Institutional Ethics Committee (IEC)
Seth G.S. Medical College and K.E.M. Hospital, Parel,
Mumbai, Maharashtra ,India – 400 012.
Web: www.kem.edu

Title: Preparation of Standard Operating Procedures (SOPs) for Institutional Ethics Committee (IEC)

SOP Code:

SOP 01 /V6 dated 15th July 2019

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to define the process for writing, reviewing, distributing and amending SOPs of the Institutional Ethics Committee (IEC), Seth GS Medical College and KEM Hospital, Parel, Mumbai. The SOPs provide clear, unambiguous instructions so that the related activities of the committee are conducted in accordance with Indian laws and relevant, National and International Guidelines.

2. Scope

This SOP covers the procedures of writing, reviewing, distributing and amending the SOPs of the Institutional Ethics Committee (IEC).

3. Responsibility

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

3.1 Secretariat of the Institutional Ethics Committee will

- Co-ordinate activities of writing, reviewing, distributing and amending SOPs
- Maintain on file all current SOPs and the list of SOPs
- Ensure that all the IEC members and involved administrative staff have access to the SOPs
- Ensure that all the IEC members and involved staff are working according to current version of SOPs
- Maintain a file of all past SOPs of the IEC
- Assist Chairperson to formulate an SOP Team

3.2 SOP team (will contain Member Secretary and at least two other members) will:

- 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
- Approve the SOPs
- Sign and date the approved SOPs

3.4 IEC members and involved administrative staff will:

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

4. Activity Table:

No.	Activity	Responsibility
1	Identify the need for new or amending 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 file 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 SOP

Any member of the IEC or Secretariat who would like a revision or notices an inconsistency/ discrepancy / has any suggestions on how to improve the existing SOPs or requests to design an entirely new SOP can put forth his request by using the Request for Formulation of new SOP/ Revision of an SOP Form *AX 04/SOP01/V6* to make a request. This annexure form is submitted to the IEC Chairperson. The SOPs will be updated regularly at the interval of 2 years or if there are major changes whichever is earlier.

The Chairperson will inform all the IEC members about this request in a regular full-board IEC meeting. If the IEC members agree to the request, an appropriate SOP team(s) will be appointed by the Chairperson and designated the task to proceed with the revision process/ formulation process of the SOP. If the IEC members do not agree, no further action will be taken. The Chairperson will inform the person/ IEC member who made the request for modification of the SOP will be informed in writing about the decision.

5.2 Appoint the SOP Team(s)

The Chairperson will constitute an SOP Committee(s) consisting of the member-secretary and two or more members of the IEC who have a thorough understanding of the ethical review process. The SOP writing team will carry out the subsequent steps. (5.3-5.7)

5.3 List all relevant SOPs

- Write down step by step all the procedures of the Institutional Ethics Committee
- Organize, divide 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 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/V6.* Each page of the SOP will bear the header which will have the effective date i.e. the date of approval and validity of the SOPs. 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 by the authors, 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/V6*
- 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 suggestion.

5.7 Preparation and submission of final draft

- IEC Members will review the revised draft SOP at a special meeting.
- The suggestions that are agreed upon by the IEC members present at the special 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 from where by the SOP will be implemented.

5.9 Ensure Implementation and file all SOPs

- The approved SOPs will be implemented from the effective date.
- 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 earlier 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 two 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.

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 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/V6*	List of SOPs of IEC
Annexure 2	*AX 02/SOP 01/V6*	Template for Standard Operating Procedures
Annexure 3	*AX 03/SOP01/V6*	Document History of the SOP
Annexure 4	*AX 04/SOP01/V6*	Request for Formulation of a new SOP/ Revision of an SOP

Annexure 1

AX 01/SOP 01/V6

List of SOPs of Institutional Ethics Committee

No	Title of the Standard Operating Procedures (SOPs)	SOP Code
1.	Preparation of Standard Operating Procedures (SOPs) for Institutional Ethics Committee (IEC)	SOP 01/V6
2.	Constituting Institutional Ethics Committee	SOP 02/V6
3.	Confidentiality / Conflict of Interest Agreements	SOP 03/V6
4.	Selection and Responsibilities of Subject Expert	SOP 04/V6
5.	Management of Initial Protocol Submissions	SOP 05/V6
A	Full Board Review of Submitted Protocol	SOP 05-A/ V6
B	Expedited Review	SOP 05-B/ V6
C	Exemption from the Ethics Review for Research Projects	SOP 05-C/ V6
D	Review of Resubmitted Protocols	SOP 05-D/ V6
6.	Review of Amended protocol/ Protocol related documents	SOP 06/V6
7.	Continuing Review of Study Protocols	SOP 07/V6
8.	Review of Study Completion Reports	SOP 08/V6
9.	Management of Premature Termination / Suspension / Discontinuation of the study / Withdrawal of study before site initiation	SOP 09/V6
10.	Protocol Deviation/Violation	SOP 10/V6
11. (A)	Constituting SAE Subcommittee	SOP 11-A/V6
(B)	Review of Serious Adverse Events (SAE) Reports and Unexpected Adverse Events (UAE)	SOP 11-B/V6
12.	Site Monitoring Visit	SOP 12/V6
13.	Agenda Preparation, Meeting Procedures and Recording of Minutes	SOP 13/V6
14.	Conduct of Emergency Meeting	SOP 14/V6
15.	Maintenance of Active Project Files	SOP 15/V6
16.	Archiving and Retrieving Documents	SOP 16/V6
17.	Responding to Research Participant's Request or Complaint	SOP 17/V6
18.	Management of complaints by investigators	SOP 18/V6
19.	Request for Waiver of Written Informed Consent	SOP 19/V6
20.	Reviewing proposals involving vulnerable Populations	SOP 20/V6
21.	Common Ethic Review of Multicentre Research	SOP 21/V6

Annexure 2

AX 02/SOP 01/V6

Template for Standard Operating Procedures

Effective date: *aa/bb/cccc*	*Short Title*	Page p of q
SOP *xx*/V*y*		
Institutional Ethics Committee Seth G.S. Medical College and K.E.M. Hospital		
Title: Title which is self-explanatory and easily understood		

