KMCT MEDICAL COLLEGE

MANASSERY, MUKKOM,
KOZHIKODE -673602

Standard Operating Procedures for
Institutional Ethics Committee
(Version No.3)
KMCT MEDICAL COLLEGE

Principal

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- 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 of the IEC

3.2 The sop team will

Assess the request for SOP S 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.

3.3 Chairperson of the IEC will

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

3.4 IEC members and involved administrative staff will

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

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4.0 Instructions

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.

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.

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4.3 write and review 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.

4.4 Format of the SOP

- The document will begin with three columns. The first column will have the institute logo printed on it.
- Second column in the header shall have title of the SOP. The title of the SOP shall be descriptive but not too long.
- The third row, first section shall have SOP number.
- The second section shall have SOP number.
- The second section shall have the effective date of the SOP printed.
- The footer of all the pages of the SOP shall include the following.
- The footer will have the "Review date of the SOOP". " SOP Title "and the page number in X of Y format.
- Numbering of site SOPs:

All SOPs will be issued with sequential numbers as follows. For example……..00.00

- KMCT IEC: Site abbreviation
- .00: Document number
- .00: Revision number
- Document number: Each SOP document will be assigned a unique sequential number (e.g. 01,02,03)

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- Revision number: Revision to a SOP is designated by a sequential number. The original SOP will always be revision number 00. Each subsequent revision will be assigned the next consecutive number (e.g. 01,02,03)

Revision number: Revision to a SOP are designed by a sequential number. The original template will always be the revision number 00.

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/SOP01/V1) along with description of the main changes.

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.

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.

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ANNEXURE 3: AX 03/SOP01/V1-list of SOPs of the IEC

No:	Title of the standard Operating Procedures(SOPs)	Version No	Effective Date
01	Preparation, review & revision of (SOPs)	KMCTIECSOP : 01.00	02 April 2018
02	Constitution of institutional ethics committee	KMCTIECSOP :02.00	02 April 2018
03	Roles and responsibilities of IEC members & handling conflict of interest.	KMCTIECSOP :03.00	02 April 2018
04	Submission of research documents.	KMCTIECSOP :04.00	02 April 2018
05	Conduct of IEC meetings	KMCTIECSOP : 05.00	02 April 2018
06	Review of research documents	KMCTIECSOP :06.00	02 April 2018
07	Review of protocol deviation & violation	KMCTIECSOP :07.00	02 April 2018
08	Review of serious adverse event reports	KMCTIECSOP :08.00	02 April 2018
09	Site monitoring and post monitoring activities.	KMCTIECSOP :09.00	02 April 2018
10	Dealing with participant's requests and/ or complaints to institutional ethics committee.	KMCTIECSOP :10.00	02 April 2018
11	Administrative support, record keeping & archival	KMCTIECSOP :11.00	
12	Training & assessment of ethics committee members	KMCTIECSOP :12.00	

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1. Purpose:

The purpose of this Standard Operating Procedure (SOP) is to describe the terms of reference (TOR), which provide the frame work for constitution, selection of EC members and procedures for maintaining confidentiality of all activities and documents.

2. Scope:

This SOP applies to the constitution of the institutional ethics committee, KMCT Medical College Kozhikode, selection roles and responsibilities of members of the IEC and maintenance of confidentiality of all activities and documents.

3. Responsibility:

The selection of Chairperson, Member Secretary and IEC members will be done by Principal, KMCT Medical College appointed at KMCT Medical College Kozhikode. It is the responsibility of all the IEC members and secretariat to read, understands, follow and respect this SOP.

4. Detailed instructions

4.1. Composition of the institutional ethics committee

The Institutional Ethics committee will be established by Principal, KMCT Medical College appointed at KMCT Medical College Kozhikode. The Chairperson and IEC

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members can suggest names of potential members but the final decision will remain with Principal, KMCT Medical College.

- The IEC will be multidisciplinary and multi-sectoral in composition.
- The IEC is composed of 11 members including Chairperson & Member Secretary.
- The members will include a combination of medical and non-medical, scientific and non -scientific persons including lay persons to represent the different points of view
- Have differing backgrounds to promote complete and adequate review of research
- Have the required qualifications as prescribed by applicable regulations and guidelines from time to time.
- Have the expertise, time, and commitment to perform all functions.
- The IEC will have representations that are varied in terms of gender, age, and social background to safeguard the interests and welfare of all sections of the community /society.
- The committee should include at least one member whose primary area of expertise is in a non -scientific area, a clinician and at least one member who is independent of the institution /research site.

The IEC may invite member(s) of specific patient group s or other special interest groups for an IEC meeting(if required ,based on the requirement of research area, e. g HIV AIDS ,genetic disorders ,stem cell research etc) for cliciting their views .Such individuals will have to sign confidentiality agreement (AX 01/SOP 02/VI) and

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declare in writing ,conflicts of interest ,if any prior to attending the meeting. They will attend the meeting in the capacity of Guest /observer and will not have right to vote.

The Composition shall be as follows:

- Chairperson (non-affiliated to the institution)
- One-member secretary (institutional)
- One person from basic medical science (Not 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)
- Clinicians affiliated to institute-2
- Members (2 persons affiliated to Institute)
- Theologian -1

4.2 CRITERIA FOR SELECTION OF MEMBERS

IEC Chairperson

- From outside the Institution
- A person with high standing in society and have more than 30 years experience and more than 5 years of experience in Ethics Committees.

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Member -Secretary

- Will be a staff member of the institution
- Having a State Medical council recognized post graduate degree.
- Should have domain specialty experience, clinical research, and ethics knowledge, personal interest and capacity, good communication skills.

Members

- Members will be selected in their personal capacities based on their qualification, experience in domain field, interest, ethical and/ or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the IEC. They should not have any known record of professional misconduct.
- Medical scientists and clinicians should have post graduate qualifications.
- Conflict of interest will be avoided while making appointments, but where unavoidable, there will be transparency with regard to such interests.

4.3 Agreement regarding Maintenance of Confidentiality

- It is the responsibility of each IEC member, reviewing research project or attending IEC meeting, to read, understand, accept and sign the agreement contained in the confidentiality form (AX 01/SOP 02/VI)

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- The staff of the secretariat will sign confidentiality agreement which should be filled with IEC (AX 01 B/SOP 02/VI)
- The Secretariat will obtain the signature of the IEC Chairperson on the confidentiality form
- The Secretariat will keep the original copies of the signed agreements in the IEC office.

4.4 Tenure of Membership

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

4.5. Appointment of New Members

a) The IEC members will be appointed by Principal, KMCT Medical College appointed at KMCT Medical College Kozhikode.

b) New members will be appointed under the following circumstances:

1. When the regular member completes his/her tenure.

2. If a regular member resigns before the tenure is completed.

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3. If a regular member ceases to be a member for any reason including death or disqualification.

4. To fulfill the membership requirements as stated in this SOP.

C) New members will be identified by the Chairperson /Member secretary according to the membership requirement (i.e., as per the composition specified in Section 4.1 of this SOP and provided the potential member fulfills the conditions of appointment) after discussion by the IEC. The names of new members to be appointed may be suggested by the IEC members and the Chairperson to the Principal KMCT Medical College .

The final decision regarding appointment of members will be taken by the Head of Institution.

4.6 Conditions to be fulfilled by a member after appointment.

Members to be appointed on the IEC will need to fulfill the following conditions.

Members must submit

- ✓ A recent signed CV
- ✓ If available training certificates in ethics and/ or GCP. If not available at time of induction as member in the IEC, the member must submit these within 6 months. Members must be willing to publicize his/her full name, profession and affiliation.

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- ✓ Sign the confidentiality Agreement (as per Annexure 3A SOP 02 V1) and maintain confidentiality regarding meetings, deliberations, research proposals, information on research participants and related matters.
- ✓ Read, understand, accept and follow the conflict of interest policy and sign the conflict of interest agreement /form.

4.7 Resignation and disqualification of Members.

- **Resignation**

An IEC member may resign from membership by submitting a letter of resignation to the Chairperson. The member may or may not assign reasons for resignation. The resignation will become effective from the day it is accepted by the Chairperson.

- **Disqualification for conduct unsuitable of an IEC member.**

A member may be disqualified from continuance should IEC determine by a three-fourth majority specifically called for the purpose that the member's conduct has been inappropriate of an IEC member.

i. 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.

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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 filled 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 2 years.

Prepared by: Signature with date----------

Reviewed by: Signature with date----------

Approved by: Signature with date----------

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ANNEXURE 1: AX 01/SOP01/V1

Template for standard Operating Procedures

	SOP Title	KMCTIECSOP: 01.00 Effective date:

Main Text:

1. Purpose: Summarizes and explains the objectives of the procedure

2. Scope: States the range of activities that the SOP applies to

3. Responsibility: Refers to person(s) assigned to perform the activities involved in the SOP

4. Detailed instructions: Describes procedures step by step in short and clear sentences.

5. Annexures: Forms to capture information pertaining to the SOP instructions

Prepared by: Signature with date----------

Reviewed by: Signature with date----------

Approved by: Signature with date----------

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ii. The Chairperson will satisfy himself / here self that a prima facie case exists before initiating action. If, in the opinion of the Chairperson, the matter is of grave significance where integrity of IEC could be questioned, the Chairperson may suspend the membership of the concerned IEC member till final decision is taken by IEC. During the period of suspension, the concerned individual will not have any rights, privileges or responsibilities of an IEC member and will not perform any duties of IEC member.

iii. The Chairperson may call for a meeting of the IEC specifically to discuss this issue or the matter will be taken up for discussion. The meeting convened will follow the usual rules of quorum.

iv. The allegation will be discussed at the IEC meeting and the member alleged of misconduct will be provided adequate opportunity to defend himself /herself.

v. The member would stand disqualified, if members present approve of disqualification by voting (voting by 2/3 rd of a majority of members present in the meeting and voting) The Chairperson will convey the disqualification to the concerned member through a written communication.

- **Disqualification for not attending IEC meeting**

A Member may be disqualified from IEC membership if the member fails to attend more than 3 regular consecutive IEC meetings without prior intimation. The process conducted will be as follows.

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i. The member Secretary will inform Chairperson, in writing, if a member has not attend more than three consecutive regular meetings of the IEC without prior intimation to the IEC.

ii. The Chairperson will initiate the process of review of membership of such a member by including the matter in the Agenda of the next regular IEC Meeting.

iii. A written communication will be sent to the concerned IEC member informing him, /her that the issue of qualification would be discussed at the meeting inviting the member to be present at the meeting to put up his /her case. Alternately, the concerned IEC member will be allowed to state his/her arguments regarding unauthorized absence in writing by a letter addressed to the Chairperson.

iv. The matter will be discussed and reviewed at the IEC meeting .The concerned member will be provided adequate opportunity to present his/her case. A written communication, if received from the concerned, if received from the concerned member will be read and reviewed at the meeting.

v. The Chairperson of Member Secretary will inform the IEC members about the cessation of membership by a confidential written communication to other members of IEC or at next meeting of IEC.

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4.8 Training of the IEC members in Research Ethics

- Member Secretary or an IEC member will provide introductory training in Research Ethics, GCP and SOPs to the new member.
- A newly inducted member should submit certificate of training in 6 months.
- All members including Chairperson and Member secretary will be encouraged to receive continued training by participating in a workshop, conference and /or re-training program related to research ethics, as a delegate, faculty, facilitator etc.
- The IEC will conduct workshops on ethics in clinical research, GCP and SOPs from time to time to impart training and update the IEC members and Human faculty members.
- The IEC may nominate and/or sponsor the expenses of (as applicable) on IEC member or prospective members for attending conference, continuing education session workshop and/ or training program etc.

4.9 Independent consultants

The IEC may call upon, or establish a standing list of independent consultants who may provide special expertise to the IEC on proposed research protocols, when the Chairperson /Member Secretary or the IEC Members determine that a study will involve procedures or information that is not within the area of expertise of the IEC members. These consultants must sign the confidentiality agreement regarding

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meeting, deliberations and related matters. These consultants or subject experts cannot vote for decision.

4.10 Hierarchy

- There will be one Chairperson, one member Secretary may be appointed amongst the members.
- The Chairperson will head the committee
- Other IEC members will be regular committee with equal ranking.
-

Prepared by: Signature with date----------

Reviewed by: Signature with date----------

Approved by: Signature with date----------

Annexure 1A: AX 03A /SOP 02/V1 confidentiality agreement form for IEC members.

Annexure 1B: AX 01B /SOP 02/V1 confidentiality agreement form for staff of the secretariat

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Annexure 1A: AX 03A /SOP 02/V1 confidentiality agreement form for IEC members.

In recognition of the fact, that I ----------

(Members name, his /her position on IEC and affiliation) herein referred to as the "undersigned" have been appointed as a member of the IEC and have been asked to assess studies involving research participants in order to ensure that they are conducted in a human and ethical manner, adhering to the highest standards of care as per the national, and local regulations and human policies and guidelines and international and national guidelines. The appointment of the undersigned as a member of the IEC is based on individual merits and not as an advocate or representative neither of a home province, territory, or community nor as a delegate of any organization. The IEC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of research participants and the undersigned, as a member of the IEC, is expected to meet the same high standards of ethical behavior to carry out its mandate.

This agreement encompasses any information deemed confidential provided to the undersigned in conjunction with the duties as a member of the IEC. All confidential information (and any copies and notes thereof) shall remain the sole property of the IEC. The undersigned agrees to hold all confidential information in trust or confidence and agrees that it shall be used only for contemplated purposes and shall not used for any

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other purpose or disclosed to any third party . Written confidential information provided for review shall not be copied or retained.

I---------- (Name of the IEC member) have read and accept the aforementioned conditions as explained in this agreement.

---------- ----------

Signature Date

---------- ----------

Chairperson`s signature Date

[The original (signed and dated agreement) will be kept on file in the custody of the IEC

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1. Purpose:

The purpose of this standard operating procedure (SOP) is to be describe the roles and responsibilities if the Institutional Ethics Committee (IEC) and to identify and manage conflict of interest among the institutional Ethics Committee (IEC) members at KMCT MEDICAL COLLEGE Kozhikode

2. Scope

This SOP covers the roles and responsibilities and the policy related to identification, declaration and management of conflict of interest of all IEC members within KMCT Medical College.

3. Responsibility

It is the responsibility of all the IEC members and the Secretariat to read, understand, follow and respect this SOP. All IEC members are responsibility for understanding definition of conflict of interest (COI) and for self -identifying and disclosing these. The Chairperson would need to ensure that COI are identified, declared and managed by all members during initial and continuing review of research studies.

4. 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

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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
- A personal COI is said to exist when
  - ✓ There is immediate family relationship[p (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.)
  - ✓ A professional COI means for IEC member or his/her immediate family member serves as trustee, director, manager, or scientific adviser of the funding agency sponsoring the research.
  - ✓ A financial COI for IEC members and immediate family exists 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.)

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5. Detailed Instructions

Roles and Responsibilities of all IEC Members are stated below.

5.1Functions of Chairperson

- ✓ The Chairperson will be responsible for conducting committee meetings, the leading all discussions and deliberations pertinent to the review of research proposals.
- ✓ The chairperson will preside over all elections as well as administrative and financial matters pertinent to the committee's functions .The Chairperson will represent the IEC at various meetings and forums.
- ✓ The Chairperson will sign documents and communications related to IEC functioning
- ✓ The Chairperson will delegate his/her responsibilities to the Co- Chairperson in accordance with IEC SOPs
- ✓ In case of anticipated absence of both Chairpersons at a planned meeting, the Chairperson will nominate a committee member as Acting Chairperson or the members present may elect the chairperson. The Acting Chairperson will have all the powers of the Chairperson for that meeting.

5.2. Functions of the Member secretary

- ✓ Receive research proposals
- ✓ Organize an effective and efficient tracking procedure for each proposal received.

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- ✓ Prepare, maintain and distribute of study files.
- ✓ Schedule and organize IEC meetings
- ✓ Prepare and maintain meeting agenda and minutes
- ✓ Maintain IEC documentation and to archive them. .
- ✓ Sign documents and communications related to IEC functioning
- ✓ Communicate with the ICC members and applicants/ investigators.
- ✓ Notify the Director Investigator regarding IEC decisions related to the submitted research proposal.
- ✓ Arrange for training of personnel and IEC members.
- ✓ Organize the preparations, review, revision and distribution of SOPs and guidelines
- ✓ Provide necessary administrative support for IEC related activities the Chairperson
- ✓ Provide updates on relevant and contemporary issues to ethics in health research as well as relevant contemporary literature to the committee members.
- ✓ Receive ethics committee review processing fees and issue official receipts for the same.
- ✓ Delegate various responsibilities to appropriate and authorized individuals
- ✓ Ensure adherence of IEC functioning as per SOPs
- ✓ Prepare for audits and inspections
- ✓ Prepare and make available for scrutiny by auditors/ inspectors annual reports annual financial statements of the IFC

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5.3 Functions of IEC members

- ✓ Attend IEC Meetings and participate in discussions and deliberations so that appropriate decisions can be arrived at
- ✓ Review, discuss and consider research Proposals submitted for evaluation.
- ✓ Monitor Serious Adverse Event reports and recommend appropriate action(s)
- ✓ Review the progress reports and monitor ongoing studies as appropriate.
- ✓ Do on site visits wherever needed
- ✓ Evaluate final reports and outcomes
- ✓ Maintain confidentiality of the documents and deliberations of IEC meetings
- ✓ Declare any conflict of interest in writing to the Chairperson, if any, at each meeting
- ✓ Participate in continuing education activities in bio medical ethics and bio medical research
- ✓ Provide information and documents related to training obtained in bio medical ethics and bio medical research to the IEC secretariat
- ✓ Provide an updated CV when requested for by the IEC secretariat
- ✓ Carry out the work delegated by Chairperson. Member-secretary and Jt. Member secretary
- ✓ Assist Chairperson, Member-secretary and J1. Member-secretary in carrying out IEC work as per SOPS
- ✓ Be updated on relevant laws and regulations

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5.4 Types of projects reviewed by IEC

The IEC will review scientific and ethical aspects of all types of research studies involving human participants, sponsored by pharmaceutical companies, sponsored by Government of India NGOs, studies in collaborations with international organizations/universities, all dissertation projects Nursing dental and any other course run by Institution as applicable research projects of undergraduate students carried out under guidance of teachers (Indian Council for Medical research studentship or any other) and investigation initiated research studies which are self-funded funded by institutional funding bodies and affiliated institution for research purpose.

5.5. Quorum Requirements

The full board meeting will be held as scheduled provided there is quorum

- For the IEC meeting, a quorum will consist of at least 5 members for regulatory clinical trials with the following representation one basic medical scientist (preferably one pharmacologist), one clinician, one legal expert, one social scientist/representatives of non-governmental voluntary/Philosopher ethicist/theologian or a similar person, one Lay person from the community, apart from Member Secretary and Chairperson mandated by Schedule Y.
- Without satisfying this condition, any decision taken by the committee shall remain null and void.

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- In absence of the Chairperson, either Chairperson can suggest an EC Member or the members can select a member from the existing list. In any case that person will be nonaffiliated to the Institute

5.6. Honorarium to the Members

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

6. Detailed Instructions regarding Conflict of Interest

Voluntary disclosure regarding COI by IEC member

The IEC member should determine whether he she has a COI before reviewing research and declare all certain of potential conflicts of interest prior to engaging in any review process

IEC members should not participate in discussing, or decision making on research proposals 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.

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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 IEC member what declares Col 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 Col 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

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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 Col has been managed or eliminated appropriately for research participant protection.
- The IEC shall not approve a research study proposal where a Col is not managed or eliminated Management of Co-In case of a COL.
- IEC members will disclose the Col 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 Col of IEC members in the IEC minutes.

Prepared by: Signature with date----------

Reviewed by: Signature with date----------

Approved by: Signature with date----------

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Annexure 1AX 01/SOP 03/1-Conflict of Interest Form Declaration for IEC Members

Annexure AN 01/SOP 03/V1-Conflict of interest Form Declaration for IEC Members

I am aware of the policy of the IEC regarding conflict of interest and that no reviewer may participate in the review, comment or participate in decision making of any activity in which ho she has actual/potential conflict of interest except to provide information as requested by the IEC

1 declare ---------- (actual or potential COI) in relation to the proposal entitled"----------"submitted for review to the IEC .The reason for COI is ---------- I will refrain from the review process and /for discussion at the IEC meeting/ and also will not take part in ongoing and periodic review and monitoring of this study----------

---------- ----------

Signature of IEC Member Date

---------- ----------

Chairperson's Signature Date

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1. Purpose:

The purpose of this Standard Operating Procedure (SOP) is to describe the administrative process and provide instructions for the preparation, review, approval and distribution of meeting agenda, and minutes for all the Institutional Ethics Committee Meeting conducted at KMCT Medical College, Manassery Kozhikode.

