Standard Operating Procedures of Institutional Ethics Committee

Seth GS Medical College & KEM Hospital, Mumbai

SOPs Version 7 Dated 19th Nov 2024

Effective From 9th Dec 2024

INSTITUTIONAL ETHICS COMMITTEE (IEC) - I, II & III

Seth GS Medical College and KEM Hospital, Mumbai, Maharashtra, India. 400012

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	IEC - I	IEC - II	IEC - III
Established on	6th Jan 1987	14th Nov 2008	12th Oct 2019
Related to	Clinical trial, bioavailability and bioequivalence and academic clinical trial as per NDCT Rule 2019	Biomedical health research as per NDCT Rule 2019	Biomedical health research as per NDCT Rule 2019
Registered with	CLA ECR/229/Inst./MH/2013/RR-24 DHR EC/NEW/INST/2019/202	DHR EC/NEW/INST/2019/200	DHR EC/NEW/INST/2019/203
Accredited by	NABH, Certificate No. EC-CT- 2018-0027	-	-

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List of Standard Operating Procedures (SOPs), V7 Dated 19th Nov 2024

Effective from 9th December 2024 Valid up to 8th December 2027

Title:	Preparation of Standard Operating Procedures (SOPs) for Institutional Ethics Committee (IEC)
SOP Code:	SOP 01 /V 7 dated 19th November 2024

Prepared by Signature with date	Reviewed by Signature with date	Approved by Signature with date	Accepted by
19/11/24 Dr. Raakhi Tripathi, Member Secretary, IEC-I	19 NOV 24 Dr. Nithya Gogtay, Jt. Member Secretary, IEC-I	9/12/2024 Dr. Manju Sengar Chairperson, IEC-I	Institutional Ethics Committee (IEC-I) Established In 1985 Seth G.S. Medical College & K.E.M. Hospital Parel, Mumbai-400 012. IEC-I
	19 NOV 2024 Dr. Vyankatesh Shivane, Member, IEC-I	09/12/24 Dr. Sunil Kuyare Chairperson, IEC-II	Institutional Ethics Committee (IEC-II) Established in 1986 Seth G.S. Medical College & K.E.M. Hospital, Parel, Mumbai - 400 012. IEC-II
		09/12/24 Dr. M. G. Karmarkar Chairperson, IEC-III	Institute Ethics Committee-III Established in 1986 Seth G.S. Medical College & K.E.M. Hospital Parel, Mumbai - 400 012. IEC-III

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to define the processes for writing, reviewing, distributing, and amending SOPs of the Institutional Ethics Committee (IEC), Seth GS Medical College and KEM Hospital, Mumbai. This SOP provides clear, unambiguous instructions so that the related activities of the IEC are conducted in accordance with Indian laws and relevant, National and International Guidelines**.** All SOPs will be updated regularly (at the interval of 3 years) or earlier if there are major changes.

2. Scope

This SOP covers the procedures of writing, reviewing, distributing, and amending the all SOPs of the all three Institutional Ethics Committees (IECs).

3. Responsibility

It is the responsibility of the Chairperson of the IEC to appoint a SOP Team to formulate the SOPs. The SOP Team shall execute this by following the same procedures, format and coding system when drafting or editing any SOP of any Institutional Ethics Committee.

3.1 Secretariat of the Institutional Ethics Committee will:

- Assist Chairperson to formulate an SOP Team
- Coordinate activities of writing, reviewing, distributing, and amending SOPs
- Maintain a file of all current SOPs along with the list of SOPs and archived passed SOPs
- Ensure that all the IEC members and involved administrative staff have access to the SOPs
- Ensure that all the IEC members and involved staff are working according to current version of SOPs
- Maintain a file of all past SOPs of the IEC
- Assist in conducting SOP training programs and maintain file of training records of the IEC members and secretariat.

3.2 Processing the request for revision of any SOP:

- Assess the request(s) for SOP revision in consultation with the Secretariat and Chairperson
- Propose new / modified SOPs as needed
- Select the format and coding system for SOPs
- Draft the SOP/modify SOP in consultation with the IEC members and involved 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 Teams
- Review and approve the SOPs with date and signature

4. Activity Table:

No.	Activity	Responsibility
1	Identify the need for new or amending an existing SOP	Any member of IEC, secretariat, or administrative staff
2	Appoint one or more SOP Teams	Chairperson
3	List all relevant SOPs	SOP Team
4	Design a format and layout	SOP Team
5	Write and review a new/revised SOP	SOP Team
6	Review by Consultation	SOP Team
7	Preparation and submission of final draft	SOP Team
8	Approve a new/revised SOP	Chairperson
9	Ensure implementation, and filing of all SOPs	IEC members and Secretariat
10	Manage current and archive superseded SOPs	Administrative staff

5. Detailed instructions

5.1 Identify the need for new or amending an existing SOP

Any member of the IEC or Secretariat can put forth the request of revision if he/she notices any inconsistency/ discrepancy / changed circumstances in health and regulatory scenario or any other relevant scenario including institutional scenario. Also, any suggestions may be made to improve the existing SOPs or requests to design an entirely new SOP. This can be done by using Revision of SOP

Form *AX 04/SOP01/V7* This annexure form needs to be submitted to the IEC Chairperson for further course of action.

The Chairperson will inform all the IEC members about this request in a regular full-board IEC meeting. Once the IEC members agree to this request, an appropriate SOP team(s) will be appointed by the Chairperson and designate the task to proceed with the revision process/ formulation process of the new or amended SOP. The Chairperson will inform the person/ IEC member who made the request for modification of the SOP in writing about the decision to modify SOP or create a new SOP.

In case there is a need for a minor amendment to an existing SOP before three years are completed, an addendum will be made for the same after consultation with the chairperson. This addendum will be displayed on the institutional website with the effective date. The addendum will be incorporated in the next SOP update carried out after three years.

5.2 Appoint the SOP Team(s)

The Chairperson will constitute one or more SOP teams consisting of the Member Secretary and two or more members of the any IEC who have a thorough understanding of the ethical review process. The SOP writing team will carry out the subsequent steps. (5.3-5.7)

5.3 List all relevant SOPs

- Write down step by step all the procedures of the Institutional Ethics Committee
- Organize, allocate and name each process

5.4 Design a format and layout

Each SOP should be given a number and a title that is self-explanatory and is easily understood. A unique code number with the format **SOP xx/Vy** will be assigned to each SOP item by the Secretariat. "xx" will be a two-digit number assigned specifically to each activity-based SOP. "V" refers to version of the SOP and "y" will be a number identifying the version.

Each annexure will be given a unique code number with the format ***AX pp/SOP xx/Vy***. AX refers to annexure form, *pp* is a two-digit number identifying the number of the annexure, while *xx/Vy* refers to the SOP number and its version.

Each SOP will be prepared according to the standard template in *AX 02/SOP01/V7 Each* page of the SOP will bear the header which will have the effective date. The SOP number will be on the right side corner while the bottom of page will bear the page number as Page - of total pages. The first page of each SOP document will be signed and dated as Prepared by, reviewed by, approved by and accepted by the IEC members who have reviewed the SOPs and the IEC Chairperson and subsequently the SOP will be implemented from that date.

5.5 Write and review a new/revised SOP

- If an SOP supersedes a previous version, the previous SOP version will be indicated in the Document History Form *AX 03/SOP01/V7*
- 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.

5.6 Review by Consultation

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

5.7 Preparation and submission of final draft

- IEC Members will review the revised draft SOP at a special meeting or full board meeting.
- The suggestions that are agreed upon by the IEC members present at the special meeting or full board meeting will be discussed and incorporated in the revised draft SOP and the final draft of the SOP will be formulated.
- The SOP team would stand automatically dissolved once the IEC takes final decision regarding the SOP.

5.8 Approve a new / revised SOP

- The final version will be presented to the Chairperson for review and approval.
- The authors, reviewers and the Chairperson sign and date the SOP on the first page of the SOP document. This date of approval will be declared as the effective date.

5.9 Ensure Implementation and file all SOPs

- The approved SOPs will be implemented from the effective date and will be available on the institutional website www.kem.edu
- The Member Secretary will discuss the approved SOPs with the administrative staff and instruct them to implement it accordingly.
- One complete original set of current SOPs will be filed centrally in the SOP Master file, by the Secretariat of the IEC in the office of Institutional Ethics Committee.
- When the revised version is implemented one copy of the superseded version will be filed centrally in the file entitled 'Past SOPs of the IEC' by the Secretariat of the IEC in the IEC office.
- The Secretariat will review the SOPs at least once in every three years and record the dates of review on the SOP Master file.
- As per the findings and opinion of the Secretariat, the Member-Secretary will inform the Chairperson about the result of review process.

5.10 Manage current and archive superseded SOPs

Old SOPs should be retained and archived in a file by the secretariat and kept in the IEC office.

6. Glossary

SOP (Standard Operating Procedure)	Detailed, written instructions, in a certain format, describing activities and actions undertaken by the IEC to achieve uniformity of the performance of a specific function. The aim of the SOPs and their accompanying checklists and forms is to simplify the functioning, while maintaining high standards of Good Clinical Practice.
IEC members	Individuals serving as regular members of the Institutional Ethics Committee. The Board has been constituted in accordance with the IEC membership requirements set forth in New Drug and Clinical Trial approval regulations 2019 dated 19 March 2019 GSR-227-E and ICMR 2017.
SOP Team	A Team of members selected from the Institutional Ethics Committee including the Member Secretary and at least two more members who oversee the creation, preparation, review and periodic revision of the Institutional Ethics Committee SOPs.
Master SOP files	An official collection of the Standard Operating Procedures (SOPs) of Institutional Ethics Committee accessible to all staff, IEC/ members, auditors and government inspectors as a paper copy with an official stamp and the signature of either member secretary/ chairperson of the IEC on the first and the last page of the SOP booklet. Photocopies made from these official paper versions of the SOP cannot be considered official.
Past SOPs of the IEC	A collection of previous official versions of a SOPs and relevant information regarding changes and all preplanned deviations.
Effective date	The date of approval of the SOPs signed and dated by the Institutional Ethics Committee- Chairperson and subsequently the SOP is implemented from that date.

7. Annexure

Annexure 1	*AX 01/SOP 01/V7*	List of SOPs of IEC
Annexure 2	*AX 02/SOP 01/ V7*	Template for Standard Operating Procedures
Annexure 3	*AX 03/SOP01/ V7*	Document History of the SOP
Annexure 4	*AX 04/SOP01/ V7*	Request for Formulation of a new SOP/ Revision of an SOP

Annexure 1

AX 01/SOP 01/ V7

List of SOPs of Institutional Ethics Committee

Sr. No.	SOP No	Title of the Standard Operating Procedures (SOPs)	SOP Code
1.	1	Preparation of Standard Operating Procedures (SOPs) for Institutional Ethics Committee (IEC)	SOP 01/*V7*
2.	2	Constituting Institutional Ethics Committee	SOP 02/*V7*
3.	3	Confidentiality / Conflict of Interest Agreements	SOP 03/*V7*
4.	4	Selection and Responsibilities of Subject Expert	SOP 04/*V7*
5.	5-A	Management of Initial Protocol Submissions	SOP 05/*V7*
6.	5-B	Full Board Review of Submitted Protocol	SOP 05-A/*V7*
7.	5-C	Expedited Review	SOP 05-B/*V7*
8.	5-D	Exemption from the Ethics Review for Research Projects	SOP 05-C/*V7*
9.	5-E	Review of Resubmitted Protocols	SOP 05-D/*V7*
10.	6	Review of Amended protocol/ Protocol related documents	SOP 06/*V7*
11.	7	Continuing Review of Study Protocols	SOP 07/*V7*
12.	8	Review of Study Completion Reports	SOP 08/*V7*
13.	9	Management of Premature Termination / Suspension / Discontinuation of the study / Withdrawal of study before site initiation	SOP 09/*V7*
14.	10	Protocol Deviation/Violation	SOP 10/*V7*
15.	11-A	Constituting SAE Subcommittee	SOP 11-A/*V7*
16.	11-B	Review of Serious Adverse Events (SAE) Reports and Suspected/ Unexpected Adverse Events (UAE)	SOP 11-B/*V7*
17.	12	Site Monitoring Visit	SOP 12/*V7*
18.	13	Agenda Preparation, Meeting Procedures and Recording of Minutes	SOP 13/*V7*
19.	14	Conduct of Emergency Meeting	SOP 14/*V7*
20.	15	Maintenance of Active Project Files	SOP 15/*V7*
21.	16	Archiving, retrieving and disposal of documents	SOP 16/*V7*
22.	17	Responding to Research Participant's Grievance or Complaint	SOP 17/*V7*
23.	18	Management of complaints by investigators	SOP 18/*V7*
24.	19	Request for Waiver of Written Informed Consent	SOP 19/*V7*
25.	20	Reviewing proposals involving vulnerable Populations	SOP 20/*V7*
26.	21	Common Ethics Review of Multicentre Research	SOP 21/*V7*
27.	22	management of initial protocol submission during epidemics/ lockdown periods	SOP 22/V7
28.	23	Emergency or Compassionate of drugs	SOP 23/V7
29.	24	Review of Case Report or Case Series	SOP 24/V7
30.	25	Audio Visual (AV) recording of Informed Consent Process	SOP 25/V7

Annexure 2

AX 02/SOP 01/V7

Template for Standard Operating Procedures

SOP Code : SOP xx/Vy **IEC (KEMH, Mumbai)**

Effective date : aa *bb cccc* **Valid up to**

Title: Title which is self-explanatory and easily understood			
SOP Code : SOP xx/Vy			
Prepared by Signature with date	**Reviewed by Signature with date**	**Approved by Signature with date**	**Accepted by**
		Xxxx Chairperson, IEC-I, II, III	**IEC-I, II, III**

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. **Activity Table:** *Simplifies the procedures in step-by-step sequence and states clearly the responsible person(s) or position for each activity*
5. **Detailed instructions**: D*escribe procedures step by step in short and clear phrases or sentences. Split a long sentence into shorter ones.*
6. **Glossary**: *Clarifies uncommon or ambiguous words or phases by explanation.*
7. **Annexure**: *Documents that explain further or clarify complex descriptions. "Description-by-example" is always recommended to avoid difficult texts which may be hard to understand.*

Annexure 3

AX 03/SOP 01/V7

Document History of the SOP

Details of superseded SOP

Name of the team of authors	Version	Effective date (dd-mm-yyyy)	Describe the main change

Annexure 4

AX 04/SOP 01/V7

Request for Formulation of new SOP/ Revision of an SOP

This form is to be completed by any member whenever a problem or a deficiency in an SOP is identified and maintained with the SOP until an authorized replacement is in place.

SOP xx/yy		
Title:		
Details of problems or deficiency in the existing SOP		
Need to formulate an entirely new SOP (i.e. SOP not existing previously)		
Identified by:	Date *(DD/MM/YYYY):*	
Discussed in Institutional Ethics Committee Meeting held on:-		
SOP revision required: ☐ Yes		☐ No
Action required: ☐ New SOP to be formulated ☐ SOP to be deleted ☐ SOP to be amended ☐ No action to be taken ☐ Any other (Please specify): If no action to be taken, please state reasons		
If action recommended: SOP team: [1] Member-Secretary: [4] [2] [5]		
Date -SOP finalized in special / full board meeting:		
Date -Final SOP approved by chairperson declared as effective date		
Chairperson, IEC-I Signature with date	Chairperson, IEC-II Signature with date	Chairperson, IEC-III Signature with date

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Title:	Constituting Institutional Ethics Committee
SOP Code:	SOP 02 /V 7 dated 19th November 2024

Prepared by Signature with date	Reviewed by Signature with date	Approved by Signature with date	Accepted by
Dr. Raakhi Tripathi, Member Secretary, IEC-I	19-11-24 Dr. Nithya Gogtay, Jt. Member Secretary, IEC-I	9/12/2024 Dr. Manju Sengar Chairperson, IEC-I	Institutional Ethics Committee (IEC-I) Established In 1985 Seth G.S. Medical College & K.E.M. Hospital Parel, Mumbai-400 012. IEC-I
	19Nov2024 Dr. Vyankatesh Shivane, Member, IEC-I	09/12/24 Dr. Sunil Kuyare Chairperson, IEC-II	Institutional Ethics Committee (IEC-II) Established in 1986 Seth G.S. Medical College & K.E.M. Hospital Parel, Mumbai - 400 012. IEC-II
		09/12/24 Dr. M. G. Karmarkar Chairperson, IEC-III	Institute Ethics Committee-III Established in 1986 Seth G.S. Medical College & K.E.M. Hospital Parel, Mumbai - 400 012. IEC-III

1. Purpose

This Standard Operating Procedure (SOP) describes the Terms of References (TOR), which provide the framework for constitution, responsibilities, and activities of the all three Institutional Ethics Committees (IECs)

2. Scope

The SOP applies to all activities performed by the all Institutional Ethics Committees.

3. Responsibility

It is the responsibility of all Institutional Ethics Committee members and the Secretariat to read, understand, follow and respect the SOPs.

4. Activity Table:

No.	Activity	Responsibility
1.	Ethical basis	Institutional Ethics Committees (**IECs)**
2.	Composition of the Institutional Ethics Committee	Head of the Institute, Chairperson, IEC Members and Secretariat
3.	Membership requirements	Head of the Institute, Chairperson
4.	Tenure of Membership	Chairperson, IEC Members and Secretariat
5.	Policy statement of the institution & Appointment of new members	Head of the Institute
6.	Resignation and disqualification of members	IEC Members and Secretariat
7.	Conditions of appointment	IEC Members and Secretariat
8.	Training of the IEC Members in Research Ethics	IEC Chairperson / Member Secretary
9.	Hierarchy	IEC
10.	Selection and appointment of Chairperson, Member Secretary, Joint Member Secretary	Head of the Institute
11.	IEC staff	Member Secretary
12.	Role of IEC members	IEC
13.	Quorum requirements	IEC Members and Secretariat
14.	Honorarium to the Members/ subject experts	IEC
15.	Responsibilities of IEC	HOI, IEC
16.	Evaluation of IEC/Chairperson/Member Secretary/Members	HOI, IEC
17.	Prepare an annual activity report of the IEC for submission to the Head of the Institute	IEC Secretariat

5. Detailed Instructions

5.1 Ethical basis

- 'Institutional Ethics Committee' (IEC) first established in 1987, is an institutional IEC of Seth G. S. medical College and K.E.M. Hospital. 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 and all dissertation projects (postgraduate students :MD, MS, MCh, DM, DNB, PhD, MSc, MPTh, MOTh, Nursing), research projects of undergraduate students (Indian Council for Medical research studentship) and investigator initiated research studies which are self funded, funded by others (societies, or any other body treated as extramural) those funded by intramural funding bodies of KEM Hospital.
- All IECs will function independently without any interference in the review and decision making process from the Head of the Institute and respective administrative department of the Institute.

Institutional Ethics Committee will have three committees, Institutional Ethics Committee (IEC) - I, II and III.

i) Those research protocols which fulfill the definition of clinical trial and academic clinical trial as per NDCT Rules 2019 (GSR 227-E) will be managed by the committee registered with CLA.

ii) Those research protocols which fulfill the definition of Biomedical and Health Research as per NDCT Rules 2019 (GSR 227-E) will be managed by the committee registered with DHR.

- The committees which are registered with CDSCO will be able to review regulatory clinical trials.
- The committees will consist of members who collectively have the qualifications and experience to review and evaluate the scientific, medical and ethical aspects of research projects involving human participants.
- In evaluating protocols and ethical issues, the IECs will be aware of the diversity of laws, culture and practices governing research and medical practices in various countries around the world and especially in India. The IECs also will periodically update themselves on new guidelines and regulations (national and international).
- Each IEC will be informed, as appropriate, by other IEC approving other trial sites and researchers of the impact of the research it has approved. The IEC is guided in its reflection, advice and decision by the ethical principles expressed in Declaration of Helsinki latest revision 2013, Brazil.
- It makes further reference to the International Ethical Guidelines for e.g.: The Nuremberg Code (1945), Belmont Report (1979), The Council for International Organizations of Medical Sciences (CIOMS)International Ethical Guidelines for Biomedical Research Involving Human Subjects (Geneva 2002), and the European Convention on Human rights and Biomedicine (1997).
- All IECs will work according to its established Standard Operating Procedures based on the Operational Guidelines for IEC that review Biomedical Research (WHO, 2000), International Conference on Harmonization-Good Clinical Practices (ICH-GCP) Guidelines (1996 & amendments 2016), New Drugs and Clinical Trials, Rules 2019, Indian GCP guidelines (2000) and National Ethical Guidelines for Biomedical Research on Human Participants by ICMR (2017), National Ethical Guidelines for Biomedical Research Involving Children ICMR 2017 and any guidelines issued by Government of India / ICMR/ DCI during epidemics/pandemics (National Guidelines for Ethics Committees Reviewing Biomedical & Health Research During Covid-19 Pandemic), and 75th WMA General Assembly, Helsinki, Finland, Oct 2024.

  The mandate will be

  a. To ensure the protection of the rights, safety and wellbeing of human participants involved in a research project.

  b. Provide public assurance of that protection.

- The IEC is established and will function in accordance with the relevant national law and regulations in force from time to time.
- The IEC will review only those projects which are carried out in this institution by the staff members and students of the institution.
- The IEC will also review projects which are carried out by institutional members in collaboration with other national or international institutions.

5.2 Composition of the Institutional Ethics Committee

- The IEC will be established by the Head of the Institution (HOI) refer Annexure 1 (*AX 01/SOP 02/ V7)* organizational chart of institution.
- The IEC will be multidisciplinary and multi-sectoral in composition.
- The IEC will be composed of at least 7 and a maximum of 15 members. At least 50% of its members will be non-affiliated to the institute. The members should be a mix of medical and non-medical, scientific and non-scientific persons including lay persons to represent the different points of view.
- The members will have differing backgrounds as this would promote complete and adequate review of research activities commonly conducted at Seth GS Medical College and KEM Hospital.
- The IEC will have representation that is varied in terms of gender, age and social background.

Constituting Institutional Ethics Committee

- The Composition shall be as follows:
  - ✓ Chairperson (who will be a member not- affiliated to the institution)
  - ✓ One Member Secretary (affiliated with the Institute)
  - ✓ One Joint Member Secretary (appointed if necessary)
  - ✓ One or more persons from basic medical science area
  - ✓ One or more clinicians from various institutes
  - ✓ One legal expert or retired judge
  - ✓ One philosopher, ethicist or theologian, independent social scientist/ representative of non-governmental agency
  - ✓ One or more lay persons from community
  - ✓ One woman member
- The IEC will share the expertise of the IEC members with each other as per the needs of research study.
- The IEC may invite member(s) of specific patient groups or other special interest groups for an IEC meeting (if required, based on the requirement of research area, e.g. HIV AIDS, genetic disorders, stem cell research etc.) for eliciting their views. Such individuals will have to sign confidentiality agreement (*AX 05/SOP 03/V7)* and declare in writing, conflicts of interest, if any prior to attending the meeting. They will attend the meeting in the capacity of 'Observer' and will not have right to vote.

5.3 Membership requirements

- The Head of the Institute (HOI) is responsible for appointing new committee members.

  The Chairperson and IEC members can suggest names of potential members but the final decision will remain with the HOI.
- Members will be selected in their personal capacities based on their interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the IEC work.
- Members must disclose in writing any interest or involvement-financial, professional or otherwise- in a project or proposal under consideration (Refer to *AX 01/SOP 03/V7andAX 02/SOP 03/V7*Confidentiality / Conflict of Interest Agreements).
- The IEC will decide the extent to which members that might have a conflict of interest may participate in bringing out an advice/decision (Refer to *AX 01/SOP 03/V7and AX 02/SOP 03/V7*Confidentiality / Conflict of Interest Agreements). Members will be required to sign a confidentiality agreement at the start of their term. (Refer to SOP *AX 01/SOP 03/V7 and AX 02/SOP 03/V7*Confidentiality / Conflict of Interest Agreements)

5.4 Tenure of Membership.

- The tenure of Institutional Ethics Committee members will be for a continuous period of three (3) years from the date of appointment. In case a member is inducted in place of a resigned / disqualified member his / her tenure may be less than three years.
- The IEC secretariat will initiate the process of filling up the forthcoming vacancies 3-6 months prior to the end of tenure of a member. The Chairperson will recommend names of individuals to the HOI. The HOI will select and appoint a member for the new tenure from the list provided by the IEC or otherwise. The retiring member will be eligible to be appointed for the new tenure maximum two times in continuation in the same IEC board.

5.5 Policy statement of the institution & appointment of new members

a) Policy statement of the institution

The policy statement of the institution will be issued by the head of institution (under whose authority it is governed) during new tenure and constitution of the IEC Annexure 2 (*AX 02/SOP 02/V7)*

b) Appointment of new members

i) The IEC members will be appointed by the HOI. New members will be appointed under the following circumstances:

1. When a member completes his/ her tenure.
2. If a member resigns before the tenure is completed.

3. If a member ceases to be a member for any reason including death or disqualification.
4. To fulfill the membership requirements as per 5.2 and 5.3 of this SOP.

ii) New members will be identified by the Chairperson according to the Section 5.2 and Section 5.3 of this SOP. If the potential member fulfills the conditions of appointment as defined in 5.8 of this SOP.

The concerned member will be invited to the IEC via email through IEC / HOI. The new member will convey his / her acceptance via email / hard copy (Annexure 7 AX07/SOP02/V7). Subsequently he / she will be appointed on IEC by the HOI. The names of new members to be appointed may be suggested by the IEC members and the Chairperson to the Head of the Institution HOI. The final decision regarding appointment of members will be taken by the HOI.

5.6 Reconstitution policy of IEC:

The IEC will get reconstituted at a three yearly interval (when the tenure of the maximum number of members ends). At the time of reconstitution with the approval of the existing chairperson and HOI, attempts would be made to retain the maximum number of existing eligible members as per section 5.4; Minimum of 20% - 30% of the total members will be permitted to continue their tenure which meets the criteria as per section 5.4. The remaining members will be newly inducted to the IEC. IEC would always prefer to retain experienced and trained IEC members.

5.7 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.
- A member desirous of resigning from the Ethics Committee is required to give at least two months' notice before the resignation becomes effective.
- The resignation letter will be addressed to the Dean of the institution and shall be submitted to the IEC office. The notice period shall begin from the date it is received in the IEC office.
- After the receipt of the letter, the IEC secretariat will issue an acknowledgment of receipt to the concerned member and shall put up the resignation letter to the Member- Secretary and/ or Chairperson.
- The Member- Secretary under the orders of the Chairperson shall forward the letter to the Dean within a period of 10 days from the receipt of the resignation letter with appropriate remarks/ recommendations: may be accepted/ may not be accepted citing reasons/ decision may be deferred citing reasons/ any other appropriate remark or recommendation citing reasons.
- The Chairperson in consultation with the Member- Secretary, is at liberty to waive the mandatory notice period and state so in the recommendation to the Dean
- The Chairperson, in consultation with the Member- Secretary shall take appropriate steps to recommend another member in place of the resigning member with due appointment from the HOI so that the composition of the IEC continues to be in compliance with the applicable regulations and SOPs.
- If a Member- Secretary desires to resign from the post of Member- Secretary, the notice period shall be for a minimum period of 3 months. The rest of the procedure will be the same
- A Member- Secretary can opt for resigning from the post of Member- Secretary while continuing in the post of Member of the IEC
- If the Chairperson decides to recommend to the Dean the acceptance of resignation of the Member- Secretary, he/ she may simultaneously recommend to the Dean that any affiliated member of the IEC may be appointed as the Member- Secretary
- The Member- Secretary who has submitted the letter of resignation, shall continue to work as and dispose of the responsibilities of the Member- Secretary till the time the resignation is accepted by the Dean and the Member- Secretary is relieved of the responsibilities by the Chairperson of the Institutional Ethics Committee-1. If the Member secretary is willing to continue as member of the board , such decision will be taken by the Head of the institution.
- Once the resignation given to IEC by MS the same person should not be preferably appointed as MS in future.

In consultation with the Member- Secretary, the IEC Board shall decide whether the resignation letter needs to be submitted by a member or Member Secretary (MS) to the Chairperson and Chairperson needs to inform to the Head of the Institute and initiate procedure for the next appointment or vacancy. In the interim period, Chairperson / IEC board will appoint the acting Member Secretary and he /she will take charge till the appointment of next Member Secretary.

MS should give notice 3 months prior to resignation to the appointing officer, (The Dean). In the meantime, till the new successor takes over, the prior MS will continue on the post or the Joint Member Secretary will take over temporarily as MS.

- Disqualification for conduct unbecoming 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 unbecoming 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.
  (ii) The Chairperson will satisfy himself/ herself 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. The allegation will be discussed at the IEC meeting and the member alleged of misconduct will be provided adequate opportunity to defend himself / herself.
  (iv) The member would stand disqualified if members present approve of disqualification by voting (voting by 2/3rd of 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 meetings: 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:
  (i) The member-secretary will inform Chairperson, in writing, if a member has not attended more than three consecutive regular meetings of 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 disqualification 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 represent his/ her case. A written communication, if received from the concerned member will be read and reviewed at the meeting.
- The Chairperson or Member-Secretary will inform the IEC members about the cessation of membership by a confidential written communication to other members of IEC or at the next meeting of IEC.

5.8 Conditions of appointment

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

- Willingness to publicize his/her full name, profession, and affiliation.
- Willingness to record reimbursement received for work and expenses incurred, related to the IEC assignment and make these records available to IEC and/ or general public on request.
- Willingness to sign the Confidentiality and Conflict of Interest Agreements regarding meeting, deliberations, applications, information on research participation and related matters.

5.9 Training of the IEC Members in Research Ethics

- An individual selected as a new member of the IEC will be required to undergo training in research ethics and applicable ethical guidelines. Member-secretary or an IEC member will provide an introductory training to the new member
- It is mandatory for the new member to attend at least two meetings (offline) as an 'Observer' before being inducted as a member of the IEC.

- All IEC members should undergo refresher courses in Good Clinical Practice (GCP) annually and IEC will maintain a record for pre and post training assessment sheets and resource material utilized for training.
- 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 may sponsor or reimburse the expenses of an IEC member or prospective members for attending conference, continuing education session workshop and/ or training program etc.

5.10 Hierarchy

- There will be one Chairperson, one Member Secretary. A Joint Member Secretary may be appointed amongst the members if necessary.
- The Chairperson will be the head of the committee.
- The Member Secretary and the Joint Member Secretary (whenever applicable) will be the guardian of all documents and funds in the possession of the committee.
- Other IEC members will be members defined as per the composition and will have equal ranking.
- The Chairperson will be appointed by the Head of the Institute,
- The Member-secretary, Joint Member-Secretary (if necessary) will be elected by and from amongst the IEC members for 3 years term. These may be re-elected any number of times. Should they resign or be disqualified, the IEC members will elect a replacement for another term.

5.11 Chairperson

- The Chairperson will be appointed by the Head of the Institute,
- The Chairperson will not be affiliated to the institution.
- The Chairperson will be accountable for independent and efficient functioning of the committee
- The Chairperson will be responsible for conducting committee meetings, and will lead all discussions and deliberations pertinent to the review of research proposals.
- The Chairperson will ensure active participation of all members (particularly non-affiliated, non-medical/ non-technical) in all discussions and deliberations
- The Chairperson will ratify minutes of the previous meetings
- The Chairperson will preside over all elections and administrative and financial matters pertinent to the committee's functions. The Chairperson will represent the IEC at various meetings and forums.
- Seek COI declaration from members and ensure quorum and fair decision making.
- Handle complaints against researchers, EC members, conflict of interest issues and requests for use of EC data, etc.
- The Chairperson will sign documents and communications related to IEC functioning.
- The Chairperson will delegate his/ her responsibilities to appropriate individuals in accordance with IEC SOPs.
- In case of anticipated absence, the Chairperson will nominate a committee member as Acting Chairperson. Or the members present may elect an Acting Chairperson on the day of the meeting. The Acting Chairperson should be a non-affiliated person and will have all the powers of the Chairperson for that meeting.

5.12 Secretariat

[1] The Secretariat will be composed of the IEC Member Secretary, Joint Member Secretary (where applicable), the General Manager and other administrative supporting staff.

[2] The Member Secretary and the Joint Member Secretary (appointed if necessary) will be elected by and from among the committee members.

[3] The administrative staff of the Secretariat will be appointed by the IEC and they will be supervised by the Member Secretaries (Refer Annexure 3 AX03/SOP2/V7)

[4] The Secretariat shall have the following functions.

✓ **Functions of the Member secretary**

- To receive research proposals
- To organize an effective and efficient tracking procedure for each proposal received.

- To prepare, maintain and distribute of study files.
- To schedule and organize IEC meetings
- To assess the need for expedited review/ exemption from review or full review.
- To assess the need to obtain prior scientific review, invite independent consultant, patient or community representatives
- To ensure quorum during the meeting and record discussions and decisions
- To prepare and maintain meeting agenda and minutes.
- To maintain IEC documentations and to archive them.
- To sign documents and communications related to IEC functioning.
- To communicate with the IEC members and applicants/ investigators.
- To notify the Principal Investigator regarding IEC decisions related to the submitted research proposal.
- To arrange for training of personnel and IEC members.
- To organize the preparations, review, revision and distribution of SOPs and guidelines.
- To provide necessary administrative support for IEC related activities to the Chairperson.
- To prepare for and respond to audits and inspections
- To provide updates on relevant and contemporary issues to ethics in health research as well as relevant contemporary literature to the committee members.
- To receive fees and issue official receipts for the same.
- To delegate various responsibilities to appropriate and authorized individuals
- To ensure adherence of IEC functioning as per SOPs

✓ **Functions of the Joint Member Secretary (whenever appointed)**

- The Joint Member Secretary will assist the Member Secretary in all the activities as required for smooth functioning of the IEC.
- The Joint Member Secretary will perform the same functions of Member Secretary in his/her absence.

✓ **Functions of the IEC Administrators**

- To support the Member Secretary in executing functions of the IEC.
- To perform any other functions as instructed by Member Secretary/ Chairperson.

5.13 Roles and Responsibilities of IEC members

- To attend IEC Meetings and participate in discussions and deliberations so that appropriate decisions can be arrived.
- To review, discuss and consider research Proposals submitted for evaluation.
- To monitor Serious Adverse Event reports and recommend appropriate action(s)
- To review the progress reports and monitor ongoing studies as appropriate.
- To evaluate final reports and outcomes.
- To review clinical trial agreement, Insurance policy and informed consent document specifically by the legal expert of the IEC.
- To maintain confidentiality of the documents and deliberations of IEC meetings.
- To declare any conflict of interest.
- To sign the Confidentiality / Conflict of Interest Agreements regarding meeting, deliberations, applications, information on research participation, and related matters.
- To participate in continuing education activities in biomedical ethics and biomedical research.
- To provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat
- To provide an updated CV when requested by the IEC secretariat
- To carry out the work delegated by the Chairperson, Member-secretary and Jt. Member-secretary.
- To assist the Chairperson, Member-secretary and Jt. Member-secretary in carrying out IEC work as per SOPs
- To add disqualification and debar criteria

5.13.1 Roles and Responsibilities of IEC member appointed as Basic Medical Scientist:

- To attend IEC meetings and participate in discussions and deliberations so that appropriate decisions can be arrived.
- To review, discuss and consider research Proposals submitted for evaluation.

- Scientific and ethical review with special emphasis on the intervention, benefit-risk analysis, research design, methodology and statistics, continuing review process, SAE, protocol deviation, progress and completion report
- To monitor Serious Adverse Event reports and recommend appropriate action(s). For clinical trials, pharmacologist to review the drug safety and pharmacodynamics.
- To review the progress reports and monitor ongoing studies as appropriate.
- To evaluate final reports and outcomes.
- To Review medical care, facility and appropriateness of the principal investigator, provision for Medical care, management and compensation.
- Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
- To perform the task of site monitoring.
- To maintain confidentiality of the documents and deliberations of IEC meetings.
- To declare any conflict of interest.
- To sign the Confidentiality/Conflict of Interest Agreements regarding meeting, deliberations, applications, information on research participation, and related matters.
- To participate in continuing education activities in biomedical ethics and biomedical research.
- To provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat.
- To provide an updated CV when requested for by the IEC secretariat.
- To carry out the work delegated by Chairperson and Member-secretary.
- To assist Chairperson and Member-secretary in carrying out IEC work as per SOPs.

5.13.2 Roles and Responsibilities of IEC member appointed as Clinician:

- To attend IEC meetings and participate in discussions and deliberations so that appropriate decisions can be arrived at.
- To review, discuss and consider research Proposals submitted for evaluation. Scientific review of protocols including review of the intervention, benefit-risk analysis, research design, methodology, sample size, site of study and statistics
- To monitor protocol deviation and violation reports and recommend appropriate action(s).
- To monitor Serious Adverse Event reports and recommend appropriate action(s).
- To review the progress reports and monitor ongoing studies as appropriate.
- To evaluate final reports and outcomes.
- To Review medical care, facility and appropriateness of the principal investigator, provision for Medical care, management and compensation.
- Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
- To perform the task of site monitoring.
- To maintain confidentiality of the documents and deliberations of IEC meetings.
- To declare any conflict of interest.
- To sign the Confidentiality/Conflict of Interest Agreements regarding meeting, deliberations, applications, information on research participation, and related matters.
- To participate in continuing education activities in biomedical ethics and biomedical research.
- To provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat.
- To provide an updated CV when requested for by the IEC secretariat.
- To carry out the work delegated by Chairperson and Member-secretary.
- To assist Chairperson and Member-secretary in carrying out IEC work as per SOPs.

5.13.3 Roles and Responsibilities of IEC member appointed as Social scientist:

- To attend IEC meetings and participate in discussions and deliberations so that appropriate decisions can be arrived at.
- To review, discuss and consider research Proposals submitted for evaluation.
- Ethical review of the proposal, ICD along with the translations, to assess impact on community involvement, socio–cultural context, religious or philosophical context, if any. To serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.
- To monitor Serious Adverse Event reports and recommend appropriate action(s).
- To review the progress reports and monitor ongoing studies as appropriate.

- To evaluate final reports and outcomes.
- To Review medical care, facility and appropriateness of the principal investigator, provision for Medical care, management and compensation.
- Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
- To perform the task of site monitoring.
- To maintain confidentiality of the documents and deliberations of IEC meetings.
- To declare any conflict of interest.
- To sign the Confidentiality/Conflict of Interest Agreements regarding meeting, deliberations, applications, information on research participation, and related matters.
- To participate in continuing education activities in biomedical ethics and biomedical research.
- To provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat.
- To provide an updated CV when requested for by the IEC secretariat.
- To carry out the work delegated by Chairperson and Member-secretary.
- To assist Chairperson and Member-secretary in carrying out IEC work as per SOPs.

5.13.4 Roles and Responsibilities of IEC member appointed as Legal Expert:

- To attend IEC meetings and participate in discussions and deliberations so that appropriate decisions can be arrived at.
- To review, discuss and consider research Proposals submitted for evaluation.
- Ethical review of the proposal, ICD along with translations, MoU, Clinical Trial Agreement (CTA), regulatory approval, insurance document, other site approvals, researcher's undertaking, protocol specific other permissions, such as, stem cell committee for stem cell research, HMSC for international collaboration, compliance with guidelines etc.
- Interpret and inform EC members about new regulations if any.
- To monitor Serious Adverse Event reports and recommend appropriate action(s).
- To review the progress reports and monitor ongoing studies as appropriate.
- To evaluate final reports and outcomes.
- To Review medical care, facility and appropriateness of the principal investigator, provision for Medical care, management and compensation.
- Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
- To perform the task of site monitoring.
- To maintain confidentiality of the documents and deliberations of IEC meetings.
- To declare any conflict of interest.
- To sign the Confidentiality/Conflict of Interest Agreements regarding meeting, deliberations, applications, information on research participation, and related matters.
- To participate in continuing education activities in biomedical ethics and biomedical research.
- To provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat.
- To provide an updated CV when requested for by the IEC secretariat.
- To carry out the work delegated by Chairperson and Member-secretary.
- To assist Chairperson and Member-secretary in carrying out IEC work as per SOPs.

5.13.5 Roles and Responsibilities of IEC member appointed as Lay person:

- To attend IEC meetings and participate in discussions and deliberations so that appropriate decisions can be arrived at.
- To review, discuss and consider research Proposals submitted for evaluation.
- Ethical review of the proposal, ICD along with the translations, to assess impact on community involvement, socio–cultural context, religious or philosophical context, if any. To serve as a patient/participant/ societal / community representative and bring in ethical and societal concerns.
- To monitor Serious Adverse Event reports and recommend appropriate action(s).
- To review the progress reports and monitor ongoing studies as appropriate.
- To evaluate final reports and outcomes.
- To Review medical care, facility and appropriateness of the principal investigator, provision for Medical care, management and compensation.

- Thorough review of protocol, investigators brochure (if applicable) and all other protocol details and submitted documents.
- To perform the task of site monitoring.
- To maintain confidentiality of the documents and deliberations of IEC meetings.
- To declare any conflict of interest.
- To sign the Confidentiality/Conflict of Interest Agreements regarding meeting, deliberations, applications, information on research participation, and related matters.
- To participate in continuing education activities in biomedical ethics and biomedical research.
- To provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat.
- To provide an updated CV when requested for by the IEC secretariat.
- To carry out the work delegated by Chairperson and Member-secretary.
- To assist Chairperson and Member-secretary in carrying out IEC work as per SOPs.

5.13.6 All the duties mentioned in the section 5.11 to 5.13.5 will be considered as Term of Reference (TOR) while appointing the IEC members.

5.14 Quorum Requirements

- The full board meeting will be held as scheduled provided there is quorum.
  a) For the regulatory and academic clinical trials, a quorum will consist of at least 5 members; one basic medical scientist (preferably one pharmacologist), one clinician, one legal expert, one social scientist/representatives of non-governmental voluntary agency/Philosopher/ethicist/theologian or a similar person, one Lay person from the community). The quorum for reviewing regulatory clinical trials should be in accordance with current CDSCO requirements.
  b) For Biomedical and Health Research (BHR) A minimum of five members present in the meeting room, The quorum should include both medical, non-medical or technical or/and non-technical members.* Minimum one non-affiliated member should be part of the quorum, Preferably the lay person should be part of the quorum.
  **Medical members are clinicians with appropriate medical qualifications. Technical members are persons with qualifications related to a particular branch in which the study is conducted, for example social sciences.*
  c) No decision is valid without fulfillment of the quorum.

5.15 Honorarium to the Members subject experts if invited

Reimbursement of traveling expense, honorarium for attending the IEC meetings and /or honoraria may be given to the IEC members/ office bearers/ subject experts if invited for meeting and any other person authorized by the IEC.

5.16 Responsibilities of the Institutional Ethics Committee

- The Committee's primary responsibilities will be protection of safety, rights and confidentiality of the research participants.
- The Committee will keep all information submitted to them confidential specially the proprietary information.
- The Committee will maintain concise but clear documentations of its views on the research proposal.
- The Committee will review the progress of each research project at appropriate and specified intervals, but not less than once a year and will also review the final report of the studies approved by them.
- The Committee will participate in activities that promote ethical research in the institution and community.
- The Committee will participate in and organize programs aimed at educating and training community members, members of the public, investigators, IEC members in ethical research.

5.17 Assessment of IEC Member

- The Committee will carry out periodic self-assessment using the 'Assessment of Ethics Committee by the IEC member (*AX05/SOP 02/ V7*) and Self-assessment form for individual IEC members (*AX06/SOP 02/ V7*).

- All members will fill these above two annexures at six monthly intervals. The chairperson will finally confirm and sign the annexures of all the members. The findings of these annexures will be presented by the member secretary in the subsequent full board meeting.
- The corrective and preventive actions (as required) will be discussed in the full board meeting and will be implemented accordingly as out line below:
- Policy statement: A CAPA is written to identify a discrepancy or problem in the self-evaluation of ethics committee members, note the root cause of the identified problem, identify the corrective action taken to prevent recurrence of the problem, and document that the corrective action has resolved the problem.
- Procedure -
    - The problems related to evaluation of members must be brought to notice by member secretary/chairperson.
    - The Chairperson will form a team of 3 members.
    - The team formed will evaluate the magnitude of the problem and potential impact of the issue on the overall functioning of Ethics Committee
    - Describe the reason for the issue and identify the root cause of the problem.
    - Describe the procedures implemented to resolve the problem. Mention the time period required for its resolution.
    - Describe the preventive actions taken or planned.
    - After the corrective procedures are implemented, evaluation of the procedures must be made after due course and submitted by 3 membered team to Chairperson.
    - The problems related to evaluation of members, procedures implemented to resolve the problem and the corrective and preventive action will be discussed with permission of chairperson in full board.
    - The documentation with respect to problems related to evaluation of members, procedures implemented to resolve the problem and the corrective and preventive action will be maintained in separate administrative file named 'Corrective and Preventive Action'.

5.18 Prepare an annual activity report of the IEC for submission to the Head of the Institute

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

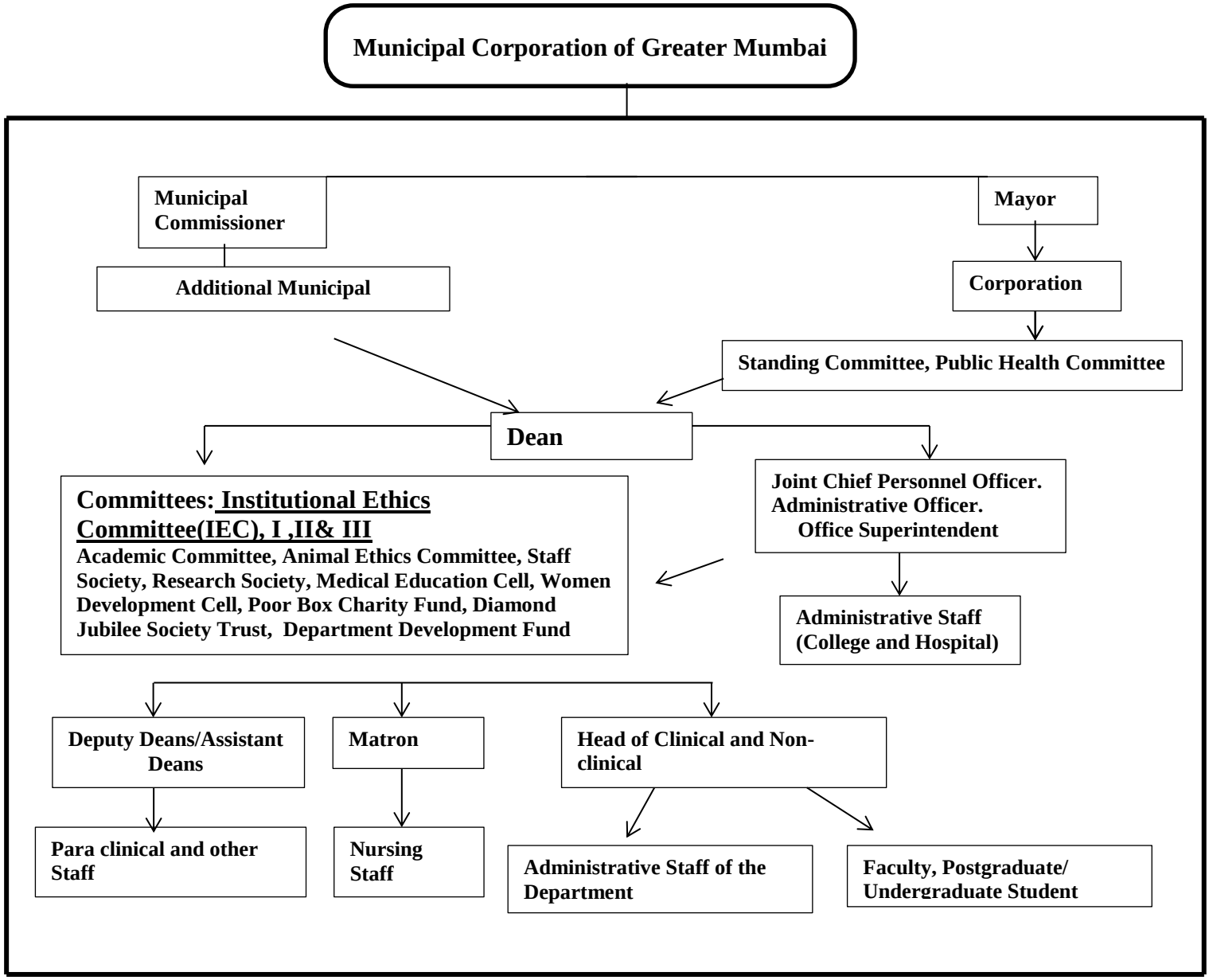
6. Glossary

Confidentiality	Prevention of disclosure, to other than authorized individuals, of IEC/ information and documents
IEC	Institutional Ethics Committee is an independent body whose responsibilities are to ensure the protection of the rights, safety and well-being of human participants involved in a clinical trial (at sites which do not have EC/EC not functional as per New Drugs and Clinical Trial Rules, 2019 and to provide public assurance of that protection).
Subject expert	Professionals with advanced training and expertise in the medical or non-medical areas related to the protocol being reviewed
Corrective and Preventive Action (CAPA) Plan:	Actions taken to collect information and identify a problem, determine root cause, identify and implement a corrective and/or preventive action to prevent further recurrence.
Root Cause:	Factor that caused a nonconformance and should be permanently eliminated through process improvement.
Root Cause Analysis:	Is a class of problem-solving methods used to identify the root causes of problems or events.
Corrective Action:	Immediate action to a problem that has already occurred or has been identified.
Preventive Action:	Taken to eliminate the root cause of a potential problem including the detection/identification of problems.

7. Annexure

Annexure 1	*AX 01/SOP 02/ V7*	Organizational Chart of the Institution
Annexure 2	*AX 02/SOP 02/V7*	Policy statement of the institution
Annexure 3	*AX 03/SOP 02/ V7*	IEC Administrative staff: Working rules
Annexure 4	*AX04/SOP02/ V7*	Finances Related to Ethics Committee Activities and Functioning
Annexure 5	*AX05/SOP 02/ V7*	Assessment of Ethics Committee by the IEC Members
Annexure 6	*AX06/SOP02/V7*	Self-Assessment Form for Members
Annexure 7	*AX07/SOP02/V7*	Template for Acceptance letter of IEC member

Annexure 1
AX 01/SOP 02/V7
Organizational Chart of the Institution



Constituting Institutional Ethics Committee

Annexure 2

AX 02/SOP 02/V7

Policy statement of the institution

(On Letter head of HOI)

Date: _____

Name of the ethics committee making this resolution
Registration number
NABH registration
Tenure of committees
Terms of resolution

The mandate will be:

a. To ensure the protection of the rights, safety and well-being of human subjects involved in a research project.
b. To provide public assurance of that protection.
c. To function independently without any interference in the review and decision-making process from the Head of the Institute and administrative department of the Institute.
d. The IEC shall adhere to existing applicable rules & regulation for its formation and functioning which includes the registration of IECs, criteria for selection, tenure, resignation, schedule of meeting, reporting to regulatory authority and other administrative process.
e. The IEC at present follow International Conference on Harmonisation – Good Clinical Practices (ICH-GCP) Guidelines (1996), Indian GCP guidelines (2001), New Drugs and Clinical Trials Rules, 2019 (NDCTR-2019) Declaration of Helsinki and the prevailing amendments from time to time), Ethical Guidelines for Biomedical Research on Human Participants by ICMR (2017)
f. The IEC will review scientific and ethical aspects any human research project in our institute and also assist the sponsors of such projects, the participants participating in them, the relevant statutory authorities, and the society at large.
g. The Committees will consist of members who collectively have the qualifications and experience to review and evaluate the scientific, medical and ethical aspects of a proposed research project. The terms of reference regarding appointment of members and schedule of meetings will be as described in the SOPs formulated by the IECs.

The list of members who will serve on the IEC with effect from_____ are as follows:

Dr. xxxx
Dean, Seth GSMC and KEMH,
Parel, Mumbai, Maharashtra, India.
Date: xxxxxx

Dr. xxxx
Academic Dean, Seth GSMC and KEMH,
Parel, Mumbai, Maharashtra, India.
Date: xxxx

Annexure 3

AX 03/SOP 02/V7

The IEC Administrative Staff: Working Rules

[1] The hierarchy of the administrative staff will be as follows:

General Manager who will overall look after the management of all three IECs and under him/her will be one deputy Manager each for IEC. For each IEC committees, there will be one executive assistant to Member secretary working under deputy Manager. One separate executive assistant will be appointed for the SAE Sub-committee. Two attendants will work for all three committees as well as SAE subcommittee, each one will be supervised by Deputy Manager. All these administrative staff will help the IEC Chairperson and Member Secretary in executing functions of the IEC. Additional staff may be appointed and duties assigned as and when deemed necessary by the IEC. The eligibility criteria for new staff to be appointed will be laid down depending on the required job profile. The decisions regarding need for appointment, eligibility criteria, job profile and remuneration will be taken by the IEC members attending a regular IEC meeting and will be recorded in minutes.

[2] The administrative staff will be appointed by conducting formal interviews (to be conducted by 2 to 3 members of the IEC, designated by the Chairperson and one teaching staff (Professor/Associate Professor / Assistant Professor) of the institution who is not affiliated to IEC).

Constituting Institutional Ethics Committee

Permission of the Diamond Jubilee Society Trust (DJST) which manages the accounts shall be sought every time a new administrative staff member is to be appointed.

[3] The terms and conditions of the appointment shall be as follows:

The appointment will be on temporary basis. A monthly stipend will be given. The amount of stipend will be decided by the IEC members. Since the posts are not Municipal Corporation of Greater Mumbai (MCGM) posts, the municipal service rules will not apply to them. The appointed staff will not get benefit of municipal employees. They will not get any preferential treatment and will not have right to the posts advertised by MCGM.

[4] Duties of the General Manager:

- Overall management of the IECs (IEC-I, IEC-II, IEC-III and SAE Subcommittee).
- Supervising the duties of the deputy Managers.
- Supervising the duties of Executive assistant to Member secretary.
- Attending the meetings of all three committees as well as SAE subcommittee.
- Maintain the attendance chart as well as an effective report of all the administrative staff monthly.
- Managing the financial expenditure of all three committees as well as SAE subcommittee and maintaining the details of the account and communication regarding the same with the DJST.
- All communication to the investigators in case of change in any policy of IEC.
- All correspondence (as per regulatory requirements) to the regulatory authorities in regards to protocol review, SAE/ compensation issue, registration / re-registration process etc.
- Overall co-ordination of the activities related to audits/registrations /accreditations /recognitions with national and international bodies.
- Confirming about the completion of the archival procedures.
- Issuing permission of retrieval of archived documents along with the Chairperson
- Confirmation that all the data (hard copy and soft copy) are maintained and are up to date.
- Managing the SOPs of the IEC, its revision as well as uploading the recent approved SOP on the institutional website as and when needed.
- Interacting with the investigators in regards to financial queries & administrative queries.
- Assisting the Chairperson/Member Secretary to reply any inquiry put forth by the regulatory authority/investigator/any person.
- Conducting self-assessment of IECs periodically with the member secretary and/or member/s of IEC
- A yearly activity report for submission to the Head of the Institute which includes:
  a) A quantitative evaluation of the activities of the committee's in a year
  b) The list of the proposals reviewed in a year with status of each study proposal
- Performance of other duties assigned by the IECs as per SOPs.

[5] Duties of the Deputy Manager/s:

- Correspondence with the IEC members and external experts
- Correspondence with the investigators (soft and hard copies).
- Arranging the IEC meetings
- Assisting in preparing agenda and minutes of the IEC meetings
- Answering queries of the investigators
- Filing study related documents
- Archiving and maintaining the study files
- Getting work done from the Executive assistants to Member Secretary.
- Keeping a track that all the soft data/soft copies are in place and complete.
- Analysis of the data if assigned by the Chairperson/Member Secretary/Committee member.
- Co-ordination of the activities related to audits/registrations /accreditations /recognitions.
- Assisting in revision of the SOPs of the IEC, as well as uploading the recent approved SOP on the institutional website as and when needed.
- Performance of other duties assigned by the Chairperson/Member Secretary/General Manager.

[6] Duties of the Executive Assistant/s to Member Secretary:

- Receiving all research proposals (hard copy as well as soft copy)
- Numbering the proposals.
- Forwarding all proposals to committee members for review.

- Establishing time limits for receipt of reviewers' comments.
- Preparation of agenda for all committee meetings.
- Inviting experts from relevant therapeutic areas to the scheduled meetings.
- Notification of review outcome to investigators of research proposals.
- Preparation and circulation of minutes (within 14 working days of the meeting).
- Reviewing project related correspondence submitted by the investigators to the IEC.
- Retention and safekeeping of all records and documentation.
- Updating of the soft copies and the soft data entry.
- Sending the reminder letters, if any.
- Co-ordination of the activities related to audits/registrations /accreditations /recognitions with national and international bodies.
- Performance of other duties assigned by the Chairperson/Member Secretary/General Manager/Deputy Manager.

[7] Duties of the (SAE) Executive Assistant/s:

- Receiving all SAE/CIOMS/SUSAR reports of ongoing studies.
- Forwarding all these documents to the Member Secretary/ subcommittee members for review.
- Establishing time limits for receipt of reviewers' comments.
- Preparation of agenda for all SAE sub-committee meetings.
- Inviting experts from relevant therapeutic areas to the scheduled meetings if required.
- Notification of review outcome to investigators.
- Preparation and circulation of SAE sub-committee minutes (within 7 days of the meeting).
- Retention and safekeeping of all records and documentation.
- Updating of the soft copies and the soft data entry.
- Sending the reminder letters, if any.
- Performance of other duties assigned by the Chairperson/Member Secretary/General Manager/Deputy Manager.

[8] Duties of the office assistant:

- Assisting the secretariat in arranging the IEC meetings
- Dispatching sets of study documents to IEC members and external experts
- Receiving the study related documents from and dispatching the IEC letters to the investigators
- Filing study related documents
- Archiving and maintaining the study files
- Correspondence with the IEC members and external experts
- Performance of other duties assigned by the Chairperson/Member Secretary/General Manager/Deputy Manager/Executive assistants.

[9] Duties of the office Attendant:

- Assistance in making arrangements for IEC meetings
- filing papers
- purchasing stationary, Xeroxing documents
- dispatching papers / projects to investigators and IEC members inside and outside institutions
- withdrawing cash/ cheques from bank
- cleaning IEC office
- Any other work assigned by Chairperson, Member secretary, Members and administrative staff.

[10] The administrative staff will report to the Chairperson and/or Member Secretary.

[11] The office timing for the General Manager will be Monday to Friday 09.30 am to 4.30 pm and Saturday 9.30 am to 1.00 pm, for the Deputy Manager and executive assistants will be Monday to Friday 9.30 am to 5.00 pm and Saturday 9.30 am to 1.30 pm. The timing for Office Attendant will be Monday to Friday 9.00 am to 5.00 pm and Saturday 9.00 am to 1.30 pm.

[12] The staff (if the contract person remains in the contract for several years) will avail 7 casual leaves and 8 medical leave in 180 days by making an application. The number of leaves granted in 180 days cannot be accumulated or carried forward to next tenure. A new staff member will be allowed to avail 6 casual leave in 180 days. Leave applications will be maintained in the personal

file of the staff members. The decision regarding granting a long leave to the staff will be taken at a regular IEC meeting by the IEC members.

[13] The pay revision will be made according to the recommendations of the IEC and DJST pay structure. The recommendations regarding pay revisions will be discussed at a regular IEC meeting and will be recorded in minutes. The final decision regarding pay revision and leaves applicable will be taken by the Diamond Jubilee Society Trust, Seth G.S. Medical College and KEM Hospital which looks after the accounts of the IEC.

[14] The duration of the contract will be 6 months, the personnel will be given a day break in contract service before the completion of the 180th day and not on the 180th day. Breaks in contract which will be LWP and there will be no reimbursement in the form of ex-gratia for the breaks in a year. Trust/ Association/ Hospital reserves the right to terminate the services at its discretion without assigning any reason. (A NOTICE PERIOD OF 30 DAYS MAY BE PROVIDED),

[15] The contract shall stand terminated automatically on the expiry of the term (duration) of the contract OR on sooner determination thereof by the Hospital / Trust / Association,

[16} The administrative staff will not receive any benefit of services such as PF, pension, gratuity, medical allowances, seniority, promotion, etc.

[17] The contract stands terminated on the date of completion of 58 years

Annexure 4
AX04/SOP02/V7
Finances Related to Ethics Committee Activities and Functioning

1. Ethics Committee Review Fees

Institutional Ethics Committee (IEC)shall charge an application fee for review of research projects. The Institute shall not charge an EC application fee.

1.1) Fee Structure:

a. The funds of the IEC are maintained in the Diamond Jubilee Society Trust (DJST) account, PAN no. AABTS5336G.
b. Payment should be done to DJST's Bank of Maharashtra only. DJST has strictly prohibited IEC transactions to their SBI account.
c. The protocol review processing fees for all type of studies will always be accepted through cheque / online.
d. If any transaction made by mistake to SBI, IEC will not be responsible for consequences.
e. No cash payment will be entertained. Don't pay cash via bank also.
f. For non-sponsored projects, detailed screen shot for payment details need to submitted to IEC and if required to DJST for cross verification (transaction ID/Reference no. etc..)
g. Transaction details (screen shot)
h. The protocol review processing fees of all types of projects will be taken by online only through following details:

Name of Account:	Seth GS Medical College & KEM Hospital, Diamond Jubilee society Trust
Account No:	60236880148
Account Type:	Saving
Name of Bank:	Bank of Maharashtra, Branch Parel
Add of Bank:	Vikas Apartment, Dr. Ambedkar Road, Parel, Mumbai, 400012.
IFSC Code:	MAHB0000079
MICR Code:	400014011
PAN No:	AABTS5336G

i. For sponsored projects fees, please note the following requirements:
   - ✓ The sponsored projects fees will be accepted by cheque / demand draft/NEFT which will include the TDS, drawn in the name of 'Diamond Jubilee Society Trust, Seth G. S. Medical College& KEM Hospital'.
   - ✓ Please note a letter from sponsor is required (on sponsors letterhead) mentioning the following details: Gross amount, TDS amount deducted and the net amount to be paid as IEC review processing fees.

