distributing and amending SOPs within KMCT Medical College.

1.3. RESPONSIBILITY:

It is the responsibility of the Chairperson of the IEC to appoint an SOP team to formulate a new SOP or to revise existing SOP. The SOP team shall do this by following the standard procedures, format and coding system that is used while drafting or editing any SOP of the IEC.

1.3.1 Secretariat of IEC

The Secretariat assists the Chairperson to formulate an SOP Team.

- Co-ordinate activities of writing, reviewing, distributing and amending of SOPs
- Ensure that all the IEC members and involved administrative staff have access to the SOPs
- Ensure that all the IEC members and involved staff are working according to current version of SOPs
- Maintain an up-to-date distribution list for each SOP distributed to the IEC members.
- Maintain a file of all current SOPs and the list of SOPs
- Maintain a file of all past SOPs

1.3.2 The SOP team (Member Secretary and one or more members)

- Assess the request for SOP revision in consultation with the Secretariat, Member Secretary and Chairperson.
- Propose new/modified SOP/s as needed
- Draft the SOP/s in consultation with the IEC members and involved administrative staff
- Review the draft SOP
- Submit the draft for approval to Chairperson

1.3.3 Chairperson of the IEC will

- Appoint one or more SOP team
- Approve the SOPs
- Sign and date the approved SOPs

1.3.4 IEC members and involved administrative staff will

- Sign and date the approved SOP when they receive it
- Maintain a file of all SOPs received

1.4 Instructions

1.4.1 Identify the need for new or amendment of current SOP

Any member of the IEC or secretariat who would feel the requirement of 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 by writing to the IEC Chairperson as an email/ letter / verbal request in a meeting. The Chairperson will inform all the IEC members about this request at a regular full -board IEC meeting. If the IEC members agree to the request, an appropriate SOP team(s) will be appointed by the Chairperson and designated the task to proceed with the revision process / formulation process of the SOP. If the IEC members do not agree no further action will be taken. The Chairperson will inform the member of the IEC or Secretariat who made the request for modification of the SOP.

1.4.2 Appoint the SOP Team(s)

- The Chairperson will constitute an SOP Team(s) consisting of the member secretary and two or more members of the IEC who have a thorough understanding of the ethical review process.
- The SOP writing team will carry out the subsequent steps
- List all relevant procedures
- Write down step by step all the procedures of the IEC that are to be standardized in the form of an SOP organize, divide and name each process.

1.4.3 Writing and reviewing a new SOP

When the need for a new sop has been identified and agreed upon, a draft will be written by one or more designated members of the SOP team, appointed by the Chairperson.

1.4.4 Format of the SOP

Each SOP will be given a number and a title that is self-explanatory and is easily understood.

- The header of the document will have the title of the SOP in the column to the left
- Second line in the left column shall have the SOP number
- The third line in the left column shall have the version number
- The column on the right will have the effective date of the SOP and the validity date.

- The footer will have the "Review date of the SOP".

The SOPs will be issued with sequential numbers as follows:

- The document number starts with the institutional and committee abbreviation as KMCT/IEC
- This will the followed by the SOP number written as SOP/01, SOP/02 etc
- The version number follows the SOP number as SOP/01/**V04** for version 4 of the SOP.

1.4.5 Write and review a revised SOP

If an SOP supersedes a previous version, the previous SOP version will be indicated in the Document History Form (AX 02/SOP/01/V01) along with description of the main changes.

1.4.6. Prepare and submit final draft

• The SOP Team will submit the reviewed SOP to the IEC Members who will review it at a meeting.

• The suggestions that are agreed upon by the IEC members present at the meeting will be discussed and incorporated in the revised draft SOP and it will be finalized.

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

1.4.7 Approve the new/revised SOP

• The final version will be presented to the Chairperson for review and approval.

• The Member Secretary & Chairperson will sign and date the SOPs on the last page of each SOP document. This date of approval will be declared as the effective date from which the SOP will be implemented.

1.4.8. Implement, distribute and file SOPs

• The approved SOP will be implemented from the effective date.

• The Member Secretary will discuss the approved SOP with the administrative staff and instruct them to implement it accordingly.

• The approved SOP (pdf copy) will be distributed via email to the IEC members.

• One complete original set of current SOP will be filed in the SOP Master file, by the IEC Secretariat in the IEC office.

• The earlier version will be filled in the file entitled 'Past SOPs of the IEC ' by the IEC Secretariat in the IEC office.

• The IEC members and Secretariat will review the SOPs at least once in every 3 years or as and when required.

Prepared by: Dr. Anupama A. Signature----------

Reviewed by: Dr. Jayakrishnan T. Signature----------

Approved by: Dr. C. Ravindran Signature----------

CONSTITUTION OF INSTITUTIONAL ETHICS COMMITTEE & TERMS OF REFERENCES (TOR)

2.1. PURPOSE:

The purpose of this SOP is to describe the terms of reference (TOR), which provide the frame work for constitution, selection of IEC members, responsibilities and activities of IEC.

2.2 SCOPE:

This SOP applies to the activities performed by the IEC.

2.3 RESPONSIBILITY:

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

2.4. DETAILED INSTRUCTIONS:

The IEC is formed by the Principal, KMCT Medical College in accordance with the guidelines laid down in the New Drugs and Clinical Trials Rules, 2019 and 2022 (Amendments) and National Ethical Guidelines for Biomedical Research on Human Participants by ICMR.

2.4.1 Appointment of members of the IEC

Appointment / relieving / acceptance of resignation of any member of the IEC would be the prerogative of the Principal on the recommendation of IEC.

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 Principal will appoint coordinating staff for IEC. They will be supervised by the Member Secretary.

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

- When a member completes his/ her tenure.
- If a member resigns before the tenure is completed.
- In special situations including death or disqualification of a member
- To fulfill membership requirements as stated in the SOP

New members will be identified by the Chairperson /Member secretary according to the membership requirement after discussion with the IEC. The names of new members to be appointed may be suggested by the Chairperson/Member Secretary to the Principal, KMCT Medical College. The final decision regarding appointment of members will be taken by the Principal.

The Principal will send an official invitation to the proposed member (Ax 01/V04) by mail who then has to send the signed consent (Ax 02/V04) to the Principal with their latest curriculum vitae(Ax 03/V04). The Principal then furnishes the appointment letter for the new member. The tenure will begin on the date of appointment by the Principal.

2.4.2 Composition of the IEC

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

The composition of the IEC will be as follows:

- Chairperson (not affiliated to the institution)
- Member secretary (institutional)
- One person from basic medical science (not affiliated to the institution)
- Two/three basic medical scientists(affiliated to the institution)
- Two clinicians (affiliated to the institution)
- One legal expert (not affiliated to the institution)
- One social scientist (not affiliated to the institution)
- Lay person (not affiliated to the institution)
- One theologian (not affiliated to the institution)

The IEC can also have a set of alternate members who can be invited as members with decision-making powers to meet the quorum requirements. These members have the same TORs as regular members and can attend meetings in the absence of regular members.

The IEC can maintain a panel of subject experts who are consulted for their subject expertise, for instance, a paediatrician for research in children, a cardiologist for research on heart disorders, etc. They may be invited to attend the meeting to give an expert opinion on a specific proposal but will not have decision making power/voting rights.

The IEC may invite subject experts as independent consultants or include a representative from a specific patient group as a member of the IEC or special invitee, for opinion on a specific proposal, for example HIV, genetic disorders, or cancer, with appropriate decision making power.

The Institutional Research Committee will priorly review the proposal before it is referred to IEC. IEC can raise scientific queries besides ethical ones as both good science and ethics are important to ensure quality of research and participant protection.

2.4.3 Criteria for selection of members

Members will be selected in their personal capacities based on their qualifications, experience, interest, commitment and willingness to volunteer the required time and effort for the IEC. Members are appointed to the EC for a particular role. They cannot substitute for the role of any other member who is absent for a meeting.

a) Chairperson

A well-respected person from any background with prior experience of having served/ serving in an IEC.

b) Member Secretary

Should be a staff member of the institution and have knowledge and experience in clinical research and ethics, be motivated and have good communication skill.

c) Basic Medical Scientist

Non-medical or medical person with qualifications in basic medical sciences.

d) Clinician(s)

Should be individual/s with recognized medical qualification, expertise and training.

e) Legal expert

Should have a basic degree in Law from a recognized university, with experience. Training in medical law is desirable.

f) Social scientist/ philosopher/ ethicist/theologian

Should be an individual with social/ behavioural science/ philosophy/ religious qualification and training and/or expertise and be sensitive to local cultural and moral values. Can be from an NGO involved in health-related activities.

g) Lay person(s)

Should be a literate person from the community and has not pursued a medical science/ health related career in the last 5 years. They may be a representative of the community from which the participants are to be drawn and should be aware of the local language, cultural and moral values of the community. Involvement in social and community welfare activities is desirable.

2.4.4 Conditions of appointment

Every IEC member must:

1. Provide a recent signed curriculum vitae (CV) and training certificates on human research protection and good clinical practice (GCP) guidelines, if applicable;

2. Either be trained in human research protection and/or GCP at the time of induction into the IEC, or must undergo training and submit training certificates within 6 months of appointment (or as per institutional policy);

3. Be willing to undergo training or update their skills/knowledge during their tenure as an IEC member;

4. Be aware of relevant guidelines and regulations;

5. Read, understand, accept and follow the conflict of interest (COI) policy of the IEC and declare it, if applicable, at the appropriate time;

6. Sign a confidentiality (Ax 04/V4) and conflict of interest agreement/s (Ax 05/V4);

7. Be willing to place her/his full name, profession and affiliation to the IEC in the public domain; and

8. Be committed and understanding to the need for research and for imparting protection to research participants in research.

2.4.5. Tenure of membership

The tenure of IEC membership will be for a continuous period of 3 years. Any member joining the committee in between the tenure will continue as member for their remaining tenure. Members may be reappointed after the expiry of three years if the appointing authority so decides.