2. Scope:

This SOP applies to administrative processes concerning the preparation of the agenda and recording minutes of all IEC meetings.

3. Responsibility

- 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 him/her.
- The Chairperson will review and finally approve the minutes

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4. Detailed instructions

4.1 Before each IEC meeting

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

4.2 Preparation of meeting agenda

The Member Secretary assisted by the Secretariat will prepare the meeting agenda includes,

- Ensure quorum by Chairperson
- . Reading and approving, minutes of the previous meeting
- All projects for Initial Review
- All resubmitted protocols for full board review
- Review of Amended protocols or protocol-related documents for Full board review
- Issues for consideration
- Continuing review of study protocols
- Review of Study Completion Reports
- Review of premature study termination
- Review of Site Monitoring Visit Reports
- SAE reports /CIOMS forms/Safety letters
- Minutes of SAE Subcommittee (if applicable)

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- Issues to be discussed including emergency concerns /IEC policies/ training of Members/ revising SOPs /any other issues raised by Member(s).
- Any other matter referred for IEC opinion or issues to be informed to the members.
- Any other matter. The Secretariat will collect and verify all forms/documents for completeness and keep ready in these papers in the meeting.
-

The Secretariat will schedule protocols in the agenda as per date of receipt.

Answers to the IEC queries und amended study related documents (Protocol, ICD, CRF and IB) 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.

The agenda for the IEC meeting is prepared 3 days in advance before the date of meeting. 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 month's meeting for discussion except in some cases when the matter is urgent and important (having direct bearing on the safety of the research participants such as SAE report or major protocol violation) in the opinion of the IEC Secretary or Chairperson.

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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 Secretarial 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

4.3 During the meeting

Meeting will be held as scheduled provided there is quorum.

For the IEC meeting, besides the Member Secretary and the Chairperson the quorum will consist of:

1. One basic medical scientist (preferably a pharmacologist),
2. One social worker (or a social scientist, theologian, ethicist, Philosopher, member or representative of a non-governmental voluntary agency or a similar person),
3. A clinician,
4. A lay person from the community, and
5. A legal expert

The Secretariat will obtain signatures on the Confidentiality Guests/ Independent Consultants prior to the start of the meeting

The Secretariat will obtain the signatures of all the IEC members on the attendance register.

The Chairperson will initiate the meeting after ensuring that the quorum has been met.

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The Chairperson at his/ her discretion will delegate the responsibility of conducting the meeting as per agenda to the Member-Secretary.

The Chairperson will ask the members whether anyone has any conflict(s) of interest in the projects to be discussed and if so, to declare the conflict.

The Secretariat will obtain signatures on the Conflict of Interest Agreement Form from members who declare a conflict (e.g. members who are Pls or Co-Is) prior to the start of the meeting

If a conflict of interest has been declared by a member the Chairperson will ask the concerned member to leave the meeting room when the concerned issue is being discussed

The Member Secretary will ask the members whether any points need to be discussed regarding minutes of the previous meeting. If no points are raised, the minutes will be considered as confirmed.

The Member Secretary will present the agenda of the day's meeting for discussion

The meeting shall generally proceed in the order organized in the agenda. However, the Chairperson may allow adjustments in the order of issues to be discussed depending on the situation.

Investigators who have been asked by the IEC secretariat to provide additional information or clarifications related to their project may do so by attending the IEC meeting. The discussion amongst IEC members will not be done while the investigator is in the meeting room.

For other points on the agenda, the member secretary will present the gist of the matter/read the relevant letters from the investigator (if deemed necessary) and request the members to give their comments. The Member-Secretary assisted by the secretarial

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staff will also record a gist of discussions and decisions arrived on other issues discussed at the meeting.

4.4 Decision making

- The final decision on each proposal issue discussed in the meeting shall be by consensus within the group
- Decisions will include approval, disapproval, request for modifications of a study. suspension or termination of an ongoing study
- The following will not vote at the meeting
- Member(s) of the committee who is/are listed as investigator(s) on a research proposal
- An investigator or study team member invited for the meeting
- An independent consultant invited for the meeting to provide opinion Specific patient groups invited for the meeting

The schedule of the next meeting will be discussed and finalized by the members

All study documents will be collected back from the EC members documents will be destroyed at the site by the EC secretariat.

One submission dossier will be maintained at the EC office for records

4.5 After the Board meeting

The Secretariat will compose the summary of each meeting discussion and decision in a concise and easy-to-read style in the minutes 7 working days of the meeting day.

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The Secretariat will make sure to cover all contents in each particular category to include the following:

- Name of person preparing the minutes
- Location where the meeting was held (city, state) • Meeting number, date/ duration of the meeting (time of commencement and end)
- Names of the IEC members and guests attending the meeting
- Name of the individual serving as Chairperson of the meeting
- Determination of a duly constituted quorum by the Chairperson to proceed with the meeting
- Requirements for each study or activity requesting Approval
- Sponsor's name, if applicable
- Protocol number/date/version of protocol, when available
- Investigator's name
- Names of the Primary Reviewers who presented their findings
- Discussion as deemed appropriate by the Chairperson
- Follow-up action decided upon
- Reference to the investigator approval letter that lists all changes requested by the board
- Determination of the next requested continuing review

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Requirements for each study or activity, requesting Expedited Review:

- Sponsor's name if applicable
- Protocol number, if applicable
- Investigator's name
- Lists of expedited approval requests and outcomes.

Requirements for each Continuing Review Report:

- Sponsor's name; if applicable
- Protocol number, if applicable
- Investigator's name
- Indication of the Board's determination to continue, terminate, or amend the study
- Lists of recommendations or actions to be taken up with the investigator, if applicable.
- Requirements for each Adverse Event notification and Final Report:
- Sponsor's name; if applicable
- Protocol number, if applicable
- Investigator's name
- SAE Report or summary of report
- Actions deemed appropriate by the Board's review

Requirements for Termination of Approval:

- Name of the sponsor ,if applicable
- Protocol number, if applicable

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- Investigator's name; reason for termination.

4.6 Approval of the minutes

The Secretariat will check the correctness and completeness of the minutes and present the minutes to the Chairperson for review and approval within 7 working days of the meeting day. The Secretariat will email the minutes of the meeting to the IEC members. The Chairperson indicates approval by signing and dating the minutes (after approval in the next meeting)

4.7. Filing the minutes

- The Secretariat will place the original version of the minutes in the minutes file.
- The Secretariat will file the IEC Decision Forms in the project files and place all correspondence in the appropriate files

4.8 Calling an Emergency Meeting of IEC

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.

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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. The administrative officer will prepare packets for distribution to the members containing the information and documents about the matter(s) for which emergency meeting is scheduled or send the relevant details via email. During the meeting, the Chairperson Secretary will determine if there is a quorum.

If a quorum is not met, the meeting will be postponed for 15 minutes. However, if there is no quorum at the end of 15 minutes, the meeting would be held without a quorum provided at least four members (at least one scientific and one nonscientific member) are present, given the urgency of the matter under consideration. 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.

Prepared by: Signature with date ----------

Reviewed by: Signature with date ----------

Approved by: Signature with date ----------

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1. Purpose:

The purpose of this procedure is to elaborate administrative process and provide instructions for preparation, distribution of meeting agenda, review, approval, minutes, and communicating the decision to the Principal Investigator. IECs meet once in a month.

2. Scope:

This SOP applies to procedures to conduct the IEC meeting

3. Responsibility:

It is the responsibility of the respective Member Secretary, IEC and IEC staff to prepare for the IEC meetings

4. Detailed Instructions:

4.1 Before full board IEC meeting

- Prepare the agenda of the IEC meeting
- Proposals submitted for initial review will be allocated to IEC-I/II via randomization Investigators are advised to submit proposals well in advance to ensure that their projects would be reviewed in either of the two meetings scheduled in a given month

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- 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.
- Lead discussants will be assigned as necessary taking into account conflicts of interests of members. In addition, the IEC Administrator will check the agenda prior to the meeting to identify IEC members who may have a conflict of interest due to their participation as key personnel on a current or proposed research project. If a conflict of interest is identified, the study is assigned to another member who does not have a conflict of interest. An IEC member who has a conflict of interest with regard to a research project that will be reviewed at a convened IEC meeting must notify the IEC office of the conflict prior to the meeting. Once the IEC office receives notice of recues, the IEC Member Secretary will seek an alternate IEC member to join, the meeting for the review of that project if necessary to meet quorum.
- It is general practice (but not required policy) that IEC Chairs are not assigned lead discussant responsibilities except in circumstances when their expertise is the most appropriate.

4.2 Distribution of Study/Documents Packages to the IEC Members

A hard copy/ soft copy of the Agenda, Study Assessment forms would be dispatched to all IEC members and soft copies of protocols under discussion will be sent on email preferably 7days in advance of the scheduled meeting

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- Verify (verbally, by e-mail) with the members whether the protocol packages are
- It is the responsibility of the IEC member to verify items of the parcel on receipt and in case of any missing items, intimate the IEC office immediately so that the relevant documents could be made available to the members before the meeting.
- It is the responsibility of the IEC member to identify any conflict of interest and notify the IEC office of the conflict prior to the meeting.

4.3 Preparation for the meeting

- Reserve the IEC meeting room on the scheduled meeting date and time. The meeting will be held in the meeting room of IEC, unless otherwise specified
- Ensure that the room, equipment (projectors, recorder, etc) and facilities are available in good working conditions
- All original files of studies on the agenda are kept in the meeting room for ready reference before the meeting
- E-copy of SOPS, Schedule Y. ICMR guidelines are kept available for ready reference.
- Secretariat informs the scheduled meeting date and time to the Principal Investigators.
- The meeting will be re-scheduled or canceled if it becomes apparent that meeting requirements (quorum, sufficient expertise) will not be met.

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4.4 Conduct of Meeting

• The members should gather in IEC meeting room on scheduled time. The Chairperson before beginning the discussion will:

- Ensure that the quorum (SOP 02/V5 section no. 2.9) is fulfilled. This should be maintained throughout the meeting and at the time of decision making
- Request to declare conflict of interest either verbally or written on any study for discussion.
- At the beginning of each convened IEC meeting, the IEC Chair or designee will ask the members if anyone has a financial or non-financial conflict of interest with regard to any of the research projects that will be reviewed at the meeting. The IEC Chair or designee will announce that members with a conflict of interest must excuse themselves from deliberation and voting on that research protocol.
- If an IEC member has conflict of interest involving a project then he/she should declare the same, before the meeting commences and leave the meeting room before the discussion on the same. This should be recorded in the minutes. The excused member can answer questions from the IEC, but cannot be present for IEC deliberations and voting.

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- If the unanticipated conflict of interest affects quorum, that particular item will not be discussed and will be deferred to the next scheduled meeting.
- Research involving vulnerable populations (vulnerable to coercion or undue influence) will be placed on the agenda only when at least one individual (IEC member or independent consultant) who is knowledgeable about or experienced in working with the population will participate in the meeting (or an independent consultant has been obtained). If expertise with a specific vulnerable population is needed but not available from the IEC members, a consultant will be obtained or the item will be scheduled for a later meeting when expertise is available.
- The Member Secretary should discuss the minutes of the previous full board/expedited 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 list of protocols that were exempted should be notified.
- The IEC may invite investigators to attend the full board meeting related to their studies, and clarify doubts, if any
- All proposals that are determined to undergo full board review must be deliberated and decision about the proposal taken at a full board meeting.
- Time allotted for the meeting should be reasonable to allow ample discussion on the each agenda item.
- The meeting proceeds in the sequential order of the agenda; however the Chairperson may change the order, if the situation so demands

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- The Member Secretary will request the lead discussant to discuss the research study. The lead discussant should submit the duly filled study assessment form only in case of initial review and resubmission preferably one day prior to the meeting
- All the scientific members including the lead discussant should score the intramural projects and submit the scoring sheet at the end of the discussion or at the conclusion of IEC meeting.
- Amendments/Continuing review Application/SAES/Documents will ordinarily be reviewed by previously assigned lead discussant
- In case the Secretary of the IEC is the Principal Investigator for project under discussion, the IEC member nominated as Acting Member Secretary will perform the function of the Secretary only for that study. The Secretary should declare his conflict of interest and leave the meeting room
- In case the lead discussant cannot attend the meeting, Secretary, IEC or any other IEC member may brief the IEC about the research study and also discuss written comments/duly filled study assessment form, if provided by the lead discussant
- The Member Secretary may identify subject experts to review the proposal as per need. The comments of an independent consultant (if applicable) could be presented by the Member Secretary or these experts may be invited to the EC meeting or join via video/ tele conference but will not participate in final decision making. However, her/his opinion must be recorded.

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- During the initial or continuing review of the research, material provided to IEC members will be considered confidential and the board members will assure the confidentiality of the information provided to them.
- The Member Secretary, IEC/IEC administrator minutes/records the proceedings of the IEC meeting

.4.5 Decision Making Process

IEC completes the adequate review of the research studies submitted. The committees will review new studies, amendments, annual /continuing review of ongoing studies, SAE reports, any other documents and assess final reports of all research activities through a scheduled agenda.

- A 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
- Decision may only be taken when sufficient time has been allowed for review and discussion of study in the absence of non-members (e.g., the investigator, representatives of the sponsor, independent consultants) from the meeting, with the exception of IEC staff
- Decisions will only be made at meetings where a quorum (SOP02/V4) is present

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- The documents required for a full review of the application should be complete and the relevant elements considered before a decision is made
- Only IEC members who attend the meeting will participate in the decision.
- Decisions will be arrived at through consensus/unanimous or majority opinion amongst the voting members of IEC. The decision-making is thus concerned with the process of deliberating and finalizing a decision. When a consensus is not possible, the IEC will vote.

Voting Procedure:

1. This may be in the form of voice vote, show of hands, or by secret ballot, as determined by the Chairperson, IEC.
2. All members of the IEC including the Chairperson and the Member Secretary present in the room have the right to vote/express their decision and should exercise this decision. If there is equality of votes, the chair will have a casting vote.
3. The concurrence / voting of the members will be recorded in the minutes as Agreed / Disagreed/Abstained / Recused.

- Agreed: in favor
- Disagreed- Against
- Abstain: Present but did not agree/disagree
- Recused: Listed under "Members Present" but not present for the discussion and decision on the study

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- Types of decision

- Approved- The study is approved in its present form
- Revision with minor modifications/amendments - refers to minor modifications that do not alter the risk-benefit assessment for the research and do not require substantial changes in protocol and informed consent document. The revisions will be reviewed by the Member Secretary, IEC or in some cases by the respective lead discussant on behalf of the full board. Such revised proposals may not be taken up for the full board review, however in some cases may be referred for a full board review. If revisions are found satisfactory approval will be granted. Examples may include but are not limited to- minor, non-substantive changes in the protocol and consent form(s), Correction of typos, grammatical errors, minor wording clarifications (in informed consent forms)
- Revision with major modifications for resubmission Extensive revisions is necessary. Principal investigator has to comply with the changes suggested by IEC and respond to the queries. The revised project will then be reviewed in the next full board meeting. Resubmit refers to major modifications that may alter the risk-benefit assessment for the research and require substantial changes in protocol and informed consent document. Examples may include but are not limited to- significant changes in the protocol (research methodology, study design) and consent form(s), and modification affecting participant

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- Not approved- The study is not approved in its current form. A negative decision on an application will be supported by clearly stated reasons. If the investigator wishes to appeal to the decision he/she may do so by contacting the IEC Secretariat
- Deferred- The decision cannot be arrived at present and therefore post pone to next meeting Grounds for this: lack of quorum, lack of expertise etc
- Noted- Study documents that are notified to IEC
- Query- Further clarification/modification required

An IEC may decide to revere its positive decision on a study if it receives information that may adversely affect the risk benefit ratio/ safety of participants.

- Any advice by the IEC that is non-binding will be appended to the decision.
- The discontinuation of a trial will be recommended if the IEC finds that the goals of the trial have already been achieved midway, unequivocal results are obtained or if the IEC feels the continuation of the trial may potentially harm participants.
- If necessary, the investigator may be invited to present the protocol or offer clarifications in the meeting. Representative of the patient groups or community can be invited during deliberations to offer their viewpoint.
- Subject expert/s may be invited to offer their views or their review comments would be considered. The expert/s should not participate in the decision making process. However, his/her opinion must be recorded.

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- The proceedings of the IEC meetings will be documented and the meeting minutes will be signed by the Chairperson/Member Secretary, IEC.

4.6 After the IEC meeting

4.6.1 Preparing the minutes and the decision letters

• The Member Secretary and IRB Administrators will compile the proceedings of IEC meeting in a concise and easy-to-read style and will check spelling, grammar and context of the written minutes

- The minutes of the meeting will be compiled by the IRD Administrators and finalized by the Member Secretary within 15 working days
- The minutes will record whether the decision was unanimous, or whether a vote was taken for the decision. The number of members voting for, against, and abstaining will be recorded The recusal of the IEC member for conflict of interest is recorded in the IEC meeting minutes.
- The basis for requiring changes in or disapproving research, and a written summary of the discussion of controversial issues and their resolution must be recorded

4.6.2 Approval of the minuets and the decision

- The minutes will be circulated to all the members for comments before final approval by Chairperson Co-Chairperson

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- The minutes of the IEC meeting will be approved and signed by Chairperson Member Secretary, IEC (or the Acting member Secretary as in 5.4.4)
- The minutes of the IEC me ting will be ratified in the subsequent IEC meeting
- The IEC decisions will be communicated to the Pls.

4.63 Filing of the minutes of the meeting

Place the original version of the minutes in the minutes file and copy of the minutes are filed only in the corresponding initial review research protocol file

4.7 Communicating Decision

The decision will be communicated in writing to the Pl 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, date version number (if applicable)
- 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

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- The name of the site(s)
- The date and place of the decision
- A clear statement of the decision reached
- Validity of approval will be for the complete duration of the study. This approval is subject to annual review. However failure to submit completed status report by the late due date may result in the expiration of approval
- Calculation of Approval an Expiration Dates

The IEC calculates the date of initial IEC approval in the following manner.

- When a research study is approved at a convened full board/ expedited review meeting, the date of the approval letter is the date of IEC approval Calculation of Expiration Date Initial Approval The expiration date is the last date that the protocol is approved

The IEC calculates the date of expiration in the following manner

- Based on the proposed duration of the project the date of expiration is calculated by the following means

Date of IEC approval +364 days Date of expiry

01/05/2016 364 days - Valid till 30/04/2017)

01/05/2016+179 days Valid till 31/10/2016

- Location of study conduct
- Number of participants to be accrued

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- To submit the continuing review application/annual status report
- To register the study in the Clinical Trials Registry (if applicable)
- Any suggestions by the IEC
- The date of approval of a study is the date of issuance of the HC approval letter.
- In the case of a positive decision, the PI is notified of the following requirements through an approval letter (AX2-VS/SOF05/V5)
- Responsibilities of the PI
- Submission of annual status reports progress report(s) is decided on case to case basis, usually yearly
- The need to notify the IEC in the case of amendments to the recruitment material like the potential research participant information, or the informed consent form
- The need to report serious and unexpected adverse events related to the conduct of the study
- The need to report unforeseen circumstances, the termination of the study, or significant decisions by other IECs or DSMBS
- The information the IEC expects to receive in order to perform ongoing review
- The final summary or final report
- The schedule/plan of ongoing review by the DSMB of sponsored trials
- IEC shall intimate the licensing authority about the approval of clinical trials intended for academic purposes such as use of approved drug formulation to study new indication or new route of administration or new dose or new dosage .The

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IEC shall await for comments from the DCGI for a period of 30 days from the date of receipt of communication from the IEC. If no communication from DCGI is received in the specified time frame, IEC shall presume that no permissions are required from the licensing authority and will issue the final approval letter for the study.

- An IEC may decide to reverse its positive decision on a study if it receives information that may adversely affect the risk/ benefit ratio
- Any advice by the IEC that is non-binding will be appended to the decision
- In the case of a negative decision, the reasons should be clearly stated in the communication to the PI
- The PI will also be notified of the cap for accrual of number of participants
- All decision and approval letters will be signed by the Member Secretary, IEC or the nominated Secretary for that meeting. In case Member Secretary IEC is Principal Investigator, the decision letters will be signed by Acting Member Secretary / Chairperson Co-Chairperson IEC
- The decisions letters will be communicated to the Principal Investigator and wherever required to the organizational offices and officials and other concerned authorities.
- Member Secretary, IEC Chairperson IEC, will sign and date the approval certificate in the original research protocol.
- The letter will mention whether the decision has been arrived at by consensus unanimous or majority opinion amongst the voting members of IEC, or by voting.