1.	Payer / remitter's reference no.	
2.	Payer PAN number	
3.	Beneficiary details	
4.	Payment date	
5.	Trans currency	
6.	Payment method	
7.	Transaction reference number	
8.	Net amount	
9.	TDS	
10.	Gross amount	

- ✓ Please note if sponsor / investigator is not deducting any TDS then they have to provide a letter stating that no TDS has been deducted and actual fees of i.e. Rs. 85,000/- is being paid.

j. TDS certificate should be provided quarterly.

k. Protocol review processing fees:

	Project Types	**Initial review processing fees in INR**		**Periodic review processing fees in INR Six monthly Review**		**Annual review processing fees in INR**	
		Gross amount Less 10% TDS	**Net Amount**	Gross amount Less 10% TDS	**Net Amount**	Gross amount Less 10% TDS	**Net Amount**
1	Pharmaceuticals sponsored project	94,445/- Less 9,444.50/-	**85,000.50/-**	11,112/- Less 1,111.20/-	**10,000.80/-**	22,223/- Less 2,222.30/-	**20,000.70/-**
2	Government sponsored projects	11,112/- Less 1,111.20/-	**10,000.80/-**	2778/- Less 277.80/-	**2,500.20/-**	5,556/- Less 555.60/-	**5,000.40/-**
3	Thesis / Dissertation	Rs. 1,500/-		NA	NA	NA	NA
4	All academic non- sponsored projects (Including DNB, DM, Nursing, PhD Research)	Rs. 2,500/-		NA	NA	NA	NA
5	Funded studies	Budget ranging from 5,00,000/- to 25,00,000/- IEC charge- Rs. 10,000/- per project Above 25 lakhs for every 5,00,000/- in addition – charges are Rs.1,000/- + TDS 10%)		NA	NA	NA	NA

1) Initial submission process will be completed subject fulfillment of above payment and submission of all mandatory documents.
2) No continuation review reports will be entertained without processing fees. Study coordinators should follow deadlines strictly.
3) Processing fees will increase by 5% for each year in the month of March.
4) For international transaction as per DJST Rule
5) Budget Preparation:
   The Committee review fee should be incorporated in budgets or payment of pharmaceutical or government sponsored studies.
   a. Deposits and Accounting:

The trust maintains the funds various committees of the institute. The DJST shall maintain deposit records according to policy of DJST. Annual compiled data related to finance of IEC (account statement) shall be shared by DJST twice in a year.

b. Memorandum of Understanding:

A Memorandum of Understanding will be drafted and revised from time to time between the IEC, Diamond Jubilee Society Trust and the Institute regarding the roles and responsibilities and financial arrangements of the establishing authorities and the trust.

c. Expenditure: The expenditure will be made from DJST account towards following points-

a) Staff salary
b) Stationary expenses
c) Maintenance of IEC facility for e.g. repair work, construction, pest control, fire proofing, computers, printers etc.
d) Making resources available for office for e.g. purchase of computers, printers, scanners etc.
e) Paying fixed honorarium to external members of Rs. 1500/- for each meeting attended and for site monitoring visit.
f) SOP, GCP and regulatory training programs organized by IEC.
g) IEC members who present papers on research ethics and representing institute IEC in national/international conference.
h) Fees related to audits/registrations /accreditations /recognitions and annual review fees.

Annexure 5

AX05/SOP 02/ V7

Assessment of Ethics Committee by the Ethics Committee Members

SECTION I: ORGANIZATIONAL ASPECTS

Sr. No	Items	Yes	No	Comments (If any)
1.	Is the IEC established under the highest authority of the Institute i.e. Head of Institute and availability of documented evidence to support it?			
2.	Does the IEC have a documented policy to ensure its independency in functioning and decision making?			
3.	Does the IEC have documented evidence to confirm appointment of Chairperson and all IEC members by Head of Institute?			
4.	Does the IEC have a policy for signing Confidentiality Agreement for all members at time of appointment and documented evidence to support it?			

SECTION II: MEMBERSHIP, QUALIFICATION AND TRAINING

Sr. No	Items	Yes	No	Comments (If any)
1.	Does the current membership of IEC comply to quorum requirements as per applicable rules and regulations?			
2.	Does IEC maintain updated educational records (i.e) Curriculum Vitae, GCP Training Certificate, Medical registration certificate or any other supporting documents etc.) of all members?			
3.	Are all members of IEC trained on the SOPs on joining the IEC & subsequently as and when necessary?			

SECTION III: CONFLICT OF INTEREST

Sr. No	Items	Yes	No	Comments (If any)
1.	Does the IEC have a policy for disclosure of conflict of interest for members of the research team?			
2.	Does IEC ask all members to declare written conflict of interest at time of appointment?			
3.	Does IEC Chairperson ask all members to declare written conflict of interest for study projects to be discussed at start of every meeting?			
4.	Do the minutes reflect that members were asked whether they had a conflict of interest regarding any of the protocols to be discussed and indicate that such members did not participate in the decision making process of the relevant protocols?			

SECTION IV:INITIAL REVIEW OF PROJECTS

Sr. No	Items	Yes	No	Comments (If any)
1.	Are the New study projects submitted to IEC as per the checklist provided in IEC SOPs			
2.	Do the IEC members receive protocol and other study related documents (initial dossier) either as soft copy or hard copy in an adequate time frame prior to IEC meeting?			
3.	Does the IEC review the investigator's qualification and experience in clinical trials to conduct the study and check his/her ICH-GCP training records?			
4.	Does the IEC review adequacy of study team including the supporting staff and facilities available to conduct the study at the site?			
5.	Does the IEC perform the risk benefits assessment, evaluate the benefit against risks involved to the human subjects while participating in the research project?			
6.	Does IEC review Clinical Trial Agreement including study budget for every clinical trial?			
7.	Does the IEC consider whether the study sponsor/PI has adequate insurance to cover treatment of injury related to the study?			
8.	Does IEC review English and other vernacular informed consent documents for adequate information provided to study participants?			
9.	Does IEC confirm the presence of 24 hr contact details of Investigator in case of emergency and contact details of IEC in the Informed Consent Documents for research participants to raise any issue related to their rights, safety and integrity?			
10.	Does the IEC ensure information on management and compensation of study related injury or death occurred during study periods in Informed Consent Documents?			
11.	Does the IEC follow IEC SOP regarding the decisions for approval or disapproval for the study are made?			
12.	Does the IEC follow IEC SOP for communicating the decision regarding the study to the investigator?			
13.	Does the IEC ensure approval from regulatory body before issuing final IEC approval letter to Principal Investigator?			
14.	Does the IEC mention approval duration and timeline for submission of periodic study reports in IEC approval letter?			
15.	Does the IEC ensure final CTRI registration of Clinical trial which includes the name of PI, Site and IEC before enrollment of first subject at site?			
16.	Does the IEC follow SOPs for reviewing research projects involving vulnerable participants and request Independent subject expert opinion if required?			
17.	Does the IEC follow IEC SOP that lists conditions requiring wavier of ICF?			

SECTION V: AGENDA AND MINUTES OF MEETING

Sr. No	Items	Yes	No	Comments (If any)
1.	Does the member secretary of IEC circulate agenda prior to Full board meeting as per timeline mentioned in SOPs to all members?			
2.	Is the Required Quorum as per regulations met for all Full Board meeting conducted by IEC?			
3.	Do the Minutes cover all required deliberations mentioned in the agenda of the meeting and are the minutes of the meeting being circulated among all members for review and approval?			

SECTION VI: ONGOING REVIEW OF PROJECTS

Sr.	Items	Yes	No	Comments

No				(If any)
1.	Does the IEC review continuing review reports and study completion report submitted by Principal Investigator in Full Board meeting?			
2.	Does the IEC ensure submission of safety updates i.e. list of adverse event occurred at site along with continuing review report?			
3.	Does the IEC review Protocol deviation/Violation or non compliance submitted by PI?			
4.	Does the IEC take required action against the investigator in case of violation, deviation, non compliance or in condition where patient safety has been compromised which has been identified during continuing review process?			
5.	Does IEC provide an approval letter to PI after reviewing continuing review application form submitted by PI?			

SECTION VII: REVIEW OF SERIOUS ADVERSE EVENTS

Sr. No	Items	Yes	No	Comments (If any)
1.	Does the IEC follow strict timelines with regard to SAE Analysis (Initial and FU Review), Compensation Calculation and reporting to the licensing authority within the stipulated time?			
2.	Does the IEC check whether compensation is paid to patient and whether amount is verified by IEC?			
3.	Does the IEC verify whether adequate medical care is provided for serious adverse events as per applicable rules and regulations?			

SECTION VIII: PERIODIC MONITORING

Sr. No	Items	Yes	No	Comments (If any)
1.	Does the IEC periodically monitor ongoing research project as per procedures defined in IEC SOPs?			
2.	Are the Monitoring reports discussed in Full Board meeting and does the IEC communicate the follow up with the PI for closure of action items including preventive and corrective actions?			

SECTION IX: RESEARCH PARTICIPANT'S RIGHTS & RESPONSIBILITIES

Sr. No	Items	Yes	No	Comments (If any)
	Does the IEC ensure display of research participants rights and responsibilities at research sites and IEC office?			
	Does the IEC have a mechanism whereby enrolled research participants can file complaints or direct concerns regarding research participant's rights, safety and well being?			

SECTION X: STORAGE AND ARCHIVAL

Sr. No	Items	Yes	No	Comments (If any)
	Does the IEC store one hard copy and one soft copy of all initial documents and protocol amendments submitted to IEC of ongoing research projects in a secure and protected place?			
	Does the IEC archive documents (1 soft copy and 1 Hard copy) for at least 3 years from date of study closeout/ termination?			

SECTION XI : RESOURCES

Sr. No	Items	Yes	No	Comments (If any)
	Does the IEC have its own yearly budget including budget for training of administrative staff and IEC members?			
	Does the IEC have Full time administrative staff to manage administrative function on day to day basis?			

	Does the IEC have resources/infrastructure i.e. Separate Office room, access to a meeting room, computer and printer, documents storage areas etc.?			
Period of Assessment by IEC member		**From**_____ **to**_____		
Name, signature and date of Assessment by IEC member:				
Presented in Full Board Meeting dated				
Chairperson, Sign and Date				

Annexure 6
AX06/SOP02/V7
Self-Assessment Form for Members

1. Name of the person who is evaluated: _____
2. Number of Meeting attended out of total meetings: ☐ / ☐
3. Number of protocol reviewed as primary reviewer for full board meeting: ☐ / ☐
4. Number of initial protocol expedited: ☐ / ☐
5. Completion of required checklist: (Study Assessment form, Informed Consent Assessment Toolkit Project Risk Benefit Assessment) Yes: ☐ No: ☐
6. Attendance at training sessions organized by IEC: ☐ / ☐
7. Number of training sessions conducted by you: ☐
8. Preparedness for meetings: (Make tick (√) in the column)
Poor: ☐ Need to improve ☐ Good: ☐ Very Good ☐ Excellent ☐
9. Contribution to IEC meetings: (Make tick (√) in the column)
Poor: ☐ Need to improve ☐ Good: ☐ Very Good ☐ Excellent ☐
10. Quality of Reviews: (Make tick (√) in the column)
Poor: ☐ Need to improve ☐ Good: ☐ Very Good ☐ Excellent ☐
11. Communication with IEC staff: (Make tick (√) in the column)
Poor: ☐ Need to improve ☐ Good: ☐ Very Good ☐ Excellent ☐
12. Have you attended site monitoring - Yes: ☐ No: ☐ if yes No of site monitoring ☐

Period of Assessment by IEC member	**From**_____ **to**_____
Name, signature and date of Assessment by IEC member:	
Presented in Full Board Meeting dated	
Chairperson, Sign and Date	

Annexure 7
AX 7/SOP 02/V7
Template for Acceptance letter of IEC member

Date: xxxxxxxxxxxx
To,
xxxxxxxx,
Dean / Head of the institute,
Seth GSMC & KEMH,
Pare, Mumbai.

Ref: Email dated XXXXXXXX.
Sub: Consent to be a member of Institutional Ethics Committee-I.

Sir / Madam,
In response to your letter stated above, I give my consent to become a Member of IEC for the tenure xxxxx to xxxxx. I shall regularly participate in the IEC meetings to review and give my unbiased opinion regarding the ethical issues. I shall not keep any literature or study related documents with me after the discussion and final review. I shall maintain all the research project related information confidential and shall not reveal the same to anybody other than project related personnel.
Thanking you,
Yours Sincerely,

XXXXXX,

Constituting Institutional Ethics Committee

Title:	Confidentiality / Conflict of Interest Agreements
SOP Code:	SOP 03/V7 dated 19th November 2024

Prepared by Signature with date	Reviewed by Signature with date	Approved by Signature with date	Accepted by
19/11/24 Dr. Raakhi Tripathi, Member Secretary, IEC-I	19.11.24 Dr. Nithya Gogtay, Jt. Member Secretary, IEC-I	9/12/2024 Dr. Manju Sengar Chairperson, IEC-I	Institutional Ethics Committee (IEC-I) Established In 1985 Seth G.S. Medical College & K.E.M. Hospital Parel, Mumbai-400 012. IEC-I
	19 NOV 2024 Dr. Vyankatesh Shivane, Member, IEC-I	09/12/24 Dr. Sunil Kuyare Chairperson, IEC-II	Institutional Ethics Committee (IEC-II) Established in 1986 Seth G.S. Medical College & K.E.M. Hospital Parel, Mumbai - 400 012. IEC-II
		09/12/24 Dr. M. G. Karmarkar Chairperson, IEC-III	Institute Ethics Committee-III Established in 1986 Seth G.S. Medical College & K.E.M. Hospital Parel, Mumbai - 400 012. IEC-III

1. Purpose

The purpose of this SOP is to describe the process to identify and manage confidentiality / conflict of interest among Institutional Ethics Committee (IEC) members.

2. Scope

This SOP covers the agreements on both Confidentiality and Conflict of Interest concerning information and procedures followed by the Institutional Ethics Committee (IEC) members.

3. Responsibility

It is responsibility of each member reviewing any research project or attending members meeting to read, understand, accept and sign the agreement contained in the confidentiality/ Conflict of Interest Form. The form should be read, understood, accepted and signed by each IEC member at the beginning of the tenure of his/her membership

It is the responsibility of each and every newly-appointed members to read, understand, accept and sign the agreement contained in the Confidentiality / Conflict of Interest form before beginning ethical and/or scientific review tasks and prior to his/her attending IEC members meetings held to review research studies to protect the rights of study participants.

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

It is the responsibility of the Subject Expert to read, understand, accept and sign the agreement contained in the Confidentiality/Conflict of Interest form before beginning their ethical review tasks with the IEC and/or attending a meeting of IEC. The Secretariat will ensure that the Confidentiality /Conflict of Interest Agreement Forms are duly signed and dated by the IEC, members, Guests or observers for IEC meetings or Subject Expert prior to attending an IEC meetings, accessing ethics committee documents or undertaking review processes (as applicable) and notify to the IEC, Chairpersons. The Secretariat will file signed Confidentiality/ Conflict of Interest Agreement forms in the files entitled 'Confidentiality /Conflict of Interest Agreement Forms'

4. Activity Table:

No.	Activity	Responsibility
1.	Provide appropriate forms to IEC, member, Guest attendees, Observers, Subject Expert	IEC, Secretariat
2	Read the text carefully and thoroughly	IEC, members / guest attendees / observers / Subject Expert
3	Clarification of doubts, if any	IEC, members / guest attendees / observers / Subject Expert
4	Sign and indicate consent	IEC, members / guest attendees / observers / Subject Expert
5	Keep the agreement in mind	IEC, members / guest attendees / observers / Subject Expert

Mandate:

- GSR 227 (E). Chapter III & IV, New Drugs and Clinical Trials (NDCT), Rule 2019.dated 19th March 2019 There should be no conflict of interest. The members shall voluntarily withdraw from the Ethic committee meeting while making a decision on an application which evokes conflict of interest which may be indicated in writing to the chairman prior to the review and to be recorded so in the minutes. All members shall sign a declaration regarding conflict of interest.
- "A member must voluntarily withdraw from the ethics committee proceedings while making a decision on an application which evokes a conflict of interest which should be indicated in writing to the chairperson prior to the review and should be recorded so in the minutes. If one of the members has her/his own proposal for review, then the member should not participate when the project is discussed".

- "No Institutional Ethics Committee (IEC) may have a member participate in the ethics committee initial or continuing review of any project in which the member *has* a conflicting interest, except to provide information requested by the IEC. [45CFR 4707(e) and 21 CFR 5707(e), Sec. 5707 IEC membership".

5. Detailed instructions

5.1 Provide appropriate forms to IEC member, Guest attendees, Observers, Subject Expert.

- The appropriate Confidentiality and/ or Conflict of Interest Agreement Form will be provided to the IEC member, Guest attendee, Observer and Subject Expert.

5.2 Read the text carefully and thoroughly.

- Every member at beginning of the tenure and before he/she commences to review research projects submitted to IEC and before he/she starts to function as an IEC member and before he/she starts attending IEC meeting will read the Confidentiality /Conflict of Interest Agreement Form - *AX 01/SOP 03/ V7 and AX 02/SOP 03/V7* carefully and thoroughly.
- Every observer or guest for IEC, committee meeting: before initiating ethical review and / or before commencement of the meeting will read the Confidentiality Form *AX 03/SOP 03/V7* carefully and thoroughly
- Every observer or guest for IEC, visiting IEC office or accessing IEC documents before initiating document access or ethical review will read the Confidentiality Form *AX 04/SOP 03/V7* carefully and thoroughly
- Every Subject Expert / advisory committee/ board member before initiating ethical review and / or before commencement of IEC meeting will read the Confidentiality /Conflict of Interest Agreement Form *AX 05/SOP 03/V7* carefully and thoroughly
- IEC, committee member, Guest attendee, observer, Subject Expert advisory committee/board member will fill up the details such as name, designation and official address.

5.3 Clarification of doubts, if any.

- If any of the IEC, members/Guests /observers for IEC, meetings/ Subject Expert have any doubt, they will seek clarifications or additional information from the Secretariat. The Member Secretary will provide explanations, additional information and/ or clarifications. If any further explanations are needed, they can be provided by the Chairperson/ Legal expert/other IEC members.

5.4 Sign to indicate consent.

- The newly appointed IEC, member, before the beginning of their tenure, Guests /observers for IEC, meetings, Subject Expert / advisory committee/ board member will sign and date the document in front of the Secretariat and hand over the document to the secretariat.
- The Secretariat will obtain the signature of the IEC, Chairperson on the Confidentiality /Conflict of Interest Agreement Form.
- The IEC secretariat will provide IEC member, Guests or observers for IEC meetings, Subject Expert a photocopy of the Confidentiality/Conflict of Interest Agreement Form for their records (duly signed and dated by them and IEC, Chairperson) and acknowledge the receipt of agreement by their signature.
- The IEC Secretariat keeps the original copies of the signed Agreements at the Institutional Ethics Committee office in the files entitled 'Confidentiality/Conflict of Interest Agreement file for members, guests, observers, Subject Expert'.
- The IEC Secretariat will store the file in a secure cabinet with limited keyholders.

5.5 Keep the Agreement in mind.

- The IEC members/Guests /observers for Institutional Ethics Committee meetings/ Subject Expert /advisory committee/ board member must implement the clauses of the signed Confidentiality Agreement Form as in *AX 01/SOP 03/V7, AX 03/SOP 03/V7, AX 04/SOP 03/V7 and AX 05/SOP 03/V7 r*espectively.

6. Glossary

Confidentiality	The non-occurrence of unauthorized disclosure of information
Confidentiality Agreement	Sometimes called Secrecy or Non-disclosure agreement An agreement designed to protect trade secrets, information and expertise from being misused by those who have learned about them. The type of information that can be included under the umbrella of confidential information is virtually unlimited. Most confidentiality agreements exclude certain types of information from the definition of confidential information. It is very important that the recipient include these exceptions in the confidentiality agreement. https://www.iitm.ac.in/downloads/ICMR_Ethical_Guidelines_2017.pdf {Last accessed on 18.11.2024}
Conflict of Interest	Conflict of interest (COI) is a set of conditions where professional judgment-concerning a primary interest such as participants welfare or the validity of research tends to be unduly influenced by a secondary interest, financial or non-financial (personal, academic, institutional or political) or financial gain. [Available from https://www.iitm.ac.in/downloads/ICMR_Ethical_Guidelines_2017.pdf {Last accessed on 18.11.2024} **Types of COI** • A personal COI is said to exist when ➢ there is immediate family relationship (spouse, parent or parent of a 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 a departmental colleague/senior (may be regarded as a personal conflicting interest if applicable) • A professional COI means the IEC member or his/her immediate family member serves as trustee, director, manager, or scientific advisor 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 honoraria), equity interests (e.g., stock, stock options, or any other ownership interests) and intellectual property rights (e.g., patents, copyrights, product or service being evaluated).

7. Annexure

Annexure 1	*AX 01/SOP 03/V7*	Confidentiality Agreement Form for IEC embers
Annexure 2	AX 02/SOP 03/V7	Conflict of Interest Agreement Form for IEC Members
Annexure 2	AX 02/SOP 03/V7	Confidentiality Agreement Form For Guest / Observer Attendees to IEC meetings
Annexure 4	AX 02/SOP 03/V7	Confidentiality Agreement Form For

		Guest / Observer Attendees to IEC office / IEC documents
Annexure 5	AX 02/SOP 03/V7	Confidentiality Agreement and Conflict of Interest Agreement Form for Subject Experts/ advisory committee/ board member (Affiliated / nonaffiliated to the institution)

Annexure 1

AX 01/SOP 03/V7

Confidentiality Agreement Form for IEC Members

In recognition of the fact, that, I

_____

(*Member's name, and his/her affiliation)* herein referred to as the "undersigned", have been appointed as a member of the IEC have been asked to assess research studies involving research participants in order to ensure that they are conducted in a humane and ethical manner, adhering to the highest standards of care as per the national, and local regulations and institutional policies and guidelines and international and national guidelines;

Whereas, the appointment of the undersigned as a member of the IEC is based on individual merits and not as an advocate or representative of a home province, territory or community nor as a delegate of any organization or private interest;

Whereas, the fundamental duty of an IEC member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, 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;

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 thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the IEC. Any written information provided to the undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

As such, the undersigned agrees to hold all Confidential or Proprietary trade secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes and shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IEC.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that his/her performance of this agreement is consistent with the institute's policies and any contractual obligations they may have to third parties.

Agreement on Confidentiality

Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the IEC. A copy will be given to you for your records.

In the course of my activities as a member of the IEC, I may be provided with confidential information and documentation (which we will refer to as the Confidential Information; subject to applicable legislation, including the Access to "Confidential Information"). I agree to take reasonable measures to protect the confidential Information; not to use the Confidential Information for any purpose outside the

Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to destroy all Confidential Information (including any minutes or notes I have made as part of my duties) to the Chairperson upon termination of my functions as a Committee member.

I, (name of the member) have read and accept the aforementioned terms and conditions as explained in this Agreement.

_____ _____

Signature Date

_____ _____

Chairperson's Signature Date

I acknowledge that I have received a copy of this Agreement signed by the IEC Chairperson and me.

_____ _____

Signature Date

Annexure2

AX 02/SOP 03/V7

Conflict of Interest Agreement Form for IEC Members

It is recognized that the potential for conflict of interest will always exist but has faith in the IEC and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of research participants.

It is the policy of the IEC that no member may participate in the review, comment, or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the IEC.

The Undersigned will immediately disclose to the Chairperson of the IEC any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the Committee, and to abstain from any participation in discussions or recommendations or decision making in respect of such proposals.

If an applicant submitting a protocol believes that an IEC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the EC member(s) in question. The Committee may elect to investigate the applicant's claim of the potential conflict.

When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the IEC review or approval except to provide information requested by the Committee.

Examples of conflict of interest cases may be any of the following:

- A member is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.
- A member's personal biases may interfere with his or her impartial judgment.

Agreement on Conflict of Interest

Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the IEC. A copy will be given to you for your records.

Whenever I have a conflict of interest, I shall immediately inform the Chairperson not to count me for discussion or decision making in respect of such proposal.

I,_____ (name) have read and accept the

aforementioned terms and conditions as explained in this Agreement.

_____ _____

Signature **Date**

_____ _____

Chairperson's Signature **Date**

I acknowledge that I have received a copy of this Agreement signed by the IEC Chairperson and me.

_____ _____

Signature **Date**

Annexure 3

AX 03/SOP 03/V7

Confidentiality Agreement Form

For Guest / Observer Attendees to IEC Meetings

I, (name), understand that I am Being allowed to attend the Institutional Ethics meeting scheduled on at am/ pm as a Guest/Observer. The meeting will be conducted in the , Seth GS Medical College and KEM Hospital. In the course of the meeting of the Institutional Ethics Committee some confidential information may be disclosed or discussed. Upon signing this form, I ensure to take reasonable measures to keep the information confidential.

_____ **Signature of the Guest**	_____ **Date**
_____ **Chairperson of IEC,**	_____ **Date**

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

_____ _____

Signature of the Guest **Date**

Annexure 4

AX 04/SOP 03/V7

Confidentiality Agreement Form

For Guest / Observer Attendees to IEC office / IEC documents

I, (name), understand that I am Being allowed to attend the Institutional Ethics office from ____ to _____ a Guest/Observer. As part of the visit I will be accessing the following IEC documents:

_____

_____

In the course of the visit of the Institutional Ethics Committee some confidential information may be disclosed or discussed. Upon signing this form, I ensure to take reasonable measures to keep the information confidential.

_____ **Signature of the Guest**	_____ **Date**
_____ **Chairperson of IEC,**	_____ **Date**

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

_____ _____
Signature of the Guest **Date**

Annexure 5
AX 05/SOP 03/V7

Confidentiality Agreement and Conflict of Interest Agreement Form for Subject Experts/ advisory committee/ board member (Affiliated / non-affiliated to the institution)

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

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

Conflict of Interest (COI) Agreement Form for Subject Experts

Tick √the appropriate box for the type of COI
I hereby declare that I have no conflict of interest in the project no. EC/XXXX ☐ **OR** I hereby declare the conflict of interest for the provided project no. EC/XXXXX ☐ I am the investigator / co-investigator/protocol author/study team member for the referenced study ☐ I have financial conflict of interest ☐ If other, please specify ☐
Signature of the recipient_____ **Date** _____ **Chairperson of IEC** _____ **Date**

The IEC will send the signed copy of this agreement to me via email / hard copy.

Title:	Selection and Responsibilities of Subject expert
SOP Code:	SOP 04/V7 dated 19th November 2024

Prepared by Signature with date	Reviewed by Signature with date	Approved by Signature with date	Accepted by
Dr. Raakhi Tripathi, Member Secretary, IEC-I	Dr. Nithya Gogtay, Jt. Member Secretary, IEC-I	Dr. Manju Sengar Chairperson, IEC-I	IEC-I
	Dr. Vyankatesh Shivane, Member, IEC-I	Dr. Sunil Kuyare Chairperson, IEC-II	IEC-II
		Dr. M. G. Karmarkar Chairperson, IEC-III	IEC-III

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide procedures for Obtaining the expertise of a professional as a subject expert (either affiliated or non-affiliated) to the Institutional Ethics Committee (IEC).

2. Scope

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

3. Responsibility

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

4. Activity Table:

No.	Activity	Responsibility
1	Maintenance of a specialty-wise list/ roster of subject expert	IEC Secretariat
2	Recommendation of a name of one or more subject expert(s)	IEC Member, Member Secretary or Chairperson
3	Selection and Appointment of subject expert (s)	Chairperson
4	Co-ordination with subject expert (s) with institution for fulfilling administrative requirements	IEC Secretariat
5	Reading, understanding and signing the Conflict of Interest document and Confidentiality agreement	Subject expert, Chairperson
6	Reviewing documents pertaining to research project,	Subject expert
7	Termination of the Services	Member-Secretary/ Chairperson

5. Detailed instructions

5.1 Maintenance of a specialty-wise list/ roster of subject experts

The Secretariat will maintain and provide a specialty-wise roster of subject experts which may or may not be affiliated with the institution. The roster of subject experts maintained at the IEC office will be updated every 2- 5 years or as required (as per individual IEC policy)

5.2 Recommendation of a name of subject experts

The IEC will select a panel of subject experts from the different specialties of Medicine and the chairperson will issue an appointment letter to the subject experts.
An IEC member/ Chairperson may suggest that the opinion be sought from one or more subject experts and may suggest the name of a particular subject expert from the roster of subject experts

maintained by the IEC or from outside the roster; if during the review process of any given research project he/she is of the opinion that the project involves procedures or information that is not within the area of collective expertise of the IEC members. Subject experts may be affiliated or not affiliated to the institute.

The IEC will decide regarding the need for acquiring the services of subject experts and identify and select the subject experts to be invited from within or outside the roster of subject experts maintained by the IEC secretariat; based on area of expertise, independence and availability.

The Chairperson/ Member Secretary on behalf of the IEC will invite subject expert selected by the IEC in writing to assist in the review of the project and provide his/ her independent opinion in writing. This may be done after seeking concurrence and confirming availability of the subject expert through any mode of communication.

The Secretariat will request subject expert to declare competing interests, if any and sign a confidentiality agreement. The Secretariat may obtain and retain a copy of the updated curriculum vitae of subject expert in the IEC office for records and future reference

5.3 Selection of subject expert(s)

The final approval from the IEC Chairperson to refer the project to the specified subject expert will be taken by the Secretariat. If any IEC member disagrees with the selection of the subject expert, the procedure in 5.1 will be repeated.

5.4 Co-ordination with subject expert(s) with institution for fulfilling administrative requirements.

- The Secretariat will forward a copy of the Confidentiality Agreement and Conflict of Interest Agreements to subject experts *AX 05/SOP 03/V7* for careful reading, understanding and signing.
- The Member Secretary will provide explanations/ clarifications (telephonically or in writing) to the subject experts if any doubts or questions are raised. Any further explanations can be provided by the Chairperson/ Legal expert/ IEC members.

5.5 Reading, understanding, and signing the Conflict of Interest document and Confidentiality Agreement

- The subject expert will sign and date the Confidentiality and Conflict of Interest Agreement document.
- The Secretariat will obtain the signed Confidentiality Agreement and Conflict of Interest Agreement and forward it to Chairperson.
- The Chairperson will sign and date the Confidentiality and Conflict of Interest Agreements. The original copies of these agreements will be retained by the Secretariat and photocopies will be sent to subject expert.
- The subject expert is expected to implement the clauses of the signed Confidentiality Agreement Form *AX 05/SOP 03/V7.*

5.6 Reviewing documents pertaining to research project

- The Secretariat will provide study protocol documents along with the Study Assessment Form to the subject experts *AX 01/SOP 04/V7*, after Confidentiality and Conflict of Interest documents (*AX 05/SOP 03/V7*) have been signed by subject expert and Chairperson and received by the IEC. The subject expert will be provided with a copy of 'Guidelines for review' *AX 01/SOP 05- B/V7*. The subject expert will be requested to complete and provide the Assessment Form (duly signed and dated) to the Secretariat within a stipulated period or by a stipulated date.
- The assessment report provided by the subject expert becomes a permanent part of the study file.
- The assessment report will be reviewed in the IEC meeting when the concerned Project is being discussed.

If deemed necessary, the Chairperson or Member-secretary may seek additional information or clarifications from the subject expert in writing. Additional Information provided by the subject expert

will be considered as a part of the Assessment Report.

If deemed necessary, the Chairperson or Member-secretary may invite subject expert. The subject expert to attend an IEC meeting for providing additional information or clarifications that may be sought by IEC members or Chairperson. However, the subject expert will not participate in decision making process on the project

5.7 Completion of services of subject expert

As the subject expert is appointed for a particular task or project and the services of subject expert get automatically completed once the final decision regarding the project is taken by the IEC. The IEC will approach the subject expert again in future for his/her expert advice, as he/she is a member included in the list of experts on the roster. If deemed necessary, subject expert may be reimbursed for expenses on travel, time spent, documents referred to in library/ internet, incidental expenses, etc.

6. Glossary

Subject Expert	An expert who gives advice, comments and suggestion upon review of the study protocols with affiliation/no affiliation to the institutes or investigators proposing the research protocols.

7. Annexure

Annexure 1 AX01/SOP04/V7 Study Assessment Form for subject expert

Annexure 1
AX 01/SOP 04/V7
Study Assessment Form for Subject Expert

IEC Protocol Number:	
Protocol Title:	
Comments on the protocol: -	
Comments on the Informed Consent Document:-	
Comments on any other issues/ aspects:-	
Remarks:	□□**Recommend approval** □□**Recommend approval after incorporation of changes suggested** □□**Recommend disapproval (Please state Reasons)** _____ □□**Any other (Please specify with reasons)**
Name of the subject expert reviewing the project: **Signature with Date:**	_____ _____

Title:	Management of Initial Protocol Submissions
SOP Code:	SOP 05-A /V7 dated 19th November 2024

Prepared by Signature with date	Reviewed by Signature with date	Approved by Signature with date	Accepted by
Dr. Raakhi Tripathi, Member Secretary, IEC-I	Dr. Nithya Gogtay, Jt. Member Secretary, IEC-I	Dr. Manju Sengar Chairperson, IEC-I	IEC-I
	Dr. Vyankatesh Shivane, Member, IEC-I	Dr. Sunil Kuyare Chairperson, IEC-II	IEC-II
		Dr. M. G. Karmarkar Chairperson, IEC-III	IEC-III

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the IEC Secretariat of the Institutional Ethics Committee (IEC) manages protocol submissions.

2. Scope

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

i. Those research protocols which fulfill the definition of clinical trial and academic clinical trial as per NDCT Rules 2019 (GSR 227-E) will be managed by the committee/s registered with CLA.
ii. Those research protocols which fulfill the definition of Biomedical and Health Research as per GSR 227-E will be managed by the committee registered with DHR.

3. Responsibility

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

4. Activity Table:

No.	Activity	Responsibility
1.	Verify the criteria of Principal Investigator (PI) as per section 5.1	IEC Secretariat
2	Receive Submitted Packages	IEC Secretariat
3	Verify submission as per checklist and forward the projects to the Member Secretary / Jt. Member secretary for screening	IEC Secretariat
4	Decision on type of review required and selection of primary reviewers a) Full Board Review (refer SOP 05-B) b) Expedited Review (refer SOP 05-C) c) Exempt from Review (refer SOP 05-D)	Member Secretary/ Jt. Member secretary
5	Allocation of protocols to member secretary for selection of Primary Reviewers (PR)	IEC Secretariat
6	Distribute submission packages to reviewers	Member Secretary

5. Detailed instructions

5.1 Verify eligibility of PI and completion of registration process:

The IEC secretariat will verify eligibility of PI by reviewing the information submitted by the PI refer Annexure 7, AX 07/SOP 05-A/V7 and satisfying the criteria to be PI for regulatory and non-regulatory studies refer section 5.1.1 and 5.1.2.

5.1.1 Criteria for Principal Investigator (PI) for both regulatory and academic clinical trials:

Principal Investigator for regulatory studies **will ALWAYS be regular/permanent faculty** of Seth GSMC & KEMH and have relevant qualification approved by Maharashtra Medical Council (except in case as mentioned below).

Principal investigator (**regular/permanent faculty** of Seth GSMC & KEMH) will have **ONLY** eight (8) regulatory trials approved by the IEC as PI and **ONLY** eight (8) regulatory trials approved by the IEC as Co-I.

With regards to exceeding this cap (applicable **ONLY for PI belonging to super specialty departments)**, contractual faculty may be made the PI as per clauses stated below:

- should have completed ONE YEAR of service in this institute and their PI ship needs to be endorsed in writing by the Head of the Department (HOD).
- HOD / regular/permanent faculty will be the CO-PI for such projects to support the contractual faculty working as PI for the given regulatory study.
- HOD / regular/permanent faculty to provide a written undertaking stating that if the contractual faculty who is working as PI of the regulatory study leaves the institute then the regulatory study will be taken up by the HOD / regular/permanent faculty as PI.
- Duly signed written undertaking from the contractual faculty which is forwarded or countersigned by permanent faculty stating that if he/she leaves the institute he/she ceases to be the PI of the project and the study / trial / project cannot be transferred outside the institute.
- The contractual faculty of super specialty department can have **ONLY** four (4) regulatory trials approved by IEC as PI and **ONLY** four (4) regulatory trials approved by the IEC as Co-I.

Responsibility of the Principal Investigator (PI): In regard to clinical research trials (regulatory trials and academic clinical trials), if an IEC approved affiliated study team member leaves the institute (anybody who resigns from KEMH, is transferred out of KEMH, or is affiliated to KEMH in some way but not on regular biometric attendance system or death of the study team member) he/she ceases to be part of the trial.
It is the responsibility of the Principal Investigator (PI) to ensure that the said person is removed from duty delegation log with immediate effect. This is to be informed to the sponsor (if applicable) and IEC. IEC will review and accord approval for the revised duty delegation. The last working day would be the end date in the duty delegation log.
All PIs should make appropriate changes in departmental clinical research SOPs pertaining to the above matter.

In case the PI leaves the department, It is duty of Head of the Department / Institution to remove the concern person's name from duty delegation log with immediate effect. If the PI is not head of the department, an undertaking from HOD would be taken. The same needs to be notified to Head of the Institution by PI and Head of the Department. IEC would like to ensure that at no point of time any trial participant is unsupervised by the study team/ Department.

5.1.2 Criteria for Principal Investigator (PI) for non-regulatory trials:

Principal Investigator for other studies/ non-regulatory studies can be regular / permanent faculty, Emeritus professor, or contractual faculty of Seth GSMC & KEMH. If the Principal investigator is an Emeritus professor or a contractual faculty of Seth GSMC & KEMH, then the Co-Principal Investigator or Co-Investigator HAS to be a regular / permanent faculty of Seth GSMC & KEMH and who will be responsible for the study oversight.

a. For resident / post graduate students, Ph.D students, MSc students, nursing students, M.Sc. Pharma Medicine (MUHS) projects, PI will be his / her guide / teacher and should be a permanent faculty of Seth GSMC & KEMH.

b. **Thesis / Dissertation of Bai Jerbai Wadia Hospital for Children and Nowrosjee Wadia Maternity Hospital.**

   Faculty from the Wadia hospital are also considered as faculty **from** Seth GSMC & KEMH. Hence faculties from Wadia can be PI for the thesis submitted by the postgraduate students of Wadia hospital, however the recruitment of patient should be from only Wadia and not from the Seth GSMC & KEMH. For dissertations from BJJWHC must be forwarded by HOD (Pediatrics) Seth GSMC.

c. **For collaborative studies** (e.g. with Government / Semi government institutes such as NIRRH, NIIH, TMH, IIT Bombay) or for studies of students from the colleges other than GSMC & KEMH, PI should be a regular / permanent faculty from Seth GSMC& KEMH.

d. If request received 'to become a Principal Investigator' by contractual Assistant Professors (speciality / super speciality)

IEC will accept the research proposals with less than minimal risk projects /retrospective/web based study/audits with contractual Assistant Professors as PI and in each protocol will need a permanent faculty as a co-investigator. It was by consensus decided that the contractual Assistant Professors should be allowed to be PI for such studies by all six members Hence the Board will have to revise the SOP as per the change.

e. **Case report and Case series** should be submitted (prior to submission to a peer reviewed journal) by the faculty of Seth GSMC & KEMH only. (for the definition of principal investigator refer SOP 5-A V7 section 5.1).

For all types of studies and for both permanent and contractual faculty as PI or Co-I to note that the study belongs to the institution and will stay with the institution whenever the contractual or permanent faculty leaves the institution. When the permanent or contractual faculty as PI or Co-I leaves the institute he / she ceases to be PI or Co-I in the project.

5.2 Receive submitted packages

IEC admin will accept the submission (one soft copy and one hard copy of the entire project with related documents), review the submission, and will perform the actions against the project submission. Upon review of submission if application is found to be complete then IEC admin will return the proposal with details of submission.

5.3 Verify submission as per checklist

5.3.1 Check and verify for submission items as per checklist

The IEC Secretariat will check the soft copy and hard copy for all types of studies for following listed annexures and documents.

- Annexures (completely filled) as applicable:

✓ Annexure 1, *AX 01/SOP 05-A/* V7 (Application Form for Initial Review for all types of trials)
✓ Annexure 2, *AX 02/SOP 05-A/* V7 (for regulatory trials / academic clinical trials)
✓ Annexure 12, AX 12/ SOP 05-A Site assessment checklist (for regulatory trials).
✓ Annexure 5, AX 05/SOP 05-A/ V7 Delegation of Responsibilities of Study team
✓ Annexure 6, AX 06/SOP 05-A/ V7 Document Receipt Form
✓ Annexure no AX01/SOP 20/V7 to AX10/SOP 20/V7 If vulnerable populations included in the research as applicable
✓ Annexure 1, AX 01/SOP 19/V7 If consent waiver is to be applied
✓ Annexure 1 AX 01/SOP 05-C/V7 if an expedited review is to be applied
✓ Annexure 1 AX 01/SOP 05-D/V7 if exempt from review is to be applied
✓ Annexure 3, *AX 03/SOP 05-A/* V7 Application Form for Human Genetics Testing Research if applicable
✓ Annexure 4, *AX 04/SOP 05-A/* V7 Application Form for Socio-Behavioural and Public Health Research if applicable

- Documents as applicable:

✓ Covering letter to Member Secretary/ Chairperson mentioning type of review requested, signed by principal investigator and forwarded by Head of the department and Collaborators if any.
✓ Protocol, to include
  a) Title of the Protocol
  b) Name and contact details of Principal Investigator
  c) Name and contact details of Sponsor /CRO/ Funding agency (if applicable)
  d) IND Number (if applicable)
  e) Abstract (summary/synopsis)
  f) Study Methodology - Type of Protocol (screening, survey, phase of clinical trial), Objectives, Inclusion/Exclusion Criteria, Withdrawal or discontinuation Criteria, Schedule and Duration of Treatment, Modes of Treatment Studied, Procedures, Activity plan / Timeline, Efficacy or Evaluation Criteria (Response/Outcome), Safety Parameters Criteria (Toxicity), Analysis (methods)
✓ Amendments to protocol (if any)

- ✓ Informed consent document in English (as per sample format in Annexure 8 AX 08/SOP 05-A/ V7)
- ✓ Informed consent document in regional languages (Hindi & Marathi)
- ✓ Back translations of Informed consent documents (for regulatory trials)
- ✓ Translation and Back translation certificate (for regulatory trials)
- ✓ Informed Consent Document (ICD) or Amendments to the Informed consent document (if any)
- ✓ Case Record Form
- ✓ Recruitment procedures: advertisement, notices, letters to participants etc (if applicable)
- ✓ Patient instruction card, identity card, diary etc. (if applicable)
- ✓ Investigator Brochure for regulatory trial / drug package insert for marketed drug
- ✓ Regulatory permissions (as applicable)
  - ➢ DCI approval
  - ➢ Investigator's Undertaking to DCI
  - ➢ FDA marketing/manufacturing license for herbal drugs
  - ➢ Health Ministry Screening Committee (HMSC) approval
  - ➢ Bhabha Atomic Research Centre (BARC) approval
  - ➢ Genetic Engineering Advisory Committee (GEAC) approval
  - ➢ Stem cell committee (ICSCR) approval
- ✓ A copy of Administrative sanction from the head of the Institution for conducting the study and for sending the samples to laboratories outside KEM Hospital.
- ✓ Departmental Review Board approval letter for Thesis / Dissertations
- ✓ Current signed and dated Brief Curriculum Vitae of all the study team members
- ✓ GCP training certificate (within 3 years) of Principal Investigator and study team members.
- ✓ MMC/State council registration certificate with validity for clinical trial team members as applicable.
- ✓ CTRI registration number / CTRI reference number (as applicable)
- ✓ Clinical Trial agreement with Sponsor, material transfer agreement (as applicable)
- ✓ Memorandum of Understanding (MOU) between collaborative institutions.
- ✓ (On Rs. 500/- stamp paper, tripartite with terms of agreements specified clearly)
- ✓ Sanction letter for central government / any funding bodies
- ✓ Entire clinical trial Insurance policy with certificate (as applicable)

- **If sponsors are unable to submit the entire insurance policy due to any reason** then they should submit an undertaking stating the following:

  Sponsor XXXX acknowledges the fact that submission of a copy of the entire Insurance Policy is one of the required documents as per Table I of Third Schedule of NDCT, Rules 2019. In line with this, the sponsor has procured insurance coverage policies and has submitted a valid insurance certificate. The sponsor is not in a position to share the entire insurance policy document due to …. reasons. Sponsor assures that a valid policy in line with Indian Insurance Regulations is available and they commit to provide complete medical management and compensation in line with applicable NDCT, Rules 2019.This undertaking must be provided on the sponsor letter head.

- ✓ Ethics Committee clearance of other centers (if applicable)

The IEC Secretariat will check if all relevant and applicable annexures and documents are in the submitted package being received at the IEC office. The correctness of the submitted package will be assessed at the time of submission by the IEC secretariat. If defects or deficiencies detected in the annexures / documents IEC secretariat will inform the trial team and request for revision of the package and its subsequent submission.

5.3.2 Complete the submission process

- **IEC Admin Review Actions**
  Upon Review of submission and if found complete then IEC Admin will send email to the PI regarding payment of protocol review processing fees (refer AX07/SOP5-A/V7section 15.1 of Guidelines for investigator) In addition the IEC admin will stamp the receiving date on the first page/last page of the covering letter and Annexure 6 *AX 06/SOP 05-A/* V7.
  The project number will be assigned by the IEC admin as per following submission types:

Pharmaceutical /CRO sponsored clinical trial	EC/PHARMA -Number 00)/ year (00)
Government sponsored clinical trial	EC/GOVT -Number (00)/ year (00)
Academic/investigator initiated clinical trial	EC/OA -Number (00)/ year (00)
Thesis /dissertation clinical trial	EC/Number (00)/ year (00)

e.g. EC/PHARMA- 01/2024 will indicate pharmaceutical / CRO sponsored study with number 01 of the year 2024.

5.3.3. Saving / Storage packages

The Administrative Officer will save the submissions which will be stored separately for IEC-I, II & III as follows:

1. External Hard disk

The submitted **hard copy** protocols and the related documents will be labeled and stored in cupboard with lock and key in separate cupboard of IEC-I, II &III.

Screening / allocation of the submitted projects to IEC-I, II & III:

- **It is the responsibility of member secretaries / Joint member secretaries to take a decision regarding the IEC review (which IEC will review which protocols as per following) within 5 working days:**
  - i) Those research protocols which fulfill the definition of clinical trial and academic clinical trial as per GSR 227-E will be managed by the committee/s registered with CLA.
  - ii) Those research protocols which fulfill the definition of Biomedical and Health Research as per GSR 227-E will be managed by the committee/s registered with DHR.
- **The secretariat will send the protocols to the member secretaries / Joint Member Secretaries for screening within 2 working days.**

Once the reply is received from Joint Member Secretaries, admin staff will save the submissions (soft and hard) which will be stored separately for IEC-I, II & III.

5.4 Decision on type of review:

Member secretary will review the protocol and related documents and will take the decision regarding the type of the review required for the particular protocol as follows:

a. Full Board Review (refer SOP 05-B/V7)
b. Expedited Review (refer SOP 05- C /V7)
c. Exempt from Review (refer SOP 05-D/ V7)

5.5 Appointment of primary reviewers

- The Member Secretary/Chairperson of respective IECs will appoint one or more primary reviewers for each project on the basis of expertise in the related field and experience. The IEC Secretariat will forward the protocol and related documents to IEC Members for initial review

6. Glossary

Clinical Trial	In relation to a new drug or investigational new drug means any systematic study of such new drug or investigational new drug in human subjects to generate data for discovering or verifying its, clinical or; pharmacological including pharmacodynamics, pharmacokinetics or; adverse effects, with the objective of determining the safety, efficacy or tolerance of such new drug or investigational new drug.
Academic Clinical Trial	A clinical trial of a drug already approved for a certain claim and initiated by any investigator, academic or research institution for a new indication or new route of administration or new dose or new dosage form, where the results of such a trial are intended to be used only for academic or research purposes and not for seeking approval of the Central Licencing Authority or regulatory authority of any country for marketing or commercial purpose;
Biomedical Health Research	Research including studies on basic, applied and operational research or clinical research, designed primarily to increase

	scientific knowledge about diseases and conditions (physical or socio-behavioral); their detection and cause; and evolving strategies for health promotion, prevention, or amelioration of disease and rehabilitation but does not include clinical trial as defined above.

(The above glossary terms are adapted from NDCT Rules 2019)

7. Annexure

Annexure 1	*AX 01/SOP 05-A/* V7	Application Form for Initial Review for all types of trials.
Annexure 2	*AX 02/SOP 05-A/* V7	Application Form for Clinical Trials
Annexure 3	*AX 03/SOP 05-A/* V7	Application Form for Human Genetics Testing Research
Annexure 4	*AX 04/SOP 05-A/* V7	Application Form for Socio-Behavioural and Public Health Research
Annexure 5	*AX 05/SOP 05-A/* V7	Delegation of Responsibilities of Study team
Annexure 6	*AX 06/SOP 05-A/* V7	Document Receipt Form
Annexure 7	*AX 07/SOP 05-A/*V7	Guidelines for Investigators
Annexure 8	*AX 08/SOP 05-A/*V7	Sample format of an Informed Consent Document
Annexure 9	*AX 09/SOP 05-A/* V7	Sample Format of an Assent to be a Participant in a Research Study (For Children between 7-18 years old) in English
Annexure 10	*AX 10/SOP 05-A/*V7	Format for submission of an Informed Consent Document for Genetic Studies
Annexure 11	*AX 11/SOP 05-A/* V7	Departmental Review Board (DRB) Guidance Document
Annexure 12	*AX 12/SOP 05-A/* V7	Site Assessment checklist

Annexure 1
AX 01/SOP 05-A/V 7
Application Form for Initial Review for all types of trials.

General Instructions:

a. Tick one or more as applicable. Mark NA if not applicable.
b. Attach additional sheets if required.
c. May select more than one option.
d. Signature of HODs of all collaborative departments is mandatory.

SECTION A- BASIC INFORMATION

1. ADMINISTRATIVE DETAILS

IEC No. of the Project:			**Submission Date:**		
a. Type of review requested:					
Exemption from Review		**Expedited Review**		**Full Committee Review**	

b. Title of the Study: ……..

……

Acronym/Short Title (If Any): …….

c. Protocol Number (If Any): …… **Version number with date:** ……

d. Details of Investigators:

	Name	**Designation & Qualifications**	**Department & Institution**

Principal Investigator			
Co-Investigator-1			
Co-Investigator-2			
Co-Investigator-3			
Co-Investigator-4			

e. Duration of the Study: ……

f. Number of study visits: ……

2. FUNDING DETAILS AND BUDGET

a. Total estimated budget for site: ……

b. Self-Funding ☐ **Institutional Funding** ☐ **Funding Agency *(Specify)*** ☐

c. Research fund will be deposited in: DJST ☐ **DDF** ☐ **Research Society** ☐ **MRU** ☐

Other ☐ **If other, please specify** ……

SECTION B- RESEARCH RELATED INFORMATION

3. OVERVIEW OF RESEARCH

a. Lay Summary (Within 300 words): ……..

……..

……..

……..

b. Type of study:

Basic Sciences	☐	Clinical	☐	Academic Clinical Trial	☐
Retrospective	☐	Epidemiological/Public Health	☐	Cross Sectional	☐
Prospective	☐	Socio-behavioural	☐	Cohort	☐
Qualitative	☐	Biological samples	☐	Systematic Review	☐
Quantitative	☐	Regulatory Clinical Trial	☐		
Mixed Method	☐	Any Other *(Specify)*	☐		

4. METHODOLOGY

a. Sample size/number of participants

KEMH …… India …… Global …… Control Group ……

Study Group ……

Justification for the sample size chosen (100 words); In Case of Qualitative study, mention the criteria used for saturation ……..

……

……..

b. Clinical: Single Centre ☐ Multicentre ☐

If Multicentre,

No. of Centres in India …….. No. of Centres Globally ……

c. Is there an external laboratory/outsourcing involved for Investigators? Yes ☐ No ☐ NA ☐

SECTION C- PARTICIPANT RELATED INFORMATION

5. RECRUITMENT AND RESEARCH PARTICIPANTS

a. Type of participants in the study:

Healthy Volunteers ☐ Patient ☐ Others ☐ ***(Specify)*** ……

Who will do the recruitment? .....

Participant recruitment methods used:

Posters/Leaflets/Letters ☐ TV/Radio ads/social media/Institution website ☐

Patients/Family/Friends visiting hospitals ☐ Telephone ☐

Others *(Specify)* ☐ ……..

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

ii. If Yes, type of vulnerable persons/special groups

Children under 18 years	☐	Pregnant or Lactating women	☐
Differently abled (Mental/Physical)	☐	Employees/Students/Nurses/Staff	☐
Elderly	☐	Institutionalized	☐
Economically and Socially Disadvantaged	☐	Refugees/Migrants/Homeless	☐
Terminally Ill (Stigmatized or Rare Diseases)	☐		
Any Other (Specify)	☐	……	

iii. Provide justification for Inclusion/Exclusion

……

……

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

……

……

c. Is there any reimbursement to the participants? Yes ☐ No ☐

If Yes, Monetary ☐ Non-monetary ☐ Provide details

……

6. BENEFITS AND RISKS

a. i. Are there any anticipated physical/social/psychological discomforts/risk to participants?

Yes ☐ No ☐

If Yes, categorized the level of risk:

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

ii. Describe the risk management strategy: ……..

……..

b. What are the potential benefits from the study?

	Yes	No	If Yes, Direct	Indirect
For the participant	☐	☐	☐	☐
For the Society/community	☐	☐	☐	☐
	☐	☐		

For Improvement in science ☐ ☐

Please describe how the benefits justify the risks ……..

……

c. Are Adverse events expected in the study? Yes ☐ No ☐ NA ☐

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

If Yes, Specify ……..

7. INFORMED CONSENT

a. Version number and date of Participant Information Sheet (PIS): ……

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

b. Type of consent planned for:

Signed Consent ☐	Verbal/Oral Consent ☐	Waiver of Consent ☐	Witnessed consent ☐
Consent from LAR ☐ (If so, specify from whom) ……..	For children <7 years parental/LAR consent ☐	Verbal assent from minor (7-12 years) along with parental consent ☐	Written assent form minor (13-18 years) along with parental consent ☐

Audio-Video Consent (AV) ☐ Others *(Specify)* ☐

……

c. Who will obtain the informed consent?

PI/Co-I ☐ Nurse/Counseller ☐ Research Staff ☐ Others *(Specify)* ☐ ……

Any tools to be used ……

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

English ☐ Local Language ☐ Others *(Specify)* ☐ ……

List the languages in which translations were done ……

If translations has not been done, please justify ……

e. Are you seeking waiver of consent? If yes, what are the reasons. Yes ☐ No ☐

……

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

Please tick in below box

Simple language		Data/Sample sharing		Compensation for study related injury	
Risks and discomforts		Need to recontact		Statement that consent is voluntary	
Alternatives to participation		Confidentiality		Commercialization/Benefit sharing	
Right to Withdraw		Storage of samples		Statement that study involves research	
Benefits		Return of research results		Use of photographs/ identifying data	
Purpose and Procedure		Payment for participation		Sponsor contact information	
Others *(Specify)*					

8. PAYMENT/COMPENSATION

a. Who will bear the costs related to participation and procedures?

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

……

b. Is there a provision for free treatment of research related injuries? Yes☐ No☐
If yes, then who will provide the treatment? ……

c. Is there a provision form compensation of research related SAE? Yes☐ No☐
If Yes, specify.
Sponsor ☐ Institutional/Corpus fund ☐ Project grant ☐ Insurance ☐

9. STORAGE AND CONFIDENTIALITY

a. Identifying Information: Study Involves samples/data *(Specify)*:
Anonymous/Unidentified ☐ Anonymized: Reversibly coded ☐ Irreversibly coded ☐ Identifiable ☐
If identifiers must be retained, what additional precautions will be taken to ensure that access is limited/data is safeguarded? (e.g. data stored in a cabinet, password protected computer etc.) ……
……

b. Who will be maintaining the data pertaining to the study? ……..

c. Where will the data be analyzed and by whom? ……..

d. For how long will the data be stored? ……

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

SECTION D- OTHER ISSUES

10. PUBLICATION, BENEFIT SHARING AND IPR ISSUES

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

b. Will you inform participants about the results of the study? Yes☐ No ☐
Are there any arrangements for continued provision of the intervention for participants, if effective, once the study has finished? Yes☐ No☐ NA ☐
If yes, describe in brief (Max 50 words) ……
……

c. Is there any plan for post research benefit sharing with participants? Yes☐ No ☐
If yes, specify ……
……

d. Is there any commercial value or a pan to patent/IPR issues? Yes☐ No☐
If yes, please provide details ……

e. Do you have any additional information to add in support of the application, which is not included elsewhere in the form? Yes☐ No ☐
If yes, please provide details ……
……..

SECTION E- DECLARATION AND CHECKLIST

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

Name of Principal Investigator (PI) **Signature with date**	
Name of Co-Investigator (Co-I)-1 **Signature with date**	
Name of Co-Investigator (Co-I)-2 **Signature with date**	
Name of Co-Investigator (Co-I)-3 **Signature with date**	
Name of Co-Investigator (Co-I)-4 **Signature with date**	

12. CHECKLIST

Sr. No.	Items	Yes	No	NA	Enclosure No.	EC Remarks (If applicable)
ADMINISTRATIVE REQUIREMENTS						
1.	Cover Letter	☐	☐	☐		
2.	Brief CV of all Investigators	☐	☐	☐		
3.	Good Clinical Practice (GCP) training of Investigators in the last 3 years.	☐	☐	☐		
4.	EC clearance of other centres	☐	☐	☐		
5.	Agreement between collaborating partners	☐	☐	☐		
6.	MTA between collaborating partners	☐	☐	☐		
7.	Insurance policy/certificate	☐	☐	☐		
8.	Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification	☐	☐	☐		
9.	Copy of contract or agreement signed with the sponsor or donor agency	☐	☐	☐		
10.	Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs/Regulatory authorities for proposed study (Whether in same location or elsewhere) and modification(s) to protocol	☐	☐	☐		
PROPOSAL RELATED						

11.	Copy of the detailed protocol	☐	☐	☐		
12.	Investigators Brochure (If applicable for drug/biologicals/device trails)	☐	☐	☐		
13.	Participants Information Sheet (PIS) and Participant Informed Consent Form (ICF) (English and translated) (Hindi & Marathi mandatory)	☐	☐	☐		
14.	Assent form for minors (12-18 years) (English and translated) Hindi & Marathi mandatory	☐	☐	☐		
15.	Proforma/Questionnaire/Case Record Forms (CRF)/Interview Guides/Guides for Focused Group Discussion (FGDs) (English and translated)	☐	☐	☐		
16.	Advertisement/material to recruit participants (Filters, posters, etc.)	☐	☐	☐		

PERMISSION FROM GOVERNING AUTHORITIES

	Other Permissions	**Required**	**Not Required**	**Received**	**Applied DD/MM/Year**	**EC Remarks**
17.	CTRI	☐	☐	☐		
18.	DCGI	☐	☐	☐		
19.	HMSC	☐	☐	☐		
20.	RCGM	☐	☐	☐		
21.	GEAC	☐	☐	☐		
22.	BARC	☐	☐	☐		
23.	Tribal Board	☐	☐	☐		
24.	Others *(Specify)*	☐	☐	☐		

ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY

	Item	**Yes**	**No**	**NA**	**Enclosure no.**	**EC Remark**
25.						
26.						

Annexure 2

AX 02/SOP 05-A/V 7

Application Form for Clinical Trial/Academic Clinical Trial

Study Title: ……

……

Principal Investigator (Name, Designation & Affiliation): ……

……

☐ ☐

1. **Type of Clinical Trial** Regulatory Trial Academic Trial
   CTRI Registration Number: ……..
2. **If Regulatory Trial, provide status of CDSCO permission letter**
   Approved and letter attached ☐ Applied, under process ☐ Not applied (State Reason) ☐
3. **Tick all categories that apply to your trial**

Phase I	☐	Phase II	☐
Phase III	☐	Phase IV or Post Marketing Surveillance	☐
Investigational medicinal products	☐	Investigational New Drug	☐
Medical Devices	☐	New Innovative procedure	☐
Drug/Device combination	☐	Bioavailability/Bioequivalence studies	☐
Non Drug Intervention	☐	Repurposing an existing intervention	☐
Indian system of medicine (AYUSH)	☐	Others *(Specify)*	☐

   ……
4. **Trial Design of the study**

Randomized	☐	Factorial	☐
Non randomized	☐	Stratified	☐
Parallel	☐	Adaptive	☐
Cross-over	☐	Comparison trial	☐
Cluster	☐	Superiority trial	☐
Matched-pair	☐	Non-inferiority trial	☐
Others *(Specify)*	☐	Equivalence trial	☐

   ……
5. **Is there a Contract Research Organization (CRO)/Site Management Organization (SMO)/Any other agency such as public relation/human resource?** Yes ☐ No ☐
   If Yes, Name and Contact details: ……
   ……
   State how the CRO/SMO/Agency will be involved in the conduct of the trial *(Tick all that apply)*

Project management	☐	Clinical and medical monitoring	☐
Regulatory affairs	☐	Data management	☐
Statistical support	☐	Medical writing	☐
Site Management	☐	Audits, Quality Control, Quality Assurance	☐
Finance management	☐	Recruitment and training	☐
Administrative support	☐	Others *(Specify)*	☐

   ……
6. Please provide the following details about the intervention being used in the protocol.
   I. Drug/s, Device/s and/or Biologics; Yes ☐ No ☐ NA ☐
   If yes, provide regulatory approval details ……
   ……
   II. Already approved drugs or a combination of two or more drugs with new indications/change in dosage form/route of administration. Yes ☐ No ☐ NA ☐
   If yes, provide details. ……...
   ……...
   III. Provide contact details of who prepared and/or is manufacturing the drug/s, device/s and biologics.

……

……

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

……

……

7. Justify the use of the placebo and risks entailed to participants. Yes☐ No ☐ NA☐

……

……

8. Will current standard of care be provided to the control arm in the study? Yes☐ No ☐ NA☐

If No, please justify ……

……..

9. Justify any plans to withdraw standard therapy during the study. Yes☐ No ☐ NA ☐

……

……

10. Describe the rules to stop the protocol in case of any adverse events. Yes☐ No ☐ NA ☐

……

……

11. Provide details of Data and Safety Monitoring Plan. Yes☐ No ☐

……

Signature of Principal Investigator (PI) with Date:

……

Annexure 3
AX 03/SOP 05-A/V 7
Application Form for Human Genetics Testing Research

Investigator: …… **IEC No. of the Project:** ……
Study Title: ……
……
……

1. Describe the nature of genetic testing research being conducted.
   (e.g.-screening/gene therapy/newer technologies/human embryos/foetal autopsy)
   ……
   ……
   ……
2. Explain the additional safeguards provided to maintain confidentiality of data generated.
   ……
   ……
   ……
3. If there is a need to share the participants information/investigations with family/community, is it addressed in the informed consent? Yes☐ No☐ NA☐
4. If findings are to be disclosed, describe the disclosure procedures (e.g. genetic counselling)
   ……
   ……

5. Is there involvement of secondary participants? Yes ☐ No ☐ NA ☐
   If yes, will informed consent be obtained? State reasons if not. Yes ☐ No ☐ NA ☐
   ……
   ……
6. What measures are taken to minimize/mitigate/eliminate conflict of interest?
   ……
   ……
7. Is there a plan for future use of stored samples for research? Yes ☐ No ☐
   If yes, has this been addressed in the informed consent? Yes ☐ No ☐
8. Is the study a gene therapy? If yes, is there approval from local EC and DBT? Yes ☐ No ☐ NA ☐

Signature of Principal Investigator (PI) with Date: ……..

Annexure 4
AX 04/SOP 05-A/V 7
Application Form for Socio-Behavioural and Public Health Research

Investigator: …… **IEC No. of the Project:** ……
Study Title: ……
……
……

1. Data collection method used in the study
   Focus Group ☐ Questionnaire/Survey ☐ Observation ☐
   Interviews ☐ Documents and records ☐ Ethnographies/Oral history/Case Studies ☐
   Others (Specify) ☐ ……
   If it is an interview, will there be audio-video recording of participants interview? Yes ☐ No ☐
   If yes, justify the reasons and storage strategies ……
   ……
2. Type of informed consent used in the study.
   Individual consent ☐ Gate-keeper consent ☐ Community consent ☐
   Others (Specify) ☐ ……
3. Provide details of safeguards to ensure privacy and confidentiality of participants in the event of data sharing.
   ……
   ……
   ……
4. Describe strategies to manage if any patterns of behaviour of self-harm or harm to the society are identified. (e.g.: Suicide or infanticide) Yes ☐ No ☐ NA ☐
   ……
   ……
5. Are cultural norms/Social considerations/Sensitivities taken into account while designing the study and participant recruitment? Yes ☐ No ☐
6. Is there a use of an interpreter? If yes, describe the selection process. Yes ☐ No ☐ NA ☐
   ……
   ……
7. Describe any preparatory work or site preparedness for the study Yes ☐ No ☐ NA ☐
   ……
   ……
   ……
8. I. Type of risk related to procedures involved in the study
   Invasive ☐ Potentially harmful ☐ Emotionally disturbing ☐ Involving disclosures ☐
   Describe the risk minimization strategies.