SOP Code: SOP xx/Vy	
Effective date: aa *bb cccc*	
Authors: xxxxxxxxx	**Signature with date ----------**
Reviewed by: xxxxxxxx	**Signature with date ----------**
Approved by: xxxxxxxxx	**Signature with date ----------**

Table of Contents:

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. **Flow chart:** *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. **References**: *Lists sources of the information given in the SOP*
8. **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/V6

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/V6

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/Vy	
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] [3] [6]	
Date -SOP re-finalized:	
Date -SOP approved:	
Date- SOP becomes effective:	
Signature with date Chairperson, IEC	

Institutional Ethics Committee (IEC)
Seth G.S. Medical College and K.E.M. Hospital, Parel,
Mumbai, Maharashtra ,India – 400 012.
Web: www.kem.edu

Title: Constituting Institutional Ethics Committee

SOP Code:

SOP 02 /V6 dated 15th July 2019

1. Purpose

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

2. Scope

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

3. Responsibility

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

4. Activity Table:

No.	Activity	Responsibility
1.	Ethical basis	Institutional Ethics Committee (**IEC)**
2.	Composition of the Institutional Ethics Committee	Head of the Institute ,Chairperson, IECMembers and Secretariat
3.	Membership requirements	Head of the Institute , Chairperson,
4.	Tenure of Membership	Chairperson, IECMembers and Secretariat
5.	Policy statement of the institution &Appointment of new membersand alternate members:	Head of the Institute
6.	Resignation and disqualification of members	IECMembers and Secretariat
7.	Conditions of appointment	IECMembers 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.	Advisory committee/ Board	Head of the Institute ,Chairperson, IECMembers
12.	IEC staff	Member Secretary
13.	Role of IEC members	IEC
14.	Quorum requirements	IECMembers and Secretariat
15.	Honorarium to the Members/ Independent Consultants	IEC
16.	Responsibilities of IEC	HOI, IEC
17.	Evaluation of IEC/Chairperson/Member Secretary/Members/Staff	HOI, IEC
18.	Prepare an annual activity report of the IEC for submission to the Head of the Institute	IECSecretariat

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 and those funded by intramural funding bodies of KEM Hospital.
- The IECwill function independently without any interference in the review and decision making process from the Head of the Institute and administrative department of the Institute.

Institutional Ethics Committee will have threecommittees, Institutional Ethics CommitteeIEC- I,II and III.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 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.

- 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 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.
- It attempts to inform itself where possible of the requirements and conditions of the various localities where proposed research is being considered.
- The IEC also seeks to 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 (Adopted by the 18thWorld Medical Assembly, Helsinki, Finland, June 1964, and amended by the29th World Medical Assembly, Tokyo, Japan, October 1975; 35thWorld Medical Assembly, Venice, Italy, October 1983; 41st World Medical Assembly, Hong Kong, September 1989; 48th World Medical Assembly, Somerset West, Republic of South Africa, October 1996; and the 52nd World Medical Assembly, Edinburgh, Scotland, October 2000; Note of Clarification on Paragraph 29 added by the World Medical Assembly, Washington 2002; Note of Clarification on Paragraph 30 added by the World Medical Assembly, Tokyo 2004), 59thWMA General Assembly, Seoul, October 2008.
- 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).
- The IEC 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), New Drugs and Clinical Trials, Rules 2019, Indian GCP guidelines (2016)and Ethical Guidelines for Biomedical Research on Human Participants by ICMR (2017).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 IECisestablished and will function in accordance with the relevant national law and regulations in force from time to time.
- The IECwill review only those projects which are carried out in this institution by the staff members and students of the institution.
- The IECwill 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 IECwill be established by the **Head of the Institution (HOI)**.
- The IEC will be multidisciplinary and multi-sectoral in composition.
- The IEC will be composed of at least 7 and a maximum of 15 member. 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 IECwill have representation that is varied in terms of gender, age and social background.
- The Composition shall be as follows:
  - ✓ Chairperson (who will be a member not -affiliated to the institution)
  - ✓ One Member Secretary
  - ✓ 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 independent social scientist/ representative of non-governmental agency
  - ✓ One philosopher, ethicist or theologian
  - ✓ One or more lay person from community
  - ✓ One woman member
- The IECmay appoint an alternate legal expert, lay person from community and a social scientist who can take part in the IEC activities in absence of regular members from the above specified categories. The requirement, appointment and terms of membership will be the same as described below in sections 5.3 to 5.9.
- The will share the expertise of the IEC members from the 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 03/SOP 03/V6)* 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 IECmembers 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/V6andAX 02/SOP 03/ V6*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/V6and AX 02/SOP 03/V6*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/V6 and AX 02/SOP 03/ V6*Confidentiality / Conflict of Interest Agreements)

5.4 Tenure of Membership.

- The tenure of Institutional Ethics Committee memberswill be for a continuous period of three (3) years from the date of appointment.
- The IEC secretariat will initiate the process of filling up the forthcoming vacancies two 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 any number of times.

5.5Policy statement of the institution & appointment of new members and alternate 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 1, SOP2)

b) Appointment of new members and alternate members

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

1. When a regular member completes his/ her tenure.
2. If a regular member resigns before the tenure is completed.
3. If a regular member ceases to be a member for any reason including death or disqualification.
4. To fulfill the membership requirements as per 5.2 of this SOP

ii) 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 provided the potential member fulfils the conditions of appointment as defined in 5.8 of this SOP after discussion by the. 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.

iii) Alternate member(s) will be appointed if deemed necessary by the HOI. The alternate member(s) will substitute a regular member and attend the meeting in absence of the regular member(s). The criteria for selection and membership requirements mentioned in 5.3, 5.4, 5.5 (b), 5.6, 5.7, 5.8 and 5.12 will be applicable to alternate members.

5.6Resignation and Disqualification of Members.

- Resignation: An IECmember 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 IEC member: A member may be disqualified from continuance should IECdetermine 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 IECChairperson or Member-secretary receives a communication in writing (provided by IECmember 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 IECmember 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 IECmeeting 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 IECmeetings: A member may be disqualified from IEC membership if the member fails to attend more than 3 regular consecutive IECmeetings 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 IECmeeting
  (iii) A written communication will be sent to the concerned IECmember 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 IECmember 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 IECmeeting. 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 IECor at the next meeting of IEC.