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- If the decision has been arrived by voting, the letter will state the number of votes for and against approval of the project.

4.8 Procedures for Appealing the IEC Decision to Disapprove or Terminate a Study

- If an investigator disagrees with the IEC decision to disapprove or terminate a study, the Investigator may submit a written appeal of the decision to disapprove of the IEC decision within 21 working days of being notified of the decision. The appeal should address the specific concerns of the IEC and the IEC basis for disapproval.
- The appeal will be reviewed by the full board. The Investigator may request to be in attendance at or be invited to the convened meeting to provide clarification or additional information to the IEC
- The IEC may decide to accept or deny the appeal (Decision making process-Voting). The Principal Investigator will be notified in writing of the decision..
- If the appeal to the decision on disapproving a study is accepted, the Investigator is invited to submit a new study application to the IEC for review and approval, according to the conditions set forth by the IEC in accepting the appeal.
- If the appeal is denied, the IEC decision is final and the study may not be approved or resumed.

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Agenda Minutes format

I. Minutes IEC & DSMU
II. SAES
III. Deviations
IV. Projects for Initial Review
V. Resubmission of projects after initial review
VI. Post approval amendments
    a) Protocol
    b) ICF
    c) IB
    d) CRF
VII. Status Reports
VIII. Monitoring Reports
IX. Letters
X. Any other

Prepared by: Signature with date----------

Reviewed by: Signature with date----------

Approved by: Signature with date----------

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1.Purpose:

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

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

3. Responsibility:

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

4. Detailed Process:

4.1 Receive submitted packages

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 5 sections mentioned

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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 documents

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.

4.2 Verification of Submission

The IEC secretariat has created an online system for submission of protocols and other study related documents. From 01 January 2018, it has become mandatory to make online submission of new research proposals. Investigators who wish to make submissions to IEC should have a login id and password to the IEC web portal and create their profile on the online system.

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

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- Check the submissions for initial review as per checklist, (AX2-V5/SOP 03/VS) to ensure that all mandatory forms and documents are submitted.

> Submission should include

  - Project submission Form (AXI-V5/SOP 03/V5)
  - Study protocol
  - Other related documents necessary for initial review (AX 2-V5/SOP 03/V5).

- Notify the investigators, if the online IEC form is incorrectly filled and/or the submission is incomplete as per the form (AX 3-V5/SOP03/V5). The investigator must login to view the notifications from the IEC secretariat which is displayed on the investigator dashboard. Additionally, an auto email is also sent to the investigator with document requests and other administrative findings and queries. 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. The PI is required to obtain permission from the Head of the concerned department, the DMG convener (if applicable) and all investigators who makes up the study team.
- Check completeness of hard copy of the research proposal submitted with necessary information and signatures at all designated places in the submission form.
- Stamp, sign & date on the cover letter confirming receipt of the documents.
- Record the completeness of submission on document receipt form (AX 3V5/SOP03/V5) and inform the investigators for necessary action
- Ensure payment of Institutional Ethics Committee processing fees for all Pharmaceutical sponsored clinical trials.

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- Store the hard copies and soft copy of the research project. The hard copies will be stored under controlled access storage in IEC office. The soft copy of the study accepted will be stored electronically.

4.2 Detailed description of Study Project Submission

The study protocol should be accompanied with the following relevant supporting documents for scientific and ethical review. These are

Checklist (Refer AX 2-V5/SOP 03/V5)

4.2.1 Project Submission Form

a. Grouping of Project b. Project Fact Sheet c. Investigator Declaration and Study Team Undertaking with Duties & Delegation d. Financial Disclosure e. Project Submission Overview f. Budget Sheet for the Proposed Study

4.2.2 Essential Documents

a. Study protocol
b. Lay summary-Provide a non-scientific summary of the proposal, including a statement about the importance of the question the research application will address, the relevance of the research to your country or region, and the potential impact of the study results.
c. Case Record Form
d. Informed Consent Documents- Participant Information Sheet & Informed Consent Forms (ICFs) for adults. For studies involving children, parent information sheet and

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consent form and child information sheet and assent form are mandated in case of children between age 7 -18 years of age

e. English, Hindi and Marathi ICDs are to be mandatorily submitted to IEC. ICDs in other languages may be submitted if required by the study [Refer (AX4VS/SOP03/V5)]. Back translations of participant information sheet & informed consent forms is mandatory for vernacular languages other than Hindi and Marathi and may be requested on a case to case basis for Hindi and Marathi.
f. Application for waiver of consent (if applicable)
g. Audio video informed consent (if applicable)
h. Investigator's Brochure (if applicable)
i. Package insert/product insert (if applicable)
j. Questionnaires (if applicable)
k. Agreement to comply with national and international GCP protocols for clinical trials
l. Regulatory clearance from appropriate regulatory authorities i.e. Drugs Controller General India (DCGI) approval/ICMR/Health Ministry Screening Committee(HMSC) (if applicable)
m. For national/international collaborative study Draft/Final Memorandum of Understanding(MoU) between the collaborating institutes
n. Draft/Final Clinical Trial Agreement (CTA) (if applicable)
o. Draft/Final Material Transfer Agreement(MTA) if applicable
p. Insurance/Indemnity policies, indicating who are covered (if applicable)
q. Participant recruitment and enrollment procedures/advertisement (if any)
r. Documentation of clinical trial registration (if applicable)
s. Decision of other Ethics Committees (If required / asked for)

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t. One page, recent, signed and dated curriculum vitae of the investigators indicating qualifications and relevant experience.

u. MMC registration certificate of the investigators (if applicable)

v. Good Clinical Practice Certificate/Training certificate in clinical research

w. Any other important information relevant to the study

x. cover letter enlisting all the documents submitting

4.3 Minor revisions of study after initial review for approval

- Minor modifications submitted after initial review of the research proposal that do not alter the risk-benefit assessment for the research and do not require substantial changes in protocol and informed consent document fall under the category of IEC decision "revision with minor modifications/amendments"
- PI will submit 1 copy of the revised study related documents along with justification for modification, and clearly highlighted / demarcated sections which have undergone change. The additional hard copies if required should be submitted by the PI.
- The IEC Secretariat will verify the completeness and reconfirm that the copies contains the revisions highlighted with respect to the earlier submission.
- The IEC Secretariat will perform the steps 3.4.2. The unchanged study related documents need not be submitted

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4.4 Major revisions of study after initial review for approval

- Major modifications submitted after initial review of the research proposal that may alter the risk-benefit assessment for the research and require substantial changes in protocol and informed consent document fall under the category of IEC decision "revision with major modifications for resubmission"
- PI will submit 1 copy of the revised study related documents along with justification for modification, and clearly highlighted / demarcated sections which have undergone change. The additional hard copies if required should be submitted by the PI.
- The IEC Secretariat will verify the completeness and reconfirm that the copies contain the revisions highlighted with respect to the earlier submission The IEC Secretariat will perform the steps 3.4.2. The unchanged study related documents need not be submitted

4.5 Post approval- Research Protocol Amendments and other study related documents

- Investigators who may wish to modify or amend their approved protocols and/or other study related documents must seek !EC approval
- The PI should submit 1 hard copy + soft copy of the amended documents. Additional hard copies if required should be submitted by the PI.
- The IEC Secretariat will verify the completeness of the submission. The PI should highlight the modifications in the amendment, and provide a summary of changes

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PI should also indicate whether these changes would entail change in the ICF as per the form.

- The Member Secretary in consultation with Chairperson will decide whether to initiate:

➢ Full board review

➢ Carry out an expedited review in case of minor administrative amendment

This process is further elaborated in SOP 06/V5

4.6 Annual Continuing Reviews of Approved Research Studies

- Behalf of the IEC will send reminders for annual report to individual PI at least 90 days prior to lapse of approval.
- The IEC Secretariat will verify the completeness of the Continuing Review Application Form (AXI-VS/SOP07/V5) /Progress report. The IEC Secretariat will sign and date the documents.
- The progress or continuing review application will be discussed in the Full Board meeting of IEC or expedited review meeting of the IEC.

4.7 Research study Completion/ Premature Termination / Suspension / Discontinuation of the study

- The IEC will receive a copy of Study Completion Report / Premature Termination /Suspension/Discontinuation of the study in the prescribed format (as per SOP 12/V5 & SOP13/V5).

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- The IEC Secretariat will verify the completeness of the Study Completion / Premature Termination / Suspension / Discontinuation of the study (SOP12/V5 & SOP 13/V5) filled by the PI.
- The Study Completion / Premature Termination / Suspension / Discontinuation of the study report will be discussed in Full Board/ Expedited meeting of IEC.

4.8 Submission of Serious Adverse Events and Deviations/Violations

- The IEC secretariat will receive a copy of SAE and Deviations and Violations in the 6 prescribed format (as per SOP 9/V5 & SOP8/V5)
- The IEC Secretariat will verify the completeness of the SAE/Deviations and Violations SOP 9/V5&SOPRVS) filled by the PI
- The SAE and Deviations and Violations will be discussed in the Full Board meeting of IEC for further action

Prepared by: Signature with date ----------

Reviewed by: Signature with date ----------

Approved by: Signature with date ----------

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KMCT Medical College	Standard Operating Procedure	Doc No:	KMCT/IEC/SOP/07
		Effective Date	01 May 2021
	Submission of Research Documents	Version No	3

1.Purpose:

The purpose of this Standard Operating Procedure (SOP) is to describe how the Secretariat of the Institutional Ethics Committee (IEC), KMCT Medical College Kozhikode manages protocol and other document submission.

2. Scope:

The scope of this SOP includes:

Submission of Research Project and related documents for Initial Review of the Protocol

- Re submission of Protocols or Research Projects with corrections
- Submission of Protocol Amendment
- Submissions of written communications related to
- Continuing Review of Approved Protocols
- Protocol completion/Termination o Protocol deviations/violation
- SAE initial/ follow up/ final reports
- Submission of Protocol deviations, Protocol violations

3. Responsibility:

It is the responsibility of the IEC Secretariat to receive, record and distribute the received protocols and any other documents for review, act on the instructions given by the appropriate member of the IEC and ensure that the communication reaches the concerned recipient.

4. Detailed Instructions

The Principal Investigator can submit research proposal to the IEC for review and approval under any of the 5 sections mentioned below:

❖ Initial Review Application

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- Re-submission of Protocols and Corrections
- Protocol Amendment or any other Amendments
- Continuing Review of Approved Protocols
- Protocol completion/Termination

4.1. Frequency of IEC Meeting:

The IEC meeting will be held once in three months or as and when required based on theResearch proposal being received for review and approval.

Study documents received at least 10 days prior to the proposed IEC meeting will be considered during the next meeting.

- All proposals should be submitted with an application duly signed by the Principal Investigator
- 13+1 copies of the proposal along with the application duly signed by the Principal Investigator (PI)/Co-investigators should be forwarded to the ethics committee.
- No subjects would be admitted into the study unless the EC issues a written opinion of the study
- The date of meeting will be intimated to the researcher.

4.3. List of documents to be submitted at the time of initial review will include, the list below but need not be restricted to it.

- Name of the applicant with designation
- Name of the Institute/Hospital/Field area where research will be conducted.
- Approval of the Head of the Department /Institution
- Protocol Version <Version No.> dated <Date>.

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- Investigator's Brochure Version <Version No.> dated <Date>
- Subject Information Sheet and Informed Consent Form <Version No.> dated <Date> in English
- Subject Information Sheet and informed Consent Form <Version No.> dated <Date> translated from English to <Name of the Language> on <Date of Translation>.
- Ethical issues if any in the study and plans to address these issues.
- Proposal should be submitted with all relevant enclosures like proforma, case report forms, questionnaires, follow-up cards, etc.
- For any drug/device trial all relevant pre-clinical animal data and clinical trial other centers within the country/countries, if available.
- List of study team members and their Curriculum vitae
- Any regulatory clearances required
- Source of funding and financial requirements for the project.
- Other financial issues including those related to insurance
- An agreement to report Serious Adverse Events (SAE) to IEC
- Statement of conflicts of interest, if any
- Agreement to comply with the relevant national and applicable international guidelines.
- A statement describing any compensation for study participation (including expenses and access to medical care) to be given to research participants; a description of arrangements for indemnity, if applicable (in study-related injuries); a description of the arrangements for insurance coverage for research participants, if applicable; all significant previous decisions (eg, those leading to a negative decision or modified protocol) by other ECS or regulatory

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authorities for the proposed study (whether in the same location or elsewhere) and an indication of the modification (s) to the protocol made on that account.

The reasons for negative decisions should be provided.

- Plans for publication of results - positive or negative - while maintaining the privacy and confidentiality of the study participants
- Any other information relevant to the study.
- Insurance and Indemnity Certificate
- Proposed methods of subject accrual including advertisement(s) etc.
- Investigator's Undertaking (Appendix V)
- Investigator's agreement with the Sponsor

Prescribed fee should be remitted favoring KMCT Medical College Kozhikode. In house Research Projects: Rs.1000

> Submission fee for Multi-centre global Clinical trial: Rs. 1,00000/
> Multi-Centre academic trials: 10000/
> Any amendments to approved trials: Rs.15,000/.
> SAE review Fee: Rs.5000/

The above mentioned fee is exclusive of the applicable taxes,

The submission fee mentioned will be revised according to the revision introduced by the Government. Any amendment will be notified to the authorities.

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4.4. Initial Review Application.

- **Check for submission items:**

The Secretariat will check the hard and soft copies of the following items:

1. 13 sets of the proposal are submitted
2. A completely filled IEC Project Submission Application Form for Initial Review AX IA/SOP 04/ VI and AX IB/SOP 04/V1
3. Document Receipt Form (AX 02/SOP 06/V1)
4. Assign a unique no: to Drug Trial Study File
5. Verify contents and adequacy of Submitted Documents.

• Complete the submission process:

The Secretariat will:

- Complete the checklist of submission
- Stamp the receiving date on the first page/last page of the covering letter and initial it

Annual Continuing Reviews of Approved Protocols, Amended Protocols and related documents, Study completion/ termination, SAE report, Protocol deviations. The IEC will receive one soft copy and one hard copy of the Continuing Review Report, Amended Protocols and related documents Study completion/ termination, SAE rep.

Prepared by: Signature with date----------

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Reviewed by: Signature with date----------

Approved by: Signature with date----------

Annexure IA AX 01-A/SOP 04/V1- Project submission application form for initial review for drug trials and other regulatory studies

Annexure 1-B AX 01B/SOP 04/V1- Project submission application form for initial review for academic (non-regulatory) studies

Annexure 2 AX 02/SOP 04/V1- Document Receipt Form

Annexure 1A AX 01-A/SOP 04/V1- Project submission application form for initial review for drug trials and other regulatory studies (Industry and Government sponsored studies)

Please fill in the details

- Tick √ in the box for the appropriate answer

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Title of the Protocol

	Name	Designation	Department
Principal Investigator			
Sub investigator			
Sub investigator			
Sub investigator			
Study coordinator			

Sponsor information

1. Indian
2. International
3. Industry national multinational
4. Contact information of sponsor
5. Contact information of CRO

For Clinical Trials

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Medicines/vaccines/Device/Herbal Remedies :(Tick the appropriate boxes)

1. What does the study involve use of?

☐ Medicine Devices Vaccines

☐ Indian Systems of Medicine Any other

If others, specify ----------

2. Is it an Investigational New Drug (IND)? Yes ☐ No ☐

If yes, IND No:

Clinical Study is in: ☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV

3. Whether DCGI's permission for testing IND obtained?

If yes, date of permission: ----------

4. Research participants Sample Size:

i. Number of research participants at this Centre:

ii. Number of research participants at other sites in India:

iii. Total number of research participants at all sites (globally)

5. Duration of study:

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6. No. of visits:

7. Vulnerable research participants' ☐ Yes ☐ No ☐ NA

8. Is the proposal being submitted for clearance from Health Ministry's screening committee (HMSC) / ICMR for international collaboration? (as applicable in case of studies involving collaborations with foreign Laboratory/Clinic/Institution)

☐ Yes ☐ No ☐ NA

Consent: ☐ Written ☐ Oral ☐ Audio-visual ☐ NA

9. Will any advertising be done for recruitment of research participants? ☐ Yes ☐ No (posters, flyers, brochure, websites - please attach a copy)

10. Is there provision for compensation for study related injury? ☐ Yes ☐ No

If Yes ☐ by Sponsor ☐ by Investigator

☐ by insurance ☐ by any other company

11. Do you have any conflict of interest in the present study? ☐ Yes ☐ No

12. Number of protocols handled by the PI at present including current Status of ongoing studies approved by IEC and carried out by the Principal Investigator.

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(Information to be given: whether study is initiated, no. of approved research participants, no. of research participants enrolled, no. of active research participants, no. of research participants who have completed the study and total duration of the study. Describe briefly in a separate sheet, if required).

13. Current Brief Curriculum Vitae (signed and dated copy) of the study team member's principal investigator, co-investigator and study coordinator.

(Information required: age, designation and department, educational qualification, previous research experience in last five years).

14. GCP training certificates of principal investigator and coordinators

15. Is the trial registered with Clinical Trial Registry? ☐ Yes ☐ No

Registration No:

If Not State reason

Annexure 1-B: AX 1-B/SOP 06/VI

Project Submission Application Form for Initial Review for Academic (non regulatory) Studies

Please fill in the details in legible hand writing

- ✓ Tick in the box for the appropriate answer/ Write NA if question is not applicable

Title of the project

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	Name	Designation	Department	Signature
Principal Investigator				
Sub Investigator				
Sub Investigator				
Sub Investigator				
Study Co-ordinator				

1. Type of study:

☐ Non-sponsored study ☐ Sponsored Study:

2. If Non-Sponsored Study:

Type of study: ☐ Thesis /dissertation ☐ ICMR ☐ Other Academic

Duration of study_____

Approx. Completion date (MM/YY) _____

3. If Sponsored,

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Kozhikod

Total Budget: Rs. _____

Funding Sources _____

Type of study: ☐ Prospective ☐ Retrospective ☐ Cross-Sectional

Is the study Observational/ Interventional? _____

If interventional, does the study involve testing of a new drug or any deviation from routine/standard of care practices?

_____

2. Does the study involve use of :

☐ Drug / Vaccine ☐ Device ☐ Alternative Medicine

☐ New technique (Surgical/PT/OT/Psychotherapy etc.) ☐ Diagnostic Kit/Investigations

If other, please specify_____

i. Is the test drug/device marketed in India ☐ Yes ☐ No

ii. Does the test drug involve a change in use, dosage, route of administration?

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☐ Yes ☐ No

If yes, please attach copy of DCGI permission.

3. Subject selection:

1) Number of subjects at this Centre:

2) If multicentric, total number of subjects:

3). Participation of Vulnerable subjects: ☐ Yes ☐ No

- ☐ Pregnant women
- ☐ illiterate
- ☐ Seriously/terminally ill
- ☐ children
- ☐ Neonates
- ☐ mentally challenged
- ☐ Elderly
- ☐ handicapped economically /socially backward
- ☐ Institutional employees /students

If other, please specify----------

4. Does the study involve use of

1) Fetal tissue or abortus Yes No
2) Organs or body fluids Yes No
3) Infectious/biohazardous specimens Yes No
4) Will pre-existing/stored/left over samples be used? Yes No
5) Will samples be collected for banking/future research? Yes No
6) Will any advertising be done for recruitment of research participants? Yes No
7) Is there provision for compensation for study related injury?

If Yes

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☐ by Sponsor ☐ by Investigator

☐ by insurance ☐ by any other company

8) Do you have any conflict of interest in the present study? ☐ Yes ☐ No

(financial/non-financial/ any other)

If yes, specify: .....

Is any other department involved in participant recruitment/investigation, but not co- investigators or collaborators? ☐ Yes ☐ No

If yes, specify.....

Name and signature of concerned Head of Department.....

We hereby declare the information given above is true. A copy of the study report will be submitted at the end of the study.

Signature of, Principal Investigator_____

Signatures of Co-investigators : 1_____

2_____

Forwarded by Heads of Department(s)_____

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Stamp/Seal of the Department(s)

Annexure2: Ax 04/SOP 06 /VI

Document Receipt Form

Protocol No:	Received No	Submitted Date
Protocol title		
Principal investigator		
Documents submitted	☑ Complete ☐ Incomplete	
Documents to be submitted later		
Received by name & signature		
Date of receipt		

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1. Purpose

The IEC should review and must approve every research study involving human participants and other forms of studies before the research is initiated. The IEC should evaluate the scientific rationale, scope and, methodology, and the ethical legal aspects of the study. The committee should evaluate the possible risks to the participants with proper justifications well as the expected benefits to participants/community. The adequacy of documentation for ensuring privacy & confidentiality should also be reviewed.