2.4.6 Resignation of a member

A member can resign by submitting a letter of resignation addressed to the Chairman and delivered to the Member Secretary the same will be informed by the Secretary to the appointing authority for formal acceptance and to initiate necessary replacement/recruitment procedure for filling up the vacancy.

The members if opts to step down due to any genuine cause may do so with prior notice and proper information to the appointing authority.

If a member affiliated to the institution resigns/retires from the institution, their resignation from IEC will also be effective from the date of resignation whether formal letter of resignation from IEC is submitted or not.

2.4.7 Disqualification of a member

For misconduct:

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

For non-attendance

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

2.4.8 Policy for updating/training of IEC members

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

2.4.9 Hierarchy

- The Chairman will be the head of the committee.
- The Member Secretary will be the guardian of all documents, record and funds in the possession of the committee.
- Other IEC members will be regular committee members with equal ranking.

2.4.10 Roles of IEC members

Chairman

- Conduct EC meetings and be accountable for independent and efficient functioning of the committee
- Ensure active participation of all members (particularly non-affiliated, non-medical/ non-technical) in all discussions and deliberations
- Ratify minutes of the previous meetings
- In case of anticipated absence of both Chairperson at a planned meeting, the Chairperson should nominate a committee member as Acting Chairperson or the members present may elect an Acting Chairperson on the day of the meeting. The Acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting.
- Seek COI declaration from members and ensure quorum and fair decision making.
- Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data etc.

Member Secretary

• Organize an effective and efficient procedure for receiving, preparing, circulating and maintaining each proposal for review

• Schedule EC meetings, prepare the agenda and minutes

• Organize EC documentation, communication and archiving

• Ensure training of EC secretariat and EC members

• Ensure SOPs are updated as and when required

• Ensure adherence of EC functioning to the SOPs

• Prepare for and respond to audits and inspections

• Ensure completeness of documentation at the time of receipt and timely inclusion in agenda for EC review.

• Assess the need for expedited review/ exemption from review or full review.

• Assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives.

• Ensure quorum during the meeting and record discussions and decisions.

Basic Medical Scientist(s)

• Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report

• For clinical trials, pharmacologist to review the drug safety and pharmacodynamics.

Clinician(s)

• Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics

• Ongoing review of the protocol (SAE, protocol deviation or violation, progress and completion report)

• Review medical care, facility and appropriateness of the principal investigator, provision for medical car, management and compensation.

• Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.

Legal expert/s

• Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol

specific other permissions, such as, stem cell committee for stem cell research, HMSC for international collaboration, compliance with guidelines etc.

• Interpret and inform EC members about new regulations if any

Social scientist/ philosopher/ ethicist/theologian

• Ethical review of the proposal, ICD along with the translations.

• Assess impact on community involvement, socio–cultural context, religious or philosophical context, if any

• Serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.

Lay person(s)

• Ethical review of the proposal, ICD along with translation(s).

• Evaluate benefits and risks from the participant's perspective and opine whether benefits justify the risks.

• Serve as a patient/participant/ community representative and bring in ethical and societal concerns.

• Assess societal aspects if any.

2.4.11 Responsibilities of IEC members

The IEC is to ensure that the research projects carried out or supported by the college are sound in scientific design, have statistical validity and are carried according to its established Standard Operating Procedures based on the operational guidelines as prescribed by New Drugs and Clinical Trials Rules (2019) and 2022 (Amendments), National Ethical Guidelines for Biomedical Research on Human Participants by ICMR (2017), Indian GCP Guidelines, WHO Operating Guidelines for Ethical Review Board that Review Biomedical Research (2000), The International Conference on Harmonization - Good Clinical Practices (ICH-GCP) Guidelines, Declaration of Helsinki and the prevailing amendments from time to time and Amendments from CDSCO office and any guidelines issued by Government of India / ICMR/ DCI during epidemics/pandemics.

The basic responsibility of an EC is to ensure protection of the dignity, rights, safety and well-being of the research participants.

- The IEC must ensure ethical conduct of research by the investigator team.
- The IEC is responsible for declaration of conflicts of interest to the Chairperson, if any, at each meeting and ensuring these are recorded in the minutes.
- The IEC should perform its function through competent initial and continuing review of all scientific, ethical, medical and social aspects of research proposals received by it in an objective, timely and independent manner by attending meetings, participation in discussion and deliberations.
- The IEC must ensure that universal ethical values and international scientific standards are followed in terms of local community values and customs.

- The IEC should assist in the development and education of the research community in the given institute (including researchers, clinicians, students and others), responsive to local healthcare requirements.
- Responsibilities of members should be clearly defined and the SOPs should be given to IEC members at the time of their appointment.
- The Secretariat should support the Member Secretary and Alternate Member Secretary (if applicable) in all their functions and should be trained in documentation and filing procedures under confidentiality agreement.
- The IEC should ensure that privacy of the individual and confidentiality of data including the documents of IEC meetings is protected.
- The IEC reviews progress reports, final reports and adverse events (AE)/serious adverse events (SAE) and gives needful suggestions regarding care of the participants and risk minimization procedures, if applicable.
- The IEC should recommend appropriate compensation for research related injury, wherever required.
- The IEC should carry out monitoring visits at study sites as and when needed.
- The IEC should participate in continuing education activities in research ethics and get updated on relevant guidelines and regulations.
- The IEC may see that conduct of same/similar research by different investigators from same institution is harmonized. Replicative research should not to be encouraged and submission of same research to different funding agencies should not be accepted.

2.4.12 Quorum requirements

- A minimum of five members present in the meeting room.
- The quorum should include both medical, non-medical or technical or/and non-technical members.*
- Minimum one non-affiliated member should be part of the quorum.
- Preferably the lay person should be part of the quorum.
- The quorum for reviewing regulatory clinical trials should be in accordance with current CDSCO requirements.
- No decision is valid without fulfilment of the quorum

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

Prepared by: Dr. Anupama A. Signature----------

Reviewed by: Dr. Jayakrishnan T. Signature----------

Approved by: Dr. C. Ravindran Signature----------

CONFIDENTIALITY AGREEMENT & HANDLING CONFLICT OF INTEREST

3.1 PURPOSE

The purpose of this SOP is to describe the process maintaining confidentiality and identifying and managing Conflict of Interest (COI) among IEC members, guest attendees, observers and subject expert.

3.2 SCOPE

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

3.3 DEFINITIONS

Conflict of interest is a set of conditions in which professional judgment concerning a primary interest like patient's welfare or the validity of research tends to be or appears to be unduly influenced by a secondary interest like non-financial (personal, academic or political) or financial gain.

Types of COI:

1. A personal COI is said to exist when:

- There is immediate family relationship of the member (spouse, parent or parent of spouse, child or child of a spouse, sibling or sibling of a spouse,or a dependent – who resides with an IEC member or consultant or who receives 50% or more support from an IEC member, regardless of age) or other close personal relationship (step relationships included) with the investigator ,or with co- investigators.
- IEC member or his /her immediate family member serves as a contributor to the research project as a collaborator, consultant, research staff or financer.
- Research study is submitted by departmental colleague /senior (may be regarded as a personal conflicting interest if applicable.)

2. A professional COI is where the IEC member or his/her immediate family member serves as trustee, director, manager, or scientific adviser of the funding agency sponsoring the research.

3. A financial COI for IEC members and immediate family exists when the IEC member or the spouse or dependent of a member receives monetary benefits including, but not limited to, salary or payments for other services (e.g. consulting fees or service being evaluated) related to the project.

3.3 RESPONSIBILITY

The IEC would refer to the GCP guidelines, ICMR guidelines and New Drugs and Clinical Trials Rules, 2019 and their modifications. It is the responsibility of each and every newly appointed members to read, understand, accept and sign the confidentiality agreement.

3.3.1. Every member at beginning of the tenure and before he/she commences to review research projects submitted to IEC and before he/she starts to function as an IEC member and before he/she starts attending IEC meeting will read the Confidentiality Agreement (Ax: 04/V04) and Conflict of Interest Agreement (Ax: 07/V04) carefully and thoroughly and will accept by signing it. No members

having a conflict of interest will be involved in the oversight of the clinical trial or bioavailability or bioequivalence or biomedical or any human research study and each member is responsible to withdraw voluntarily from review if there is a conflict of interest after signing a declaring of COI form (Ax: 10/V04) . He/she will sign and date the document and hand over the document to the Secretariat.

3.3.2 Every observer or guest for IEC committee meeting will read the Confidentiality (Ax: 05/V04) and Conflict of Interest Agreement Form (Ax: 08/V04) carefully and thoroughly and will accept by signing it before initiating ethical review and/or before commencement of the meeting. The Secretariat will obtain the document for record.

3.3.3 Every Subject Expert meeting will read the Confidentiality (Ax: 06/V04) /Conflict of Interest Agreement Form (Ax: 09/V04) carefully and thoroughly and will accept by signing it before initiating ethical review and / or before commencement of IEC. The Secretariat will obtain the document for record.

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

3.4.2 DETAILED INSTRUCTIONS

Voluntary disclosure regarding COI by IEC member

The IEC member should determine whether they have a COI before reviewing the research and declare all sources of potential conflicts of interest prior to engaging in any review process. IEC members should not participate in discussing, or decision making on research proposal applications reviewed at any level (exempt, expedited, or full-board) when they have conflicts of interest except to provide information requested by the IEC.

a) If an IEC member has a COI for review outside a meeting (e.g., the expedited procedure amendments), he or she should notify the IEC Secretariat and return the documents.

b) If an IEC member has a COI for a study for which he or she has been assigned as a primary reviewer, he or she will inform the IEC secretariat so that the review is reassigned to other members.

c) If an IEC member has a COI for review of research study at a meeting, he or she will inform the Chairperson and leave the meeting room while discussion of the study takes place. He/she may stay in the meeting room only to answer questions about the research. This is applicable also for IEC meetings at which discussion on serious adverse events, deviations/violations, amendments/ continuing review reports related to studies are discussed.

d) Recusal of IEC member that declares COI and leaves the meeting does not count towards the quorum for the vote. The member's absence under these circumstances is called a recusal, not an abstention or an absence.

e) If an IEC member finds that he/she has a COI during the conduct of a research project approved by IEC, he/she shall report the conflict to the IEC at the next IEC meeting.