……
……

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

……
……

III. Describe how do societal benefits outweigh individual harm.

……
……

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

   ……
   ……

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

    ……
    ……

Signature of Principal Investigator (PI) with Date: ……

Annexure 5
AX 05/SOP 05-A/V 7
Delegation of Responsibilities of Study Team

Date: ……
IEC No. of the Project: ……
Study Title: ……
……

Name	Role	No.
	Principal Investigator	1
	Co-Investigator	2
	Co-Investigator	3
	Co-investigator	4
	Co-Investigator	5
	Co-investigator	6
	Study co-ordinator *	7
	Study co-ordinator *	7
	Laboratory Technician	8
	Any Other Role	9
		10

* Study coordinator may preferably be a person specifically appointed for coordinating the clinical trial; other than the staff member (assistant / associate professor) (Please place tick marks against assigned duties for each member in the following table)

Code	TASKS	Role 1	Role 2	Role 3	Role 4	Role 5	Role 6	Role 7	Role 8	Role 9	Role 10
A	All relevant documents pertaining to protect blinding										
B	Research participants selection/ Screening										
C	Obtain informed consent										
D	Evaluate inclusion/ exclusion criteria										
E	Conduct the visit assessments										
F	Physical examination										
G	Complete the source documents										
H	Complete Case Record Form										
I	Final review and sign Case Record Form										
J	Collect laboratory safety test samples										
K	Processing of blood samples										
L	Preparing aliquots & keeping a track of the samples sent										
M	Review & sign of the lab reports										
N	Receive the study drug**,** document drug dispensing, storage & accountability										
O	Person to whom research participants should contact in case of adverse event										
P	Report all serious adverse events										
Q	Follow up of Serious Adverse Event										
R	Maintaining study site master file										
S	In-charge of inventory & supplies										
T	Archiving of study documents										
U	Resolution of queries										
V	Overall coordination and supervision										

Signature with date of Principal Investigator:
……

Annexure 6
AX 06/SOP 05-A/V 7
Document Receipt Form for initial review

IEC No. of the Project:		**Project Submitted date:**
Project Title		
Principal Investigator		
Department		
Communication with the IEC	E-mail address: Phone No.:	
For office use only		
Documents submitted	☐ Complete ☐ **I**ncomplete, will submit on……..	
Documents to be submitted later	☐ final signed clinical trial agreement with final budget allocation ☐ informed consent form (Local 3rd Vernacular language) ☐ DCGI ☐ CTRI ☐ Other sites EC permission ☐ Others……	Check what documents are received later on. ☐ final signed clinical trial agreement with final budget allocation ☐ informed consent form (Local 3rd Vernacular language) ☐ DCGI ☐ CTRI ☐Other sites EC permission ☐ Others……
Received by (Name and signature with date)		

Current Contact Details:

Institutional Ethics Committee (IEC), New UG/PG Hostel, 20th Storey Hostel Building, Ground Floor, KEM Hospital Campus, Near Main Boy's Hostel, Parel, Mumbai-400 012.

Contact No.: +91 87792 21293, 022 2410 7515

Email IDs: iec-1@kem.edu, iec-2@kem.edu, iec-3@kem.edu

Annexure 7
AX 07/SOP 05-A/V7
Guidelines for Investigators

1. All the studies satisfying the following definitions as per NDCT Rules 2019 need to be submitted for the Institutional Ethics Committees review:
   - Clinical Trial: (Regulatory trial).
   - Academic clinical trial

- Bio medical and health research (Non-regulatory trial).

As per the above definitions an Investigator planning to conduct a research study involving human participants; **funded by Government agencies and Pharmaceutical companies** at Seth G.S. Medical College & K.E.M. Hospital will need an approval by the **Institutional Ethics Committee (IEC)** before commencing a study.

Research studies which are undertaken as **dissertation projects** (postgraduate students: MD, MS, MCh, DM, DNB, PhD, MSc, MPTh, MOTh, Nursing), **research projects of undergraduate students** (Indian Council for Medical research studentship) and **investigator initiated** research studies which are **self funded / intra or extra mural funded** will need an approval by the **Institutional Ethics Committee (IEC)** before commencing a study.

2. Those research protocols which fulfill the definition of clinical trial and academic clinical trial as per NDCT Rules 2019 (GSR 227-E) will be managed by the committee/s registered with CLA (IEC-I).

3. Those research protocols which fulfill the definition of Biomedical and Health Research as per GSR 227-E will be managed by the committee registered with DHR (IEC-II & IEC-III).

4. Criteria for Principal investigator of regulatory and non regulatory trials:

- **Criteria for Principal Investigator (PI) of regulatory and academic clinical trials:**

Principal Investigator for regulatory studies **will ALWAYS be regular/permanent faculty** of Seth GSMC & KEMH and have relevant qualification approved by Maharashtra Medical Council (except in case as mentioned below).

Principal investigator (**regular/permanent faculty** of Seth GSMC & KEMH) will have **ONLY** eight (8) regulatory trials approved by the IEC as PI and **ONLY** eight (8) regulatory trials approved by the IEC as Co-I.

With regards to exceeding this cap (applicable **ONLY for PI belonging to super specialty departments)**, contractual faculty may be made the PI as per clauses stated below:

- should have completed ONE YEAR of service in this institute and this needs to be endorsed in writing by the HOD.
- HOD / regular/permanent faculty will be the CO-PI for such projects to support the contractual faculty working as PI for the given regulatory study.
- HOD / regular/permanent faculty to provide an undertaking stating that if the contractual faculty who is working as PI of the regulatory study leaves the institute then the regulatory study will be taken up by the HOD / regular/permanent faculty as PI.
- Duly signed undertaking from the contractual faculty which is forwarded or countersigned by permanent faculty stating that if he/she leaves the institute he/she ceases to be the PI of the project and the project cannot be transferred outside the institute.
- The contractual faculty of super specialty department can have **ONLY** four (4) regulatory trials approved by IEC as PI and **ONLY** four (4) regulatory trials approved by the IEC as Co-I.

Responsibility of the Principal Investigator (PI): In regard to clinical research trials (regulatory trials and academic clinical trials), if an IEC approved affiliated study team member leaves the institute (anybody who resigns from KEMH, is transferred out of KEMH, or is affiliated to KEMH in some way but not on regular biometric attendance system or death of the study team member) he/she ceases to be part of the trial.

It is the responsibility of the Principal Investigator (PI) to ensure that the said person is removed from duty delegation log with immediate effect. This is to be informed to the sponsor (if applicable) and IEC. IEC will review and accord approval for the revised duty delegation. The last working day would be the end date in the duty delegation log.

All PIs should make appropriate changes in departmental clinical research SOPs pertaining to the above matter.

In case the PI leaves the department, It is duty of Head of the Department / Institution to remove the concern person's name from duty delegation log with immediate effect. If the PI is not head of the department, an undertaking from HOD would be taken. The same needs to be notified to Head of the

Institution by PI and Head of the Department. IEC would like to ensure that at no point of time any trial participant is unsupervised by the study team/ Department.

- **Criteria for Principal Investigator (PI) of non-regulatory trials:**

Principal Investigator for other studies/ non-regulatory studies can be regular / permanent faculty, Emeritus professor, or contractual faculty of Seth GSMC & KEMH. If the Principal investigator is an Emeritus professor or a contractual faculty of Seth GSMC & KEMH, then the Co-Principal Investigator or Co-Investigator HAS to be a regular / permanent faculty of Seth GSMC & KEMH and who will be responsible for the study oversight.

a. For resident / post graduate students, Ph.D students, MSc students, nursing students, M.Sc. Pharma Medicine (MUHS) projects, PI will be his / her guide / teacher and should be a permanent faculty of Seth GSMC & KEMH.

b. Thesis / Dissertation of Wadia Maternity and Paediatrics
Faculty from the Wadia hospital are also considered as faculty **from** Seth GSMC & KEMH. Hence faculties from Wadia can be PI for the thesis submitted by the postgraduate students of Wadia hospital, however the recruitment of patient should be from only Wadia and not from the Seth GSMC & KEMH. For dissertations from BJJWHC must be forwarded by HOD (Pediatrics) Seth GSMC.

c. For collaborative studies with NIRRH, NIIH, TMH, IIT Bombay or for studies of nursing students from the colleges other than GSMC & KEMH, PI should be a regular / permanent faculty from Seth GSMC& KEMH.

d. If request received 'to become a Principal Investigator' by contractual Assistant Professors (speciality / super speciality)

e. IEC will accept the research proposals with less than minimal risk projects /retrospective/web based study/audits with contractual Assistant Professors as PI and in each protocol will need a permanent faculty as a co-investigator. It was by consensus decided that the contractual Assistant Professors should be allowed to be PI for such studies by all six members Hence the Board will have to revise the SOP as per the change.

- **Case report and Case series should be submitted by the faculty** (as per criteria for Principal Investigator mentioned above) **of Seth GSMC & KEMH only.**

For all types of studies and for both permanent and contractual faculty as PI or Co-I to note that the study belongs to the institution and will stay with the institution whenever the contractual or permanent faculty leaves the institution. When the permanent or contractual faculty as PI or Co-I leaves the institute he / she ceases to be PI or Co-I in the project.

5. Location and Office Address:
Institutional Ethics Committee (IEC),
New UG/PG Hostel, 20 Storey hostel building, ground floor, KEM Hospital Campus, near main boy's hostel, Parel, Mumbai 400 012. Telephone no. (GSMC and KEMH): 91 22 410 7000 Ext. 7515, 24107515, 24122188, Email: iec-1@kem.edu iec-2@kem.edu and iec-3@kem.edu
The IEC office hours for submission of documents, enquiries and telephonic communication with the IEC staff are as follows:
Monday to Friday - 1.30 p.m. to 4.30 p.m.
Saturday - 10.30 a.m. to 01.00 p.m.
The office will remain closed on Sundays, all public holidays and last working day of every month.

6. There will be no meetings held in the month of May and November (during college vacations) except during emergency and epidemics/pandemics. In case a meeting is to be held during vacation due to unavoidable reasons, the decision will be taken by the Member Secretary in consultation with Chairperson.

7. The clinical trial (Any investigation in human research participants intended to discover or verify the clinical, pharmacological, and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy [ICH-GCP]) must be registered with the Clinical Trial Registry of India (CTRI) or any other WHO platform registry and a copy of the documentation of registration must be provided at the time of submission of a new study proposal for review.

8. General responsibilities of PI and Co-PI
   - **MMC/State Medical Registration council:**
     Investigators involved in the trial are competent having a valid medical degree registered with the Medical Council of India (MCI) / State Medical Council or a dental degree registered with the Dental Council of India / State Dental Councils or OTPT COUNCIL
   - **Updated and signed CVs:**
     Investigators responsible for conduct of clinical trials are adequately qualified, experience.
   - **GCP:**
     Investigators should have knowledge about clinical trial process, ethical issue and applicable rules and regulation ensuring data integrity and protection of subject rights, safety and wellbeing.
     Investigators should be GCP trained regularly at the interval of three years and GCP training certificate should be provided to the IEC at the time of submission of a new study proposal / prior to initiation as applicable.
   - **SOPs of IECs:**
     Investigators should follow documented procedure i.e. Standard Operating Procedures (SOPs) of IEC in compliance with the regulation and the approved protocol or informed consent, safety reporting management, delegation of responsibilities and training, investigational product, clinical trial documentation, record retention, archival and destruction.
   - **Trial site specific SOPs for regulatory studies:**
     Investigator should prepare site specific SOPs which should be approved by the IEC and one copy should be handed over to the IEC for its records. Site specific SOPs should also cover the following elements related to the conduct of the clinical trial.
     - Updated investigators Brochure and clinical trial oversight plan
     - Work delegation log signed by the PI
     - SOP/Policy document to ensure continuity of trial in case of staff and investigator attrition
     - Clinical trial site shall have a policy of investigators handling over the trial case he /she to leave investigator will continue to be responsible for the trial until such time another investigator takes over the trial. Authorized person from the site shall communicate with the sponsor and ethics committee if needed. There should be back up research staff to ensure that recruited subject's rights safety and wellbeing is not compromised.

9. The IEC is currently following version 7 dated 19th November 2024 of the Standard Operating Procedures (SOPs), which are individual activity based and are 25 in number. The updated SOPs are available at our website **www.kem.edu- Department – Committees and Societies - Institutional Ethics committee**

10. Project proposals submitted **on or before 20th of every month will** be taken up for discussion at the next month's IEC meeting. All proposals (all documents need to be typed on A4 size paper) need to be submitted as soft copy and one hard copy set (sponsored study preferably filed in Box File & non sponsored study in card board file) documents appropriately labelled and arranged in the file in orderly manner. The list of documents to be submitted as per SOP5-A Section 5.3.1. Incompletely filled forms / forms without signatures / proposals will not be accepted and same will be conveyed to the PI.

11. The investigator should ensure that there is an 'Ethics Section' in the protocol which is in compliance with the Indian Council for Medical research 2017 Guidelines. The section should include the following aspects:
    - A statement saying that the study will be conducted in adherence to relevant national/international laws.
    - Policy regarding autonomy (voluntariness, right to withdraw).
    - Confidentiality
    - Recruitment policy ensuring equitable enrollment.

- Protection of vulnerable participants.
- Process of obtaining informed consent.
- Policy regarding treatment of study related injury, compensation for study related injury and compensation for participation.
- Policy regarding dissemination of data, presentation of data, publication.

12. Decision on type of review:

Member secretary will review the protocol and related documents and will take the decision regarding the type of the review required for the particular protocol as follows:

- Full Board Review (refer SOP 05-B)
- Expedited Review (refer SOP 05-C)
- Exempt from Review (refer SOP 05-D)

Note: For management of initial protocol submission during epidemics/lockdown periods refer to SOP 22/V7

13. An investigator may refer to the SOP. No. 19 for 'Request for Waiver of Written Informed Consent' whenever necessary.
14. An investigator is required to refer to the format of an Informed Consent Document for genetic study whenever applicable *AX 10/SOP 05-A/*V7

15. The processing fees Details:

Institutional Ethics Committee (IEC)shall charge an application fee for review of research projects. The Institute shall not charge an EC application fee.

15.1) **Fee Structure:**

- The funds of the IEC are maintained in the Diamond Jubilee Society Trust (DJST) account, PAN no. AABTS5336G.
- Payment should be done to DJST's Bank of Maharashtra only. DJST has strictly prohibited IEC transactions to their SBI account.
- The protocol review processing fees for all type of studies will always be accepted through cheque / online.
- If any transaction made by mistake to SBI, IEC will not be responsible for consequences.
- No cash payment will be entertained. Don't pay cash via bank also.
- For non-sponsored projects, detailed screen shot for payment details need to submitted to IEC and if required to DJST for cross verification (transaction ID/Reference no. etc.)
- Transaction details (screen shot)
- The protocol review processing fees of all types of projects will be taken by online only through following details:

Name of Account:	Seth GS Medical College & KEM Hospital, Diamond Jubilee society Trust
Account No:	60236880148
Account Type:	Saving
Name of Bank:	Bank of Maharashtra, Branch Parel
Add of Bank:	Vikas Apartment, Dr. Ambedkar Road, Parel, Mumbai, 400012.
IFSC Code:	MAHB0000079
MICR Code:	400014011
PAN No:	AABTS5336G

- For sponsored projects fees, please note the following requirements:
  - ✓ The sponsored projects fees will be accepted by cheque / demand draft/NEFT which will include the TDS, drawn in the name of 'Diamond Jubilee Society Trust, Seth G. S. Medical College & KEM Hospital'.
  - ✓ Please note a letter from sponsor is required (on sponsors letterhead) mentioning the following details: Gross amount, TDS amount deducted and the net amount to be paid as IEC review processing fees.

1.	Payer / remitter's reference no.	
2.	Payer PAN number	

3.	Beneficiary details	
4.	Payment date	
5.	Trans currency	
6.	Payment method	
7.	Transaction reference number	
8.	Net amount	
9.	TDS	
10.	Gross amount	

- ✓ Please note if sponsor / investigator is not deducting any TDS then they have to provide a letter stating that no TDS has been deducted and actual fees of i.e. Rs. 85,000/- is being paid.

- TDS certificate should be provided quarterly.

- Protocol review processing fees:

	Project Types	**Initial review processing fees in INR**		**Periodic review processing fees in INR Six monthly Review**		**Annual review processing fees in INR**	
		Gross amount Less 10% TDS	**Net Amount**	Gross amount Less 10% TDS	**Net Amount**	Gross amount Less 10% TDS	**Net Amount**
1	Pharmaceuticals sponsored project	94,445/- Less 9,444.50/-	**85,000.50/-**	11,112/- Less 1,111.20/-	**10,000.80/-**	22,223/- Less 2,222.30/-	**20,000.70/-**
2	Government sponsored projects	11,112/- Less 1,111.20/-	**10,000.80/-**	2778/- Less 277.80/-	**2,500.20/-**	5,556/- Less 555.60/-	**5,000.40/-**
3	Thesis / Dissertation	Rs. 1,500/-		NA	NA	NA	NA
4	All academic non- sponsored projects (Including DNB, DM, Nursing, PhD Research)	Rs. 2,500/-		NA	NA	NA	NA
5	Funded studies	Budget ranging from 5,00,000/- to 25,00,000/- IEC charge- Rs. 10,000/- per project Above 25 lakhs for every 5,00,000/- in addition – charges are Rs.1,000/- + TDS 10%)		NA	NA	NA	NA

Initial submission process will be completed subject fulfillment of above payment and submission of all mandatory documents.

16. The research study may be self funded / intra or extra mural funded. The PI should distinguished between funding agency and sponsor. Sponsor is defined as a person, a funding agency or an institution or an organisation responsible for initiation and management of a clinical trial / clinical study.

Funding agency is defined as a person, a funding agency or an institution or an organisation who provides bulk of the funding for the trial. Money is usually like a grant for the advancement of science or for public good.

Thus, in a PI-initiated trial that is funded it is important to ensure that:

- the funding is not to obtain and / or use the data for commercial gain for the funding agency
- the funding is not to promote the product of the funding agency
- the funding agency would receive only a summary report of the trial
- the report of the trial cannot be used by the pharmaceutical industry if it is a funding agency for commercial gain; or to obtain licenses or permissions, etc.
- the funding agency will not have access to participant (anonymized) data, CRF, reports, or will not be sent samples for testing, storage, etc.
- the funding agency will not provide compensation or insurance for the trial participants or the trial. The PI will be responsible for free medical management and providing financial compensation for any trial related injury.
- the funding agency has no control on the publication of the trial by the PIs, and the PIs are not obliged to inform or share their drafts or publications with the funding agency
- if the PI discovers or invents something new with the product of the funding agency, the intellectual property rights would be with the PI and/or the institute and not the funding agency
- Funding agency may at most do a financial audit of the funding provided to the PI. But, funding agency cannot do an audit of or monitor the trial.
- Registering the trial on the CTRI website would be the responsibility of the PI or the institution, but not the funding agency.

CTA / MOU between Funder and Department conducting the study in particular should address the following clauses:

- The title must mention through whom the Institutes are a party i.e. the Head of the Institutes, and their names, and the Departments in the institutes that are involved, and the name of the PI or Co-PI , designation, etc. Please mention addresses of all the parties too.
- The MoU/CTA must state the purpose of the project/ trial, and if there are any financial transactions or payments to be made by one party to the other for the purpose of the project/ trial.
- The roles and responsibilities of each party to the MoU should be stated. It also needs to be stated who will be responsible for taking the informed consent, conduct of the trial, final report writing, etc.
- Material Transfer Agreement or clauses need to be added to the MoU/CTA or a separate agreement to be made for MTA, where samples collected by one party will be transported to another party (who will be responsible for the transport, how will it be done, who will ensure that the samples will not be adulterated or tampered with, at what temperature will they be transferred, etc.).
- It also needs to be stated that the samples sent will be anonymized by KEMH, to maintain the confidentiality of the participants.
- It needs to be stated that the tests conducted by one party on the samples shared, whether the results will be shared with KEMH. The results will be shared also needs to stated in the MoU/CTA and process of result sharing need to be specified.
- It needs to be stated in the MoU/CTA which party will take the trial insurance policy and/or pay compensation to the participants in case of any injury or adverse or serious adverse event.
- The study should be registered on the CTRI website, and which party will be responsible for the same should also be mentioned. If DCGI Permission is required for the study, it needs to be stated, and which party will be responsible for the same should be stated in the MoU/CTA.
- The parties that can publish and report the study/ trial/ project, should be stated clearly in the MoU/CTA. If permission of another party is required, then that also should be stated.
- The MoU/CTA should mention the clauses on confidentiality, not only of the product or project, but also of the data generated, and the personal information of the participants of the trial/ research/ project.
- The MoU /CTA must state that qualifications of the persons involved in the trial/ project, and that they would follow the law, rules, guidelines, etc. in relation to conducting research trials.
- There should be a clause on arbitration or amicable settlement of any disputes that may arise between the parties. The parties must try to amicably settle the dispute, however, if it remains unresolved, then a common arbitrator could be involved to resolve the dispute. If the dispute does not still get resolved, then each party to appoint an arbitrator, and agree upon a common arbitrator to resolve the disputes under the Arbitration Act, 1996. The jurisdiction of the arbitration should be Mumbai.

17. If funding is awaited: PI to notify the IEC regarding sanction and receipt of funding subsequently IEC will issue approval letter.

18. Duplicate copy of any document (for e.g. Permission letter, certificate, query letter) will be charged Rs. 250/-).

19. An investigator may be invited (telephonically/ through written communication) to the IEC meeting to discuss issues related to the study proposal.

20. For clinical study planned on an "alternative system of medicine" (Ayurveda, Homeopathy, Siddha, Unani), a Co-Investigator/ Collaborator from that system should be included in the study team. This is in accordance with the Indian Council of Medical Research 2017 guidelines.

21. An investigator is expected to submit a reply to the 1st query sent by the IEC within 180 days of date of receipt of the letter. The reply to subsequent query letters must be submitted within 60 days of receipt of the query letter. In the absence of any response, the project will be declared closed for the IEC office records. In case of any valid reason IEC must be communicated within the said period to increase the validity period. The documents for these projects will be shredded by IEC staff and same will be recorded in the log book for shredded documents as well as the master register book. The project can not be revived if the documents are shredded.

22.1 For regulatory Trial If PI fails to submit the reply to 1st query letter for the new project which is under review with IEC **within 180 days for regulatory trials:**

- Before the expiration / termination of validity of the query letter, an extension request should be submitted to IEC before the end of 180 days (are counter from the date mentioned on the query letter). If an extension request is not received in the timeline, then the project file will be shredded and declared closed for IEC records.
- If PI wishes to reply to the queries or re-opening of the trial file AFTER 180 days but within one year from the date of receipt of query letter, PI should re-submit the entire project and related documents (day 181 to day 365 from the date of the receipt of the query letter) along with 50% of the prevailing protocol review processing fees with TDS 10%. (project registration number will continue to be the same).
- If PI wishes to reply to the queries or re-opening of the trial file after 365 days, PI should re-submit the entire project and related documents along with 100% of the prevailing protocol review processing fees with TDS 10%. On resubmission the project will receive a new registration number.

22.2 For regulatory Trial If PI fails to submit the reply to 2nd / subsequent query letter within 60 days then the project will be closed and shredded off for the IEC records. If PI wishes to reply to the queries or re-opening of the trial file after 60 days, PI should re-submit the entire project and related documents along with 100% of the prevailing protocol review processing fees with TDS 10%. On resubmission the project will receive a new registration number.

23. Reply **to the query letter as provided by the PI will be subjected to review as per IEC Decision form (AX 06/ SOP 05-B/V7). If found satisfactory IEC will issue final approval for the study.** An approval will be granted for the entire duration of the study. *(***AX 07/SOP 05-B/V7),** (**AX 08/ SOP 05-B/V7**) & (**AX 09/SOP 05-B/V7**)
24. For all regulatory clinical trials it is the responsibility of the principal investigator to submit a periodic review report / continuing review report (within 1 month of the due date i.e. 5 months from the date of approval for studies which will continue beyond six months). Such periodic reports have to be submitted to IEC at six monthly intervals till the completion of the study.
25. It is the responsibility of the principal investigator / study coordinator to ensure the periodic review processing fees along with the periodic review report need to be submitted within the timelines for all regulatory and sponsored trials. The coordinators should make the appropriate invoices as per AX 07/05-A/V7 section 15.1 regarding review fees.
26. For academic / non-regulatory trials it is the responsibility of the principal investigator that 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)
    For submission of continuing review report Refer to SOP 7 /V 7

27. For submission of **Study Completion Report r**efer to SOP 8 /V7

28. **In case a study is not initiated or terminated** Refer to SOP 9 V 7

29. Agenda for the IEC meeting is prepared 3 working days in advance before the date of meeting and is sent to the IEC members at least 1-2 working days in advance. Hence, all study related documents like answers to the IEC queries and amended study related documents (Protocol, ICD, CRF and IB) received seven days before and other types of documents received 3 days before the preceding date of the meeting will be considered for the meeting. It will be deferred to the next month's meeting for discussion (**Exception -** any matter which in the opinion of the IEC secretariat has direct bearing on the safety of the research participants such as SAE report, major protocol violation).

30. Submission of Amended Protocol and Protocol Related Documents
    All amendments to the approved research proposal (only one set) should be submitted to the committee for its review no later than 7 seven days prior to the date of forthcoming meeting.
    No changes in the protocol, case record form and /or Informed Consent Document shall be initiated without prior written approval from the committee, except when necessary to eliminate immediate hazards to the research participants, or when the change(s) involve only logistical or administrative aspects of the trial (e.g. change of monitor(s), telephone number(s).
    A covering letter should be submitted mentioning reason/s for amendments and summary of changes and the amended text must be highlighted in the revised Protocol and Protocol Related Documents along with the Annexure 1 SOP6 Amendment request form.

31. Submission of Report of Protocol Deviations / Violations in the study protocol. PDs should be reported quarterly (not exceeding three months from the detection of the deviation). Please use Annexure 1 SOP 10 Deviation / Non-Compliance / Violation Record AX 01/SOP 10/V 7 for submitting report of Protocol Deviations / Non-Compliance / Violations.

32. Submission of Report of Serious Adverse Events (SAEs) Refer to SOP 11B V7 Any new information that may adversely affect the safety of the research participants or conduct of the trial should be informed to the IEC.

33. If an investigator wishes to appeal against the decision about rejection of a research proposal by the IEC, please contact the IEC and submit your appeal in writing, addressed to the IEC Chairperson with justification relevant to the issues/ objections raised by the committee within twelve (12) weeks of the receipt of the committee's decision. In absence of appeal, the project will be declared closed for the IEC office records.

34. **The following regulatory permissions will be required prior to issue of IEC approval letter.**

- **DC(I) approval**
  Studies which plan to use a new drug (as defined in NDCT Rule 2019 (GSR-227 -E) require DC(I) permission. For such studies, a copy of the permission letter issued by the DC(I) to the sponsor also needs to be submitted to the IEC. If the DC(I) permission is awaited, a letter of provisional 'approval will be issued by the IEC and the final IEC approval will be given after a copy of DC(I) permission is submitted to the IEC. No study should be initiated until the final letter of permission is issued by the IEC.
- FDA marketing/manufacturing license for Ayurvedic/ herbal formulations/ nutraceutics.
- Health Ministry Screening Committee (HMSC) approval in case a study involves collaboration with any foreign laboratory/clinic/institution
- Bhabha Atomic Research Centre (BARC) approval in case a study involves use of radioisotopes/ ionizing radiations
- Genetic Engineering Advisory Committee (GEAC) approval in case a study involves use of gene therapy.
- **Administrative sanction** from the head of the Institution should be sought by investigators
  - for studies involving collaboration with other Indian or foreign Laboratory/ Clinic/Institution.
  - For conducting the study
  - For sending the samples to laboratories outside KEM Hospital.
- to register clinical trial / academic clinical trial at www.ctri.gov.in before enrolling first patient in the study.

35. For regulatory trials PI to collect participant feedback (as per Annexure 10, AX 10/SOP 05-B/V7) from all enrolled participants during any scheduled visits (preferably this feed back may be collected during any of the initial three visits) and this duly filled feedback form to be kept in the participant file.

36. For regulatory trials PI to display patient Charter reflecting rights of the research participant in patient recruitment areas.

37. **List of forms / annexures required for submission of study related documents**
The following forms / annexures are available on the website www.kem.edu and should be used for submission of study protocol and other study related documents as per revised SOPs of the IEC:
- Project Submission Application Form for Initial Review and any additional forms as per your Research Project
- Serious Adverse Event Report Assessment Form for SAE at our site *AX 01/SOP 11-B/V7*
- Deviation/Non-Compliance/Violation Record *AX 01/SOP 10/V7*
- Continuing Review Report Form *AX 01/SOP 07/V7*
- Study Completion Report *AX 01/SOP 08/V7*
- Premature Termination Report *AX 01/SOP 09/V7*
- Document Request Form *AX 01/SOP 16/V7*
- Guidance document for Department Review Boards (*AX 11/SOP 05-A/V7)*
- AV consent checklist for participants (SOP 12, AX02/SOP12/V7)
- Common Ethic Review of Multicentre Research (SOP 21)

Initial submission of project
Sample format of covering letter by Principal Investigator (PI)
for review of pharmaceutical & GOVT sponsored / Funded studies.

1) Sample format of covering letter by Principal Investigator (PI) for initial submission of protocol review for pharmaceutical & GOVT sponsored / Funded studies.

Date:
To,
The Member Secretary,
IEC.
Sub: Submission of clinical trial / trial documents for Ethics Committee review and approval.
Ref: Protocol number XXX Version XX dated XXX entitled, "XXXXXXX".
Sir / Madam,
We are conducting a study in our department. XXX sponsor has approached us for the conduct of the abovementioned study. The study will be conducted as per the ICH-GCP, ICMR guidelines and NDCTR, 2019.

Please find enclosed the following documents for review and approval:

Sr. No.	Document title	Version no. and date
1		
2		

Also kindly note the following:

1	Co-Investigators: 1)_____ 2)_____ Clinical Research Coordinator: 1)_____ 2)_____	Signature of co-investigator
2	If PI is retired/promoted/transferred/suspended/intended to leave the institute (during study period) who will take over the responsibility of PI	
3	**Recruitment Strategy**	
	a) Word of mouth	
	b) OPD or IPD	
	c) Notices / Advertisement (English, Hindi and Marathi)	

	d) Consecutive – roll over.		
	e) Collaboration with other departments or institutes		
	f) Departmental database		
4	Collaboration department signature of HOD required if applicable		
5	Study conduct – Sponsor / CRO		
6	Funding agency		
6.a	*Intramural funding (DJST/DDF/Research Society/ any other funding body under KEMH) applied / Status		
6.b	Extramural funding (GOVT/NGO/Pharmaceutical industry/International body)		
7	Approximate budget per patient and overall budget		
8	Name & number of the Indian sites		
9	Local laboratory address (if applicable)		
10	Outside KEMH laboratory address (if applicable)		
11	Reprimanding letters from IEC in the last five years inclusive all types of studies **(**PHARMA, GOVT, OA & Thesis**)**		
12	Administrative sanction for: 1.Conducting the study: 2. Sending samples outside KEMH: 3.Collaboration with other Indian or foreign laboratory/clinic /Institution:		

Note: * Any funding from outside will not be treated as intramural funded studies.

Ongoing trial * **status as PI and as Co-I**

Sr. No.	Project no.	Title	Recruited participants	Time given by PI for the project each day

Note: * Ongoing trials i.e- Study Approved by IEC.

Status of trials which are under process as PI and as Co-I

Sr. No.	Project no.	Title	Participants to be enrolled	Time to be given by PI for the project each day

With this I would like to request you to review this project and consider for approval.
Thanking you,
Sincerely yours,

Dr. XXXXXXX **Forwarded by Head of the Department**
Principal Investigator **Seal**

[Definition of Principal investigator (PI): Refer SOP 05-A section 5.1.1 and 5.1.2.

2) <u>Sample format of covering letter by Principal Investigator (PI) for initial submission of protocol review for thesis/dissertations & investigator initiated/ Other Academic(OA) studies.</u>

Date:
To,
The Member Secretary,
IEC.
Sub: Submission of trial documents for Ethics Committee review and approval.
Ref: Protocol number XXX Version XX dated XXX entitled, “XXXXXXX”.
Sir / Madam,

I'm submitting the study entitled, "xxxxxxx". This is a dissertation topic for my post graduate student / an investigator initiated study. Requesting for review and approval as per IEC SOPs. The study will be conducted as per the ICH-GCP, ICMR guidelines and NDCTR, 2019 whichever is applicable.

Please find enclosed the following documents for review and approval:

Sr. No.	Document title	Version no. and date
1		
2		

Also kindly note the following:

1.	Co-Investigator (if applicable): 1)_____ 2)_____	Signature of Co-I	
2	If PI is retired/promoted/transferred/suspended/intended to leave the institute who will take over the responsibility of PI		
3	Recruitment Strategy	1_____ 2_____	
4	Collaboration department signature of HOD required if applicable		
5	Funding agency		
5.a	*Intramural funding (DJST/DDF/Research Society/ any other funding body under KEMH) applied / Status		
5.b	Extramural funding (GOVT/NGO/Pharmaceutical industry/International body)		
6	Approximate budget per patient and overall budget		
7	Name & number of the Indian sites (if applicable)		
9	Local laboratory address (if applicable)		
10	Outside KEMH laboratory address (if applicable)		
11	Reprimanding letters from IEC in last five years inclusive all type studies **(**PHARMA, GOVT, OA & Thesis**)**		

Note: * Any funding from outside will not be treated as intramural funded studies.

Ongoing trial status as PI and as Co-I (PHARMA, GOVT, OA & Thesis)

Sr. No.	**Project no.**	**Title**	**Recruited participants**	**Time given by PI for the project each day**

Status of trials which are in under process as PI and as Co-I (PHARMA, GOVT, OA & Thesis)

Sr. No.	**Project no.**	**Title**	**Participants to be enrolled**	**Time to be given by PI for the project each day**

With this I would like to request you to review this project and consider for approval.
Thanking you,
Sincerely yours,

Dr. XXXXXXXx **Forwarded by Head of the Department**
Principal Investigator **Seal**

[Definition of Principal investigator (PI): Refer SOP 05-A section 5.1.1 and 5.1.2.

CHARTER OF RIGHTS OF PARTICIPANTS IN RESEARCH

- Every participant in a research study has the right to autonomy, right to decide whether to participate in a research trial, or refuse to participate or to withdraw from it

- Every participant has a right to life and the right to health, including the right to the enjoyment of the highest attainable standard of physical and mental health
- Every participant has the right to privacy and confidentiality
- It is the privilege of the researcher to do research on the participant, and in case of any injury, adverse event, serious adverse event or death of the participant, the participant has a right to be compensated adequately
- Compensation shall be provided for physical, mental, social and other harms as decided by the regulatory authorities and research ethics committee
- The participant shall have a right to her/ his own medical records during and after the completion of research trial as well.

PROTECTION TO PARTICIPANTS

- Research must be scientifically valid and able to answer the questions it asks; subjecting the participants to risks otherwise is unjustifiable
- Research to be done only where it minimizes risks and if the potential benefits to individuals and society justify and exceed the risks
- Each participant shall be given enough information about the research such that the participant can make a voluntary, un-coerced, un-influenced decision to participate. The potential harms of the research, risks, and benefits shall be informed to the participant.
- It shall be made clear to the participant that it is a research trial and not a known or established method, therapy, etc.
- In case of children, and individuals unable to give consent themselves, informed consent shall be taken from their guardians or next friend – called as proxy consent
- Research proposals must be submitted and reviewed in advance by research ethics committees with authority to approve research trials or to disapprove trials that do not satisfy ethical norms
- Research participants can stop or withdraw from the research at anytime. No explanation should be required for their withdrawal, and the health needs of the participant shall continue to be taken care of by the hospital or doctors or research team
- Post- trial access and obligations shall be fulfilled by the sponsor of the research trial

- Any new benefits, risks, or side effects discovered during the research shall be informed to the participant by the researcher

PARTICIPANTS SHOULD AND ALSO HAVE A RIGHT TO:-

- Read, ask for a translation, interpretation of the consent form and other documents relating to the trial
- The participants have a right to ask questions, clarifications, and get their doubts cleared prior to and any time during the research trial
- The participants shall also be provided information on who will answer their queries and who they can complain to if they have a complaint or have some questions about the research trial
- Participants should weigh the risks and benefits carefully prior to consenting to enter into the research trial
- Once the participant is enrolled in the research, the participant must follow the directions for proper use, dosing and storage of any self-administered research/ trial medications, providing biological samples and preparing for tests, procedures and examinations
- The participant should follow directions for abstaining from non-study-related medications, or other contraindicated medications or procedures
- If the participant has doubts or difficulties in following or even in understanding the instructions, then the participant must not hesitate but should speak about the same to the researcher and try and resolve the problems or get clarifications
- The participant should attend to the scheduled appointments on time, and inform the researcher within a reasonable time if they need to reschedule an appointment
- The participant must report any observation or untoward event or possible side effect of the research or trial to the researcher. The researcher shall take care of the participant on observing or on reporting of any untoward event or side effect that the participant may face
- The participant must provide the updated contact information to the researcher for proper follow up
- The participant shall be given reasons as to any decision taken by the researchers to withdraw the participant from the research trial and adequate procedure for withdrawal shall be followed without any loss or damage to the participant

अनुसंधान प्रतिभागियों का अधिकार-पत्र

- अनुसंधान अध्ययन में हर प्रतिभागी को स्वायत्तता का अधिकार, यह तय करने का अधिकार है कि क्या अनुसंधान परीक्षण में भाग लेना है या भाग लेने से मना करना है या इससे वापसी करना है।
- हर प्रतिभागी को जीवन का अधिकार और स्वास्थ्य का अधिकार है, जिसमें शारीरिक और मानसिक स्वास्थ्य के उच्चतम प्राप्य मानक के उपभोग का अधिकार शामिल है।
- हर प्रतिभागी को निजता और गोपनीयता का अधिकार है।
- प्रतिभागी पर अनुसंधान करना अनुसंधानकर्ता का विशेषाधिकार है, और प्रतिभागी की किसी भी चोट, प्रतिकूल घटना, गंभीर प्रतिकूल घटना या मृत्यु की स्थिति में, प्रतिभागी को पर्याप्त रूप से क्षतिपूर्ति का अधिकार है।
- शारीरिक, मानसिक, सामाजिक और अन्य हानियों के लिए क्षतिपूर्ति प्रदान की जाएगी, जैसा कि नियामक प्राधिकरणों और अनुसंधान आचार समिति द्वारा निर्धारित किया गया है।
- साथ ही प्रतिभागी को अनुसंधान परीक्षण के दौरान और पूरा होने के बाद अपने स्वयं के चिकित्सीय अभिलेखों का भी अधिकार होगा।

प्रतिभागियों की सुरक्षा

- प्रतिभागियों को अन्यथा अनुचित जोखिम के अधीन लाते हुए; अनुसंधान को वैज्ञानिक रूप से मान्य होना चाहिए और इसके द्वारा पूछे जाने वाले प्रश्नों का उत्तर देने में सक्षम होना चाहिए।
- अनुसंधान केवल तभी किया जाएगा, जहाँ यह जोखिम कम से कम करता है और यदि लोगों और समाज को होने वाले संभावित लाभ जोखिमों को उचित ठहराते हैं और जोखिम से अधिक हैं।
- प्रत्येक प्रतिभागी को अनुसंधान के संबंध में पर्याप्त जानकारी दी जाएगी ताकि प्रतिभागी भाग लेने का ऐच्छिक, स्वैच्छिक, अप्रभावित निर्णय ले सकें। प्रतिभागियों को अनुसंधान की संभावित हानियों, जोखिमों और लाभों की सूचना दी जाएगी।
- प्रतिभागी को स्पष्ट किया जाएगा कि यह एक अनुसंधान परीक्षण है और कोई ज्ञात या स्थापित विधि, चिकित्सा, आदि नहीं है।
- बच्चों और स्वयं सहमति देने में असमर्थ व्यक्तियों की स्थिति में, सूचित सहमति उनके संरक्षकों या निकटतम मित्र से ली जाएगी - जिसे प्रतिनिधि - संबंधी सहमति कहा जाता है।
- अनुसंधान आचार समितियों द्वारा अग्रिम में अनुसंधान प्रस्ताव प्रस्तुत और समीक्षित किए जाने चाहिए जो अनुसंधान परीक्षण स्वीकृत करने या आचार-शास्त्रीय मानदंडों को पूरा नहीं करने वाले परीक्षणों को अस्वीकृत करने का प्राधिकार रखती हैं।
- अनुसंधान प्रतिभागी किसी भी समय अनुसंधान रोक सकते हैं या अनुसंधान से वापसी कर सकते हैं। उनकी वापसी के लिए कोई भी स्पष्टीकरण नहीं माँगा जाना चाहिए, और अस्पताल या चिकित्सक या अनुसंधान दल द्वारा प्रतिभागियों की स्वास्थ्य आवश्यकताओं का ध्यान रखा जाना चाहिए।
- परीक्षण उपरांत पहुँच और दायित्व अनुसंधान परीक्षण के प्रायोजक द्वारा पूरे किए जाएँगे।

- अनुसंधान के दौरान पाया जाने वाला कोई भी नया लाभ, जोखिम या दुष्प्रभाव अनुसंधानकर्ता द्वारा प्रतिभागी को सूचित किया जाएगा।

प्रतिभागियों को निम्नांकित का अधिकार होना चाहिए और है भी: -

- सहमति प्रपत्र और परीक्षण से संबंधित अन्य दस्तावेजों को पढ़ना, उनका अनुवाद प्राप्त करना, स्पष्टीकरण माँगना।
- प्रतिभागियों को अनुसंधान परीक्षण से पहले और अनुसंधान परीक्षण के दौरान किसी भी समय अपने प्रश्न पूछने, स्पष्टीकरण माँगने, और अपना संदेह दूर करवाने का अधिकार है।
- प्रतिभागियों को इस संबंध में भी जानकारी प्रदान की जाएगी कि कौन उनके प्रश्नों का उत्तर देगा और किससे वे शिकायत कर सकते हैं यदि उनकी कोई शिकायत है या अनुसंधान परीक्षण के संबंध में कुछ प्रश्न हैं।
- अनुसंधान परीक्षण में प्रवेश करने के लिए सहमति देने से पहले प्रतिभागियों को ध्यान से जोखिमों और लाभों को समझ लेना चाहिए।
- प्रतिभागी के अनुसंधान में नामांकित होने के बाद, प्रतिभागी को किसी भी स्व-प्रशासित अनुसंधान / परीक्षण दवाओं के उचित उपयोग, खुराक और भंडारण के निर्देशों का पालन करना होगा, जैविक नमूने प्रदान करना और जांचों, प्रक्रियाओं और परीक्षणों के लिए तैयारी करना होगा।
- प्रतिभागी को अध्ययन से असंबंधित दवाओं, या अन्य प्रतिदिष्ट दवाओं या प्रक्रियाओं से बचने के लिए निर्देशों का पालन करना चाहिए।
- यदि निर्देशों का पालन करने या यहाँ तक कि समझने में भी प्रतिभागी को संदेह है या कठिनाइयों का सामना करना पड़ता है, तो प्रतिभागी को संकोच नहीं करना चाहिए, बल्कि अनुसंधानकर्ता से इसके बारे में बात करना चाहिए और कोशिश करनी चाहिए और समस्याएँ हल करवाना या स्पष्टीकरण प्राप्त करना चाहिए।
- प्रतिभागी को निर्धारित समय पर उपस्थित रहना चाहिए, और यदि वे अपॉइंटमेंट फिर से तय करना चाहते है तो उन्हें अनुसंधानकर्ता को उचित समय के भीतर सूचित करना चाहिए।
- प्रतिभागी को अनुसंधानकर्ता को अनुसंधान या परीक्षण के किसी भी प्रेक्षण या प्रतिकूल घटना या संभावित दुष्प्रभाव की सूचना देनी चाहिए। किसी भी प्रतिकूल घटना या दुष्प्रभाव का प्रेक्षण करने पर या की सूचना देने पर जिसका प्रतिभागी को सामना करना पड़ सकता है, अनुसंधानकर्ता द्वारा प्रतिभागी का खयाल रखा जाएगा।
- प्रतिभागी को उचित अनुवर्तन के लिए अनुसंधानकर्ता को अद्यतन संपर्क जानकारी प्रदान करनी होगी।
- अनुसंधान परीक्षण से प्रतिभागी को वापस लेने के अनुसंधानकर्ताओं द्वारा लिए गए किसी भी निर्णय के संबंध में प्रतिभागी को कारण बताए जाएंगे और प्रतिभागी के लिए किसी भी नुकसान या क्षति के बिना वापस लेने के लिए पर्याप्त प्रक्रिया का पालन किया जाएगा।

संशोधनामधील सहभागींच्या हक्कांची सनद

- संशोधन अभ्यासामधील प्रत्येक सहभागीला स्वायत्ततेचा हक्क आहे, संशोधन परीक्षणामध्ये सहभागी व्हावे अथवा नाही हे ठरविण्याचा, किंवा सहभागी होण्यास नकार देण्याचा किंवा अभ्यासातून माघार घेण्याचा हक्क आहे.
- प्रत्येक सहभागीला शारीरिक किंवा मानसिक आरोग्याच्या सर्वोच्च साध्य दर्जाचा आनंद घेण्याच्या हक्कासह, जीवनाचा हक्क आणि आरोग्याचा हक्क आहे.

- प्रत्येक सहभागीला खाजगीपणाचा व गोपनीयतेचा हक्क आहे.
- संशोधकाला सहभागीवर संशोधन करण्याचा खास हक्क आहे, आणि सहभागीला कोणतीही इजा, प्रतिकूल घटना, गंभीर प्रतिकूल घटना उदभवण्याच्या बाबतीत किंवा सहभागीचा मृत्यू होण्याच्या बाबतीत, सहभागीला पुरेशा प्रमाणात भरपाई प्राप्त करण्याचा हक्क आहे.
- नियामक प्राधिकरणांद्वारे आणि संशोधन नीतिमत्ता समितीद्वारे ठरविण्यात आल्याप्रमाणे शारीरिक, मानसिक, सामाजिक व इतर अपायांसाठी भरपाई प्रदान करण्यात येईल.
- संशोधन परीक्षणादरम्यान आणि ते पूर्ण झाल्यानंतरही सहभागीला त्याच्या/तिच्या वैद्यकीय नोंदी पाहण्याचा हक्क आहे.

सहभागींना संरक्षण

- संशोधन हे शास्त्रीयदृष्ट्या वैध असणे आवश्यक आहे आणि त्याला त्याने विचारलेल्या प्रश्नांची उत्तरे देता यायला हवीत; हे अन्यथा सहभागींना असणारी जोखीम असमर्थनीय असण्याच्या सापेक्ष आहे.
- संशोधन जेथे जोखमी कमी करेल आणि व्यक्तींना व समाजाला असणारे संभाव्य लाभ रास्त असतील व जोखमींपेक्षा अधिक असतील तेथेच संशोधन करायचे आहे.
- सहभागीला सहभागी होण्यासाठी ऐच्छिक, बळजबरीविना, प्रभावाविना निर्णय घेता येऊ शकेल अशा प्रकारे प्रत्येक सहभागीला पुरेशी माहिती देण्यात येईल. संशोधनाचे संभाव्य अपाय, जोखमी व लाभ ह्यांविषयी सहभागीला कळविण्यात येईल.
- सहभागीला हे स्पष्ट करण्यात येईल की हे एक संशोधन परीक्षण आहे आणि ही कोणतीही ज्ञात किंवा स्थापित पद्धत, उपचारपद्धती इत्यादी नाही.
- स्वतः संमती देऊ न शकणाऱ्या मुलांच्या, आणि व्यक्तींच्या बाबतीत, त्यांच्या पालकांकडून किंवा जवळच्या मित्राकडून संमती घेण्यात येईल - ह्याला प्रतिपत्री संमती असे म्हटले जाते.
- संशोधन परीक्षणांना मंजुरी देण्यासाठी किंवा नीतिमत्ता निकषांची पूर्तता न करणाऱ्या परीक्षणांना नामंजूर करण्यासाठी अधिकारक्षम अशा संशोधन नीतिमत्ता समित्यांकडे संशोधन प्रस्ताव आधीच सादर करण्यात येणे आणि त्यांचा आढावा घेतला जाणे आवश्यक आहे.
- संशोधन सहभागी हे कोणत्याही वेळी संशोधन थांबवू शकतील किंवा संशोधनातून माघार घेऊ शकतील. त्यांच्या माघारीबाबत कोणतेही स्पष्टीकरण प्राप्त करणे आवश्यक नसेल, आणि रुग्णालयाद्वारे किंवा डॉक्टर्सद्वारे किंवा संशोधन टीमद्वारे सहभागीच्या आरोग्यविषयक गरजांची काळजी घेणे पुढे चालू ठेवल्यात येईल.
- संशोधन परीक्षणाच्या प्रायोजकांद्वारे चाचणीपश्चातच्या उपलब्धतेची व आबंधनांची पूर्तता करण्यात येईल.
- संशोधनादरम्यान शोधण्यात आलेले कोणतेही नवीन लाभ, जोखमी, किंवा आनुषंगिक परिणाम हे संशोधकांद्वारे सहभागीला कळविण्यात येतील.

सहभागीला पुढील गोष्टींसाठी हक्क असायला हवे आणि हक्कदेखील आहेत: -

- परीक्षणाशी संबंधित संमती प्रपत्राचा आणि इतर दस्तऐवजांचा अनुवाद, अर्थान्तरण वाचणे, आणि त्यासाठी विचारणा करणे.
- सहभागींना संशोधन परीक्षणाच्या आधी व संशोधन परीक्षणादरम्यान कोणत्याही वेळी प्रश्न विचारण्याचा, स्पष्टीकरणे प्राप्त करण्याचा, आणि त्यांच्या शंकाचे निरसन करून घेण्याचा हक्क आहे.
- सहभागींना संशोधन परीक्षणाविषयी काही तक्रार असल्यास किंवा काही प्रश्न असल्यास, त्यांच्या प्रश्नांची उत्तरे कोण देईल आणि ते कोणाकडे तक्रार करू शकतील ह्याबद्दल सहभागींना माहितीदेखील प्रदान करण्यात येईल.
- सहभागींनी संशोधन परीक्षणासाठी संमती देण्याआधी त्यासंबंधीच्या जोखमी व लाभ काळजीपूर्वक तोलूनमापून पाहायला हव्यात.
- सहभागी हा संशोधनामध्ये दाखल झाल्यावर, सहभागीने संशोधनविषयक/परीक्षणविषयक स्वतः घ्यावयाच्या कोणत्याही औषधोपचाराचा योग्य वापर, मात्रा व साठवण करणे, तसेच जीवशास्त्रीय नमुने गोळा करणे आणि चाचण्या, प्रक्रिया व तपासण्या ह्यांसाठी तयार राहणे ह्यासंबंधीच्या निर्देशनांचे पालन करणे आवश्यक आहे.
- सहभागीने अभ्यासाशी संबंधित नसलेले औषधोपचार, किंवा इतर प्रतिषेध औषधोपचार किंवा प्रक्रिया ह्यांपासून दूर राहण्यासाठीची निर्देशांचे पालन करायला हवे.

- सहभागीला सूचनांचे पालन करण्यामध्ये किंवा त्या समजून घेण्यामध्ये काही शंका किंवा अडचणी असल्यास, सहभागीने संकोच न करता संशोधकांशी त्याविषयी बोलायला हवे आणि समस्यांचे निवारण करण्याचा किंवा स्पष्टीकरणे प्राप्त करण्याचा प्रयत्न करावा.
- सहभागीने नियोजित भेटींसाठी वेळेवर उपस्थित राहायला हवे, आणि त्याला भेटीची पुनर्आखणी करण्याची असल्यास रास्त वेळेमध्ये संशोधकांना त्याबाबत कळवायला हवे.
- सहभागीने संशोधनसंबंधीचे किंवा परीक्षणासंबंधीचे कोणतेही निरीक्षण किंवा अनिष्ट घटना किंवा संभाव्य आनुषंगिक परिणाम ह्यांबाबत संशोधकाला कळविणे आवश्यक आहे. सहभागीला सामोरे जावे लागू शकणाऱ्या कोणत्याही अनिष्ट घटनेचे किंवा आनुषंगिक परिणामाचे निरीक्षण केल्यावर किंवा त्याबाबत कळविल्यावर संशोधक हे सहभागीची काळजी घेतील.
- योग्य पाठपुराव्यासाठी सहभागीने संशोधकाला अद्ययावत संपर्क माहिती प्रदान करणे आवश्यक आहे.
- संशोधन परीक्षणामधून सहभागीला बाहेर करण्यासंबंधी संशोधकांकडून घेण्यात आलेल्या कोणत्याही निर्णयासंबंधीचे कारणे सहभागीला कळविण्यात येतील आणि सहभागीला कोणतीही हानी किंवा नुकसान न होता अभ्यासातील माघारीसाठीच्या योग्य प्रकियेचे पालन करण्यात येईल.

Annexure 8

AX 08/SOP 05-A/V7

Sample Format of an Informed consent document in English

(This template should be customized according to the requirement of individual research project)

I Project title:

To test the efficacy and tolerability of XXXXXXXX (an antihypertensive test drug) as compared to XXXXX (a standard antihypertensive drug)

II Introduction:

You are invited to participate in a research study. It is important that you read this description of the study and understand your role in it including the nature and risks of participation.

Please give your consent to participate in this clinical study only if you have completely understood the nature and course of this study and if you are aware of your rights as a participant.

III Purpose of the study:

It is well known that people who suffer from high blood pressure are at high risk for cardiovascular disease, including heart attacks, strokes and even death. Anti-hypertensive medications are commonly prescribed to such patients to prevent the occurrence of cardiovascular events. XXXX is a new drug, which has been found to decrease the blood pressure in initial studies. The study plans to study the efficacy and safety of this drug in patients having high blood pressure.

IV Number of research participants and expected duration of each participant in the study:

You will be one of approximately XXX people who will participate in this study. You will be in the study for about XXX days. (In multicentric study, mention that the study is also being carried out at xxx other centers).

V Study procedures to be followed:

If you agree to participate in this study you will a) be asked about previous medical problems, your current health and your medications; b) have a brief physical examination (to give details); c) need to undergo baseline investigation such as XXXXXX(to give details)

The study staff will review the results of these evaluations & test. If you are eligible to participate you will be randomly assigned (like the flip of a coin) to a study group to receive one of the two study treatments.

The study would require a total of XX visits. At each visit XX ml (mention1-2 tsp/tbsp as applicable) of your blood will be withdrawn after fasting for XX hours. The blood samples that are drawn, will be used to check your blood sugar levels, kidney and liver function etc. (mention whatever is applicable).

Regardless of the group to which you have been assigned, you will return to the study centre after XXXX days / weeks / months. It is important that you bring all of your study medications, diary etc. along with you.

At each visit, a) you will be asked about your health, side effects of medications, b) your physical examination will be carried out c) you will be given a new supply of study drug.

VI Risks and discomforts of participating:

The study testing 2 different therapies in high risk people that may prevent heart attacks, strokes or death from cardiovascular causes:

Based on studies in animals and other studies with people, the drug(s) used in this study may cause some side effects. The known risks and side effects associated with the drugs proposed for use here are summarized below.

Side effects of test drug – XXXXX (Give Details) (for interventional trial)

Side effects of standard drug – XXXXX (Give Details) (for interventional trial)

Other side effects that you may experience could include injection site reactions, allergic reactions to the medication, itching rash and pain at the injection site (if the drug is to be administered parenterally). While collecting blood from your vein, you will have to undergo the discomfort of brief pain or rarely develop bruising or even a minor infection. In case this occurs appropriate management will be provided

Finally new problems or side effects other than those that have been seen before could occur during this study. You will therefore be asked about side effects at each visit. It is important that you report any of the side effects described in this form or any other ones to the study physician immediately at the numbers listed below.

Because the safety of the study drugs for an unborn fetus or newborn is unknown, if you intend to become pregnant, are pregnant or are breastfeeding you cannot participate in this study. If you are a woman who is able to have children, you will be required to undergo a urine pregnancy test. If you are no pregnant you will be asked to take precautions to prevent pregnancy until the end of the study. The doctors will discuss the contraception options with you. Pregnancy test may be repeated during the study. If you become pregnant despite these precautions you should immediately notify the study team. Pregnancy will be a reason to stop study treatment.

Any new important information that is discovered during the study and which may influence your decision to continue in the study will be provided to you or your legally acceptable representative in a timely manner. You will be told of any new risks or side effects.

VII Possible benefits of the study:

By participating in this study, you may have a possible cure or improvement in your condition. However, there is no guarantee that you will receive direct health benefit from being in this study your participation in this study may provide information that may in the future help other patients suffering from high blood pressure.

VIII What happens when the research trials stops?

Because this is a research trial, the test drug will not be available at the end of this trial for treatment of this disease. Alternate therapy, if appropriate, will be provided once the trial is finished. Occasionally the funding agency sponsoring the research may stop the study early – if this occurs the reason(s) will be explained to you.

IX Compensation for participation:

Participation in this study will be at no cost to you. The medication and clinic visits will be provided free of charge. No compensation will be provided for your participation. Payment for things such as lost wages is not available. (Wherever applicable give details e.g. reasonable travel assistance will be provided for your participation etc.)

X Treatment and Compensation for study related injury: (for interventional trial)

You will be provided medical treatment at this institute for any physical injury or illness that occurs as a direct result of your participation in this study. This medical treatment will be at no cost to you. The study doctor/sponsor will compensate anyone in case there is temporary/ permanent disability or death as a direct result of participation in this trial In case of death, their dependents are entitled to material compensation.(provision of insurance coverage by the sponsor for study related injury, if available, may be stated here). You will not give up any of your legal rights by signing this form.

Any injury or death of the participant occurring in clinical trial due to following reasons shall be considered as clinical trial related injury or death and the subject or his/her nominee (s) as the case can be are entitled for financial compensation.

a) adverse effect of investigational product (s)
b) violation of the approved protocol, scientific misconduct by the sponsor or the investigator.
c) failure of the investigational product to provide intended therapeutic effect
d) Use of placebo
e) Adverse effects due to concomitant medication excluding standard care, necessitated as part of approved protocol.
f) For injury to child in utero because of the parents participation in the trial
g) Any clinical trial procedure involved in the study.

[**Paragraph from ICMR 2017 guidelines** –
Obligation of the sponsor to pay: The sponsor whether a pharmaceutical funding agency, government, or an institution, should agree, before the research begins, in the a priori agreement to provide compensation for any physical or psychological injury for which participants are entitled or agree to provide insurance coverage for an unforeseen injury whenever possible.]

A. "In event of any injury occurring to the clinical trial subject, such subject shall be provided free medical management as long as required.
In the event of a trial related injury or death, the sponsor or his representative should provide financial compensation for the injury or death . The financial compensation will be over and above any expenses incurred on the medical management of the subject.
In case of clinical trial related death of the subject, his/her nominee(s) would be entitled for financial compensation as per the order of the Licensing Authority and same should be included in Patient Information Sheet / Informed Consent Form"].

B. Date of Birth /Age ……..
Address of the subject…….
Qualification…….
Occupation- student/self-employed/service/housewife/other (please tick as appropriate)
Annual income of the subject ……
Name and address of the nominee(s) and his relation to the subject ……..
(for the purpose of compensation in case of trial related death)
C. Name of the witness ……..
(copy of the Patient information sheet and duly filled ICF shall be handed over to the participant or his/her attendant)

XI Right to withdraw from the study:

Participation in this study is entirely voluntary. You may choose not to take part or you may leave the study at any time. Your decision will not affect your further treatment at this institute. If you decide to leave the study, you may have to undergo some tests and/or procedures, which will be done to protect your safety.

XII Confidentiality:

All study records will be kept confidential at all times. Your identity will not be revealed except as required by law, DSMB and IEC. The results of your treatment (details: laboratory tests, photographs, x-rays etc.) may be published for scientific reasons. Your identity will not be revealed in these publications.

XIII Contact for further information:

Thank you for taking the time to read (or have read to you) the information about this study. Before you sign this document, you should ask questions about anything that you do not understand. The study staff will answer questions before, during & after the study.

If you have questions about this study or how it is being run, drug side effects or a possible research related illness or injury, you can contact the study doctor XXXXXXXX, designation, department XXXXXXXX at telephone number XXXXXX during the office hours, or at XXXXX at outside office hours.

If you have any questions about your rights as a research participant, or complaints regarding the research study, you should call the Member Secretary of Institutional Ethics Committee on the following telephone number on working days. Tel. no.: 91 22 2410 7000, Ext. 7515, 91 22 24107515, 8779221293 (Monday to Friday- 09.30 am to 05.00 pm; Saturday 09.30 am to 01.00 pm)

XIV Consent:

[1] I have read or have had read to me the information given in the Informed Consent Document for this study entitled **"XXXXXXX"**

[2] I have received an explanation of the nature, purpose, duration, and foreseeable effects and risks of the trial and what I will be expected to do. My questions have been answered satisfactorily.

[3] I understand that my participation in the trial is voluntary and that I may refuse to participate or may withdraw from the trial at any time, without penalty or loss of benefits to which am otherwise entitled.

[4] I further understand that any information that becomes available during the course of the study that may affect my willingness to take part will be informed to me.

[5] Institutional Ethics Committee authorities may wish to examine my medical records to verify the information collected. By signing this document, I give permission for this review of my records.

[6] I understand that my identity will not be revealed in any report or publication.

[7] I agree to take part in the above study.