The purpose of this Standard Operating Procedure (SOP) is to describe how the IEC members will review an initial submission of the research study for approval using the Assessment Form .The Assessment Form AXL-VS/SOP04a/VS is designed to standardize the review process and to facilitate reporting, recommendations and comments offered to each study.

2. Scope:

This SOP applies to the review and assessment of all studies submitted for initial review and review of revised and resubmitted protocols submitted for approval of the IEC. The specific elements in the Assessment Form must be adequately addressed in the protocol and/or protocol-related documents submitted for review. Relevant comments made during discussion and deliberation about a study should be recorded in the minutes of the meeting The decision reached by the IEC will be communicated to the Pl

3. Responsibility:

4. Detailed Instructions

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4.1 Categorization of Protocols

The Member Secretary, IEC or secretariat shall screen the proposals for their completeness. Depending on the risk involved, the research proposals are categorized into three types, viz

1. Full board review

Ii Expedited review

iii. Exemption from review

An investigator may categorize his/her protocol into the above three types. In case the PI wishes to apply for expedited review or exemption from review of the submitted research proposal, a standard request form needs to be filled out, providing justification for the same.

Standard Request Forms for Expedited Review and Exemption from review are available as annexures AXI-VS/SOP045/VS (SOP 04b/V5) and AXI-VS/SOMMENS (SOP 4VS) respectively.

However, the decision to accept the request for Expedited Review (Exemption from review will be made by the Member Secretary, IEC.

This SOP describes the process of full board review of research proposals

Full board Review

All research proposals presenting more than minimal risk that are not covered under exempt or expedited review should be subjected to full committee review: Some examples are ;

- Research involving vulnerable populations, even if the risk in minimal
- Research with minor increase over minimal risk. This includes increment in probability of harm or discomfort is only a little more than the minimal risk threshold. This may present in situations such as routine research on children and

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adolescents, research on persons incapable of giving consent; delaying or withholding a proven intervention or standard of care in a control or placebo group during randomized trials, use of minimally invasive procedures that might cause no more than brief pain or tenderness, small braises or scars, or very slight, temporary distress, such as drawing a small sample of blood for testing; trying a new diagnostic technique in pregnant and breastfeeding women etc. Such research should have a social value. Use of personal identifiable data in research also imposes indirect risks. Social risks, psychological harm and discomfort may also fall in this category.

- Studies involving deception of participants Some types of research studies require deception due to nature of research design. A true informed consent may lead to modification and may defeat the purpose of research. Such research may be carefully reviewed by the EC before implementation.
- Research proposals that have received exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee.
- Amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, etc.)involving an altered risk
- Major deviations and violations in the protocol
- Any new information that emerges during the research for deciding whether or not to terminate the study in view of the altered benefit-risk assessment

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- Research during emergencies and disasters either through an expedited review scheduled or unscheduled full committee meetings. This may be decided by Member Secretary depending on the urgency and need.
- Prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs

4.2 Full board Review

The primary task of the IEC is to review research proposals and their supporting documents with special attention to the scientific validity, competence of the investigators, informed consent and elements of the study covered in the submission form to evaluate the suitability and feasibility of the study.

The following will be considered as applicable:

4.2.1 Scientific Design and Conduct of the Study

- Is the project original and innovative? e.g. Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools or technologies for this area?
- Is this an attempt to validate, prove or disapprove the validity of existing knowledge?
- Appropriateness of study design, work plan and structure to achieve the stated objectives. Are the conceptual or clinical framework, design, methods and

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analyses adequately developed, well integrated, well-reasoned and appropriate to the aims of the project?

- Relevance of the work in the context of contemporary translation or clinical cancer research: Does this study addresses an important research question or is it predominantly, a service proposal? If the aim of the application are achieved, how will scientific knowledge or clinical practice be advanced What will be the effect of the these studies on the concepts, methods technologies treatments, services or preventive interventions that drive this field?
- Appropriateness of the study design in relation to the objectives of the study.
- The statistical methodology (including sample size calculation), and the potential for reaching sound conclusions with the smallest number of research participants,
- The available non clinical and clinical information on an investigational product is adequate to support the proposed clinical trial.
- The justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities.
- The outcome of the research should be relevant to the health problems of society
- The justification for the use of control arms.
- Potential of the work that would be conducted to lead to a larger and high impact study.
- Criteria for prematurely withdrawing research participants, and criteria for suspending or terminating the research as a whole.
- The adequacy of provisions made for monitoring and auditing the conduct of the research, including the constitution of a Data Safety Monitoring Board.

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- Investigator's capability, availability of infrastructure and scientific environment to conduct the study within the time frame and carry it forward.
- The adequacy of the site, including the support staff, available facilities, and emergency procedures
- Study Reporting and publication of the research. Regulatory permission for conduct of the study, HMSC clearance for international collaborative studies
- MOU/CTA and MTA for national and international collaborative research to safeguard the interests of participants and ensure compliance while addressing issues related to confidentiality, sharing of data, joint publications, benefit sharing, etc.

4.2.2 Risk Benefit Assessment

- The benefits accruing from the planned research either to the participants or to the community or society in general must justify the risks inherent in the research
- Risks may be physical, psychological, economic, social or legal and harm may occur either at an individual level or at the family, community or societal level. It is necessary to first look at the intervention under investigation and assess its potential harm and benefits and then consider the aggregate of harm and benefits of the study as a whole
- The EC should review plans for risk management, including withdrawal criteria with rescue medication or procedures.
- The EC should give advice regarding minimization of risk /discomfort wherever applicable.

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- Adequate provisions must be made for monitoring and auditing the conduct of the research, including the constitution of a Data and Safety Monitoring Board (DSMB) if applicable (for example in clinical trials)

4.2.3 Care and Protection of Research Participants

- Qualifications and experience of the investigators for the conduct of the proposed study.
- Any plans to withdraw or withhold standard therapies for the purpose of the research and the justification for such action.
- Plans to withdraw participants from the study by the investigator.
- Medical care to be provided to research participants during and after the course of the research
- Adequacy of medical supervision and psycho-social support for the research participants.
- Steps to be taken if research participants voluntarily withdraw during the course of the research.
- Criteria for extended access to, the emergency use of, and/or the compassionate use of study products.
- Arrangements, if appropriate, for informing the research participant's general practitioner or family doctor, including procedures for seeking the participant's consent to do so.

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- Description of any plans to make the study product available to the research participants following the research and description of any financial costs to research participants.
- Rewards and compensations for research participants (including money, services, and/or gifts).
- Provision for payment on cash or kind or both for incidental expenses and other inconveniences, free services and the processes involved without amounting to undue inducement.
- Provisions for compensation/treatment in case of injury/disability/death lost wages of a research participant attributable to participation in the research (as per institutional policy/ICMR guidelines existing national legislation (CDSCO, DCGI).
- Insurance and indemnity arrangements.

4.2.4Protection of Research Participant Confidentiality

- A description of the persons who will have access to personal data of the research participants, including medical records and biological samples
- Measures taken to ensure the confidentiality and security of personal information concerning research participants.

4.2.5 Informed Consent/ Consent Process

4.2.5.1 Essential Elements:

1. Statement that the study involves research and explanation of the purpose of the research in

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sufficient details in layman's language.

2. Statement that the study is approved by IEC after evaluation of scientific and ethical validity.
3. Expected duration of the Participant's participation and total number of participants that will be accrued on the study .
4. Description of the procedures to be followed, including all invasive procedures:
5. Description of any reasonably foreseeable risks or discomforts to the Participant.
6. Description of any benefits to the Participant or others reasonably expected from research. If no benefit is expected from the study, whether the Participant is being made aware of this through the consent document
7. Disclosure of specific appropriate alternative procedures or therapies available to the Participant.
8. Statement describing the extent to which confidentiality of records identifying the Participant will be maintained and who will have access to Participants medical records.
9. Trial treatment schedule(s) and the probability for random assignment to each treatment (for randomized trials)
10. Compensation and/or treatment(s) available to the Participant in the event of trial
11. An explanation about whom to contact for trial related queries, rights of Participants and in the event of any study related injury
12. The anticipated prorated payment, if any, to the Participant for participating in the trial. In particular, the IEC must review payments to determine that:
    - The amount of payment and the proposed method and timing of disbursement neither is coercive nor presents undue influence.
    - In case any amount paid as a bonus for completion is reasonable and not so large as

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to unduly induce participants to stay in the study when they would otherwise have withdrawn

- A description of acceptable and unacceptable payment arrangements for the sponsor, organization, researcher, and those referring research participants, if applicable:

✓ Address the acceptability of payments in exchange for referrals of prospective participants (finder's fees" or "referral fees").

✓ Address payments designed to accelerate recruitment that are tied to the rate or timing of enrollment (bonus payments")

13. Participant's responsibilities on participation in the trial.
14. Statement that participation is voluntary, that the participant can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the Participant is otherwise entitled.
15. Any other pertinent information.

• Additional elements, which be required:

a. Statement of foreseeable circumstances under which the Participant's participation may be terminated by the Investigator without the Participant's consent
b. Additional costs to the Participant that may result from participation in the study.
c. The consequences of a Participant's decision to withdraw from the research and procedures for orderly termination of participation by Participant.
d. Statement that the Participant or Participant's representative will be notified in a timely manner if significant new findings develop during the course of the research which may affect the Participant's willingness to continue in the study.

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

- A full description of the process for obtaining informed consent, including the identification of those responsible for obtaining consent.
- Adequacy, completeness and comprehension of written and oral information to be given to the research participants, and, when appropriate, their Legally Acceptable Representative(s) (LAR) and/or Impartial witness (if applicable)
- Clear justification for the intention to include research participants who cannot consent, and a full account of arrangements made to obtain their consent/authorization/consent of LAR and/or Impartial witness (if applicable).
- Assurances that research participants will receive information that becomes available during the course of the research relevant to their participation including their rights, safety, and well-being.
- Provisions made for receiving and responding to queries and complaints from research participants or their representatives during the course of a research project.
- Provision for audio-visual recording of consent process, if applicable relevant regulations. The protocol meets the criteria for approval of application for consent waiver or verbal/oral consent request.

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4.2.5.2 Types of consent processes and their implications

Blanket or broad consent: This is an open consent given only once to collect the sample, store it and use it for any research at any time in future without the need to revert to the individual for a re-consent. A consent model that allows for current and future access and of samples or data for research without necessarily specifying what the focus of such studies might be

Tiered consent: This model of consent offers several options from which participants can use. It includes an option for future use specifying general permission or use only related to some aspects of research, sharing of biospecimens data benefit sharing, etc. It also takes into consideration return of results for which options are also provided for consent

Specific consent: Consent is obtained for a specific research purpose Participants are recontacted for every new use of their stored samples/data if the scope of research is outside that for which they had originally given consent.

Delayed consent: It may be administered in the post-medical procedure period when biospecimen or data may be collected for appropriate research from critically ill patients who may not have given prior consent for research. Consent may be taken from the participant or LAR when it is practical.

Dynamic consent: This consent is different from one of static, paper-based consent and involves an ongoing engagement and interactions over time with participants to re-contact in response to changing circumstances using technology based platforms. It incorporates a flexible, configurable, technology-based design accommodating both participant and researcher needs. Modern longitudinal bio banks equipped with advanced technology strive for this type of consent.

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Withdrawal of consent or destruction of sample: The donor has the right to ask for destruction of her/his collected sample(s) and discontinuation /withdrawal from participation in the research. In longitudinal studies, a participant may withdraw from one component of the study, like continued follow-up/data collection when withdrawal may be referred to as partial.

Waiver of consent. While using anonymized (de-identified) samples/data, researchers should seek the approval of the EC of the institution or the repositor for waiver of consent from the donors

Re consent: Secondary or extended uses of stored samples/dataset: In such an instance, one of the preliminary considerations for ECS must be to identify the circumstances under which the research requires re-use of collected identifiable biological material to generate the data or utilize the pre-existing identifiable dataset. This must also include review of the informed consent obtained originally to see if reconsent is warranted. There may be situations where consent would be impossible or impracticable to obtain for such research, in which case the research may be done only after independent evaluation by an EC (Declaration of Helsinki, Donors from October 2013).

Pediatric donors: In longitudinal studies once the child donor attains the legal age of consent re-consent should be sought for the storage and use of her/his issue or sample. In pediatric biobanks or biobanks with pediatric samples it is important to address the issue of children reaching legal age of consent. Sometimes re-contact may lead to withdrawal, resulting in limited data analysis. This may lead to bias Orit could evoke emotional distress about past research. On the other hand, re-consent may give the participant the power to agree. A biobank should decide the policy it would like to adopt for re-contact

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4.2.6 Community Considerations

• The EC should ensure that due respect is given to the community, their interests are protected and the research addresses the community's needs.

• The proposed research should not lead to any stigma or discrimination. Hamm, if any should be minimized.

• Impact and relevance of the research to the local community and the concerned communities from which the research participants are drawn.

• Steps taken to consult with the concerned communities during the course of designing the research

- Influence of the community on the consent of individuals.
- Proposed community consultation during the course of the research.
- Extent to which the research contributes to capacity building, such as the enhancement of local healthcare, research, and the ability to respond to public health needs
- A description of the availability and affordability of any successful study product to the concerned communities following the research.
- The manner in which the results of the research will be made available to the research participants and the concerned communities.
- It is important to examine how the benefits of the research will be disseminated to the community.

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4.2.7 Recruitment of Research Participants

- The characteristics of the population from which the research participants will be drawn (including gender, age, literacy, culture, economic status, and ethnicity)
- The means by which initial contact and recruitment is to be conducted.
- The means by which full information is to be conveyed to potential research participants or their representatives.
- Inclusion criteria for research participants.
- Exclusion criteria for research participants.
- Students or staff recruitment in research.
- Healthy volunteers,
- Vulnerable groups
- Information contained in the advertisement and mode of its communication.
- Final copy of printed advertisements
- Final audio or video taped advertisements

4.2.8 Advertisements

The IEC reviews advertising to ensure that advertisements do not

- State or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.
- Include exculpatory language.
- Emphasize the payment or the amount to be paid, by such means as larger or bold type.

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- Promise "free treatment" when the intent is only to say participants will not be charged for taking part in the investigation.

Advertisements are limited to the information prospective participants need to determine their eligibility and interest, such as:

- The name and address of the researcher or research facility.
- The purpose of the research or the condition under study. summary form, the criteria that will be used to determine eligibility In
- A brief list of benefits to participants, if any.
- The time or other commitment required of the participants
- The location of the research and the person or office to contact for further information

4.2.9 Disclosure of Conflict of Interest

IEC evaluates each study in the light of any disclosed conflict of interest and ensure appropriate action is taken to mitigate this and makes appropriate suggestions for management, if conflict of interest is detected at the institutional or researchers level

4.2.10 Social values:

The basic requirement for health research to be ethically permissible is that it must have anticipated social value. The outcome of the research should be relevant to the health problems of society. All stakeholders, including sponsors, researchers and EC must ensure that the planned research has social value

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4.3 Responsibility

The IEC Secretariat is responsible for receiving, verifying, and managing the hard copies of the received submission. In addition, the Secretariat should create a study specific file, distribute the packages and study assessment forms to the IEC members (lead discussants) for review, and communicate the review results to the investigates IEC members are responsible for receiving, verifying, and reviewing the research protocols.

4.4 Detailed instructions

Only investigator-initiated trials/studies seeking intramural grants if required may be sent prior to the meeting for external review otherwise these projects will be reviewed and scored in the respective full board IEC meeting Project is scored by the EC member (IEC committee scoring Form AX2-VS/SOPO4/VS). The scores will be considered for granting intramural funds. The comments from external consultants if received on time will be considered during the IEC discussion. However, Pharma-sponsored studies extramurally funded investigator initiated studies and in-house studies requiring no intramural funds will be tabled in the IEC meeting without any prior external review

Distribution of the project documents

The distribution of the project documents for IEC review will be as follows: E-copies hard copies of study documents be reviewed in the full board meeting would be circulated along with Agenda to the Committee members preferably 7 days in advance of the scheduled meeting. The reviewers can also access new research proposals and other study related documents such as CRAS, SAES etc. through the online IEC portal.

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Assigning Lead discussants

• The Member Secretary, IEC will assign lead discussions to each research study for scientific, ethical and statistical review. The lead discussants will be members of the IEC and will have to present a detailed relevant review of the assigned study. Generally, 2 lead discussants will be assigned to new research proposals. However, for studies involving multiple specialties, complexity, high risk or vulnerable populations more than two lead discussants may be assigned. The scientific member reviews the scientific, ethical, and informed consent issues and the Social scientist NGO representatives/Ethicist Lay Person has the responsibility of reviewing the ethical the aspects of the study and finalizing the informed consent documents.

Legal expert will review legal documents which includes CTA/ MTA/ MOU etc. and advice on any legal matters such as data sharing, IPR and compensation issues.

- The lead discussants will present the research study at a regular full board meeting of the IEC.
- The Investigator may be called for any questions or clarification required by the Committee.
- The lead discussant is informed no less than 7 days prior to the meeting through the Agenda. In case the lead discussant is not in a position to review the assigned Project/s due to some reason, he/she should inform the Member Secretary, IEC at the earliest, so that the research study can be assigned to another member.

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- In the event of his/her absence, a lead discussant can send written comments on the research protocols to the Member Secretary, which will be tabled and discussed during the meeting. However, a final decision on the research protocol will be arrived at, by a broad consensus at the end of discussion among attending members and not solely based on written comments.
- It is the responsibility of the assigned lead discussant's to review the research protocols assigned to them thoroughly and communicate their observations comments and decisions to the IEC during the meeting
- All members are expected to read all protocols and submissions before a meeting.and to participate in meeting discussions.
- The Member Secretary can invite an independent consultant (if necessary) for comments during the full board meeting.

Responsibilities of IEC members

- Check the meeting date to see if he/she is available to attend the meeting.
- Check the contents of the e-copy/ hard copy of study documents received via email or mail.
- Identify the project/study related documents assigned for review.
- Notify the IEC Secretariat 3 days prior to the convened IEC meeting regarding missing documents, if any.
- The lead discussants should submit the online /offline Study Assessment Form and comments to the IEC Secretariat on or before the scheduled meeting. In case an IEC member is not in a position to attend the scheduled meeting the responsibility of

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submitting the study assessment form and comments would be that of the respective IEC member.

- The non-medical member of the IEC shall specifically address ethical aspects of the study in the study assessment form such as study population involved, consenting process, waiver of consent etc.

4.5 Review the Protocol:

Review all elements as per section 4a.3, 4a.4, 4a.5. The protocol will be reviewed by lead discussants as per guidelines to review a study protocol described in AXI V5/SOP04/V5.

4.6 Use of study assessment forms and scoring sheet

It is the responsibility of the IEC members (lead discussants) to use assessment form as a checklist while reviewing each research protocol. The duly filled, signed and dated assessment forms may be returned along with the research protocols to the Secretariat one day prior to the meeting. The assessment form is designed to standardize the review process. The study assessment form (AXI-VS/SOP04/V5) helps to ensure that all elements of research study are reviewed and are accordingly documented during the discussion / meeting. The lead discussant(s) of the research proposal shall complete the study assessment form for initial review and expedited review. The lead discussant needs to submit comments for the resubmitted projects via AXI-VI/SOPO4/VI. All scientific IEC members shall score the studies seeking intramural funds as per scoring sheet (AX2-V5/SOP04a/V5)

Note: The completed assessment form is the official record of the decision reached by the IEC for the specific protocol. The study assessment form is applicable only for first initial

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full board or expedited review. The lead discussant needs to submit comments for the resubmitted projects via AXI-VI/SOP04 VI.

4.6.1 Collection of the assessment reports

The IEC Secretariat will collect the Assessment Forms AXI-VS/SOPO4a/VS and the comments from each lead discussant and file them in the original set of the study file

4.7 Guidance for addressing ethical issues related to research.

4.7.1 Role of the EC: ECS play a key role in oversight and use of the bio- and data repositories for research, scientific and public health programs. Research proposals, which require bio repository services including material transfer and available data sets, should be reviewed by the EC, either an institutional one or that of the bio repository.

4.7.2 As per National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017 Bio banks can use the stored material data for doing research to research themselves or they can outsource or supply such material data to other researchers institutions on a nonprofit basis.

4.7.3 Ownership of the biological samples and data: The participant owns the biological sample and data collected from her/him and therefore, could withdraw both the biological material donated to the bio bank and the related data unless the latter is required for outcome measurement and is so mentioned in the initial informed consent document. Complete anonymization would practically make the original donor lose the right of ownership. Bio banks/institutes are the custodians or trustees of the samples and

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data through their ECs as their present and future use would be done under supervision of the respective EC Researchers have no claim for either ownership or custodianship.