• At the beginning of each meeting, the IEC Chairperson asks the members to disclose any COI concerning any of the items on the agenda. During the meeting, IEC member having conflict disclose the existence of the conflict just before the review of the relevant item begins

• If the Chairperson has conflict of interest for a particular project, this should be so declared and handled like any other member's conflict is handled. An acting Chair should be appointed for discussion on such a project. When determination regarding existence of COI is uncertain more information is gathered from relevant sources and determination is done by LEC member with the help of IEC Chairperson Member Secretary or by IEC Chairperson / Member Secretary (as applicable)

• The IEC Chairperson has the final authority to determine whether a COI has been managed or eliminated appropriately for research participant protection.

• The IEC shall not approve a research study proposal where a COI is not managed or eliminated

Management of COI

In case of a COI:

• IEC members will disclose the COI as discussed above

• IEC members will not serve as reviewers

• IEC members will not influence the discussion and decision making of the concerned study by staying away during the IEC meeting

• IEC Member Secretary and the Secretariat will record the points related to disclosure and management of COI of IEC members in the IEC minutes.

Prepared by: Dr. Anupama A. Signature----------

Reviewed by: Dr. Jayakrishnan T. Signature----------

Approved by: Dr. C. Ravindran Signature----------

TRAINING AND EVALUATION OF MEMBERS OF IEC

4.1. PURPOSE

The purpose of this SOP is to describe requirements and methodology for training performance assessment of the Institutional Ethics Committee (IEC) members and the Secretariat at KMCT Medical College.

4.2. SCOPE

The SOP applies to all the IEC members and the Secretariat.

4.3. RESPONSIBILITY

It is the responsibility of the IEC Chairperson with the assistance of Member Secretary to ensure that there is adequate initial and continuing training of the IEC members and the Secretariat. The Chairperson is responsible for assessment of all IEC members and complete a self-assessment exercise at prescribed intervals.

4.4. DETAILED INSTRUCTIONS

4.4.1. Topics for training

IEC members should have knowledge of the following:

- Relevant research ethics and regulatory guidelines
- Roles and Responsibilities of IEC members
- Review of protocol and related documents, including concepts of Risk Benefit assessment. Equity in recruitment, Autonomy, Confidentiality and Privacy
- Recent Developments in relevant health science specialties
- SOPS of the IEC

Secretariat should have knowledge and relevant skills for conducting the following activities:

- Competency in working on Microsoft word, Excel, IEC office software
- Maintenance of IEC Database
- Communication skills- written and verbal
- Knowledge about the SOPs

4.4.2. Training of new IEC Members

Every time a new committee is constituted, the members must undergo initial training on ethics in clinical research and good clinical research and SOPs. One training every year at the minimum should be provided. Member Secretary or an IEC member will provide an introductory training to the new member. The new IEC members would be encouraged to undergo online EC training program me too. The IEC Member Secretary, member, Chairperson will be encouraged to receive continued training by participating in a workshop, conference and/ or retraining program related to research ethics, as a delegate, faculty, facilitator, etc. at least once every year. The IEC will conduct workshops on ethics in clinical research and good clinical research practices from time to time to impart training to the IEC

Members to the Institutional faculty members. The IEC may sponsor or reimburse the expenses of an IEC member or prospective members for attending conference, continuing education session workshop and/ or training program (if applicable).

4.4.3. Training of the Secretariat

The IEC Member Secretary along with other members will train the Secretariat on SOPs. There will be initial training and at least one training session per year on SOPs. The competency of staff in computers and communication skills will be evaluated and ensured initially at the time of appointment by the Member Secretary and Chairperson

4.4.4. Maintenance of training records of the IEC Members and the Administrative Staff

The Secretariat should maintain copies of the certificates of all training workshops and conferences in research ethics attended by the individual IEC members. The copies will be filed in the individual members files. The records regarding training copies of the Secretariat will also be maintained in their respective files.

4.4.5 Evaluation of IEC members

The committee will conduct periodic self-assessment annually through internal meeting of the members using the self-evaluation forms.

- Self-evaluation of Chairman will be done (Ax:11/V04).
- The Chairman will do evaluation of the IEC members and Member Secretary (Ax:12/V04).
- The individual feedback will be provided to all members by Member Secretary.

Prepared by: Dr. Anupama A. Signature----------

Reviewed by: Dr. Jayakrishnan T. Signature----------

Approved by: Dr. C. Ravindran Signature----------

AGENDA PREPARATION, MEETING PROCEDURES & RECORDING OF MINUTES

5.1 PURPOSE

The purpose of this procedure is to elaborate the administrative process and provide instructions for preparation of meeting agenda, review, approval, minutes, and communicating the decision to the Principal Investigator.

5.2 SCOPE

This SOP applies to administrative processes concerning the conduct of IEC meetings.

5.3 RESPONSIBILITIES

It is the responsibility of the Member Secretary assisted by the Secretariat to prepare the agenda for the IEC meeting. The Chairperson will review and approve the agenda. It is the responsibility of the Member Secretary to ensure proper recording and dissemination of the minutes after the meeting is over. It is the responsibility of all members to read and approve the minutes sent to them. The Chairperson will review and finally approve the minutes.

5.4 DETAILED INSTRUCTIONS

The IEC Full Board meeting will be regularly scheduled once in three months/as and when required. In every meeting, the tentative date of the next meeting will be decided.

5.4.1. Before full board IEC meeting

- Prepare the agenda of the meeting
- 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.

The agenda for the IEC meeting is prepared 3 days in advance before the date of meeting. Answers to the IEC queries and amended study related documents from the investigators received 7 days before and other types of documents received 3 days prior to the date of full board IEC meeting will be included in the agenda. Any study-related document (except if related to safety of a participant including SAE report) received within 3 days preceding the date of meeting will not be considered for the meeting. It will be deferred to the next meeting for discussion except in some cases when the matter is deemed urgent and important (having direct bearing on the safety of the research participants such as SAE report or major protocol violation).

In case a meeting is to be rescheduled due to avoidable circumstances, the date and time will be informed to the IEC members telephonically and /or via e-mail. The Secretariat will send via e-mail to members the agenda of the meeting at least 1 day in advance of the scheduled meeting. The Secretariat will make sure that the meeting venue, equipment and facilities are available for the meeting day.

5.4.2 Conduct of the meeting

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

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

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

5.4.3 Decision making

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

Types of decision:

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

5.4.4 Preparation of minutes of the meeting

- The Member Secretary will record the minutes of the meeting as per (Ax:13/V04) and disseminate the same to the members within seven days of the meeting for their signed approval.

- The minutes of the IEC meeting will be ratified in the subsequent IEC meeting.
- In the record section of IEC secretariat, approved minutes will be maintained by the coordinating staff with confidentiality for a minimum period of five years both as soft and hard copies.
- The records will be maintained in such a way that it can be retrieved by tracking the records maintained in the tracking records of the minutes of the meeting.

5.5.5 Conduct of emergency meeting

The Member Secretary in consultation with Chairperson may decide to call an emergency meeting for any one or more of the following reasons:

- Urgent issues (which, if not decided upon early could adversely affect or have adverse impact on patient safety, public safety or national economy etc.)
- Occurrence of unexpected serious adverse event(s).
- Other reasons, as deemed appropriate by the Member Secretary/Chairperson.

Arrangement of an emergency meeting:

The Secretariat will endeavor to contact each and every IEC member and inform about the date, time and venue of the meeting as well as the reason for calling for the meeting. For the purpose of calling an emergency meeting, contact by telephone or email to the email address provided by the member would be considered as sufficient.

The Secretariat will ensure the distribution of all relevant documents for which emergency meeting is scheduled. The relevant details can be sent via email.

Emergency meetings may be arranged through teleconference or any virtual platform.

The emails received from the members will be considered for the attendance.

Discussion and decision-making process:

The Chairman / Member Secretary / Secretariat will determine the quorum is maintained as per requirement.

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

5.5.6 Honorarium to the Member

Reimbursement of traveling expenses and reasonable honorarium will be provided to the EC members for attending the IEC meetings.

5.5.7 Communicating Decision

The decision will be communicated in writing to the PI and relevant stakeholders, preferably within a period of 15 working days of the IEC meeting at which the decision was made.

The communication of the decision will include, but is not limited to, the following

- KMCT Medical College Project No. and title of the research proposal reviewed.
- The clear identification of the protocol of the proposed research or amendment
- The names and specific identification number version numbers /dates of the documents reviewed, including the potential research participant information sheet/material and informed consent form
- The name and title of the Principal Investigator
- The name of the site(s), date and place of the decision
- A clear statement of the decision reached
- Validity of approval will be for the complete proposed duration of the study. This approval is subject to annual review. However failure to submit completed status report by the last due date may result in the expiration of approval.

Prepared by: Dr. Anuparna A. Signature----------

Reviewed by: Dr. Jayakrishnan T. Signature----------

Approved by: Dr C. Ravindran Signature----------

MANAGEMENT OF PROTOCOL SUBMISSIONS

6.1 PURPOSE

This SOP is designed to describe and act as a guideline for the IEC Secretariat to manage research study submissions.

6.2 SCOPE

The scope includes the following:

- Submission for initial review
- Re-submission of study with modifications
- Submission of protocol amendments and any other amendments
- Submission of status reports/continuing review of the study
- Submission of Serious Adverse Events and Deviations/Violations
- Submission of study completion/termination report
- Submission of any other study related documents

6.3 RESPONSIBILITIES

It is the responsibility of the IEC secretariat to receive record and distribute the study documents for IEC review.