_____	_____	_____
Name of research participants	**Signature/ thumb impression of research participants**	**Date**

_____	_____	_____	_____
Name of Legal Representative (LAR)	**Relation to research participants**	**Signature / Thumb Impression of LAR**	**Date**

_____	_____	_____
Name of the Impartial Witness	**Signature of the Impartial-Witness**	**Date**

_____	_____	_____
Name of the person Administering consent	**Signature of the person administering consent**	**Date**

(Copy of the Patient Information Sheet and dully filled Informed Consent Form shall be handed over to the patient or his/her attendant)

PLEASE NOTE THAT THE INFORMED CONSENT DOCUMENT SHOULD HAVE PAGE NUMBERS

परिशिष्ट ८

एएक्स ०८/एसओपी ०५-अ/वी ७

(यह टेम्पलेट व्यक्तिगत शोध परियोजना की आवश्यकता के अनुसार अनुकूलित किया जाना चाहिए)

हिंदी में सूचित सहमति दस्तावेज का नमूना प्रारूप

दिनांक:
संस्करण:

१. **परियोजना का शीर्षक**:

XXXXX (एक मानक उच्च रक्तचाप प्रतिरोधक दवा) की तुलना में XXXXXXXX (एक उच्च रक्तचाप प्रतिरोधक जांच दवा) की प्रभावकारिता और सहनशीलता की जांच करना

२. **परिचय**:

आपको शोध अध्ययन में भाग लेने के लिए आमंत्रित किया जाता है। यह महत्वपूर्ण है कि आप अध्ययन का यह विवरण पढ़ें और इसमें अपनी भूमिका को समझें, जिसमें भागीदारी की प्रकृति और जोखिम शामिल हैं।

कृपया इस चिकित्सकीय अध्ययन में भाग लेने के लिए अपनी सहमति तभी दें जब आप इस अध्ययन की प्रकृति और पाठ्यक्रम (कोर्स) को पूरी तरह से समझ गए हों और यदि आप एक प्रतिभागी के रूप में अपने अधिकारों से अवगत हों।

३. **इस अध्ययन का उद्देश्य**:

यह सर्वविदित है कि उच्च रक्तचाप से पीड़ित लोगों को हृदय संबंधी बीमारियों का जोखिम अधिक होता है, जिसमें दिल का दौरा, स्ट्रोक और यहां तक कि मृत्यु भी शामिल है। ऐसे रोगियों को हृदय संबंधी घटनाओं के होने की रोकथाम के लिए आमतौर पर उच्च रक्तचाप रोधी (एंटीहाइपरटेन्सिव) दवाएं लिखके दी जाती हैं। XXXX एक नई दवा है, जो प्रारंभिक अध्ययनों में रक्तचाप को कम करने वाली पाई गई है। उच्च रक्तचाप वाले रोगियों में इस दवा की प्रभावकारिता और सुरक्षा का अध्ययन करने की योजना अध्ययन में है।

४. **शोध प्रतिभागियों की संख्या और अध्ययन में प्रत्येक प्रतिभागी की अपेक्षित अवधि**:

आप लगभग XXX लोगों में से एक होंगे जो इस अध्ययन में भाग लेंगे। आप लगभग XXX दिनों तक अध्ययन में रहेंगे। (बहुकेन्द्रीय अध्ययन में, उल्लेख करें कि अध्ययन XXX अन्य केन्द्रों पर भी किया जा रहा है)।

५. **पालन की जाने वाली अध्ययन प्रक्रियाएं**:

यदि आप इस अध्ययन में भाग लेने के लिए सहमत हैं तो आपसे अ) पिछली चिकित्सा समस्याओं, आपके वर्तमान स्वास्थ्य और आपकी दवाओं के बारे में पूछा जाएगा; ब) संक्षिप्त शारीरिक जांच की जाएगी (विवरण देने के लिए); क) XXXXXX जैसी आधारभूत जांच से गुजरने की आवश्यकता होगी (विवरण देने के लिए)

अध्ययन स्टाफ इन मूल्यांकनों और जांचों के परिणामों का परीक्षण करेगा। यदि आप भाग लेने के लिए पात्र हैं तो आपको दो अध्ययन उपचारों में से एक प्राप्त करने के लिए क्रमरहित तरीके से (सिक्का उछालने की तरह) एक अध्ययन समूह में सौप दिया जाएगा।

अध्ययन के लिए कुल XX मुलाकात की आवश्यकता होगी। हर मुलाकात पर XX घंटे तक निराहार रखने के बाद आपका XX मिली रक्त (जैसा लागू हो १-२ छोटी चम्मच/बड़ी चम्मच उल्लेख करें) निकाला

जाएगा। निकाले गए रक्त के नमूनों का उपयोग आपके रक्त शर्करा के स्तर, गुर्दे और यकृत के कार्य आदि की जांच करने के लिए किया जाएगा। (जो भी लागू हो उसका उल्लेख करें)।

चाहे आपको किसी भी समूह में सौप दिया गया हो, आप XXXX दिन/सप्ताह/महीने के बाद अध्ययन केंद्र पर वापस लौटेंगे। यह महत्वपूर्ण है कि आप अपनी सभी अध्ययन दवाएं, डायरी आदि अपने साथ लाएं।

प्रत्येक मुलाकात पर, अ) आपसे आपके स्वास्थ्य, दवाओं के दुष्प्रभावों के बारे में पूछा जाएगा, ब) आपकी शारीरिक जांच की जाएगी क) आपको अध्ययन दवा की एक नई आपूर्ति दी जाएगी।

६. **भाग लेने के जोखिम और असुविधाएँ**:

उच्च जोखिम वाले लोगों पर २ अलग-अलग चिकित्सा की जांच कर रहा अध्ययन, जो हृदय संबंधी कारणों से होने वाले हृदयाघात (हार्ट अटैक), स्ट्रोक या मृत्यु को रोक सकते हैं:

पशुओं पर किए गए अध्ययनों तथा लोगों पर किए गए अन्य अध्ययनों के आधार पर, इस अध्ययन में प्रयुक्त दवा(एकाधिक) के कुछ दुष्प्रभाव हो सकते हैं। यहां उपयोग के लिए प्रस्तावित दवाओं से जुड़े ज्ञात जोखिम और दुष्प्रभावों का सारांश नीचे दिया गया है।

जांच दवा के दुष्प्रभाव - XXXXX (विस्तार से बताए) (अन्तःक्षेपी परीक्षण के लिए)

मानक दवा के दुष्प्रभाव - XXXXX (विस्तार से बताए) (अन्तःक्षेपी परीक्षण के लिए)

अन्य दुष्प्रभाव जो आप अनुभव कर सकते हैं उनमें इंजेक्शन लगाए जाने वाली जगह पर प्रतिक्रिया, दवा के प्रति एलर्जी, खुजली युक्त चकत्ते और इंजेक्शन लगाए जाने वाली जगह पर दर्द (यदि दवा को पैरेन्टेरल (आन्त्रेतर) रूप से दिया जाना है) शामिल हो सकते हैं। आपकी नस से रक्त एकत्रित करते समय, आपको थोड़े समय के दर्द की असुविधा से गुजरना पड़ेगा या कभी-कभी नील का निशान या मामूली संक्रमण भी हो सकता है। यदि ऐसा होता है तो उचित प्रबंधन प्रदान किया जाएगा।

अंततः इस अध्ययन के दौरान पहले देखी गई समस्याओं के अलावा नई समस्याएं या दुष्प्रभाव भी हो सकते हैं। इसलिए प्रत्येक मुलाकात पर आपसे दुष्प्रभावों के बारे में पूछा जाएगा। यह महत्वपूर्ण है कि आप इस प्रपत्र में वर्णित किसी भी दुष्प्रभाव या अन्य किसी भी दुष्प्रभाव की सूचना अध्ययन चिकित्सक को नीचे सूचीबद्ध नंबरों पर तुरंत दें।

क्योंकि अजन्मा भ्रूण या नवजात शिशु के लिए अध्ययन दवाओं की सुरक्षा अज्ञात है, इसलिए यदि आप गर्भवती होने का इरादा रखती हैं, गर्भवती हैं या स्तनपान करा रही हैं तो आप इस अध्ययन में भाग नहीं ले सकती हैं। यदि आप ऐसी महिला हैं जो बच्चे पैदा करने में सक्षम हैं, तो आपको मूत्र गर्भावस्था जांच करवाने की आवश्यकता होगी। यदि आप गर्भवती नहीं हैं तो आपको अध्ययन के अंत तक गर्भधारण से बचने के लिए सावधानी बरतने के लिए कहा जाएगा। चिकित्सक आपके साथ गर्भनिरोधक विकल्पों पर चर्चा करेंगे। अध्ययन के दौरान गर्भावस्था जांच दोहराई जा सकती है। यदि इन सावधानियों के बावजूद आप गर्भवती हो जाती हैं तो आपको तुरंत अध्ययन समूह को सूचित करना चाहिए। गर्भावस्था अध्ययन उपचार रोकने का एक कारण होगा।

अध्ययन के दौरान खोजी गई कोई भी नई महत्वपूर्ण जानकारी और जो अध्ययन जारी रखने के आपके निर्णय को प्रभावित कर सकती है, वह आपको या आपके कानूनी रूप से स्वीकार्य प्रतिनिधि को समय पर प्रदान की जाएगी। आपको किसी भी नए जोखिम या दुष्प्रभाव के बारे में बताया जाएगा।

७. **अध्ययन के संभावित लाभ**:

इस अध्ययन में भाग लेने से आपकी स्थिति में संभावित उपचार या सुधार हो सकता है। हालाँकि, इस बात की कोई गारंटी नहीं है कि इस अध्ययन में भाग लेने से आपको प्रत्यक्ष स्वास्थ्य लाभ मिलेगा। इस अध्ययन में आपकी भागीदारी से ऐसी जानकारी मिल सकती है जो भविष्य में उच्च रक्तचाप से पीड़ित अन्य रोगियों के लिए मददगार हो सकती है।

८. **जब शोध परीक्षण बंद हो जाते हैं तो क्या होता है**?

क्योंकि यह एक शोध परीक्षण है, इसलिए इस रोग के उपचार के लिए जांच दवा इस परीक्षण के अंत में उपलब्ध नहीं होगी। परीक्षण समाप्त होने के बाद, यदि उपयुक्त हो तो वैकल्पिक थेरेपी प्रदान की जाएगी। कभी-कभी शोध को प्रायोजित करने वाली कंपनी अध्ययन को समय से पहले ही रोक सकती है - यदि ऐसा होता है तो आपको इसका कारण (एकाधिक) बता दिया जाएगा।

९. **भागीदारी के लिए मुआवजा**:

इस अध्ययन में भाग लेने के लिए आपको कोई शुल्क नहीं देना होगा। दवाइयां और चिकित्सालय की मुलाकातें निःशुल्क होगी। आपकी भागीदारी के लिए कोई मुआवजा नहीं दिया जाएगा। वेतन की हानि जैसी चीजों के लिए भुगतान उपलब्ध नहीं है। (जहां भी लागू हो, विवरण दें, उदा. आपकी भागीदारी के लिए उचित यात्रा सहायता प्रदान की जाएगी आदि)

१०. **अध्ययन से संबंधित चोट के लिए उपचार और मुआवजा**: (अन्तःक्षेपी परीक्षण के लिए)

इस अध्ययन में आपकी भागीदारी के प्रत्यक्ष परिणामस्वरूप होने वाली किसी भी शारीरिक चोट या बीमारी के लिए आपको इस संस्थान में चिकित्सा उपचार प्रदान किया जाएगा। यह चिकित्सा उपचार आपके लिए निःशुल्क होगा। अध्ययन चिकित्सक/प्रायोजक इस परीक्षण में भाग लेने के प्रत्यक्ष परिणामस्वरूप किसी व्यक्ति की अस्थायी/स्थायी विकलांगता या मृत्यु होने पर उसे मुआवजा देंगे। मृत्यु की स्थिति में, उसके आश्रितों को भौतिक मुआवजा पाने का अधिकार होगा। (अध्ययन से संबंधित चोट के लिए प्रायोजक द्वारा बीमा कवरेज का प्रावधान, यदि उपलब्ध हो, तो यहां बताया जा सकता है)। इस प्रपत्र पर हस्ताक्षर करके आप अपने किसी भी कानूनी अधिकार का त्याग नहीं करेंगे।

चिकित्सकीय परीक्षण में निम्नलिखित कारणों से प्रतिभागी को लगी किसी भी चोट या मृत्यु को चिकित्सकीय परीक्षण से संबंधित चोट या मृत्यु माना जाएगा तथा प्रतिभागी या उसके नामांकित व्यक्ति (एकाधिक) जैसा भी मामला हो, वित्तीय मुआवजे के हकदार होंगे।

अ) अन्वेषणात्मक उत्पाद (एकाधिक) का प्रतिकूल प्रभाव
ब) अनुमोदित प्रोटोकॉल का उल्लंघन, प्रायोजक या अन्वेषक द्वारा वैज्ञानिक कदाचार।
क) अन्वेषणात्मक उत्पाद का आशयित थेराप्यूटिक प्रभाव प्रदान करने में विफल रहना
ड) प्लेसिबो का उपयोग
ई) मानक देखभाल को छोड़कर सहवर्ती दवा के कारण होने वाले प्रतिकूल प्रभाव, अनुमोदित प्रोटोकॉल के भाग के रूप में आवश्यक हैं
फ) माता-पिता के परीक्षण में भाग लेने के कारण गर्भ में बच्चे को चोट लगने के लिए
ग) अध्ययन में शामिल कोई भी चिकित्सकीय परीक्षण प्रक्रिया।

[**आईसीएमआर २०१७ दिशानिर्देशों से पैराग्राफ**-

प्रायोजक का भुगतान करने का दायित्व: शोध शुरू होने से पहले प्रायोजक, चाहे वह फार्मास्यूटिकल कंपनी हो, सरकार हो या कोई संस्था हो, को किसी भी शारीरिक या साइकोलॉजिकल चोट के लिए मुआवजा देने के लिए पूर्व सहमति पर सहमत होना चाहिए, जिसके लिए प्रतिभागी हकदार हैं या जब भी संभव हो अनपेक्षित चोट के लिए बीमा कवरेज प्रदान करने के लिए सहमत होना चाहिए।]

अ. "यदि चिकित्सकीय परीक्षण के प्रतिभागी को कोई चोट लगती है, तो ऐसे प्रतिभागी को जब तक आवश्यक हो तब तक निःशुल्क चिकित्सा प्रबंधन प्रदान की जाएगी।

परीक्षण से संबंधित चोट या मृत्यु की स्थिति में, प्रायोजक या उसके प्रतिनिधि को चोट या मृत्यु के लिए वित्तीय मुआवजा प्रदान करना चाहिए। वित्तीय मुआवजा, प्रतिभागी के चिकित्सा प्रबंधन पर किए गए किसी भी व्यय के अतिरिक्त होगा।

चिकित्सकीय परीक्षण से संबंधित प्रतिभागी के मृत्यु की स्थिति में, उसके नामांकित व्यक्ति (एकाधिक) लाइसेंसिंग प्राधिकरण के आदेश के अनुसार वित्तीय मुआवजे के हकदार होंगे और उसे रोगी सूचना पत्रक / सूचित सहमति प्रपत्र में शामिल किया जाना चाहिए"।

ब. जन्म तिथि/आयु.....
प्रतिभागी का पता.....
योग्यता.....
व्यवसाय- विद्यार्थी/स्वरोज़गाररत/नौकरी/गृहिणी/अन्य (कृपया जो उचित हो उस पर सही का निशान लगाएं)
प्रतिभागी की वार्षिक आय .....
नामांकित व्यक्ति (एकाधिक) का नाम और पता तथा प्रतिभागी से उसका संबंध.....
(परीक्षण से संबंधित मृत्यु के मामले में मुआवजे के उद्देश्य से)

क. गवाह का नाम.....
(रोगी सूचना पत्रक और विधिवत रूप से भरे हुए सूचित सहमती दस्तावेज की प्रति प्रतिभागी या उसके परिचारक को सौंपी जाएगी)

११. **अध्ययन से हटने का अधिकार**:

इस अध्ययन में भागीदारी पूर्णतः स्वैच्छिक है। आप भाग न लेने का निर्णय ले सकते हैं या किसी भी समय अध्ययन से हट सकते है। आपके निर्णय से इस संस्थान में आपके आगे के उपचार पर कोई प्रभाव नहीं पड़ेगा। यदि आप अध्ययन छोड़ने का निर्णय लेते हैं, तो आपको कुछ जांचों और/या प्रक्रियाओं से गुजरना पड़ सकता है, जो आपकी सुरक्षा की रक्षा के लिए की जाएगी।

१२. **गोपनीयता**:

सभी अध्ययन अभिलेख हर समय गोपनीय रखे जाएंगे। आपकी पहचान तभी उजागर की जाएगी अगर कानूनी, डीएसएमबी और संस्थागत नैतिक समिती के लिए आवश्यक हो इनके अलावा किसी और स्थिति में उजागर नहीं की जाएगी। आपके उपचार के परिणाम (विवरण: प्रयोगशाला जांच, तस्वीरें, एक्स-रे आदि) वैज्ञानिक कारणों से प्रकाशित किए जा सकते हैं। इन प्रकाशनों में आपकी पहचान उजागर नहीं की जाएगी।

१३. **अधिक जानकारी के लिए संपर्क करें**:

इस अध्ययन के बारे में जानकारी को समय निकाल कर पढ़ने के लिए (या इसे आपके लिए पढ़वाने के लिए) आपका धन्यवाद। आपके द्वारा इस दस्तावेज पर हस्ताक्षर करने से पहले, आपको उन सभी चीज़ों के बारे में प्रश्न पूछना चाहिए जो आपको समझ में नहीं आतें है। अध्ययन कर्मचारी अध्ययन से पहले, उसके दौरान और उसके बाद प्रश्नों के उत्तर देंगे।

यदि इस अध्ययन या यह कैसे संचालित किया जा रहा है, दवा के दुष्प्रभावों या संभावित शोध से संबंधित बीमारी या चोट के बारे में आपके प्रश्न हैं, तो आप कार्यालय समय के दौरान अध्ययन चिकित्सक XXXXXXXX, पदनाम, विभाग XXXXXXXX से टेलीफोन नंबर XXXXXX पर या कार्यालय समय के बाद XXXXX पर संपर्क कर सकते हैं।

यदि आपके शोध प्रतिभागी के रूप में अपने अधिकारों के बारे में कोई प्रश्न हैं या शोध अध्ययन के संबंध में कोई शिकायत है, तो आपको कार्य दिनों में निम्नलिखित टेलीफोन नंबर पर संस्थागत नैतिक समिती के सदस्य सचिव को कॉल करना चाहिए। टेलीफोन नं.: ९१ २२ २४१० ७०००, एक्सटेंशन ७५१५, ९१ २२ २४१० ७५१५, ८७७९२२१२९३ (सोमवार से शुक्रवार - सुबह ०९.३० बजे से शाम ०५.०० बजे तक; शनिवार सुबह ०९.३० बजे से दोपहर ०१.०० बजे तक)

१४. **सहमति**:

[१] मैंने **"XXXXXXX"** नामक इस अध्ययन के लिए सूचित सहमति दस्तावेज में दी गई जानकारी पढ़ ली है या मुझे पढ़कर सुनाई गई है।

[२] मुझे परीक्षण की प्रकृति, उद्देश्य, अवधि, तथा संभावित प्रभावों और जोखिमों तथा मुझसे क्या करने की अपेक्षा की जाएगी, इसके बारे में स्पष्टीकरण प्राप्त हुआ है। मेरे प्रश्नों का संतोषजनक उत्तर दिया गया है।

[३] मैं समझता/समझती हूं कि परीक्षण में मेरी भागीदारी स्वैच्छिक है और यह कि मैं भाग लेने से इंकार कर सकता/सकती हूं या किसी भी समय, बिना किसी जुर्माने या ऐसे लाभों की हानि के, जिसका/जिसकी मैं अन्यथा हकदार हूं, परीक्षण से हट सकता/सकती हूं,

[४] मैं आगे यह भी समझता/समझती हूं कि अध्ययन की अवधि के दौरान कोई भी जानकारी जो उपलब्ध होगी, जो भाग लेने की मेरी इच्छा को प्रभावित कर सकती है, उसके बारे में मुझे सूचित किया जाएगा।

[५] संस्थागत नैतिक समिती के प्राधिकारी एकत्रित जानकारी सत्यापित करने के लिए मेरे चिकित्सा अभिलेख की जांच करना चाह सकते हैं। इस दस्तावेज पर हस्ताक्षर करके, मैं अपने अभिलेख की इस समीक्षा के लिए अनुमति देता/देती हूँ।

[६] मैं समझता/समझती हूं कि किसी भी रिपोर्ट या प्रकाशन में मेरी पहचान उजागर नहीं की जाएगी।

[७] मैं उपरोक्त अध्ययन में भाग लेने के लिए सहमत हूं।

_____	_____	_____
शोध प्रतिभागी का नाम	**शोध प्रतिभागी के हस्ताक्षर/अंगूठे का निशान**	**दिनांक**

_____	_____	_____	_____
कानूनी प्रतिनिधि का नाम (एलएआर)	**शोध प्रतिभागी से संबंध**	**कानूनी प्रतिनिधि के हस्ताक्षर / अंगूठे का निशान**	**दिनांक**

_____	_____	_____
निष्पक्ष गवाह का नाम	**निष्पक्ष-गवाह के हस्ताक्षर**	**दिनांक**

_____	_____	_____
सहमति लेने वाले व्यक्ति का नाम	**सहमति लेने वाले व्यक्ति के हस्ताक्षर**	**दिनांक**

(रोगी सूचना पत्रक और विधिवत रूप से भरे हुए सूचित सहमति दस्तावेज की प्रति रोगी या उसके परिचारक को सौंपी जाएगी)

कृपया ध्यान दें कि सूचित सहमति दस्तावेज में पृष्ठ संख्याएँ हो

परिशिष्ट ८

एएक्स ०८/एसओपी ०५-अ/व्ही ७

(हे टेम्पलेट वैयक्तिक संशोधन प्रकल्पाच्या आवश्यकतेनुसार सानुकूलित केले जावे)

मराठीमध्ये माहितीपूर्ण संमती प्रपत्र नमुना स्वरूप

दिनांक:
आवृत्ती:

१ **प्रकल्पाचे शीर्षक:**

XXXXX (एक प्रमाणक उच्च रक्तदाब प्रतिबंधक औषध) च्या तुलनेत XXXXXXXX (एक उच्च रक्तदाब प्रतिबंधक चाचणी औषध) च्या परिणामकारकतेची आणि सहनशीलतेची चाचणी करणे

२ **परिचय:**

तुम्हाला संशोधन अभ्यासात सहभागी होण्यासाठी आमंत्रित केले आहे. तुम्ही अभ्यासाचे हे वर्णन वाचणे आणि सहभागाचे स्वरूप आणि जोखीम यासह त्यात तुमची भूमिका समजून घेणे महत्त्वाचे आहे.
कृपया या चिकित्सीय अभ्यासात सहभागी होण्यासाठी तुमची संमती तेव्हाच द्या जेव्हा तुम्हाला या अभ्यासाचे स्वरूप आणि अभ्यासक्रम पूर्णपणे समजला असेल आणि जर तुम्हाला सहभागी म्हणून तुमच्या अधिकारांची जाणीव असेल.

३ **अभ्यासाचा उद्देश:**

हे सर्वज्ञात आहे की ज्या लोकांना उच्च रक्तदाबाचा त्रास होतो त्यांना हृदयविकाराचा झटका, स्ट्रोक आणि मृत्यूच्याही समावेशासह हृदय व रक्तवाहिन्यासंबंधी रोगाचा उच्च धोका असतो. हृदय व रक्तवाहिन्यासंबंधी घटना घडण्यापासून रोखण्यासाठी अशा रुग्णांना उच्च रक्तदाब प्रतिबंधक (अँटीहायपरटेन्सिव्ह) औषधे सामान्यतः लिहून दिली जातात. XXXX हे एक नवीन औषध आहे, जे प्रारंभिक अभ्यासांमध्ये रक्तदाब कमी करत असल्याचे दिसून आले आहे. उच्च रक्तदाब असलेल्या रुग्णांमध्ये या औषधाची परिणामकारकता आणि सुरक्षितता यांचा अभ्यास करण्याची योजना या अभ्यासात आहे.

४ **संशोधन सहभागींची संख्या आणि अभ्यासातील प्रत्येक सहभागीचा अपेक्षित कालावधी:**

या अभ्यासात सहभागी होणाऱ्या अंदाजे XXX लोकांपैकी तुम्ही एक असाल. तुम्ही सुमारे XXX दिवस अभ्यासात असाल. (बहुकेंद्रित अभ्यासामध्ये, XXX इतर केंद्रांवर देखील अभ्यास केला जात असल्याचे नमूद करा).

५ **पुढील अभ्यास प्रक्रियांचे पालन करणेः**

जर तुम्ही या अभ्यासात सहभागी होण्यास सहमत असाल तर तुम्हाला अ) पूर्वीच्या वैद्यकीय समस्या, तुमचे सध्याचे आरोग्य आणि तुमच्या औषधांबद्दल विचारले जाईल; ब) संक्षिप्त शारीरिक तपासणी केली जाईल (तपशील देण्यासाठी); क) मूलभूत तपासणी करणे आवश्यक असेल जसे की XXXXXX (तपशील देण्यासाठी)

अभ्यास कर्मचारी या मूल्यमापन आणि चाचणीच्या परिणामांचा आढावा घेतील. जर तुम्ही सहभागी होण्यास पात्र असाल तर तुम्हाला स्वैरिकृतपणे (नाणेफेकिप्रमाणे) दोन अभ्यास उपचारांपैकी एक प्राप्त करण्यासाठी एका अभ्यास गटाला नियुक्त केले जाईल.
अभ्यासासाठी एकूण XX भेटींची आवश्यकता असेल. प्रत्येक भेटीच्या वेळी XX तास उपवास केल्यानंतर तुमचे XX मिली (लागू असेल त्याप्रमाणे १-२ लहान चमचा/मोठा चमचा नमूद करा) रक्त घेतले जाईल. जे रक्त नमुने काढले जातात, ते तुमच्या रक्तातील साखरेची पातळी, मूत्रपिंड आणि यकृताचे कार्य इत्यादी तपासण्यासाठी वापरले जातील (जे काही लागू असेल ते नमूद करा).

तुम्हाला कोणत्याही गटात नियुक्त केले गेले असले तरीही, तुम्ही XXXX दिवस/आठवडे/महिने नंतर अभ्यास केंद्रावर परत जाल. तुम्ही तुमची सर्व अभ्यास औषधे, नोंदवही इत्यादी तुमच्यासोबत आणणे महत्त्वाचे आहे.

प्रत्येक भेटीत, अ) तुम्हाला तुमच्या आरोग्याबद्दल, औषधांच्या दुष्परिणामांबद्दल विचारले जाईल, ब) तुमची शारीरिक तपासणी केली जाईल क) तुम्हाला अभ्यास औषधाचा नवीन पुरवठा केला जाईल.

६ **सहभागी होण्याच्या जोखमी आणि असुविधा:**

उच्च जोखीम असलेल्या लोकांमध्ये २ वेगवेगळ्या उपचारपद्धतींची चाचणी करत असलेला हा अभ्यास हृदय व रक्तवाहिन्यासंबंधी कारणांमुळे हृदयविकाराचा झटका, स्ट्रोक किंवा मृत्यू टाळू शकतो:

प्राण्यांवरील अभ्यास आणि लोकांवरील इतर अभ्यासांवर आधारित, या अभ्यासात वापरल्या जाणाऱ्या औषध(धां)मुळे काही दुष्परिणाम होऊ शकतात. येथे वापरण्यासाठी प्रस्तावित औषधांशी संबंधित ज्ञात धोके आणि दुष्परिणाम खाली सारांशित केले आहेत.

चाचणी औषधाचे दुष्परिणाम - XXXXX (तपशील द्या) (हस्तक्षेपात्मक परीक्षणासाठी)

प्रमाणक औषधाचे दुष्परिणाम - XXXXX (तपशील द्या) (हस्तक्षेपात्मक परीक्षणासाठी)

इतर दुष्परिणाम जे तुम्हाला जाणवू शकतात त्यामध्ये इंजेक्शन दिलेल्या जागी प्रतिक्रिया, औषधामुळे संसर्गजन्य प्रतिक्रिया, खाजयुक्त पुरळ आणि इंजेक्शन दिलेल्या जागेवर वेदना (जर औषध पॅरेंटेरल पद्धतीने (आंत्रेतर) दिले जात असेल तर) यांचा समावेश असू शकतो. तुमच्या रक्तवाहिनीतून रक्त गोळा करताना, तुम्हाला थोड्या वेदनांचा त्रास सहन करावा लागेल किंवा क्वचितच काळेनिळे होणे किंवा अगदी किरकोळ संसर्ग देखील होईल. असे झाल्यास योग्य व्यवस्थापन केले जाईल.

शेवटी या अभ्यासादरम्यान पूर्वी दिसलेल्या समस्यांव्यतिरिक्त नवीन समस्या किंवा दुष्परिणाम होऊ शकतात. त्यामुळे प्रत्येक भेटीत तुम्हाला दुष्परिणामांबद्दल विचारले जाईल. हे महत्त्वाचे आहे की तुम्ही या प्रपत्रामध्ये वर्णन केलेल्या कोणत्याही दुष्परिणामांची किंवा इतर कोणत्याही दुष्परिणामांची माहिती खाली सूचीबद्ध क्रमांकावर ताबडतोब अभ्यास चिकित्सकाला द्या.

न जन्मलेल्या गर्भासाठी किंवा नवजात शिशूसाठी अभ्यास औषधांची सुरक्षितता अज्ञात असल्यामुळे, जर तुम्ही गरोदर राहण्याचा विचार करत असाल, गर्भवती असाल किंवा स्तनपान करत असाल तर तुम्ही या अभ्यासात सहभागी होऊ शकत नाही. जर तुम्ही जिला मूल होऊ शकते अशी स्त्री असाल, तर तुम्हाला मूत्र गर्भधारणा चाचणी करणे आवश्यक असेल. जर तुम्ही गरोदर नसाल तर तुम्हाला अभ्यासाच्या शेवटपर्यंत गर्भधारणा टाळण्यासाठी खबरदारी घेण्यास सांगितले जाईल. वैद्य तुमच्याशी गर्भनिरोधक पर्यायांवर चर्चा करतील. अभ्यासादरम्यान गर्भधारणा चाचणीची पुनरावृत्ती होऊ शकते. या सावधगिरी बाळगूनही तुम्ही गरोदर राहिल्यास तुम्ही ताबडतोब अभ्यास संघाला सूचित करावे. गर्भधारणा हे अभ्यास उपचार थांबवण्याचे एक कारण असेल.

अभ्यासादरम्यान शोध लागलेली कोणतीही नवीन महत्त्वाची माहिती आणि जी अभ्यास सुरू ठेवण्याच्या तुमच्या निर्णयावर परिणाम करू शकते, अशी माहिती तुम्हाला किंवा तुमच्या कायदेशीररित्या स्वीकार्य प्रतिनिधीला वेळेवर प्रदान केली जाईल. तुम्हाला कोणत्याही नवीन जोखमी किंवा दुष्परिणामांबद्दल सांगितले जाईल.

७ **अभ्यासाचे संभाव्य फायदे:**

या अभ्यासात भाग घेतल्याने, तुमच्या स्थितीत संभाव्य उपचार किंवा सुधारणा होऊ शकते. तथापि, या अभ्यासात असल्याने तुम्हाला थेट आरोग्य लाभ मिळेल याची शाश्वती नाही. या अभ्यासात तुमचा सहभाग अशी माहिती देऊ शकतो जी भविष्यात उच्च रक्तदाबाने ग्रस्त असलेल्या इतर रुग्णांना मदत करू शकते.

८ **जेव्हा संशोधन परीक्षणे थांबतात तेव्हा काय होते?**

कारण हे एक संशोधन परीक्षण आहे, या परीक्षणाच्या शेवटी या आजाराच्या उपचारासाठी चाचणी औषध उपलब्ध होणार नाही. परीक्षण पूर्ण झाल्यावर पर्यायी थेरपी, योग्य असल्यास, प्रदान केली जाईल. अधूनमधून संशोधन प्रायोजित करणारी कंपनी अभ्यास लवकर थांबवू शकते - जर असे घडले तर तुम्हाला कारण(कारणे) समजावून सांगितले जाईल.

९ **सहभागासाठी भरपाई:**

या अभ्यासात सहभागी होण्यासाठी तुम्हाला कोणताही खर्च करावा लागणार नाही. औषधोपचार आणि क्लिनिक भेटी विनामूल्य असतील. तुमच्या सहभागासाठी कोणतीही भरपाई दिली जाणार नाही. वेतनाचे नुकसान यासारख्या गोष्टींसाठी रक्कम उपलब्ध नाही. (जेथे लागू असेल तेथे तपशील द्या उदा. तुमच्या सहभागासाठी वाजवी प्रवास सहाय्य प्रदान केले जाईल इ.)

१० **अभ्यासाशी संबंधित इजेसाठी उपचार आणि भरपाई:** (हस्तक्षेपात्मक परीक्षणासाठी)
या अभ्यासात तुमच्या सहभागाचा थेट परिणाम म्हणून उद्भवणारी कोणतीही शारीरिक इजा किंवा आजारासाठी तुम्हाला या संस्थेत वैद्यकीय उपचार दिले जातील. हे वैद्यकीय उपचार तुमच्यासाठी मोफत असतील. या परीक्षणात सहभागी झाल्याचा थेट परिणाम म्हणून तात्पुरते/कायमचे अपंगत्व किंवा मृत्यू झाल्यास अभ्यास वैद्य/प्रायोजक कोणालाही भरपाई देतील, मृत्यू झाल्यास, त्यांचे अवलंबित भौतिक भरपाईसाठी पात्र आहेत. (अभ्यासाशी संबंधित इजेसाठी प्रायोजकाकडून विमा संरक्षणाची तरतूद, उपलब्ध असल्यास, येथे सांगितली जाऊ शकते). या प्रपत्रावर स्वाक्षरी करून तुम्ही तुमचे कोणतेही कायदेशीर अधिकार सोडणार नाही.
चिकित्सीय परीक्षणामध्ये खालील कारणांमुळे होणारी कोणतीही इजा किंवा मृत्यू ही चिकित्सीय परीक्षणाशी संबंधित इजा किंवा मृत्यू म्हणून ग्राह्य धरली जाईल आणि जशी स्थिती असेल त्याप्रमाणे, व्यक्ती किंवा त्याची/तिची नामनिर्देशित व्यक्ती आर्थिक भरपाईसाठी पात्र असतील.

अ) संशोधनात्मक उत्पादनाचा प्रतिकूल परिणाम
ब) मंजूर प्रोटोकॉलचे उल्लंघन, प्रायोजक किंवा संशोधकाद्वारे वैज्ञानिक गैरवर्तन.
क) अपेक्षित उपचारात्मक प्रभाव प्रदान करण्यात संशोधनात्मक उत्पादनाचे अपयश
ड) प्लेसिबोचा वापर
ई) मंजूर प्रोटोकॉलचा भाग म्हणून आवश्यक प्रमाणक देखभाल वगळता सहवर्ती औषधांमुळे प्रतिकूल परिणाम.
फ) परीक्षणामध्ये पालकांच्या सहभागामुळे गर्भाशयात मुलाला झालेल्या इजेसाठी
ग) अभ्यासात समाविष्ट असलेली कोणतीही चिकित्सीय परीक्षण प्रक्रिया.

[**आयसीएमआर २०१७ मार्गदर्शक तत्त्वांमधील परिच्छेद -**
देय देण्याचे प्रायोजकाचे दायित्व: प्रायोजक हे फार्मास्युटिकल कंपनी, सरकार किंवा संस्था असो, संशोधन सुरू होण्यापूर्वी, कोणत्याही शारीरिक किंवा मानसिक इजेसाठी भरपाई देण्यासाठी पूर्वानुमत सहमत असले पाहिजेत ज्यासाठी सहभागी पात्र आहेत किंवा अनपेक्षित इजेसाठी जेव्हा शक्य असेल तेव्हा विमा संरक्षण प्रदान करण्यास सहमत असायला हवेत.]

अ. "चिकित्सीय परीक्षण प्रयुक्ताला कोणतीही इजा होण्याच्या अशा घटनेच्या बाबतीत, आवश्यक असेल तोपर्यंत अशा प्रयुक्ताला मोफत वैद्यकीय व्यवस्थापन प्रदान केले जाईल.
परीक्षणाशी संबंधित इजा किंवा मृत्यू झाल्यास अशा घटनेच्या बाबतीत, प्रायोजक किंवा त्याच्या प्रतिनिधीने इजा किंवा मृत्यूसाठी आर्थिक भरपाई द्यावी. आर्थिक भरपाई ही प्रयुक्ताच्या वैद्यकीय व्यवस्थापनेवर करण्यात येणाऱ्या कोणत्याही खर्चाहून अधिक असेल.
प्रयुक्ताच्या चिकित्सीय परीक्षणाशी संबंधित मृत्यू झाल्यास, परवाना प्राधिकरणाच्या आदेशानुसार त्याच्या/तिच्या नामनिर्देशित व्यक्ती आर्थिक भरपाईसाठी पात्र असतील आणि सदर रुग्णाच्या माहिती पत्रकात/माहितीपूर्ण संमती प्रपत्रामध्ये समाविष्ट केले जावे"].

ब. जन्मतारीख/वय .....
सहभागीचा पत्ता .....
पात्रता .....
व्यवसाय- विद्यार्थी/स्वयं-रोजगार/नोकरी/गृहिणी/इतर (कृपया योग्य ठिकाणी खूण करा)
सहभागीचे वार्षिक उत्पन्न.....
नामनिर्देशित व्यक्ती(व्यक्तीं)चे नाव आणि पत्ता आणि त्यांचे सहभागीशी नाते .....
(परीक्षणाशी संबंधित मृत्यूच्या बाबतीत भरपाईच्या उद्देशाने)

क. साक्षीदाराचे नाव.....

(रुग्ण माहिती पत्रक आणि योग्यरित्या भरलेले माहितीपूर्ण सहमती दस्तऐवज याची प्रत सहभागीला किंवा त्याच्या/तिच्या काळजी घेणाऱ्या व्यक्तीला सुपूर्द केली जाईल)

११ **अभ्यासातून माघार घेण्याचा अधिकार**:

ह्या अभ्यासातील सहभाग पूर्णपणे स्वैच्छिक स्वरूपाचा आहे. तुम्ही सहभागी न होण्याची निवड करू शकता किंवा तुम्ही कोणत्याही वेळी अभ्यास सोडून जाऊ शकता. तुमच्या निर्णयाचा ह्या संस्थेतील तुमच्या पुढील उपचारांवर परिणाम होणार नाही. तुम्ही अभ्यास सोडून जाण्याचा निर्णय घेतल्यास, तुम्हाला काही चाचण्या आणि/किंवा प्रक्रिया कराव्या लागतील, ज्या तुमच्या सुरक्षिततेचे संरक्षण करण्यासाठी केल्या जातील.

१२ **गोपनीयता**:

सर्व अभ्यास नोंदी नेहमी गोपनीय ठेवल्या जातील. कायदा, डीएसएमबी आणि संस्थात्मक नितिमत्ता समिती द्वारे आवश्यक असल्याशिवाय तुमची ओळख उघड केली जाणार नाही. तुमच्या उपचारांचे परिणाम (तपशील: प्रयोगशालीन चाचण्या, छायाचित्रे, एक्स-रेज इ.) वैज्ञानिक कारणांसाठी प्रकाशित केले जाऊ शकतात. ह्या प्रकाशनांमध्ये तुमची ओळख उघड केली जाणार नाही.

१३ **अधिक माहितीसाठी संपर्क**:

ह्या अभ्यासाविषयीची माहिती वाचण्यासाठी (किंवा तुम्हाला ती वाचून दाखवण्यात आल्याबद्दल) वेळ दिल्याबद्दल धन्यवाद. तुम्ही या दस्तऐवजावर स्वाक्षरी करण्यापूर्वी, तुम्हाला समजत नसलेल्या कोणत्याही गोष्टीबद्दल तुम्ही प्रश्न विचारले पाहिजेत. अभ्यास कर्मचारी अभ्यासापूर्वी, दरम्यान आणि त्यानंतर प्रश्नांची उत्तरे देतील.

जर तुम्हाला ह्या अभ्यासाविषयी किंवा तो कसा पार पाडला जात आहे त्याविषयी, औषधांचे दुष्परिणाम किंवा संभाव्य संशोधनाशी संबंधित आजारपण किंवा इजा याबद्दल प्रश्न असल्यास, तुम्ही अभ्यास वैद्य XXXXXXXX, हुद्दा, विभाग XXXXXXXX येथे दूरध्वनी क्रमांक XXXXXX वर कार्यालयीन वेळेत, किंवा कार्यालयीन वेळेनंतर XXXXXXX येथे संपर्क साधू शकता.

संशोधन सहभागी म्हणून तुमच्या हक्कांबद्दल तुम्हाला कोणतेही प्रश्न असल्यास, किंवा संशोधन अभ्यासाबाबत तक्रारी असल्यास, तुम्ही कामाच्या दिवशी खालील दूरध्वनी क्रमांकावर संस्थात्मक नितिमत्ता समितीच्या सदस्य सचिवांना कॉल करावा. दूरध्वनी क्रमांक: ९१ २२ २४१० ७०००, विस्तार. ७५१५, ९१ २२ २४१० ७५१५, ८७७९२२१२९३ (सोमवार ते शुक्रवार- सकाळी ०९.३० ते संध्याकाळी ०५.००; शनिवारी सकाळी ०९.३० ते दुपारी ०१.००)

१४ **संमती**:

[१] मी **"XXXXXXX"** असे शीर्षक असलेल्या या अभ्यासासाठीच्या माहितीपूर्ण संमती प्रपत्रात दिलेली माहिती वाचली आहे किंवा मला ती वाचून दाखवण्यात आली आहे.

[२] मला परीक्षणाचे स्वरूप, उद्देश, कालावधी आणि दृष्टीपथातील परिणाम आणि जोखीम आणि मी काय करणे काय अपेक्षित आहे याचे स्पष्टीकरण मिळाले आहे. माझ्या प्रश्नांची समाधानकारक उत्तरे दिली गेली आहेत.

[३] मला माहित आहे की परीक्षणामधील माझा सहभाग स्वैच्छिक स्वरूपाचा आहे आणि मी सहभाग घेण्यास नकार देऊ शकेन किंवा कोणत्याही वेळी, कोणत्याही दंडाशिवाय किंवा अन्यथा हक्कदार असणाऱ्या फायद्यांचे नुकसान न होता मी परीक्षणातून माघार घेऊ शकेन.

[४] मला पुढे समजते की अभ्यासाच्या कोर्सदरम्यान उपलब्ध होणारी कोणतीही माहिती जी माझ्या सहभाग घेण्याच्या इच्छेवर परिणाम करू शकते, ती मला कळवली जाईल.

[५] गोळा केलेल्या माहितीची पडताळणी करण्यासाठी संस्थात्मक नीतिमत्ता समितीचे अधिकारी माझ्या वैद्यकीय नोंदी तपासण्यास इच्छुक असू शकतात. ह्या दस्तऐवजावर स्वाक्षरी करून, मी माझ्या नोंदींचा आढावा घेण्यासाठी परवानगी देत आहे.

[६] मला माहित आहे की माझी ओळख कोणत्याही अहवालात किंवा प्रकाशनात उघड केली जाणार नाही.

[७] मी वरील अभ्यासात भाग घेण्यास सहमत आहे.

_____	_____	_____
संशोधन सहभागींची नावे	**संशोधन सहभागींची स्वाक्षरी/अंगठ्याचा ठसा**	**तारीख**

_____	_____	_____	_____
कायदेशीर प्रतिनिधीचे नाव (एलएआर)	**संशोधन सहभागींशी नाते**	**एलएआरची स्वाक्षरी / अंगठ्याचा ठसा**	**तारीख**

_____	_____	_____
निःपक्षपाती साक्षीदाराचे नाव	**निःपक्षपाती साक्षीदाराची स्वाक्षरी**	**तारीख**

_____	_____	_____
संमती घेणाऱ्या व्यक्तीचे नाव	**संमती घेणाऱ्या व्यक्तीची स्वाक्षरी**	**तारीख**

(रुग्ण माहिती पत्रकाची आणि यथोचितरित्या भरलेल्या माहितीपूर्ण संमती प्रपत्राची प्रत रुग्णाला किंवा त्याच्या/तिच्या काळजी घेणाऱ्या व्यक्तीला सुपूर्द केली जाईल**)**

कृपया याची नोंद घ्या की माहितीपूर्ण संमती दस्तऐवजात पृष्ठ क्रमांक असावेत

Annexure 9

AX 09/SOP 05-A/V7

Sample Format of an Assent to be a Participant in a Research Study
(For Children between 7-18 years old) in English
(This template should be customized according to the requirement of individual research project)

1. What do we wish to tell you?
I am Dr. _____We want to tell you about something we are doing called a research study. A research study is when doctors collect a lot of information to learn more about something related to health and disease.
After we tell / explain you about it, we will ask if you'd like to be in this study or not.
2. Why are we doing this study?
We want to find out
So we are getting information from…… boys and girls of your age.
3. What will happen to you if you are in this study?
Only if you agree, two things will happen:
(as applicable to research study)

1. A small amount of your blood will be drawn. That means it will be taken by a needle in your arm. This will happen…...times. [If some or all of blood draws would be done anyway as part of child's clinical care, emphasize here what will be done extra for the study.]
2. The doctors will do some tests on ……..
3. You will need to answer some questions about ……...
4. You will be given a medicine ……(explain as applicable)
4. **Is this bad or dangerous for you to get involved in this research? Will this study hurt? (explain risks involved as applicable)**

The stick from the needle to draw your blood will hurt, but it will soon disappear.

5. How will this research study be useful to you?

No, this study won't make you feel better or get well. But the doctors might find out something that will help other children like you later.

6.Will everybody come to know about your condition? (Confidentiality)

We will not tell other people that you are in this research and we won't share information about you to anyone who does not work in the research study.

7.Do you get anything for being in the research?

[Mention any reimbursements or small gifts/incentives]

8. Will you tell me the results?

[Include details if relevant. Also inform about possibility of publication and keeping confidentiality in publication]

9. Do you have any questions?

You can ask questions any time. You can ask now. You can ask later. You can talk to me or you can talk to someone else.

10. Do you have to be in this study?

No, you don't. No one will be force you if you don't want to do this. If you don't want to be in this study, just tell us. And remember, you can say yes now and change your mind later. It's up to you. This will not affect in any way your future treatment in this hospital.

11.Who can you talk to or ask questions to?

[Contact information for those people who the child can contact easily (a local person who can actually be contacted). Tell the child that they can also talk to anyone they want to about this (their own doctor, a family friend, a teacher).]

12. Signature of Person Conducting Assent Discussion

I have explained the study to _____(print name of child here) in language he/she can understand, and the child has agreed to be in the study.

_____ _____
Signature of Person Conducting Assent Discussion Date

_____
Name of Person Conducting Assent Discussion (print)

Assent Statement

I have read this information (or had the information read to me) I have had my questions answered and know that I can ask questions later if I have them.
I agree to take part in the research.
Name of child _____ Signature of child: _____
Date: _____

OR

I do not wish to take part in the research and I have not signed the assent below. _____ (initialed by child/minor)
I have witnessed the accurate reading of the assent form to the child, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely. [in case of illiterate child]
Name of witness (not a parent)_____ and
Thumb print of participant
Signature of Witness _____
Date _____ Name of Investigator ----------
Signature of Investigator _____ Date : ----------

(Copies of the Child information sheet and duly filled and signed ICFs of child and parent shall be handed over to the participant or his/her attendant)

Annexure 10

AX 10/SOP 05-A/V7

Format for Informed Consent Document for Genetic Studies

This document will, in general, follow the format of the informed consent document contained in Annexure 8 AX 08/SOP 05-A/V 7. The additional specific components related to genetic studies are elucidated here.

These guidelines are meant to provide assistance in framing informed consent documents for genetic research studies. The examples given may be inserted, where relevant, by the investigator/sponsor.

A. Project Title and Purpose of the Study

Given the more complex nature of genetic research, the sponsor/investigator should make the nature of the research abundantly clear to the research participant. The sponsor/investigator should also generally define genetic/genomic research in the context of the study under consideration in layman's terms. If the investigator so desires, a glossary of genetic terms used may also be provided.

Example:

1. *The purpose of this document is to enable you to understand the nature of the research that we are undertaking. Do take time to review this document IEC fully and do not hesitate to ask the investigator any question or clarification related to the research.*
2. *This study involves the analysis of how genes, blood components or DNA relate to the way that investigational therapies are absorbed, broken down and eliminated from the body, how they affect the body and how DNA relates to human disease."*

B. Study Procedures to be followed

The sponsor/investigator should explain in layman's terms the procedure to obtain any genetic material/tissue from a research participant.

C. Risks and Discomforts

The sponsor/investigator must explain the risks involved in the procedures to obtain any genetic material/tissue. Separate risks relating to genetic information obtained should also be explained.

Example: "There is a chance that participation in this study could cause psychological distress, social and economic harm either to you individually or to your community."

D. Possible benefits of the study

The sponsor/investigator ought to mention benefits if any that may accrue to the participants/community. If no such benefits are seen/ guaranteed at this point in time, the same may be explicitly stated. However, if there is a possibility of long-term societal benefits, this should be incorporated. The sponsor should also state his/her policy regarding commercial benefit to participant/community.

E. What happens when the research trial stops?

The storage of samples, the duration of such storage, the method of destruction of such samples should be stated. The possibility, if any, of using such samples in the future by the same or different investigators should be mentioned. Also, if the genetic study is being carried out as a sub-study, it ought to be stated that stoppage of the genetic study would not result in automatic cessation of the main study. If the study is stopped before schedule and the data is not anonymised, the option of knowing the results of the study should be made available to the research participant. Moreover, if the results of the study indicate that there might be implications for the participant, as regards future medical conditions; appropriate counseling ought to be provided. For example, the necessity of avoiding certain drugs in the future should be explained.

The genetic studies are often carried out as part of basic research and the data generated in initial studies is inadequate. It may inappropriate to use the preliminary data in management of patient's condition. This aspect needs to be explained (whenever applicable).

Example: *These analyses are done as part of basic research. Basic research analyses are performed under conditions that are different from routine laboratory testing that your doctor may do. Therefore, it would not generally be appropriate for your doctor to use these results as part of your IEC."*

F. Compensation for participation and Treatment and Compensation for study related injury

The provisions of the earlier format contained in Annexure 8 AX 08/SOP 05-A/V 7 are applicable.

G. Right to withdraw from the study

If the genetic study is being carried on as a sub-study, withdrawal from the genetic study should not affect participation in the main study**.** The participant should be given the right to request for destruction of his/her sample provided the sample has not been anonymised till that time.

H. Confidentiality

The participant should be informed whether the samples are to be unidentified, unlinked or coded as defined in the ICMR Guidelines, 2017. If the investigator does not intend to disclose the results of the study (for example, in the case of a preliminary/pilot study), the samples should be 'anonymous.'

If the investigator intends to disclose the results of the genetic testing, the participant should have the right to decide whether or not he desires such disclosure. Family members are not entitled to know each others' diagnosis and specific consent is needed from a participant before sharing the information with family members.
Example: *The investigator will provide the genetic analyses to your family, the doctor conducting the main study or any doctor involved in your IEC, your insurance funding agency or your employer, only after obtaining your written consent. However, this is subject to the requirement of disclosure of such information to a court of law. It may also be made accessible to members of the IEC and regulators.*"

Annexure 11
AX 11/SOP 05-A/V7
Departmental Review Board (DRB) Guidance Document & sample format of DRB approval letter (for all MD/MS/Post graduate Theses /Dissertation)

Purpose:
To facilitate the review process for the investigators in term of time.
Composition:
- The DRB will be established by the **Head of the Department.**
- There will be one Chairperson, a Co-Chairperson who will be appointed from amongst the members (The Co-chairperson will perform the functions of Chairperson in his/her absence or at the time of Conflict of Interest).
- The DRB will be composed of at least 3 and a maximum of 7 members.

Detailed instructions:
The board should opine on the scientific aspects of the proposal. The Board should also consider the feasibility of the proposal and collaboration with any other department if required.
Roles and responsibilities of the DRB members:
- It is the responsibilities of the DRB members to read, understand, and follow the guidance document.
- The DRB will consist of members who collectively have the experience in research methodology and should have at least ≥ 5 years' experience or > 5 years PG teaching experience.
- **All Dissertations /** Theses (MD/MS/Post graduate thesis) will be reviewed and approved by the DRB before submission to Institutional Ethics Committee.
- The signature of the Chairperson/ Co-chairperson of the DRB will be mandatory on the DRB approval letter. Please note that the chairperson signing the DRB approval letter cannot be an investigator in that study.
- It is the responsibility of the DRB member to attend DRBC Meetings and participate in discussions and deliberations so that appropriate decisions can be arrived at.
- It is the responsibility of the DRB member to review, discuss and consider research proposals submitted for evaluation.
- It is the responsibility of the DRB member to carry out the work delegated by Chairperson.
- DRB should ask for submission of IEC approval letter within 6months of the DRB and if delayed should submit the reason to the chairperson of DRB.
- It is the responsibility of the DRB member to assist Chairperson in carrying out DRB work.

Note: *If there is a delay in submission (12 months after joining the MD/MS course) of thesis proposal to IEC, then a letter with reason for delayed submission needs to be submitted to IEC with signature of HOD, PI (guide) and student.*

Sample Format of DRB Approval letter

Date _____ **(mandatory)**

To,
Dr. _____, (name of the Guide)
Dr. _____ (Name of MD/MS/MSc/PhD student)
Dept. of _____.

Ref: The project entitled (Please put your department name / no of the protocol/year) "_____".
Sub: Departmental Review Board (DRB) approval

Dear Dr. _____,

The meeting of the Departmental Review Board (DRB) of _____ (name of the dept.) was held on _____ at _____ am / pm, in the _____ with Dr. _____ as Chairperson.

____ members attended the meeting held on _____. The list of members who attended the meeting is as follows.

Name of Members	Position on DRB	Qualification

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

It is understood that this study will be undertaken by _____ (name of the student) under your guidance during _____(period) and will follow the principle of Good Clinical Practices (GCP).

Dr._____ had been admitted to the _____course in the year_____. His/ Her title / synopsis will be registered in the Maharashtra University of Health Sciences (MUHS), Nashik in year_____. He/ She will submit the Dissertation on (approximate month and year) _____ to the MUHS, Nashik and appear for MD/MS Examination during (month and year) _____.

The DRB hereby approves the proposal entitled, "_____" at the meeting.

Sincerely yours

_____

Signature of Chairperson

DRB (Signed and dated by the DRB Chairperson or Acting Chairperson or any one of the members who does not have a conflict of interest)

Note: *If there is a delay in submission (12 months after joining the MD/MS course) of thesis proposal to IEC, then a letter with reason for delayed submission needs to be submitted to IEC with signature of HOD, PI (guide) and student.*

Annexure 12
AX 12/ SOP 05-A/V7
Site Assessment Checklist

IEC No. of the Project: ……..
Title of Study:
……..
Principal Investigator (Name, Designation & Affiliation):
……

		State Y (Yes) or N (No)	If No, Comment
1.	**Patient Population**		
	1. Do you have access to the desired participants pool? If no direct access, is the collaborating department providing access?		
	2. Will you need to recruit patients from external sources? If so, will sponsor /CRO provide funding?		
	3. Is the proposed enrollment goal for a given period realistic?		
	4. Will enrollment compete with other studies seeking the same patients?		
	5. Is Patient Charter of Rights of Participants in research available and displayed at the site, including English and vernacular languages		
	6. Is Participant's Request/ Complaint Record form drop box available?		
	7. Are services/ investigations available (e.g., lab, radiology-accreditation) t o meet the protocol requirements present Are these laboratories accredited		
	8. Are necessary equipment /instruments (availability, validation and calibration) required for protocol execution present at site?		
	9. Does protocol execution require dedicated internet/phone/fax facilities If yes, are they available at the site? -eCRF - patient monitoring (eg phone call)		
2.	**Procedures**		
	1. Are the study visits frequent? (more than those in clinical practice for a given disease)		
	2. Are the procedures during each visit difficult and time consuming? If yes measures taken to minimize patient risk at the site		
3.	**Study Team**		
	1. Does the study require special study team members with additional expertise?		
	2. In case study visits are complex, do they present scheduling difficulties for the team?		
	3. How many study team members will be required /participant / visit?		
	4. In case of unavailability of any protocol required equipment / procedures willsponsor / CRO provide it If yes: permanent / rental for the trial period		
4.	**Trial Procedure**		
	1. Is adequate space available?		
	2. Does the site have dedicated with restricted access area for - Investigational product (IP) storage / - Mention IP accountability		
	3. IP storage room has a facility to record temperature/ humidity 24*7		
	4. Will electronic or remote data retrieval systems be used? If so, will the sponsor/CRO provide training?		
	5. Does the site have dedicated computer, printer, cupboard, stationary for storage of study documents		

Name and Signature of the PI & Date:
……

IEC office use only:
Date of the physical site assessment: _____ Time in _____ Time out_____
Assessment performed by
Name of IEC member:
1. **……**
2. **……**
3. **……**

Type of facilities: ……
Confirmation of all items in AX 12/ SOP 05-A addendum, Site Assessment Checklist Yes __ No___ if no list the deficiencies
1. **……..**
2. **……..**
3. **……..**

Interaction with clinical trial members at the site:

Name of the trial team members	Query asked	Reply provided
PI		
Co-I 1		
Co-I 2		
Co-I 3		
CRC1		
CRC2		
CRC3		
Lab Technician		
Any other trial team member		

Date and signature of the monitors:
1. **……..**
2. **……..**
3. **……..**

Title:	Full Board Review of Submitted Protocol
SOP Code:	SOP 05-B/V7 dated 19th November 2024

Prepared by Signature with date	Reviewed by Signature with date	Approved by Signature with date	Accepted by
Dr. Raakhi Tripathi, Member Secretary, IEC-I	Dr. Nithya Gogtay, Jt. Member Secretary, IEC-I	Dr. Manju Sengar Chairperson, IEC-I	IEC-I
	Dr. Vyankatesh Shivane, Member, IEC-I	Dr. Sunil Kuyare Chairperson, IEC-II	IEC-II
		Dr. M. G. Karmarkar Chairperson, IEC-III	IEC-III

1. Purpose

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

2. Scope

This SOP applies to the review of all protocols submitted for initial review and decisions thereof by the IEC.

3. Responsibility

It is the responsibility of Member Secretary (MS) to identify the Primary Reviewer (PR) as per expertise and allocate the projects to the respective IECs. All the IEC members can review all the protocols. However, Primary Reviewer (PR) must review and give comments via email along with the assessment form no Annexure 2 (*AX 02/SOP 05-B/V7)* for the projects assigned to him/her by member secretary. PR, after reviewing each study protocol will lead the discussion on the relevant protocol in the subsequent meeting (refer to SOP 13).

4. Activity Table:

No.	Activity	Responsibility
1	Determine the protocol for full board review.	Member Secretary
2	Selection of PR to review the project.	Member Secretary
3	Review of the assigned protocols	IEC Member
4	Compile the comments of IEC members	IEC secretariat

5. Detailed Instructions

5.1 Consider the protocol for full board review.

- All research proposals presenting more than minimal risk that are not covered under exempt or expedited review shall be subjected to full board review (as per National Ethical Guidelines for Biomedical & Health Research Invovling Human Participants Indian Council of Medical Research ICMR-2017).
- 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. Please refer to SOP 14/V7 and SOP 22/V7.
- Prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.

5.2 Selection of PR to review the project

- The Member Secretary will assign PR based on expertise in the related field and experience along with nonscientific member to each research study for scientific, ethical and statistical review. The PR will be members of the IEC and will have to present a detailed relevant review of the assigned study.
- The Primary Reviewers will present the research study at a regular full board.
- In case the PR is not in a position to review due to some reason, he/she should inform the Member Secretary at the earliest, so that the research study can be assigned to another PR (other IEC member).
- In the event of his/her absence, PR can send comments (fill the annexure no. Annexure 2 *AX 02/SOP 05-B/V7*) on the research protocols to the Member Secretary, which will be 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 comments.

- It is the responsibility of the assigned PRs to review the research protocols assigned to them thoroughly and communicate their observations, comments and decisions to the IEC during the meeting. The PRs should return the research protocols and relevant documents to the IEC secretariat on the day of the meeting. The protocol will be reviewed by PR as per guidelines (described in *AX 01/SOP 05-B/V70).*
- In addition to PR, the review of projects will be performed by other IEC members. The queries raised by the members on the protocol and related documents will be communicated to IEC secretariat either via email or via project assessment annexure. The protocol will be reviewed by each member as per guidelines (described in *AX 01/SOP 05-B/V7).*
- All IEC members to send acknowledgement email stating that project documents are received for review and the privacy and confidentiality of these documents will be maintained by the concerned IEC member.
- Record of Emails will be maintained in the project master file by the IEC secretariat.
- The Member Secretary can invite an subject expert (if necessary) for comments during the full board meeting (refer SOP 04V7).
- The IEC member will consider the following criteria when performing the review of the study protocol:

5.2.1 Examine the qualification of investigators and assess adequacy of study sites

The IEC members must consider whether the qualifications of the participating investigators relate to the study by reviewing their CVs, MMC/ OT/PT council registration for allied health Registration certificates and GCP training certificates (preceding 3 years).

- The IEC members must examine disclosure or declaration of potential conflicts of interest.
- The IEC members must assess / ascertain, if required by reviewing the study site whether the facilities and infrastructure at study sites can accommodate the study.

5.2.2 Guidelines for PR and other IEC member for evaluation of a project (refer *AX 01/SOP 05-B/V7***): few points are listed here**

- 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 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:
    - Does this study address an important research question or is it a predominantly service proposal?
    - If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced?
    - What will be effect of these studies on the concepts, methods, technologies, treatments, services, or preventive interventions that drive this field?
- 'Recruitment strategy' of the participants for study.
- Statistical methodology (including sample size calculation), and the potential for
- reaching sound conclusions with the smallest number of research participants;
- Justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities.
- Justification for the use of control arms/placebo.

- 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.
- 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, emergency procedures.
- Study Reporting and publication of the research.
- Presence of regulatory permission for conduct of the study, HMSC clearance for international collaborative studies, MOU and CTA (Tripartite/Bipartite) refer AX03/SOP5-B/V7 for national and international collaborative research.
- Provision of rescue medication
- Perform risk benefit assessment of the project refer AX05/SOP5-B/V7, to review the measures taken for:
    - Minimization of risks to participants
    - Risk mitigation strategies
    - Reasonable risks in relation to anticipated benefits
    - Equitable selection of participants
    - Adequacy of informed consent is adequate, easy to understand and properly documented
    - Adequate provision for monitoring the data collected to ensure the safety of participants, where appropriate
    - Adequate provisions to protect the privacy of participants and to maintain the confidentiality of data, where appropriate; and
    - Appropriate safeguards are included to protect vulnerable participants.

5.2.3 Review study participation

The IEC member will examine for the presence of the following points while reviewing the patient information sheet/Informed Consent Form as per guidelines *AX 01/SOP 05-B/V7* to review protocol and Informed Consent Document/Patient Information Sheet in *AX 04/SOP 05-B/V7.*

- Voluntary, non-coercive recruitment, participation/ withdrawal
- Procedures for obtaining informed consent
- Contents of the patient 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
- Contact persons with address and phone numbers for questions about research participants rights and study or injury
- Privacy and confidentiality
- Risks and discomforts – physical / mental / social
- Alternative treatments
- Benefits – to participants, community, institution and society
- Compensation for participation: (Whether it will act as undue inducement)
- Involvement of vulnerable participants
- Provisions for medical/ psychosocial support

- Treatment for study related injuries
- Compensation for study-related injuries: Reasonable
- Use of biological materials
- Check for provision for signatures with dates of participant, person conducting informed consent discussion, investigator and witness
- Provision of rescue medication

5.2.4 Examine community involvement and impact

The IEC members will also consider the following points in the protocol, Informed Consent Form/ Patient Information Sheet

- Community consultation/ involvement
- Benefit to local communities
- Contribution to development of local capacity for research and treatment
- Availability of study results for the community

5.3 Compile the comments of IEC members

The Member Secretary will compile the comments from each reviewer and present in the scheduled full board meeting.

5.4 Presentation of the comments for each project in the full board meeting

The member secretary will present the project summary and the compiled comments in the full board meeting. The comments will be discussed by all the IEC members and final decision on a project will be as per IEC decision form refer annexure *AX 06/SOP 05-B/V7*.