4.7.4 Transfer of bio specimens: An MTA should be executed if the bio specimens are likely to be shipped from the host institution to collaborating institutions within the country or abroad. The EC should oversee the process of the in-country and international material transfer. Mandatory regulatory clearances with appropriate MoU are required if bio specimens are to be sent overseas. Directorate General of Foreign Trade (DGFT) has issued a notification related transfer of human biological material for commercial purposes.

4.7.5 Secondary or extended uses of stored samples/re-consent: The EC will examine circumstances under which the biological material or the data were originally collected, and informed consent obtained. The decision about anonymization informed consent waiver or reconsent will be made on a case-by-case basis.

The following must be considered when stored samples are to be used:

1. Whether the proposed use is aligned with the original consent given for the enter research and scrutinizes the validity of the objectives of the new research
2. Whether provisions for ensuring anonymity of the samples for secondary use are stated:
3. Whether the permission of LAR is obtained for post-mortem uses of samples
4. Whether the consent form mentions retention and various possible future uses of times in the form of a tiered consent.

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5. Whether provisions have been made for allowance of waiver of consent if the donor is not traceable or the sample/data is anonymized or it is impractical to conduct the research.

4.7.6 Return of research results to individual/groups:

Results of the study should be communicated back to the providers of samples data. Wherever applicable, research findings in aggregate form (which does not reveal individual results) must be discussed with the community, especially when research involves vulnerable populations.

In the absence of an appropriate mechanism to deal with informational harm that can occur if participants are provided feedback when they are not prepared to face it or if it is on actionable or when such information is unrelated a lot of distress could be caused to participants concerned. At the time of sample collection, it may be a good approach to offer donors the choice of receiving the results of the research whether they are beneficial or not. Participants may also choose not to be contacted about their results. Another alternative is to give participants the option of receiving an aggregate report of all the results of the may which could become a shared benefit for the community. The aforementioned options may be incorporated in a tiered consent.

4.7.7 Benefit sharing: Biological materials and/or data have potential commercial value but the participants' contribution and their share in this benefit is very often not known to them. The informed consent document should emphasize this aspect with necessary clauses forclarity about benefit sharing.

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Prepared by: Signature with date ----------

Reviewed by: Signature with date ----------

Approved by: Signature with date ----------

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1.Purpose

To provide instructions for preparation and maintenance of active study files and other related documents approved by the Institutional Ethics Committee (IEC), KMCT Medical College, Kozhikode .IEC administrative documents, archival of closed files and retrieval of documents

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.

3. Responsibility

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

4. Detailed instructions

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

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Annexure 1 AX 01/SOP Date of Receipt of complaint form

Date of receipt of complaint	
Request/Complaint received through	Telephone no ----------
	Letter /date
	E-mail/Date
	Walk-in/Date/Time
	Other, specify
Participant's Name:	
Contact details Address & Phone: Title of the Project	
Starting date of participation	
Information requested/complaint /query	
Action taken	
Reviewed by	
Final decision	
Date of IEC meeting (if applicable)	

Name & Signature of Member Secretary

Date

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- 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 Chairperson based on the recommendation of any one of the above and it will be informed tithe 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 AX 01/SOP 17/V1 and the form is signed and dated. The IEC members will be informed about the action taken and the outcomes in the forthcoming IEC meeting (in case of requests complaints not discussed in full board meeting) and minuted. The Secretariat will place all documents in the relevant study file,

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Reviewed by: Signature with date----------

Approved by: Signature with date----------

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The Member Secretary may receive a request, complaint or query directly from the participant. He/she will record it in the request record form AX 01/SOP 17/V1 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 Chairperson 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 Chairperson will provide the information himself/ herself or will designate one or more IEC Member(s) to provide such information. In case of a complaint received from a research participant:

- The Member Secretary, in consultation with the Chairperson will initiate a process to address any injustice that may have occurred. Depending on the seriousness of the matter, the Chairperson 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 Chairperson/ 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.

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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 complaints that is/are related to their participation in research approved by the Institutional Ethics Committee (IEC), KMCT Medical College Kozhikode

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 by the IEC.

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.

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

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All reporting process completed	
Compensation paid for study related injury.	
Are storage of data investigating products locked ?	
Duration of visit	
Name of IEC Members present	
Name of study team members	
Completed by	

Date of IEC meeting where the monitoring report is discussed

Signature of chairperson

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Recruitment Status	
Total Screened	
Total Randomized	
Total Screen failure	
Total withdraw Reason	
Total Discontinue Reason	
Total completed	
Total Active	
Is the study using all IEC approved documents (Protocol, ICF etc)	
Study team Members are adequate and trained	
Site Infrastructure adequate	
Any SAE reported If Yes, how many	
Any drug related SAEs reported: If yes, how many related unrelated Probably Related	

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Annexure 1 AX 01/SOP 17/V1 -Site Monitoring Visit Report

Annexure 2 AX 02/SOP 17/V1-Monitoring of audio visual recording of AV consent process.

Annexure 1 AX 01/SOP 17/V1 -Site Monitoring Visit Report

Date of Visit	
Study Title	
Principle Investigator	
Department	
Type of study	☐ Investigator Initiated ☐ Pharma ☐ Thesis ☐ Others
Date of IEC approval:	
Date of Initiation of the study	
Duration of study:	
Reason for Monitoring	☐ Routine ☐ For cause (Reason) ☐ Protocol Deviation/Protocol Violation ☐ SAE reporting ☐ Recruitment Rate ☐ Others
Last monitoring done, if any.	☐ Yes ☐ Date of Last Monitoring---------- ☐ No
Project Status	

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If the Monitor has findings that impact on safety of the participant the Monitor will inform the Member Secretary on the same day. The Member Secretary will discuss with the Chairperson and any one of the actions described above will be taken.

The Secretariat will convey the decision to the Principal Investigator in writing within 14 working days of the meeting. The Secretariat will place the cops of the report in the protocol file.

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Reviewed by: Signature with date ----------

Approved by: Signature with date ----------

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the safety data i.e. Adverse Events (AES) and SAEs for the volume or severity of adverse events.

- Review the project files of the study to ensure that documentation is filed appropriately.
- Review the source documents for their completeness, Collect views of the study participants, if possible,
- The Monitor will fill the Site Monitoring Visit Report Form- AX 01/SOP09/V1

4.4. After the visit

The Monitor will submit the completed Site Monitoring Visit Report Form AX 01/SOP 09/v1 to the IEC secretariat within 7 working days of conducting a site monitoring visit or at the time of full board meeting.(whichever is earlier). The report should describe the findings of the monitoring visit. The member secretary will present the monitoring report at the next full board IEC meeting and the concerned monitor will provide additional details / clarifications to members as required.

The IEC will discuss the findings of the monitoring process and take appropriate specific action by voting or combination of actions, some of which are listed below:

- Continuation of the project with or without changes
- Restrictions on enrollment,
- Recommendations for additional training,
- Recruiting additional members in the study team.
- Revising providing qualification experience criteria for member of the study team, termination of the study,
- Suspension of the study, etc.

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4.3. During the visit

The Monitor will follow the check list and :

- Check the log of delegation of responsibilities of study team,
- Check if the site is using latest IEC approved current versions of the protocol, informed consent documents, case record forms, diaries, advertisements, etc
- observe the informed consent process, if possible,
- Review randomly selected participants files to ensure that participants are signing the correct informed consent.
- Check investigational product 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)
- Check for storage times, conditions and expiry dates to be acceptable and not supplies available, wherever applicable,
- Verify that the investigator follows the approved protocol and all approved amendment (s) if any.
- Ensure that the investigator and the investigator's trial staff are adequately informed about the trial,
- Verify that the investigator and the investigator's trial staff are performing specified study functions, in accordance with the approved protocol and any other written agreement between the sponsor and the investigator institution, and have not delegated these functions to unauthorized individuals,
- Verify that the investigator is enrolling only eligible subjects,
- Determine whether all SAEs are appropriately reported within the time as per the applicable regulatory requirement(s) .Case record forms would be checked to review

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- High number of protocol violations
- Large number of studies carried out at the study site or by the investigator Large number of Serious Adverse Events(SAE) reports
- High recruitment rate,
- Large number of Protocol deviations
- Complaints received from participants or any other person
- Frequent failure to submit the required documents
- Any other cause as decided by IEC.

4.2. Before the visit

Irrespective of the cause for conducting monitoring the following procedure will be followed

- The Chairperson Member Secretary will identify and select one or more IEC members (henceforth referred to as monitors) to conduct monitoring of a site.
- The selected members will be informed via email/ letter in this regard.
- The agenda of monitoring will be decided by the identified monitors in consultation with the Member Secretary and Chairperson
- The Secretariat will decide the date of the monitoring in consultation with the monitors and the PL
- The final date will be communicated to the PI (with a request to be available and monitors
- The monitor will receive from secretariat and review the relevant project documents and make appropriate notes.
- The Secretariat provided Monitors with relevant reference material/documents related to the project

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4.3. During the visit

The Monitor will follow the check list and :

- Check the log of delegation of responsibilities of study team,
- Check if the site is using latest IEC approved current versions of the protocol, informed consent documents, case record forms, diaries, advertisements, etc
- observe the informed consent process, if possible,
- Review randomly selected participants files to ensure that participants are signing the correct informed consent.
- Check investigational product 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)
- Check for storage times, conditions and expiry dates to be acceptable and not supplies available, wherever applicable,
- Verify that the investigator follows the approved protocol and all approved amendment (s) if any.
- Ensure that the investigator and the investigator's trial staff are adequately informed about the trial,
- Verify that the investigator and the investigator's trial staff are performing specified study functions, in accordance with the approved protocol and any other written agreement between the sponsor and the investigator institution, and have not delegated these functions to unauthorized individuals,
- Verify that the investigator is enrolling only eligible subjects,
- Determine whether all SAEs are appropriately reported within the time as per the applicable regulatory requirement(s) .Case record forms would be checked to review

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1. Purpose:

The purpose of this standard operating procedure (SOP) is to describe the procedures for site monitoring of Institutional Ethics Committees (IEC) approved protocol conducted at KMCT Medical College Kozhikode.

2. Scope:

This SOP applies to all IEC approved studies for which a mine for monitoring may be undertaken by the IEC.

3. Responsibility

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

4. Detailed instructions

4.1. Selection of study sites (Departments)

Routine monitoring for a site may be decided at the time of approval of the project by the Fall Board.

This is recorded in the IEC minutes

"For-cause monitoring" will be performed at sites for reasons identified by any member of the IEC, after approval by the Chairperson

The reasons for identifying a particular site for "for-cause monitoring could include any

one or more of the following:

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participants changes, for e.g. unconscious patient gaining consciousness or a schizophrenic patient regains insight, the participant will be re-consented.

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Reviewed by Signature with date ----------

Approved by: Signature with date ----------

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5. Detailed instructions

5.1. Reviewing protocols with vulnerable participants

The protocol should be reviewed. Additionally, the protocol should be reviewed to assess if the following points are addressed:

- 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 IEC members dealing with such protocols should be well versed with the potential harm risk of such population participating in the study, IEC Members will review the protocol and the informed consent document or assent Form The IEC members 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.

5.2 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

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programs All IEC members are responsible for conducting review of research planned for vulnerable populations, including an assessment of potential for coercion

4. Definition and Mandate

4.1 Definition

Vulnerable Subjects: Individuals whose willingness to volunteer in a clinical trial 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. 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 subjects include patients with incurable diseases persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

4.2 Mandate

Gazette notification dated 31st July 2015 (GS.R. 611(E) has mandated audio-visual recording of informed consent process in case of vulnerable participants in clinical trials of new chemical entity/ new molecular entity

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1. Purpose:

Standard Operating Procedure (SOP) describes the requirements and process of review of research that involves vulnerable participants at KMCT Medical College Kozhikode

2. Scope

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

Participation of Vulnerable subjects:

- ☐ Pregnant women
- ☐ Seriously/terminally ill
- ☐ Neonates
- ☐ Elderly
- ☐ Institutional employees /students
- ☐ illiterate
- ☐ children
- ☐ mentally challenged
- ☐ handicapped economically /socially backward

If other, please specify----------

3. Responsibility

It is the responsibility of the Member Secretary with Secretariat to maintain up-to-date tools, like checklists, for reviewing research concerning vulnerable groups based on new and evolving applicable regulations and guidelines, IEC Chairperson / Member Secretary are responsible for ensuring that IEC members are well-versed in new and evolving regulations and guidelines pertaining to vulnerable populations, through regular training

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5.1 Reports of SAE Occurring at other Sites

The investigator will need to submit the SAES occurring at other sites (CIOMS and SUSARS) with the appropriate covering letter (hard copy) mentioning the total number of reports and its details. The SAEs occurring at other sites will be reviewed by the Secretary of the IEC and informed to other members and discussed in the forthcoming scheduled meeting. The agenda and minutes of the meeting will include the information on SAEs at other sites.

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- Any clinical trial related procedures involved in the study

The Investigator and Sponsor should provide the EC a follow up report within 14 calendar days of the Initial report with recommendations for the SAE being Clinical Trial Related or Clinical Trial Unrelated as per above listed criteria. Based on the initial and follow up report the EC to assess the SAE to be Clinical Trial Related or Clinical Trial Unrelated. The EC to discuss and decide if the subjects/nominee are entitled to Compensate. The Member Secretary should sign this recommendation and forward to the DCGI office within 30 calendar days since the SAE occurred. The document should be sent through acknowledgment revert courier. The EC should maintain a copy of the Air Way Bill of the courier released and also of the Acknowledgment of Receipt at the regulator's office along with the SAE report in the EC files. A copy of this recommendation should be provided to the Investigator to place on study file and to share a copy with the sponsor. The EC to use EC Recommendation for Compensation Letter to report document their recommendation to the regulators (and copy to Investigator / Sponsor). The EC should instruct the investigator is provide an update on the status of compensation paid by sponsor within 150 days of the date of the SAE.

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4.2. 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 casual relationship with this treatment. An AE can therefore be any unfavorable 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.

5. Detailed Instructions:

All Investigators are requested to submit all SAEs to the IEC within 24 hours of occurrence enclosing the following documents. The IEC will verify and accept only reports that are complete, signed and dated by the PI/designee.

- Appendix XI as per Schedule Y
- Cover letter including whether the report is final or follow up
- Copy of SAE reports send to the Sponsor.

In case of Institutional holidays and SAEs occurring post 12:00 hours the day previous to such a holiday, the same may be emailed to the Member Secretary, IEC. Hard copy of a submission package should be handed over to the Secretariat before 10:00 hours then next working day.

Email address of Chairperson:

Email address of Member Secretary:

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1.Purpose:

The purpose of this Standard Operating Procedure (SOP) is to describe procedures for the review of initial and follow-up reports of serious adverse events (SAE) reported to the IEC for any study under the oversight of the Institutional Ethics Committee (IEC) KMCT Medical College Kozhikode:

2. Scope

This SOP applies to the review of SAE reports (Adverse events SAE on site as well as SAES of the multicenter studies occurring at other sites off site) submitted to the TEC

3. Responsibility

It is the responsibility of the IEC to review all SAEs reported to the IEC in a timely manner.

4. Definitions

4.1. Serious Adverse Event:

Any untoward medical occurrence that at any dose results in death is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results persistent or significant disability/incapacity, or is a congenital anomaly birth defect An AE or ADR 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 [Indian Good-Clinical-Practice in Guideline guidelines,

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5.5 Records and follow up to be kept by IEC secretariat

The Secretariat will keep a copy of the notification letter in the respective project file.

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Approved by: Signature with date----------

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- 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 PL.
- 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 Pl 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 Pl/ Co-Pl under abeyance. Review and/ or inspect other studies undertaken by PI/Co-Pl.

6. This final decision will be recorded by the Member Secretary.

5.4 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 Pl 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).

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2. Member Secretary will decide on the impact of the protocol deviation / violation and act accordingly. Depending upon the seriousness, the IEC shall do the following (not limited to these actions):

- Ask PI for written clarification as soon as the deviation is received
- If the impact is serious, this report will be shared with the Chairperson and two or more IEC members designated by the Chairperson.
- If the impact of the protocol deviation is serious enough, the Member Secretary will instruct the Secretariat to call for and schedule a full-board meeting specifically to discuss the issue within 7 working days of the initial scrutiny
- The Secretariat will put up the information and communication at the next full board meeting for discussion.

3. The Member Secretary in consultation with IEC members will review the information available and deliberate on it.

4. The Chairperson will take a final decision depending on the seriousness of the violation. The decision will be taken to ensure that the safety and rights of the research participants are Safeguarded. The decision will be taken by consensus within the members.

5. 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.

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annual/periodic reports/ SAE reports any other communication received from the Investigator/ trial site/ sponsor/ study monitor/ contract research organization.

V. The IEC Secretariat and/ or IEC members may become aware of a protocol deviation/ violation while reviewing study-related documents including reports filed in by the Principal Investigator (PI).

VI. Communication/ complaint/ information received from a research participant who has been enrolled or any individual who has been approached for enrolment.

VII. Any report/ communication brought to the notice of Member, Secretary/ Chairperson of IEC by an independent person.

III. Communication received from the Head of the Institution informing IEC about an alleged protocol violation/ protocol deviation.

5.2 Receipt of protocol deviation /violation report by the secretariat

I. The PI will report the protocol deviation/violation

II. The Secretariat will notify the Member Secretary of any protocol deviation/violation report received from the PI/ from any source within 2 working days of receipt of the notification

5.3 Actions to be taken

1. The action of the IEC will be based on:

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

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Minor Protocol Deviation- A minor protocol deviation is any change, divergence, or departure from the study design or procedures of a research protocol that has not been approved by the IRB and which DOES NOT have a major impact on the subject's rights, safety or well-being, or the completeness, accuracy and reliability of the study data.

If the protocol and related documents satisfy the above stated criteria, the Member Secretary in consultation with the Chairperson will review the brief summary of the project. The Member Secretary records the decision in the response letter. The Secretariat communicate the decision to the investigator. The Member Secretary / Chairperson may keep the application for review and decision regarding exemption at the next full board meeting

5. Detailed instructions

5.1 Detection of Protocol deviation/ violation

Protocol deviation/ violation may be detected in one the following ways (but not limited to those listed below)

I. Protocol deviation violation may be reported by Investigator/ study site/ sponsor/Monitor
II. The IEC members performing monitoring of the project at trial site may detect protocol deviation/violation if the project is not been conducted as per protocol/national/international regulations
III. The Secretariat may detect protocol deviation/ violation from failure to comply with statutory requirements failure to respond to requests from IEC within reasonable time limit/ failure to respond to communication made by IEC
IV. The IEC members may detect protocol deviation/ violation when scrutinizing

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1. Purpose:

The purpose of this Standard Operating Procedure (SOP) is to describe action(s) to be taken by the IEC when investigator(s)/ trial site(s) fail(s) to: follow the procedures written in the approved protocol, comply with national and/ or international guidelines.

2. Scope:

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

3. Responsibility

The IEC Secretariat is responsible for receiving deviation/ violation reports submitted by the Principal Investigator (PI) /others and placing it on the agenda of the meeting. The IEC members should review and take action on such reports,

4. Definitions

Protocol Deviation and Protocol Violation:

Protocol Deviation- A protocol deviation is any change, divergence, or departure from the study design or procedures of a research protocol that is under the investigator's control and that has not been approved by the IEC. Upon discovery, the Principal Investigator is responsible for reporting protocol deviations to the IRB using the standard reporting form.

Protocol Violation- A protocol violation is a deviation from the IEC approved protocol that may affect the subject's rights, safety, or well being and/or the completeness, accuracy and reliability of the study data. If the deviation meets any of the following criteria, it is considered a protocol violation

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4.2 Decision

- If the IEC approves the amendments, the decision is communicated to the Pl
- .If the IEC does not approve the amendments, the secretary should immediately notify the investigator in writing of the decision and the reason for not approving the amendment.
- If the IEC recommends or suggests modifications to any of the documents, or the amendments, the secretariat sends a written communication to the investigator about the specific changes asking him or her to make the necessary changes and resubmit the document to IEC.
- Member Secretary will issue an approval letter to the Principal Investigator, if response from the PI found to be satisfactory

4.3 Storage of Documents:

File the amendments in the corresponding research protocol file, as per the documentation and archival.