6.4 DETAILED INSTRUCTIONS

6.4.1 Initial submission

For the initial review of study, investigators should submit all study related documents to the IEC, no fewer than fourteen (14) days before the next scheduled meeting. The PI should submit research proposal to the IEC for review and approval under any of the sections mentioned below:

- Initial review application
- Re-submission of Study with Corrections
- Protocol Amendment or any other amendments
- Annual Status Reports /Continuing Review of the study
- Study Completion/Termination
- Submission of Serious Adverse Events and Deviations/Violations
- Any other relevant document/s

The IEC will accept new submissions from Principal Investigators only after ensuring that continuing review applications/status reports of the previously approved studies have been submitted by the Principal investigator in a timely manner. The IEC shall not process a new research proposal from the

PI unless the PI has submitted continuing review application/status reports for ongoing IEC approved studies.

The IEC secretariat has created an online system for submission of protocols and other study related documents. From 2023, it has become mandatory to make online submission of new research proposals via the official mail id of the IEC (iec@kmctmedicalcollege.org). After receiving the proposal by an investigator, the IEC Secretariat will disseminate the same to individual members at the earliest. They will also be informed through telephonic conversation regarding the same.

6.4.2 Verification of submission

On receipt of the study related documents via mail, the IEC members will scrutinize the documents for the completeness of the online submission. The scope of administrative review is as enlisted:

Check the submissions for initial review as per checklist, (Ax:14/V04) to ensure that all mandatory forms and documents are submitted.

Notify the investigators, if the online IEC form is incorrectly filled and/or the submission is incomplete as per the checklist. The investigator will be intimated regarding document requests and other administrative findings and queries via email. Upon satisfactory online submission of research proposals by investigators, a notification is sent to the investigators to submit a hard copy of all documents submitted online. Covering letter addressed to the Chairman/Member Secretary of the IEC and forwarded by Head of the department and guide (if any) along with the list of identifying documents are also to be submitted by Principal Investigator (PI).The Secretariat will verify eligibility of PI / research staff involving in the study along with delegation of responsibilities of study team before accepting the protocol of regulatory studies/non-regulatory studies (if needed) and will perform the actions against the submission.

All clinical trials, academic trials, bioequivalence, bioavailability, biomedical and health research and other academic research (UG, PG, DNB, Nursing) study proposals will be submitted to the Member Secretary of the IEC in the prescribed Application format along with checklist and detailed study protocol at least three weeks in advance (especially for all clinical trials). The investigators shall submit their research study proposals for ethical review as per the checklist (Ax:14/V04) along with application form (Ax:15/V04).

Additionally, the investigator shall submit separate application forms according to specific projects as given below:

- For clinical trials, bioequivalence, bioavailability research (Ax: 16/V04)
- For Human Genetics Testing Research (Ax: 17/V04)
- For Socio-behavioral and Public Health research (Ax:18/V04)

The protocol would include the following:

i. Title of the Protocol

ii. Name and contact details of Principal Investigator

iii.Name and contact details of Sponsor/CRO

iv. Recent curriculum vitae of the investigators indicating qualification and experience and medical registration certificates

v. Summary / Synopsis

vi. Clear research objectives and rationale for undertaking the investigation in human subjects in the light of existing knowledge

vii. Participant recruitment procedures or proposed methods / advertisement / notices

viii. Inclusion and exclusion criteria for entry of participants in the study

ix. Precise description of methodology of the proposed research, including intended dosages of drugs, planned duration of treatment and details of invasive procedures if any

x. A description of plans to withdraw or withhold standard therapies in the course of research

xi. The details of statistical analysis of the study

xii. Procedure for seeking and obtaining informed consent with sample of patient information sheet and informed consent forms in English as per (Ax: 19/V04) and vernacular languages and the validity of the translation and back translation (certificate) or amendments to the Informed consent document (if any)

xiii. Assent form, if applicable (Ax: 20/V04)

xiv. Safety of proposed intervention and any drug or vaccine to be tested, including results of relevant laboratory and animal research*

xv. For research carrying more than minimal risk, an account of plans to provide medical therapy for such risk or injury or toxicity due to over-dosage should be included.

xvi. Case Record Form / Proforma / Questionnaire

xvii. Patient instruction card, identity card, diary etc., if any

xviii. Proposed compensation for participation and reimbursement of incidental expenses/ serious adverse events occurring during the study participation*

xix. Plans for storage and maintenance of all data collected during the trial

xx. Plans for publication of results – positive or negative – while maintaining the privacy and confidentiality of the study participants

xxi. A statement on probable ethical issues and steps taken to tackle the same.

xxii. Activity plan / Timeline

xxiii. Amendments to protocol (if any)

xxiv. Protocol signature page

xxv. All other relevant documents related to the study protocol including regulatory clearances and insurance documents as applicable*

xxvi. Investigator's agreement with the sponsor / Clinical Trial Agreement (CTA) / Agreement to comply with national and international GCP protocols for clinical trials*

xxvii. Clinical trial budget

xxviii. GCP training certificate (< 3 yrs.) of Principal investigator and study team members

xxix. Details of Funding agency / Sponsors and fund allocation for the proposed work*

xxx. Insurance policy of the study*

xxxi. Investigator's Brochure*

xxxii. Undertaking by the Investigator*

xxxiii. Memorandum of Understanding (MOU) between collaborative institutions

xxxiv. CTRI registration*

xxxv. DCGI Approval letter*

xxxvi. FDA marketing/manufacturing license for herbal drugs*

xxxvii. Health Ministry Screening Committee (HMSC) approval*

xxxviii. Genetic Engineering Advisory Committee (GEAC) approval*

xxxix. Stem cell committee (ICSCR) approval*

xl. Ethics Committee clearance of other centers (if applicable)

xli. Any additional document(s), as required by IEC

Note: The copies of the research proposals for clinical trial and checklist filled in by PI along with soft copy in CD or in any storage media device need to be submitted, one for the records of the IEC and one each for every member. IEC may constraint the need for hard-copy based submission of research projects

to practice eco-friendly paperless system of operation. For this purpose, IEC would review for a brief PowerPoint Presentation (PPT) to be presented by PI covering all the key topics which shall have equal importance as documentation.

*(Applicable for Clinical trials)

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

6.4.3 Policy for fees for review

The policy for fees for IEC review is as follows:

All undergraduate research proposals from the institution for academic purposes will be reviewed without any fees.

Undergraduate research proposals from user institutions will be processed with a fee of Rs.1000/-

Post graduate research proposals will be reviewed with a fee of Rs.2500/-.

Faculty research proposals will be reviewed with a fee of Rs.2500/-.

For funded research:

- Funded research(non-interventional study) with funding amount below ₹1,00,000/- Rs.2500/-
- Funded research (Non-interventional study) with funding amount up to ₹10,00,000/- = ₹3,000/- as entry fees and ₹500/- per year thereafter till the termination of the project.
- Funded research (Non-interventional study) with funding amount more than₹10,00,000/- up to ₹50,00,000/- = ₹5,000/- as entry fees and ₹700/- per year thereafter till the termination of the project.
- Funded research (Non-interventional study) with funding amount more than ₹50,00,000/- = ₹7,000/- as entry fees and ₹1000/- per year thereafter till the termination of the project.
- Funded research (Interventional / Clinical Trial) having single centre operation

- ₹15,000/- as entry fees, and ₹7,000/- per year thereafter till the termination of the project. Additional fees ₹10,000/- for expedited review and ₹5,000/- for amendments.
- Funded research (Interventional / Clinical Trial) having multi-centric operation ₹20,000/- as entry fees and ₹10,000/- per year thereafter till the termination of the project. Additional fees ₹15,000/- for expedited review and ₹5,000/- for amendments.

Method of payment:

All such processing charges should be deposited in the bank account of IEC, KMCT Medical College at Union Bank of India, Manassery branch.

Expenditure

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

- Paying honorarium to external members (₹2000/- each) for each meeting attended and invited experts.
- Ethical guidelines/GCP training programme organized by IEC.
- Sponsorship of IEC members to present papers on research ethics and represent the IEC in national/international conference.

Prepared by: Dr. Anupama A. Signature----------

Reviewed by: Dr. Jayakrishnan T. Signature----------

Approved by: Dr. C. Ravindran Signature----------

FULL BOARD REVIEW PROCEDURE

7.1 PURPOSE

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

7.2 SCOPE

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

7.3 RESPONSIBILITY

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

7.4 DETAILED INSTRUCTIONS

7.4.1.The research proposals presenting more than minimal risk that are not covered under exempt or expedited review shall be subjected to full committee review. The members will review every research proposal as per checklist (Ax: 21/V04).

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

a) Extension of the study beyond the approved period.

b) Amendment to the study related document not involving the study design.

c) Restarting a previously discontinued research project.

d) All notifications related to adverse events.

7.4.3. Reviewing of academic research proposals submitted by post-graduate and under-graduate students:

The Ethics committee will review the proposals of academic research submitted by postgraduate students as part of their thesis work & undergraduate students.

7.4.4 The following types of research are considered to involve more than **minimal risk** and require ethical approval with a full board review:

- 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 inwhere 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 etc. In particular, where participants are persuaded to reveal information which they would not otherwise disclose in the course ofeveryday life.
- The Committee would evaluate the possible risks to the participants, the expected benefits and adequacy of documentation for ensuring privacy, confidentiality and justice issues.

7.5 Informed consent review process

The principal investigator must obtain the participant's consent in writing using Informed Consent Form (ICF). Patient information sheet and Informed consent form should be approved before initiation of study and furnished to Central Licensing Authority (CLA). Any changes in Informed Consent Document (ICD) should be approved before implementation and submitted to CLA. As per the requirements, Table 3 of Third Schedule in New Drugs and Clinical Trials Rules, 2019 and 2022 (Amendments), IEC shall review the ICD using checklist (Ax: 22/V04). The ICD should clearly state that the participant 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 primary investigator, sponsor and ethics committee representative should be provided in the ICD. In order to aid the calculation of compensation amount, the ICD 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 participant. A copy of ICD should be provided to participant and same should be mentioned in the ICD document. The IEC periodically review the following (by the way of performing random inspection visits).