- The final decision regarding the project shall include any one of the following:
  - ✓ If the IEC decision is 'Approved', it implies the approval of the study as it is presented with no modifications and the approval letter (as per format (**AX 07/SOP 05-B/V7),** (**AX 08/ SOP 05-B/V7**) & (**AX 09/SOP 05-B/V7**)) can be issued to the Principal Investigator.
  - ✓ If the IEC decision is 'Approved with minor modification, then the IEC secretariat will send query letter to the PI. The IEC Chairperson may authorize the Secretary/Primary reviewer + secretary to review the reply letter submitted by the PI. The reply letter when submitted will be reviewed as per SOP5 E Resubmitted protocol.
  - ✓ If the IEC decision is 'Approved with major modification, then the IEC secretariat will send query letter to the PI. The IEC Chairperson may authorize the Secretary/Primary reviewer + secretary to review the reply letter submitted by the PI. The reply letter when submitted will be reviewed as per SOP5 E Resubmitted protocol.
  - ✓ If the IEC decision is 'Approved with major modification, then the IEC secretariat will send query letter to the PI. The IEC Chairperson may authorize the Primary reviewer + secretary to review the responses and subsequently discussed in full board meeting as per IEC Decision Form AX 06/ SOP 05-B/V7.

5.5 Written communication of the IEC decision.

The decision will be communicated to the PI within 14 working days. For the projects which will be discussed in the full board meeting the decision will be communicated within 14 working days of the FB meeting. Response from the PI to the IEC communication is expected within 180 days of date of receipt of the letter and in the absence of any response, the project will be declared closed for the IEC office records. Reply to subsequent queries should be sent in 60 days (for regulatory trials refer SOP5A version 7 Annexure 7 Guidelines for investigators)

- ✓ The Secretariat will record the decision reached on the response in the minutes of the meeting.

6. Glossary

Document	Document may be of any forms, e.g., paper, electronic mail (e-mail), faxes, audio or video tape, etc.
Pre-clinical study	Animal and *in vitro* studies provide information on possible toxicities and mechanisms of action, and starting doses for human studies.
Vulnerable research participants	A vulnerable category of research participants includes children, prisoners, pregnant women, handicapped or mentally disabled persons, refugees, displaced persons and economically or educationally disadvantaged persons, who are likely to be vulnerable to coercion or undue influence.
Initial Review	The first review of that protocol made by two or three individual reviewers (IEC members or non-members) in advance of the full Committee meeting, and comments of the reviewers will be reported to the full Committee meeting. Other members can add their comments before or at the time of review.
Phase I study	Initial introduction of an investigational new drug (IND) into humans, studies designed to determine the metabolism and pharmacological actions of drugs in humans, and studies designed to assess the side effects associated with increasing doses.
Phase II study	A Study of drug metabolism, structure-activity relationships, and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes.
Phase III study	A Study expands controlled and uncontrolled trials performed after preliminary evidence suggesting effectiveness of the drug has been obtained. They are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling.
Phase IV study	A study that seeks to expand an approved medication's use into a new population, new indication, or new dose.
Less than minimal risk:	Probability of harm or discomfort anticipated in the research is nil or not expected. For example, research on anonymous or non-identified data/samples, data available in the public domain, meta-analysis, etc.
Minimal Risk	Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests where occurrence of serious harm or an adverse event (AE) is unlikely. Examples include research involving routine questioning or history taking, observing, physical examination, chest X-ray, obtaining body fluids without invasive intervention, such as hair, saliva or urine samples, etc.
Minor increase over minimal risk or Low risk	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 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 bruises 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.
More than minimal risk or High risk	Probability of harm or discomfort anticipated in the research is invasive and greater than minimal risk. Examples include research involving any interventional study using a drug, device or invasive procedure such as lumbar puncture, lung or liver biopsy, endoscopic procedure, intravenous sedation for diagnostic procedures, etc.

Benefit	A research benefit is considered to be something of a health-related, psychosocial, or other value to an individual research subject, or something that will contribute to the acquisition of generalizable knowledge. Money or other compensation for participating in research is not considered to be a benefit. A great deal of research in the social and behavioral sciences offers little potential for direct benefits to the subjects themselves. Rather, the benefits often encompass the importance of the knowledge to be gained, and/or to the contributions the research makes to science or society.

(The above glossary terms are adapted from https://www.iitm.ac.in/downloads/ICMR_Ethical_Guidelines_2017.pdf Last accessed on 18.11.2024)

7. Annexure

Annexure 1	*AX 01/SOP 05-B/V7*	Guidelines for review of study protocol & ICD
Annexure 2	*AX 02/SOP 05-B/V7*	Assessment form for review of study protocol
Annexure 3	*AX 03/SOP 05-B/V7*	Checklist of Clinical Trial Agreement and study budget
Annexure 4	*AX 04/SOP 05-B/V7*	Informed Consent Assessment Toolkit for IEC members
Annexure 5	*AX 05/SOP 05-B/V7*	Project Risk Benefit Assessment Tool for IEC members
Annexure 6	*AX 06/SOP 05-B/V7*	IEC Decision Form for initial review and resubmitted protocols where decision is full board review
Annexure 7	*AX 07/SOP 05-B/V7*	Format of Project Approval letter (for regulatory and academic clinical trial)
Annexure 8	*AX 08/SOP 05-B/V7*	Format of Project Approval letter (for interventional / other than regulatory and academic clinical trial)
Annexure 9	*AX 09/SOP 05-B/V7*	Format of Project Approval letter (for biomedical health research study)
Annexure 10	*AX 10/SOP 05-B/V7*	Participant Feedback Form

Annexure 1
AX 01/SOP 05-B/V7
Guidelines for review of study protocol & ICD

Reviewers should think about and try to find answers to the following questions while reviewing the protocol, ICD and related documents and fill the AX 02/SOP 05-B/V7:

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.
   - ❑ 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 is minimized.
   - ❑ Unbiased assignment (e.g. randomization, etc.) is in practice.
   - ❑ Inclusion and exclusion criteria are carefully selected to eliminate confounding factors as 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, if needed.

3. Who will be the participants in the study? Whether
   - ❑ The described population is appropriate for the study.
   - ❑ Predictable vulnerabilities are considered.
   - ❑ It is completely necessary to conduct the study in a vulnerable population. If not, is there any other way to get the study answers?
4. Recruitment strategy:
   - ❑ OPD/ IPD
   - ❑ Advertisement/ mouth to mouth publicity
   - ❑ Notices
   - ❑ Collaboration with other departments / institutes
5. 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?
6. Does the study design have adequate built-in safeguards for risks?
   - ❑ Appropriate screening of potential participants?
   - ❑ 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 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.
7. 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 to detect expected possible risks and side effects?
8. Do the study and the informed consent process include issues of special concern, such as:
   - ❑ Waiver or alteration of consent?
   - ❑ Delayed consent (e.g., emergency treatment, etc.)?
   - ❑ Deception?
   - ❑ Sensitive information of participants that may require a confidentiality statement?
9. Risk benefits assessment categories:

   Risk Categories
   - ❑ The research involves less than minimal risk to subjects.
   - ❑ The research involves minimal risk to subjects.
   - ❑ The research involves minor increase over minimal risk / low risk to subjects.
   - ❑ The research involves more than minimal risk/high risk to subjects.

   Benefits Categories
   - ❑ The research provides no prospect of direct benefit to individual subjects, but likely will yield generalizable knowledge about subject's disorder or condition.

- The research provides no prospect of direct benefits to individual subjects, but likely will yield generalizable knowledge to further society's understanding of the disorder or condition under study.
- The research provides the prospect of direct benefits to individual subjects.
- The research provides no prospect of direct benefits to individual subjects, to science, or to society.

Guidelines to review Informed Consent Document/Patient Information Sheet

The actual process of informed consent should:

- 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.
- 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.

Procedures or methods used in the informed consent process

- A physical copy consent form
- Verbal consent
- Brochures, Pamphlets or other reading materials (i.e., letters to participants, phone pre-screening questionnaires, phone hold messages)
- Internet information
- Instruction sheets
- Audio-visual presentations
- Charts, diagram or posters
- Discussions
- Consultation with others

Techniques to improve the readability of consent forms:

- Use short sentences and paragraphs
- Limit to one thought or topic in a sentence, avoid run-on sentence
- Use simple words, less syllables in a word.
- Use common words; remove technical jargon and medical terms.
- Try to use correct basic grammar and form.
- Use "gene transfer" instead of "gene therapy" (less implied effectiveness).
- Use "agent" instead of "drug" or "medicine" (less implied effectiveness).
- Try to avoid the use of "treatment", "therapy" or "therapeutic" in studies involving gene transfer (because these words imply effectiveness)

Checklist for Placebo Justification

Background conditions, such as benefits of standard treatment, risk of using placebo, risk management and disclosure should be considered. The followings are some guides to ease Board decision.

I. Benefits of standard treatment

1) Is there a standard treatment?
2) Is the standard treatment widely accepted?
3) Has efficacy of the treatment been consistently proven?
4) Are all newly diagnosed patients with this condition put in standard treatment (versus observed or other)?
5) Does the treatment act on the basic mechanism of the disease (vs. symptoms)?
6) Are most (≥85%) of the patients with this condition responsive to standard treatment alternatives (vs. resistant or refractory)?

   If the answers of (1) to (6) are "yes", placebo is not recommended.

   If any one or more answers are "no", placebo may be possible.
7) Are the side effects of the standard treatment severe?
8) Does standard treatment have many uncomfortable side effects?
9) Does standard treatment have contraindications that prevent some research participants from being treated?
10) Is there substantial (≤25%) placebo response in this disease or symptom?

    If the answer of (7) *to* (10) *are "no", placebo is not recommended.*

    If any one or more answers are "yes", placebo may be possible.

II. Risks of placebo

1) Is the risk of using placebo instead of treatment life threatening?

   If yes, placebo is not acceptable.
2) Is the use of placebo instead of treatment likely to lead to permanent damage?

   If yes, placebo is not acceptable.
3) Is the risk of using placebo instead of treatment likely to cause irreversible disease progression?

   If yes, placebo is not acceptable.
4) Can the use of placebo instead of treatment lead to an acute emergency?
5) Is the risk of using placebo instead of treatment the persistence of distressing symptoms?
6) Is the risk of using placebo instead of treatment severe physical discomfort or pain?

   If answers of (4) *to* (6) *are "yes", placebo is not acceptable unless risk management is adequate.*

III. Risk management

1) Is there benefit in the overall management of the research participants?

   ☐ *Yes, consider placebo*

   ☐ *No, placebo not recommended*.
2) Will the discontinuation of previous treatment put the participant in danger of acute relapse when transferred to placebo?

   ☐ *No, consider placebo*

   ☐ *Yes, placebo not recommended*.
3) Are research participants at high risk for the use of placebo excluded?

   ☐ *Yes, consider placebo*

   ☐ *No, placebo not recommended*.
4) Is the duration of the study the minimum necessary in relation to the action of the drug?

   ☐ *Yes, consider placebo*

   ☐ *No, placebo not recommended*.

5) Are there clearly defined stopping rules to withdraw the research participants in case he/she does not improve?

☐ *Yes, consider placebo*

☐ *No, placebo not recommended*.

6) Is risk monitoring adequate to identify progression of the disease before the research participants experience severe consequences?

☐ *Not applicable.*

☐ *Yes, consider placebo*

☐ *No, placebo not recommended*.

7) Are there clearly defined stopping rules to withdraw the research participants before the advent of severe disease progression?

☐ *Yes, consider placebo*

☐ *No, placebo not recommended*.

8) If the risk of placebo is an acute emergency, are rescue medication and emergency treatment available?

☐ *Not applicable.*

☐ *Yes, consider placebo*

☐ *No, placebo not recommended*.

9) If the risk of placebo is the persistence of distressing symptoms, is concurrent medication to control them allowed?

☐ *Not applicable.*

☐ *Yes, consider placebo.*

☐ *No, placebo not recommended*.

10) If the risk of placebo is severely physical discomfort or pain, is there rescue medication?

☐ *Not applicable.*

☐ *Yes, consider placebo.*

☐ *No, placebo not recommended*.

IV. Risk disclosure in the consent form

1) Are the risks of getting placebo instead of active treatment fully disclosed?

☐ *Yes, consider placebo.*

2) Are the risks of the test drug disclosed?

☐ *Yes, consider placebo.*

3) Are the advantages of alternative treatments explained?

☐ *Yes, consider placebo.*

Conclusions:

1. The use of placebo is ethically acceptable because:

☐ 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 in the consent form.

Annexure 2

AX 02/SP 05-B/V7

Study assessment form for project submitted for initial review

IEC Project Number:
Protocol number and title:
Name of Principal Investigator:
Reviewer's name:
Mark and comment on whatever items applicable to the study.

1	Objectives of the Study	Clear/ Unclear
What should be improved?		
2	Background and Rationale	Sufficient/ insufficient
Comment:		
3	Methodology	Clear/ Unclear
What should be improved?		
5	If diagrammatic representation given:	Clear/ Unclear
What should be improved?		
6	Study Design and Sample size	Appropriate/ Inappropriate
Comment:		
7	Inclusion Criteria	Appropriate/ Inappropriate
Comment:		
8	Exclusion Criteria	Appropriate/ Inappropriate
Comment:		
9	Risk Benefit assessment	Appropriate/ Inappropriate
Comment:		
10	Type of Vulnerable population	Clear/ Unclear
Comment:		
11	Statement for protection of rights and interests of Vulnerable Participants	Applicable/ Not Applicable Appropriate/ Inappropriate
Comment:		
12	Voluntary, Non-Coercive Recruitment of Participants	Yes/ No
Comment:		
13	Are Qualification and experience of the Participating Investigators appropriate?	Yes/ No
Comment:		
14	Disclosure or Declaration of Potential Conflicts of Interest	Yes/ No
Comment:		
15	Facilities and infrastructure of Participating Sites	Appropriate/ Inappropriate
Comment:		
16	Involvement of Local Researchers and Institution in the Protocol Design, Analysis and dissemination of Results	Yes/ No
Comment:		
17	Contribution to Development of Local Capacity for Research and Treatment	Yes/ No
Comment:		
18	Community consultation where needed	Yes/ No
Comment:		
19	Benefit to Local Communities	Yes/ No/ Not applicable

Comment:		
20	Are blood/tissue samples sent abroad?	Yes/ No
Comment:		
21	MoU's with collaborating organization	Yes/ No
Comment:		
Any other comment :		

Signature with date: _____

Annexure 3

AX 03/SP 05-B/V7

Checklist of Clinical Trial Agreement and study budget

To ensure that:

☐ Trial conduct details regarding trial site, compliance of investigator, safety reporting are mentioned. Yes ___ No ___

☐ Details regarding the trial drug, material transfer if any, record retention and inspection are mentioned. Yes ___ No ___

☐ Ownership of data and data sharing is clarified. Yes ___ No ___

☐ Details of publication rights are clearly stated. Yes ___ No ___

☐ Maintenance of confidentiality of all trial related information is clearly stated. Yes ___ No ___

☐ General considerations such as publicity and details of termination of contract are stated. Yes ___ No ___

☐ Patient compensation has been covered and is appropriate. Yes ___ No ___

☐ Terms of Termination of the project clearly stated. Yes ___ No ___

☐ **Detail budget is included mentioning the following points:**

a) Payment to be made to the participants/ travel reimbursement. Yes ___ No ___
b) Payment for laboratory testing and other investigations. Yes ___ No ___
c) Payment for any other procedures if required. Yes ___ No ___
d) Payment to investigator. Yes ___ No ___

☐ **The CTA is tripartite** INSTITUTION, PI and Sponsor's/CRO:

☐ **Provision of j**urisdiction and arbitration clause with courts of respective states only: Yes ___ No ___

☐ **CTA is on appropriate s**tamp paper as per law: Yes ___ No ___

☐ **Any other comments by the legal expert:** _____

Reviewed by

Name of legal expert

signature and date

Annexure 4

AX 04/SOP 05-B/V7

Informed Consent Assessment Toolkit for IEC members

1. Essential documents:

Indicate

	Yes	No
• A statement that the study involves research and explanation of the purpose of the research ……	☐	☐
• The expected duration of the drug trial and individual patient's participation and frequency of visits during the study…….	☐	☐
• The approximate number of study Subjects ……	☐	☐
• A description of the procedures to be followed, including all invasive procedures	☐	☐
• Identification of any procedures which are experimental ……	☐	☐
• A description of any reasonably foreseeable risks or discomforts to the Subject……	☐	☐
• A description of any benefits to the Subject or others reasonably be expected from the research. If no benefit is expected the Subject should be made aware of this …… `	☐	☐
• A disclosure of specific appropriate alternative procedures or therapies available to the Subject …….	☐	☐
• A statement describing the extent to which confidentiality of records identifying the Subject will be maintained & who will have access to Subject's Medical Records……	☐	☐
• Trial treatment schedule and the probability for random assignment to each treatment (for randomized trials) …….	☐	☐
• Statement describing the financial compensation and payment for the medical management as under: a) In case of the injury occurring to the Subject during the Clinical Trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the Clinical Trial, whichever is earlier……	☐	☐

b) In the event if a trial related injury or death , the Sponsor and its representative or the investigator or the centre, as the case may be, in accordance of the rule 39, as the case may be, shall provide financial compensation for the injury or death.. ☐ ☐

- An explanation about whom to contact for trial related queries, rights of the Subjects and in the event of any injury …… ☐ ☐
- The anticipated prorated payment, if any, to the Subject for participating in the trial. ☐ ☐
- Responsibilities of Subject on participation in the trial…… ☐ ☐
- Statement that participation is voluntary, that the subject can withdraw from the study at any time and that refusal to participate will not involve any penalty or loss of benefits to which the Subject is otherwise entitled……... ☐ ☐
- Statement that there is a possibility of failure of investigational product to provide intended therapeutic effect……. ☐ ☐
- Statement that in the case of placebo-controlled trial, the placebo administered to the subjects shall not have any therapeutic effect……. ☐ ☐
- Any other pertinent information……. ☐ ☐

2. Additional elements, which may be required:

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

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

Annexure 5
AX 05/ SOP 05-B/V7
Project Risk Benefit Assessment Tool for IEC members

High Risk/ Low Benefit (Class-A)	**High Risk/ High Benefit (Class-B)**
Risks:	**Risks:**
• Completely new drug / formulation	• Completely new drug/formulation
• Highly Toxic substances	• Highly Toxic substances
• Safety/Effectiveness not established through earlier studies	• Safety/Effectiveness not established through earlier studies
• High incidence of SAEs/side effects in prelim studies	• High incidence of SAEs/side effects in prelim studies
• Inadequate or no risk AE handling mechanisms	• Inadequate or no risk AE handling mechanisms
• High data disclosure and data leakage possibilities	• High data disclosure and data leakage possibilities
• Affects large no. Of participants	• Affects large no. of participants
• Violation legal/statutory regulations	• Violation legal/statutory regulations
• Inadequate project documentation	• Inadequate project documentation
• Inadequate PI/Staff expertise	• Inadequate PI/Staff expertise
• New/untried procedures	• New/untried procedures
Benefits:	**Benefits:**
• Cost of treatment/drug borne by participant	• Completely new cure
• Replaces current drugs with no extra benefits either treatment wise or cost wise	• Preventive for life i.e. Vaccinations
• Short term relief as opposed to long term action	• Significant improvement over o Existing cures/treatments
• No post-trial alternatives	• Minimal side effects vis a vis existing treatments
	• Elimination of disease rather than temporary curative
	• Significant reduction in treatment costs/mode (ex. Pelvis surgery)
	• Extension of benefits/ availability of Treatment post trial
	• Benefits large no. of participants

Low Risk/Low Benefit (Class-D)	**Low Risk/High Benefit (Class-C)**
Risks:	**Risks:**
• Proven/Acceptable toxicity	• Proven/Acceptable toxicity
• Proven safety and efficacy	• Proven safety and efficacy
• Drug/formulation a variation of approved drug/class of drugs	• Drug/formulation a variation of approved drug/class of drugs
• SAEs indicate minor/acceptable reactions, side effects	• SAEs indicate minor/acceptable reaction, side effects
• No drug but only data analysis	• No drug but only data analysis
• Minimal data disclosure /leakage possibilities	• Minimal data disclosure/leakage possibilities
• Minimal risk to legal/statutory regulations	• Minimal risk to legal/statutory Regulations
• Standard operating / surgical procedures	• Standard operating/ surgical procedures
Benefits:	**Benefits:**
• Cost of treatment/drug borne by participant	• Completely new cure
• Replaces current drugs with no extra benefits either treatment wise or cost wise	• Preventive for life i.e. Vaccinations
• Short term relief as opposed to long term action	• Significant improvement over existing cures/treatments
• No post trial alternatives	• Minimal side effects vis a vis existing treatment
	• Elimination of disease rather than temporarily curative
	• Significant reduction in treatment costs/mode (e.g.. Pelvis surgery)
	• Extension of benefits/availability of treatment post-trial
	• Benefits large no. of patients

IEC member to mark the class as per the project risk benefit assessment.

Annexure 6

AX 06/ SOP 05-B/V7

IEC Decision Form for initial review and resubmitted protocols where decision is full board review

Date of IEC meeting: _____

Protocol number: _____

	IEC Protocol No. and Title:		
Principal Investigator:	Department:		
Final Decision atthe meeting:	Approved		
	Revision with minor modification/amendments	Member Secretary (MS)	
		MS + Primary Reviewer (PR)	
	Revision with major modification	MS + PR	
		MS + PR+ Full Board (FB)	
	Not approved (Reason)		
	Monitoring required (Reason)		

No.	Names of Members present	Approved	Modification		Disapproved	Comments/ Recommendations to be incorporated in the Letter of permission	Signature
			Major	Minor			

Comments:

No. of members voting for the decision:

No. of members voting against the decision:

No. of members abstaining from voting:

Any Dissent (mention details):

_____

Signature of Chairperson **Date:** _____

Annexure 7

AX 07/SOP 05-B/V7

Format of Project Approval letter (for regulatory / academic clinical trial)

Date XX/XX/XXXX

To,

Dr. xxxxxxxxxxx,

Dept. of xxxxxxxxxxxx.

Ref: The project no. EC/xxx/20xx entitled, “xxxxxxxxx”.

Sub: Letter no.

Dear Dr. XXXX,

The meeting of the Institutional Ethics Committee (IEC) was held on xxxxx at xxxx, in the xxxxxxxxxxxx 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	Role/Position on IEC	Designation & Affiliation	Qualification	Gender

It is to be noted that neither you nor any of your proposed study team members were present during the decision-making procedures of the Institutional Ethics Committee-I.

In addition, the members of the IEC-I do not have any conflict of interest for the above mentioned study.

The Institutional Ethics Committee-I has 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 (mention number xxxx)/ duration research participants, at Dept. of (Name of the Department), Seth G. S. Medical College and K. E. M. Hospital as per the submitted protocol.

- Expert opinion from ___ was sought for this study (if required).
- IEC should be informed after the recruitment of first participant.
- Please note that in event of premature termination, rights of the participants (including medical care) be protected.
- It is the policy of IEC that, on site AE reports to be submitted by the Principal Investigator at six monthly to the IEC (regulatory trial) and annually (or earlier if deemed necessary) for academic clinical trial.
- It is the policy of IEC that monitoring reports received by the investigator from the sponsor and DSMB recommendations to be submitted to the IEC within fifteen days (if applicable).
- It is the policy of IEC that, it be informed about any onsite serious adverse event or the unexpected adverse event report within 24 hours as per the format specified in AX 01/SOP11-B/V7 (G.S.R .227 (E)) and AX 02/SOP 11-B/V7 to the IEC 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 days of SAE or death.
  The sponsor has to forward the report of SAE or death after due analysis to the chairman of the IEC and the head of the institution where the trial is been conducted within fourteen days of occurrence of the SAE or death. The report of the SAE other than death after due analysis shall be forwarded to chairman of the IEC and the head of the institution.
  In case of injury or death occurring trial subject the sponsor (whether a pharmaceutical company or an institution) or his representative, whosever 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 in the manner as prescribed in SOP 5 A, Version 7, Annexure 8. (applicable for regulatory/interventional academic studies)
- 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.
- Site monitoring report (by sponsor) needs to be submitted within 90 days of the date of site monitoring.

- The Clinical Trial was unanimously approved by all IEC members present in the meeting. This clinical Trial has been approved by the IEC-I to be **conducted as per trial documents stated in this approval letter (presented form) and is valid** for the entire duration of the study.
- The first periodic review report needs to be submitted (end of the 6th month from the date of approval for regulatory trial and 11th month from the date of approval for academic clinical trial) on or before **xxxxxx.** Please note that submission of the periodic review report is mandatory. Delay in submission of the periodic review report can result in some action taken against the PI as deemed appropriate by IEC-1.
- For regulatory trials PI to collect participant feed back form (as per AX 10/SOP 05-B/V7) for enrolled participants during any scheduled visits (preferably this feedback may be collected during any of the initial three visits)
- A copy of the final report should be submitted to the IEC for review.
- The IEC functions in accordance with ICH GCP, G.S.R .227 (E), ICMR guidelines and other applicable regulatory requirements.

Annexure08

AX 08/SOP 05-B/V7

Format of Project Approval letter (for interventional trial other than regulatory / academic clinical trial)

Date XX/XX/XXXX
To,
Dr. xxxxxxxxxxxx,
Dept. of xxxxxxxxxxxxx.
Ref: The project no. EC/xxx/20xx entitled, “xxxxxxxxxx”.
Sub: Letter no.
Dear Dr. XXXX,
The meeting of the Institutional Ethics Committee (IEC) was held on xxxxx at xxxx, in the xxxxxxxxxxxxx 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	Role/Position on IEC	Designation & Affiliation	Qualification	Gender

It is to be noted that neither you nor any of your proposed study team members were present during the decision-making procedures of the Institutional Ethics Committee-I.

In addition, the members of the IEC-I do not have any conflict of interest for the above-mentioned study.

The Institutional Ethics Committee-I has reviewed the above –mentioned clinical study and approved the following documents submitted for this clinical study at the meeting:

1 Xx

2 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 (mention number xxxx)/ duration research participants, at Dept. of (Name of the Department), Seth G. S. Medical College and K. E. M. Hospital as per the submitted protocol.

- Expert opinion from ___ was sought for this study (if required).
- IEC should be informed after the recruitment of first participant.
- Please note that in event of premature termination, rights of the participants (including medical care) be protected.

- It is the policy of IEC that, on site AE reports to be submitted by the Principal Investigator annually (or earlier if deemed necessary) for interventional trial.
- It is the policy of IEC that, it be informed about any onsite serious adverse event or the unexpected adverse event report within 24 hours as per the format specified in AX 01/SOP11-B/V7 (G.S.R .227 (E)) and AX 02/SOP 11-B/V7 to the IEC 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 days of SAE or death.

  In case of injury or death occurring in trial subjects provision for payments for medical management of the subject and financial compensation for the clinical trial related injury or death. As applicable in Indian Council of Medical Research (ICMR) 2017.
- 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.
- The trial was unanimously approved by all IEC members present in the meeting. This trial has been approved by the IEC-I to be **conducted as per trial documents stated in this approval letter (presented form) and is valid** for the entire duration of the study.
- The first periodic review report needs to be submitted (end of the 6th month from the date of approval for regulatory trial and 11th month from the date of approval for academic clinical trial) on or before **xxxxxx.** Delay in submission of the periodic review report can result in some action taken against the PI as deemed appropriate by IEC-1.
- A copy of the final report should be submitted to the IEC for review.
- The IEC functions in accordance with ICH GCP, G.S.R .227 (E), ICMR guidelines and other applicable regulatory requirements.

Annexure 9

AX 09/SOP 05-B/V7

Format of Project Approval letter (biomedical health research study)

Date XX/XX/XXXX
To,
Dr. xxxxxxxxxxx,
Dept. of xxxxxxxxxxxxx.
Ref: The project no. EC/xxx/20xx entitled, “xxxxxxxxxx”.
Sub: Letter no.
Dear Dr. XXXXX,
The meeting of the Institutional Ethics Committee (IEC) was held on xxxxx at xxxx, in the xxxxxxxxxxxxx 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	Role/Position on IEC	Designation & Affiliation	Qualification	Gender

It is to be noted that neither you nor any of your proposed study team members were present during the decision-making procedures of the Institutional Ethics Committee-I.

In addition, the members of the IEC-II/III do not have any conflict of interest for the above mentioned study.

The Institutional Ethics Committee-I 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 Dept. of xxxx, Seth G. S. Medical College and K. E. M. Hospital as per the submitted protocol.

This approval is valid for the entire duration of the study.

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 trial subjects and about any new information that may affect adversely the safety of the subjects 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 xx xx xxxx.
A copy of the final report should be submitted to the IEC-I for review.
Sincerely yours,

Member Secretary,
IEC
(Signed and dated by the IEC Member Secretary)
Date of approval of the study: XX/XX/20XX

Annexure 10

AX 10/SOP 05-B/ V7

Participant Feedback Form/प्रतिभागी प्रतिक्रिया प्रपत्र/सहभागी अभिप्राय फॉर्म

Sr. NO	**Questions / प्रश्न**	**Yes/** हाँ/ **होय**	**No/** नहीं/ **नाही**
1	Did the person administering the consent give enough time to answer your queries? क्या सहमति लेने वाले व्यक्ति ने आपके प्रश्नों का उत्तर देने के लिए पर्याप्त समय दिया? संमती घेणाऱ्या व्यक्तीने आपल्या प्रश्नांची उत्तरे देण्यासाठी पुरेसा वेळ दिला का?		
2	Was the explanation about the project given in a simple manner? अध्ययन के संबंध में स्पष्टीकरण सरल शब्दों में दिया गया था? स्पष्टीकरण सोप्या पद्धतीने दिले गेले होते का?		
3	Do you know that you can refuse to be a part of the study at any given time without giving any explanation or facing any detrimental consequences? क्या आप जानते हैं कि आप बिना कोई स्पष्टीकरण दिए या किसी हानिकारक परिणाम का सामना किए बिना किसी भी समय अध्ययन का हिस्सा बनने से इनकार कर सकते हैं? तुम्हाला माहीत आहे का की तुम्ही कोणत्याही वेळी कोणतेही स्पष्टीकरण न देता किंवा कोणत्याही हानिकारक परिणामांना सामोरे न जाता अभ्यासाचा भाग होण्यास नकार देऊ शकता?		
4	Are you aware of the person to contact in case of emergency or any queries? क्या आप जानते हैं कि ,आपातकाल / प्रश्नों के मामले में, आप किससे संपर्क करेंगे? आपत्कालीन परिस्थिती किंवा शंका असल्यास आपण कोणाशी संपर्क साधता हे आपल्याला माहिती आहे का?		
5	Are you aware who should be contacted pertaining to your rights as a research participant or complaints regarding the research study? क्या आप जानते हैं कि एक शोध प्रतिभागी के रूप में अपने अधिकारों या शोध अध्ययन से संबंधित		

	शिकायतों के लिए किससे संपर्क किया जाना / करना चाहिए? संशोधन सहभागी म्हणून तुमच्या अधिकारांच्या संबंधित किंवा संशोधन अभ्यासासंबंधी तक्रारींबाबत कोणाशी संपर्क करावा तुम्हाला माहिती आहे का?		
6	Did you consent in the language you understood the best? Did you receive the copy for the same? क्या आपने अपनी सहमति उस भाषा में दी है जिसे आप सबसे अच्छी तरह समझते हैं? क्या आपको इसकी प्रति प्राप्त हुई? तुम्हाला उत्तम समजत असलेल्या भाषेत तुम्ही संमती दिली आहे का? तुम्हाला त्याची प्रत मिळाली का?		
7	Are you aware about payment for / क्या आप जानते हैं भुगतान के बारे में / तुम्हाला माहिती आहे का पैशाच्या बाबतीत a) for participation in the trial अ) परीक्षण में भाग लेने के लिए अ) चाचणीमध्ये सहभागी होण्यासाठी b) for study related injury ब) अध्ययन से संबंधित चोट के लिए ब) अभ्यासाशी संबंधित दुखापतीसाठी		
8	Are you explained visit wise trial procedures / investigations / study drug in detailed. क्या आपको परीक्षण प्रक्रिया/ जांच/ अध्ययन दवा के बारे में विस्तार से बताया गया है? तुम्हाला चाचणी प्रक्रिया/तपास/ औषधाच्या अभ्यासाबद्दल समजावून सांगितले आहे का?		
9	Have you understood your role and responsibilities as research participant for this study? क्या आपने इस अध्ययन के लिए शोध प्रतिभागी के रूप में अपनी भूमिका और जिम्मेदारियों को समझा है? या अभ्यासासाठी संशोधन सहभागी म्हणून तुमची भूमिका आणि जबाबदाऱ्या तुम्हाला समजल्या आहेत का?		
10	Any Doubts/Grievances regarding the study or study team (कोई संदेह / शिकायत) (कोणतीही शंका / तक्रारी): अध्ययन या अध्ययन दल के संबंध में कोई संदेह/ शिकायतें अभ्यास किंवा अभ्यास कर्मचारी संबंधित कोणतीही शंका/तक्रारी		

OPD no. (ओपीडी नं): _____

Name of Participant / Relative: _____

_____

प्रतिभागी / रिश्तेदार का नाम:

सहभागी/नातेवाईकाचे नाव:

Signature of participant / Thumb impression: _____

प्रतिभागी हस्ताक्षर/अंगुठेका निशान : _____

सहभागी स्वाक्षरी /अंगठ्याचा ठसा: _____

Note: This form can be submitted to IEC-Office.

Address: **Institutional ethics Committee, UG/PG Hostel address:Building, Ground Floor, Seth G.S medical college and KEM Hospital Parel, Mumbai - 400012.Tel: +91 22 2410 7515 Mob.: +91 87792 21293**

ध्यान दें: फॉर्म नैतिक समिति कार्यालय में जमा किया जा सकता है।

पता:**नैतिक समिति, यु जी पी जी छात्रावास तल मंजिल, सेठ गोरधनदास सुंदरदास चिकित्सा महाविद्यालय और रा. ए. स्मारक रुग्णालय परेल, मुंबई -४०००१२. टेलीफोन क्रमांक- (०२२)२४१०७५१५ दूरध्वनी क्रमांक- ८७७९२२१२९३**

लक्षात घ्या: हा फॉर्म नीतिमत्ता समिती कार्यालयामध्ये जमा केला जाऊ शकतो.
पत्ता: नीतिमत्ता समिती, पदवीपूर्व (UG) पदव्युत्तर (PG) वसतिगृह तळमजला, सेठ गोरधनदास सुंदरदास वैद्यकीय महाविद्यालय आणि रा. ए. स्मारक रुग्णालय, परेल, मुंबई -४०००१२. टेलिफोन क्रमांक- (०२२)२४१०७५१५ दूरध्वनी क्रमांक- ८७७९२२१२९३

Title	Expedited Review
SOP Code	SOP 05-C/V7 dated 19th November 2024

<table>
<tr><th>Prepared by
Signature with date</th><th>Reviewed by
Signature with date</th><th>Approved by
Signature with date</th><th>Accepted by</th></tr>
<tr><td rowspan="3">19/11/24
Dr. Raakhi Tripathi,
Member Secretary,
IEC-I</td><td>19.11.24
Dr. Nithya Gogtay,
Jt. Member Secretary,
IEC-I</td><td>9/12/2024
Dr. Manju Sengar
Chairperson, IEC-I</td><td>Institutional Ethics Committee (IEC-I) Established In 1985 Seth G. S. Medical College & K.E.M. Hospital Parel, Mumbai-400 012.
IEC-I</td></tr>
<tr><td rowspan="2">19.11.24
Dr. Swapna Kanade,
Member Secretary,
IEC-III</td><td>09/12/24
Dr. Sunil Kuyare
Chairperson, IEC-II</td><td>Institutional Ethics Committee (IEC-II) Established in 1986 Seth G.S. Medical College & K.E.M. Hospital, Parel, Mumbai - 400 012.
IEC-II</td></tr>
<tr><td>09/12/24
Dr. M. G. Karmarkar
Chairperson, IEC-III</td><td>Institute Ethics Committee-III Established in 1986 Seth G.S. Medical College & K.E.M. Hospital, Parel, Mumbai - 400 012.
IEC-III</td></tr>
</table>

1. Purpose

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

2. Scope

This SOP applies to the review and approval of research studies and documents, which qualify for expedited review by the IEC. Any protocol that carries not more than minimal risk and fulfills criteria for expedited review **(SOP 05-C/V7)** is covered in this SOP.

3. Responsibility

It is the responsibility of the Member Secretary / Chairperson of the Institutional Ethics Committee (IEC) to determine if a Project/ Protocol qualifies for an expedited review and designate one / two primary reviewers. Designated IEC members (including Member Secretary and/or Chairperson) will be responsible for reviewing the research protocols and related documents within the given time frames.
It is the responsibility of all the designated IEC members to give comments and recommendations after reviewing each study protocol.
The Member Secretary / Chairperson are responsible to take the decision.

4. Activity Table

No.	Activity	Responsibility
1.	Receive the submitted documents	IEC Secretariat
2.	Determine protocols for expedited review & designate the primary reviewers	Member Secretary/Chairperson
3	Review protocol & give comments and recommendations	Primary reviewers
4.	Decision of IEC	Member Secretary/Chairperson
5.	Communicate with the IEC and the Investigator	IEC Secretariat/ Members

5. Detailed instructions

5.1 Check and receive the submitted documents.

- The IEC Secretariat will check and forward it to the member secretary.
- The IEC Secretariat will check the project and forward it to member secretary. The IEC Secretariat will send email to PI for protocol review processing fees.

5.2 Determine protocols for expedited review & designate the primary reviewers

The proposal submitted for initial review or where investigator have requested for the expedited review (AX01/SOP05-C/V7) stating the reasons in the covering letter forwarded by signature of HOD to the IEC will be evaluated for the expedited review. The protocols satisfying any of the following criteria (as per ICMR 2017 guidelines) may be considered for expedited review. The IEC Chairperson will take the final decision.

IEC may do expedited review only if the protocols involve –

- Proposals that pose no more than minimal risk may undergo expedited review, for example;
- research involving non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples;
- research involving clinical documentation materials that are non-identifiable (data, documents, records) (retrospective studies);
- modification or amendment to an approved protocol including administrative changes or correction of typographical errors and change in researcher(s)
- revised proposals previously approved through expedited review, full review or continuing review of approved proposals;
- Minor deviations from originally approved research causing no risk or minimal risk;
- Progress/annual reports where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee; and
- For multicentre research where a designated main EC among the participating sites has reviewed and approved the study, a local EC may conduct only an expedited review for site specific requirements in addition to the full committee common review.
- Research during emergencies and disasters Refer to SOP 22/V7(See Section 12 of ICMR 2017 for further details).

5.3 Review protocol & give comments and recommendations

- Primary reviewers will review the protocol and give their comments and recommendations to the member secretary within seven days from the date of receipt of the protocol via email.

5.4 Decision of IEC

- The comments of the Primary reviewers will be discussed by the Member Secretary with the Chairperson and the decision about approval will be taken by the member secretary in consultation with the Chairperson.
- The decision will be informed to the IEC members at the full board meeting.
- If deemed necessary by Primary reviewers, Member Secretary/ Chairperson, the project shall be discussed at the forthcoming full board meeting.
- The expedited review process should be completed within 14 working days.

5.5 Communicate with the IEC and the investigator.

- The Secretariat will send the Project approval letter (AX 02/SOP 05-C/V7 or AX 03/SOP 05-C/V7) via hard copy to the Principal Investigator if the Project/Protocol amendments are approved.
- If the project is disapproved or requires resubmission after certain modifications, this will be informed to the Principal Investigator. The reasons for disapproval of a project will be specified in the letter sent to Principal Investigator via hard copy.

6. Glossary

Expedited approval	An IEC approval granted only by the Chairperson of the Institutional Ethics Committee or a designated Institutional Ethics Committee member (not the full Board) for research which involves no more than minimal risk.
Expedited review	A review process by one / two designated IEC members (Primary reviewers) who then report the decision to the full Board meeting. An expedited review is a speedy one for research proposals with minimal risk in nature.

7. Annexure:

Annexure 1 AX 01/SOP 05-C/V7 Application form for expedited review.

Annexure 2 AX 02/SOP 05-C/V7 Approval letter format in case of Expedited Review for prospective observational study

Annexure 3 AX 03/SOP 05-C/V7 Approval letter format in case of Expedited Review retrospective observational study

Annexure 1
AX 01/SOP 05-C/V7
Application form for expedited review.

Date: ……

Study Title: ……

Principal Investigator (Name, Designation & Affiliation):
……

1. Choose reason why expedited review from EC is requested?
   i. Involves non-identifiable specimen and human tissue from sources like blood banks, tissue banks and left-over clinical samples. ☐
   ii. Involves clinical documentation materials that are non-identifiable (Data, Documents, Records). ☐
   iii. Modification or amendment to approved protocol (Administrative Changes/Correction of typographical errors and change in researcher(s)). ☐
   iv. Revised proposal previously approved through expedited review, full review or continuing review of approved proposals. ☐
   v. Minor deviation from originally approved research causing no risk or minimal risk. ☐
   vi. Progress/Annual Report where there is no additional risk, for example activity limited to data analysis. Expedited review of SAEs/unexpected AEs will be conducted by SAE subcommittee. ☐

vii. For Multicentric research where a designated 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.
viii. Research during emergencies and disasters (See Section 12 of ICMR Ethical Guidelines, 2017). ☐
ix. Any Other (Please Specify) ……

2. Is waiver of consent being requested? Yes ☐ No ☐
3. Does the research involve vulnerable persons? Yes ☐ No ☐

If Yes, give details ……

Signature of Principal Investigator (PI) with date: ……

Comments of EC Secretariat: ……

Signature of Member Secretary with date: ……

Annexure 2
AX 02/SOP 05-C/V7
Approval letter format in case of Expedited Review for prospective observational study

Date: xxxxxxxxx

To,
Dr. xxxxxxxxxxxxx,
Dept. of xxxxxxxxx.

Ref: Your project no. **xxxxxxxx** entitled, "xxxxxxxxxxxxxxx".

Dear Dr. xxxxxxxxx,

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

1xxx
2.xxxxxxx
3.xxxxxxxxxx

It is understood that the study will be conducted under your direction, in a total of **xxx** research participants, at Dept. of xxxxxxxxx**,** Seth G. S. Medical College and K. E. M. Hospital as per the submitted protocol.

The IEC approves the above-mentioned study.
The approval is valid for the entire duration of the study.
It is the policy of IEC that, it be informed about any onsite serious adverse event or the unexpected adverse event report within 24 hours as per the format specified in AX 01/SOP 11-B/V7 (NDCTR, 2019) and AX 02/SOP 11-B/V7 to the IEC 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 sponsor has to forward the report of SAE or death after due analysis to the chairman of the IEC and the head of the institution where the trial is been conducted within ten calendar days of occurrence of the SAE or death. The report of the SAE other than death after due analysis shall be forwarded to chairman of the IEC and the head of the institution.
In case of injury or death occurring trial subject the sponsor (whether a pharmaceutical company or an institution) or his representative, whosever 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 in the manner as prescribed.

No deviations 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 for studies and during epidemics/pandemics continuing review report needs to be submitted at 45 days) on or before xxxxxx.
A copy of the final report should be submitted to the IEC for review.

Sincerely yours,
xxxxxxxxxxx
Chairperson /Member Secretary/ Designated Institutional Ethics Committee member of IEC
Date of approval of the study: xxxxxx

Annexure 3
AX 03/SOP 05-C/V7
Approval letter format in case of Expedited Review for retrospective observational study

Date: xxxxxxxxx

To,
Dr. xxxxxxxxxxxxxx,
Dept. of xxxxxxxxx.

Ref: Your project no. **xxxxxxxx** entitled, “xxxxxxxxxxxxxxx”.

Dear Dr. xxxxxxxxx,

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

1xxx
2.xxxxxxx
3.xxxxxxxxxx

It is understood that the study will be conducted under your direction, in a total of **xxx** research participants, at Dept. of xxxxxxxxx**,** Seth G. S. Medical College and K. E. M. Hospital as per the submitted protocol.

The IEC approves the above-mentioned study.
The approval is valid for the entire duration of the study.
No deviations 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 xxxx.
A copy of the final report should be submitted to the IEC for review.
Sincerely yours,
xxxxxxxxxxx
Chairperson /Member Secretary/ Designated Institutional Ethics Committee member of IEC
Date of approval of the study: xxxxx

Title	Exemption from the review the Ethics Review for Research Projects
SOP Code	SOP 05-D/V7 dated 19th November 2024

Prepared by Signature with date	Reviewed by Signature with date	Approved by Signature with date	Accepted by
Dr. Raakhi Tripathi, Member Secretary, IEC-I 19/11/24	Dr. Nithya Gogtay, Jt. Member Secretary, IEC-I 19.11.24	Dr. Manju Sengar Chairperson, IEC-I 9/12/2024	IEC-I
	Dr. Swapna Kanade, Member Secretary, IEC-III 19.11.24	Dr. Sunil Kuyare Chairperson, IEC-II 09/12/24	IEC-II
		Dr. M. G. Karmarkar Chairperson, IEC-III 09/12/24	IEC-III

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe which clinical research projects can be exempted from ethics review and do not require the approval of the Institutional Ethics Committee (IEC). The Exemption Form AX 01/SOP 05-D/V7 is designed to standardize the process of exemption.

2. Scope

This SOP applies to the all protocols submitted for exemption from review by the IEC. The specific points in the Exemption Form should guide the Member Secretary to determine whether the protocol qualifies for exemption from review. The decision will 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 forwarded by HOD signature. The IEC Secretariat is responsible for recording and filing the decision including the reasons for that decision. The Chairperson/ Member Secretary must sign and date letter conveying the decision AX 01/SOP 05-D/V7.

4. Activity table

No.	Activity	Responsibility
1	Receive the submitted documents.	IEC Secretariat
2	Review of protocol and Exemption Form	Member Secretary
3	Recording the decision on Exemption Form in consultation with the Chairperson	Member Secretary
4	Communicate the decision to the Investigator & IEC members in forthcoming meeting	Member Secretary / IEC Secretariat

5. Detailed instructions

5.1 Receive the submitted documents.

- The Secretariat will receive the Exemption from review Application Form AX 01/SOP 05-D/V7, Protocol and other documents (soft and hard copy) submitted by the investigators.

5.2 Determine protocols eligible for exemption from review

The proposal submitted for initial review or where investigator have requested for the exemption from review stating the reason in the 'Review Exemption Application Form' to the IEC will be evaluated for the exemption from review.

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

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

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

- ✓ Audits of educational practices
- ✓ Research on microbes cultured in the laboratory
- ✓ Research on immortalized cell lines
- ✓ Research on cadavers or death certificates provided such research reveals no identifying personal data
- ✓ Analysis of data freely available in public domain

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

- ✓ The publisher of the research

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

5.3 Recording the decision on Exemption Form in consultation with the Chairperson

- If the protocol and related documents satisfy the criteria as listed in 5.2, the 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.

5.4 Communicate the decision to the Investigator & IEC members in forthcoming meeting

- The Secretariat communicates the decision to the Principal Investigator within 14 working days after the decision regarding the exemption is taken.
- The Member Secretary informs the IEC members about the decision at the next full board meeting and minute it in the meeting notes.
- The Member Secretary / Chairperson may keep the application for review and decision regarding exemption at the next full board meeting.
- Any changes to the protocol must be brought to the notice of the IEC prior to implementation by the investigator. Any correspondence with the IEC office regarding this action should mention the allocated study number indicated at the top of this letter.
- The IEC will determine if requested protocol changes alter the risks: benefits analysis of the study, thereby requiring a change in review or exemption category. In such cases investigator will have to resubmit the study protocol and related documents for change review process.

6. Glossary

Exemption from review	A research study is said to be exempt from review when it does not require the Ethics Committee approval for its conduct.

7. Annexure

Annexure 1 AX 01/SOP 05-D/V7 Review exemption application form

Annexure 2 AX 02/SOP 05-D/V7 Certificate of Exemption from Review

Annexure 1
AX 01/SOP 05-D/V7
Review Exemption Application Form

Date: ……

Study Title: ……

……

Principal Investigator (Name, Designation & Affiliation): ……

……

Choose reason why exemption from ethics review is requested:

1. Research on data in the public domain/systematic reviews or meta-analysis. ☐
2. Observation of public behaviour/information recorded without linked identifiers and disclosure would not harm the interests of the observed person. ☐
3. Quality control and quality assurance adults in the institution. ☐
4. Comparison among instructional techniques, curricula, or classroom management methods. ☐
5. Consumer acceptance studies related to taste and food quality. ☐
6. Public Health programmes by Government agencies. ☐
7. Any other (Please specify in 100 words): ……

Signature of Principal Investigator (PI) with date: ……

Comments of EC Secretariat: ……

Signature of Member Secretary with date: ……

Annexure 2

AX 02/SOP 05-D/V7

Certificate of Exemption from Review

Date:
To,
Name of the PI_____
Dept. Of _____

Ref: Your project no. _____entitled **"_____".**

Sub: _____.

Dear Dr. _____,
This letter certifies that the application for the protocol stated above has been reviewed by Institutional Ethics Committee designated reviewer/Member Secretary and Chairperson. The Institutional Ethics Committee has given due consideration and concludes that the said proposal is exempt from IEC review as it does not involve direct contact with human participants. (SOP 05-D/V7; ICMR 2017 Section 4, Ethical review procedures page no.36). Please note that the provision to collect the identifiable (indirectly identifiable) information *viz* Initials, Age and Gender needs to be removed from the case record form.
Please note that any changes to the protocol must be brought to the notice of the IEC prior to implementation. The IEC must determine whether the requested protocol changes alter the risks: benefits analysis of the study, thereby requiring a change in review or exemption category.
Please contact the IEC office if you have any questions. Any correspondence with the IEC office regarding this action should mention the allocated study number indicated at the top of this letter.
With Regards,
Sincerely yours,

_____
Chairperson / Member Secretary

Title:	**Review of Resubmitted Protocols**
SOP Code:	**SOP 05-E/V7 dated 19th November 2024**

Prepared by Signature with date	Reviewed by Signature with date	Approved by Signature with date	Accepted by
Dr. Raakhi Tripathi, Member Secretary, IEC-I	Dr. Nithya Gogtay, Jt. Member Secretary, IEC-I	Dr. Manju Sengar Chairperson, IEC-I	IEC-I
	Dr. Vyankatesh Shivane, Member, IEC-I	Dr. Sunil Kuyare Chairperson, IEC-II	IEC-II
		Dr. M. G. Karmarkar Chairperson, IEC-III	IEC-III

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how Institutional Ethics Committee (IEC) manages study protocols and related documents resubmitted after initial review.

2. Scope

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

3. Responsibility

It is the responsibility of the IEC Secretariat to ensure the completeness of the documents submitted to the IEC for reconsideration.

A re-submitted protocol may be reviewed by either member secretary / Primary Reviewers / two or more IEC members designated by the Chairperson/ Member Secretary, as per IEC decision determined by the IEC at the time of the initial review of the project during the full board IEC meeting. This information can be found on the IEC Decision Form (AX 06/ SOP 05-B/V7).

4. Activity Table

No.	Activity	Responsibility
1	Receive resubmitted protocol and related documents, check contents, ensure completeness of the documents submitted and distribution of protocol and study-related documents	IEC Secretariat
2	Review of the revised protocol	IEC Members/Member Secretary/ Chairperson
3	Written communication of the IEC decision to investigator	IEC Secretariat

5. Detailed instructions

5.1 Receipt of resubmitted protocol package and its distribution

- The Secretariat will verify if the principal investigator has forwarded the reply within 180 days of receipt of IEC letter for resubmission.
- The Secretariat will check the resubmitted protocol packages (hard and soft copy) for the following items
  - ✓ Reply to the IEC letter of comments with covering letter (signed and dated by PI), query reply in question-answers format.
  - ✓ Revised version of protocol and/ or the informed consent document and /or any other related documents such as, case report forms, diary sheets, etc are included as part of the package with the changes made to the documents highlighted and with appropriate version number and date on each page of the document.
  - ✓ Additional documents sought during initial review.
- If above items are not submitted the Principal Investigator will be told to submit the requisite documents.
- The Secretariat will refer to the IEC Decision Form AX 06/ SOP 05-B/V7 on the given protocol and distribute the reply to the query letter, revised protocol and related documents for resubmitted protocol to the Member Secretary.

For Minor modifications

The protocol and related documents will be reviewed by either member secretary or one / two designated primary reviewers as per decision taken during initial review.

For Major modifications

The protocol and related documents will be reviewed by Member secretary / designated primary reviewers. If primary reviewers are not available then two or more IEC members designated by the Chairperson / Member secretary will review the resubmitted protocol and related documents. After review by Member secretary / designated primary reviewers / other IEC members the comments will be discussed in the upcoming Full Board (FB) meeting as per decision taken during initial review. In case the decision is to discuss the revised protocol at the full board meeting, the Primary reviewer / member Secretary will present a brief oral summary of the study design and the comments of the IEC members/Chairperson in the IEC Full Board meeting.

5.2 Review the revised protocol to be carried out by IEC member/ Member Secretary/ Chairperson:

- The IEC member / Primary Reviewer / Member Secretary / Chairperson will refer to the query letter/ comments as guidance for the review and check whether the recommendations of the IEC have been followed or adequately responded to. The primary reviewer will also check for completeness of protocol and related documents as per requirements. The primary reviewers / designated IEC member/ Member Secretary should complete the review process within seven days.
- The IEC member/ Member Secretary/ Chairperson will make further comments where appropriate
- The final decision regarding the query reply shall include one of the following:
  - ✓ If the IEC decision is 'Approved', it implies the approval of the study as it is presented with no modifications and the approval letter (as per format *(*AX 07/SOP 05-B/V7), (AX 08/ SOP 05-B/V7) & (AX 09/SOP 05-B/V7))can be issued to the Principal Investigator.
  - ✓ If the IEC decision is 'Approved with minor modification, the IEC Chairperson may authorize the Secretary/Primary reviewer + secretary to determine if the response and changes are satisfactory and decide if letter of permission can be issued to the Principal Investigator.
  - ✓ If the IEC decision is 'Approved with major modification, the IEC Chairperson may authorize the Primary reviewer + secretary to review the responses. If the response and changes are satisfactory the member secretary will inform in the subsequent full board meeting. If the response and changes are approved in the full board, letter of permission can be issued to the Principal Investigator.
  - ✓ If the IEC decision is 'Approved with major modification, the IEC Chairperson may authorize the Primary reviewer + secretary to review the responses and subsequently discussed in full board meeting as per IEC Decision Form AX 06/ SOP 05-B/V7 if the decision was to discuss in the full board meeting during initial review. If the response and changes are approved in the full board, letter of permission can be issued to the Principal Investigator.

5.3 Written communication of the IEC decision.

The decision will be communicated to the PI within 14 working days. For the projects which will be discussed in the full board meeting the decision will be communicated within 14 working days of the FB meeting. Response from the PI to the IEC communication is expected within 180 days of date of receipt of the letter and in the absence of any response, the project will be declared closed for the IEC office records. Reply to subsequent queries should be sent in 60 days (for regulatory trials refer SOP5A version 7 Annexure 7 Guidelines for investigators)

- ✓ The Secretariat will record the decision reached on the response in the minutes of the meeting.

Title:	Review of Amended Protocol /Protocol related documents
SOP Code:	SOP 06 /V 7 dated 19th November 2024

Prepared by Signature with date	Reviewed by Signature with date	Approved by Signature with date	Accepted by
Dr. Raakhi Tripathi, Member Secretary, IEC-I	19-11-24 Dr. Nithya Gogtay, Jt. Member Secretary, IEC-I	9/12/2024 Dr. Manju Sengar Chairperson, IEC-I	Institutional Ethics Committee (IEC-I) Established In 1985 Seth G.S. Medical College & K.E.M. Hospital Parel, Mumbai-400 012. IEC-I
	19 NOV 2024 Dr. Vyankatesh Shivane, Member, IEC-I	09/12/24 Dr. Sunil Kuyare Chairperson, IEC-II	Institutional Ethics Committee (IEC-II) Established in 1986 Seth G.S. Medical College & K.E.M. Hospital Parel, Mumbai - 400 012. IEC-II
		09/12/24 Dr. M. G. Karmarkar Chairperson, IEC-III	Institute Ethics Committee-III Established in 1986 Seth G.S. Medical College & K.E.M. Hospital Parel, Mumbai - 400 012. IEC-III

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how amended protocol/ protocol related documents are managed and reviewed by the Institutional Ethics Committee (IEC).

2. Scope

This SOP applies to previously approved study protocols but later being amended and submitted for approval to the IEC. Amendments made to protocols cannot be implemented until reviewed and approved by the IEC.

3. Responsibility

It is the responsibility of the IEC Secretariat to manage protocol amendments. The Member Secretary/ Chairperson will determine whether the proposed protocol amendment(s) is minor or major in nature. Minor amendments would undergo review by the Member Secretary/Chairperson in expedited manner and will be informed in full board. If the amendment is major it will undergo review by primary reviewers and be discussed in full board.

4. Activity Table:

No.	Activity	Responsibility
1	Receive amended pro, check contents, ensure completeness of the documents submitted and distribution of amended protocol and study-related documents	IEC Secretariat
2	Review the amended protocol and related documents	IEC Members/Member Secretary/ Chairperson
3	Written communication of the IEC decision to investigator	Member Secretary

5. Detailed instructions

5.1 Receive amended protocol, check contents, ensure completeness of the documents submitted and distribution of protocol and study-related documents

a. Receive amended protocol package, check contents, ensure completeness of the documents:

- The amendment package (hard and soft copy) forwarded by the Principal Investigator will be received by the IEC Secretariat.

  The IEC Secretariat will confirm the request for review of amended Protocol/Protocol related documents from the Principal Investigator on previously approved Protocol/Protocol related documents as per the form AX 01/SOP 06/V7.

- The request form should:
  - ✓ State / describe the amendment
  - ✓ provide the reason for the amendment
  - ✓ Impact of the amendment on present study at this site: (modifications in the ICD, re-consent of research participants, untoward effects likely to occur because of the amendment or any other)

  _____

- The IEC Secretariat will confirm submission of:
  - ✓ Amended version of the protocol and related documents
  - ✓ Summary sheet (changes from previous version to present version)
  - ✓ Changes or modifications in the amended version are highlighted

- The IEC Secretariat will check for completeness of the contents of protocol amendment submission package and inform the Principal Investigator to submit the required documents at the earliest, if any of the documents are missing / incomplete.

b. distribution of protocol and study-related documents

- After receipt of the amendment package, the IEC Secretariat will forward the amendment to the Member Secretary/ Chairperson.
- The IEC Secretariat will send the request for amendment and the protocol and related documents to the Member Secretary / Chairperson within 7 working days of receipt of the documents with the Protocol Amendment Request Form AX 01/SOP 06/V7
- The member secretary or chairperson will categorize the amendments as minor or major amendment as per section 5.2.

5.2 Review the amended protocol and related documents

The member secretary will review the amendment summary and decide whether the amendment is major or minor and decide the review process as follows:

- **For minor amendment**

The minor amendments of the protocol and related documents it will be reviewed by member secretary within five working days.

- **For Major amendment**

- The amendment is considered to be major if any of the following changes (but is not limited to) are made in the protocol and related documents:
  a. Change in study design
  b. additional treatments or the deletion of treatments
  c. Changes in inclusion/exclusion criteria.
  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

The protocol and related documents will be reviewed by member secretary / either designated primary reviewers. After review by the member secretary / designated primary reviewers, the amendment if required will be discussed in the upcoming full board meeting. At the full board meeting, the Secretary /primary reviewer will present a brief oral summary of the study design and the comments of the primary reviewer /Chairperson in the IEC Full Board meeting.

Protocol Amendment Review Process

- The member secretary / primary reviewers will review the amended documents and assess the change in risk / benefit ratio and impact of the amendment (modifications in the ICD, re-consent of research participants, untoward effects likely to occur because of the amendment or any other) and will send the comments to the IEC office within seven days.
- The final decision regarding the amendments (minor and major) as discussed in IEC full board meeting shall include one of the following:
  - ✓ If the IEC decision is 'Approved', it implies the approval of the amendment as it has been submitted modifications and the letter of permission for amendment can be issued to the Principal Investigator.
  - ✓ If the IEC decision is 'Approved with minor modification, the IEC Chairperson may authorize the member Secretary to issue a recommendation letter to the Principal Investigator. If the response from the PI found satisfactory a letter of permission can be issued to the Principal Investigator.
  - ✓ If the IEC decision is 'Approved with major modification, the IEC Chairperson may authorize the Primary reviewer + secretary to determine the review of the amendments which may or may not be discussed in next full board meeting depending on the comments of the reviewers. Member Secretary will issue a recommendation letter to the

Principal Investigator and if response from the PI found satisfactory a letter of permission can be issued to the Principal Investigator.

- ✓ If the IEC decision is Disapproved after the member secretary / chairperson / designated IEC members / Full board review the decision will be communicated to the PI giving reasons for disapproval.
- ✓ If the PI has requested expedited review in the ANNEXURE 1 (AX 01/SOP 06/V7), (applicable only for minor amendment) then the approval letter (AX02/SOP06/V7) will be issued to the PI and the same will be informed in the subsequent full board meeting.

5.3 Written communication of the IEC decision to investigator

- ✓ The decision will be communicated to the PI within 14 working days and for the amendments which will be discussed in the full board meeting the decision will be communicated within 14 working days of the meeting.
- ✓ The IEC Secretariat will record the decision reached on the proposed amendment in the minutes of the meeting.

6. Glossary

Amendment protocol package	A package of the amended parts and related documents of the protocol previously approved by the IEC. In the course of the study, the PI may decide to make changes in the protocol.
Minor protocol amendments	Minor amendments are those that do not increase the risk or decrease the potential benefit to the subjects
Major protocol amendments	Major amendments are those that adversely affect the risk benefit ratio of the study or specifically increase the risk to the participants of the study

7. Annexure

Annexure 1 AX 01/SOP 06/V7 Protocol Amendment Request Form
Annexure 2 AX 02/SOP 06/V7 Project Amendment/Document Amendment Approval letter

Annexure 1
AX 01/SOP 06/V7
Protocol / Protocol related documents Amendment Request Form

Date: ……

Study Title: ……

Principal Investigator (Name, Designation & Affiliation): ……

……..

1. Date of EC approval: …….. **Date of start of study:** ……
2. Details of Amendment(s)

Sr. No.	Existing Provision	Proposed Amendment	Reason	Location in the Protocol/Informed Consent Document (ICD)

3. Impact on benefit-risk analysis **Yes** ☐ **No** ☐

If Yes, describe in brief ……

……..

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

Signature of Principal Investigator (PI) with date: ……

Annexure 2
AX 02/SOP 06/V7
Protocol Amendment/Document Amendment Approval letter

To

XXXXX (PI)
Department

Ref: - IEC No. Project title
Dear Dr._____

We have received from you the following document (s).
1.
2.

At the Institutional Ethics Committee meeting held on _____ the abovementioned documents were reviewed.
After consideration, the IEC has decided to approve:
(a) The aforementioned study-related documents OR
(b) The following documents:
1.
2.
The members who attended this meeting held on _____ at which the above-mentioned document was discussed are listed below.
1.
2.
3.
It is to be noted that neither you nor any of your proposed study team members were present during the decision-making procedures of the Institutional Ethics Committee.
OR
After reviewing the documents, the IEC has decided to approve the aforementioned study-related documents.