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Approved by: Signature with date----------

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d) change in method of dosage formulation, such as, oral changed to intravenous

e) 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)

f) A significant decrease or increase in dosage amount

g) Change in risk/benefit ratio

4.1.2 Minor amendments and notifications:

Minor amendments (those that do not increase the risk or decrease the potential benefit to subjects) and minor changes in previously approved research during the period covered by the original approval: Where the research is permanently closed to the enrolment of new subjects; all subjects have completed all research-related interventions may be reviewed in the expedited review subcommittee meeting

Minor notifications may be noted by the Member Secretary, IEC and not tabled in IEC meeting. This may include but may not restrict to:

- Renewed insurance policy
- DCGI approvals
- Administrative notes
- Documents of administrative nature

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- The Secretariat will check for completeness of the submission and inform the Principal Investigator telephonically to submit the required documents at the earliest, if any of the documents are missing/ incomplete.
- The secretariat of the IEC should follow the procedures (Procedures for Management of protocol submission)
- The Member Secretary, IEC, classifies the amendments into minor or major and tables the major amendments on the agenda of the subsequent scheduled meeting.

4. Detailed Instructions:

4.1 Review amended protocols/documents/letters:

4.1.1 Review process for major protocol amendment:

The protocol amendment and other related documents will be reviewed by primary reviewers and will be discussed in the scheduled full board meeting. The reviewer will present a brief summary list of amendment and the comments on the amendment in the IEC Full Board meeting. The primary reviewers will review the amended documents and assess the change in risk benefit ratio and impact of the amendment (modifications in the ICD, reconsent of research participants, untoward effects likely to occur because of the amendment or any other)

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

a) Change in study design

b) Additional treatments or the deletion of treatments

e) Changes in inclusion/exclusion criteria.

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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.

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.

3. Responsibility:

Pls 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/ documents and letters.

Receipt of the Amendment Package

- The amendment /documents along with the appropriate soft copy forwarded by the Pl is received by the secretariat. The amendment /documents along with the covering letter should be accompanied by Amendment Reporting Form •
- The secretariat will confirm that the changes or modifications in the amended version are underlined or colour highlighted along with detailed summary of changes

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or the IEC does not approve continuation of the research, the research must stop. All of the following research procedures must stop:

- . Subject recruitment or enrollment .
- Collection of data/information
- All research-related interventions or interactions with currently enrolled subject
- Data analyses involving subject identifiable data

Exception: Research-related interventions or interactions with currently enrolled subjects can continue only if stopping the research would jeopardize the rights or welfare of current subjects. The IEC must make this determination and decide which subjects should continue with the intervention during the lapse. A request for such an exception must be made in the writing to the IEC by the PI.

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Approved by: Signature with date----------

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3) Continuing review of research previously approved by the convened IEC (e.g., not originally subject to expedited review) may be eligible for expedited review:

a. Where

i. the research is permanently closed to the enrollment of new subjects:

ii. all subjects have completed all research-related interventions, and

iii. the research remains active only for long-term follow-up of subjects, or

b. Where no subjects have been enrolled and no additional risks have been identified, or

c. Where the remaining research activities are limited to data analysis.

4.8 Store original documents

The IEC secretariat will file the continuing review application in master file of the research study

4.9 Communicate the IEC decision to the Principal Investigator

The Secretariat will notify the Principal Investigator of the decision of the IEC. If IEC has recommended modifications, the decision will be notified to the Principal Investigator and he/she will be requested to comply to IEC recommendations/ respond to IEC queries within 1 week of receipt of the IEC decision letter. In case the IEC decision is to put the study on-hold, then the subject recruitment or enrollment is suspended, however in case of safety concerns the project is completely suspended.

4.10 Lapses in IEC Approval

Investigators must plan ahead to meet IEC determined dates of submission of continuing review application. If an investigator fails to submit continuing review application to the IEC

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i. Approval to continue the study

ii. Revision with minor modifications-- Studies for which modifications have been suggested by the IEC may not proceed until the conditions set by the IEC have been met. Studies should be amended and submitted to the IEC within one month for rereview.

iii. Query - The IEC has raised queries against the continuing review application submitted.

iv. Deferred/On-hold-The IEC has postponed the decision on approval of continuing the study due to reasons such as awaiting expert opinion, awaiting site monitoring reports etc.

v. Not approved-The IEC feels that there are major concerns in the conduct of the study. The decision will also include any significant findings that have arisen during review process and this will be communicated to Principal Investigator. It is the responsibility of Principal Investigator to provide this information to the participants and once done submit the report to IEC.

- The decision regarding the approval / recommended modifications / disapproval will be noted and documented in the minutes of the meeting by the Member Secretary and maintained as part of the official record of the review process.
- Continuing review of the study may not be conducted through an expedited review procedure, unless

1) The study was eligible for, and initially reviewed by, an expedited review procedure;
2) The study has changed such that the only activities remaining are eligible for expedited review.

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(a) randomly selected projects;

(b) complex projects involving unusual levels or types of risk to subjects;

(c) projects conducted by investigators who previously have failed to comply with regulatory/IEC requirements: and

d) projects where concern about possible material changes occurring without IEC approval have been raised based upon information provided in continuing review reports or from other sources.)

- The Secretary will review the Continuing Review Application and will record his/her comments on the application and the same will be forwarded to the IEC Secretary
- .In case any clarifications or queries are raised by the Secretary, the same will be intimated to Pl and reply will be awaited. The IEC Secretary will decide whether to discuss the application along with the comments and Principal Investigator's response in the next full board meeting or expedited review meeting.

4.6 Prepare meeting agenda

- The Secretariat will follow procedures on the preparation of meeting agenda and place the forwarded Annual Progress Report/Continuing Review Application on the agenda for the full board/expedited review meeting of the IEC

4.7 Review Process

The IEC Chairperson Member Secretary/ members will use the Continuing Review Application Form (AXI-VS/SOP07/VS) to guide the review and deliberation process. The IEC members could arrive at any one of the following decisions at the IEC meeting:

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4.3 Manage continuing review application upon receipt

- The Secretariat will receive the Continuing Review Application submitted by the Principal Investigator for each approved study.
- Upon receipt of the Continuing Review Application, the Secretariat of the IEC will review the application for its completeness and forward it to the Member Secretary for further scrutiny, However, IEC may verify from sources other than the investigators to ensure that no material changes had occurred since previous IEC review by conducting monitoring of the study. The projects for which this may be done includes complex projects involving unusual levels or types of risk to subjects; projects conducted by investigators who previously have failed to comply with the regulatory/IEC requirements, projects in which concern about possible material changes occurring without IEC approval have been raised based upon continuing review reports or from other sources.

4.4 Verify the contents of the package

- The Secretariat will check for duly complete and signed application by Principal Investigator

4.5 Review of Continuing Review Application

- If IEC determines that a project needs verification from sources other than the investigators that no material changes have occurred since previous IEC review, including specific criteria used to make these determinations(eg, such criteria could include some or all of the following:

and assess final reports of all research activities. The protocol, informed consent documents and assent documents are examined to ensure that the information remains accurate. The IEC has delegated this responsibility of initial detailed review of Continuing Review Application.

4. Detailed Instructions:

4.1 Determine the date of continuing review

- The secretariat will identify the list of IEC approved projects that are due for continuing review on a regular basis
- The Secretariat should receive the continuing review application well in advance i.e. 10 months after IEC final approval and at least annually.

4.2 Notify the Principal Investigator or the study team

- Reminder emails are sent from the IEC secretariat to the Principal Investigators for submission of continuing review applications for projects, 3 months prior to the expiry of study approval/CRA approval validity date. Principal Investigators are required to submit one signed hard copy.
- First reminder will be sent 3 months in advance to the lapse in validity/annual review
- Failure to submit the CRA within the due date after the 1st reminder will result in issuance of warning letter and necessary action
- I EC may close the study if PI fails to submit CRA on time,

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1. Purposes

The purpose of continuing review is to monitor the progress of the study which was previously approved; not only for the changes but to ensure continued protection of the rights and welfare of research subjects

2. Scope:

This SOP applies to conducting continuing review of studies involving human subjects at intervals appropriate to the degree of risk but not less than once a year. Depending upon the degree of risk to the participants, the nature of the study, the vulnerability of the study participants and duration of the study, IEC may choose to review the study more frequently.

3. Responsibility:

It is the responsibility of the IEC secretariat to send reminders to Principal Investigators regarding the submission of Continuing Review Application/Annual Status Report. All IEC approved studies will be reviewed annually. IEC is responsible for determining the date of submission of continuing review application of the IEC approved projects including those that are reviewed more frequently in the year based on specific criteria. (e.g., an IEC may set a shorter approval period for high-risk protocols or protocols with a high risk: potential benefit ratio). This decision is taken during the IEC meeting wherein the project is finally approved.

IEC is primarily responsible for reviewing the study progress, the rate of accrual of participants, the occurrence of unexpected events or problems along with protocol deviation/violation and noncompliance, any new information pertaining to the research

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☐ Rejected

- Reason for rejection

Prepared by

Member secretary

Approved by

Chairperson

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- The time or other commitment required of the participants.
- The location of the research and the person or office to contact for further information.
- The HEC reviews advertising to ensure that advertisements DO NOT:
- State or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.
- Include exculpatory language.
- Emphasize the payment or the amount to be paid, by such means as larger or bold type
- Promise "free treatment" when the intent is only to say participants will not be charged for taking part in the investigation.

Based on the above factors

The study is

- Approved
    - Approved with Modification
    - Modifications:
- Resubmission with modification
    - Modifications
- Approved after receiving the clarification to the following queries
    - Query 1
    - Query 2
    - Query 3

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- Make sure that all information is understood and satisfied by the participants.
- Make sure the participants understand the study and the consent process.
- Obtain voluntary informed consent to participate.
- Make sure the participants can freely consent without coercion, pressure or other undue influences.
- Consent should be informally verified on a continuing basis.
- Continue to inform the participants throughout the study.
- Continue to re-affirm the consent to participate throughout the study
- research participants are not exposed to severe or permanent harm by the use of placebo.
- research participants under placebo will benefit from the overall treatment of the disease.
- risks of the use of placebo are minimized.
- risks are Adequately disclosed the consent form.

Guidelines to review advertisements

- Advertisements are limited to the information prospective participants need to determine their eligibility and interest, such as:
- The name and address of the researcher or research facility.
- The purpose of the research or the condition under study.
- In summary form, the criteria that will be used to determine eligibility for the study.
- A brief list of benefits to participants, if any.

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appropriate?

- Is appropriate follow-up designed into the study? For instance, gene transfer research may require following the participants for years or for their entire lifetime after they receive the gene transfer agent.

6. Is pre-clinical and/or early clinical studies sufficiently performed before this study?
   - The animal study and in vitro testing results?
   - Previous clinical results, if done?
   - Whether the proposed study is appropriately built on the pre-clinical and/or early clinical results.
   - The selected dose based on adequate prior results?
   - Monitoring tests designed detect expected possible risks and side effects?

Guidelines to review Informed Consent Document/Patient Information Sheet

The actual process of informed consent should: (Reviewed and confirmed Layperson)

- Give the participants significant information about the study.
- Make sure the participants have enough time to carefully read and consider all options.
- Answer all questions of the participants before making decision to participate.
- Explain risks or concerns to the participants.

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- It is completely necessary to conduct the study in a vulnerable population. If not, is there any other way to get the study answers?
- There will be secondary participants..

4. Do the inclusion and exclusion criteria
- Selectively include participants most likely to serve the objective of the study?
- Equitably include participants?
- Properly exclude participants who can predictably confound the results?
- Properly exclude participants who may predictably be at increased risk in the study due to coexisting conditions or circumstances? -

5. Does the study design have adequate built-in safeguards for risks?
- Appropriate screening of potential
- Use of a stepwise dose escalation with analysis of the results before proceeding?
- *Does the frequency of visits and biological samplings reasonably monitor* the expected effects?
- Are there defined stopping (discontinuation)/ withdrawal criteria for participants with worsening condition?
- Is there minimized use of medication withdrawal and placebo whenever possible?
- Will rescue medications and procedures be allowed when appropriate?
- Is there a defined safety committee to perform interim assessments, when

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- Provide safety data or more competitive choices.

2. Does the study design will be able to give answers to the objectives? Whether
   - The endpoints are appropriately selected.
   - The participating duration of a study participant is adequate to allow sufficient change in the endpoints.
   - The control arm is appropriately selected for best comparison.
   - The placebo is justified.
   - The number of study participants in non-treatment (or placebo) arm minimized.
   - Unbiased assignment (e.g. randomization, etc.) is in practice.
   - Inclusion and exclusion criteria are carefully selected to eliminate confounding factors much as possible.
   - The sample group size appropriate with the given statistical assumptions.
   - Predictable risks are minimized.
   - The tests and procedures that are more than minimal risk are cautiously used. Research participants deception is avoid.
   - Instruction and counseling for study participants are included (if needed) when deception is integral to the study design.
   - The study participants are adequately assessed and provided follow-up care, needed.

3. Who will be the participants in the study? Whether
   - The described population is appropriate for the study.
   - Predictable vulnerabilities are considered.

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The IEC functions in accordance with ICH GCP, Schedule Y, ICMR guidelines and other applicable regulatory requirements. COM

Sincerely yours

Member Secretary/ Chairperson,

IEC

(Signed and dated by the IEC Chairperson or Member Secretary)

Date of approval of the study: XX/XX/20XX R

Annexure 4: AX 04/SOP 11/V1 Guidelines for reviewing a study protocol

Checklist completed by the Member Secretary after review & discussion of the protocol

Reviewers should make use of the following points while reviewing research studies which relate to scientific validity, informed consent documents, placebo justification, suitability and feasibility of the study, advertisements review.

Protocol:

PI:

Date of Meeting:

Quorum present

1. How will the knowledge, result or outcome of the study contribute to human well being?

☐ Knowledge from the basic research may possibly benefit.

☐ A new choice of method, drug or device that benefits the research participants during the study and others in the future,

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It is hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee.

The IEC reviewed the above mentioned clinical study and approved the following documents submitted for this clinical study at the meeting.

1. Xxx
2. Xxx
3. xxx

The IEC hereby approves the proposal entitled, "xxxxxxxxxxxxx". It is understood that the study will be conducted under your direction, in a total of xxxx research participants, at xxxxxxxxxxxxx as per the submitted protocol.

This approval is valid for the entire duration of the study. It is the policy of IEC that, it be informed about any on site serious adverse event or the unexpected adverse event report within 24 hours or by email if there is holiday. The report of SAE or death after due analysis shall be forwarded by the Investigator to chairman of the IEC and the head of the institution where the trial is been conducted within 14 calendar days of SAE or death. The IEC expects that the investigator should promptly report to IEC any deviations from, or changes of, the protocol to eliminate immediate hazards to the research participants and about any new information that may affect adversely the safety of the research participants or the conduct of the trial. For studies which will continue for more than a year, a continuing review report needs to be submitted (within 1 month of the due date i.e. 11 months from the date of approval) on or before xxxxxxxxxxx. A copy of the final report should be submitted to the IEC for review.

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Annexure 3: AX 03/SOP 11/V1 Format of Interventional Research Study Approval letter

Date xx/xx/xxxx

To, Dr.

Dept. of

Ref: The study entitled, "xxxxxxxxxx".

Sub: Letter no. Dear Dr. XXXXX,

The meeting of the Human Ethics Committee (IEC) was held on xxxxx at xxxx, in the xxxxx with xxxxx as Chairperson, xxxx members attended the meeting held on xxxx

The list of members who attended the meeting is as follows.

Name of Members	Position on IEC	Affiliation	Qualification	Voting status

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It is the policy of IEC that, it be informed about any on site serious adverse event or any unexpected adverse event report within 24 hours to IEC or by email if there is holiday. The report of SAE or death after due analysis shall be forwarded by the Investigator to the chairman of IEC and the head of the institution where the trial is been conducted within 14 calendar days of SAE or death.

In case of injury or death of participant(s) occurring during the trial, the sponsor (whether pharmaceutical company or an institution) or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial shall make payments for medical management of the subject and also provide financial compensation for the clinical trial related injury or death.

No deviations from, or changes of the protocol and Informed Consent Document should be initiated without prior written approval by the IEC of an appropriate amendment. The IEC expects that the investigator should promptly report to the IEC any deviations from, or changes of the protocol to eliminate immediate hazards to the research participants and about any new information that may affect adversely the safety of the research participants or the conduct of the trial.

For studies which will continue for more than a year, a continuing review report needs to be submitted (within 1 month of the due date i.e. 11 months from the date of approval) on or before xxxxxx. A copy of the final report should be submitted to IEC for review.

Date of approval of the study: xxxxxxx

Sincerely yours

Member Secretary/ Chairperson

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Annexure 2: AX 02/SOP 11/VI Approval letter format in case of expedited Review

Date:

To, Dr.

Dept. of

Ref: Your project entitled,"xxxxxxxxxxxxxxxxxx"

Dear Dr. xxxxxxxxxxxxxxxxxxxxx

The following documents of the above mentioned project were reviewed and approved through an expected review process.

1. xxx
2. xxxxxx
3. xxxxxxxxxx

It is understood that the study will be conducted under your direction, in a total of XXX research participants, at as per the submitted protocol. The IEC approves the above mentioned study. This approval is valid for the entire duration of the study.

It is the policy of IEC that, it be informed about any on site serious adverse event or any unexpected adverse event report within 24 hours to IEC or by email if there is holiday. The report of SAE or death after due analysis shall be forwarded by the investigator to the Chairman of IEC.

It is understood that the study will be conducted under your direction, in a total of xxx research participants, at as per the submitted protocol. The IEC approves the above mentioned study. This approval is valid for the entire duration of the study.

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Annexure 1: AX 01/SOP 11/VI Form for nomination of IEC Members for Review

Date:

To,
MEMBER
IEC , Ref:

The project no. entitled "xxxxxxxx"

Sub: Review of xxxxxxx.

Dear Dr.xxxxxx,

The following document/s has/have been submitted to the IEC for review.

1.
2.
3.

The following members are nominated to review /carry out an expedited review if the above mentioned documents.

1.
2.
3.

For expedited review, you are requested review the study and provide your comments and send to the IEC office within 7 working days:

_____

Signature of the Member Secretary/Chairperson with date

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Storage of Documents

The Secretariat will keep a copy of the Approval letter (Query letter/Disapproval letter in the study file along with all the reviewed documents. The Administrative offIECr will store the file on an appropriate shelf in the designated cabinet.

Prepared by: Signature with date----------

Reviewed by: Signature with date----------

Approved by: Signature with date----------

Annexure 1: AX 01/SOP 11/VI Form for nomination of IEC Members for Review

Annexure 2: AX 02/SOP 11/VIApproval letter format in case of expedited Review

Annexure 3: AX 03/SOP 11/VI Format of Interventional Research Study Approval letter

Annexure 4: AX 04/SOP 11/VI Guidelines for reviewing a study protocol

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IEC members at the next full board meeting. The continuing review report may be discussed at full board if deemed necessary by Chairperson/Member Secretary.
The IEC Secretariat will notify the PI of the decision within 14 days of the meeting at which the report was discussed or of the date of review by the chairperson/Member Secretary/IEC Member/s.

Non-submission of continuing review report by Principal Investigator before due date.
If a PI fails to submit the continuing review report within one month of the due date (i.e.11 months from the date of approval, or earlier on the dates as specified), the Secretariat will send a telephonic and /or email reminder at least 15 days prior to due date of review.

If there is no response, the IEC secretariat will put up the matter for discussion at the forthcoming full board meeting for appropriate action which may consist of but not limited to sending:

a) A reminder letter again
b) A letter asking explanation for non – submission
c) A letter asking the PI to put recruitment of new participants on hold till report is submitted
d) Any other action as deemed appropriate by IEC.

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will verify the correctness of the wordings and spelling in all the letters and process all above tasks within 14 days after the meeting.

Continuing review

The date of the continuing review will always be at least once in the year.

The IEC may recommend more reviews during the approval process depending on the level of risk. This will be documented in the minutes. The Secretariat will inspect the minutes of meeting to set a timetable for continuing review. The Secretariat will identify and record the due dates of each project. The continuing review submission may undergo expedited review of full board review as deemed appropriate by the IEC Chairperson/Member Secretary.

The IEC Chairperson/Member Secretary /member/s could reach one of the following decisions after review:

1. Noted-The IEC approves the continuation of the project without any modifications.
2. Modifications recommended: The study of protocols that have been suggested modifications by the IEC may not proceed until the conditions set by the IEC decision in the have been met. The amendments and the required documents should be amended and submitted to the IEC within one month for re-view.

3. The project cannot be continued. The reasons for discontinuation of the project should be mentioned in the letter notifying the decision to the principal Investigator. The IEC Chairperson/Member Secretary will sign and date the IEC decision on continuing Review report after a decision has been reached. The decision on continuing review taken by the Chairperson/Member/Member/s will be informed to all

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- Study title
- A listing each document approved , the date set by the committee for frequency of continuing review, and a review of other obligations and expectations from the investigator throughout the courses of the study.
- The approval is provided for the entire duration of the study.
- List of IEC members present at the meeting when the study was approved.