5.7Conditions of appointment

Members and Independent consultants will be appointed to the IECif 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 IECand/ 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.

5.8 Training of the IEC Members in Research Ethics

- An individual selected as a new member of the IEC will be required to attend two meetings as an 'Observer' before being inducted as a member of the IECMember-secretary or an IECmember will provide an introductory training to the new member.
- All IEC members should undergo refresher course in Good clinical practice (GCP) annually.
- 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.

5.9Hierarchy

- 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 regular committee members with 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 IECmembers will elect a replacement for another term.

5.10 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 responsible for conducting committee meetings, and will lead all discussions and deliberations pertinent to the review of research proposals.
- 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.
- The Chairperson will sign documents and communications related to IECfunctioning.
- 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. The Acting Chairperson will have all the powers of the Chairperson for that meeting.

5.11 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 amongst the committee members.

[3] The administrative staff of the Secretariat will be appointed by the IECand they will be supervised by the Member Secretaries.

[4] The Secretariat shall have the following functions.

- ✓ **Functions of the Member secretary**
  1. To receive research proposals
  2. To organize an effective and efficient tracking procedure for each proposal received.
  3. To prepare, maintain and distribute of study files.
  4. To schedule and organize IEC meetings
  5. To prepare and maintain meeting agenda and minutes.
  6. To maintain IEC documentations and to archive them.
  7. To sign documents and communications related to IEC functioning.
  8. To communicate with the IECmembers and applicants/ investigators.
  9. To notify the Principal Investigator regarding IEC decisions related to the submitted research proposal.
  10. To arrange for training of personnel and IEC members.
  11. To organize the preparations, review, revision and distribution of SOPs and guidelines.
  12. To provide necessary administrative support for IECrelated activities to the Chairperson.
  13. To provide updates on relevant and contemporary issues to ethics in health research as well as relevant contemporary literature to the committee members.
  14. To receive fees and issue official receipts for the same.
  15. To delegate various responsibilities to appropriate and authorized individuals
  16. To ensure adherence of IECfunctioning as per SOPs
- ✓ **Functions of the Joint Member Secretary (**whenever appointed)

  The Joint Member Secretary will perform the same functions of Member Secretary in his/her absence.
- ✓ **Functions of the Administrators**
  1. To support the Member Secretary in executing functions of the IEC.
  2. To perform any other functions as instructed by Member Secretary/ Chairperson.

5.12Roles and Responsibilities of IEC members

- To attend IECMeetings and participate in discussions and deliberations so that appropriate decisions can be arrived at.
- 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 for by the IEC secretariat
- To carry out the work delegated by Chairperson, Member-secretary and Jt. Member-secretary.
- To assist Chairperson, Member-secretary and Jt. Member-secretary in carrying out IECwork as per SOPs
- To add disqualification and debar criteria

5.13Quorum Requirements

- The full board meeting will be held as scheduled provided there is quorum. For the IECmeeting, a quorum will consist of at least 5 members one regular member (preferably onepharmacologist), the social worker, a clinician, the lay person and the legal expert besides Member Secretary and Chairperson. (As per theNew Drugs and Clinical Trials, Rules 2019, for review of each protocol the quorum of IEC should be 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) one woman member.

5.14 Honorarium to the Members/ Independent Consultants

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

5.15Responsibilities 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.

5.16 Evaluation of IEC/ Chairperson / Co-Chairperson / Member Secretary / Members / IECStaff

- The Committee will carry out periodic self-assessment using the 'Self Assessment Tool'

  (http://www.fercap-sidcer.org/selftool.php)not less than 2 times in a year. The member/s and administrative staff will be designated by Chairpersons for carrying out self assessment. The corrective and preventive actions (as required) will be discussed in the full board meeting and will be implemented accordingly.
- Annual Self Evaluation of Chairperson will be done. (AX04/SOP02/V6)
- Annual Evaluation of IECmembers/Member Secretary will be done by Chairperson*(AX05/SOP02/V6)*.The individual feedback will be provided by email to the members.
- Annual Evaluation of IEC staff will be done by Member Secretary (*AX06/SOP02/V6*).

  The individual feedback will be provided to the staff.

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

- The 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

5.18Advisory panel

a) Appointment of new members of advisory panel

- The members of theadvisory panel will be nominated by the Chairpersons of the two Ethics Committees and will be appointed by the**Head of the Institution (HOI).**
- The advisory panel will be composed of at least 5 and a maximum of 20 members. The members should have sufficient experience in the field of research.
- Members should have experience of serving the ethics committee as member / consultant / expert at least of 3-5 years' duration.
- Members should be trained in GCP &updated with recent regulations and guidelines
- Members of the advisory committee can be internal or external to the institute.
- The tenure of the members of advisory panel will be minimum 3 years upto 5 years.
- While forming the advisory panel, it needs to be ensured that the Members in the panel are free from conflict of interests and / or an appearance of a loss of impartiality.

b) Functions of the advisory panel

The primary function of the advisory panel is

- to give advice and / or opinion to the Ethics Committee(s) on any research project, matter or issue that the Ethics Committee needs advice upon

- routine site monitoring as required
- to take advice relating to financial and administrative matters of the Ethics Committees and their staff.
- to address complex ethical questions or internal issues, disputes, etc. that require deliberation or expert opinion of the advisory panel.

c) Procedure for Advisory Panel:

- The Chairman of the Ethics Committee shall upon consensus in the full board, refer the matter/ issue before the Advisory Panel.
- The Chairman of the Advisory Panel, who does not have any conflict of interest or loss of impartiality, shall upon receiving the matter/ issue, form the panel from amongst the Members of the Advisory Panel to consist of a minimum of 5 members in various disciplines, expertise in the matter/ issue before the Advisory Panel, and should have at least one non-medical member. The Chairman shall take care that there is a gender balance in the panel so formed to delve into the issue/ matter.
- In case the Chairman has a conflict of interest, then the next senior most member of the Advisory Panel should form the panel and conduct the issue/ matter as the Chairman of the panel.
- The Advisory Panel so formed by the Chairman shall review the matter/ issue within a period of 10 days (kindly change number of days, if you think appropriate), either via email, phone, conference call, skype, or meeting face to face to discuss the issue before it.
- The Advisory Panel shall have the authority to call upon the papers, records or any relevant material on the issue/ matter before it, and shall conduct a thorough inquiry, where required, to reach a conclusion or a decision or an opinion.
- The Advisory Panel shall send its written opinion or decision to the referring Ethics committee.
- The advisory panel will record the decision on the decision form which will be discussed either by the Member Secretary/ Joint Member Secretary or one of the advisory panel representatives in the upcoming full board meeting of the respective IEC.
- The advisory panel member attending the meeting will give his / her opinions and participate in the discussion however will not be part of the final decision or will not take part in the voting.

d) **Responsibilities of the** advisory panel

- The panel will keep all information submitted to them confidential specially the proprietary information and declare conflict of interest before review if any.
- The panel will maintain concise but clear documentations of its views on the research proposal.

6. Glossary

Confidentiality	Prevention of disclosure, to other than authorized individuals, of IEC/ information and documents
IEC	Institutional Ethics Committeeindependent 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 ClinicalTrialRules, 2019 and to provide public assurance of that protection.
Independent Consultants	Professionals with advanced training and expertise in the medical or non-medical areas related to the protocol being reviewed

7. Annexure

Annexure 1	*AX 01/SOP 02/V6*	Policy statement of the institution
Annexure 2	*AX 02/SOP 02/V6*	IEC Administrative staff: Working rules
Annexure 3	*AX03/SOP02/V6*	Finances Related to Ethics Committee Activities and Functioning
Annexure 4	*AX04/SOP02/V6*	IEC Evaluation Form of Chairs & Co- chairs
Annexure 5	*AX05/SOP02/V6*	IEC Evaluation Form of IEC Member Secretary/Members
Annexure 6	*AX06/SOP02/V6*	IEC Evaluation Form of Staff
Annexure 7	*AX07/SOP02/V6*	Corrective Action and Preventive Action
Annexure 8	*AX 08/SOP 02/V6*	Organizational Chart of the Institution

Annexure 1

AX 01/SOP 02/V6

Policy statement of the institution

(On Letter head of HOI)

Date: _____

The Ethics Committees of Seth G. S. Medical College and K.E.M Hospital, known as the 'Institutional Ethics Committee–I' will continue to review scientific and ethical aspects of all types of research studies involving human participants. It is resolved that IEC-I, II and III are reconstituted on _____ and the new committees will serve for a 3 years term from _____ to _____.
The IEC has been registered with the Central Licensing Authority [Registration nos._____ and _____]will work according to the revised Standard Operating Procedures (SOPs) which have been formulated for this purpose and are effective from ___1st August 2019_____
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 IECshall 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 IECat present follow International Conference on Harmonisation – Good Clinical Practices (ICH-GCP) Guidelines (1996), Indian GCP guidelines (2001), New Drugs and ClinicalTrials,Rules 2019, Declaration of Helsinki and the prevailing amendments from time to time), Ethical Guidelines for Biomedical Research on Human Participants by ICMR (2006)

f. The IECwill review scientific and ethical aspects any human research project in our institute and also be an asset to 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 IEC.

The list of members & alternate members who will serve on the IEC with effect from)_____ are as follows:

a. Xxxxxxxxxx

b. xxxxxxxxxxx

_____ _____

Dr. _____ **Date**
Dean, Seth GSMC and KEMH,
Parel, Mumbai.

Annexure 2

AX 02/SOP 02/V6

The IEC Administrative Staff: Working Rules

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

GeneralManager 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 IECcommittees, there will be one executive assistant to Member secretary working under deputy Manager. One separate executive assistant to Member Secretary will be allotted for SAE Sub-committee who will work directly under the General Manager. Two attendants will work for all three committees as well as SAE subcommittee, each one will be supervised by Deputy Manager. All theseadministrative 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 IECmembers attending a regular IECmeeting 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). 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 IECmembers. 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 ofthe 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 of SAE subcommittee.
- Attending the meetings of all three committees as well as SAE subcommittee.
- Maintain the attendance chart as well as effective of all the administrative staff monthly.
- Managing the financial expenditure of all three committees as well as SAE subcommitteeand 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.
- Co-ordination for the upgrading or modification in the software/hardware of the committee.
- 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
- 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 software data/soft copies are in place and complete.
- Analysis of the data if assigned by the Chairperson/Member Secretary/Committee member.
- 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 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 software data entry.
- Sending the reminder letters, if any.
- Performance of other duties assigned by the Chairperson/Member Secretary/General Manager/Deputy Manager.

[6] 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 software data entry.
- Sending the reminder letters, if any.
- Performance of other duties assigned by the Chairperson/Member Secretary/General Manager/Deputy Manager.

[7] 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.

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

[8] The office timing for the General Manager will be Monday to Friday 09.00 am to 4.00 pm and Saturday 9.00 am to 12.30 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 Assistant will be Monday to Friday 8.30am to 4.30 pm and Saturday 8.30 am to 1.00 pm.

[9] The staff will avail 15 casual leaves and 15 privileges leave every year by making an application. The number of leaves granted per year cannot be accumulated or carried forward to next year. A new staff member will be allowed to avail a casual leave 6 months after joining and privilege leave after completing one year. 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 IECmembers.

[10] The pay revisions will be made according to the recommendations of the IEC. 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 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.

[11] Technical break of seven days will be compulsory for all the administrative staff every six monthly as suggested by DJST.

Annexure 3

AX03/SOP02/V6

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:

1.1.1) Initial Review fee:

The IEC shall charge for initial review fee of the proposal. The charges of the same are dependent on the type of study. Following are the charges for review-

- Pharmaceutical sponsored study – Rs. 60,000/- + TDS (10%)
- Government sponsored study – Rs. 7000/- + TDS (10%)
- Thesis/ Dissertation– Rs. 1000/-(in hard cash).
- All academic non- sponsored projects(**Including DNB, DM, Nursing, PhD Research**)– Rs. 1,500/-project (in hard cash).