7.5.1 The investigator shall provide information about the study verbally as well as using a patient information sheet, in a language that is nontechnical and understandable by the subject.
7.5.2 The PI shall describe procedures for obtaining informed consent including the procedure

of Audio Video recording from the research participant prior to enrolling into a research study, especially vulnerable subjects.

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

7.5.4 If the LAR is unable to read or write, an impartial witness who is not a part of the research team should be included in the consent process who will sign in the consent on behalf of his / her.

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

- Written informed consent should be obtained from the parent or legal guardian. However, all pediatric participants should be informed to the fullest extent possible about the study in a language and in terms that they are able to understand.
- Where appropriate, pediatric participants should additionally assent to enroll in the study. Mature minors and adolescents (7-18 age group) should personally sign and date a separately designed written assent form.
- Although a participant's wish to withdraw from a study must be respected, there may be circumstances in therapeutic studies for serious or life- threatening diseases in which, in the opinion of the Investigator and parent or legal guardian, the welfare of a pediatric patient would be jeopardized by his or her failing to participate in the study. In this situation, continued parental or legal guardian consent should be sufficient to allow participation in the study.

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

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

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

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

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

Molecular Entity (NME) including procedure of providing information to the subject and his understanding on such consent, should be maintained by investigator for record:

In case of clinical trial of anti-HIV and anti-leprosy drugs, only audio recording of the informed consent process of individual subject including the procedure of providing information to the subject and his understanding on such consent should be maintained by the investigator for record.

7.6 Clinical Trial Agreement (CTA) review process:

As per regulatory requirement, the PI must provide a legal agreement or contract with the head of the institute and sponsor where trial is to be conducted. The investigator should sign the same to conduct the trial in accordance with the protocol, good clinical practice guidelines, and all applicable requirements, among other things. EC should review the agreement and contract budget with the following mentioned terms using checklist as per (Ax: 23/V04) before giving approval:

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

The allocation of roles and responsibilities of the investigators can be mentioned:

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

Prepared by: Dr. Anupama A. Signature----------

Reviewed by: Dr. Jayakrishnan T. Signature----------

Approved by: Dr. C. Ravindran Signature----------

EXPEDITED REVIEW POLICY

8.1 PURPOSE

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

8.2 SCOPE

This SOP applies to the review and approval of research studies and documents which qualify for expedited review by IEC.

8.3 RESPONSIBILITY

It is responsibility of the Chairman / Member Secretary to determine if a project / protocol qualifies for an expedited review. . IEC may appoint designate one / more members as primary reviewers to expedite the review of such proposals.

8.4 DETAILED INSTRUCTIONS

8.4.1 The Member Secretary, IEC will screen the study for its completeness and depending on the risk involved in the research study categorise it into three types, viz.

1. Full board review (full board/regular review)
2. II. Expedited review
3. III. Exemption from review

An investigator may apply for expedited review for the study protocol using Expedited Review Application Form (Ax: 24/V04). 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

Expedited review may be done in the following circumstances:

- Research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples
- Research involving clinical documentation materials that are non-identifiable (data, documents, records)
- Modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s)
- Revised proposals previously approved through expedited review, full review or continuing review of approved proposals
- Minor deviations from originally approved research causing no risk or minimal risk
- Progress/annual reports where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee
- For multicentre research where a designated main EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full committee common review.
- Research during emergencies and disasters

8.4.2. Review protocol & give comments and recommendations:

The designated primary reviewers of the IEC may review the protocol and give their comments and recommendations to the Member Secretary within five days from date of receipt of the protocol. The designated primary reviewers, after reviewing each study protocol will lead the discussion on the relevant protocol in the subsequent meeting.

8.4.3. Decision of IEC:

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

Prepared by: Dr. Anupama A. Signature----

Reviewed by: Dr. Jayakrishnan T. Signature----

Approved by: Dr. C. Ravindran Signature----

POLICY FOR EXEMPTION FROM REVIEW

9.1 PURPOSE

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

9.2 SCOPE

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

9.3 RESPONSIBILITY

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

9.4 DETAILED INSTRUCTIONS

The proposals submitted for initial review or requested for the exemption from review stating the reason in the application form for exemption from review (Ax: 25/V04) to the IEC will be evaluated for the exemption from review.

Proposals with less than minimal risk where there are no linked identifiers, like:

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

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

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

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

- The publisher of the research.

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

9.4.2 Decision of IEC:

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

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

Prepared by: Dr. Anupama A. Signature----

Reviewed by: Dr. Jayakrishnan T. Signature----

Approved by: Dr. C. Ravindran Signature----

POLICY FOR REVIEW OF RESUBMITTED PROTOCOL

10.1 PURPOSE

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

10.2 SCOPE

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

10.3 RESPONSIBILITY

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

10.4 DETAILED INSTRUCTIONS

10.4.1 Reviewing procedure:

The secretariat will verify the resubmitted documents if the principal investigator has replied within 30 days of receipt of IEC letter or PI will be asked to submit the requisite documents and forward it to Member Secretary.

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

If there are **major** modifications, the protocol and related documents will be reviewed by the Member Secretary or designated members or all the IEC members and will be discussed in the next full board meeting as per decision taken during initial review.

In case the decision is to be discussed, the Primary reviewer(s) / Member Secretary will present a brief oral summary of the study design and the comments of the IEC members/Chairman in the IEC full board meeting will be sought.

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

10.4.2 Decision of IEC:

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

- If the IEC decision is 'Approved', it implies the approval of the study as it is presented with no modifications and the letter of permission can be issued to the Principal Investigator.
- If the IEC decision is 'Approved with minor modification, the IEC Chairman may authorize the Member Secretary / Primary reviewer + Member Secretary to determine if the response and changes are satisfactory and decide if letter of permission can be issued to the Principal Investigator.
- If the IEC decision is 'Approved with major modification, the IEC Chairman may authorize the Primary reviewer + Member Secretary to review the responses which may or may not be discussed in next full board meeting depending on the comments of the reviewers. If the response and changes are approved in the full

board, letter of permission can be issued to the Principal Investigator. The decision will be communicated to the PI within 14 days. For the projects which will be discussed in the full board meeting, the decision will be communicated within 14 days of the meeting. Response from the PI to the IEC communication is expected within 30 days of date of receipt of the letter and in the absence of any response, the project will be declared closed for the IEC office records. Reply to subsequent queries should be sent in 15 days. The Secretariat will record the decision reached on the response in the minutes of the meeting.

Prepared by: Dr. Anupama A. Signature

Reviewed by: Dr. Gayakrishnan T. Signature

Approved by: Dr. L. Ravindran Signature

POLICY FOR REVIEW OF AMENDED PROTOCOL/RELATED DOCUMENTS

11.1 PURPOSE

The purpose of this procedure is to describe how protocol amendments (post approval modifications) or any other amendments/letters are reviewed by the IEC.

11.2 SCOPE

This SOP applies to amended study protocols/ documents and letters that are modified after IEC approval. Amendments made to protocols or any other amendments related to the study may not be implemented until reviewed and approved by the IEC.

11.3 RESPONSIBILITY

PIs are responsible for obtaining IEC approval of proposed amendments to an IEC approved protocol before implementing them. Amendment is a revision, modification, addition to or deletion from an approved research protocol.

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

11.4 DETAILED INSTRUCTIONS

11.4.1 Reviewing procedure:

IEC Secretariat will accept the amended protocol submitted by the PI and ensure completeness of content of the protocol amendment (the details of amendment including the summary of changes from previous version to present version and mention the reason for amendment) and will forward it to the Member Secretary / Chairman with the protocol amendment request form (Ax: 26/V04). If any of the documents or information are missing / incomplete, the Secretariat will inform the Principal Investigator to submit the required documents. The Member Secretary or Chairman will categorize the amendments as minor or major amendment.

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

Following aspects are considered as protocol amendment (which may include but is not limited to):

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

11.4.2 Decision of IEC:

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

Prepared by: Dr. Anupama A. Signature----------

Reviewed by: Dr. Jayakrishnan T. Signature----------

Approved by: Dr. C. Ravindran Signature----------

POLICY FOR PERIODIC REVIEW OF PROTOCOLS

12.1 PURPOSE

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

12.2 SCOPE

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

12.3 RESPONSIBILITY

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

12.4 DETAILED INSTRUCTIONS

12.4.1 Reviewing procedure:

The Member Secretary will plan for periodic review of protocol in consultation with the Chairman in the full board meeting. The progress of clinical trial research proposals will be followed (via periodic reports from PI) at regularintervals 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:27/V04). But, in special situations IEC will ask for follow up report from PI at shorter intervals based on the need, nature and events of research project. IEC members will review the progress of the entire study, protocol/Informed consent Document amendments, not just the changes init, to ensure continuous protection of the rights and welfare of research participants. If the Principal Investigator fails to submit the periodic update report within one month of the due date unless specified otherwise, the IEC secretariat will send a reminder. If there is no response within 15 days after the date of reminder, the IEC secretariat will put up the matter for discussion in the next full board meeting for appropriate action which may consist of but not limited to:

- A letter reprimanding the Investigator
- Suspending review of projects for a specified time.
- A letter asking the Investigator to put recruitment of new participants on hold.If deemed necessary, principal investigators may be called for the discussion.

12.4.2 Decision of IEC:

The committee will ensure research are conducted in accordance with the ICH GCP, New Drugs & Clinical Trial Rules 2019 and 2022 (Amendments), National Ethical Guidelines for Biomedical and Health Research Involving Human Participants 2017 and current regulatory guidelines/ requirements. If IEC found there is no need of any modifications, the IEC shall approve the study to continue as it is. The protocol that have been suggested modifications by the IEC may not approve until the conditions have been met by the PI. The research may be discontinued with reason if the established procedure found to be not satisfactory or any significant findings that have arisen during the review process by the IEC. The decision of IEC will be communicated to the PI within 14 days. The Secretariat will record the decision reached on the proposed periodic review report in the minutes of the meeting.