The Chairperson / Member Secretary will sign the approval letter and the secretariat will send it to the Principal Investigator within 14 days.

If the committee disapproves a study, the Secretariat immediately notifies the investigator in writing about the decision and the reason/s for not approving the study within 7 working days. A notifying letter to the investigator should state the following:

"If you wish to appeal this decision, please contact the IEC and submit your appeal in writing within twelve (12) weeks of the receipt of the committee's decision, addressed to the IEC Chairperson with justification as to why the appeal should be granted. In absence of appeal, the study will be declared closed for the IEC off IEC records."

If the committee requires modifications to any of the documents, the Secretariat will send a written request for carrying out specific changes to the investigator asking him or her to make the necessary changes and resubmit the documents to the IEC. The Principal investigator will be asked to respond to the letter of comments/queries within 180 days of the receipt of the letter by the investigator. In the absence of any response, the study will be declared closed for the IEC office records. The Secretariat

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The committee will decide whether the query responses and (if applicable) revised protocol will go only to Member Secretary/Chairperson, or to Member Secretary/Chairperson, or to Full Board Before final approval.

The response and changes carried out may be considered for discussion at a future IEC meeting.

If the discussion is 'Disapproved ' or any other, the decision should be made on the basis of specific reasons, which are communicated by the IEC to the principal investigator in the letter of notification.

The secretariat will obtain the signature of all the members and of the Chairperson of the IEC on the Attendance log. If the study is approved, the committee will recommended monitoring for a study if it is so determined at the meeting depending on factors like risk is high in the protocol, the PI has a history of repeated protocol violations; PI has many protocols and any other reason so deemed. The Secretariat will list participating members in the meeting and summarize the guidance, advice and decision reached by the IEC members.

Final Communication of the IEC decision taken on the study to the Principal Investigator

The Secretariat will prepare an approval letter as AX 03/SOP 06/V1 to be sent to the Principal Investigator when the study is approved at an IEC meeting.

The letter contains, at a minimum:

- Study reference number

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- Detailed guidelines will be used while reviewing the Research documents (AX 4 /SOP 06/V01)

4.7 IEC meeting

During the discussion at the meeting, the Principal Investigator/Sub investigator shall be invited to present and brief the IEC members about summary of the study protocol

The study team members will leave the Meeting room after the presentation.

The Independent consultant (If required), IEC members shall give their comments right after the presentation.

The IEC members will discuss and clarify the comments and suggestions

The member secretary (assisted by the Secretarial staff) shall record the discussions

The final decision on the study will be recorded as:"Approved/ Disapproved/ Suggested recommendations or any other in the meeting shall be made by majority consensus and will be recorded

The following will not be eligible to vote

- Members(s) of the committee who is/are listed as investigator(s) on a research proposal
- An investigator or study team member invited for the meeting
- An Independent consultant invited for the meeting to provide opinion.
- Specific patient group invited for the meeting will not or participate in the decision making procedures of the committee.

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- Procedures for obtaining informed consent
- Contents of the patients information sheet – title ,objective, study design and procedures
- Contents and language of the informed consent document Translation of the informed consent document in the local languages.
- Language used –plain and easy to understand by general public
- Rights and responsibilities of the subject is clearly mentioned in the consent.
- Contact persons with address and phone numbers for questions about research
- Participants rights and study or injury
- Privacy and confidentially
- Risks and discomforts-physical/mental/social
- Alternative treatments
- Benefits to participants, community, institution and society
- Compensation for participants: (whether it will act as undue inducement)
- Involvement of vulnerable participants
- Ensure that Subject/LAR/Impartial witness are provided appropriate information
- Provisions for medical /psycho social support
- Treatment for study related injuries.
- Compensation for study – related injuries : as per applicable local regulations
- Use of biological materials
- Check for provision for signatures with dates of participant, person conducting informed consent discussion, investigator and witness
- Provision for audio visual recording of consent process in case of regulatory drug trials.

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- The IEC member will verify all the contents
- The IEC member will Check the meeting date to see if it is convenient to attend the meeting
- The IEC member will notify the IEC Secretariat if any documents are missing or if the specified date of the IEC meeting is not convenient to attend.

4.6 Review by the IEC members Review of the protocol

The Protocol will be reviewed by each member as per guidelines to review a study protocol

The IEC member will consider the following criteria when performing the review of the study protocol and the study related documents:

1. Scientific design and conduct of the study
2. Risk and potential benefits
3. Selection of study population and recruitment of research participants.
4. Inducements, financial benefits and financial costs.
5. Protection of research participants' Privacy and confidentially
6. Community considerations.
7. Qualifications of Investigators and assess adequacy of sites
8. Disclosure or declaration of potential conflicts of interest

The IEC member will consider the following criteria when performing the review of the informed Consent Document.

- Voluntary, non-coercive recruitment participation/withdrawal

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The reply from the PI will be discussed by the member Secretary within the Chairperson or the designated IEC members and a decision be reached. The decision will be informed to the IEC members at the full board meeting.

If deemed necessary by reviewers(s), Member Secretary/Chairperson, the project shall be discussed at the forthcoming full board meeting before final decision.

The Secretariat will send the Study approval letter to the PI (AX 02/SOP 06/VI)

If project is disapproved or requires re submission after certain modifications, this will be informed to the principal Investigator in writing.

The reasons for disapproval of a project will be specified in the letter sent to PI

The expedited review process should be completed within 14 days.

Full Committee Review:

All research proposals presenting more than minimal risk that are not covered under exempt or expedited review should be subjected to full committee review, some examples are;

1. Distribute the Protocol package

2. The secretariat will send the submission dossier to the IEC members.

3. Letter to IEC Members requesting Initial Review

4. Study submission Application form

5. Protocol and related documents.

6. Receive the distributed protocol package

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The member secretary will inform the IEC members of the decision at the next regular meeting and minute it.

4.3 Expedited Review

The proposals that pose no more than minimal risk may undergo expedited review,

4.4 Expedited Review Process

After determining that the protocol / project qualifies for an expedited review, the member Secretary (in consultation with chairperson) will nominate two or more IEC members to review the amended protocol. Nomination letter as per Annexure AX1/SOP 06/VI.

Designated IEC members will review the protocol package with the application

IEC members will review the protocol within the stipulated time line.

The IEC Secretariat will collect from each designed reviewer and communicate to the IEC Member Secretary /Chairperson.

4.5Decision and communication

The member secretary will discuss the comments of the members with the chairperson and a decision about the protocol will be taken.

If there are the enquiries these will be sent to the PI within one working day after receipt by the Secretariat in consultation with member secretary.

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4.Detailed Instructions

Categorisation of new proposals for review by IEC

The member secretary [in consultation with chairperson (as applicable)] will categorise the proposals into three types based on the criteria laid down in the Indian Council of Medical Research(ICMR) 2017 Ethical Guidelines. The types of review processes and the criteria to decide the type of views are explained below.

4.1 Exemption from review

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

Exemption process

If the protocol and related documents satisfy the above stated Criteria, the member Secretary in consultation with the chairperson will review the brief summary of the project.

- The member secretary records the decision in the response letter
- The secretariat communicates the decision to the investigator.
- The member secretary / Chairperson may keep application for review and decision regarding exemption at the next full board meeting.

4.2 Communication

The decision regarding the Exemption from review, signed by the IEC Chairperson /member secretary, will be forwarded by the Secretariat to the Principal investigator within 14 working days after the decision regarding the exemption is taken

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1.Purpose:

The purpose of the SOP is to describe the procedure to categorise & review of study protocols /any study related documents submitted by investigators for initial/continuing review and to decide on full board/expedited review or exemption from review process to the IEC , KMCT Medical college Kozhikode

2.Scope:

This SOP applies to the process of categorisation, review and approval of (initial/Expedited/Exemption) and assessment of all research study protocols &documents submitted for review and approval from the IEC.

3. Responsibility

- It is the responsibility of the member-secretary [in consultation with chairperson (as applicable)] to categorise the research studies in one of the three types of reviews, depending on the risks involved for prospective research participants: full board review, expedited review and exemption from review.
- IEC members (including member secretary) will be responsible for reviewing the research protocol and related documents within given time frames
- IEC members are responsible for attending and participating actively in the discussion at the bull Board Meeting/Expedited Meeting.
- The IEC Secretariat is responsible for recording and filing the decision, relevant points and deliberation about a specific protocol, including the reasons for that decision.
- The chairperson is responsible to sign and date the decision.

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- If there are interactions with participants, the IEC should determine whether there should be a consent process that will disclose such information as:
    i. That the activity involved in the research.
    ii. A description of the procedures.
    iii. That participation is voluntary.
    iv. Name and contact information of the researcher.
    v. There are adequate provisions to maintain the privacy and interests of participants.

Exempt research does not require continuing review or submission status report.

4.3.4 Communication between the IEC and the investigator

- .The decision regarding request for exemption from review, signed by the IEC Member Secretary/Chairperson, will be forwarded by the Secretariat to the Principal Investigator within 15 days after the decision regarding the exemption is taken.
- The Member Secretary will inform the IEC of the decision at the forthcoming regular meeting and minute it in the meeting notes.

Prepared by: Signature with date

Reviewed by: Signature with date

Approved by: Signature with date

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- Acknowledge the submitted documents Hand over the received documents to the Member Secretary, IEC

4.3.2 Determine protocols eligible for exemption from review

The IEC-Member Secretary will determine whether a protocol qualifies for exemption from review based on criteria explained in section 4.2.

4.3.3 Exemption Process

- If the protocol and documents satisfy the criteria as listed in 4.2, the IEC Member Secretary in consultation with the Chairperson will review the brief summary of the project and the Exemption Form.
- The Member Secretary will record the decision on the Exemption Form.
- The Secretariat will communicate the decision to the investigator.
- The Member Secretary will inform the IEC about the decision at the next full board meeting
- In case the study does not qualify for exemption from review, the Member Secretary/Chairperson will refer the study for full board/expedited meeting as appropriate.
- . Exempt research should fulfil organization's ethical standard, such as:

  - The research should hold less than minimal risk to participants.
  - Selection of participants should be equitable.
  - If there is recording of identifiable information, there should be adequate provisions to maintain the confidentiality of the data.

IV. Vulnerable groups

V. Cross cultural research

VI. Investigation of illegal behaviour(s)

VII. Invasion of privacy

VIII. Collection of information that might be disadvantageous to the participant

IX. Use of information already collected that is not in the public area which might be disadvantageous to the participant

X. Use of information already collected which was collected under agreement of confidentiality

XI. Participants who are unable to give informed consent

XII. Conflict of interest e.g. the researcher is also the lecturer, teacher, treatment provider, colleague or employer of the research participants, or there is any other power relationship between the researcher and the research participants.

XIII. Deception

XIV. Audio or visual recording without consent

XV. Withholding benefits from "control groups

XVI. Inducements

XVII. Risks to the researcher

4.3 Detailed instructions to the IEC secretariat:

4.3.1 Receive the submitted documents

- The Secretariat will receive the Exemption from Review Application Form AXIVI/SOPO4c/V5, Protocol and other documents submitted by the investigators.

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- Public health programmes by Govt. agencies such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers).

Exceptions:

a. When research on use of educational tests, survey or interview procedures, or observation of public behaviour can identify the human participant directly or through identifiers, and the disclosure of information outside research could subject the participant to the risk of civil or criminal or financial liability or psychosocial harm.

b. When interviews involve direct approach or access to private papers.

1. In circumstances where research appears to meet minimal risk criteria may need to be reviewed by the IEC. This might be because of requirements of:
    a. The publisher of the research.
    b. An organization which is providing funding resources, existing data, access to participants etc.
2. No research can be considered as minimal risk if it involves but is not restricted to the following:
    I. Invasive physical procedures or potential for physical harm
    II. Procedures which might cause mental/emotional stress or distress, moral or Cultural offence
    III. Personal or sensitive issues

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using Review Exemption Application Form (AXI-V5/SOP04c/V5). However, the decision to accept the request will be made by the Member Secretary, IEC with permission from the Chairperson.

4.2 Exemption from review

Proposals which involve less than minimal risk fall under this category Minimal risk would be defined as probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities
of a healthy individual or general population or during the performance of routine physical or psychological examinations or tests. However, in some cases like surgery, chemotherapy or radiation therapy, great risk would be inherent in the treatment itself, but this may be within the range of minimal risk for the research participant since it would be undertaken as part of current everyday life. (ICMR)

Review Exemption: A research study is said to be exempt from review when it does not require the IEC approval for its conduct. Proposals that can be exempt from review include those with less than minimal risk where there are no linked identifiers such as;

- Research conducted on data available in the public domain for systematic reviews or meta- analysis.
- Observation of public behaviour when information 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.

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Purpose:

The purpose of this Standard Operating Procedure (SOP) is to describe the IEC review exemption process and delineate the research studies that can be exempted from full board expedited IEC review. The Exemption Form AXI-VS/SOPO4c/V5 is designed to standardize the process of exemption.

2. Scope:

This SOP applies to the studies submitted for exemption from review by the IEC. This SOP describes exemption from review in detail. The specific points in the Exemption Form shall guide the Member Secretary to determine whether the study qualifies for exemption from review. The decision should be taken by the Member Secretary in consultation with the Chairperson and should be informed to the members in the forthcoming IEC meeting.

3. Responsibility:

It is the responsibility of the Member Secretary to record the decision in the Exemption Form with reasons. The IEC Secretariat is responsible for recording and filing the Exemption Form. The Member Secretary/Chairperson must sign and date, the letter conveying the decision.

AX01-V5/SOP04c/V5.

4. Detailed Instructions:

4.1 Categorization of protocols

The Member Secretary, IEC or secretariat shall screen the proposals for their completeness and depending on the risk involved in the research proposals categorize them into three types, viz, Exemption from review, Expedited review and Full review. An investigator may also apply for exemption from IEC review of the study protocol

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4.3.3 Communication between the IEC and the investigator

- . The decision of the IEC subcommittee will be communicated to the Principal Investigator at the latest by one week of the expedited meeting. The minutes of expedited review will be ratified in the full board meeting
- If the project is approved or has to be revised with minor modifications, this will be informed to the Principal Investigator in writing and the modifications submitted by PI will be reviewed by the Member Secretary or lead discussants for final approval. The PI will need to submit the modifications/revisions within 5 working days of receipt of communication from the IEC.

Prepared by: Signature with date----------

Reviewed by: Signature with date----------

Approved by: Signature with date----------

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IEC members who are conducting expedited review must disclose to the IEC Member Secretary any conflicts of interest related to the study under review, and must not review those items. If IEC Member Secretary has any conflicts of interest related to the study under review, he must disclose the same to the IEC subcommittee Chair and must not review that project. Items identified to have a conflict of interest by the IEC Member Secretary are presented to an IEC subcommittee Chair or designee who does not have a conflict with the study.

In reviewing the research, the lead discussants may exercise all the authorities of the IEC except that the lead discussants may not disapprove the research. If that is the case, it must go through full board review. The decision of the full board meeting will be communicated to the PI.

The lead discussants while reviewing the projects meeting the criteria for expedited review are required to document in the study assessment form the justification for using the expedited procedure for initial and continuing review of research, actions taken by the reviewer and any findings required by laws, regulations, codes, and guidance. The lead discussant using expedited procedures should complete the online study assessment form to document protocol-specific reasons justifying a waiver of consent. The expedited review process should ordinarily be completed within 5 working days after it has been accepted and categorized for expedited review by the Member Secretary of the IEC. Although the project qualifies for expedited review, it may be reviewed in the full board meeting due to logistics or any other reason. Research proposals that have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee.

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4.3 Detailed instructions to the IEC secretariat:

4.3.1 Receive the submitted documents

• Receive the application and documents submitted by investigators as described in SOP03/V5

4.3.2 Expedited Review

Procedure: The PI submits a completed IEC submission form along with the study protocol, waiver of consent form, case record form and any other documents [as applicable- Document Checklist (AX2-VS/SOP 03/V5)] to IEC. Principal Investigator may submit expedited review application form to IEC, if he/she feels the study meets the eligibility criteria for expedited review. Upon receipt of the application, IEC staff screens it for completeness and accuracy. Member Secretary, IEC makes a preliminary determination that the application/research proposal/documents meet the criteria for expedited review, including minimal risk, and identifies the research categories. If the application does not meet the criteria for expedited review, IEC informs the PI to resubmit the study for full board review (as per SOPO4a). After deciding that the study or study documents qualify for an expedited review, Member Secretary informs the Chairperson. Member Secretary in consultation with the Chairperson forms a subcommittee comprising of the Member Secretary of the IEC, an external IEC member and one or two IEC members from TMC. The external member will chair the meeting. The project documents will be provided to the lead discussant. Two lead discussants will be assigned. Review may be made either by circulation of comments, email, telephone discussion or meeting. The lead discussant should complete the online study assessment form (AXI-V5/SOP04a/V5).

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I. When consent of person/ patient/ responsible relative or custodian/ team of designated doctors for such an event is not possible. However, information about the intervention should be given to the relative/ legal guardian when available later;

II. When the intervention has undergone testing for safety prior to its use in emergency situations and sponsor has obtained prior approval of DCGI;

III. Only if the local IEC reviews the protocol since institutional responsibility is of paramount importance in such instances.

IV. If Data Safety Monitoring Board (DSMB) is constituted to review the data;

DHHS (CFR) criteria may be applicable only when research involving human subjects is conducted, supported or otherwise subject to regulation by any United States government federal department or agency funded by a U.S. federal agency.

The expedited review procedure is not applicable:

1. When the research involves more than minimal risk to the subjects;

2. Where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing. employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protection will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal;

3. For studies intended to evaluate the safety and effectiveness of medical devices, including studies of cleared medical devices for new indications.

4. When the research involves no more than minimal risk to the subjects but require funding

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- Continuing review of research previously approved by the convened IEC (e.g. not originally subject to expedited review) may be eligible for expedited review if

  a) The research is permanently closed to the enrolment of new subjects.
  b) All subjects have completed all research-related interventions
  c) The research remains active only for long-term follow-up of subjects.
  d) Where no subjects have been enrolled and no additional risks have been identified.
  e) Where the remaining research activities are limited to data analysis.

- Expedited review of SAE/unexpected AES of minor nature 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.
- Premature Termination/ Discontinuation/ Suspension/Withdrawal of study before site initiation.
- Research on interventions in emergency situation - When proven prophylactic, diagnostic, and therapeutic methods do not exist or have been ineffective, physicians may use new intervention as investigational drug (IND)/ devices/ vaccine to provide emergency medical care to their patients in life threatening conditions. Research in such instance of medical care could be allowed in patients.

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4.2 Expedited Review

Expedited review is a procedure through which certain kinds of research proposals that pose no more than minimal risk may be reviewed and approved by a subcommittee (refer section 4.3.2) without convening a meeting of the full Board for example:

- 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) handover of trials or projects
- Minor changes in previously approved research during the period covered by the original approval may be eligible for expedited review where:

a) The research is permanently closed to the enrolment of new subjects

b) All subjects have completed all research-related interventions

- Revised proposals previously approved through expedited review, full board review or continuing review of approved proposals.
- Minor amendments/corrections in the CRF, eCRF, budget Minor deviations from originally approved research causing no risk or minimal risk.

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1. Purpose:

The purpose of this SOP is to provide criteria for those research Studies which qualify for expedited review by IEC and describe the expedited review process in detail.

2. Scope:

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

3. Responsibility:

It is the responsibility of the Member Secretary to identify the research studies or documents which are eligible for expedited review.

4. Detailed Instructions:

4.1 Categorization of protocols

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)

II. Expedited review

III. Exemption from review

An investigator cannot categorize his/her study into the above three types. An investigator may apply for expedited review for the study protocol using Expedited Review Application Form (AXI-V5/SOP04b/V5), However decision to accept the request will be made by the Member Secretary, IEC with permission from the Chairperson.

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- All original research proposals reviewed and approved,
- Reviewer's assessment forms
- Study approval letter
- Reviewed and approved consent documents,
- Amendments and any other correspondence
- Study progress reports and interim reports,
- Serious adverse event report forms submitted by investigators,
- Any other reports
- IEC correspondence

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

4.2. Maintenance of the IEC Administrative Records

The IEC records will include the following:

1. IEC members' records

i. Appointment and acceptance letters of each member

ii. Signed and dated confidentiality agreements

iii. Updated Curriculum vitae (hard copy or soft copy)

iv. Training records for each IEC member (GCP, SOP)

v. Documentation of resignations/terminations

2 IEC membership roster-An IEC roster will be maintained which will contain:

i. Names of IEC members

ii Age

iii. Gender

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iv. Evidence of qualifications

v. Role on the IEC

vi. Status of affiliation to institution (e.g., unaffiliated or affiliated

vii. Regular/ Alternate member to the IEC (if applicable)

3. IEC mandate
4. Correspondence related to changes in IEC membership with DCGI, or concerned authority
5. IEC attendance roster
6. Agenda and Minutes of IEC meetings
7. Standard operating procedures (SOPs)
8. Annual reports
9. Documents related to Workshops & conferences organized by IEC (Continuing education for members and staffs)
10. SOP training and distribution logs.