1.1.2)Fee for continuing review:

The IECshall charge for continuing review of ongoing pharmaceutical sponsored and government sponsored studies annually. The charges of continuing review is Rs. 10,000/- + TDS(10%)for pharmaceutical sponsored study and Rs. 1,000/- for government sponsored study.

1.1.3) Method of payment:

The payment will be taken by cash or can be paid by cheque drawn infavorof "Diamond Jubilee Society Trust Seth GS Medical College".The review fee for pharmaceutical and government sponsored study will always be accepted through cheque.

1.2) Budget Preparation:

The Committee review fee should be incorporated in budgets or payment of pharmaceutical or government sponsored studies.

1.3) Deposits and Accounting:

The EC administrative staff shall collect the fees (cash or cheque). The deposits shall be made to DJST-EC account (Diamond Jubilee Society Trust-Ethics Committee). 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 shall be shared by DJST.

1.4) Memorandum of Understanding:

The details regarding the role and guidelines of DJST related to the manner of increment of staff salary, utilization of interest amount, purchase of equipments or services through DJST-EC

account are mentioned in MoU between DJST, IEC and the head of the institute. The steps taken in case of dispute between DJST and IECis also discussed in MoU. The MoUalso discusses that IECmust becommunicated in case of any change of norms /guidelines of DJST related to finance.

1.5) 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 etc.
d) Making resources available for office for e.g. purchase of computers, printers, scanners etc.
e) Paying fixed honorarium to external membersof Rs. 1000/- for each meeting attended.
f) SOP and GCP training programmes organized by IEC.
g) IEC members who present papers on research ethics and representing institute IEC in national/international conference.

Annexure 4

AX04/SOP02/V6

IEC Evaluation Form of Chairs & Co- chairs

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

Self – evaluation :☐

Supervisor or other administrator :☐

Member secretary IEC:☐

IEC members or other chairs or vice- chairs :☐

2. Name of the person who is evaluated :

---

3. Number of Meeting attended out of total meetings :☐/☐

4. Number of exempt determination made :☐

5. Number of protocol reviewed by the expedited procedure :☐

6. Number of protocol reviewed that went to the convened IEC:☐

7. Number of reviews completed as the primary reviewer :☐

8. Completion of educational requirements :☐ Yes ☐ No

9. Attendance at educational sessions (Make tick (√) in the column)

Regular :☐

Irregular :☐

10. Number of educational sessions conducted :☐

Evaluation of Chairs & Co- chairs

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

Poor Fair Average Good		Excellent	
1 2 3 4 5			

ii) Contribution to IEC meetings
Scale

Poor Fair Average Good		Excellent	
1 2 3 4 5			

iii) Quality of reviews

Scale

Poor Fair Average Good		Excellent	
1 2 3 4 5			

iv) Communication with IEC staff
Scale

Poor Fair Average Good		Excellent	
1 2 3 4 5			

Feedback-
Signature:
Date:

Annexure 5

AX05/SOP02/V6

IECEvaluation Form for Member Secretary/Members

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

Self – evaluation :☐

Supervisor or other administrator :☐

Member secretary IEC :☐

IEC members or other chairs or vice- chairs: ☐

2. Name of the person who is evaluated: _____

3. Number of Meeting attended out of total meetings :☐/☐

4. Number of exempt determination made :☐

5. Number of protocol reviewed by the expedited procedure :☐

6. Number of protocol reviewed that went to the convened IEC :☐

7. Number of reviews completed as the primary reviewer :☐

8. Completion of required checklist : (Make tick (√) in the column)

Yes: ☐No: ☐

9. Completion of educational requirement : (Make tick (√) in the column)

Yes: ☐No :☐

10. Attendance at educational sessions : (Make tick (√) in the column)

Regular:☐Irregular: ☐

11. Number of educational sessions conducted:☐

12. Preparedness for meetings : (Make tick (√) in the column)

Good: ☐ Average: ☐Poor:☐

13. Contribution to IECmeetings: (Make tick (√) in the column)

Good: ☐Average: ☐Poor:☐

14. Quality of Reviews : (Make tick (√) in the column)

Good: ☐Average: ☐Poor:☐

15. Communication with IECstaff : (Make tick (√) in the column)

Good: ☐Average: ☐Poor:☐

Annexure 6
AX06/SOP02/V6
IEC Evaluation Form of Staff

1. Mention (√) the individual who is performing the evaluation:
   Self – evaluation :
   Member secretary IEC:
   Name of the person who is evaluated :

2. Handles workload efficiently : (Make tick (√) in the column)

   Yes: ☐ No: ☐

3. Number of protocol processed that were reviewed by the expedited procedure :☐

4. Number of protocols processed that went to the convened IEC :☐

5. Completion of required checklists and documentation : (Make tick (√) in the column)

   Yes: ☐No:☐

6. Maintains paper files efficiently and correctly : (Make tick (√) in the column)

   Yes:☐No: ☐

7. Prepares agenda and minutes in timely manner : (Make tick (√) in the column)

   Yes: ☐ No: ☐

8. Maintain IEC rosters efficiently and correctly : (Make tick (√) in the column)

   Yes: ☐ No: ☐

9. Prepare IEC records efficiently and correctly : (Make tick (√) in the column)

   Yes:☐No: ☐

10. Completion of educational requirement : (Make tick (√) in the column)

    Yes:☐No: ☐

11. Attendance at educational sessions : (Make tick (√) in the column)

    Yes:☐No: ☐

12. Number of educational sessions conducted :☐

13. Preparedness for meetings : (Make tick (√) in the column)

    Good: ☐Average: ☐Poor:☐

14. Quality of pre-reviews : (Make tick (√) in the column)

    Good: ☐Average: ☐Poor:☐

15. Communication with IEC chair and vice-chair : (Make tick (√) in the column)

    Good: ☐Average: ☐Poor:☐

16. Communication with supervisor: (Make tick (√) in the column)

    Good: ☐Average: ☐Poor:☐

17. Communication with investigators : (Make tick (√) in the column)

Good: ☐Average: ☐Poor:☐

18. Ability to help investigator :

Good: ☐Average: ☐Poor:☐

Feedback-

Signature:

Date:

Annexure 7
AX07/SOP02/V6
Corrective Action and Preventive Action

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

Scope: This SOP covers the corrective and preventive action concerninginformation and procedures followed by the Institutional Ethics Committee (IEC).