Prepared by: Dr. Anupama A. Signature----

Reviewed by: Dr. Jayakrishnan T. Signature----

Approved by: Dr. C. Ravindran Signature----

POLICY FOR PROTOCOL DEVIATION/VIOLATION

13.1 PURPOSE

The purpose of this SOP is to describe actions to be taken by the IEC when investigator(s)/ trial site(s) fail(s) to follow the procedures written in the approved protocol or comply with national and/ or international guidelines or respond to the IEC requests regarding statutory, ethical, scientific or administrative matters.

13.2 SCOPE

This SOP applies to all IEC approved research protocols involving human research participants.

13.3 RESPONSIBILITY

The IEC shall be responsible to receive the deviation / violation reports. Protocol deviation/ non-compliance/ violation will be reported by the Investigator/ study site monitor/sponsor/ Contract-Research Organization to the IEC in the prescribed format (Ax: 28/V04). The Member Secretary / Chairman will categorize the act as deviation/violation. The IEC members or designated member(s) (if any), will review and take a decision depending on the seriousness of the deviation/non-compliance/violation. The decision will be taken to ensure that the safety and rights of the research participants are safeguarded.

13.4 DEFINITIONS

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.
Protocol violation/s: Any 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.

13.4 DETAILED INSTRUCTIONS

The Chairman / Member Secretary / primary reviewers will review the submitted protocol deviations/ non-compliances/ violations and assess the impact on the safety wellbeing of the participants and data integrity of the study along with risk benefit analysis.
Primary reviewers (if appointed) will send the comments to the MemberSecretary with the decision.
The Chairman / Member Secretary / IEC members will review the information available and take a decision depending on the seriousness of the deviation / non-compliance/ violation. The decision will be taken to ensure that the safetyand rights of the research participants are safe guarded. The decision will be taken by consensus / voting. The actions taken by IEC could include one or more of the following:

- Inform the Principal Investigator that IEC has noted the deviation /violation
- Direct the PI to ensure that deviations/violations do not occur in future andfollow IEC recommendations.
- Enlist measures that the PI would undertake to ensure that deviations/violations do not occur in future
- Reprimand the PI.
- Call for additional information.

- Suspend the study till additional information is made available and is scrutinized.
- Suspend the study till recommendations made by the IEC are implemented by the PI and found to be satisfactory by the IEC.
- Suspend the study for a fixed duration of time.
- Inform the Dean/Principal
- Revoke approval of the current study.
- Inform DCGI or Other relevant regulatory authorities.
- Keep other research proposals from the PI/ Co-I under abeyance.
- Review and/ or inspect other studies undertaken by PI/Co-I.
- Refuse to review subsequent applications from an investigator cited for non-compliance for a specified duration of time.
- Any other action considered appropriate by the IEC for safeguarding the interests of the research participants participating in the current trial or in future trials.

13.5 Decision taken by IEC

The action will be taken by the IEC based on:

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

The decision taken by IEC could include one or more of the following:

- Determine that no further action is required, or take other actions as appropriate.
- Inform the PI that the IEC has noted the violation/deviation, and instruct the PI to ensure that deviations violations do not occur in future and to follow IEC recommendations
- Enlist measures that the PI would undertake to ensure that such deviations/violations do not occur in future.
- Observe the research or consent process (depending on the nature and frequency of the deviation)
- Suggest modifications to the protocol.
- Alter the interval for submission of the continuing review/ annual project status.
- Ask for additional training of the investigator and study team
- Seek additional information from the PI.
- Conduct audit of trial by the IEC.
- Suspend the study till additional information is made available and scrutinized.
- Suspend the study till recommendations made the IEC are implemented by the PI and found to be satisfactory by the IEC.
- Suspension or termination of the study.
- Revoke approval of the current study.
- Inform DCGI/ other relevant regulatory authorities.
- Keep other research proposals from the PI/ Co-PI under abeyance. Review and/ or

inspect other studies undertaken by PI/Co-PI.

This final decision will be recorded by the Member Secretary.

13.6 Procedure for notifying the PI and other concerned authorities

The Member Secretary will draft a notification letter/acknowledge the notification letter from Investigator. The signed letter by Member Secretary will be sent to the PI and Department Head(s) (if required on case to case basis) and Institutional Officials (if required on case to case basis). The IEC secretariat will send a copy of the notification to the relevant national authorities (if required on case to case basis) and institutes (if required on case to case basis in case of multi-centric trials).

Prepared by: Dr. Anupama A. Signature----------

Reviewed by: Dr. Jayakrishnan T. Signature----------

Approved by: Dr. C. Ravindran Signature----------

POLICY FOR REVIEW OF ADVERSE EVENTS/SERIOUS ADVERSE EVENTS

14.1 PURPOSE

The purpose of this SOP is to describe procedures for the review of initial and follow-up reports of adverse events (AE) and serious adverse events (SAE) reported to the IEC for any study under its oversight.

14.2 SCOPE

This SOP applies to the review of AE/SAE reports (events on-site as well as of the multi-centre studies occurring at off site) submitted to the IEC.

14.3 RESPONSIBILITY

It is the responsibility of the IEC to review all SAEs reported to the IEC in a timely manner. IEC should make sure that researchers are made aware of the policies and procedures concerning reporting and continuing review requirements.
The Member Secretary is responsible for receiving the complete SAE /AE reports and directing them to the members/designated expert reviewers for detailed review.

14.4 DEFINITIONS

14.4.1. Adverse Event: An AE is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.

14.4.2. Serious Adverse Event: An AE that is associated with death, inpatient hospitalization (in case the study was being conducted on out-patients), prolongation of hospitalization (in case the study was being conducted on in-patients), persistent or significant disability or incapacity, a congenital anomaly or birth defect, or is otherwise life threatening.

14.5 DETAILED INSTRUCTIONS

14.5.1 SAE related activities for clinical trials or bioavailability or bioequivalence study:

The IEC secretariat shall receive the initial reports of SAEs occurred for IEC approved studies within 24 hours of the occurrence of the SAEs of a clinical trials or bioavailability or bioequivalence study as per format (Ax: 29/V04) mentioned in the New Drugs and Clinical Trials Rules, 2019 (Third Schedule Table 5). The Member Secretary/ Secretariat will verify that the SAE reports in the prescribed format are complete, signed and dated by the PI. In case he/she notes that the report is incomplete, it will be forwarded to PI, to revert with adequate data.
If the investigator fails to report any serious adverse event within the stipulated period,

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

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

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

14.5.2 SAE related activities for academic or other than clinical trials:

The IEC secretariat shall receive the initial reports of SAEs occurred for IEC approved studies within 24 hours of the occurrence of the SAEs as per format (Ax: 29/V04) and SAEs of biomedical and health research as per (Ax: 30/V04). Such trials will be conducted in accordance with the approved clinical trial protocol, ethical principles specified in National Ethical Guidelines for Biomedical and Health Research Involving Human Participants by ICMR with a view to ensuring protection of rights, safety and wellbeing of trial subject during conduct of trials.

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

14.6 ACTIONS TO BE TAKEN

- The Member Secretary after receipt of the SAE Report will forward it to the designated reviewer within 2 working days for review through email or in writing a letter.
- Designated reviewers will review the SAE and communicated the opinion by e-mail or telephone/written report to inform the Chairman/ Member Secretary, IEC.
- He/she may ask PI for further follow up information and/ or additional details on causality of the event, provision of medical treatment till SAE is resolved and financial compensation.
- The Member Secretary will ratify the designated reviewer's report along with relevant documents from PI at the next IEC meeting.

- The final review opinion of IEC will be communicated to DCGI within 30 days from the SAE report. The IEC decision will also be communicated to the PI through email.
- Compensation if applicable will be calculated as per formula specified in the New Drugs and Clinical Trial Rules, 2019 and 2022 (Amendments) and ICMR guidelines and appropriate compensation will be given to the subject according to regulatory guidelines.

Prepared by: Dr. Anupama A. Signature

Reviewed by: Dr. Jayakrishnan T. Signature

Approved by: Dr. C. Ravindran Signature

POLICY FOR RESEARCH INVOLVING VULNERABLE POPULATION

15.1 PURPOSE

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

15.2 SCOPE

This SOP covers the policies and procedures applied to all research dealing with vulnerable participants submitted to the IEC.

15.3 RESPONSIBILITY

IEC members are responsible for receiving, verifying and reviewing the research protocols pertaining to vulnerable populations. The Chairman/ Member Secretary may assign appropriate primary reviewers who have thorough understanding of the ethical review process with appropriate expertise to conduct the reviews of such research. Chairman / Member Secretary are responsible for ensuring that IEC members are well-versed in new and evolving regulations and guidelines pertaining to vulnerable populations.

15.4 DETAILED INSTRUCTIONS

15.4.1. Policies for reviewing the protocol with vulnerable population:

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

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

- Can the research be performed in any other non-vulnerable participants?
- Is there justification to use vulnerable population?
- Do the benefits justify the risks?

- Are the participants selected equitably?
- Have the measures to protect Autonomy of the vulnerable population been described?

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

IEC will review the protocol and the informed consent document or assent form. The IEC will discuss the comments from the members and understand the recruitment strategies from the study team and ensure the protection of Vulnerable groups are confirmed in the IEC meeting and letter regarding approval/modification disapproval will be sent to the principal investigator. The discussion will be documented in the minutes. The Member Secretary will ensure that the IEC recommendations have been incorporated in the revised protocol and protocol related documents as applicable.

15.4.2 Approval of the protocol

The final version of the protocol will be approved at a full board meeting. Wherever necessary the IEC approval should state that if in future the vulnerability status of the participants change, for e.g. unconscious patient gaining consciousness or a schizophrenic patient regains insight, the participant will be re-consented.