Yours truly,

Signature of Chairperson/ Member Secretary
with Date
IEC

Title:	**Continuing Review of Study Protocols**
SOP Code:	**SOP 07/V7 dated 19th November 2024**

Prepared by Signature with date	Reviewed by Signature with date	Approved by Signature with date	Accepted by
Dr. Raakhi Tripathi, Member Secretary, IEC-I	Dr. Nithya Gogtay, Jt. Member Secretary, IEC-I	Dr. Manju Sengar Chairperson, IEC-I	IEC-I
	Dr. Vyankatesh Shivane, Member, IEC-I	Dr. Sunil Kuyare Chairperson, IEC-II	IEC-II
		Dr. M. G. Karmarkar Chairperson, IEC-III	IEC-III

1. Purpose

The purpose of this Standard Operating Procedure is to describe how continuing reviews of previously approved protocols are managed by the Institutional Ethics Committee (IEC).
The purpose of the continuing review is to monitor the progress of the entire study, not just the changes in it, to ensure continuous protection of the rights and welfare of research participants.

2. Scope

This SOP applies to conducting any continuing review of study protocols involving research participants at intervals appropriate to the degree of risk. All the regulatory projects approved by the Institutional Ethics Committee registered with CLA will be reviewed twice in a year and non-regulatory trials/ academic clinical trials will be reviewed at least once a year. Depending upon the degree of risk to the participants, the nature of the studies, the vulnerability of the study participants and duration of the study, the IEC may choose to review the protocols more frequently then as stated above.

3. Responsibility

It is the responsibility of the IEC Secretariat to remind the IEC and the principal investigators regarding study protocols that should be continuously reviewed. The Chairperson is responsible for determining the date of continuing review if the project will be reviewed more frequently in the year. This decision is taken during the IEC full board meeting wherein the project is finally approved or can be taken later based on the continuing review reports, SAE reports, IEC monitoring reports, protocol deviations or new safety data received.
The IEC is responsible for reviewing the progress made in the protocol, the occurrence of unexpected events or problems, and the rate of accrual of participants.

4. Activity Table

No.	Activity	Responsibility
1	Determine the date of continuing review and Notify the Principal Investigator or study team	IEC Secretariat
2.	Manage continuing review package upon receipt and distribute to member secretary/chairperson	IEC Secretariat
3.	Review the annexure/ related documents of continuing review	Member Secretary/ IEC Members
4.	Written communication of the IEC decision to investigator	IEC Secretariat

5.Detailed Instructions

5.1. Determine the date of continuing review:

- For regulatory trials:
All the regulatory projects approved by the Institutional Ethics Committee registered with CLA will be reviewed twice in a year. Depending upon the degree of risk to the participants, the nature of the protocol, vulnerability of the study participants and duration of the study, the IEC may request the PI to submit continuing review reports more frequently (less than six months) while issuing the project approval letter.
The IEC may request to submit continuing review reports more frequently for ongoing regulatory trials if there is change in the risk benefit ratio as perceived by the IEC members in the full board meeting while reviewing continuing review reports, SAE reports, IEC monitoring reports, protocol deviations or new safety data received.

- For non-regulatory / academic clinical trials:

All the non-regulatory projects / academic clinical trials approved by the IEC will be reviewed once in a year. Depending upon the degree of risk to the participants, the nature of the protocol, vulnerability of the study participants and duration of the study, the IEC may request the PI to submit continuing review reports more frequently (less than twelve months) while issuing the project approval letter.
The IEC may request to submit continuing review reports more frequently for ongoing non regulatory / academic clinical trials if there is change in the risk benefit ratio as perceived by the IEC members in the full board meeting while reviewing continuing review reports, SAE reports, IEC monitoring reports, protocol deviations or new safety data received.

- The IEC will notify the Principal Investigator or study team the period of continuing review required for the given project.
  - For all regulatory clinical trials it is the responsibility of the principal investigator to submit a periodic review report / continuing review report (within 1 month of the due date i.e. 5 months from the date of approval for studies which will continue beyond six months). Such periodic reports have to be submitted to IEC at six monthly intervals till the completion of the study.
    It is the responsibility of the principal investigator / study coordinator to ensure the periodic review processing fees along with the periodic review report need to be submitted within the timelines for all regulatory and sponsored trials. The coordinators should make the appropriate invoices as per section 15.1 of Guidelines for Investigators regarding review fees.
  - For academic / non-regulatory trials it is the responsibility of the principal investigator that 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)
    For submission of continuing review report Refer to SOP 7 V 7

- Notifying the Principal Investigator or the study team about the required frequency of the continuing review of the project.

- The IEC Admin will look through the document archives/master chart of projects approved by the IEC for the due date of continuing review of the projects. If continuing review reports are not received as per the timelines (end of 5 months for regulatory projects and end of 11 months for non regulatory / academic clinical trials) the IEC secretariat will send 1st reminder letter to the PI in the subsequent week (1st week of the six/ twelve month)

- If the Principal Investigator(PI) fails to submit the Continuing review report within one month of the due date (i.e. 11th months / 5th Months from the date of approval, unless specified otherwise), the IEC secretariat will send a reminder as per the format mentioned in *AX 01/SOP 07/*V7 within 7 working days of this due date. If there is no response within 15 days after the date of reminder, the IEC secretariat will put up the matter for discussion at the forthcoming full board meeting for appropriate action /s which may consist of the following but not limited to:
  a) Second reminder to the PI
  b) Third reminder (if no response to second reminder received within 30 days) with communication to the Dean about the same.
  c) Discussion in the full board meeting regarding no response to three reminders sent to the PI. The following decision will be taken by the IEC on case to case basis:
  - Refuse to review subsequent applications of new projects from the principal investigator for a specified duration of time.
  - Suspending review of new projects (not approved by the IEC) already submitted by the PI.
  - Put recruitment of new participants on hold for the concerned project.
  - Suspend the present concerned project.
  - Revoke approval of the concerned project and inform DCGI for regulatory projects.
  - Suspend other projects done by the PI for specified duration of time.

5.2 Managing the continuing review package upon receipt.

- The IEC Secretariat will receive a package (soft and hard copy) submitted by the Study Team for continuing review for each approved protocol. The IEC Secretariat will make sure that the contents of the package include the following documents:
  - Continuing Review Application Form (*AX 02/SOP 7/ V7)* duly filled with an explanation for any "yes" (ticked on the Continuing Review Application Form (*AX 02/SOP 07/ V7)* answers on the application form.

  - The IEC Secretariat will check for complete information and for the presence of the required signatures of the Principal Investigator in the Continuing Review Application Form. The IEC secretariat will ensure the periodic review processing fees (refer section 15.1 of Guidelines for Investigators)

5.3 Review process of annexure /related documents of continuing review

Member Secretary will review the Continuing Review Application Form (AX 02/SOP 07/V7). The member secretary can designate (if required) one/two IEC members to review the Study report and related documents and inform the decision to the other IEC members at the next full board meeting.

5.4 Review of Continuing Review Application

- The Continuing review submission may undergo expedited review (as per the procedure described in SOP 05-C/ V7) or full board review (as per the procedure described in SOP 05-B/ V7) 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 above-mentioned project without any modifications (as per the format *AX 03/SOP 07/* V7)
2. Modifications recommended: Protocols that have been suggested modifications by the IEC may not proceed until the conditions set by the IEC in the decision have been met. Protocols should be amended and submitted to the IEC, within one month for re-review.
3. The project cannot be continued: The reasons for discontinuation of the project will be mentioned in the letter notifying the decision to the Principal Investigator.
4. 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.

5.5 Payment for continuing review:

For regulatory and sponsored projects there is a payment for continuing review (refer section 15.1 of Guidelines for Investigators) if PI fails to submit the fees for continuing review as per the timelines, but has submitted the continuing review report as per the timeline then the pending fees has to be submitted within three months of the stipulated time period.

Non payment of this fees within the given timelines will be discussed in the subsequent full board meeting and IEC will take action on case to case basis.

5.6 Written communication of the IEC decision to investigator

- ✓ The decision will be communicated to the PI within 14 working days of the meeting.
- ✓ The IEC Secretariat will record the decision reached on the proposed continuing review report in the minutes of the meeting.

6. Annexure

Annexure 1	*AX 01/SOP 07/* V7	Reminder letter by the IEC to investigator
Annexure 2	AX 02/SOP 07/ V7	Continuing Review/Annual Report Format
Annexure 3	AX 03/SOP 07/ V7	Continuing Review report Approval Letter

Annexure 1

AX 01/SOP 07/ V7

Reminder letter by the IEC to Investigator for non-regulatory / non-sponsored studies

Date:-
Name of Principal Investigator :-
Department :-
Ref: - Project Title: XXXXXX

The above referenced project was approved by the IEC on xxxx and will due for the continuing Annual Review by the IEC You are requested to submit an periodic Status Report in one of the prescribed format as given below at the earliest on or before xxx

a) If ongoing, status report in the format as per form no. (*AX 02/SOP 07/* V7)
b) If completed – status report in the format as per form no. (*AX 01/SOP 08/* V7)
c) If terminated / not initiated – status report in the format as per form no. (*AX 01/ SOP 09/* V7)

Signature with date _____
Member Secretary_____

OR

Annexure 1

AX 01/SOP 07/ V7

Reminder letter by the IEC to Investigator for regulatory / sponsored studies

Date:-
Name of Principal Investigator :-
Department :-
Ref: - Project Title: XXXXXX

Respected Sir,

The above referenced project was approved by the IEC-I on xxxx and will be due for the periodic Review by the IEC-I/II/III. You are requested to submit a periodic Status Report in one of the prescribed format as given below at the earliest on or before **xxxxxxxxxx.**

a) If ongoing, status report in the format as per form no. **(*AX 02/SOP 07/V7*)**
b) If completed – status report in the format as per form no. **(*AX 01/SOP 08/ V7*)**
c) If terminated / not initiated – status report in the format as per form no. **(*AX01/ SOP 09/V7*)**

Please note the **sponsored projects** fees will be accepted by cheque / demand draft/ NEFT which will include the TDS, drawn in the name of 'Diamond Jubilee Society Trust, Seth G. S. Medical College & KEM Hospital' or by online **only through following details:**

Name of Account:	Seth GS Medical College & KEM Hospital, Diamond Jubilee society Trust
Account No:	60236880148
Account Type:	Saving
Name of Bank:	Bank of Maharashtra Parel Branch
Add of Bank:	Vikas Apartment, Dr. Ambedkar road, Parel, Mumbai 400012.
IFSC Code:	MAHB0000079
MICR Code:	400014011
PAN No:	AABTS5336G

Kindly submit periodic protocol review processing fees i.e. Rs. 10,000/- / 2500/- + 10% TDS to IEC-I. Please note a letter from sponsor is required (on sponsors letterhead) mentioning the following details: Gross amount, TDS amount deducted and the net amount to be paid as IEC periodic review processing fees.

Please note if sponsor / investigator is not deducting any TDS then they have to provide a letter stating that no TDS has been deducted and actual fees of Rs. 10,000/- is being paid.

1.	Payer / remitter's reference no.	
2.	Payer PAN number	
3.	Beneficiary details	
4.	Payment date	
5.	Trans currency	
6.	Payment method	
7.	Transaction reference number	
8.	Net amount	
9.	TDS	
10.	Gross amount	

Thanking you,
Sincerely yours,

Signature with date _____
Member Secretary_____

Annexure 2
AX 02/SOP 07/V 7
Continuing Review/Annual Report Format

Date: ……

IEC No. of the Project: ……

Study Title: ……
……

Principal Investigator (Name, Designation & Affiliation): ……
……

1. Date of EC Approval: ……
2. Date of Start of Study: …… Proposed Date of Completion: ……
   Period of Continuing Report: …… to: ……..
3. Does the study involve recruitment of participants?
   a. If Yes, Total number of participants approved by IEC: …… Number Screened: ……
      Number Enrolled: …… Number Ongoing: …… Number Completed: ……
   b. Report of DSMB/Sponsor site monitoring report during this period. Yes ☐ No ☐
      If yes, state the number: ……
4. Have there been any amendments in the research protocol/Informed Consent Document (ICD) during this continuing review period? Yes ☐ No ☐
   If No, Skip to point no. 5
   a. If Yes, date of approval for Protocol and ICD; ……
   b. In case of amendment in the ICD was re-consent sought from participants? Yes ☐ No ☐
      If yes, state the number: ……
5. Is any new information that is available does it change the benefit-risk analysis of human participants involved in this study during this continuing review period? Yes ☐ No ☐

If yes, discuss in detail: ……

6. Have any ethical concerns occurred during this continuing review period Yes ☐ No ☐

   If yes, give details: ……

7. a. Have any adverse events been noted during this continuing review period? Yes ☐ No ☐

   If yes, state the number: ……

   b. Have any SAE occurred during this continuing review period? Yes ☐ No ☐

   If yes, number of SAE: ……

   c. Have you reported the SAE to EC during this continuing review period? Yes ☐ No ☐

   ……

8. Has there been any protocol deviations/violations that occurred during this continuing review period?

   Yes ☐ No ☐

   If yes, number of deviations ……

   Have you reported the deviations to EC? Yes ☐ No ☐

   ……

9. In Case of Multicentric trials, have reports of off-site SAEs been submitted to the EC during this continuing review period? Yes ☐ No ☐ NA ☐

10. Are there any publications or presentations during this continuing review period?

    Yes ☐ No ☐

If yes, give details ……..

……

Signature of Principal Investigator (PI) with Date: ……

Annexure 3
AX 03/SOP 07/ V7
Continuing Review report Approval Letter

Name of the Principal Investigator: -
Department:-

Ref: - Project Title: _____
Sub: - Letter dated: _____

This is with reference to the above stated letter regarding the continuing review report of the above mentioned project. The Continuing Review Report was noted and reviewed in the IEC meeting held on XXXXXXXX

The IEC allows continuation of the above-mentioned project without any modifications.
You are requested to submit the next continuing review report within 1 month of the due date i.e. on or before XXXXX.

_____
Signature with date
Member Secretary

Date of approval:

Title:	**Review of Study Completion Reports**
SOP Code:	**SOP 08/V7 dated 19th November 2024**

Prepared by Signature with date	Reviewed by Signature with date	Approved by Signature with date	Accepted by
Dr. Raakhi Tripathi, Member Secretary, IEC-I	Dr. Nithya Gogtay, Jt. Member Secretary, IEC-I	Dr. Manju Sengar Chairperson, IEC-I	IEC-I
	Dr. Vyankatesh Shivane, Member, IEC-I	Dr. Sunil Kuyare Chairperson, IEC-II	IEC-II
		Dr. M. G. Karmarkar Chairperson, IEC-III	IEC-III

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide instructions on the review of Study Completion Report for every study previously approved by the Institutional Ethics Committee (IEC).

2. Scope

This SOP applies to the review of the Study Completion Report which is an obligatory review of each investigator's activities presented to the IEC as a written report of study completed.

3. Responsibility

It is the responsibility of Principal Investigator for DHR studies to submit the completion report incorporating the introduction, aim and objectives, material and methods with results along with the completion annexure (AX 01/SOP 08/ V7) to IEC for review.
It is the responsibility of Principal Investigator for clinical trials and academic clinical trials to submit the Clinical Study Report (CSR) along with the completion annexure (AX 01/SOP 08/ V7) to IEC for review. If the CSR is awaited, it is the responsibility of PI to submit the completion annexure and ensure IEC as clinical study report (CSR) will be submitted within one year from the date of completion notification and if CSR is not available from sponsor within a year same should be notified to IEC.
It is the responsibility of the IEC Chairperson/ Member secretary to review the study report and notify it or request for further information, if necessary.

4. Activity Table

No.	Activity	Responsibility
1.	Manage completion report package upon receipt and distribute to member secretary/chairperson	IEC Secretariat
2.	Review the annexure/ related documents of completion report	Member-Secretary/ IEC Member
3.	Written communication of the IEC to investigator	Member-Secretary

5. Detailed instructions

5.1 Manage completion report package upon receipt and distribute to member secretary/chairperson

- The IEC Secretariat will receive 1 copy (soft and hard) of Study Completion Report filled as per the format – AX 01/SOP 08/ V7 from the Principal Investigator. The study completion report is expected from the investigator within 1 month of completion of the study at the site. A brief study report containing data analysis from all centres can be submitted by the investigator once available from the sponsor.
- It is the responsibility of the IEC Secretariat to review the report for completeness. If necessary, the IEC secretariat will retrieve the master file from the archiving with permission of the Member Secretary.
- The IEC Secretariat shall forward the Study Completion Report along with Study Completion Report Form- AX 01/SOP 08/V7 and sends it to the Member secretary.

5.2 Review the annexure/ related documents of completion report

- The completion report submission may undergo expedited review (as per the procedure described in SOP 05-C/V7) or full board review (as per the procedure described in SOP 05-B/ V7) as deemed appropriate by the Member Secretary.
- The member secretary can designate (if required) one/two IEC members to review the Study report and related documents and inform the decision to the other IEC members at the next full board meeting.
- The IEC Secretariat will send the Study Completion Report Form AX 01/SOP 08/V7 to the designated IEC members if required.
- In case there is a significant finding during the review process by the designated IEC members this will be communicated to Principal Investigator. It is the responsibility of Principal Investigator to provide the required information to the IEC.

5.3 Procedures for review and communication

5.3.1 During the Board meeting

- The IEC Secretariat shall request the IEC member(s) designated the task to review a copy of the Final Report to present his/her comments.
- The Member Secretary entertains any discussion of the study.
- If appropriate to the discussions, the Chairperson may call for voting for final decision or whether to request further information or to take other action with the investigator.

5.3.2 After the Board meeting

- The IEC Secretariat will note the decision in the meeting minutes and the study shall be considered as closed if decision by IEC is "Noted".
- The IEC decision is notified to the investigator as
  a) noted in the IEC records
  b) request for additional information / clarification
- Once the completion report is accepted by IEC, the decision will be communicated to the PI within 14 working days of the date of the receipt from the investigator/ full board meeting. The Admin will archive the entire study protocol for a period of 5 years for regulatory trials and 3 years for non-regulatory/ academic clinical trials from the date of completion of the project if the decision is noted and closed.
- For regulatory trials when the PI submits only completion notification and trial site status then the project will go for archival for 5 years from this date. Subsequently if the PI submits the complete study report the date of receipt of this report will be noted and IEC admin will now modify the start of archival period date to this date and project will be archived for 5 years from this date.
- For thesis / dissertations no dues certification will be stamped only after confirming the submission of study completion report.

6. Annexure

Annexure 1 AX 01/SOP 08/V7 Study Completion Report Form

Annexure 1
AX 01/SOP 08/V7
Study Completion report form

Date: ……
IEC No. of the Project: ……
Study Title: ……
Principal Investigator (Name, Designation & Affiliation): ……

1. **Date of EC approval:** ……
2. **Date of start of study:** …… **Date of study completion:** ……..
3. **Provide details of**:
   a. Total number of study participants approved by the EC for recruitment: ……
   b. Total number of study participants recruited: ……
   c. Total number of participants withdrawn from the study (If any): ……
   Provide the reasons for the withdrawal of participants: ……
4. Describe in brief the publication/presentation/dissemination plans of the study findings. (Also, mention if both positive and negative results will be shared) ……
   ……
5. Describe the main ethical issues encountered in the study (If any)? ……
   ……
6. State the number (if any) of Deviations/Violations/Amendments made to the study protocol during the study period
   Deviations: …… Violations: …… Amendments: ……
7. Describe in brief plans for archival of records/record retention ……
   ……
8. Is there a plan for post study follow-up? Yes ☐ No ☐
   If Yes, describe in brief: ……
   ……
9. Do you have plans for ensuring that the data from the study can be shared/accessed easily?
   Yes ☐ No ☐

If Yes, describe in brief**:** ……
……..

10. Is there a plan for post study benefit sharing with the study participants? Yes ☐ No ☐
If Yes, describe in brief**:** ……
……..

11. Describe results (Summary) with conclusion? ……..
……..

12. Number of SAEs that occurred in the study: ……

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

14. Is Medical management or compensation for SAE provided to the participants? **Yes** ☐ **No** ☐
If Yes, provide details ……..

Signature of Principal Investigator (PI) with date: ……

Title:	Management of Premature Termination / Suspension / Discontinuation of the study/ Withdrawal of study
SOP Code	SOP 09/V7 dated 19th November 2024

Prepared by Signature with date	Reviewed by Signature with date	Approved by Signature with date	Accepted by
Dr. Raakhi Tripathi, Member Secretary, IEC-I 19/11/24	Dr. Nithya Gogtay, Jt. Member Secretary, IEC-I 19.11.24	Dr. Manju Sengar Chairperson, IEC-I 09/12/24	IEC-I
	Dr. Vyankatesh Shivane, Member, IEC-I 19 NOV 2024	Dr. Sunil Kuyare Chairperson, IEC-II 09/12/24	IEC-II
		Dr. M. G. Karmarkar Chairperson, IEC-III 09/12/24	IEC-III

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the Institutional Ethics Committee (IEC) proceeds and manages the premature termination/ suspension / discontinuation of the study / withdrawal of study before site initiation / during the conduct of a research study. Protocols may be terminated at the recommendation of the IEC, Data Safety Monitoring Board (DSMB), Principal Investigator, sponsor, Regulator or other authorized bodies wherein subject enrollment and subject follow-up are discontinued before the scheduled end of the study.

2. Scope

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

3. Responsibility

1. It is responsibility of IEC secretariat to receive premature termination/ Suspension / Discontinuation of the study / Withdrawal of study before site initiation / during the conduct of a research study report as per (AX 01/SOP 09/V7) submitted by the Principal Investigator and forward it to the member secretary / chairperson with required documents if needed.
2. It is responsibility of the member secretary / chairperson to review the report and take the decision.
3. It is responsibility of the IEC secretariat to record and communicate the decision to the IEC members and PI.

4. Activity Table

No.	Activity	Responsibility
1	Receive premature termination/ Suspension / Discontinuation of the study / Withdrawal of study before site initiation / during the conduct of a research study	IEC Secretariat
2	Review the report and take the decision.	Member Secretary / Chairperson
3	To record and communicate the decision to the IEC members and PI.	IEC Secretariat
4	Store the Protocol Documents	IEC Secretariat

5. Detailed instructions

5.1 Receive premature termination/Suspension/Discontinuation of the study/Withdrawal of study before site initiation / during the conduct of a research study.

The IEC Secretariat will receive 1 copy (soft and hard) of premature termination/ Suspension / Discontinuation of the study / Withdrawal of study before site initiation / during the conduct of a research study filled as per the format – AX 01/SOP 09/V7 with covering letter from the Principal Investigator.

- It is the responsibility of the IEC Secretariat to review the report for completeness. If necessary, the IEC secretariat will retrieve the master file from the archiving with permission of the Member Secretary.
- The IEC Secretariat shall forward the premature termination/Suspension / Discontinuation of the study / Withdrawal of study before site initiation / during the conduct of a research study Form- AX 01/ SOP 09/V7 and sends it to the Member secretary.

5.2 Review the report and take the decision.

- The member secretary shall review the results, reasons and accrual data and discuss the report at the next up-coming Full Board meeting.
- The Member Secretary in the meeting will inform members of the premature termination of the project and the IEC members will review the Premature Termination Report AX 01/ SOP09/V7
- If the Premature termination/ suspension/discontinuation Report is unclear or more

information is required from the PI, the Chairperson shall instruct the IEC Secretariat to seek clarifications/ additional information from the Principal Investigator.

- The Chairperson/member secretary / IEC members will review the information available and take a decision depending on the seriousness of the termination. The decision will be taken to ensure that the safety and rights of the research participants are safeguarded. The decision will be taken by consensus /voting.
- This action will be recorded by the Member Secretary.

5.3 Record and communicate the decision to the PI

The decision will be communicated to the PI within 14 working days and IEC Secretariat will record the decision reached on the Premature Termination/Suspension/Discontinuation of the study/Withdrawal of study before site initiation / during the conduct of the research study in the minutes of the meeting.

5.4 Storage and Archival of the protocol documents

- The IEC Secretariat will keep the original version of the Premature Termination Report AX 01/ SOP 09/V7 in the Protocol file and send the file to archive.
- The regulatory protocol documents will be stored for a period of 5 years and non-regulatory for a period of 3 years from the date of project Termination.

6. Annexure

ANNEXURE1 AX 01/SOP 09/V7 Premature Termination/Suspension/Discontinuation Report Format

Annexure 1
AX 01/ SOP 09/V7
Premature Termination/Suspension/Discontinuation Report Format

Date: ……

IEC No. of the Project: ……

Study Title: ……..

Principal Investigator (Name, Designation & Affiliation): ……

1. Date of EC approval: …… Date of start of study: ……
2. Date of last progress report submitted to EC: ……
3. Date of Termination/Suspension/Discontinuation: ……..
4. Tick the appropriate

   Premature Termination ☐ Suspension ☐ Discontinuation ☐

   Reason for Termination/Suspension/Discontinuation: ……

   Action taken post Termination/Suspension/Discontinuation (If any): ……
5. Plans for Post study follow up/withdrawal (If any): ……
6. Details of study participants:

   Total participants to be recruited: …… Screened: ……. Screen Failures: ……

   Enrolled: …… Consent Withdrawn: ……. Reason (Give details): ……

   ……

   Withdrawn by PI: …….. Reason (Give details): ……

   Active on treatment: ……. Complete treatment: …… Participants on follow-up: ……

   Participants lost to follow-up: …… Any other: …… Number of drop outs: ……..

   Reasons for each drop-out: ……
7. Total number of SAEs reported till date in the study: ……

Have any unexpected adverse events or outcomes observed in the study been reported to the EC?
Yes ☐ No ☐

8. Have there been participant complaints or feedback about the study? Yes ☐ No ☐
   If Yes, provide details: ……
9. Have there been any suggestions from the SAE Sub Committee? Yes ☐ No ☐
   If Yes, have you implemented that suggestion? Yes ☐ No ☐
10. Do the procedures for withdrawal of enrolled participants take into account their rights and welfare?
    Yes ☐ No ☐
    (e.g., making arrangements for medical care of research participants): If Yes, provide details
    ……
    Summary of results (If any): ……

Signature of Principal Investigator (PI) with Date: ……

Title:	Protocol Deviation/Violation
SOP Code:	SOP 10/V7 dated 19th November 2024

Prepared by Signature with date	Reviewed by Signature with date	Approved by Signature with date	Accepted by
Dr. Raakhi Tripathi, Member Secretary, IEC-I	Dr. Nithya Gogtay, Jt. Member Secretary, IEC-I	Dr. Manju Sengar Chairperson, IEC-I	IEC-I
	Dr. Vyankatesh Shivane, Member, IEC-I	Dr. Sunil Kuyare Chairperson, IEC-II	IEC-II
		Dr. M. G. Karmarkar Chairperson, IEC-III	IEC-III

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide instructions for taking action(s) when investigator(s)/trial site(s) fail(s)to:

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

2. Scope

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

3. Responsibility

- It is responsibility of IEC secretariat to receive deviation /violation reports as per (AX 01/SOP10/V7) with covering letter mentioning details of deviations (as per table mentioned below the annexure 1) submitted by the Principal Investigator and forwards it to the member secretary.
- It is responsibility of the member secretary to categorized the submitted protocol deviations as minor and major and assign one/ two primary reviewers if required.
- It is responsibility of the member secretary / designated reviewers to review the protocol deviations and take the decision in the full board meeting regarding the same.
- It is responsibility of the IEC secretariat to record and communicate the decision to the PI.

4. Activity Table

No.	Activity	Responsibility
1	Receiving deviation /violation reports and forward it to the member secretary/chairperson	IEC Secretariat
2	categorized the protocol deviations and assign one/ two primary reviewers	Member Secretary
3	To review the protocol deviations	Member Secretary / Reviewers
4	Record and communicate the decision to the PI.	IEC Secretariat

5. Detailed instructions

Detection of Protocol deviation/ non-compliance/violation

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

- Protocol deviation/ non-compliance/ violation may be reported by Investigator/ study site/ sponsor/ Contract-Research Organization to the IEC
- The IEC members performing monitoring of the project at trial site may detect protocol deviation/non-compliance/violation if the project is not been conducted as per protocol/ national/international regulations.
- The IEC Secretariat may detect protocol deviation/non-compliance/violation from failure to comply with statutory requirements/failure to respond to requests from IEC within reasonable time limit/failure to respond to communication made by IEC.
- The IEC members may detect protocol deviation/non-compliance/violation when scrutinizing annual/ periodic reports/ SAE reports /sponsor monitoring report any other communication

received from the Investigator/ trial site/ sponsor/ study monitor/ contract research organization/ethics committee monitor.

- The IEC secretariat and/ or IEC members may become aware of a protocol deviation/ non-compliance/ violation while reviewing study-related documents including reports filed in by the Principal Investigator.
- Communication/ complaint/ information received from research participant who has been enrolled or any individual who has been approached for enrollment
- Any report/ communication brought to the notice of Member, Secretary/ Jt. Secretary/ Chairperson of IEC by an independent person
- Communication received from the Head of the Institution informing IEC about an alleged protocol violation/ non-compliance/ protocol deviation
- At least PDs should be reported quarterly (**not exceeding three months** from the detection of the deviation).

5.1 Receiving deviation /violation reports and forward it to the member secretary

The IEC Secretariat will receive 1 copy (soft and hard) of protocol deviation Report filled as per the format – AX 01/SOP 10/V7 with covering letter from the Principal Investigator. Investigator must give in writing the Root Cause Analysis for Protocol Deviations with CAPA (Corrective and Preventive Action) plan in the covering letter.

- It is the responsibility of the IEC Secretariat to review the report for completeness. If necessary, the IEC secretariat will retrieve the master file from the archiving with permission of the Member Secretary.
- The IEC Secretariat shall forward the protocol deviation Report along with protocol deviation Form-AX 01/SOP 10/V7 and covering letter and sends it to the Member secretary.

5.2 Categorize the protocol deviations and assign one/ two primary reviewers

The member secretary will categorize the protocol deviations as minor or major. The definition of major and minor are as follows:

- **Protocol Deviation (Minor) and Protocol Violation (Major):**

- **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 IEC using the standard reporting form.
- **Protocol Violation (Major protocol deviations):** - A protocol violation is a deviation from the IEC approved protocol that may affect the subject's rights, safety, or wellbeing and/or the completeness, accuracy and reliability of the study data. If the deviation meets any of the following criteria, it is considered a protocol violation. Example list is not exhaustive.

  I. The deviation has harmed or posed a significant or substantive risk of harm to the research subject. For example:
     - A research participant has received the wrong treatment
     - A research participant had met withdrawal criteria during the study but was not withdrawn.
     - A research participant received an excluded concomitant medication.

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

III. The deviation is a willful or knowing breach of human participant protection regulations, policies, or procedures on the part of the investigator(s). For example:
- Failure to obtain informed consent prior to initiation of study-related procedures
- Falsifying research or medical records.
- Performing tests or procedures beyond the individual's professional scope or privilege Status (credentialing)

IV. The deviation involves a serious or continuing noncompliance with federal, state, local or Institutional human participant protection regulations, policies, or procedures. For example
- Working under an expired professional license or certification
- Failure to follow federal and/or local regulations, and intramural research policies
- Repeated minor deviations

V. The deviation is inconsistent with the NIH Human Research Protection Program's research, Medical and Ethical principles. For example.
- A breach of confidentiality.
- Inadequate or improper informed consent procedure.

5.3 To review the protocol deviations

The **Minor** protocol deviations and related documents will be reviewed by either member secretary and will be notified in the full board meeting.

Major protocol deviations and related documents will be reviewed by either member secretary / one / two designated primary reviewers. After review by the member secretary / designated primary reviewers the report will be discussed in the upcoming full board meeting.

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

additional necessary action (as listed above and will be taken on case to case basis)

- Deviations reported > 50% of the approved sample size.
- >5 deviations are reported in the same patient.

However, the nature of the deviations will be looked at prior to this (e.g. distinguishing between patient related protocol deviations versus investigator related deviations)

- This action will be recorded by the Member Secretary.

5.4 Record and communicate the decision to the PI.

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

6. Annexure

Annexure1 AX 01/SOP 10/V7 Deviation/Violation Record

Annexure1
AX 01/SOP 10/V7
Protocol Violation/Deviation Reporting Form (Reporting by case)

Date: ……
Study Title:
……
Principal Investigator (Name, Designation & Affiliation):
……

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

Consenting	☐	Source Documentation	☐
Enrollment	☐	Staff	☐
Laboratory assessment	☐	Participant non-compliance	☐
Investigational Product	☐	Others (Specify)	☐
Safety Reporting	☐		

6. **Provide details of Deviation/Violation:**
   ……
7. **Corrective action taken by PI/Co-I:**
   ……
8. **Impact on (If any):** Study Participants ☐ Quality of data ☐
9. **Are any changes to the study/Protocol required?** Yes ☐ ☐ No

   If Yes, give details
   ……

Signature of Principal Investigator (PI) with Date:
……..

Title	Constituting SAE Subcommittee
SOP Code	SOP 11-A /V 7 dated 19th November 2024

Prepared by Signature with date	Reviewed by Signature with date	Approved by Signature with date	Accepted by
19/11/24 Dr. Raakhi Tripathi, Member Secretary, IEC-I	19.11.24 Dr. Nithya Gogtay, Jt. Member Secretary, IEC-I	9/12/2024 Dr. Manju Sengar Chairperson, IEC-I	Institutional Ethics Committee (IEC-I) Established In 1985 Seth G.S. Medical College & K.E.M. Hospital Parel, Mumbai-400 012. IEC-I
	19 NOV 2024 Dr. Vyankatesh Shivane, Member, IEC-I	09/12/24 Dr. Sunil Kuyare Chairperson, IEC-II	Institutional Ethics Committee (IEC-II) Established in 1986 Seth G.S. Medical College & K.E.M. Hospital, Parel, Mumbai - 400 012. IEC-II
		09/12/24 Dr. M. G. Karmarkar Chairperson, IEC-III	Institute Ethics Committee-III Established in 1986 Seth G.S. Medical College & K.E.M. Hospital, Parel, Mumbai - 400 012. IEC-III

1. Purpose

This Standard Operating Procedure (SOP) describes the Terms of References (TOR), which provide the framework for constitution, responsibilities, and activities of the SAE Subcommittee.

2. Scope

The SOP applies to all activities performed by the SAE Subcommittee.

3. Responsibility

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

4. Activity Table

No.	Activity	Responsibility
1	Composition of the SAE Subcommittee	Chairperson, IEC Members and IEC Secretariat
2	Membership requirements	Chairperson
3	Tenure of Membership	Chairperson, IEC Members and IEC Secretariat
4	Initiation of the process of appointment	IEC Secretariat
5.	Appointment of new members	Chairperson
6.	Resignation and disqualification of members	IEC Members and IEC Secretariat
7.	Conditions of appointment	IEC Members and IEC Secretariat
8.	Selection and appointment of Head of the SAE subcommittee	Chairperson of the IEC for CT
9.	Quorum requirements	IEC Members and IEC Secretariat

5. Detailed Instructions

5.1 Ethical basis:

- Serious Adverse Event (SAE) Subcommittee of the Institutional Ethics Committee' (IEC) first established in 21st April 2009. The SAE Subcommittee will review all serious adverse events (SAE) and unexpected adverse events (UAE) and adverse events (AEs) at this site / other sites in all types of research studies involving human participants approved by IEC.
- The committee will consist of members who collectively have the qualifications and experience to review and evaluate the scientific, medical and ethical aspects of adverse event reports involving human participants.
- In evaluating all the adverse event reports, the SAE Subcommittee is aware of the diversity of laws, culture and practices governing research and medical practices in various countries around the world and especially in India.
- The SAE subcommittee attempts to keep itself informed of the requirements and conditions of the various localities where proposed research is being considered.
- The committee will follow all applicable guidelines released by the regulatory authorities and revised from time to time
- The SAE Subcommittee will work according to its established Standard Operating Procedures and follows all applicable guidelines
- The mandate is to
    - To ensure the protection of the rights, safety and wellbeing of human participants involved in clinical research projects.
    - To provide public assurance of that protection.

5.2 Composition of the SAE Subcommittee:

- The SAE Subcommittee will be appointed by the Chairperson of Ethics Committee (IEC-I).
- The SAE Subcommittee will be multidisciplinary and multi-sectoral in composition.
- The SAE Subcommittee will be composed of at least 5 and a maximum of 12 members.
- The members preferably should be from medical and scientific backgrounds.
- The Composition shall be as follows:
  - Head of the SAE Subcommittee (who is a member of the IEC-I or Clinical trial (CT)).
  - One Executive Secretary (who is a member of the any IEC -I, II or III.).
  - At least one member possessing post graduate degree in the subject of Pharmacology (who is the member of the any IEC I,II,III).
  - At least one member possessing post graduate degree in the subject of General Medicine (who is the member of any IEC).
  - Member Secretary of the committee/s reviewing regulatory proposals.
- The requirement, appointment and terms of membership will be the same as described below in sections 5.3 to 5.8.
- The SAE Subcommittee may invite legal expert member of the IEC to provide opinion on the legal implication of adverse event.

5.3 Membership requirements:

- The Chairperson of Ethics Committee/ Clinical trial (CT) is responsible for appointing the SAE Subcommittee members.
- The IEC members can suggest names of potential IEC members but the final decision will remain with the Chairperson.
- Members will be selected in their personal capacities based on their interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the SAE Subcommittee work.

5.4 Tenure of Membership:

- The tenure of Institutional Ethics Committee members will be for a continuous period of three (3) years from the date of appointment and will co-incide with the appointment on IEC board.
- The IEC members will recommend names of individuals to the Chairperson. The Chairperson will select and appoint a member for the new tenure from the list provided by the IEC or otherwise

5.5 Appointment of new members:

The SAE Subcommittee members will be appointed by the Chairperson. New members will be appointed under the following circumstances:

- When any member completes his/ her tenure.
- If any member resigns before the tenure is completed.
- If any member ceases to be a member for any reason including death or disqualification.
- To fulfill the membership requirements as per 5.3 of this SOP.
- New members will be identified by the Chairperson according to the requirement (i.e. as per the composition specified in Section 5.2 of this SOP), membership requirement (Section 5.3 of this SOP) and if the potential member fulfils the conditions of appointment as defined in 5.5 of this SOP after discussion by the IEC he/she will be appointed on SAE Subcommittee. The final decision regarding appointment of members will be taken by the Chairperson.

5.6 Resignation and Disqualification of Members:

- Resignation: An SAE Subcommittee 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 unbecoming of an SAE Subcommittee 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 unbecoming of an SAE Subcommittee member.

- The process will be initiated if IEC Chairperson or Head of SAE Subcommittee receives a communication in writing (provided by IEC member) alleging misconduct by a SAE Subcommittee member.
- The Chairperson will satisfy himself/herself 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 SAE Subcommittee 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 SAE Subcommittee member.
- 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. The allegation will be discussed at the IEC meeting and the member alleged of misconduct will be provided adequate opportunity to defend him/her.
- The member would stand disqualified if members present approve of disqualification by voting (voting by 2/3rd of majority of members present in the meeting and voting). The Chairperson will convey the disqualification to the concerned member through a written communication.

5.7 Conditions of appointment:

Members will be appointed on SAE Subcommittee if they accept the following conditions:

- Willingness to publicize his/her full name, profession and affiliation.
- Willingness to sign the Confidentiality and Conflict of Interest Agreements regarding meeting, deliberations, applications, information on research participation and related matters.
- Willingness and commitment in terms of time to perform the role and responsibility as SAE Subcommittee member.

5.6 Hierarchy:

- There will be one SAE Subcommittee-Head, one executive Secretary of SAE Subcommittee.
- The Member Secretary of the IEC for CT will be the guardian of all documents in the possession of the committee. In case of anticipated absence, the head of SAE subcommittee will nominate a SAE subcommittee member as Acting Executive Secretary. The Acting executive secretary will have all the powers of the executive secretary of the SAE subcommittee for that meeting.
- Other SAE Subcommittee members will be regular committee members with equal ranking.
- The Head of the SAE Subcommittee will be appointed by the Chairperson.
- The executive secretary, will be nominated by and from amongst the SAE Subcommittee members for 3 years term. The executive secretary may be re-elected any number of times. Should he/she resign or be disqualified, the SAE Subcommittee members will elect a replacement for another term.

5.7 Head of the SAE Subcommittee:

- The Head of the SAE Subcommittee will be appointed by the Chairperson.
- The Head of the SAE Subcommittee will be affiliated to the institution.
- The Head of the SAE Subcommittee will be responsible for conducting SAE subcommittee meetings, and will lead all discussions and deliberations pertinent to the review of All type of adverse event reports [Serious Adverse Event (SAE), Unexpected Adverse Event (UAE), Adverse Event (AE), Suspected Unexpected Serious Adverse Event (SUSAR)].
- The Head and secretary of the SAE Subcommittee will sign minutes of the SAE Subcommittee meeting.
- In case of anticipated absence, the head of SAE subcommittee will nominate a SAE subcommittee member as Acting Head. The Acting Head will have all the powers of the Head of SAE subcommittee for that meeting.

5.8 Functions of the Executive secretary of the SAE Subcommittee:

- To receive All type of adverse event reports (SAE, UAE, AE, SUSAR's).
- To organize an effective and efficient tracking procedure for each onsite adverse event
- report received.

- To inform the adverse events (serious and unexpected) reports to other members of the
- SAE Subcommittee.
- To schedule and organize the SAE Subcommittee meetings.
- To prepare and maintain meeting agenda and minutes.
- To prepare the communication letters related to the adverse event reports.
- To communicate with the IEC members and applicants/investigators and regulators.
- To provide necessary administrative support for SAE Subcommittee related activities.
- To ensure adherence of the SAE Subcommittee functioning as per SOPs.

5.9 Functions of the IEC Secretariat:

The IEC Secretariat will perform the functions as mentioned in **SOP11-B/V7** for the SAE Subcommittee:

- Functions of the Administrative Manager, Officer/s, Executive Assistant.
- To support the Executive Secretary in executing functions of the SAE Subcommittee.
- To prepare the agenda of the SAE subcommittee with help of Secretary of the SAE Subcommittee. The agenda of the SAE Subcommittee will include the information on SAE/ UAE at the site in the following format:

Participant ID	**Letter no./ and date of reporting**	**Type of report**	**Type of SAE/ UAE**	**Date of onset**	**whether study drug withheld**	**Outcome**	**Causality in the opinion of PI**

Summary:
Total no. of SAE Reported=00
Total no. of Death = 00

- The agenda will also include information about SAE/UAE reports for the SAE /UAE occurring at other trial sites.
- To prepare the minutes (to be prepared within 5 working days of the meeting) with the help of the Secretary of the Subcommittee The minutes of the SAE Subcommittee will include the information on SAE /UAE at the site in the following format:

Participant ID	**Letter no./ and date of reporting**	**Type of report**	**Type of AE/SAE/ UAE**	**Date of onset**	**whether study drug withheld**	**SAE Outcome**	**Causality in the opinion of PI**

- The minutes will also include IEC opinion regarding relatedness of the SAE on receipt of Follow up report with due analysis. For SAE reports wherein IEC opinion regarding causality of the SAE is related then the minutes will also include calculation of financial compensation as per NDCT rules 2019. In addition the notification /recommendation on the other site SAE/UAE reports will be reported in the minutes.
- To perform any other functions as instructed by Executive Secretary/ Head of the SAE Subcommittee.

5.10 Roles and Responsibilities of the SAE Subcommittee members:

- To attend the SAE Subcommittee Meetings and participate in discussions and deliberations so that appropriate decisions can be arrived at.
- To review Serious Adverse Event and unexpected adverse reports and recommend appropriate action(s) as follows:
  - The SAE /UAE reports will be reviewed completely in the SAE subcommittee meeting with a special focus on relatedness to the clinical trial, medical management and financial

compensation to be given to the research participant as per New Drugs and Clinical Trials, Rules (NDCTR,2019, 19th March 2019). The SAE subcommittee while reviewing may solicit opinion of one or more subject expert in writing, if the Sub-committee decides to consult experts. The information can be provided to expert after he/ she/ they agree(s) to the confidentiality clause and abide by the rules and regulations of IEC and the necessary confidentiality documents are signed.

- The subject expert would be requested to provide an opinion in writing within 2 working days, depending upon the gravity and seriousness.

- The following decisions/actions including the following but not limited to, are listed below:
  - Note the information about the SAE in records for future reference.
  - To opine on compensation entitled to research participants (as per New Drugs and Clinical Trials, Rules (NDCTR 2019, 19th March 2019) experiencing Serious Adverse Event and unexpected adverse events and recommend appropriate action(s).
  - Request further follow up information and/ or additional details on causality of the event, provision of medical treatment till SAE is resolved and financial compensation.
  - Provide periodic follow-up of the research participant till SAE is resolved or till death occurs (whichever is earlier). In case of pregnancy which is reported as SAE to send follow up reports of the child in utero and after delivery. Additional reports on the follow up of the new born baby may be requested by the IEC on case to case basis.
  - If appropriate to the discussions, the recommendation regarding a specific action or combination of actions to be taken is arrived at by the SAE subcommittee meeting. The recommendations will be communicated to the other IEC members (Members include the IEC which accorded approval to the study) within 5 working days.
  - To maintain confidentiality of the documents and deliberations of the SAE Subcommittee meetings.
  - To declare any conflict of interest.
  - To provide information and documents related to training obtained in biomedical ethics and biomedical research to the IEC secretariat.
  - To carry out the work delegated by Head of the SAE Subcommittee.
  - To assist Head of the SAE Subcommittee in carrying out IEC work as per SOPs.

5.11 Quorum Requirements:

The SAE Subcommittee meeting will be held as scheduled provided there is quorum. For the SAE Subcommittee meeting, a quorum will consist of at least 4 members as follows- one member (preferably pharmacologist), one member (preferably clinician), executive secretary and Head/ Acting head of the SAE subcommittee.

5.12 Minutes of the SAE subcommittee meeting:

Minutes of SAE subcommittee meeting will be prepared by SAE subcommittee Executive secretary. These minutes will be communicated to the other IEC members via email (Members include the IEC which accorded approval to the study) within 5 working days. The IEC members will be requested to approve / raise queries within working 2 days. If queries are raised SAE sub committee to reply to these queries satisfactorily within 1 working day. The final minutes will then be presented by the members secretary in the next Full Board meeting of IEC (The IEC which accorded approval to the study).

5.13 Responsibilities of the SAE Subcommittee:

- The SAE Subcommittee primary responsibilities will be protection of safety, rights and confidentiality of the research participants.
- The SAE Subcommittee will keep all information submitted to them confidential specially the proprietary information.
- The SAE Subcommittee will maintain concise but clear documentations of its views on each adverse event report.
- The SAE Subcommittee will review the serious adverse event, unexpected adverse event and adverse event and other site SAE reports (CIOMS, SUSARs) of each research project at appropriate and specified intervals.
- The SAE Subcommittee will ensure that appropriate compensation is paid to the research participant as per (New Drugs and Clinical Trials, Rules (NDCTR 2019, 19th March 2019).

Title	**Review of Serious Adverse Events (SAE) Reports and Suspected/ Unexpected Adverse Events (UAE)**
SOP Code	**SOP 11-B /V 7 dated 19th November 2024**

Prepared by Signature with date	Reviewed by Signature with date	Approved by Signature with date	Accepted by
Dr. Raakhi Tripathi, Member Secretary, IEC-I	Dr. Nithya Gogtay, Jt. Member Secretary, IEC-I	Dr. Manju Sengar Chairperson, IEC-I	IEC-I
	Dr. Vyankatesh Shivane, Member, IEC-I	Dr. Sunil Kuyare Chairperson, IEC-II	IEC-II
		Dr. M. G. Karmarkar Chairperson, IEC-III	IEC-III

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) at our site and reports of Suspected/ unexpected adverse events (UAE) occurring at other trial sites.

2. Scope

This SOP applies to the review of SAE reports at our site and Suspected / UAE reports of other trial sites submitted to the IEC.

3. Responsibility

It is the responsibility of the IEC to review SAE reports at our site and Suspected / UAE reports of other trial sites submitted to the IEC.

4. Activity Table

No.	Activity	Responsibility
1	Receipt of AE, Serious adverse events (SAE) at our site and reports of Suspected/ unexpected adverse events (UAE) occurring at other trial sites.	IEC Secretariat.
2.	Submission of AE, Serious adverse events (SAE) at our site and reports of Suspected/ unexpected adverse events (UAE) occurring at other trial sites	IEC Secretariat.
3	Preparation of the Agenda for the Subcommittee Meeting.	Secretary of the SAE Sub-committee.
4.	Review and discussion of SAE report at the Subcommittee meeting.	SAE Subcommittee members.
5.	Discussion/Decision at the IEC meeting.	Members of the IEC.
6	Preparation of the Minutes for the Subcommittee Meeting.	IEC Secretariat.
7	Communication of the IEC decision about SAE review to the principal investigator.	IEC Secretariat.
8	Communication of the IEC decision about SAE review to DCI.	Member Secretary / Chairperson of the IEC.
9	Discussion/Information at the full board IEC meeting	Member Secretary of the IEC.

5. Detailed Instructions

5.1 Onsite SAE and reports of offsite Suspected/ UAE:

5.1.1 Receipt of Onsite SAE and reports of offsite Suspected/ UAE:

- The IEC Secretariat will receive the following documents within the specified time frame pertaining to SAE experienced by the research participants ON SITE for research proposals approved by the IEC:
    - On site SAE report to be submitted by the Principal Investigator within 24 hours Initial report and with due analysis report within 14 days of their occurrence as per the format specified in
        - Annexure 1: AX 01/SOP 11-B/V7 (Table 5 Data elements for reporting serious adverse

events occurring in a clinical trial or bioavailability or bioequivalence study of Initial Report/Follow up report As per NDCTR 2019) *&*

- Annexure 2: AX 02/SOP 11-B/V7 (SAE Reporting format for Biomedical Health Research)

- In the case of SAE, the report with due analysis will be submitted by the sponsor (as applicable by NDCT rules 2019) within 14 days along with the format specified in AX 01/SOP 11-B/V7 (TABLE 5 Data Elements for Reporting Serious Adverse Events occurring in a clinical trial or bioavailability or bioequivalence study)
- On site SAE close out report to be submitted by the Principal Investigator with the format specified in AX 03/SOP11-B/V7.

- The IEC Secretariat will verify that the report is complete in all respects and is signed and dated by the Principal Investigator (PI) or Sponsor as the case may be and that it has been received at the IEC office within the specified timelines above. If the report has been received beyond the specified time, this will be considered as a deviation (and PI will be requested to submit duly filled Deviation Annexure AX 01/SOP 10/V7).
- The IEC Secretariat will sign and write the date and type of report when the report is received.
- For all the onsite SAE reports received at the IEC office, the executive assistant will forward these reports to the executive secretary of the SAE Subcommittee within two working days.

5.1.2 Review of Onsite SAE and reports of offsite Suspected/ UAE:

- The secretary of the SAE Subcommittee will review the SAE / Suspected /UAE report and arrange a meeting to gather IEC opinion complying to the timelines as per NDCT rules.
- The SAE and Suspected/ UAE reports submitted to the IEC will be reviewed by the SAE subcommittee as per requirement.
- At the meeting, the members of the SAE subcommittee will review all the SAE/ Suspected/ UAE reports received and the committee will deliberate on issues involved in the report and decide further course of action as any of the following:
  - Noted
  - Seek clarification
  - Ask further details
- If clarification/ further details are required regarding the SAE the PI will be communicated and requested to respond within 7 days of receipt of the letter.

5.1.3 Process of communication

- Minutes of SAE subcommittee meeting will be prepared by SAE subcommittee Executive secretary within 5 working days.
- These minutes will be communicated to the other IEC members via email (Members include the IEC which accorded approval to the study) on the same day.
- The IEC members will be requested to approve / raise queries within working 2 days. If queries are raised SAE sub committee to reply to these queries satisfactorily within 1 working day. If objection is received from more than 2 IEC members an emergency IEC meeting (refer SOP 14) will be scheduled within 7 days for the same.
- The final minutes will then be presented by the members secretary in the next Full Board meeting of IEC (The IEC which accorded approval to the study).
- If approval is obtained from all the IEC members the decision will be communicated to the Licensing authority (DCGI) within 30 days of the occurrence of the SAE as per NDCT rules 2019. The IEC opinion regarding relatedness and the quantum of financial compensation as per NDCT rules 2019 will be communicated to the Licensing authority (DCGI) within 30 days of the occurrence of the SAE.

5.1.4 Inform Investigator:

- The IEC secretariat will draft a formal letter to the concerned Principal Investigator and inform him/

her about the IEC decision. This letter will be signed and dated by the Member Secretary (IEC) and will be sent to the Principal Investigator within a period of 7 days from the date of the SAE subcommittee meeting.

- The Principal Investigator will be requested to reply to the query letter on the SAE report within 7 working days. If no response is received (within 7 days of dispatch of EC query letter) from the investigator regarding the query raised on the given SAE, a reminder letter will be sent to the investigator stating that the response to the query letter must be sent within 5 working days of the dispatch of reminder letter. If no response is received to the reminder letter, this should be informed by the member secretary of the IEC in the full board meeting and decision will be taken on case to case basis.
- The Administrative Officer will file a copy of the query letter in the study file.

5.1.5 Inform Licensing authority (DCGI):

- The Member-Secretary of the IEC will forward the letter describing the opinion on the SAE report, along with the opinion on financial compensation, to the to the DCGI within 30 days of the occurrence of the SAE-death.
- The Administrative Officer will file a copy of these letters in the study file.

5.2 Onsite AE:

5.2.1 Receipt of AE report:

- The IEC Secretariat will receive the following documents pertaining to AE experienced by the research participants for research proposals approved by the IEC:
  - On site AE reports to be submitted by the Principal Investigator periodically 6th Months (With continuation report) as decided by the IEC
  - In view of the risk assessment of a given research proposal the IEC can request adverse events to be reported earlier, if deemed necessary at specified timelines in the project approval letter.
- The SAE/IEC Secretariat will verify that the report is complete in all respects and is signed and dated by the Principal Investigator (PI) and that it has been received at the IEC office within the specified timelines above. If the report has been received beyond the specified time, this will be considered as violation.
- The IEC Secretariat will sign and write the date on which the report is received.
- For all the onsite AE reports received at the IEC office, the Executive Assistant will forward these reports to the Member Secretary within two working days.

5.2.2 Review of AE Reports:

- AE reports submitted to the IEC will be reviewed by the member secretary and if required present in the fullboard meeting of IEC.

5.2.3 Inform Investigator:

- The IEC secretariat will draft a formal letter to the concerned Principal Investigator and inform him/ her about the IEC decision on the concerned AE report. This letter will be signed and dated by the Member-Secretary and will be sent to the Principal Investigator within a period of 14 working days from the date of the IEC meeting.
- If in the IEC meeting queries are raised on the AE report, the principal investigator will be requested to reply to the query letter on the AE report.
- If no response is received prior to the next full board meeting the issue will be discussed in the forthcoming full board meeting and decision will be taken on case to case basis.

5.2.4 Further action:

- The executive will file a copy of these letters in the study file.

5.3 SAEs occurring at other sites:

- The investigator will need to submit the SAEs occurring at other sites (CIOMS, SUSARS) in the form of soft copies only (Pendrive) along with the appropriate covering letter (hard copy) mentioning the total number of reports and its details in the following format:

Sr. No.	Country	MFR Control No.	Type of Report	SAE event	Date of onset of ADR	Date of ADR report	Outcome	Causality	
								Investigator	Sponsor

- For every SAE term use separate row. Do not club SAE terms.
- Please mentioned causality as Related (R) or Not Related (NR)[do not use word possibly, unlikely, probable, associated, No]
- The SAEs occurring at other sites will be reviewed by the Secretary of the SAE Subcommittee and informed to other members of the Subcommittee and discussed in the forthcoming scheduled Subcommittee meeting. The agenda and minutes of the SAE Subcommittee will include the information on SAEs at other sites.
- The discussion will be communicated by the SAE Subcommittee Executive Secretary to the Secretariat who will include it in the appropriate IEC agenda

5.4 <u>During the Full board IEC meeting:</u>

- The IEC Member Secretary will read out the minutes of all the SAE Sub- committee meetings including the recommendations/decisions of the SAE sub- committee.
- The member secretary may present project wise onsite SAE data if required and any issues put forth by SAE subcommittee, the issue can be re-discussed and decision can be arrived requesting any of the following actions which are listed below:
  - *Terminate the study.*
  - *Suspend the study till review is completed (safety monitoring of ongoing patients to be continued).*
  - *Suspend the study till additional information is available.*
  - *Suspend the study for a specified duration of time.*
  - *Suggest changes/ amendments in protocol, Patient Information Sheet/ Informed Consent Document/ Investigators' Brochure/ any other study-related documents.*
  - *Suspend the study till amendments requested for by the IEC are carried out.*
  - *Suspend enrollment of new participants.*
  - *Suspend certain activities under the protocol.*
  - *Direct the Investigator to inform participants already enrolled in the study about the AEs and if required obtain their consent again (re-consent) regarding continuation in the research trial.*
  - *Direct the Investigator to inform participants already enrolled in the study about the AE and request them to undertake additional visits, additional procedures, additional investigations, etc. as prescribed in the amendment.*
  - *Note the information about the SAE in records for future reference.*
  - *Request further follow up information and/ or additional details.*
  - *Provide periodic follow-up of the research participant till SAE is resolved or till death occurs (whichever is earlier).*
  - *Any other appropriate action.*
  - The decision shall be recorded in the minutes of the full board IEC meeting:

- If the recommendation from the IEC includes suspension of the study or suspension of any one or more of the study-related procedures or activities, amendments in the protocol or other study-related documents (excluding Investigators' brochure), re- consenting of research participants, the decision will be conveyed to the Principal Investigator through telephone, or via email within 24 hours. Such a communication will be documented by the IEC Member-Secretary in the study file. A formal letter to the Principal Investigator informing about the IEC recommendations in such situations will be sent within 5 working days of the IEC meeting having taken place.

6. Glossary:

Adverse Event	Any untoward medical occurrence in a patient or clinical investigation participant administered an investigational product and which does not necessarily have a causal relationship with this treatment. The adverse event can therefore be any unfavorable or unintended sign or experience associated with the use of the investigational product, whether or not related to the product.
Adverse Drug Reaction	A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function.
IND	Investigational New Drugs means substances with potential therapeutic actions during the process of scientific studies in human in order to verify their potential effects and safety for human use and to get approval for marketing.
Unexpected adverse event	An adverse event, the nature or severity of which is not consistent with the applicable product information (e.g.: Investigator's brochure for an unapproved investigational product or package insert /summary of product characteristics for an approved product)
SAE (Serious Adverse Event)	The adverse event is SERIOUS and should be reported when the patient outcome is: **Death:** Report if the patient's death is suspected as being a direct outcome of the adverse event. **Life-Threatening:** Report if the patient was at substantial risk of dying at the time of the adverse event or it is suspected that the use or continued use of the product would result in the patient's death. *Examples: Pacemaker failure; gastrointestinal hemorrhage; bone marrow suppression; infusion pump failure which permits uncontrolled free flow resulting in excessive drug dosing.* **Hospitalization**(initial or prolonged) - Report if admission to the hospital or prolongation of a hospital stay results because of the adverse event. *Examples: Anaphylaxis; pseudomembranous colitis; or bleeding causing or prolonging hospitalization.* **Disability**- Report if the adverse event resulted in a significant, persistent, or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities or quality of life. *Examples: Cerebrovascular accident due to drug-induced hypercoagulability; toxicity; peripheral neuropathy.* **Congenital Anomaly**- Report if there are suspicions that exposure to a medical product prior to conception or during pregnancy resulted in an adverse outcome in the child. *Examples: Vaginal cancer in female offspring from diethylstilbestrol during pregnancy; malformation in the offspring caused by thalidomide.* **Requires Intervention to Prevent Permanent Impairment or Damage**– Report if suspect that the use of a medical product may result in a condition which required medical or surgical intervention to preclude permanent impairment or damage to a patient. Examples: Acetaminophen overdose-induced hepatotoxicity requiring treatment with acetylcysteine to prevent permanent damage; burns from Radiation equipment requiring drug therapy; breakage of a screw requiring replacement of hardware to prevent malunion of a fractured long bone.

SUSAR (Suspected Unexpected Serious Adverse Report)	An adverse reaction that is classed in nature as serious and which is not consistent with the information about the medicinal product in question set out. • In the case of a licensed product, in the summary of product characteristics (SmPC) for that product. • In the case of any other investigational medicinal product, in the IB relating to the trial in question.

7. Annexure:

Annexure 1	AX 01/SOP11-B/V7	Table 5 Data Elements for Reporting Serious Adverse Events occurring in a clinical trial or bioavailability or bioequivalence study of Initial Report/Follow up report
Annexure 2	AX 02/SOP11-B/V7	Serious Adverse Event Report (Biomedical Health Research)
Annexure 3	AX03/SOP11-B/V7	Serious Adverse Event Close out Report (For SAE at the site)

Annexure 1
AX 01/SOP 11-B/V7
Table 5
THIRD SCHEDULE
Data Elements for Reporting Serious Adverse Events occurring in a clinical trial or bioavailability or bioequivalence study of Initial Report/Follow up report

Sr. No.	**Details**		
1.	**Country (Name of the country should be specified)**	**INDIA**	
2.	**SAE report of death or other than death, Please tick (✓)**	**Death** □	**Other than Death** □
		Page No.	**Yes/No**
3.	Patient Details:		
	Initials and other relevant identifier (hospital or out-patient department (OPD) record number etc)*		
	Gender		
	Age or date of birth		
	Weight		
	Height		
4.	Suspected Drug(s) :		
	Generic name of the drug*		
	Indication(s) for which suspect drug was prescribed or tested.		
	Dosage form and strength.		
	Daily dose and regimen (specify units - e.g., mg, ml, mg/kg).		
	Route of administration.		
	Starting date and time of day.		
	Stopping date and time, or duration of treatment		
5.	Other Treatment(s):		
	Provide the same information for concomitant drugs (including non-prescription or Over the Counter OTC drugs) and non-drug therapies, as for the suspected drug(s).		
6.	Details of Serious Adverse Event :		
	Full description of the event including body site and severity, as well as the criterion (or criteria) for considering the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the event*		
	Start date (and time) of onset of event.		