1.2) Responsible individuals: All ethics committee members.

1.3) Definitions: Corrective and Preventive Action (CAPA) Plan: actions taken to collect information and identify a problem, determine root cause, identify and implement a corrective and/or preventive action to prevent further recurrence.

1.4.1) Root Cause: factor that caused a nonconformance and should be permanently eliminated through process improvement.

1.4.2) Root Cause Analysis: is a class of problem solving methods used to identify the root causes of problems or events.

1.4.3) Corrective Action: Immediate action to a problem that has already occurred or has been identified.

1.4.4) Preventative Action: Taken to eliminate the root cause of a potential problem including the detection/identification of problems.

1.5. 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.

1.6. Procedure -

1.6.1)The problems related to evaluation of members must be bought to the notice by member secretary/chairperson.

1.6.2) The Chairperson will form a team of 3 members.

1.6.3) The team formed will evaluate the magnitude of the problem and potential impact of the issue on the overall functioning of Ethics Committee

1.6.4) Describe the reason for the issue and identify the root cause of the problem.

1.6.5) Describe the procedures implemented to resolve the problem. Mention the time period required for its resolution.

1.6.6) Describe the preventive actions taken or planned.

1.6.7) After the corrective procedures are implemented, evaluation of the procedures must be made after due course and submitted by 3 membered team to Chairperson.

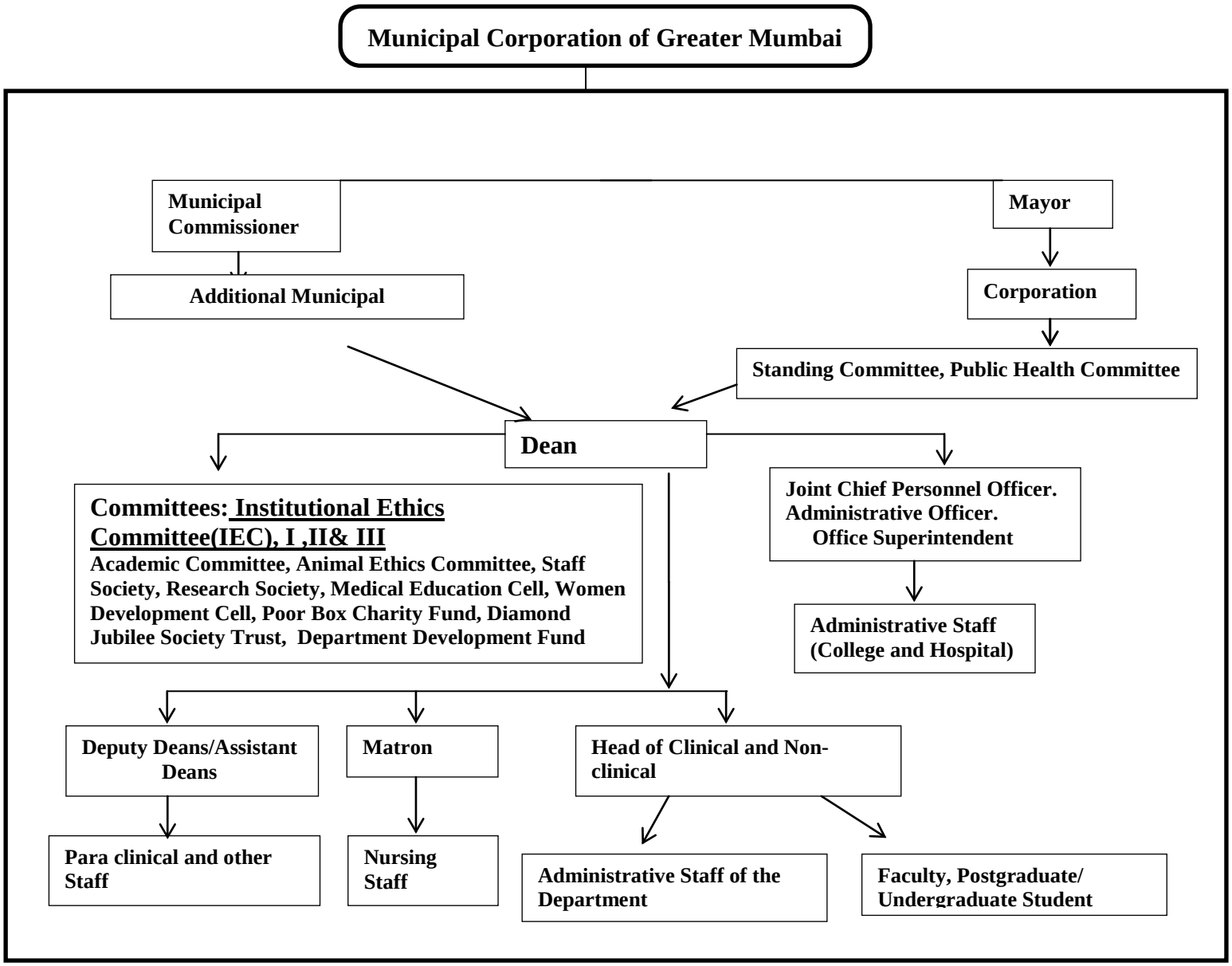
1.6.8) The problems related to evaluation of members, procedures implemented to resolve the problem and the corrective and preventive action will be discussed with permission of chairperson in full board.

1.6.9) 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'.

Annexure 8

AX 08/SOP 02/V6

Organizational Chart of the Institution



Institutional Ethics Committee (IEC)
Seth G.S. Medical College and K.E.M. Hospital, Parel,
Mumbai, Maharashtra, India – 400 012.
Web: www.kem.edu

Title: Confidentiality / Conflict of Interest Agreements

SOP Code:

SOP 03 /V6 dated 15th July 2019

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 members reviewing 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 member of 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 an members 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 Independent Consultant (IC) 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 Independent Consultants 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, Independent Consultant	IEC, Secretariat
2	Read the text carefully and thoroughly	IEC, members / guest attendees / observers / Independent Consultant
3	Clarification of doubts, if any	IEC, members / guest attendees / observers / Independent Consultant
4	Sign and indicate consent	IEC, members / guest attendees / observers / Independent

		Consultant
5	Keep the agreement in mind	IEC, members / guest attendees / observers / Independent Consultant

Mandate

- *GSR 227 (E). Chapter III & IV , New drugs and clinical trials, 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 on conflict of interest.