Prepared by: Dr. Anupama A. Signature----------

Reviewed by: Dr. Jayakrishnan T. Signature----------

Approved by: Dr. C. Ravindran Signature----------

POLICY FOR MONITORING AND OVERSIGHT

16.1 PURPOSE

The purpose of this SOP is to describe the procedures for site monitoring of any IEC approved research.

16.2 SCOPE

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

16.3 RESPONSIBILITY

It is the responsibility of the Full Board or Chairperson and Member Secretary to decide a conduct on-site monitoring. Designated IEC member(s) can also perform on-site monitoring of selected study site(s).

16.4 DETAILED INSTRUCTIONS

Monitoring can be routine or "for cause" and must be decided at a full committee meeting. For research that involves higher risk or vulnerable participants or if there is any other reason for concern, the IEC at the time of initial review or continuing review can suggest that routine monitoring may be conducted at more frequent intervals.
Some indications for "for cause" monitoring are given below:

- high number of protocol violations/ deviations;
- large number of proposals carried out at the study site or by the same researcher
- large number of SAE reports;
- high recruitment rate;
- complaints received from participants;
- any adverse media report;
- adverse information received from any other source;
- non-compliance with IEC directions;
- misconduct by the researcher; and
- any other cause as decided by the IEC

16.4.1 Before the visit:

The Chairman / Member Secretary will designate one or more IEC members or appoint an independent monitor who along with IEC members will perform the task of monitoring. The selected members or independent monitor will be provided the information with an appointment letter in this regard. The identified monitors in consultation with the Member Secretary and the Chairman will decide the agenda. The Secretariat will intimate in writing about the date/time of monitoring visit and request for confirmation from the Principal Investigator or Co-investigator to be available for the monitoring visit. The secretariat will provide relevant reference material/ documents related to the project for review. The monitoring board will review the project related documents and make appropriate notes.

16.4.2 During the visit:

Key focus areas during oversight are listed below:

- Delegation log of responsibilities of study team.
- Protocol understanding of the site team.

- Approved protocols, Informed consent, Audio-Visual recording of consent, case record forms and subject diaries and make sure that the site is using the most recent version.
- Informed consent process or audio-visual consent or audio consent process, if possible.
- Randomly selected participants' files to ensure that participants are signing the correct informed consent.
- Investigational Drug accountability is adequately controlled and documented throughout the product flow at the study site (arrival, dispensing, use, return from the subject and return/destruction after the study.
- Laboratory and other facilities necessary for the study at the site.
- Source documents.
- Verify the investigator is enrolling only eligible subjects.
- Investigator's oversight adequacy.
- Availability of study specific logs and forms.
- Protocol deviation/violation (if any).
- Views of the study participants, if possible.
- SAEs are appropriately reported within the time as per the applicable regulatory requirement(s). Case record forms would be checked to review the safety data i.e. Adverse Events (AEs) and SAEs for the volume or severity of adverse events.
  The Monitor will fill the Site Monitoring Visit Report Form (Ax: 31/V04).

16.4.3 After the visit:

The IEC member/ Independent monitor will submit the completed Site Monitoring Visit Report (Ax: 31/V04) to the IEC secretariat within 7 days of conducting a site monitoring visit. On the basis of the information and comments received from the designated IEC members/ Independent monitor, IEC will take appropriate action by voting or combination of actions, some of which are listed below, but are not limited to:

- Continuation of the project with or without changes
- Restrictions on enrolment
- Recommendations for additional training
- Recruiting additional members in the study team
- Revising the protocol or ICD / providing qualifications/ experience criteria for members of the study team, termination of the study
- Suspending enrolment of new research participants till further review by the IEC
- Suspending all trial related procedures (except those intended for safety and wellbeing of the participant) till further review by the IEC
- Call a meeting for emergency review. (This review should be initiated within 48 working hours (2 working days) of receipt of information). This review could be done through a meeting, teleconference, email or telephonic conversation. The Member secretary will take appropriate steps to ensure that IEC members are informed about this full board meeting.
- Depending upon the complexity of the issue(s) and if they 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. Their opinions would be valuable but they would not be involved in the decision making process of the Ethics committee. The expert would be requested to provide an opinion in writing within 30 working days, depending upon the gravity and seriousness of the matter. They would be designated as Subject expert during the meetings of the IEC.
- The Member Secretary / Secretariat will share the outcome of the visit /issues raised by the

monitoring board with the concerned investigator in form of a report within 14 working days. The PI should reply within 14 working days to IEC.

- If the PI fails to comply with the requirements, IEC can take punitive action as Protocol deviation / non-compliance/violation.

Prepared by: Dr. Anupama A. Signature----------

Reviewed by: Dr. Jayakrishnan T. Signature----------

Approved by: Dr. C. Ravindran Signature----------

POLICY FOR REQUESTS/COMPLAINTS FROM RESEARCH PARTICIPANTS

17.1 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 a research approved by the IEC.

17.2 SCOPE

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

17.3 RESPONSIBILITY

It is the responsibility of the IEC Secretariat and Chairperson/ 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.

17.4 DETAILED INSTRUCTIONS

A request, complaint or query from a research participant will be accepted by the Secretariat and forwarded to the IEC Member Secretary after entering into the request record form - Request/ Complaint Form (Ax:32/V04). The request / complaint form will be available at all clinical trials' sites.

- The Member Secretary may receive a request, complaint or query directly from the participant. He/she will record it in the request record form and notify the Secretariat.
- The Member Secretary will additionally ascertain details of the request/ complaint by examining any relevant documents and by interviewing the participant, if necessary. If required, the Member Secretary will call for additional relevant information and documents from the Principal Investigator (PI).
- The Secretariat will inform the Chairman about the request, query or complaint received from the research participant.
- In case of a request for additional information or clarification, the Member Secretary in consultation with the Chairman will provide the information himself / herself or will designate one or more IEC member(s) to provide such information.

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

- Rights of Research Participant:
- Right to voluntary participation in research study.
- Right to have enough time to decide whether or not to be in the research study, and to make that decision without any pressure from the people who are conducting the research.
- To ask any questions you may have.
- Right to know about Institutional Ethics Committee and its responsibilities towards protecting patients' rights, safety and well-being involved in a research project and to provide public assurance of that protection Right to information about Research Study in an understandable language.

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

Responsibilities of Research Participant:

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

In case of a complaint received from a research participant:

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

Prepared by: Dr. Anupama A. Signature----------

Reviewed by: Dr. Jayakrishnan T. Signature----------

Approved by: Dr. C. Ravindran Signature----------

POLICY FOR RECORD KEEPING AND ARCHIVING

18.1 PURPOSE

The purpose of this SOP is to provide instructions for preparation and maintenance of active study files and other related documents, IEC administrative documents, archival of closed files and retrieval of documents.

18.2 SCOPE

This SOP applies to maintenance, archival and retrieval of all study files and study related documents and IEC administrative documents by the IEC Secretariat.

18.3 RESPONSIBILITY

It is the responsibility of Member Secretary with assistance of Secretariat to ensure that all active study files and IEC documents and records are prepared, maintained during the study period and kept securely for a period of three years after the closure/ termination of the project.

18.4 DETAILED INSTRUCTIONS

18.4.1 Maintenance of the active study files

A study master file is the file comprising all essential documents and correspondence related to the study. This should be created for all proposals at the time of initial submission to the IEC office. All related documents of the approved study will be gathered, classified appropriately and placed in the study master file: These could include copies of:

- One hard copy and a soft copy of the initial research proposal and all related documents
- Decision letters
- Any amendments submitted for review and approval
- Regulatory approvals
- SAE, AE reports
- Protocol deviations/violations
- Progress reports, continuing review activities, site monitoring reports
- All correspondence between the IEC and researchers
- Record of notification issued for premature termination of a study with a summary of the reasons
- Final report of the study
- Publications, if any

Strict confidentiality will be maintained for the contents of the files. All active files will be kept secured in a file cabinet with restricted access.

18.4.2 Maintenance of the IEC administrative records

The following documents related to IEC administration should be maintained:

- Constitution and composition of the IEC
- Appointment letters

- Signed and dated copies of the most recent curriculum vitae of all IEC members
- Signed confidentiality agreements
- COI declarations of members
- Training records of IEC members
- Financial records of IEC
- Registration/accreditation documents, as required
- A copy of national and international guidelines and applicable regulations
- Regulatory notifications
- Meeting-related documents
- Agenda and minutes
- All communications received or made by the IEC
- SOPs

18.4.3 Archival and Retrieval of records

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

- Remove the contents (hard and soft copies) of the entire files from the active study files to the archived study files.
- All correspondence between the IEC 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 for a minimum period of three years after the completion of the research so that the records will be accessible to the authorized persons.
- The cupboard where hard copies of the archived study files are kept will be kept in a lock and key and will have controlled access only to the secretariat.
- The coordinating staff will maintain the confidentiality for control and archiving of the records.

Retrieving Documents:

The written request for retrieval can only be made request by IEC members, auditors or any authorized person in the specified format (Ax:33/V04).

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

18.4.4 Disposal of documents:

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

Prepared by: Dr. Anupama A. Signature

Reviewed by: Dr. Jayakrishnan T. Signature

Approved by: Dr. C. Ravindran Signature

POLICY FOR REVIEWING PROTOCOLS OF AFFILIATED INSTITUTIONS

19.1 PURPOSE

The purpose of this SOP is to describe the procedures for reviewing protocols of submitted from:

- Other Institutions under KMCT Trust in the Campus who do not have a separate IEC - Nursing College, Pharmacy College, etc.
- Other Institutions which have signed MoU with KMCT Medical College.

These institutions will be referred to as "user" institutions and KMCT Medical College will be the "host" institution.

19.2 SCOPE

Applicable to affiliated institutions & other institutions which have signed MoU for this purpose.

19.3 RESPONSIBILITY

The members of IEC KMCT Medical College are responsible for implementing this SOP.