	Stop date (and time) or duration of event.		
	Dechallenge and rechallenge information.		
	Setting (e.g., hospital, out-patient clinic, home, nursing home).		
7.	Outcome:		
	Information on recovery and any sequelae; results of specific tests or treatment that may have been conducted.		
	For a fatal outcome, cause of death and a comment on its possible relationship to the suspected event; Any post-mortem findings.		
	Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse; family history; findings from special investigations etc.		
8.	Details about the Investigator*		
	Name and Address		
	Telephone number		
	Profession (specialty)		
	Date of reporting the event to Central Licencing Authority:		
	Date of reporting the event to ethics committee overseeing the site:		
	Signature of the Investigator or Sponsor		
	Note: Information marked * must be provided.		
9.	Causality assessment of SAE by: (Related/Not Related):		
	Principal Investigator		
	Sponsor		

Annexure 2

AX 02/SOP 11-B/V7

Serious Adverse Event Report (For Biomedical Health Research)

Investigator:…… IEC No. of the Project:……..
Study Title:……
……
……
……
……

1. Participant details:
   Initials and ID …… Age at the time event …… Gender Male ☐ Female ☐ Weight:……..(Kgs) Height:……(Cms)
   …… ……
2. Suspected SAE diagnosis:……
3. Date of onset of SAE: dd mm yy Date of reporting SAE: dd mm yy
   Describe the event:
   ……
   ……
   ……
   ……
   ……
4. Details of suspected intervention causing SAE:
   ……
   ……
   ……
   ……
   ……
5. Report type: Initial ☐ Follow-up ☐ Final ☐
   If Follow-up report, state date of Initial report dd mm yy
6. Have any similar SAE occurred previously in this study? If, yes, please provide details: Yes ☐ No ☐

……
……

……
……
……
……

7. In case of a multi-centric study, have any of the study sites reported similar SAEs?
   (Please list number of cases with details if available)
   ……
   ……
   ……
8. Tick whichever is applicable for the SAE: (Kindly note that this refers to the intervention being evaluated and not disease process)
   A. Expected event ☐ Unexpected event ☐
   B. Hospitalisation ☐ Increased Hospital Stay ☐ Death ☐ Congenital anomaly/ birth Defect ☐
   Persistent or significant disability / incapacity ☐ Event requiring intervention (Surgical or medical) to prevent SAE ☐ Event which poses threat of life ☐ Other ☐
   ……

   In case of death, state probable cause of death……
   C. No permanent/significant functional/cosmetic impairment ☐
   Permanent/significant functional/cosmetic impairment ☐
   Not Applicable ☐

9. Describe the medical management provided for adverse reaction (if any) to the research participant. (Include information on who paid, how much was paid and to whom).
   ……
   ……
   ……
10. Provide details of compensation provided/ to be provided to participant (include information on who pays, how much, and to whom)
    ……
    ……
    ……
11. Outcome of SAE
    Resolved ☐ Ongoing ☐ Death ☐ Others (Specify) ☐
……

12. Provided any other relevant information that can facilitate assessment of the case such as medical history
    ……
    ……
    ……
    ……
    ……
13. Provide details about PI's final assessment of SAE relatedness to trial.
    ……
    ……
    ……
    ……
    ……

Signature of Principal Investigator: …… dd mm yy

Annexure 3
AX 03/SOP11-B/V7
Serious Adverse Event Close out Report
(For SAE at the site)

Sr. No.	**Details**

1.	EC Project No. & Title	
2.	SAE term:	
3.	Date of onset:	
4.	Initial reporting date to IEC	
5.	Follow up reporting date to IEC:	
6.	Causality assessment of SAE by	Related / Not related
	a. Principal Investigator	
	b. IEC	
	c. Sponsor	
	If related compensation recommended by IEC:	
7.	Medical care expenses paid by PI/ participants.	
8.	Reimbursement by PI if SAE is related: Yes/ No. Proofs provided - Yes/No.	
9.	SAE narrative in short	
10.	Event resolved- participant recovered / temporarily disabled/permanently disabled/ Death	
11.	Compensation paid or not paid	
12.	SAE Close out details	
13.	Procedures completed – Yes /No, if not completed what are the reasons?	

For IEC office use only

Verified by:

Name:_____

(Signature with date of IEC administrative staff) _____

Signature of Principal Investigator:_____Date

Title:	**Site Monitoring Visit**
SOP Code:	**SOP 12/V7 dated 19th November 2024**

Prepared by Signature with date	Reviewed by Signature with date	Approved by Signature with date	Accepted by
Dr. Raakhi Tripathi, Member Secretary, IEC-I	Dr. Nithya Gogtay, Jt. Member Secretary, IEC-I	Dr. Manju Sengar Chairperson, IEC-I	IEC-I
	Dr. Vyankatesh Shivane, Member, IEC-I	Dr. Sunil Kuyare Chairperson, IEC-II	IEC-II
		Dr. M. G. Karmarkar Chairperson, IEC-III	IEC-III

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide the procedures to identify a site for monitoring and how the site will be monitored.

2. Scope

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

3. Responsibility

It is the responsibility of the designated IEC member(s) or designated qualified Independent monitor identified by the chairperson of IEC to perform on-site monitoring of selected study site(s) of projects approved by IEC.

The IEC members or IEC Secretariat in consultation with the Chairperson may initiate an on-site evaluation of a study site for a routine monitoring or for cause monitoring.

4. Activity Table

No.	Activity	Responsibility
1	Selection of study sites and Identification of monitors for site monitoring	IEC members / Chairperson
2	Before the visit	IEC members / representative, IEC Secretariat
3	During the visit	IEC members / representative
4	After the visit	IEC members /representative, IEC Secretariat

5. Detailed instructions

5.1 Selection of study sites and Identification of monitors for site monitoring

- IEC will identify the site(s) for routine monitoring at the time of approval of the project depending upon the reason provided by any IEC member or later after the start of the project can be for cause monitoring. This decision will be recorded in the IEC Decision Form - *AX 06/SOP 05-B/V7*
- For all regulatory trials one routine monitoring will be performed by the IEC during the conduct of the trial (preferably before 1/3 of the participants are enrolled at the site).
- For cause monitoring conducted by IEC could include any one or more of the following as discussed in the IEC full board meeting:
    - High number of protocol violations or
    - On case to case basis if
        - Remarkable number of SAE reports, or
        - High recruitment rate, or
        - Non-compliance, or
        - Suspicious conduct, or
        - Complaints received from participants, or
        - Any other cause as decided by IEC.
- The Chairperson will identify and designate one or more IEC members or independent monitor to carry out routine and for cause monitoring of the study site in full board meeting.
- The reason (whether routine / for cause) for identifying a particular site for 'monitoring' will be provided to an IEC member.

5.2 Before the visit

- The IEC Chairperson will designate an IEC member or appoint an Independent monitor (who has no conflict with the project) who along with IEC members will perform the task of monitoring. The email regarding appointment as monitor for the concerned project will be sent to the selected member. If independent monitor is appointed he / she will sign a Confidentiality/ Conflict of Interest Agreement Form prior to accessing documents related to study and visiting the study site.
- The IEC Secretariat will inform the Principal Investigator in writing about the date/time of monitoring visit and request for confirmation from the Principal Investigator or Co-investigator to be available for the monitoring visit. If possible PI will be requested to schedule patients visits (monitoring visit and participants schedule visit must match) on the day of the monitoring to ensure that EC monitor is able to interact with the enrolled participant.
- The IEC member(s)/ Independent monitor along with IEC members will:
    - Contact the site to notify them that they will be visiting them. At that time, the monitor and the site will coordinate the time for the site evaluation visit.
    - Review the IEC project files for the study and site profile and make appropriate notes.
    - Be provided with relevant reference material/ documents related to the project that may have to be referred to during the study visits and collect the Site Monitoring Visit Report Form- AX 01/SOP 12/V7 from the IEC Secretariat.

5.3 During the visit

- The IEC member/Independent monitor along with IEC members will-
    - Check the log of delegation of responsibilities of study team
    - Check if the site is using latest IEC approved versions of the protocol, informed consent documents, case record forms, diaries, advertisements, etc.
    - Review the informed consent document to make sure that the site is using the most recent version,
    - Observe the informed consent process or audio visual consent or audio consent, if applicable (refer annexure 1 *AX 01/SOP 25/* V1)
    - Review randomly selected participants files to ensure that participants are signing the correct informed consent form,
    - Observe laboratory and other facilities necessary for the study at the site.
    - Review the project files of the study to ensure that documentation is filed appropriately.
    - Review the source documents for their completeness.
    - To review the log book in the room where Investigational Product (IP) is stored. Check the temperature log of the room and whether there is access control.
    - Whenever possible interview a small number of study participants to check for understanding of the trial procedures and safety of the intervention / procedures.
    - Fill the Site Monitoring Visit Report Form- *AX 01/SOP 12/*V7, sign and date it.
    - Check the site assessment checklist annexure 12 (AX12/SOP05-A/V7)
    - Check whether any duly filled participant feedback form (as per Annexure 10 AX 10/SOP 05-B/V7) are available at the trial site for regulatory trials.

5.4 After the visit

- The IEC member/ Independent monitor will submit the completed Site Monitoring Visit Report Form- *AX 01/SOP 12/* V7 *to* the IEC secretariat within 14 days of conducting a site monitoring visit.
- The report should describe the findings of the monitoring visit.

- The IEC will discuss the findings of the monitoring process and take appropriate specific action in the subsequent full board meeting, 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 the protocol or ICD or CRF / providing qualifications/ experience criteria for members of the study team, termination of the study,
  - Suspension of the study
- Subsequent to the discussion of the monitoring report in the full board meeting the decision will be communicated to the PI.
- The IEC Secretariat will convey the decision to the Principal Investigator in writing within 14 working days of the meeting.
- The PI should reply within 14 working days to IEC.
- The IEC Secretariat will place the copy of the report in the protocol file.
- If the PI fails to comply to the requirements, IEC can take further action as per SOP 10.

6. Glossary

Independent monitor	The expert with appropriate experience and training, who is not an IEC member, who may or may not be affiliated to the institution and who will perform the tasks of site monitoring along with designed IEC members.
Monitoring visit	An action that IEC or its representatives visit study sites to assess how well the selected investigators and the institutes are conducting research, taking care of participants, recording data and reporting their observations, especially serious adverse events found during the studies. Normally monitoring visit will be arranged in advance with prior notification to the principal investigators.

7. Annexure

Annexure 1 *AX 01/SOP 12/* V7 Site Monitoring Visit Report

Annexure 1
AX 01/SOP 12/ V7
Site Monitoring Visit Report

1)	CT Project No:
2)	Title:
3)	Principal Investigator:
4)	Institute:
5)	Type of study: ☐ Investigator initiated ☐ Pharma ☐ Thesis Source of funding: ☐ Intramural ☐ Extramural ☐ Pharma
6)	a) Date of IEC approval: b) Is the period of IEC approval valid: ☐ Yes ☐ No ☐ NA
7)	Start Date of study: ____/____/_____

8)	Duration of study:
9)	Date of monitoring visit: ____/____/_____
10)	Reason for monitoring: ☐ Routine ☐ For Cause (State reason) ☐ Protocol Violations/Deviations ☐ SAE reporting ☐ Recruitment rate ☐ Any complaints related to the research ☐ Non Compliance / Suspicious conduct ☐ Other _____
11)	Last Monitoring done: ☐ Yes Date of last monitoring ____/____/_____ ☐ No ☐ NA
12)	Project Status: ☐ Ongoing ☐ Accrual Completed ☐ Follow-up ☐ Completed ☐ Suspended ☐ Terminated ☐ Closed ☐ Closed Prematurely In case of the response to the above question is option 5, 6, or 8 kindly provide reason: _____ _____
13)	Recruitment Status: ➢ Total participants/samples to be recruited - _____ ➢ Screened: _____ ➢ Screen failures: _____ ➢ Enrolled: _____ ➢ Withdrawn: _____ Reason: _____ ➢ Discontinued: _____Reason: _____ ➢ Completed: _____ ➢ Active: _____ ➢ Follow up: _____
14)	Is the recruitment on schedule? ☐ Yes ☐ No If 'No' is it acceptable? ☐ Yes ☐ No ☐ NA If 'No' State reasons/Steps taken by PI to improve recruitment: _____ _____ _____ _____
15)	Drug reconciliation: **Received:** **Used:** **Balance:**

16)	Protocol a) Have there been any amendments to the Protocol? ☐ Yes ☐ No ☐ NA If Yes, then state changes leading to amendment: _____ b) Is the Protocol version approved by IEC? ☐ Yes ☐ No ☐ NA c) Is the latest version of the protocol being used for the study? ☐ Yes ☐ No ☐ NA
17)	Informed Consent a) Is Informed consent obtained from all enrolled participants? ☐ Yes ☐ No ☐ NA b) Have there been any amendments to the ICF? ☐ Yes ☐ No ☐ NA If Yes, then state changes leading to amendment: _____ _____ _____ _____ c) Is the Informed consent form version approved by IEC? ☐ Yes ☐ No ☐ NA d) Is the latest version of the ICF being used for the study? ☐ Yes ☐ No ☐ NA e) Is there source documentation of the ICF process? ☐ Yes ☐ No ☐ NA f) Is ICF signed by PI /Co-Principal Investigator/Co-I? ☐ Yes ☐ No ☐ NA g) Is ICF signed by Participant? ☐ Yes ☐ No ☐ NA h) Is ICF signed by LAR? ☐ Yes ☐ No ☐ NA j) Is ICF signed by Impartial Witness? ☐ Yes ☐ No ☐ NA K) Is the correct language used for the participant ☐ Yes ☐ No ☐ NA
18)	Any Protocol Deviations/Violations noted? ☐ Yes ☐ No ☐ NA Have all the deviations/violations notified to IEC? ☐ Yes ☐ No ☐ NA Comments (If Any)
19)	Have the eligibility, inclusion exclusion criteria been adhered to? ☐ Yes ☐ No ☐ NA
20)	Are all the Case report forms complete? ☐ Yes ☐ No ☐ NA
20)	Have there been any AE/SAE on the study? ☐ Yes ☐ No ☐ NA If Yes a) No. of Adverse events: _____ b) No. of Serious adverse events: _____ c) No. of deaths reported: _____ ➢ Deaths unrelated to participation in the trial: _____ ➢ Deaths possibly related to participation in the trial: _____ ➢ Deaths related to participation in the trial: _____ d) Were all the SAE reports notified and submitted to IEC within with in 24hrs of the knowledge of PI? ☐ Yes ☐ No ☐ NA Comments (If Any) _____
21)	Is the log book available in the Investigational Product (IP) Room Yes☐ No☐ NA☐ Comments (if any) _____

22)	Are the Investigational drugs accountability and prescription procedures performed and documented? ☐ Yes ☐ No ☐ NA If 'Yes' kindly state the issues: _____ _____
23)	Any are there any changes to the study personnel? ☐ Yes ☐ No ☐ NA If 'Yes' kindly state the same: _____ _____ Is the change notified to IEC? ☐ Yes ☐ No ☐ NA Is the utilization of sanctioned funds appropriate? ☐ Yes ☐ No ☐ NA If 'No' kindly state the issues: _____ _____
24)	No of participants monitored during this visit: _____
25)	Feed back form from the participant (Annexure 10 AX 10/SOP 05-B/V7) available as per IEC Policy ☐ Yes ☐ No
26)	Patient charter displayed ☐ Yes ☐ No
27)	Duration of the visit: _____
28)	Any outstanding tasks/action items from the visit?

Monitoring visit conducted by:

_____

	Name	**Signature with date**
Lead monitor		
Monitor 1		
Monitor 2		
IEC Admin 1		
IEC Admin 2		
Study team member present: 1)		
2)		
3)		

Title:	Agenda Preparation, Meeting Procedures and Recording of Minutes
SOP Code:	SOP 13/V7 dated 19th November 2024

Prepared by Signature with date	Reviewed by Signature with date	Approved by Signature with date	Accepted by
Dr. Raakhi Tripathi, Member Secretary, IEC-I	Dr. Nithya Gogtay, Jt. Member Secretary, IEC-I	Dr. Manju Sengar Chairperson, IEC-I	IEC-I
	Dr. Vyankatesh Shivane, Member, IEC-I	Dr. Sunil Kuyare Chairperson, IEC-II	IEC-II
		Dr. M. G. Karmarkar Chairperson, IEC-III	IEC-III

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the administrative processes and provide instructions for the preparation, review, approval and distribution of meeting agenda, minutes and action, invitation and notification letters of Institutional Ethics Committee (IEC) meetings.

2. Scope

This SOP applies to administrative processes concerning the preparation of the agenda for all Full Board IEC meetings. These are tasks to be completed before, during and after the meeting.

3. Responsibility

It is the responsibility of the IEC Secretariat to prepare the agenda for the IEC meeting and to ensure proper recording and dissemination of the minutes after the meeting is over. The Chairperson will review and approve the agenda and the minutes sent to him/her as per the timelines stated in the below sections (5.1.1 and 5.3).

4. Activity Table

No.	Activity	Responsibility
1	Preparation of meeting agenda prior to a board meeting	IEC Secretariat
2	During the Meeting	IEC Secretariat, Members and Chairperson
3	After the Board Meeting and Preparing the minutes	IEC Secretariat/ Member Secretary
4	Approval of minutes	IEC members / Chairperson
5	Filing the minutes	IEC Secretariat

5. Detailed instructions

5.1 Before each Board meeting

5.1.1 Preparation of meeting agenda

- The IEC Secretariat will prepare the agenda to include:

Meeting no.:
Date : -
Venue : -
Time : -

Period 1

1. Confirmation of quorum by the chairperson
2. Welcoming members by chairperson Roll call and apologies from absent IEC member:
3. Discussion of points, if any arising from minutes of the last meeting
4. Declaration of Conflict of interest
   (All of the above will be documented in the minutes of the meeting)

Period 2 Issues to be discussed

A. New protocol presentation, review, discussion and reaching a consensus to approve/raise queries

B. Review the responses forwarded by the Principal Investigator to the query letter /resubmitted protocols

C. To discuss protocol/ICD amendments and other project related documents
D. To discuss continuing review report, Completion, Termination

- **To discuss continuing review report**

- **Reminders already sent to PI for continuing review report not yet received**
- **To discuss Completion report**
- **To discuss termination report**

E. To discuss Deviation report
F. To discuss other letters related to the projects
G. IEC Site monitoring reports

H. To inform about the SAE Subcommittee meeting and to read out minutes of the SAE Subcommittee meeting.

Period 3:

1] ISSUES TO BE REPORTED FOR CONSIDERATION:

A] i) Responses forwarded by the Principal Investigator to the query letter/resubmitted protocols reviewed and approved by the Primary reviewers /member Secretary / Chairperson (n =00)

ii) Responses forwarded by the Principal Investigator to the query letter/resubmitted protocols reviewed by the Primary reviewers / member Secretary / Chairperson query for which needs to be communicated to the PI

B] Projects Exempted from review:

C] Expedite review process done for the following projects and query letter / approval given: (n =NIL)

D] Minor Protocol / ICD amendments and other project related documents reviewed and approved by the IEC member Secretary and Chairperson

E] Continuing review report/ completion report/ final clinical trial report reviewed and approved by The IEC member Secretary and Chairperson.

- **Continuing review report**
- **Completion report:-**
- **Termination report:-**

F] Protocol deviations reviewed and noted by the IEC member Secretary and Chairperson
G] IEC Site monitoring reports
H] Other letters reviewed and noted by the IEC member Secretary / Chairperson

2] ISSUES TO BE INFORMED TO THE MEMBERS AT FULL BOARD which are reviewed / approved by the IEC member Secretary / Chairperson and letters already sent to the principal investigators

A. Responses forwarded by the Principal Investigator to the query letter/resubmitted protocols

B. Minor Protocol / ICD amendments and other project related documents reviewed and approved by the IEC member Secretary and Chairperson

C. Continuing review report/ completion report/ final clinical trial report reviewed and approved by the IEC member Secretary and Chairperson.

- **Continuing review report**
- **Completion report:-**
- **Termination report:-**

F] Protocol deviations reviewed and noted by the IEC member Secretary and Chairperson

G] IEC Site monitoring reports
Period 5:

A. Other points for discussion (n =0)

1. Policy decisions of the meeting of IEC-I /II/III.
2. Report of any other subcommittee or group appointed/ designated by Chairperson for any specific or general purpose.

B. Other issues of interest to the members with permission of chairperson

C. Next Meeting to be scheduled on xxxxxx (19, 20, reserved for staff society)

- The IEC Secretariat will collect and verify all forms/documents for completeness to keep all these papers in the meeting.
- The IEC Secretariat will prepare the meeting agenda, according to the above mentioned format.
- The IEC Secretariat will schedule protocols in the agenda on a first-come first-serve basis.
- IEC-I / IEC-II / IEC-III will preferably meet every month. Duration of meeting between three committees should not be more than 2 weeks.
- Answers to the IEC queries and 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.
- Agenda for the IEC meeting is prepared 3 days in advance before the date of meeting, any study-related document 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 where in the opinion of the IEC Secretary or Chairperson has direct bearing on the safety of the research participants (such as SAE report, major protocol violation). Such important matters will be taken up at the imminent meeting.
- In case a meeting is to be rescheduled due to unavoidable circumstances, the date and time will be informed to the IEC members telephonically and/ or via e-mail.
- The IEC Secretariat will send the agenda of the meeting to members via e-mail at least 1 day in advance of the scheduled meeting.
- The IEC Secretariat will make a meeting room reservation for the scheduled meeting date and time.
- The IEC Secretariat will make sure that the room, equipment and facilities are available in good running conditions and cleaned for the meeting day.

5.2 Conduct of the meeting

- The committee will endeavor to hold regular meetings at least once every month. The gap between any two meetings will not exceed 60 days. Even if there are no research proposals for review, the gap between two meetings will not exceed 12 (twelve) weeks. Regular meetings may not be held in the months of May and October/ November when the college is closed for vacation. Meeting will be held as scheduled provided there is quorum.
- To review the regulatory protocol, a quorum for IEC-1 meeting will consist of at least 5 of its members as detailed below:

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

To review the non-regulatory or biomedical & health research protocol, a quorum for IEC-2 & 3 meeting will consist of at least 5 of its members as detailed below:

- The quorum should include both medical, non-medical or technical or/and non-technical members.
- Minimum one non-affiliated member, preferably the lay person

- All full board meetings will be conducted offline only with physical presence of the IEC members. In situations where one or two members are unable to come physically then the review of the studies may be done through virtual / hybrid EC meeting ensuring appropriate scientific and ethical review and fulfilling the quorum requirements. EC members present during the virtual / hybrid meeting should decide through consensus or cast online vote expressing their decision. Any disagreement to be recorded with reasons.

  Meeting could be digitally recorded (audio/video) with permission of members and IEC secretariat is responsible to note the attendance/ participation in the online meeting.
- At the discretion of the Chairman, guests may be allowed to observe the Board meetings.
- These guests may include a potential client, student, inspectors, auditors, members of other Ethics Committees, surveyors, regulators, members of regulatory agencies, representatives of patient groups, representatives of special interest groups, representatives of accrediting organizations, members of general public etc. and are required to sign a confidentiality agreement AX 03/SOP 03/V7 prior to attending the meeting.
- The IEC Secretariat will obtain signatures on the Confidentiality Form AX 03/SOP 03/V7 from newly appointed members/ Guests/ observers/ Subject Expert prior to the start of the meeting.
- The IEC Secretariat will obtain the signatures of all the IEC members on the attendance register.
- Regarding consent of IEC members, the attendance register will record consent and attendance in the template described in Annexure 3 AX 03/SOP 13/V7.
- The IEC Secretariat will obtain from members the written conflict of interest AX 01/SOP13/V7 prior to the start of meeting
- The Chairperson will initiate the meeting after ensuring that the quorum has been met. 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 Chairperson will decide if the Conflict of Interest is potentially significant enough to cloud the member's judgment. If yes, 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.
- In case of projects submitted for initial review; the detailed instructions given in SOP 05-B/*V7* are followed.

- 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 staff will also record a gist of discussions and decisions arrived on other issues discussed at the meeting.
- In regard to regulatory clinical trials, a maximum of 5 initial protocols will be taken up for discussion at every monthly meeting.

During the discussion at the meeting

The primary reviewer shall brief the members about summary of the study protocol and read out the comments and evaluation provided. The comments of subject expert (if applicable) will be discussed by the member secretary. The other IEC members shall give their comments right after the presentation.

- The investigator/sub-investigator may be called in to provide clarifications on the study protocol that he/she has submitted for review to the IEC.
- The IEC members will discuss and clarify the comments and suggestions. The Member secretary (assisted by the Secretarial staff) shall record the discussions

Decision making

- The final decision on the project as: "Approved/ Approved with minor modification/ approved with major modification/Disapproved or any other/Monitoring required ----" in the meeting shall be by consensus and will be recorded in the IEC Decision Form AX 06/SOP 05-B/V7 *by the Member Secretary*.
- In case no consensus reached, voting will be taken. A majority vote for approval, disapproval, request for modifications of a study suspension or termination of an ongoing study is defined as 2/3rd of the members (who have reviewed the project), present at the meeting and voting. If there is dissent it will be minuted with reasons.
- The following will not vote at the meeting:
  a. Member(s) of the committee who is/are listed as investigator(s) on a research proposal
  b. An investigator or study team member invited for the meeting
  c. An independent consultant invited for the meeting to provide opinion Specific patient groups invited for the meeting
- If the IEC decision is '*Approved'*, it implies the approval of the study as it is presented with no modifications and the study can be initiated.
- If the IEC decision is *'Approved with minor modification*, the IEC Chairperson may authorize the Secretary/Primary reviewer + secretary to determine if the response and changes are satisfactory and to decide if letter of permission can be issued to the Principal Investigator.
- If the IEC decision is 'Approved with major modification, the IEC Chairperson may authorize the Primary reviewer + secretary to determine to review the responses which will be discussed in next full board meeting. If the response and changes are approved in the full board, letter of permission can be issued to the Principal Investigator.
- If the IEC decision 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 IEC Secretariat will obtain the signature of all the members and of the Chairperson of the IEC on the IEC Decision Form *AX 06/SOP 05-B/V7*.
- If the study is approved, the Committee will determine the frequency of Continuing Review from each investigator.
- The IEC Secretariat will list participating members in the meeting and summarize the guidance, advice and decision reached by the IEC members.

5.3 After the Board meeting and preparing the Minutes

- The IEC Secretariat will compose the summary of each meeting discussion and decision in a concise and easy-to-read style in the minutes within 14 working days of the meeting day. During epidemics/ emergency meetings it will be done as early as possible.
- The IEC Secretariat will make sure to cover all contents in each particular category to include the following as in annexure 2 AX 02/SOP 13/V7.

5.4 Approval of the minutes

- The IEC Secretariat will check the correctness and completeness of the minutes and forward the minutes to the IEC members/Chairperson for review within 14 working days of the meeting day.
- After obtaining approval from the Chairperson via email, the minutes will be approved and signed by the chairperson in upcoming full board meeting.

5.5 Filing the minutes

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

6. Glossary

Quorum	Number of IEC members required to act on any motion presented to the Board for action.
Majority vote	A motion is carried out if one half plus one member of the required quorum votes in its favor.

7. Annexure

Annexure 1	AX 01/SOP 13/V7	Conflict of Interest form
Annexure 2	AX 02/SOP 13/V7	Sample format for minutes of the meeting
Annexure 3	AX 03/SOP 13/V7	Template for consent for recording and attendance

Annexure 1
AX 01/SOP 13/V7
Conflict of Interest form

Date:
To,
The Chairperson,
IEC-I / IEC-II/IEC -III,
I hereby declare the conflict of interest for the project no. EC/ /
entitled,_____
as:

1. I am the investigator / co-investigator/Author/study team
2. I have Financial interest
3. _____
4. _____

in the project which will be discussed in today's meeting i.e. xxx.
Dr. _____
Member, IEC-I / IEC-II/IEC-III.

_____
Chairperson,
IEC-I / IEC-II/IEC-III.

Annexure 2
AX 02/SOP 13/ V7
Sample format for minutes of the meeting

Institutional Ethics Committee-I/II/III

Seth GS Medical College and KEM Hospital
Meeting number xx/xxxx

Minutes of the Meeting held on xxxxxx

The minutes of the meeting no. xxxx of the Institutional Ethics Committee (IEC) –I/II/III, Seth GS Medical College and KEM Hospital held on xxxxx have been prepared by _____, Member Secretary of the IEC-I/II/III.

The meeting of the IEC-I/II /III was **held on xxx at xxx pm in the xxx Venue**____.

___ chaired the meeting. After making sure that the quorum was duly constituted, ____ initiated the meeting by welcoming all the members. _____ asked the members whether anyone has any conflict of interest in the projects to be discussed and if so, to declare the conflict.

Roll call

The following IEC-I/II/III members attended the meeting:
1. Chairperson
2. Member Secretary
3. Legal Expert
4. Social scientist
5. Lay person
6. Basic medical scientist
7. Physician
8. Member
9. Member

Apologies were received _____

- **Discussion of points, if any arising from minutes of the last meeting held on xxxxx circulated by email to the members.**

Period 2 Issues to be discussed

A. SAEs - Lead Discussant: **xxx**

1. **SAE at our site letter:**
2. **SAE/SUSAR/CIOMS/IND Safety reports from other site:**

B. Discussion on SAEs minutes of the meeting scheduled on xxxxx.

1. **SAE at our site letter:**

Participant ID	Letter no./ and date of reporting	Type of report	Type of SAE/UAE	Date of onset	whether study drug withheld	Outcome	Causality in the opinion of PI	IEC Opinion on Causality
							Related / Not Related /Noted	Related / Not Related /Noted

2. **SAE/SUSAR/CIOMS/IND Safety reports from other site:**

C. To discuss Deviation report (n=xx)

D. New protocol presentation, review, discussion and reaching a consensus to approve/raise queries (n=xx)

1. **EC/PHARMA-xx/xxxx Sponsored By** _____
   Name of the Principal Investigator: _____Dept. of _____
   Name of the Co-Investigators: _____, _____
   Title: "_____".

Primary reviewers	
Non-scientific members	
Documents reviewed	
Summary by	
Recruitment Strategy (RS)	
Administrative issues	
Scientific issues	
Ethical issues	
Risk Benefit Assessment	**Risk Categories** ❑ The research involves less than minimal risk to subjects. ❑ The research involves minimal risk to subjects. ❑ The research involves more than minimal risk to subjects. **Benefits Categories** ❑ The research provides no prospect of direct benefit to individual subjects, but likely will yield generalizable knowledge about subject's disorder or condition. ❑ The research provides no prospect of direct benefits to individual subjects, but likely will yield generalizable knowledge to further society's understanding of the disorder or condition under study. ❑ The research provides the prospect of direct benefits to individual subjects. ❑ The research provides no prospect of direct benefits to individual subjects, to science, or to society.
Vulnerability	

Final Decision at the meeting:	Approved		
	Minor modification	MS	
		MS + PR	
	Major modification	MS + PR	
		MS + PR+ FB	
	Disapproved (Reason)		
	Monitoring required (Reason)		

E. Review the responses forwarded by the Principal Investigator to the query letter /resubmitted protocols
F. To discuss protocol/ICD amendments and other project related documents
G. To discuss continuing review report, Completion, Termination
- To discuss continuing review report
- Reminders already sent to PI for continuing review report not yet received
- To discuss Completion report
- To discuss termination report

H. To discuss other letters related to the projects
I. IEC Site monitoring reports

Period 3:

1] ISSUES TO BE REPORTED FOR CONSIDERATION:

A] i) Responses forwarded by the Principal Investigator to the query letter/resubmitted protocols reviewed and approved by the Primary reviewers /member Secretary / Chairperson (n =00)
ii) Responses forwarded by the Principal Investigator to the query letter/resubmitted protocols reviewed by the Primary reviewers / member Secretary / Chairperson query for which needs to be communicated to the PI (n =00)

B] Projects Exempted from review:
C] Expedite review process done for the following projects and query letter / approval given:
D] Minor Protocol / ICD amendments and other project related documents reviewed and approved by the IEC member Secretary and Chairperson
E] Continuing review report/ completion report/ final clinical trial report reviewed and approved by The IEC member Secretary and Chairperson.

- Continuing review report
- Completion report:-
- Termination report:-

F] Protocol deviations reviewed and noted by the IEC member Secretary and Chairperson
G] IEC Site monitoring reports
H] Other letters reviewed and noted by the IEC member Secretary / Chairperson

2] ISSUES TO BE INFORMED TO THE MEMBERS AT FULL BOARD which are reviewed / approved by the IEC member Secretary / Chairperson and letters already sent to the principal investigators

A. Responses forwarded by the Principal Investigator to the query letter/resubmitted protocols
B. Minor Protocol / ICD amendments and other project related documents reviewed and approved by the IEC member Secretary and Chairperson
C. Continuing review report/ completion report/ final clinical trial report reviewed and approved by the IEC member Secretary and Chairperson.

- Continuing review report
- Completion report:-
- Termination report:-

D. Protocol deviations reviewed and noted by the IEC member Secretary and Chairperson

Period 5:

A. Other points for discussion (n =0)
e. g.
1. Policy decisions of the meeting of IEC-I /II/III.
2. Report of any other subcommittee or group appointed/ designated by Chairperson for any specific or general purpose.

B. Next Meeting to be scheduled on xxxxxx
C. Other issues of interest to the members with permission of chairperson

Since there was no other business, chairperson concluded the meeting by thanking all the members.

Member Secretary **Chairperson**

Annexure 3
AX 03/SOP 13/ V7
Template for consent for recording and attendance

Meeting Date: XXX
Venue: xxx
Time: xxx
I consent for recording of the IEC meeting held on xxxxx.

Sr. No.	Name	Designation in the IEC	Signature with Date
1.		Chairperson	
2.		Member Secretary	
3.		Basic Medical Scientist)	
4.		Clinician	
5.		Legal Expert	
6.		Lay person	
7.		Social scientist	
8.			

Title:	Conduct of Emergency Meeting
SOP Code:	SOP 14/V7 dated 19th November 2024

Prepared by Signature with date	Reviewed by Signature with date	Approved by Signature with date	Accepted by
Dr. Raakhi Tripathi, Member Secretary, IEC-I	Dr. Nithya Gogtay, Jt. Member Secretary, IEC-I	Dr. Manju Sengar Chairperson, IEC-I	IEC-I
	Dr. Vyankatesh Shivane, Member, IEC-I	Dr. Sunil Kuyare Chairperson, IEC-II	IEC-II
		Dr. M. G. Karmarkar Chairperson, IEC-III	IEC-III

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to identify the administrative process for preparing for an emergency meeting; and to provide instructions on the review and approval of study activities using the Emergency Meeting Procedures

2. Scope

This SOP applies to emergency Institutional Ethics Committee (IEC) meetings. Emergency meetings may be scheduled to approve safety / life threatening issues, SAE and other study activities that require Full Board review.

3. Responsibility

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

4. Activity Table

No.	Activity	Responsibility
1	Call for an emergency meeting	IEC Member Secretary and Chairperson
2	Arrangement of an emergency meeting	IEC Secretariat
3	Discuss the matter and take a decision	IEC Members, Member Secretary and Chairperson

5. Detailed instructions

5.1 Call for an emergency meeting

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

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

5.2 Arrangement of an emergency meeting

Contact and inform IEC members

- The IEC Secretariat will endeavor to contact each and every IEC member and inform about the date, time and venue of the meeting as well as the reason for calling for the meeting. For the purpose of calling an emergency meeting, contact by telephone or email to the email address provided by the member would be considered as sufficient.
- The IEC Secretariat/ General Manager/Deputy manager will ensure distribution of all relevant documents to the members containing relevant information about the matter(s) for which Emergency Meeting is scheduled or send the relevant details (incase the documents are too many) via email.
- The General Manager/ Deputy manager will attach a separate sheet with information about meeting date, time, phone numbers, the meeting ID number and an attendance confirmation form to the packets.
- The General Manager / Deputy manager will refer to and act according to the relevant SOPs depending upon the matter under consideration.

5.3 Discuss the matter and take a decision 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 with a quorum of at least three

members (other than Chairperson and including at least one scientific 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.

6. Glossary

Emergency meeting	An IEC meeting that is scheduled outside of a normally scheduled meeting to review study activities that require full IEC review and approval. In order to hold an emergency meeting, a quorum decided earlier must be maintained throughout the entire discussion. Emergency meetings may be held via teleconference, online meeting, if applicable.

Title:	Maintenance of Active Project Files
SOP Code:	SOP 15/ V7 dated 19th November 2024

Prepared by Signature with date	Reviewed by Signature with date	Approved by Signature with date	Accepted by
19/11/24 Dr. Raakhi Tripathi, Member Secretary, IEC-I	19.11.24 Dr. Nithya Gogtay, Jt. Member Secretary, IEC-I	9/12/2024 Dr. Manju Sengar Chairperson, IEC-I	Institutional Ethics Committee (IEC-I) Established in 1985 Seth G.S. Medical College & K.E.M. Hospital Parel, Mumbai-400 012. IEC-I
	19/NOV/2024 Dr. Vyankatesh Shivane, Member, IEC-I	09/12/24 Dr. Sunil Kuyare Chairperson, IEC-II	Institutional Ethics Committee (IEC-II) Established in 1986 Seth G.S. Medical College & K.E.M. Hospital Parel, Mumbai - 400 012. IEC-II
		09/12/24 Dr. M. G. Karmarkar Chairperson, IEC-III	Institute Ethics Committee-III Established in 1986 Seth G.S. Medical College & K.E.M. Hospital Parel, Mumbai - 400 012. IEC-III

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide instructions for preparation, circulation and maintenance of active study files and other related documents approved by the Institutional Ethics Committee (IEC).

2. Scope

This SOP applies to all active study files and their related documents that are maintained in the IEC office.

3. Responsibility

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

4. Activity Table

No.	Activity	Responsibility
1	Organize the contents of the active study files	IEC Secretariat
2	Maintain the active study files	IEC Secretariat

5. Detailed instructions

5.1 Organize the contents of the active study files

The IEC Secretariat will:

- Submission receive in the IEC office. Preserve soft copy and one original set (hard copy) of the entire package called as master file. A Study Master File is the file comprising all essential documents and correspondence related to the study/protocol. Study master files should be established at the time of initial submission.
- The study files are assigned unique identifiers (serial project no.EC/PHARMA-XX/20XX, EC/GOVT-XX/20XX, EC/OA-XX/20XX & EC/XX/20XX.)
- All documents related to the study file are gathered, classified and combined together appropriately.
- The IEC admin will save the submissions (softcopy) which will be stored separately for IEC-I, IEC- II & IEC-lll on external hard (Nasbox) disk in office PC.
- The submitted hard copy protocols and the related documents will be labelled and stored in cupboard with lock and key in separate cupboard of IEC-I, II & III.

5.2 Maintain the active study files

The IEC Admin will:

- Collect and file related documents of the approved study appropriately.
- Attach an identity Label to the set of documents.
- Keep all active study documents in a secure place.
- Maintain the study files in an easily accessible, but secure place until the final report is received, reviewed and accepted by the IEC or the matter will be discussed at Full Board by IEC.
- The soft copies of active study files stored on computer which are password protected and will be accessible only to the IEC secretariat.
- The cupboard where hard copies of the active study files are kept will be kept in a lock and key and will have controlled access only to the IEC secretariat.
- The active study files will be password protected and will be accessible only to the IEC secretariat.

- If any IEC member/non-members (auditor or other authorized person) of IEC wants to have access, they can access the project file with the help of IEC secretariat after the permission of MS/ chairperson.
- Annual subscription of appropriate anti-virus and malware protector will be availed for the soft copy submissions.
- Annual maintenance of fireproof service provider and paste control provider will be availed for the protection of hard copies.
- Send all closed study files to the archive.

6. Glossary

Active Study File	Any approved protocol, supporting documents, records containing communications and reports that correspond to each approved study.

Title:	**Archiving and Retrieving Documents**
SOP Code:	**SOP 16 /V7 dated 19th November 2024**

Prepared by Signature with date	Reviewed by Signature with date	Approved by Signature with date	Accepted by
Dr. Raakhi Tripathi, Member Secretary, IEC-I	Dr. Nithya Gogtay, Jt. Member Secretary, IEC-I	Dr. Manju Sengar Chairperson, IEC-I	IEC-I
	Dr. Vyankatesh Shivane, Member, IEC-I	Dr. Sunil Kuyare Chairperson, IEC-II	IEC-II
		Dr. M. G. Karmarkar Chairperson, IEC-III	IEC-III

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide instructions for archival / disposal of closed files and retrieval of documents in a secure manner while maintaining access for review by auditors, inspectors and other authorized persons. This SOP is made to ensure protection, maintenance and archival of its documents submitted to the IEC and confirms to the applicable regulations and guidelines. The SOP seeks to enhance transparency, accountability, and better relationship with stakeholders, by providing a framework for archival that can be viewed by all stakeholders.

2. Scope

This SOP applies to archiving the study files and administrative documents that are retained for at least five years or for longer duration if specifically mandated after completion of the research/ termination of research so that the records are accessible to auditors, inspectors and other authorized persons. Copying files and documents for or by authorized representatives of the national authority is allowed when required.

3. Responsibility

It is the responsibility of the Institutional Ethics Committee (IEC) Secretariat to maintain closed study files and administrative documents.

4. Activity Table

No.	Activity	Responsibility
1	After receiving the notification of termination, completion / final report	IEC members, secretariat
2	Retrieving Documents	IEC secretariat
3	Disposal of closed files and copies of protocols and documents submitted for IEC review	IEC secretariat

5. Detailed instructions:

5.1 After receiving the notification of termination, completion / final report*:*

- IEC Secretariat and Members will review the termination, completion / final report of the study.
- A member of the IEC Secretariat should:
    - Remove the contents of the entire file from the active study folder (soft copy) to the archived study folder.
    - Remove the contents of the entire file from the active study cupboard (hard copy) to the archived study cupboard in the archival room.
    - Verify that all documents are present in an organized manner.
    - The soft archived study files will be password protected and will be accessible only to the IEC Secretariat.
    - The cupboard where hard copies of the archived study files are kept will be kept in a lock and key and will have controlled access only to the IEC secretariat with pest control and fire control.
    - If any IEC member/ non-members of IEC (auditor or other authorized person) wants to have access, they can access the project file with the help of IEC secretariat after the permission of chairperson.
    - A staff of the IEC Secretariat should
        - Perform inventories of miscellaneous administrative documents.

- Send it/ them to the appropriate storage facility so that it/ they may be retrieved.

- The IEC Secretariat maintains past board membership information as well as the active administrative documents as permanent records.
- Shift the contents (hard copy) to the archival room specifying the cupboard / shelf / location of the files as per Annexure 3 AX 03/ SOP16/ V7.

5.2 Retrieving Documents

- The request for retrieval can only be made by an IEC member, auditor or other authorized person in by filling up, signing and dating request form: AX 01/SOP 16/V7
- The requestor must also sign and date the log of request. (AX 02/SOP 16/V7)
- Retrieval of documents can only be done when a request is made in the request form (AX 01/SOP 16/V7) that is approved (signed and dated) by the IEC Chairperson/Member Secretary.
- For administrative purpose and while discussing / keeping the study completion report & CSR, IEC Secretary can retrieve archived file(s) without having to require IEC Chairperson's approval. For this purpose the IEC secretary can authorize a staff member of the IEC secretariat to physically retrieve a file. In such a situation, the register/ log will be signed by the IEC secretariat member physically retrieving the file.
- A member of IEC Secretariat will retrieve archived document(s) and will return the remaining file back to its place.
- The IEC Secretariat maintains a register with following information related to retrieval: File number, Name and designation of individual making a request for retrieval with his/her signature, Date of approval of request by IEC chairperson, Date and time of retrieval, Name and signature of IEC staff/ IEC Secretariat retrieving the file, Date and time of returning the file.
- The IEC Secretariat will also record, sign and date when the document has been returned and kept.

5.3 Disposal of closed files and copies of protocols and documents submitted for IEC review.

- The trial master file will be maintained in the IEC office for complete period of the study and for five years following closure of the study. After completion of the archival period the closed files will be shredded and disposed off in the IEC office shredding facility. However, all the copies of the research projects and documents submitted for IEC review will be shredded by the authorized IEC personnel after the IEC meeting without any notification to the Principal Investigator. A log book of disposed documents will be maintained.
- After the disposal of documents, if the investigator now submits study related documents (e.g. audit report etc.) then these documents will be noted by IEC and will be shredded within six months.

6. Glossary

Administrative Documents	Documents include official minutes of Board meetings and the Standard Operating Procedures, both historical files and Master Files, Account related documents as.
Closed Study File	Any approved protocol, supporting documents, records containing Communications and reports that correspond to a study which is completed or terminated or discontinued or suspended or not initiated.

7. Annexure

Annexure 1	AX 01/SOP 16/V7	Document Request Form
Annexure 2	AX 02/SOP 16/V7	Log of Requested IEC Documents
Annexure 3	AX 03/SOP 16/V7	Template Log of archived files and their location

Annexure 1
AX 01/SOP 16/V7
Document Request Form

Name of Document requested:
Requested by: Name: ----------
☐ Chairperson ☐ IEC Secretariat ☐ IEC Member
☐ IEC Secretariat staff ☐ Authority ☐ Others _____
Purpose of the request:

_____ _____

Signature of person requesting and date

Signature of Member Secretary/ Chairperson and date

Annexure 2
AX 02/SOP 16/V7
Log of requested IEC Documents

No	File Number and Document	Name and Designation of person requesting with his/her signature	Date Requested	Date of approval	Retrieved by (Name, Signature and Date)	Returned Date	Archived by (Name, Signature and Date)

Annexure 3
AX 03/ SOP 16/V7
Template Log of archived files and their location

IEC Project registration number	Protocol ID	Date of completion	Date of Archival	Location of File		Proposed Date of Shredding	Signature of IEC Secretariat
				Cupboard No.	Shelf No.		

(Archiving, retrieving and disposal of documents)

Title:	Responding to Research Participant's Grievance or Complaint
SOP Code:	SOP 17/V7 dated 19th November 2024

Prepared by Signature with date	Reviewed by Signature with date	Approved by Signature with date	Accepted by
Dr. Raakhi Tripathi, Member Secretary, IEC-I	Dr. Nithya Gogtay, Jt. Member Secretary, IEC-I	Dr. Manju Sengar Chairperson, IEC-I	IEC-I
	Dr. Vyankatesh Shivane, Member, IEC-I	Dr. Sunil Kuyare Chairperson, IEC-II	IEC-II
		Dr. M. G. Karmarkar Chairperson, IEC-III	IEC-III

1. Purpose

The purpose of this SOP is to describe procedures for dealing with any grievance put forth by research participant/s regarding their rights or to resolve their queries and / or complaint/s that is/are related to their participation in research approved by the Institutional Ethics Committee (IEC).

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 provide the information asked by research participants or to address any injustice that has occurred, if any complaints are received.

4. Activity Table

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

5. Detailed instructions:

- A grievance, complaint or query, from a research participant will be accepted by the IEC Secretariat and forwarded to the IEC Member Secretary after entering into the Participant's grievance / Complaint Record Form **(**AX 01/ SOP17/V7**)**
- The Member Secretary may receive a grievance, complaint or query directly from the participant. He/she will record it in the grievance /complaint record form AX 01/SOP 17/V7 and notify the IEC Secretariat.
- Participant's grievance /Complaint record form AX 01/SOP 17/V7 is available at the reception / OPD counters of KEM Hospital and at all the clinical trial sites.
- The Member Secretary will additionally ascertain details of the grievance / 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 IEC Secretariat will inform the Chairperson about the grievance, 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.

5.1 Participant Grievance redressal policy

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 (at least 1 IEC member should be non-affiliated) 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 Member Secretary/ designated IEC members will assess the situation and mediate a dialogue between the research participant and PI in an attempt to resolve the matter.
- The IEC will insist on factual details to determine the gap, if any, between truth and individual perception.
- Call an mediator or arbitrator as required
- Report writing and documentation of the facts.
- Prepare recommendation to the research participant.

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 to the research participant and the PI by the IEC Secretariat.

The information including any action taken or follow-up and final decision will be recorded in the form AX 01/ SOP 17/V7 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 and will be documented in the minutes of the meeting.

The IEC Secretariat will place all documents in the separate file labeled as Research Participant Grievance and redressal actions.

6. Annexure

Annexure 1 *AX 01/SOP 17/V7* Participant's Grievance / Complaint Record Form

Annexure 1

AX 01/SOP 17/V7

Participant's Grievance / Complaint Record Form

Date:	
Received by:	
Grievance received through	❑ Letter / Date: _____ ❑ E-mail / Date: _____ ❑ Walk-in / Date / Time: _____ ❑ Other, specify: _____
Participant's Name:	
Contact Address: **Phone:**	_____ _____
Title of the Participating Study:	_____ _____
Starting date of participation:	_____
Information requested/ complaint/query	_____ _____

Action taken:	_____
	_____
Final Decision:	_____
	_____
	_____

Signature of the IEC Member Secretary

Date

अनुलग्नक १

एएक्स **०१/एसओपी १७/वी ७**

प्रतिभागी की शिकायत अर्जी

तारीख:	
द्वारा प्राप्त:	
के माध्यम से प्राप्त अनुरोध	❑ पत्र / तिथि: _____ ❑ ई-मेल/ तारीख: _____ ❑ वॉक-इन/तारीख/समय: _____ ❑ अन्य, निर्दिष्ट करें: _____
प्रतिभागी का नाम:	
संपर्क करें: पता: फ़ोन:	_____ _____
प्रतिभाग लेने वाले अध्ययन का शीर्षक:	_____
प्रतिभागी होनेवाली प्रारंभिक तारीख:	_____
मांगी गई जानकारी / शिकायत / पूछताछ	_____ _____
कार्रवाई का वर्णन: अन्तिम निर्णय :	_____ _____

नीतिमत्ता समिती सदस्य सचिव के हस्ताक्षर:
तारीख:

परिशिष्ट १

एएक्स ०१ / एसओपी १७ / व्ही ७

सहभागीची तक्रार नोंदवण्याचा फॉर्म

दिनांक	
द्वारा प्राप्त:	
द्वारा विनंती प्राप्त:	❑ पत्र / दिनांक: _____ ❑ ई-मेल/ दिनांक : _____ ❑ वॉक-इन// दिनांक /वेळ: _____ ❑ इतर, निर्दिष्ट करा : _____
संपर्क: पत्ता: फोन:	
सहभागी अभ्यासाचे शीर्षक:	
सहभाग घेतल्याची दिनांक:	
विनंती केलेली माहिती / तक्रार / प्रश्न	_____ _____
कारवाईचे वर्णन: अंतिम निर्णय:	_____ _____

नैतिक संस्थेच्या सदस्य सचिवाची सही
दिनांक:

Title:	Management of complaints by investigators
SOP Code:	SOP 18/V7 dated 19th November 2024

Prepared by Signature with date	Reviewed by Signature with date	Approved by Signature with date	Accepted by
Dr. Raakhi Tripathi, Member Secretary, IEC-I 19/11/24	19.11.24 Dr. Nithya Gogtay, Jt. Member Secretary, IEC-I	9/12/24 Dr. Manju Sengar Chairperson, IEC-I	Institutional Ethics Committee (IEC-I) Established In 1985 Seth G.S. Medical College & K.E.M. Hospital Parel, Mumbai-400 012. IEC-I
	19 NOV 2024 Dr. Vyankatesh Shivane, Member, IEC-I	09/12/24 Dr. Sunil Kuyare Chairperson, IEC-II	Institutional Ethics Committee (IEC-II) Established in 1986 Seth G.S. Medical College & K.E.M. Hospital Parel, Mumbai - 400 012. IEC-II
		04/12/24 Dr. M. G. Karmarkar Chairperson, IEC-III	Institute Ethics Committee-III Established in 1986 Seth G.S. Medical College & K.E.M. Hospital Parel, Mumbai - 400 012. IEC-III

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide guidelines for dealing with the appeal/complaint made by the investigator (Principal Investigator (PI) / Co-Investigator from KEMH as per the (PI definition refer section SOP5-A V7 section 5.1.1 & 5.1.2) against the IEC office /members.

2. Scope:

This SOP applies to handling of appeal/complaint made by the investigator (principal investigator, co-investigator) against the IEC office/ members. The investigator/s may submit the appeal/complaint to IEC office/ IEC Chairperson/ Member Secretary to the Head of the Institution.

3. Responsibility:

It is the responsibility of the IEC to adhere to the principles of fairness, confidentiality, integrity and prevention of detriment while addressing appeal/ investigating the complaints by investigators.

It is the responsibility of the Member Secretary in consultation with the Chairperson to initiate a process to give information to the participants or to identify and address any injustice that has occurred if complaints are received from investigators.

4. Activity Table

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

5. Detailed instructions:

5.1 Receiving the appeal/complaint from investigators

- IEC secretariat will receive a request, complain or appeal by the investigator directly or via Letter / email written to Head of the Institution.
- The annexure 1, AX 01/SOP 18/V7 will be filled and forwarded by the IEC secretariat to the member secretary/chairperson.

5.2 Initiating process to identify the problem

- The Member Secretary /IEC Secretariat will call for relevant information and documents from the Investigator, as required.
- In case of a request for additional information or clarification, the Chairperson/ Member Secretary may decide to provide the information himself/herself or will designate one or more IEC member to provide such information. The IEC Secretariat will make all documents relevant to the request, available to the Chairperson/ designated member.

5.3 Deliberations to arrive at solution

- The Member Secretary/ designated IEC members will assess the situation and mediate a dialogue between the investigator and member/ IEC office representative against whom complaint is lodged in an attempt to reach the amicable solution.
- The Chairperson / Member Secretary may consider the matter for discussion at the next full board meeting or call an emergency meeting of two or more IEC members for discussion in order to resolve the matter.
- The IEC will insist on factual details to determine gap, if any, between truth and individual perception.
- The Head of the institution if involved in the matter by investigator will be informed about the deliberations between investigator/s and IEC and the final decision on the matter. The

suggestions/ recommendations of the Head of the institution will be followed by IEC and the investigator/s.

- If the mutual agreement regarding workable solution is reached the matter will be considered as resolved.
- If there is no mutual agreement and matter is not resolved, a meeting will be called as soon as possible with Head of the institution and Chairperson and Member secretary and / or IEC member and the concerned investigator/s to resolve the matter.
- The information of all these meetings including any action taken or follow-up will be recorded in the form AX 01/SOP 18/V7 and the form is signed and dated.

5.4 Communication with the investigator

- The final decision will be informed to the investigators by the IEC Secretariat.
- The IEC members will be informed about the action taken and the outcomes in the forthcoming IEC meeting.

5.5 File the request document

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

6. Annexure

Annexure 1 AX 01/SOP18/V7 Complaint/ Appeal Record Form

Annexure 1
AX 01/SOP 18/V7
Complaint / Appeal Record Form for Investigators

Date:	
Received by:	
Complaint/ Appeal received through:	❑ Letter to Head of the Institution:_____ ❑ Letter /Date:_____ ❑ E-mail /Date:_____ ❑ Walk-in / Date /Time:_____ ❑ Other, specify:_____
Investigator's Name:	
Contact address: **Phone:**	
Details of complaint/appeal:	_____
Deliberations with investigators:	
Actions taken: **Outcome:**	_____ _____

Signature of the IEC Member Secretary/ Chairperson:

Date:

Title:	Request for Waiver of Written Informed Consent
SOP Code:	SOP 19/V7 dated 19th November 2024

Prepared by Signature with date	Reviewed by Signature with date	Approved by Signature with date	Accepted by
Dr. Raakhi Tripathi, Member Secretary, IEC-I	Dr. Nithya Gogtay, Jt. Member Secretary, IEC-I	Dr. Manju Sengar Chairperson, IEC-I	IEC-I
	Dr. Swapna Kanade, Member Secretary, IEC-III	Dr. Sunil Kuyare Chairperson, IEC-II	IEC-II
		Dr. M. G. Karmarkar Chairperson, IEC-III	IEC-III

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the type of research projects for which the Institutional Ethics Committee (IEC) may grant waiver for requirement of obtaining written informed consent and the format of the application form to be used by the investigators for requesting waiver of consent. The Application Form AX 01/SOP 19/V7 is designed to standardize the process of applying for consent waiver.

2. Scope

This SOP applies to all protocols with a request of granting consent waiver submitted for review by the IEC. The decision should be taken by the IEC members during expedited review or at the Full Board meeting.

3. Responsibility

It is the responsibility of the IEC Secretariat to manage waiver of consent application form. The Member Secretary/ Chairperson/ Primary reviewers to review and take a decision regarding the waiver of consent application. It is the responsibility of the IEC secretariat to communicate the decision to the investigator.

4. Activity Table

No.	Activity	Responsibility
1	Receive the submitted documents.	IEC Secretariat
2	Review of protocol and application for waiver of consent	IEC Members
3	Decision regarding waiver of consent	IEC Members at Full Board meeting
4	Communicate and record the decision to the Investigator	IEC Secretariat

5. Detailed instructions

Receive the submitted documents.

- When a request for waiver of consent is submitted by the Principal Investigator to the IEC secretariat, in the given format AX 01/SOP 19/V7 stating the reasons for the consent waiver. The IEC Secretariat will check if the concerned documents are filled completely, and the required list of documents is enclosed and forward the package to the member secretary /chairperson.

Review of protocol and application for waiver of consent

- ✓ The IEC Primary reviewer / Member Secretary /Chairperson will review the request taking into consideration the types of studies for which waiver of consent may be granted. (Criteria stated on the back of the annexure AX 01/SOP19/V7).
- ✓ The IEC will ensure that there are adequate mechanisms described in the protocol for protection of the identity of the research participants and maintaining confidentiality of the study data. This is necessary as the participant cannot be assured directly about confidentiality of health data through a formal informed consent process, when consent waiver is granted.

Decision regarding waiver of consent

- ✓ The decision regarding approval/disapproval of waiver is informed to the principal investigator in writing. If the waiver is not granted, the IEC will provide reasons for the same.
- ✓ The decision whether to grant the waiver is taken and will be inform in the upcoming full board meeting.

6. Annexure

Annexure 1 AX 01/SOP19/V7 Application form for requesting waiver of consent

Annexure 1
AX 01/SOP 19/V7
Application form for requesting waiver of consent

1. **IEC No. of the Project:** ……
2. **Principal Investigator's Name:** …… **Department:** ……
3. **Title of project:** ……
   ……
4. **Names of other participants, staffs and students:** ……..
   ……
5. **Request for waiver of informed consent:**
   - Please check the reason(s) for requesting waiver (Please refer the back of this annexure for criteria that will be used by IEC to consider waiver of consent).
     a. Research involves 'not more than minimal risk'.
     b. There is no direct contact between the researcher and participant.
     c. Emergency situations as described in ICMR Guidelines (ICMR 2017 Guidelines), National Guidelines for Ethics Committees Reviewing Biomedical & Health Research.
     d. Any other (please specify): ……
     ……
   - Statement assuring that the rights of the participants are not violated
     ……
   - State the measures described in the Protocol for protecting confidentiality of data and privacy of research participants
     ……

Signature with date of Principal Investigator: ……..
Final decision at full board meeting held on: ……..
Waiver granted: Yes ☐ No ☐
If not granted, reasons: ……
……

Signature of the Chairperson/Member Secretary with Date: ……..

Type of research projects which may qualify for consent waiver: A request to waiver written informed consent must be accompanied by a detailed explanation. The investigator is also required to provide assurance regarding protection of identity of research participants and maintenance of confidentiality about the data of the research participants. The following criteria (ICMR 2017 & National Guidelines for Ethics Committees Reviewing Biomedical & Health Research) must be met for a research project so that it can qualify for granting a waiver of both written and verbal consent.

1. The proposed research presents no more than minimal risk to participants. (ICMR guidelines 2017, National Guidelines for Ethics Committees Reviewing Biomedical & Health Research) e.g. a retrospective review of patient case records to determine the incidence of disease/ recurrence of disease. [Minimal risk would be defined as that which may be anticipated as harm or discomfort not greater than that encountered in routine daily life activities of general population or during the performance of routine physical or psychological examinations or tests. However, in some cases like surgery, chemotherapy or radiation therapy, great risk would be inherent in the treatment itself, but this may be within the range of minimal risk for the research participant undergoing these interventions since it would be undertaken as part of current everyday life.
2. When it is impractical to conduct research, since confidentiality of personally identifiable information has to be maintained throughout research as maybe required by the sensitivity of the research objective. *(*ICMR 2017guidelines, National Guidelines for Ethics Committees Reviewing Biomedical & Health Research).

e.g. conducting interviews with citizens about their religious beliefs/ people with HIV and AIDS/conducting phone interviews with homosexuals.

The only record linking the participant and the research would be the consent document and when there is a possible legal, social or economic risk to the participant entailed in signing the consent form as they might be identified as such by signing the consent form, the requirement for obtaining consent can be waived of by the IEC.

[In case of telephonic interviews, waiver of written informed consent may be requested but this does not mean that verbal consent cannot be utilized].

The following points need to be considered.

a. The following documents need to be submitted for the IEC review.
   - A script for verbal consent - a verbal consent script provides all of the elements of consent in a more

informal style. In addition, each subject should be provided with an information sheet that describes the study and gives contact names and numbers.
- The interview schedule (questions to be asked???) will confirm that the interview is a simple 5-minute call and that no questions are asked that compromise a person's confidentiality or position.

b. Normally, investigators will be asked to keep a log of those who were approached about the study and offered verbal consent. A simple chart can indicate the participants as participant 1, participant 2, and participant 3. A column can indicate that verbal consent was given and a date. Since a specific number of study participants are to be recruited. It is important that investigators keep some record to indicate that they are not enrolling more participants than they originally requested.

3. Research on publicly available information, documents, records, work performances, reviews, quality assurance studies, archival materials or third-party interviews, service programs for benefit of public having a bearing on public health programs, and consumer acceptance studies. (ICMR 2017 guidelines, National Guidelines for Ethics Committees Reviewing Biomedical & Health Research).
4. Research on anonymized biological samples from deceased individuals, left over samples after clinical investigation, cell lines or cell free derivatives like viral isolates, DNA or RNA from recognized institutions or qualified investigators, samples or data from repositories or registries etc. (ICMR 2017 guidelines, National Guidelines for Ethics Committees Reviewing Biomedical & Health Research).
5. In emergency situations when no surrogate consent can be taken. (ICMR 2017 guidelines, National Guidelines for Ethics Committees Reviewing Biomedical & Health Research) When consent of person/patient/responsible relative or custodian/team of designated doctors for such an event is not possible, the IEC can allow waiver of consent for recruiting participant in a research study. However, information about the intervention should be given to the patients whenever he/she gains consciousness or to relative/legal guardian when available later.

Title	Reviewing proposals involving vulnerable Populations
SOP Code	SOP 20/V7 dated 19th November 2024

Prepared by Signature with date	Reviewed by Signature with date	Approved by Signature with date	Accepted by
Dr. Raakhi Tripathi, Member Secretary, IEC-I	Dr. Nithya Gogtay, Jt. Member Secretary, IEC-I	Dr. Manju Sengar Chairperson, IEC-I	IEC-I
	Dr. Vyankatesh Shivane, Member, IEC-I	Dr. Sunil Kuyare Chairperson, IEC-II	IEC-II
		Dr. M. G. Karmarkar Chairperson, IEC-III	IEC-III

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe procedures to review proposals involving vulnerable populations. The SOPs provide clear, unambiguous instructions so that the related activities of the Board are conducted in accordance with Indian laws and relevant, National and International Guidelines. It describes the requirements concerning review of research that involves groups that could be potentially vulnerable to coercion in regard to autonomy, and present conditions that may affect risk/benefit determinations or bearing unequal burden in research.

2. Scope

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

3. Responsibility

- It is the responsibility of the Secretariat of IEC to maintain up-to-date tools for review of research pertaining to vulnerable groups based on new and evolving applicable regulations and guidelines.
- IEC Chairperson/ Member Secretary is responsible for ensuring that IEC members are well versed in new and evolving regulations and guidelines pertaining to vulnerable populations, for selecting primary reviewers with appropriate expertise to conduct the reviews of such research, and for securing appropriate consulting expertise as needed for selected reviews.
- IEC member is responsible for conducting appropriate review of research planned for vulnerable populations, including an assessment of potential for coercion, in consultation with any appropriate experts and resources as described in this SOP.

3.1 IEC Secretariat of the Institutional Ethics Committee will perform following task

- Maintain on file the updated checklist (1-8) which conforms to applicable regulations and guidelines.
- Document review of risk assessment in IEC minutes for the protocols involving vulnerable population.
- Confirm that the complete informed consent and assent documents as relevant.

3.2 Chairperson / Member Secretary will:

Select appropriate primary reviewer(s).

3.3 IEC members will:

- Complete checklist during review of research with vulnerable populations and present recommendations at the convened meeting.