2.4.2.6. "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".

56.107 "No Institutional Ethics Committee (IEC), may have a member participate in the ethics committee's initial or continuing review of any project in which the member *h*as a conflicting interest, except to provide information requested by the IRB. [45CFR 46.107(e) and 21 CFR 56.107(e), Sec. 56.107 IEC membership".

5. Detailed instructions

5.1 Provide appropriate forms to IEC member, Guest attendees, Observers, Independent Consultant

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

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/ V6 and AX 02/SOP 03/V6,*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 /Conflict of Interest Agreement Form *AX 03/SOP 03/V6*carefully and thoroughly
- Every Independent Consultant / 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 04/SOP 03/V6*carefully and thoroughly
- IEC, committee member, Guest attendee, observer, Independent Consultant, 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/Independent Consultants have any doubts, need clarifications or if any part or sentences is not clear, 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, Independent Consultants / advisory committee/ board member will sign and date the document before a member of the Secretariat.
- They will give the signed form back to the Secretariat
- The Secretariat will obtain the signature of the IEC, Chairperson on the Confidentiality /Conflict of Interest Agreement Form.
- The secretariat will provide IEC , member, Guests or observers for IEC meetings, Independent Consultants 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 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, Independent Consultants (IC)'
- The Secretariat will store the file in a secure cabinet with limited key holders.

5.5 Keep the Agreement in mind.

- The IEC, members/Guests /observers for Institutional Ethics Committee meetings/Independent Consultants / advisory committee/ board member must implement the clauses of the signed Confidentiality Agreement Form as in *AX 01/SOP 03/V6,AX 03/SOP 03/V6*and *AX 04/SOP 03/V6 r*espectively.

6. Glossary

Confidentiality	The nonoccurrence 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. An important point that must be covered in any confidentiality agreement is the standard by which the parties will handle the confidential information. The agreement must establish a time period during which disclosures will be made and the period during which confidentiality of the information is to be maintained.
Conflict of	Conflict of interest (COI) is a set of conditions where professional judgement concerning

Interest	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 or political). [Available from https://www.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf. Last accessed on 05.06.2019] Conflict of interest is a set of conditions in which professional judgment concerning a primary interest like patient's welfare or the validity of research tends to be or appears to be unduly influenced by a secondary interest like non-financial (personal, academic or political) or financial gain. [*http://icmr.nic.in/ethical_guidelines.pdf accessed on 23rd Nov 2015*]. **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/V6*	Confidentiality Agreement Form for IEC, members
Annexure 2	*AX 02/SOP 03/V6*	Conflict of Interest Agreement Form for IEC Members
Annexure 3	*AX 03/SOP 03/V6*	Confidentiality Agreement for Guest/Observer Attendees to IEC Meetings

Annexure 4 *AX 04/SOP 03/V6* Confidentiality Agreement Form for Subject Experts (Affiliated / nonaffiliated to the institution)

Annexure 1

AX 01/SOP 03/V6

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 Information Act, not to disclose the Confidential Information to any person; 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/V6

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/V6

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. 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 as 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/V6

Confidentiality Agreement Form for Subject Experts/ advisory committee/ board member

(Affiliated / nonaffiliated 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 as Confidential.

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

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

_____ **_____**

Signature **Date**

Annexure 5

AX 05/SOP 03/V6

Confidentiality Agreement Form for Institutional Funding Societies

I,_____

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

_____ **Signature of the member/ staff of Funding Society**	_____ **Date**
_____ **Chairperson of IEC-I**	_____ **Date**
_____ **Chairperson of IEC-II**	_____ **Date**
_____ **Chairperson of IEC-III**	_____ **Date**

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

_____ _____

Signature **Date**

Institutional Ethics Committee (IEC)
Seth G.S. Medical College and K.E.M. Hospital, Parel,
Mumbai, Maharashtra ,India – 400 012.
Web: www.kem.edu

Title: Selection and Responsibilities of Subject expert

SOP Code:

SOP 04 /V6 dated 15th July 2019

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide procedures for Obtaining the expertise of a professional as an 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) 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 an 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 will be either 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

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 *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 04/SOP 03/V6* -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 04/SOP 03/V6*.

5.6 Reviewing documents pertaining to research project

- The Secretariat will provide study protocol documents along with the Study Assessment Form for subject experts *AX 01/SOP 04/V6* to the subject expert after Confidentiality and Conflict of Interest documents 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 04/SOP 05-A/V6*. 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 the decision making process on the project

5.7 Termination of the Services

As the subject expert is appointed for a particular task or project and the services of subject expert get automatically terminated once the final decision regarding the project is taken by the IEC. The IEC will document the termination of the services of subject expert by providing a letter thanking the subject expert for the services rendered . 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	*AX 01/SOP 04/V6*	Study Assessment Form for subject expert

Annexure 1

AX 01/SOP 04/V6

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:**	_____ _____

(Selection and Responsibilities of Subject expert)

Institutional Ethics Committee (IEC)
Seth G.S. Medical College and K.E.M. Hospital, Parel,
Mumbai, Maharashtra ,India – 400 012.
Web: www.kem.edu

Title: Management of Initial Protocol Submissions

SOP Code:

SOP 05 /V6 dated 15th July 2019

1. Purpose

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

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 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 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 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 eligibility of Principal Investigator(PI) and completion of registration process on e-EC	IEC Secretariat
2	Receive Submitted Packages	IEC Secretariat
3	Verify submission as per checklist	IEC Secretariat
4	Allocation of protocols to member secretary for selection of Primary Reviewers (PR)	IEC Secretariat
5	Decision on **type of review** required and selection of primary reviewers a) Full Board Review (refer SOP 05-A) b) Expedited Review (refer SOP 05-B) c) Exempt from Review (refer SOP 05-C)	Member Secretary
6	Distribute submission packages to reviewers	Member Secretary

5. Detailed instructions

5.1 Verify eligibility of PI and completion of registration process on e-EC

IEC secretariat will verify eligibility of PI by reviewing the information submitted by the PI (Refer Annexure 7, *AX 07/SOP 05/V6*):
Once registered, PI can forward the project to IEC admin using e-EC software.
Definition of Principal investigator (PI): (as per policy decision13 march 2014):
Principal investigator must be a faculty / employee of Seth G. S. Medical College and KEM Hospital and have appropriate graduate/post graduate qualification approved by respective statutory council.