19.4 DETAILED INSTRUCTIONS

All the affiliated institutions & the institutions which have signed MoU are given details of SOP. The Principal/Dean/Administrator of the user institution should sign a MoU agreeing upon the conditions followed for the review of protocols in the host institution and to implement any instructions given by the IEC for the research purpose in view of ethical considerations.

Procedure:

- Every proposal will be sent not less than 14 days before the meeting to all members of IEC. They will evaluate them on ethical issues, scientific soundness and technical excellence of the proposed research, before it is taken up for main IEC review.
- All the members will evaluate the possible risks to the study participants with proper justifications, the expected benefit and adequacy of documentation for ensuring privacy, confidentiality and justice issue.
- Informed consent form should mention the rights of the research participants to claim compensation in case of research related injuries and whom to contact for such claims.
- The IEC review will be done through formal meetings and will not resort to decision through circulation of proposal.
- Expert opinion of additional person would be obtained if necessary.
- In cases where a conflict of interest is determined that may damage the scientific integrity of a project or cause harm to research participants, the members would take decision carefully after a thorough review. In case of decision to approve, appropriate advise must be given to the investigators (to declare such conflicts of interest to the ethics committee and future publications) and verify if the participants are informed of the sponsorship of the research as applicable.
- Policy for fees for review:
  Undergraduate research will be reviewed for a fee of Rs.1000/-.
  Post-graduate and faculty research will be reviewed for a fee of Rs.2500/-.

For funded research the policy will be same as that of the host institution (ref: KMCT/IEC/SOP/06/V04).

Prepared by: Dr. Anupama A. Signature----------

Reviewed by: Dr. Jayakrishnan T. Signature----------

Approved by: Dr. C. Ravindran Signature----------

POLICY FOR USE OF ARTIFICIAL INTELLIGENCE IN RESEARCH

20.1 PURPOSE

The purpose of this SOP is to provide instructions for ethical use of Artificial Intelligence (AI) in research.

20.2 SCOPE

This SOP covers processes involved in review of research involving AI.

20.3 RESPONSIBILITY

It is the responsibility of the IEC members to ensure ethical conduct of research involving AI. The IEC is responsible for assessing both the scientific rigor and ethical aspects of all health research and should ensure that the proposal is scientifically sound and weigh all potential risks and benefits for the population where the research is being carried out. IEC should check the proposals for data source, quality, safety, anonymization, and/or data piracy, data selection biases, participant protection, payment of compensation, possibility of stigmatization and others.

20.4 DEFINITIONS

Artificial intelligence (AI): A system's ability to correctly interpret external data and to use those learnings to achieve specific goal and tasks through flexible adaption. AI uses complex computer algorithms to emulate human cognition albeit with far reaching capabilities of analysing large datasets.

20.5 DETAILED INSTRUCTIONS

The use of AI in healthcare covers (but is not limited to) the following fields:

- Diagnostics and Screening
- Therapeutics, Drug Discovery and Development
- Clinical Care
- Epidemiology and Prevention of Disease
- Behavioural and Mental Healthcare
- Health Management Systems using AI

20.5.1 Subject experts may be invited if AI related proposals are to be reviewed occasionally. If frequency of AI-technology projects are increasing, the IEC may consider including legal experts who have experience in IT and medical law, data scientists and computer scientists with expertise in AI technology.

20.5.2 Training: Members should be occasionally trained in emerging AI technologies such as big data, DL, internet of things (IoT), so that they are informed about these subjects to an appropriate level before they start evaluating proposals for the same.

20.5.3 Roles and responsibilities of the IEC: The IEC reviews research proposal, progress and final reports as well as reporting of adverse events and provides suggestions for minimizing the risk to the study. Recommendations regarding appropriate compensation for research related injury should be made by the EC, wherever it is required. Monitoring visits at study sites should

be carried out by the EC as and when needed. In case of conflicts in ethical requirements during implementation of key ethical requirements, decisions on the tradeoff should be evaluated regularly.

20.5.4 Types of review: As provided in the ICMR Ethical guidelines the type of review will be based on the type and degree of risk involved and can be exempt, expedited or full committee review as the case may be.

20.5.5 Ethical issues related to reviewing a protocol: All research proposals require scientific and ethical review by the EC. While in general all issues specified in the National ethical guidelines should be followed while reviewing a protocol based on AI technologies, there are certain specific additional requirements to be examined by the committee before taking the decision such as:

- Essentiality and appropriateness of the system
- Alternates available and opportunity/cost comparison
- Qualifications of researchers/ developers
- Training for Data collection procedures
- Selection of Training and Testing populations
- Possible Technology malfunctions / glitches / failures and the redressal mechanisms Stakeholder responsibility and accountability to different aspects of AI technology malfunction / injury
- Adequacy assessment of study sites
- Informed Refusal process
- Data source, participant selection process and quality assessment
- Opportunity to constantly upgrade AI technology with additional data and technology and its influence on participants
- Quality check of the AI technology
- Participants 'right-to-be forgotten'
- Data storage and sharing policies
- Community considerations
- Compensation for study related injury including medical management

Prepared by: Dr. Anupama A. Signature----------

Reviewed by: Dr. Jayakrishnan T. Signature----------

Approved by: Dr. C. Ravindran Signature----------

MANAGEMENT OF PREMATURE TERMINATION /SUSPENSION / DISCONTINUATION OF THE STUDY

21.1 PURPOSE:

The purpose of this SOP is to proceed and manage the premature termination/ suspension / discontinuation of 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.

21.2 SCOPE:

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

21.3 RESPONSIBILITY:

It is responsibility of IEC secretariat to receive premature termination/ Suspension / Discontinuation of the study / Withdrawal of study before site initiation of a research study report submitted by PI as per (Ax: 34/V04). 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.

21.4 DETAILED INSTRUCTIONS:

Review the report:

- The member secretary / Chairman shall review the results, reasons and accrual data and discuss the report (Ax: 34/V04) at the full board meeting.
- If the Premature termination/ suspension/discontinuation report is unclear or more information is required from the PI, the Chairman shall instruct the Secretariat to seek clarifications/ additional information from the Principal Investigator.
- The Chairman/Member Secretary / IEC members will review the information available and take a decision depending on the seriousness of the termination. The decision will be taken to ensure that the safety and rights of the research participants are safeguarded. The decision will be taken by consensus / voting.

Record and communication:

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

KMCT
AYURVEDA MEDICAL COLLEGE
Approved by NCISM and Affiliated to Kerala University of Health Sciences

TO WHOM SO EVER IT MAY CONCERN

This is to certify that the information in the attached documents is verified by me and is true to the best of my knowledge.

PRINCIPAL
K.M.C.T. AYURVEDA
MEDICAL COLLEGE

K.M.C.T. AYURVEDA MEDICAL COLLEGE

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Institutional research committee

KMCT AYURVEDA MEDICAL COLLEGE

MISSION

The Institutional Research Committee (IRC) is dedicated to fostering a culture of research excellence and innovation within KMCT Ayurvda medical college. Our mission is to support, guide, and advance research endeavors across all disciplines, contributing to the intellectual growth, scholarly output, and societal impact of our institution.

STANDARD OPERATIVE PROCEDURE

Objective

Institutional Research Committee (IRC) of K M C T Ayurveda Medical College, constituted under the chairmanship of Principal ensures high scientific research standards and offers technical guidance and complete critical appraisal to the submitted research proposals.

Authority of research committee

The Director Principal, Chairperson of IRC will appoint all the committee members based on their competence, experience and integrity

Responsibility of research committee

IRC will go through the research protocol / proposal and state whether or not it is acceptable. IRC of KAMC is committed to:

- Evaluate all the scientific aspects of research proposals. Review and approve proposals for basic and clinicalResearch projects

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- Develop and implement education and training programs. Create awareness by conducting seminars andworkshops amongst hospital faculty and staff regarding clinical practice and research along with IEC (Institutional Ethics Committee).
- Development and implementation of guidelines for smooth functioning of IRC

Composition of IRC

The committee consist of members from various clinical, non clinical departments, who have the qualification and experience to review and evaluate the scientific, ethical and legal aspects of research projects.

Quorum requirements

Minimum of 6 members are required to constitute the quorum for the meeting. All decisions will be taken in meetings. The meetings are flexible depending on the number of projects submitted or the need to review post-graduate thesis proposals.

Conduct of IRC meetings

The Chairperson will conduct all meetings of the PIMS- IRC. The Member Secretary is responsible for organizing the meetings, maintaining the records and communicating with all concerned. The IRC members will receive the soft copies of all research proposals on their respective email IDs. The member secretary will prepare the minutes of the meetings and get it approved by the Chairperson and all the members. The Chairman can hold the meeting at any time if the need arises.

Elements of review

The IRC will consider issues like study design, relevance of sample size, statistical correlation, experimental details and its feasibility, conduct of the study, risk benefit analysis, enrollment procedure, outcome of the proposal, facilities & infrastructure and plans for data analysis during the review process

Decision making

- Decision will be made only in meetings where quorum is complete. Members will discuss the various issues before arriving at a consensus decision. When consensus is not arrived, the decision of the Chairperson will be final.
- Decision may be to approve, reject or revise the proposals. Specific suggestions and reasons for modifications and reasons for rejection will be given.

After thorough review and discussion of submitted study protocols, IRC will give any one of the following decision

- Approved without suggestions Revision with minor amendments - approval of revised version is given by member secretary
- Revision with major amendments - approval of revised protocol is given after repeat review by full committee
- Not approved - the clear cut reasons for not approving

The researcher will modify the proposal as per suggestions of IRC and resubmit revised proposal within 7 days of issuing of decision.

Archiving / Record Keeping

- All the documents and communications of IRC will be dated, filed and archived in IRC office.
- Only the member secretary or persons, who are authorized by the Chairman of IRC will have the access to various documents.
- No document (except agenda) will be retained by any IRC member.
- Final report of the approved projects.

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K.M.C.T. AYURVEDA MEDICAL COLLEGE MANASSERY P.O. MUKKAM KOZHIKODE