4.3. Maintenance of Closed Study Files

Once the study file is closed (following completion/premature termination), the related study files will be shifted to the IEC Archival room at Government Medical College. All closed study files will be archived in the IEC archival room for a period of five years from the date of closure of the study. A log book for archival of study documents will be maintained.

4.4. Accessibility/Retrieval

Study files and administrative records will be made available for audit, making photocopies (if requested by investigator) or any other purpose (e.g., research on

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SAES) on request (AX 01/ SOP 18/V1) if authorized by Member Secretary/Chairperson. Representatives of regulatory authorities may have access at all times. A log book of retrieval of documents will be maintained.

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4.5. Disposal of Closed Files and Copies of Protocols and Documents Submitted for IEC Review

At the end of the archival period, the closed files will be shredded and disposed off by authorized IEC personnel. Extra copies of protocols and documents submitted for IEC review and any other extra copies will be shredded by authorized IEC personnel after the IEC meeting without any notification to PI. A formal disposal log will be maintained, providing details of documents that will be disposed. (AX 02/ SOP 18/V1)

Prepared by: Signature with date----------

Reviewed by: Signature with date----------

Approved by: Signature with date----------

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Annexures

Annexure 1 AX 01/ SOP 19/VI Document Request Form Annexure 2 AX 02/ SOP 19/V1 Log for disposal of study documents

Annexure 1 AX 01/ SOP 19/VI Document Request Form

Project Title	
Name of Principal Investigator (PI):	
Requested by	
Documents requested:	
Purpose of the Request	
Signature of Requesting person	
Signature of Pl:	
Signature of Member Secretary / Chairperson with date:	

Annexure 2: AX 02 /SOP 19/V1 Log for disposal of study documents

Study of Title	Name of PI	No. of Files	Date of EC approval	Date of Initiation	Date of Study Closure	Disposed by (Name & Sign of authorized personal	Date of Disposal

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1.Purpose:

To promote research activities in the affiliated institutions of the trust & institutions which has an MOU with the IEC KMCT Medical College

To review the protocols submitted from

a) Other Institutions under KMCT Trust in the Campus who do not have a separate IEC - Nursing College, Pharmacy College, etc.

b) Other Institutions which have signed MOU for the above purpose.

2. Scope

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

3. Responsibility

For the members of IEC KMCT Medical College are responsible for implementing this purpose.

4. Detailed instructions

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

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Procedure

a) Every proposal will be sent not less than 10 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.

b) 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.

c) 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.

d) The IEC review will be done through formal meetings and will not resort to decision through circulation of proposal.

e) Expert opinion of additional person would be obtained if necessary.

f) 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.

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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.

2. Scope

The SOP applies to all the IEC members and the Secretariat

3. Responsibility

It is the responsibility of the IEC Chairperson with the assistance of Member Secretary to ensure that there is adequate initial and continued 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. Detailed instructions

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

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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

4.2. 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)

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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. Assessment of IEC members

The IEC members' performance should be evaluated once a year using an assessment form (AX 01/SOP 20/V1) by the Chairperson. The Chairperson should do self-assessment once a year

4.5. 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.

Prepared by: Signature with date----------

Reviewed by: Signature with date----------

Approved by: Signature with date----------

Principal
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Kozhikode

5. Annexures

Annexure 1AX 01/SOP 20/V1- Self Assessment Form for EC Member Secretary /Member

Annexure 1: AX 01/SOP 20/V1

Assessment Form for Ethics Committee Members

1. Current tenure
2. Terms served
3. Training received
4. Type of training received
5. No of meetings attended
6. No of projects reviewed per meeting as primary reviewer
7. No of projects reviewed per meeting as secondary reviewer
8. Participation in SAE report review process- yes/no
9. Participation in site monitoring visits - yes/no
10. Number and type of continuing training workshops organized for IEC members (applicable to Member Secretary)
11. Number and type of continuing training workshops IEC secretariat (applicable to Member Secretary)
12. Any other significant contribution to the field of research ethics
13. Remarks by the Chairperson on the self-assessment

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Annexure 2: AX 02/SOP 20/V1

Self Assessment Form for IEC Chairperson

1. Current tenure
2. Terms served -
3. Training received -
4. Type of training received -
5. No. of meetings held in current year
6. No of meetings attended
7. Whether quorum requirement fulfillment ensured as per schedule Y in IEC meetings 8. Whether considerations related to conflict of interest considered
9. Any significant contribution to the field of research ethics
10. Any other comments----------

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DOCUMENT 1

KMCTMC/IEC/Ref. No: Date:

From

The Principal
KMCT Medical College.
Manassery,Kozhikode

To

Sub: Institute Ethics Committee –Letter of Invitation- Reg.

Dear Sir / Madam,

On behalf of KMCT Medical College, I request your concurrence for possible appointment as a member of Institute Ethics Committee of this institute. The committee will review the research/Dissertation/Thesis Proposals for its approval before initiating the research work.

In this regard it is our pleasure to invite you to become ..... of our Institutional Ethics Committee.

Please return the enclosed consent letter dully filled and signed. Kindly attach your C.V also.

Yours sincerely,

Signature:

Name:
Seal of the Office

Enclosed: Consent Letter

Principal
KMCT Medical College
Manassery P.O.
Kozhikode

DOCUMENT 2

From,

_____

_____

_____

To
The Principal
KMCT Medical College.
Manassery, Kozhikode.

Sub: Consent to be a member of Institute Ethics Committee - Reg.
Ref: Your Letter No: Dated:

Madam,

In response to your letter stated above, I give my consent to become a member of IEC of KMCT Medical College for a period of three years. I shall regularly participate in the IEC meeting to review and give my unbiased opinion regarding the ethical issues.
I shall maintain all the research project related information confidential and shall not reveal the same to anyone other than project related personnel.

I herewith enclose my CV.

Thanking you,

Signature _____

Name : _____

Address : _____

_____

_____

Email Id : _____ Tel/Mobile No: _____

Principal
KMCT Medical College
Manassery P.O.
Kozhikode

DOCUMENT 3

INSTITUTIONAL ETHICS COMMITTEE

KMCTMC/IEC/Ref. No: Date:

OFFICE ORDER

I herewith establish and constitute an Institutional Ethics Committee of KMCT Medical College,to ensure a competent review of all ethical aspects of project proposal received and execute the same free from any bias and influence that could affect the objective.
The following members will constitute the Institutional Ethics Committee.

1. Chairman_____ Affiliation
Designation_____

2. Member secretary (Convener)
Designation_____ Affiliation

3. Member
Designation_____ Affiliation

4. Member
Designation_____ Affiliation

5. Member
Designation_____ Affiliation

6. Member
Designation_____ Affiliation

7. Member
Designation_____ Affiliation

8. Member
Designation_____ Affiliation

9. Member
Designation_____ Affiliation

10. Member
Designation_____ Affiliation

11. Member
Designation_____ Affiliation

12. Member
Designation_____ Affiliation

The tenure of this membership will be for a period of 3 years from the date of appointment.

Signature

Principal, KMCT Medical College

Principal
KMCT Medical College
Manassery P.O.
Kozhikode

DOCUMENT 4

INSTITUTIONAL ETHICS COMMITTEE, KMCT Medical College

Minutes of the meeting

KMCTMC/IEC/Ref No..... Date: _____

The _____ meeting of the Institute Ethics Committee for the year _____ was held on _____ at _____under the chairmanship of _____.

Following attended the meeting.

_____ (Chairman)
_____ (Member Secretary),
_____(Member),
_____(Member)
_____(Member)
_____(Member)

After the initial proceedings, the proposals listed for the meeting were taken up for discussion. After deliberations, the following decisions were arrived:

No. of proposals reviewed - _____
No. of proposals approved - _____
No. of proposals approved subject to corrections - _____

The recommendations made by the committee are given below.

The investigators whose proposals need minor modifications are required to send three copies of revised proposals to Member-Secretary. If the revision is satisfactory, the approval certificate will be issued after consulting the Chairman of committee.

The recommendations of the committee to each proposal are detailed below

DEPARTMENT _____

Sl No.	Reg. No.	Name of the student/Principal Investigator	Title of dissertation	Name of Guide/co-Guide	Recommendations of the committee

- Any change, modification or deviation in the protocol, must be informed to ethics committee within fourteen days. Any protocol modification or amendment must receive IEC approval.
- Any serious adverse event must be informed to ethics committee within Seven days.
- Investigator should conduct the study as per the recommended GCP/GLP guidelines.

(Signature & Name)
Member Secretary
Institutional Ethics Committee

(Signature & Name)
Chairman
Institutional Ethics Committee

Principal
KMCT Medical College
Manassery P.O.
Kozhikode

DOCUMENT 5

KMCT Medical College

Manassery,(P.O.), Mukkam, Kozhikode Kerala -673602
Institutional Ethics Committee

KMCTMC/IEC/Ref No..... Date:.....

CERTIFICATE

This is to certify that the Proposal No....., entitled "..... ....." submitted by ..... Department of ..... has been approved by the Institute Ethics Committee, at the meeting held on .....under the following terms and conditions.

a. This approval is valid for three years or the duration of the project whichever is less.

b. Any serious adverse event occurring during the course of the study should be reported to the IEC within a period of seven days.

c. A yearly progress report of the project has to be submitted to the IEC for review.

d. Any change in the study procedure/site/investigator should be informed to the IEC

Member Secretary
Institutional Ethics Committee
KMCT Medical College

To
The Principal investigator
Co-investigators

Principal
KMCT Medical College
Manassery P.O.
Kozhikode

FORM IA

Proforma to be submitted to the Institutional Ethics Committee, KMCT Medical College

(For projects other than those mentioned in Form I B)

Kindly submit 15 copies of proforma and consent forms in 2 parts to the Member Secretary, Institute Ethics Committee

1. Title of the project:
2. Name of the investigators/co-investigators with designation & department:
3. Number of projects already with the investigators/co-investigators:
4. Date of approval by Research Council
5. Sources of funding
6. Objectives of the study
7. Justification for the conduct of the study
8. Methodology: It should provide details of number of patients, inclusion criteria, exclusion criteria, control(s), study design, dosages of drug, duration of treatment, investigations to be done etc
9. Permission from Drug Controller General of India (DCGI) if applicable
10. Costs involved (Appx. in Rs.)
11. Investigations
12. Disposables
13. Implants
14. Drugs/Contrast Media
15. Who will bear the costs of the requirements?

a. Patient b Investigator c. Other (Specify)

16. Ethical issues involved in the study:

less than minimal risk / minimal risk / more than minimal risk to the study subjects (for guidance please consult ICMR guidelines)

[Along with the level of risk, the risks should be discussed in detail]

17. Do you need exemption from obtaining Informed Consent from study subjects - if so give justifications?
18. Whether Consent forms part 1 and 2 in English and in local language are enclosed?

(if the consent form in local language is not applicable, appropriate explanations must be provided)

19. Documents attached

a. Brief CV of investigators (including no. of projects with him/her) - Needed only for Investigator/s from outside KMCT Medical College.

b. Investigator's Brochure

c. Others

20. Conflict of interest for any other investigator(s) (if yes, please explain in brief)
21. Whether soft copy of the proforma (CD) has been attached?
22. We, the undersigned, have read and understood this protocol and hereby agree to conduct the study in accordance with this protocol and to comply with all requirements of the current ICMR guidelines.

Signature of the Investigators: Date:

Signature of the Head of the Department: Date:

(Note: The proforma must be accompanied by Consent forms part 1 & 2 in English and Malayalam. Consent form part 1 is equivalent to Patient Information Sheet. The investigator must provide information to the subjects in a simple language, and it should address the subjects, in a dialogue format).

FORM IB

Proforma to be submitted to the Institute Ethics Sub-Committee

(Proposals for expedited review and approval for the studies having/involving:
i. No or minimum risk to the trial participants.
ii. Re examination of a proposal already examined by the IEC.
iii. Study of minor nature like the study of Patient case records etc.
iv. An urgent proposal of national interest having minimum risk.)

Kindly submit 5 copies of proforma and consent forms in 2 parts to the Member Secretary, Ethics committee

1. Title of the project:
2. Name and department/address of the investigator:
3. Name of Faculty (Guide/Co-guide) with designation & department:
4. Date of approval by Institute Research Council/ Scientific Advisory Committee/ PG Committee/ Doctoral committee:
5. Sources of funding
6. Objectives of the study:
7. Justification for the conduct of the study:
8. Methodology: It should provide details of number of patients, inclusion criteria, exclusion criteria, control(s), study design, dosages of drug, duration of treatment, investigations to be done etc
9. Permission from Drug Controller General of India (DCGI) if applicable
10. Ethical issues involved in the study:
less than minimal risk/ minimal risk/ more than minimal risk to the study subjects (for guidance please consult ICMR guidelines)
[Along with the level of risk, the risks should be discussed in detail]
11. Do you need exemption from obtaining Informed Consent from study subjects – if so give justifications.
12. Whether Consent forms part 1 and 2 in English and in local language are enclosed?
(if the consent form in local language is not applicable, appropriate explanations must be provided)
13. Conflict of interest for any other investigator(s) (if yes, please explain in brief)
14. Whether soft copy of the proforma (CD) has been attached?
15. We, the undersigned, have read and understood this protocol and hereby agree to conduct the study in accordance with this protocol and to comply with all requirements of the ICMR guidelines (2006)

Signature of the Investigators: Date:

Signature of the Head of the Department: Date:

(Note: The proforma must be accompanied by Consent forms I & II in English and Local Language. Consent form part 1 is equivalent to Patient Information Sheet. The investigator must provide information to the subjects in a simple language, and it should address the subjects, in a dialogue format)

Principal
KMCT Medical College
Manassery P.O.
Kozhikode

CONSENT FORM

PART 1 of 2

INFORMATION FOR PARTICIPANTS OF THE STUDY

Instructions - This is the patient information sheet. It should address the participant of this study. Depending upon the nature of the individual project, the details provided to the participant may vary. A separate consent form for the patient/test group and control (drug/procedure or placebo) should be provided as applicable. While formulating this sheet, the investigator must provide the following information as applicable in a simple language in English and Local Language which can be understood by the participant

- Title of the project
- Name of the investigator/guide
- Purpose of this project/study
- Procedure/methods of the study
- Expected duration of the subject participation
- The benefits to be expected from the research to the participant or to others and the post trial responsibilities of the investigator
- Any risks expected from the study to the participant
- Maintenance of confidentiality of records
- Provision of free treatment for research related injury
- Compensation of the participants not only for disability or death resulting from such injury but also for unforeseeable risks.
- Freedom to withdraw from the study at any time during the study period without the loss of benefits that the participant would otherwise be entitled
- Possible current and future uses of the biological material and of the data to be generated from the research and if the material is likely to be used for secondary purposes or would be shared with others, this should be mentioned
- Address and telephone number of the investigator and co-investigator/guide
- The patient information sheet must be duly signed by the investigator.

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KMCT Medical College
Manassery P.O.
Kozhikode

CONSENT FORM

PART 2(A) of 2- Participant consent form

Participant's name: Address:

Title of the project:

The details of the study have been provided to me in writing and explained to me in my own language.I confirm that I have understood the above study and had the opportunity to ask questions. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without the medical care that will normally be provided by the hospital being affected. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). I have been given an information sheet giving details of the study. I fully consent to participate in the above study.

Signature of the participant: Date:

Signature of the witness: Date:

Signature of the investigator: Date:

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ASSENT FORM (for participants between 7 to 18 years of age)

PART 2 (B) of 2- Parent/Legally accepted representative (LAR)

Participant's name: Address:

Parent/LAR's name:

Title of the project:

The details of the study have been provided to me in writing and explained to me in my own language. I confirm that I have understood the above study and had the opportunity to ask questions. I understand that my child/ward's participation in the study is voluntary and that I am free to withdraw my child/ward at any time, without giving any reason, without the medical care that will normally be provided by the hospital being affected. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). I have been given an information sheet giving details of the study. I fully consent for the participation of my child/ward in the above study.

Assent of child/ward obtained:
(for participants between 7 to 18 years of age)

Signature of the parent/ LAR: Date:

Signature of the witness: Date:

Signature of the investigator: Date:

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FORM II

Submitted Initial Check list to verify completeness of documents

*For official use only Proposal No.*_____

1. Fifteen copies of the proposal for regular ethics committee along with a soft copy in CD format.

2. Five copies of proposal for ethics sub-committee meeting along with a soft copy in CD format

3. Proforma and consent forms (English)

4. Proforma completely filled with all the questions answered in complete sentences

5. Proforma duly signed by the investigator(s), guides, co-guides and Head of concerned departments, with date.

6. Consent forms part 1 and 2 in both English language and the local language

7. Consent form part 1 completely filled with all the questions answered in complete sentences and in simple language. (Abbreviations to be avoided)

8. Consent form part 1 written in dialogue format addressing the patient/participant

9. Complete address and phone number of the investigator/guide provided in the appropriate place in consent form part 1

10. Appropriate Consent form part 2 enclosed for adults and children (less than 18 years)

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FORM III

Check list for verification of proposals submitted to Institute Ethics committee

For official use only *Proposal No:* _____

	YES	NO	NA	COMMENT
Is all the documentation provided?				
Scientific importance and validity				
1. Will the study lead to improvements in human health and wellbeing or increase knowledge?				
2. If the study is a replication of a previous study, is it justified				
3. Can the intervention studied be practically implemented				
4. Is there provision for dissemination of results of the research?				
6. Should the study first be referred to a technical expert, policy maker or statistical expert?				
7. Are the objectives stated clearly?				
8. Is the study design appropriate in relation to the objectives?				
9. Are the investigators qualifications, competence and experience appropriate to conduct the study?				
10. Are the facilities at the site adequate to support the study?				
11. Is the manner in which the results of research will be reported and published ethical?				
Assessment of Risks/Benefits				
1. Is the involvement of human participants necessary to obtain the necessary information?				
2. Are the researcher qualifications, competence, and experience suitable to ensure safe conduct of the study?				
3. Is the justification of predictable risks and inconveniences weighted against the anticipated benefits for the research participant and the concerned communities adequately?				
4. Are there any plans to withdraw or withhold standard therapy for the purpose of research and such actions if any justified?				
5. Is there provision for compensation for participants who sustain injuries?				

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6. Have adequate provisions been made for dealing with and reporting adverse effects?				
7. Have adequate provisions been made for safety monitoring and termination of the research project?				
Respect for the dignity of the research participants				
Informed consent				
1. Is the process for obtaining informed consent appropriate?				
2. Are the participants competent to give consent?				
3. Is the justification adequate for the intention to include individuals who cannot consent?				
4. Will dissent be respected?				
5. Is the written and oral information to be given to the research participants appropriate, adequate, complete and understandable?				
6. Do you approve the incentives offered?				
7. Is the consent given voluntarily and not due to deception, intimidation or inducement?				
Confidentiality				
1. Will the researcher collect only the minimum information/samples required to fulfil the study objectives?				
2. Is the privacy of the research participant safeguarded?				
3. Are data/sample storage and disposal procedures adequate?				
Rights of the participants				
1. Is the participant's right to unconditionally withdraw from the research at anytime safeguarded?				
2. Is there provision for participants to be informed about newly discovered risks or benefits during the study?				
3. Is there provision for the subjects to be informed of results of clinical research?				
Fair participant selection				
1. Has the study population been determined, primarily, based on the scientific goals of the study (and not on convenience, ethnicity, age, gender, literacy, culture or economic status)?				
2. Is the selection of participants (inclusion and exclusion criteria) appropriate so that risks are minimized and benefits are maximized and the burden of research equitably distributed?				

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3. Does the selection of participants stigmatize any group?				
4. Does selection of subjects favour any group?	Yes	No	NA	Comments
5. Is the research conducted on vulnerable individuals or groups?				
6. Is the research externally sponsored?				
7. Is the research a community research?				
8. Is the research a clinical trial?				
Responsibilities of the researcher				
1. Is the medical care to be provided to the research participants during and after the research adequate?				
2. Has the researcher obtained permission from the relevant authorities?				
3. Are there any conflicts of interest, including payments and other rewards?				
4. Are there any other ethical / legal/ social /financial issues in the study?				

Additional Comments:

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Recommendation: Approve [ ] Reject [ ] Conditional Approval (please state the conditions)

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Name of Reviewer:

Signature:

Date:

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