4. Activity Table

No.	Activity	Responsibility
1.	Reviewing the protocol with vulnerable population	Any member of IEC and designated reviewer, IEC secretariat or administrative staff
2.	Appoint one or more reviewers	Chairperson/ Member Secretary
3.	Review the protocol	IEC members

5. Detailed instructions

5.1 Reviewing the protocol with vulnerable population

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

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

- measure to protect autonomy,
- risk/benefit determinations with respect to the vulnerability
- bearing unequal burden in research.

Any member of the IEC or Secretariat who would be dealing with such protocols should be well versed with the potential harm or risk of such population participating in the study. The checklist for different vulnerable population is being provided in Annexure (1–8). Special justification is required for inviting vulnerable individuals to serve as research participants and, if they are selected, the means of protecting their rights and welfare must be strictly applied.

5.2 Appoint the Reviewers

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

IEC Secretariat duties

- Provide a suitable checklist according to the participants to be recruited in study to the investigator. Inform the investigator to download the appropriate application form and informed consent document/ assent form. If the checklists are not available the investigators want to include vulnerable population in the study. They have to mention in the protocol details regarding justification of including the vulnerable population for the study, risk and benefits to the study participants along with mechanism of minimizing risks, measures to protect their autonomy, measures for recruitment of such participants along with measures taken for protection of privacy and confidentiality.
- IEC can recommend for written / verbal Informed consent /audio –visual consent /audio consent (leprosy patients) in the vulnerable population. This decision will be taken on case to case basis. All the protocol dealing with vulnerable population will be considered for Full Board review.
- Provide appropriate reference material or help reviewer to locate such material related to vulnerable populations when specifically requested for, by a reviewing member.

5.3 Review the protocol

- IEC Members will review the protocol and the informed consent document or assent form.
- The member secretary will confirm that the IEC recommendations have been incorporated in the revised protocol and in the final draft of informed consent document or assent form.
- Research involving vulnerable populations will not be considered for expedited review or exemption from review.

<u>Approval of the protocol</u>

- The final version of the protocol will be approved by the board with the appropriate checklist as given in annexure (1- 8).
- Wherever necessary the IEC approval should state that if in future the vulnerability status of the participants changes for e.g.; unconscious patient gaining consciousness, then the protocol and ICD should be amended and resubmitted to the IEC for reconsideration and

approval Following which the participant should be re-consented and reconsidered for the same.

6. Glossary

SOP (Standard Operating Procedure)	Detailed, written instructions, in a certain format, describing activities and actions undertaken by the IEC to achieve uniformity of the performance of a specific function. The aim of the SOPs and their accompanying checklists and forms is to simplify the functioning, whilst maintaining high standards of Good Clinical Practice.
IEC members	Individuals serving as regular members of the Institutional Ethics Committee. The Committee has been constituted in accordance with the EC membership requirements set forth in NDCTR,2019.
Vulnerable population	Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests. More formally, they may have insufficient power, intelligence, education, resources, strength, or other needed attributes to protect their own interests.
Children	Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.
Assent	Assent means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.
Pregnant women	Pregnancy encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.
Fetus	Fetus means the product of conception from implantation until delivery.
Viable fetus	Viable, as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.
Non viable fetus	Nonviable neonate means a neonate after delivery that, although living, is not viable.
Neonate	Neonate means a newborn.
Mentally impaired persons	Mentally incapable to give consent due to the situation /condition
Situational vulnerability	Disasters create vulnerable persons and groups in society, particularly so in disadvantaged communities,
Harm	is a negative safety or health consequence; any detrimental effect of a significant nature
Risk	“chance”/probability that harm can occur

7. Annexure

Annexure 1	AX01/SOP 20/V7	Checklist–Requirements for Research Involving Children
Annexure 2	AX02/SOP 20/V7	Checklist–Requirements for Research Involving Pregnant Women & Fetuses
Annexure 3	AX03/SOP 20/V7	Checklist- Research Involving Cognitively Impaired Adults
Annexure 4	AX04/SOP 20/V7	Checklist-Research Involving Students, Employees or Residents
Annexure 5	AX05/SOP20/ V7	Checklist- Considerations for Genetic Research
Annexure 6	AX06/SOP 20/V7	Checklist- Requirements for Research involving terminally ill patients
Annexure 7	AX07/SOP 20/V7	Checklist- Considerations for Research in HIV participant
Annexure 8	AX08/SOP 20/V7	Checklist- Requirements for Research involving economically/socially backward/illiterate patients
Annexure 9	AX09/SOP 20/V7	Checklist–Requirements for Research involving elderly patients
Annexure 10	AX10/SOP 20/V7	Checklist–Requirements for Research involving institutionalized/Refugees/Migrants/Homeless

Annexure 1
AX 01/SOP 20/V 7
Checklist-Requirements for Research Involving Children

Investigator: …… **IEC No. of the Project:** ……
Study Title: ……
……

For the Principal Investigator		IEC Office
RISK DETERMINATION	BENEFIT ASSESSMENT	IEC ACTION
☐ Minimal *	☐ Direct benefit	Approvable
	☐ No direct benefit	
☐ Greater than minimal risk	☐ Potential to child	Approvable
☐ Greater than minimal risk	☐ No direct benefit to individual offer general knowledge about the child's condition or disorder.	Approvable case –by- case **

* Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or occurring during the performance of routine physical or psychological examinations or tests.

** Risk may not be more than a minor increase over minimal risk, consent of both parents is required under normal circumstances.

	Yes	No	NA
Does the research pose greater than minimal risk to children?	☐	☐	☐
If yes: Are convincing scientific and ethical justifications given?	☐	☐	☐
If yes: Are adequate safeguards in place to minimize these risks?	☐	☐	☐
Does the study involve normal volunteers?	☐	☐	☐
If yes: Is the inclusion of normal volunteers justified?	☐	☐	☐
Are the studies conducted on animals and adults appropriate and justified?	☐	☐	☐
If No: Is the lack of studies conducted on animals and adults justified?	☐	☐	☐
Will older children be enrolled before younger ones?	☐	☐	☐
Is permission of both parents necessary?	☐	☐	☐
If Yes: Are conditions under which one of the parents may be considered: "not reasonably available" described?	☐	☐	☐
If Yes: Are the conditions acceptable?	☐	☐	☐
Will efforts be made ensure that parents' permission to involve their children in research studies is free from coercion, exploitation, and /or unrealistic promises?	☐	☐	☐
Are provisions made to obtain the assent of children over 7 and, where appropriate, honoring their dissent?	☐	☐	☐
Are provisions made to protect subjects' privacy and the confidentiality of information regarding procedures?	☐	☐	☐
Are there special problems that call for the presence of a monitor or IEC member during consent procedures?	☐	☐	☐
Are special needs of adolescents such as counseling and confidentiality accounted for in the research design?	☐	☐	☐
Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?	☐	☐	☐
Does the research involve implications for other family members? (for example, genetic risk, HIV infection, Hepatitis C)	☐	☐	☐
If Yes: Are there adequate mechanisms in place to deal with other members of the family?	☐	☐	☐
Are parents required to be present during the conduct of the research? (Are proposed participants to be very young? Are the procedures involved painful? Must the subject stay overnight in the hospital when they otherwise would not have to?)	☐	☐	☐
Recruitment strategies for paediatric studies: a. OPD or IPD b. By a qualified pediatrician or neonatologist c. From the departmental database d. From the well baby clinic e. Any other	☐	☐	☐

Signature of Principal Investigator: …….. **Date:** ……

IEC Office use only	
Comments	
Primary Reviewer Signature & Date:	

Annexure 2
AX 02/ SOP 20/V 7
Checklist-Requirements for Research Involving Pregnant Women & Fetuses

Investigator: ……. **IEC No. of the Project:** ……
Study Title: ……
……..

THIS RESEARCH INVOLVES PREGNANT WOMEN OR FETUSES

No.		Yes	No	NA

1.	Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;	☐	☐	☐
2.	The risk to the fetus is not greater than minimal, or any risk to the fetus which is greater than minimal is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus;	☐	☐	☐
3.	Any risk is the least possible for achieving the objectives of the research;	☐	☐	☐
4.	The woman's consent or the consent of her legally authorized representative is obtained in accord with the informed consent provisions, unless altered or waived.	☐	☐	☐
5.	The woman or her legally authorized representative, as appropriate, is fully informed regarding the reasonably foreseeable impact of the research on the fetus.	☐	☐	☐
6.	No inducements, monetary or otherwise, will be offered to terminate a pregnancy;	☐	☐	☐
7.	Women's participation in the research will not have an effect on the decisions by investigator with respect to the timing, method or procedures used to terminate a pregnancy; and	☐	☐	☐
8.	The decision of investigator determining the viability of a fetus will not have an effect if the women participates in the research.	☐	☐	☐

A.	**Fetuses of uncertain viability**	**Yes**	**No**	**NA**
1.	Does the **research** hold out the prospect of enhancing the probability of survival of the particular fetus to the point of viability, and any risk is the least possible for achieving the objectives of the **research;**	☐	☐	☐
	OR			
	The purpose of the **research** is the development of important biomedical knowledge which cannot be obtained by other means and there will be no risk to the fetus resulting from the **research**;	☐	☐	☐
2.	The legally effective informed consent of either parent of the fetus or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained.	☐	☐	☐

B.	**Nonviable fetuses**	**Yes**	**No**	**NA**
1.	Vital functions of the fetus will not be artificially maintained;	☐	☐	☐
2.	There will be no risk to the fetus resulting from the research;	☐	☐	☐
3.	The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and	☐	☐	☐
4.	The legally effective informed consent of both parents of the fetus will be obtained except that the waiver and alteration provisions do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable fetus will suffice to meet the requirements of this paragraph. The consent of a legally authorized representative of either or both of the parents of a nonviable fetus will not suffice to meet the requirements of this paragraph.	☐	☐	☐

Signature of Principal Investigator: …… **Date:** ……

IEC Office use only	
Comments	
Primary Reviewer Signature & Date:	

Annexure 3
AX 03/ SOP 20/ V7
Checklist- Research Involving Cognitively Impaired Adults

Investigator: …… **IEC No. of the Project:** ……
Study Title: ……

- The purpose of this checklist is to provide support for IEC members or the Designated Reviewer when reviewing research involving cognitively impaired adults as subjects.
  1. For review, using this checklist is to be completed by the **Designated Reviewer** to document determinations required by the regulations and protocol specific findings justifying those determinations and retained.
  2. For review using the convened IEC is to document determinations required by the regulations and protocol specific findings justifying these determinations.

1.	**Research Involving Cognitively Impaired Adults in which there is Anticipated Direct Benefit to the subject** (All items must be "Yes")		
	One of the following is true (Check the box that is true) ☐ The risk to the participants is presented by an intervention or procedure that holds out prospect of direct benefit for the individual subject. ☐ More than minimal risk to participants is presented by monitoring procedure that is likely to contribute to the participants well – being.	☐ Yes	☐ No
	The risk is justified by the anticipated benefit to the participants.	☐ Yes	☐ No
	The relation of anticipated benefit to the risk is at least as favourable to the participants as that presented by available alternative approaches.	☐ Yes	☐ No
	The proposed plan for the assessment of the capacity to consent is adequate.	☐ Yes	☐ No
	Assent is required of: (One of the following must be **"Yes")** One of the following is true (**Check box that is true)** ☐ All participants ☐ All participants capable of being consulted. ☐ None of the participants	☐ Yes	☐ No
	The consent document includes a signature line for a legally authorized representative.	☐ Yes	☐ No
2.	**Research Involving Cognitively Impaired Adults in which there is No Anticipated Direct Benefit to the subject** (All items must be "Yes")		
	The proposed plan for the assessment of the capacity to consent is adequate.	☐ Yes	☐ No
	The objectives of the trial cannot be met by means of study of participants who can give consent personally.	☐ Yes	☐ No
	The foreseeable risks to the participants are low.	☐ Yes	☐ No
	The negative impact on the participants' well-being is minimized and low.	☐ Yes	☐ No
	The trial is not prohibited by law.	☐ Yes	☐ No
	Participants have a disease or condition for which the procedures in the research are intended.	☐ Yes	☐ No
	Participants will be particularly closely monitored.	☐ Yes	☐ No
	Participants will be withdrawn if they appear to be unduly distressed.	☐ Yes	☐ No
	The proposed plan for the assessment of the capacity to consent is adequate.	☐ Yes	☐ No
	Assent is required of (One of the following must be **"Yes")** One of the following is true **(Check box that is true**) ☐ All participants ☐ All participants capable of being consulted. ☐ None of the participants	☐ Yes	☐ No
	The consent document includes a signature line for a legally authorized representative.	☐ Yes	☐ No

Signature of Principal Investigator: …….. **Date:** ……

IEC Office use only	
Comments	
Primary Reviewer Signature & Date:	

Annexure 4
AX 04/SOP 20/V 7
Checklist-Research Involving Students, Employees or Residents

Investigator: ……. **IEC No. of the Project:** ……
Study Title: ……
……

Participants who are students, employees or residents require special considerations.

Does the employer or supervisor of the research participant need to be aware of the research project?	□ Yes	□ No
Is there a letter of support from the employee\administrator?	□ Yes	□ No
Have the participants been assured that their status (education, employment, and/or promotion) will not be affected by any decision to participate or not?	□ Yes	□ No
Have the risks to participants been minimized?	□ Yes	□ No
Have participants been assured that participation is voluntary (no signs of coercion)?	□ Yes	□ No
Have participants been assured that confidentiality will be protected or maintained?	□ Yes	□ No

Signature of Principal Investigator: …….. **Date:** ……

IEC Office use only	
Comments	
Primary Reviewer Signature & Date:	

Annexure 5
AX 05/SOP 20/V 7
Checklist-Considerations for Genetic Research

Investigator: ……. **IEC No. of the Project:** ……
Study Title: ……
……

		Yes	**No**
1.	Will the samples be made anonymous to maintain confidentiality?	□	□
2.	Has the investigator established clear guidelines for disclosure of information, including interim or inconclusive research result?	□	□
3.	Has the appropriateness of the various strategies for recruiting participants and their family members been considered?	□	□
4.	Does the proposed study population comprise family members?	□	□
5.	Will family members be implicated in the studies without consent?	□	□
6.	Will the samples be destroyed in the future?	□	□
7.	Is genetic counseling being offered?	□	□

Signature of Principal Investigator: …….. **Date:** ……

IEC Office use only	
Comments	
Primary Reviewer Signature & Date:	

Annexure 6
AX 06/SOP 20/V7
Checklist-Requirements for Research involving terminally ill patients

Investigator: …… **IEC No. of the Project:** ……
Study Title: ……
……

	Yes	**No**	**NA**
Does the research pose greater than minimal risk to terminally ill patients?	□	□	□
If yes: Are convincing scientific and ethical justification given?	□	□	□
If yes: Are adequate safeguards in place to minimize these risks?	□	□	□
Are appropriate studies that have been conducted on animals and adults justified?	□	□	□
If No: Is the lack of appropriate studies conducted on animals and adults justified?	□	□	□
Do the anticipated benefits justify requiring the subjects to undertake the risks?	□	□	□
Is the inclusion of vulnerable population warranted?	□	□	□
Can the research question be answered by using a non-vulnerable population?	□	□	□
Will efforts be made to ensure that participants are free from coercion, exploitation, and/or unrealistic promises?	□	□	□
Are provisions made to obtain the consent?	□	□	□
Are provisions made to protect participant's privacy and the confidentiality of information regarding procedures?	□	□	□
Are there special problems that call for the presence of a monitor or IEC member during consent procedures?	□	□	□
Are special needs of counseling and confidentiality accounted for in the research design?	□	□	□
Are there any special problems such as confidentiality and reporting that might arise in this research?	□	□	□

Signature of Principal Investigator: …….. **Date:** ……

IEC Office use only	
Comments	
Primary Reviewer Signature & Date:	

Annexure 7
AX 07/SOP 20/V 7
Checklist - Considerations for Research in HIV participant

Investigator: …… **IEC No. of the Project:** ……
Study Title: ……
……

No.		**Yes**	**No**
1.	Was the consent taken voluntarily?	□	□
2.	During the consent process, is the privacy maintained?	□	□
3.	Is the pre testing counseling provisions are in place?	□	□
4.	Will the samples be made anonymous to maintain confidentiality? If yes, stop here in stored sample study.	□	□

5.	Has the investigator established clear guidelines for disclosure of information, including interim or inconclusive research result?	□	□
6.	Where is the test being carried out? Is the laboratory provide high-quality testing services, and quality assurance mechanisms.	□	□
7.	The disclosure of the test results will be done only to the study team/sponsors/regulators with the participant consent.	□	□
8.	Has the appropriateness of the various strategies for recruiting participants and their care takers been considered?	□	□
9.	Does the proposed study require family members/caretakers permission?	□	□
10.	Will confidentiality be maintained?	□	□
11.	Will family members/care takers be disclosed about the test results?	□	□
12.	Will the samples be destroyed in the future?	□	□
13.	Will the samples be stored for future?	□	□
14.	Is post HIV testing counseling being offered and given?	□	□
15.	Will the participant provided with effective referral to appropriate follow-up services as indicated, including long term prevention and treatment support?	□	□

Signature of Principal Investigator: …….. **Date:** ……

IEC Office use only	
Comments	
Primary Reviewer Signature & Date:	

Annexure 8
AX 08/SOP 20/V 7
Checklist-Requirements for Research involving economically/socially backward/illiterate patients

Investigator: ……. **IEC No. of the Project:** ……
Study Title: …….
……

	Yes	**No**	**NA**
Does the research pose greater than minimal risk to patients?	□	□	□
If yes: Are convincing scientific and ethical justification given?	□	□	□
If yes: Are adequate safeguard in place to minimize these risks?	□	□	□
Do the anticipated benefits justify requiring the subjects to undertake the risks?	□	□	□
Is inclusion of vulnerable population warranted?	□	□	□
Can the research question be answered by using a non-vulnerable population?	□	□	□
Will efforts be made ensure that participants are free from coercion, exploitation, and /or unrealistic promises?	□	□	□
Are provisions made to obtain the consent?	□	□	□
Are provisions made to protect participants' privacy and the confidentially of information regarding procedures?	□	□	□
Are there special problems that call for the presence of a monitor or IEC member during consent procedures?	□	□	□
Are special needs of counseling and confidentiality accounted for in the research design?	□	□	□
Are there any special problems such as confidentiality and reporting that might arise in this research?	□	□	□

Signature of Principal Investigator: …….. **Date:** ……

IEC Office use only

Comments	
Primary Reviewer Signature & Date:	

Annexure 9
AX 09/SOP 20/V 7
Checklist-Requirements for Research involving elderly patients

Investigator: …… **IEC No. of the Project:** ……
Study Title: ……
……

	Yes	**No**	**NA**
Does the research pose greater than minimal risk to elderly patients?	□	□	□
If yes: Are convincing scientific and ethical justification given?	□	□	□
If yes: Are adequate safeguards in place to minimize these risks?	□	□	□
Do the anticipated benefits justify requiring the subjects to undertake the risks?	□	□	□
Is the inclusion of vulnerable population warranted?	□	□	□
Can the research question be answered by using a non-vulnerable population?	□	□	□
Will efforts be made to ensure that participants are free from coercion, exploitation, and /or unrealistic promises?	□	□	□
Are provisions made to obtain the consent?	□	□	□
Are provisions made to protect participants' privacy and the confidentiality of information regarding procedures?	□	□	□
Are there special problems that call for the presence of a monitor or IEC member during consent procedures?	□	□	□
Are special needs of counseling and confidentiality accounted for in the research design?	□	□	□
Are there any special problems such as confidentiality and reporting that might arise in this research?	□	□	□

Signature of Principal Investigator: …….. **Date:** ……

IEC Office use only	
Comments	
Primary Reviewer Signature & Date:	

Annexure 10
AX 10/SOP 20/V7
Checklist-Requirements for Research involving institutionalized/Refugees/Migrants/Homeless

Investigator: …… **IEC No. of the Project:** ……
Study Title: ……
……

	Yes	**No**	**NA**
Does the project involve recruiting			
□ **Institutionalized**			
□ **Refugees**			
□ **Migrants**			
□ **Homeless**			
Does the research pose greater than minimal risk to these patients?	□	□	□
If yes: Are convincing scientific and ethical justification given?	□	□	□
If yes: Are adequate safeguard in place to minimize these risks?	□	□	□
Do the anticipated benefits justify requiring the subjects to undertake the risks?	□	□	□

Is inclusion of vulnerable population warranted?	□	□	□
Can the research question be answered by using a non-vulnerable population?	□	□	□
Will efforts be made ensure that participants are free from coercion, exploitation, and /or unrealistic promises?	□	□	□
Are provisions made to obtain the consent?	□	□	□
Are provisions made to protect participants' privacy and the confidentially of information regarding procedures?	□	□	□
Are there special problems that call for the presence of a monitor or IEC member during consent procedures?	□	□	□
Are special needs of counseling and confidentiality accounted for in the research design?	□	□	□
Are there any special problems such as confidentiality and reporting that might arise in this research?	□	□	□

Signature of Principal Investigator: …….. **Date:** ……

IEC Office use only	
Comments	
Primary Reviewer Signature & Date:	

Title:	Common Ethic Review of Multicentre Research
SOP Code:	SOP 21/V7 dated 19th November 2024

Prepared by Signature with date	Reviewed by Signature with date	Approved by Signature with date	Accepted by
19/11/24 Dr. Raakhi Tripathi, Member Secretary, IEC-I	19.11.24 Dr. Nithya Gogtay, Jt. Member Secretary, IEC-I	9/12/2024 Dr. Manju Sengar Chairperson, IEC-I	Institutional Ethics Committee (IEC-I) Established In 1985 Seth G.S. Medical College & K.E.M. Hospital Parel, Mumbai-400 012. IEC-I
	19 NOV 2024 Dr. Vyankatesh Shivane, Member, IEC-I	09/12/24 Dr. Sunil Kuyare Chairperson, IEC-II	Institutional Ethics Committee (IEC-II) Established in 1986 Seth G.S. Medical College & K.E.M. Hospital, Parel, Mumbai - 400 012. IEC-II
		09/12/24 Dr. M. G. Karmarkar Chairperson, IEC-III	Institute Ethics Committee-III Established in 1986 Seth G.S. Medical College & K.E.M. Hospital, Parel, Mumbai - 400 012. IEC-III

1. Purpose

In case of multicentric studies wherein IEC has been given the responsibility of designated IEC (DEC), IEC will undertake a common review of the study proposal with mutual agreement of all the ECs of participating centers (PEC).

2. Scope

This SOP applies to concerned ECs designated and participating investigators from centers involved, and other stakeholders involved in multicentric, clinical trials and biomedical and health research**.**

3. Responsibility

Coordinating PI will submit the study proposal to IEC as DEC for review using the ICMR common forms for EC review. It is the responsibility of the IEC as a DEC to conduct a detailed initial review of the proposal which is common for all centers involved in a multicenter research. IEC as DEC will communicate recommendations and final decision to the coordinating PI. PI from other sites will submit the same proposal to PEC. PEC will primarily review the local issues specific to the center.

4. Activity Table

No.	**Activity**	**Responsibility**
1	Determine the protocol submitted by coordinating PI for Common ethical FB review.	Member Secretary/ chairperson
2	Selection and allocation of projects to IEC members	Member Secretary
3	Review of the assigned protocols	Designated IEC Members
4	Compile the comments of IEC members	Member Secretary
5.	Discussion of the comments in FB meeting	All IEC members
6.	Communication of recommendations and final decision to coordinating PI	Member Secretary

5. Detailed Instructions

5.1 Consider the protocol submitted by coordinating PI for common ethical full board review.

In case of request by PIs of multicentric study, member secretary/ chairperson will review/screen the study proposal for its eligibility for common review as per ICMR guidelines 2017. The study determined to have low or minimal risk, survey or multicentric studies using anonymized samples or data or those that are public health research studies will be considered for common review by IEC as DEC.

5.2 Selection and allocation of projects to IEC members (Selection of PR)

- The Member Secretary will assign Primary Reviewer based on expertise in the related field and experience along with nonscientific member to the research study for scientific, ethical and statistical review. The Primary Reviewer will be members of the IEC and will have to present a detailed relevant review of the assigned multicentric study proposal.
- The Primary Reviewers will present the research study at a regular full board.
- In case the PR is not in position to review due to some reason, he/she should inform the Member Secretary at the earliest, so that the research study can be assigned to another member.
- In the event of his/her absence, a PR can send 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 comments.
- It is the responsibility of the assigned PRs to review the research protocol assigned to them thoroughly and communicate their observations, comments and decisions to the IEC during the meeting.
- The Member Secretary can invite an expert (if necessary) for comments during the full board meeting.

5.3 Review of the assigned protocols ~~on e-EC~~

IEC members will carry out initial review of proposal which is common to all participating centers. The protocol will be reviewed by each member as per guidelines (how to review a study protocol described in AX 01/SOP 05-B/V7.)

5.3.1 Examine the qualification of investigators and assess adequacy of study sites

- The IEC members must examine disclosure or declaration of potential conflicts of interest
- The IEC members must assess / ascertain, if required by reviewing the local study site whether the facilities and infrastructure at study sites can accommodate the study.

5.3.2 Guidelines for PR for evaluation of a project

Refer to SOP 5B section 5.3.2

6. Discussion of the comments in FB meeting.

The proposal will be discussed in FB meeting by all IEC members. The comments compiled by MS will be presented in the FB. Representatives from the participating ethics committees (PEC) may be invited to discuss local ethical issues if required. These special invitees will not have voting rights but can participate in DEC meeting to provide their comments and local perspectives.

7. Communication with the coordinating PI/PEC.

The final recommendations and final decision regarding the proposal will be communicated to the coordinating PI. Coordinating PI is directed to communicate the recommendations of DEC to PEC so that study can be initiated at the local center as and when the approval from PEC is obtained without waiting for PEC approvals at other participating centers. DES will review continuing review reports, annual reports, serious adverse events related to the study, causality assessment, protocol deviations, unanticipated problems involving risks to participants or others, significant complaints/any potential noncompliance, monitoring reports of PEC reported to DEC from other centers.

DEC will direct the PEC to monitor the corresponding local site. Report of which will be submitted to DEC for review.

6. Glossary

Designated Ethics Committee (DEC):	The participating EC of a multicentre study which assumes the responsibility to undertake a common initial and continuing review of study proposal with mutual agreement of all the participating centres of a multicentre study is called as the Designated Ethics Committee.
Participating Centre Ethics Committee (PEC):	The Participating Centre ECs are located at the participating centres in a multicenter research (including DEC) and are responsible for detailed review of research in accordance to ICMR National Ethical Guidelines, 2017.
Coordinating PI:	Coordinating PI is the PI at DEC who takes an overall responsibility for the conduct of the multicentre research along with PIs from all the participating centres and is also responsible for ongoing communication between DEC and PIs at other participating centres.
Principal Investigator:	The PI is the person who takes an overall responsibility for the conduct of multicentre research at various centres involved in research. Each centre can have additional co-investigator(s), who may coordinate the study with in the centre.
Multicentre research	Multi-centre study is conducted at more than one centre by different researchers usually following a common protocol. However, certain studies where each centre with a PI is involved in different research roles according to the objective/methodology such as quality control, data management may also be considered as multi centre studies. Each centre can have multiple sites from which participants can be recruited. However, each site should have a responsible nodal person as applicable at the local level. (one PI but different sites)

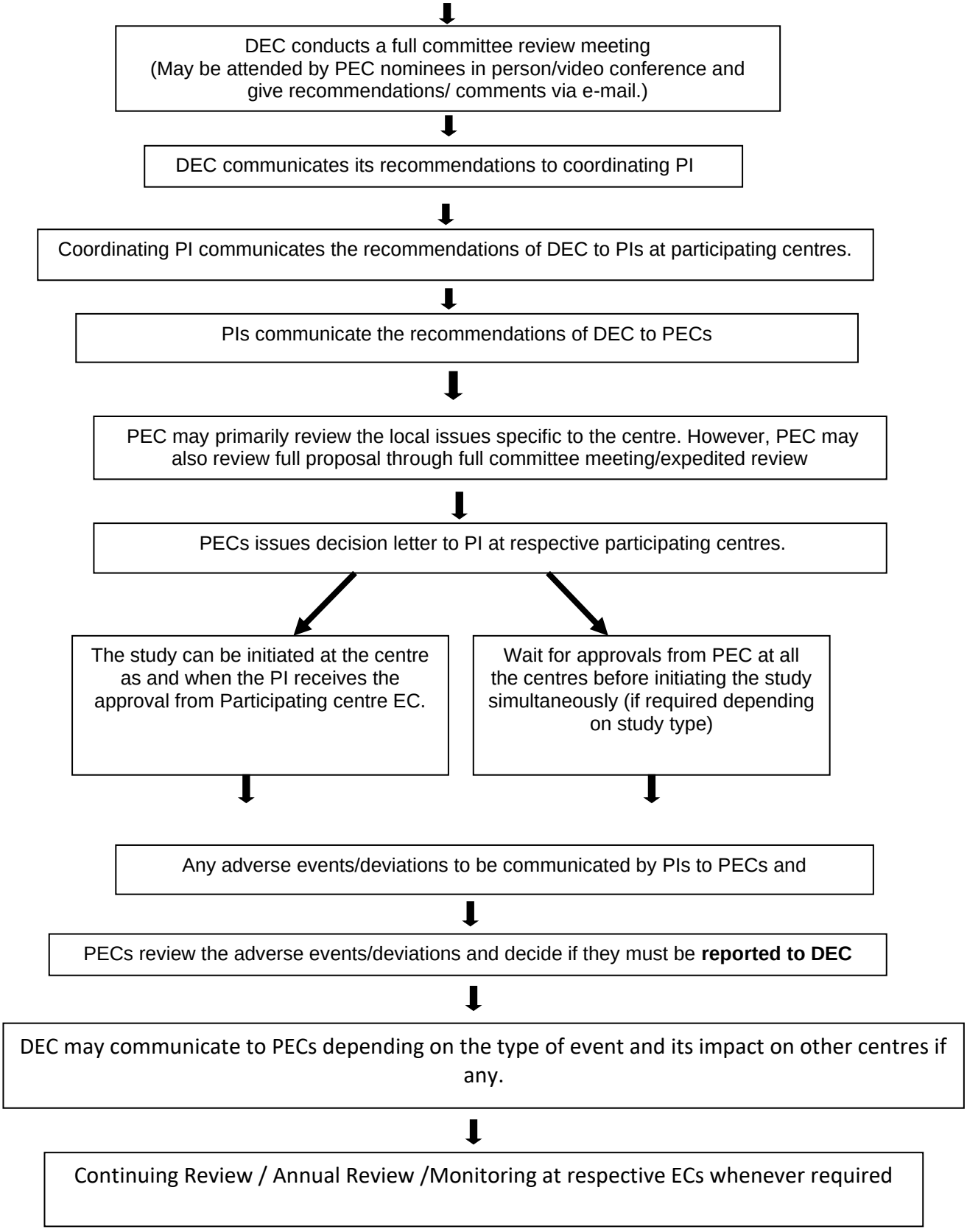
7. Annexure

Annexure 1	AX 01/SOP 21/V7	Flow chart for common review process of multicentric study
Annexure 2	AX 02/SOP 21/V7	Draft - LoU format for Common Review of multicenter research

Annexure 1

AX 01/SOP 21/V7

Flow chart for Common Review Process of Multicentre Research



Annexure 2
AX 02/SOP 21/V7
Draft - LoU format for Common Review of multicenter research Designated EC

Name of EC:
……
Name (Institution/ Organization):
……
EC Registration No, if any:
……

Participating Centre ECs (Add additional sheets according to the number of centres involved)

Name of EC:
……
……..
Name (Institution/ Organization):
……
EC Registration No, if any:
……
The Officials signing below agree that Participating centre EC of …… (name of the institution) may utilize the services of the Designated EC ……
……. (name of the institution) for efficient Common Ethics Review of Multicentre Research protocols.

It is understood that Designated Ethics Committee would undertake full ethics committee review. Ethical issues related to local centres may be reviewed by Participating Centre EC in expedited or full review and the final decision may be communicated to Designated Ethics Committee.
This agreement is limited to the following specific Proposal(s):
Title of Research Proposal:
……
……
Name of Principal Investigator/ Coordinating PI:……
Sponsor or Funding Agency:
……
The responsibilities of centres will be fulfilled in accordance with the ICMR Guidelines and they are responsible for ensuring compliance with the Guidelines.
For Designated Ethics Committee:

Signature:…… Date: ……
Name: ……
Address: ……
……
……
……

For Participating Centre EC:

Signature:…… Date: ……
Name: ……
Address: ……
……
……
……

Title:	**Management of Initial Protocol Submissions during epidemics/pandemics lockdown periods**
SOP Code:	**SOP 22/V7 dated 19th November 2024**

Prepared by Signature with date	Reviewed by Signature with date	Approved by Signature with date	Accepted by
Dr. Raakhi Tripathi, Member Secretary, IEC-I	Dr. Nithya Gogtay, Jt. Member Secretary, IEC-I	Dr. Manju Sengar Chairperson, IEC-I	IEC-I
	Dr. Vyankatesh Shivane, Member, IEC-I	Dr. Sunil Kuyare Chairperson, IEC-II	IEC-II
		Dr. M. G. Karmarkar Chairperson, IEC-III	IEC-III

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe how the IEC Secretariat of the Institutional Ethics Committee (IEC) manages protocol submissions to the IEC during periods of lockdown/ epidemics.

2. Scope

Initial submission received during periods of lockdown or epidemics will be managed collectively by the three boards.
Lockdown Periods: Any announcement by Hospital, Municipal, State or National Authorities restricting movements of individuals for certain duration. It will also be applicable to research during epidemics.

3. Responsibility

It is the responsibility of the IEC secretariat to ascertain epidemics/ periods of lockdown with the three member secretaries and follow the procedure of submission, review and decision conveying as follows : receive the submission, ensure complete documentation, record receipt of the submission, forward to the member secretary, review the protocol, and schedule a meeting

4. Activity Table:

SN	Procedure	Responsibility
	Submission and initial review	
a.	Submit research proposal (electronically)	Researchers
b.	Receive, record, verify completeness and allot reference no.	IEC Secretariat / Member Secretary
c.	Categorize depending on risk (Exempt/ Expedited, Full board), identify need for review by experts/ independent consultants/ patient / others, designate reviewers	Member Secretary in consultation with Chairperson
d.	Perform Initial review of documents as described in Table 4.3 of ICMR National Ethical Guidelines, fill study evaluation form	Primary/ secondary Reviewers
e.	Schedule virtual Meeting, Prepare Agenda, invite members (Independent Consultants/Subject Experts/ PI/ Member secretary of local EC/ in consultation with Chairperson).	IEC Secretariat/Member Secretary

5. Detailed instructions for meeting

Virtual EC meeting

SN	Procedure	Responsibility
a.	Open the meeting, determine quorum (Section 4.8.4 of ICMR National Ethical Guidelines), COI declaration, Summaries Agenda	Chairperson
b.	Brief presentation and/or address queries on the research proposal and leave meeting prior to decision	Researchers/ subject experts (optional)
c.	Present observations on item reviewed	Primary/ secondary Reviewers
d.	Discuss further on the item and reach consensus	EC members
e.	Record Decision and rejoin member who had declared COI before moving on to subsequent item on agenda	IEC Secretariat / Member Secretary
f.	Record minutes of meeting, ratify approved decisions of exemption/expedited review/ Full board before closing meeting	Member Secretary/ Chairperson

6. Communication with the investigator:

SN	Procedure	Responsibility
a.	Communication of decision and maintaining records.	IEC Secretariat/ Member Secretary
b.	Follow up/monitoring/ analysis of SAE/ handling of issues related to non-compliance, violation, complaints etc.	Member Secretary in consultation with Chairperson

Title:	Emergency or Compassionate use of drugs.
SOP Code:	SOP 23/ V7dated 19th November 2024

Prepared by Signature with date	Reviewed by Signature with date	Approved by Signature with date	Accepted by
19/11/24 Dr. Raakhi Tripathi, Member Secretary, IEC-I	19.11.24 Dr. Nithya Gogtay, Jt. Member Secretary, IEC-I	9/12/2024 Dr. Manju Sengar Chairperson, IEC-I	Institutional Ethics Committee (IEC-I) Established In 1985 Seth G.S. Medical College & K.E.M. Hospital Parel, Mumbai-400 012. IEC-I
	19 Nov 2024 Dr. Vyankatesh Shivane, Member, IEC-I	09/12/24 Dr. Sunil Kuyare Chairperson, IEC-II	Institutional Ethics Committee (IEC-II) Established in 1986 Seth G.S. Medical College & K.E.M. Hospital Parel, Mumbai - 400 012. IEC-II
		09/12/24 Dr. M. G. Karmarkar Chairperson, IEC-III	Institute Ethics Committee-III Established in 1986 Seth G.S. Medical College & K.E.M. Hospital Parel, Mumbai - 400 012. IEC-III

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to identify the administrative process to assist treating physicians to comply with Central Drug Standard Control Organisation (CDSCO) requirements for <Emergency Uses>, <Compassionate Uses>, and <Single Patient Expanded Access>.

2. Scope

This SOP applies to emergency use of drugs. Out side review or emergency meeting may be scheduled to approve life threatening issues, and issues related to emergency drug use in practice.

3. Responsibility

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

4. Activity Table

No.	Activity	Responsibility
1	Call for an emergency meeting or review	IEC Member Secretary and Chairperson
2	Arrangement of an emergency meeting or review	IEC Secretariat
3	Discuss the matter and take a decision	IEC Members, Member Secretary and Chairperson

5. Detailed instructions

5.1 Call for an emergency meeting or review

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

- Urgent issues related to emergency Uses>, <Compassionate Uses>, and <Single Patient Expanded Access>.
- Other reasons, as deemed appropriate by the Chairperson.

5.2 Arrangement of an emergency meeting or review

Contact and inform IEC members

- The Secretariat will endeavor to contact each and every IEC member and inform about the date, time and venue of the meeting as well as the reason for calling for the meeting. For the purpose of calling an emergency meeting, contact by telephone or email to the email address provided by the member would be considered as sufficient.
- The IEC Secretariat/ IEC administrator will check the following required documents:
    - Letter from clinician forwarded by Dean, Seth GSMC & KEMH regarding requirement of emergency use of drug / device.
    - Complete drug/ device information
    - Letter from sponsor/Clinician (clinical dilemma in case of off label use)
- The IEC administrator will prepare packets for distribution to the members containing the information and documents about the matter(s) for which review / Emergency Meeting is scheduled or send the relevant details (incase the documents are too many) via email.
- The IEC administrator will attach a separate sheet with information about meeting date, time, phone numbers, the meeting ID number and an attendance confirmation form to the packets.
- The IEC administrator will refer to and act according to the relevant SOPs depending upon the matter under consideration.

5.3 Policy

- Whenever possible, Clinician are to notify the IEC in advance of a proposed <Emergency Use>.
- Clinician are to notify the IEC in advance of a proposed <Compassionate Uses>.
- cannot be used in a non-exempt systematic investigation designed to develop or contribute to generalizable knowledge.
- < Primary Reviewers> can inform Clinician of whether a proposed use, if carried out as described, will meet CDSCO requirements or whether a use already carried out met CDSCO/DCGI requirements.
- KEMH Clinicians follow "SOP7: (continuing review)" to provide written notification to the Clinician of the results of this SOP.
- The <Emergency Use> of a drug or biologic and <Single Patient Expanded Access> are "research" as defined by CDSCO, the patient is a "subject" as defined by CDSCO, and the CDSCO may require data from an <Emergency Use> to be reported in a marketing application.
- <Single Patient Expanded Access> and <Compassionate Use> require continuing review.
- Initial and continuing review of <Single Patient Expanded Access> and <Compassionate Use> follow this procedure as well to check for any AEs /SAEs along with post trial access issues if patient benefits.

5.4 Discuss the matter and take a decision during the meeting/without meeting in circulation

- The Chairperson/Secretary will determine if there is a quorum (chairperson, secretary and one scientific member and one external member) during the meeting.
- Outside the meeting, it can be circulated to one scientific and one nonscientific person for review.
- The minutes of the emergency meeting would be prepared, distributed, approved and filed as described in the steps above for regular full board meeting.

6. Glossary

Emergency meeting	An IEC meeting that is scheduled outside of a normally scheduled meeting to review study activities that require full IEC review and approval. In order to hold an emergency meeting, a quorum must be maintained throughout the entire discussion. Emergency meetings may be held via teleconference, if applicable.
Compassionate use of drugs	The World Health Organization defines compassionate use (CU) as a "program that is intended to provide potentially life-saving experimental treatments to patients suffering from a disease for which no satisfactory authorized therapy exists and/or who cannot enter a clinical trial.

Title:	**Review of case reports and case series**
SOP Code:	**SOP 24/V7 Dated 19th November 2024**

Prepared by Signature with date	Reviewed by Signature with date	Approved by Signature with date	Accepted by
Dr. Raakhi Tripathi, Member Secretary, IEC-I	Dr. Nithya Gogtay, Jt. Member Secretary, IEC-I	Dr. Manju Sengar Chairperson, IEC-I	IEC-I
	Dr. Swapna Kanade, Member Secretary, IEC-III	Dr. Sunil Kuyare Chairperson, IEC-II	IEC-II
		Dr. M. G. Karmarkar Chairperson, IEC-III	IEC-III

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide criteria to determine if a study case or case series qualifies for review and provide instructions on management, review and approval of a case or case series through the expedited review process by ratification in full board.

2. Scope

This SOP applies to the review and approval of case or case series and documents, which qualify for expedited review by ratification in full board by the IEC.

3. Responsibility

It is the responsibility of the Member Secretary / Chairperson of the Institutional Ethics Committee (IEC) to determine if a case / case series qualifies for an expedited / full board review and if required designate one / two primary reviewers. Designated IEC members (including Member Secretary and/or Chairperson) will be responsible for reviewing the case / case series and related documents within the given time frames. The Member Secretary / Chairperson are responsible to take the decision.

3.1 IEC Secretariat of the Institutional Ethics Committee

The IEC Secretariat will receive and verify the following documents and will forward these documents to the member secretary for further course of action.

- A request / cover letter signed by the faculty / investigator forwarded by Head of the Department to IEC for review.
- The manuscript in its entirety.
- Images accompanying case report/case series (e.g. clinical and imaging)
- Xerox copy of written consent from the patient if prospective.

4. Activity Table

No.	Activity	Responsibility
1.	Receive the submitted documents	IEC Secretariat
2.	Determine case / series for expedited / full board review	Member Secretary / Chairperson
3.	Review of case study/series	Designated IEC Member
4.	Decision of IEC	Secretary/Chairperson
5.	Communicate with the IEC and the Investigator	IEC Secretariat

5. Detailed instructions

5.1 Process of IEC review and requirements from investigator /faculty

- The case report or case series should be submitted **BEFORE** submitting to a peer reviewed journal along with the processing fees.
- The submission should include –
  - A request / cover letter to IEC for review forwarded by HOD
  - The manuscript in its entirety
  - Written consent from the patient in case of prospective case.

    (In the event that the patient is deceased, consent from the next of kin must be included in the submission. In case the next of kin cannot be traced, the investigator must provide evidence that every effort was made to contact the relative/next of kin and that failed)

  - IEC review charges: The review processing fees shall be collected as Rs 500/- for case series and Rs 250/- for case reports. The payment details will be given to the writer via email once the submission is complete.
- The case report/case series should not have ANY personal identifiers.

- If an identifier is required for the case report/case series for advancing medical knowledge [for example the face is not fully hidden], then the consent form must state that so that the patient/next of kin is aware of the same.
- Images accompanying case report/case series (e.g. clinical and imaging)
- The CARE guidelines for the manuscript must be followed.

5.2 Review protocol & give comments and recommendations.

Member Secretary in consultation with chairperson will send the case / case series for review to designated EC member to give their comments and recommendations to the IEC Secretariat within seven days from date of receipt of the proposal.

5.3 Decision of IEC

- Decision about approval will be taken by the member secretary in consultation with Chairperson.
- Decision will be communicated to investigator/ faculty within 14 working days of receipt of proposal.
- The decision will be informed to the IEC members at the next full board meeting.
- If deemed necessary by Primary reviewers, Member Secretary/ Chairperson, the project shall be discussed at the forthcoming full board meeting.
- The review process should be completed and the reply should be given within 14 working days. If by any reason the case / series is taken for full board, then the decision will be communicated within 14 working days after full board meeting.

5.4 Communicate with the IEC and the investigator/faculty.

- The IEC Secretariat will send the no objection letter via mail or Hard copy to the faculty / Investigator if the case / series has no objection.
- If case / series is disapproved or requires resubmission after certain modifications or clarification, this will be informed to the faculty / Investigator. The reasons for disapproval of a case / series will be specified in the letter sent to faculty / Investigator hard copy.

6. Glossary

Case report	A report of 1-2 patients; usually 800-1500 words
Case series	A report of more than 2 patients. Word count will depend upon the journal

Title:	**Audio Visual (AV) Recording of Informed Consent Process**
SOP Code:	**SOP 25/V 7 dated 19th November 2024**

Prepared by Signature with date	Reviewed by Signature with date	Approved by Signature with date	Accepted by
Dr. Raakhi Tripathi, Member Secretary, IEC-I	19-11-24 Dr. Nithya Gogtay, Jt. Member Secretary, IEC-I	9/12/2024 Dr. Manju Sengar Chairperson, IEC-I	Institutional Ethics Committee (IEC-I) Established In 1985 Seth G.S. Medical College & K.E.M. Hospital Parel, Mumbai-400 012. IEC-I
	19 NOV 2024 Dr. Vyankatesh Shivane, Member, IEC-I	09/12/24 Dr. Sunil Kuyare Chairperson, IEC-II	Institutional Ethics Committee (IEC-II) Established in 1986 Seth G.S. Medical College & K.E.M. Hospital Parel, Mumbai - 400 012. IEC-II
		09/12/24 Dr. M. G. Karmarkar Chairperson, IEC-III	Institute Ethics Committee-III Established in 1986 Seth G.S. Medical College & K.E.M. Hospital Parel, Mumbai - 400 012. IEC-III

1. Purpose

The purpose of this SOP is to describe the procedures for Audio-Visual (AV) recording, storage and archival of the informed consent and assent process for regulatory studies.

2. Scope

This SOP applies to all those regulatory clinical trials approved by the DCGI, which require documenting of the written informed consent and assent process.

2.1 An audio-video recording of the informed consent process in case of vulnerable subjects in clinical trials of New Chemical Entity or New Molecular Entity including procedure of providing information to the subject and his understanding on such consent, shall be

2.2 maintained by the investigator for record:

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

2.4 Statement that there is a possibility of failure of IP to provide intended therapeutic effect Statement that in case of Placebo controlled trials, the placebo administered to the subjects shall not have any therapeutic effect

2.5 Any other pertinent information

3. Responsibility

1. IEC will ensure that Principal investigator will conduct AV recording of the informed consent process, store and archive without violating the participant confidentiality as detailed below in section 6.

2. IEC will specifically ask for consent for AV Consenting in addition to the ICF

3. AV recordings may be reviewed by IEC members

4. Applicable rules, regulations and guidelines:

GSR 227-E, New Drugs and Clinical Trials Rules, 2019 published in the Gazette of India dated 19th March 2019.

5. Detailed Instructions for PI to follow:

All basic principles and procedures for the administration and documentation of the informed consent process are described in SOP Initial review of submitted protocol.

1) If the participant is unable to give consent for medical or legal reasons, the consent should be taken from the legally acceptable representative (LAR) and the process recorded.
2) If the participant/LAR is illiterate, then an impartial witness is needed. This person should also be in the frame for the entire duration of the consent process.
3) AV recording should be done with assent wherever applicable.
4) Ensure the following infrastructure is available prior to counseling of potential participant:
   a. The informed consent process should be carried out in the designated area when the following conditions should be met that is -
      i. Free from disturbance
      ii. Well lit
      iii. Ensures privacy for the participant
      iv. Participant should be comfortable
   b. Camera having video facility with
      - ✓ Good resolution (at least1280x720 pixels)
      - ✓ Sufficient memory (at least 4 GB)

- ✓ Sufficient battery backup (at least 2 hours)
- ✓ Show non-editable date & time on video (preferably)
    a. Mike system
    b. Computer/laptop with CD/DVD writer
    c. Blank CDs/DVDs with cover
    d. External Hard disk (at least 500 GB to 1 TB)

5) Before starting the informed consent process (and the AV recording of the same)
   i. Ensure that all the necessary equipment mentioned above is functional.
   ii. The potential participant/LAR/ Impartial witness should be informed that the whole process of taking the consent is being recorded as per Govt. of India notification to ensure that he/she has understood all the potential risks and benefits involved in the study including failure of the IMP, study details and his/her rights for the purpose of documentation and the confidentiality of the same is assured.
   iii. The potential participant/LAR/ impartial witness should be made aware that his/her recording may be shown to government agencies or members from the IEC and independent auditors.
   iv. His/her consent should be documented in a separate ICD that states the same. The process of obtaining signatures of the potential participant/LAR/ impartial witness & Principal Investigator or her designee on this Audio-video consent form should be carried out as per specified in Annexure 2 *AX 02/SOP 25/* V7

6. Actual AV recording process:

i. The PI/Co-I/medically qualified person delegated by the PI and the potential participant/LAR (and if need be the impartial witness) should sit comfortably facing each other / side-by-side in such a way that their faces will be captured in the frame simultaneously.
ii. The PI/Co-I/medically qualified person delegated by the PI should introduce himself/herself by name, designation and his/ her role in the research, and state the current date and time.
iii. Participant/LAR should be requested to introduce his/her name, age and address and in case of LAR, he/she should clearly state relation to actual participant as well as the reason why the participant cannot give consent. Participant/LAR should also state the language he/she understands best and is literate in. The PI/Co-I/medically qualified person delegated by the PI may facilitate this process to ensure all above points are captured in the recording.
iv. In case participant/LAR is illiterate and an impartial witness is needed, the impartial witness should be requested to introduce him/her, give his/her address and state the language that he/she is literate in.
v. The Participant/LAR should state that he has been informed about the fact that the entire consent process is being recorded and that he/she has agreed for the same.
vi. The Informed Consent Process should be carried out as per *AX 08/SOP 05-A/*V7 and *AX 01/SOP 25/* V7:Administering and documenting informed consent.
vii. The participant should be allowed to read the consent document (and this process should be recorded)
viii. The PI/Co-I/medically qualified person delegated by the PI should explain all the elements of the approved ICF in the language best understood by the potential participant
ix. Explanation or narration given by the PI/Co-I/medically qualified person delegated by the PI, all the questions asked by the potential participant/LAR and answers given to them should be clearly audible and recorded.
x. At any point during the consent process, if the participant wishes to take more time to read/ understand the consent document, including, for example, take it home to discuss with relatives the recording shall be stopped mentioning the time of stopping.
xi. The participant/LAR (wherever applicable) should be invited to sign the consent form only after satisfactory answers (in the investigator's judgement) have been given by the participant/ LAR to all the above-mentioned questions.
xii. Participant/LAR should read out all the statements mentioned in ICF as per Schedule-Y and state whether he/she agrees or not for each statement and affix signature/thumb print at the end
xiii. The actual signing process should be recorded.

xiv. The impartial witness should be requested to enter the name and details of the participant and the date the consent is documented. The impartial witness will also be requested to sign and date the consent form.

xv. The PI/Co-I/medically qualified person delegated by the PI will also sign and date the consent form at the end of the process.

xvi. The recording will be stopped after thanking the participant.

- The recording should be checked for completeness and clarity of both audio and video recording.
- No editing should be done on the recording so as to maintain authenticity.
- The computer/laptop should be password protected. The password will be known only to the PI and members of the study team as designated by the PI. A register should be maintained wherein, each time the data is accessed, the details of who accessed thedata, date and reasons for the same this should be entered into the designated register.
- The recording should be then transferred to a CD labeled according to study name, unique identifier assigned to the participant, date and time of the recording, no. of recordings (applicable during re-consenting) and archived in the external Hard drive. The CD should be filed in the participant binder.
- The study participants should be informed that there is possibility of failure of investigational product to provide intended therapeutic effect.
- In case of placebo-controlled trial, the placebo administered to the subjects shall not have any therapeutic effect.

7. Archival

a. The soft copies of the recordings should be stored in a password protected external hard drive for minimum of five years.

b. The original recording in the computer/laptop will be deleted when study is closedout.

8. Annexure

Annexure 1, *AX 01/SOP 25/* V7, Checklist for Monitoring of Audiovisual recording of AV consent Process

Annexure 2, *AX 02/SOP 25/* V7, Guidance document for audio visual recording of AV consent Process

Annexure 1
***AX 01/SOP 25/* V7**

Checklist for Monitoring of Audiovisual recording of AV consent Process

1. Facility where informed consent process should be carried out - (well lit, free from noise, privacy ensured, dedicated room, camera permanently set /temporary arrangement, voice recording to be tested before hand):
   a. Yes_____No_____
   b. Remarks: _____

2. Whether consent for AV recording already taken before start of recording/ it is taken in front of the camera Yes_____No ___

3. Whether elements enlisted in Appendix V of NDCTR is covered during discussion.
   a. Yes_____No_____
   b. Remarks: _____

4. Introduction of each person – name , age (person conducting the informed consent discussion participant/ legally acceptable representative (LAR) wherever relevant / impartial witness wherever relevant) involved during informed consent process and

information about necessity for audiovisual recording - by name, designation and his/ her role in the research, current date and time, enquiry of the language participant understands , showing the consent form in the camera which is going to be used for the study

a. Yes_____No_____
b. Remarks: _____

5. The following minimum elements should feature in the recording of the informed consent process: (Purpose, treatment allotment, randomization , procedure , follow up , benefit/risks, compensation for Participation, Compensation for Study related Injury, nominee name and details , voluntariness and right to withdraw and contact for further information – Investigator name and EC Chair/member secretary name)
   a. Yes_____No_____
   b. Remarks:

6. If Inclusion Criteria has been administered by a designated person who is not medically qualified?
   a. Yes_____No_____
   b. Remarks: _____

7. Is there evidence that subject's queries of a medical nature were answered in the process or assurance was given to clarify the same later?
   a. Yes_____No_____
   b. Remarks: _____

8. The consent is taken in language the participant/ legally acceptable representative (LAR)understands best and is literate in.
   a. Yes_____No_____
   b. Remarks: _____
9. Information to the participant/ LAR and impartial witness (as applicable) that the process of taking the consent is being recorded for the purpose of documentation as required by the government rules.
   a. Yes_____No_____
   b. Remarks: _____

10. Information to the participant/ LAR and impartial witness (as applicable) that the confidentiality of information and privacy of participants is assured.
    a. Yes_____No_____
    b. Remarks: _____

11. Information to the participant/ LAR and impartial witness (as applicable) that the recording may be shown to government agencies or members from the IEC.
    a. Yes_____No_____
    b. Remarks: _____

12. Explanation or narration by the person conducting the informed consent discussion.
    a. Yes_____No_____
    b. Remarks: _____

13. Whether audio-visual recording is performed for all subjects, independently.
    a. Yes_____No_____
    b. Remarks: _____

14. Questions regarding participation asked by the potential participant/LAR are answered satisfactorily.
    a. Yes_____No_____
    b. Remarks: _____
15. Ample time was given to read and understand the consent as per the content?
    a. Yes_____No_____
    b. Remarks: _____
16. Opportunity to discuss the same with family members
    a. Yes_____No_____
    b. Remarks: _____
17. Reading out by the participant/LAR (or having read out by impartial witness) the statements mentioned in Informed Consent
    a. Yes_____No_____
    b. Remarks: _____
18. Stating whether participant agrees or not for each statement.
    a. Yes_____No_____
    b. Remarks: _____
19. Whether checked for participants understanding of the informed consent process
    a. Yes_____No_____
    b. Remarks: _____
20. Documentation of signatures of all those involved in the Informed Consent Process.
    a. Yes_____No_____
    b. Remarks: _____
21. Clarity and completeness of AV recording (pages vis-a- vis timing)
    a. Yes_____No_____
    b. Remarks: _____
22. Check whether re-consenting is done for changes in ICF/LAR inclusion in the beginning if any.
    a. Yes_____No_____
    b. Remarks: _____
23. Check whether re-consenting is done by the same Investigator
    a. Yes_____No_____
    b. Remarks: _____
24. Whether re-consenting is done in same language
    a. Yes_____No_____
    b. Remarks: _____
25. How much timing taken for the re-consent
    a. Yes_____No_____
    b. Remarks: _____
26. Storage of recording in password protected laptop/ desktop computer and/ or hard drive and labelled CD
    a. Yes_____No_____ Remarks: _____
27. Access of AV consent recorded allowed only to the principal investigator and designated members of the study team.
    a. Yes_____No_____ Remarks: _____

Signature of IEC Monitors:

Signature of IEC Monitors

	Name	Signature with date
Lead monitor		
Monitor 1		
Monitor 2		
IEC Admin 1		
IEC Admin 2		

Annexure 2
AX 02/SOP 25/V7
Guidance document for audiovisual recording of AV consent Process

Pre-recording checklist:

1. Equipment is functioning correctly - YES /NO
2. All parties (trial team personnel conducting the consent, the patient and as applicable legally acceptable representative (LAR), impartial witness and/or translator are seated comfortably and are seen within the frame of the video recording. YES /NO
3. All parties are reminded that this AV recording is in compliance with regulatory requirements YES /NO
4. All parties are informed that this AV recording will be kept confidential but can be shown to others as per legal requirements or for ensuring compliance with law. YES /NO

AV recording:

1. Reconfirm that the video recording frame includes all concerned parties. YES /NO
2. The member of the research team should state the date, time, title of the research protocol and the language of the written informed consent document. YES /NO
3. All concerned parties should identify themselves by stating their names, designation and role with respect to the consent process for this research. YES /NO
4. If LAR is involved, he/she should state relation to participant. YES /NO
5. If translator is involved, he/she should confirm that he/she is proficient in the language of the informed consent document as well as the language in which the medically qualified authorized member of the research team is proficient in for the consent process. YES /NO
6. At any point during the recording, any participant may request for a break (*e.g.* to go to the bathroom or answer a phone or if mother want to feed her baby). In such a case, the AV recording shall be stopped mentioning the time of stopping. It will be resumed/ restarted by stating the date and time of restarting the recording. YES /NO
7. The medically qualified authorized member of the research team administering the consent shall use the checklist to ask the potential participant/ LAR questions to document the authenticity of the informed consent process. Translation will be done as applicable. The answers of the participant/ LAR shall be recorded for each point. YES /NO
8. The actual signing process by all concerned parties should also be recorded. YES /NO

Post recording checklist:

1. The memory card/ storage device used in the camera for video recording will be the source document. Check the file for clarity regarding the audio and video recording. YES /NO
2. Rename the file with the unique number for the patient on this research protocol. YES /NO
3. Make backup one by copying that file onto the dedicated external Hard Disk which will be used to document all consent AV recording for a specific research protocol. YES /NO
4. This external HDD should be suitably labeled and password protected. YES /NO
5. Store the external HDD in a secure location to ensure confidentiality. YES /NO
6. Make backup two by copying that file onto a remote cloud storage with encryption using the computer with internet access. YES /NO
7. This should also be suitably located, labeled and password protected. YES /NO

References used for drafting the SOP

- New Drugs and Clinical Trials Rules, 2019 – cdsco [Internet] 2019 June. [updated 2019 March ;cited 2019 June 5]Available from https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf
- National Ethical Guidelines For Biomedical And Health Research Involving Human Participants, Indian Council Of Medical Research,2017-Internet [updated 2017 ;cited 2019 June 5]Available fromhttps://www.iitm.ac.in/downloads/ICMR_Ethical_Guidelines_2017.pdf
- Article link: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6251259/
- National Guidelines for Ethics Committees Reviewing Biomedical & Health Research During Covid-19 Pandemic from https://ethics.ncdirindia.org//asset/pdf/EC_Guidance_COVID19.pdf Last Accessed ON 31st July,2020
- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), INTEGRATED ADDENDUM TO ICH E6(R1): GUIDELINE FOR GOOD CLINICAL PRACTICE E6(R2) from https://www.fda.gov/media/93884/download
- Good Clinical Practices: Guidelines for Clinical Trials on Pharmaceutical Products in India [Internet] New Delhi: CDSCO; 2001. [cited 2013 on July 19]. Central Drugs Standard Control Organization, Directorate General of Health Services, India. Good Clinical Practices for Clinical Research in India. Available from: http://cdsco.nic.in/html/gcp1.html
- National Guidelines For Stem Cell Research - Indian Council of Medical Research & Department of Biotechnology 2017. [updated 2017 ;cited 2017 July 31]Available from http://dbtindia.gov.in/regulations-guidelines/guidelines/national-guidelines-stem-cell-research-%E2%80%93-2017
- The Nuremberg Code(1947)- [updated 2011 March ;cited 2019 June 5]Available from https://globalhealthtrainingcentre.tghn.org/site_media/media/medialibrary/2011/04/BMJ_No_7070_Volume_313_The_Nuremberg_Code.pdf
- The Belmont report: Ethical principles and guidelines for the protection of human subjects of research, United States. (1978)[updated 2018 July 9].- https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html
- WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects, (adopted in 1964, final amendment 2013)- [updated 2019 March ;cited 2019 June 5]Available from https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
- "CFR Title 21". US Food and Drug Administration.[Internet] 2019 July [updated 2018 1stApril; cited 2019 June 5] Available from https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
- Protection of Human Subjects, Title 45 CFR Part 46, Amended on January 2018. Office of Human Research Protection & Department of Health and Human Services, USA- .[Internet] 2019 July [updated 2018 feb 16]; cited 2019 June 5] Available from https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html
- Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants WHO. [Internet] 2019 July [updated 2011]; cited 2019 June 5] -Available from https://apps.who.int/iris/bitstream/handle/10665/44783/9789241502948_eng.pdf;jsessionid=2ECE640AD348DADEE140E9554D4E6964?sequence=1
- International Ethical Guidelines for Health-related Research Involving Humans-CIOMS and WHO2016 [Internet] 2016 [updated 2011]; cited 2019 June 5] Available fromhttps://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf

- Assessment of risk and potential benefit-[Internet] 2017; cited 2019 July 23] Available from https://bioethicsarchive.georgetown.edu/nbac/capacity/Assessment.htm
- NACO Operational guidelines 2019. [Internet] updated 2015(cited on 2019 July 23) Available fromhttp://naco.gov.in/operationalguidelines
- Central Drugs Standard Control Organization Directorate General of Health Services Ministry of Health & Family Welfare Government of India (cited on 2019 July 23) Available from https://cdsco.gov.in/opencms/opencms/en/Medical-Device-Diagnostics/Medical-Device-Diagnostics/
- Central Drugs Standard Control Organization Directorate General of Health Services Ministry of Health & Family Welfare Government of India (cited on 2019 July 23) Available from https://cdsco.gov.in/opencms/opencms/en/Clinical-Trial/clinical-trials/
- National Accreditation Board for Hospitals and Healthcare Providers (NABH) file:///C:/Users/IEC/Downloads/HCO_Manual.pdf

INSTITUTIONAL ETHICS COMMITTEE (IEC) - I, II & III

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	IEC - I	IEC - II	IEC - III
Established on	6th Jan 1987	14th Nov 2008	12th Oct 2019
Related to	Clinical trial, bioavailability and bioequivalence and academic clinical trial as per NDCT Rule 2019	Biomedical health research as per NDCT Rule 2019	Biomedical health research as per NDCT Rule 2019
Registered with	CLA ECR/229/Inst./MH/2013/RR-24 DHR EC/NEW/INST/2019/202	DHR EC/NEW/INST/2019/200	DHR EC/NEW/INST/2019/203
Accredited by	NABH, Certificate No. EC-CT- 2018-0027	-	-