If PI is retired/promoted/transferred/disaster/suspended/intended to leave the institute then, either he/she should authorize or Co-PI can take responsibility of PI with permission from departmental head.
For e-EC software submission, only PI can forward the project to IEC.

5.2 Receive submitted packages

IEC admin will view and review the submission and will perform the actions against the project submission. Upon review of submission if application found to be complete IEC admin will enter with details of submission. IEC admin will then take the action depending on observations (Refer annexure 10 Guidance document for IEC Admin).

5.3 Initial Review Application

5.3.1 Check for submission items

- The Secretariat will check the soft copies of all types of studies and hard copy for regulatory studies (1 hard copy for regulatory/non-regulatory studies if needed) of following items
  1. A completely filled IEC Project Submission Application Form for Initial Review (As per Research Project)
  2. Delegation of Responsibilities of Study team *AX 05/SOP 05/V6*
  3. Document Receipt Form *AX 06/SOP 05/V6*

5.3.2 Verify submission as per checklist

The Secretariat will:

- Check if all relevant and applicable forms and documents are in the submitted package being submitted to the IEC office. The correctness of the IEC application form will be assessed at the time of submission by the secretariat. Verify the completeness of the contents of the protocol submitted package to include the following documents:
  - ✓ Project submission application form for initial review and any additional form as per the requirement
  - ✓ Covering letter to Member Secretary/ Chairperson mentioning type of review requested
  - ✓ Protocol, to include
    a) Title of the Protocol
    b) Name and contact details of Principal Investigator
    c) Name and contact details of Sponsor
    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 Annex AX 06/SOP 05/V6)
  - ✓ Informed consent document in Regional languages (Hindi & Marathi)

- ✓ Back translations of Informed consent documents
- ✓ Translation and Back translation certificate
- ✓ 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
- ✓ 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
  - ➢ A copy of Administrative sanction from the head of the Institution 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 Principle investigator and study team members.
- ✓ Investigator's agreement with Sponsor
- ✓ Memorandum of Understanding (MOU) between collaborative institutions/LoU in case of common review

  (On Rs 100 stamp paper, tripartite with terms of agreements specified clearly)
- ✓ Sanction letter for central government funding bodies
- ✓ Entire Insurance policy with certificate
- ✓ Ethics Committee clearance of other centers (if applicable)
- ✓ Institutional Stem cell committee approval (if applicable)
- ✓ Any additional document(s), as required by IEC (Cheque/ Demand Draft drawn in the name of "Diamond Jubilee Society Trust, Seth GS Medical College and KEM Hospital" towards payment of IEC processing fees, as decided upon by the IEC from time to time)

5.4 Complete the submission process

- **IEC Admin Review Actions**

Upon Review of submission, IEC Admin may choose one of the following action depends on his observations.

- ➢ **Forward (to IEC MS)**

The Administrative Officer/ any one designated by IEC will

If online application found to be complete, IEC Admin will enter following details (depends on submission type):

- ✓ Processing Fee Paid (Yes/No)
- ✓ Hard copy of project documents submitted (Yes/No)

Stamp the receiving date on the first page/last page of the covering letter, on the first page of received documents and IEC admin will assign the inward number for hard copies.

- ✓ Reviewed by (IEC Staff / Admin Name, signature and date)
- ✓ Project Number (textbox for entering allotted Project Number)

The project number will be assigned by the IEC admin as per following submission types:

For clinical trial, bioavailability and bioequivalence studies	Pharmaceutical sponsored clinical trial	EC/CT/PHARMA Number 00)/ year (00)
	Government sponsored clinical trial	EC/CT/GOVT Number (00)/ year (00)
	Academic/investigator initiated clinical trial	EC/CT/OA Number (00)/ year (00)
	Thesis /dissertation clinical trial	EC/CT Number (00)/ year (00)
For Biomedical and Health Research trials	Pharmaceutical sponsored trial	EC/PHARMA Number (00)/ year (00)
	Government sponsored trial	EC/GOVT Number (00)/ year (00)
	Academic/investigator initiated trial	EC/OA Number (00)/ year (00)
	Thesis /dissertation trial	EC/Number (00)/ year (00)

e.g. EC/PHARMA 01/19 will indicate pharmaceutical sponsored study with number 01 of the year 2019.

Stamp the receiving date on the first page/last page of the covering letter, on the first page of received documents and IEC admin will assign the inward number for hard copies.

Keep the copies of the submitted documents with original signatures in the protocol "Submission" files.

Allocation of Projects among IECs

- All clinical trials, academic clinical trial and pharmaceutical sponsored studies will be allocated to IEC-I.
- All government sponsored and academic projects will be alternatively distributed to either IEC-I, IEC-II or IEC-III member secretaries *for the further actions*.

- **Return (to PI)**

The incomplete submissions will be returned back to the respective investigator with mentioning reason for the same.

5.5 Saving / Storage packages

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

1. e-EC software cloud based
2. Google drive
3. 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.

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-A/V6)
b. Expedited Review (refer SOP 05- B /V6)
c. Exempt from Review (refer SOP 05-C/V6)

5.4 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 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.

7. Annexure

Annexure 1	-	Application Form for Initial Review for all types of trials.
Annexure 2 (ICMR Form Annexure 8)	-	Application Form for Clinical Trials
Annexure 3 (ICMR Form Annexure 10)	-	Application Form for Human Genetics Testing Research
Annexure 4 (ICMR Form Annexure 11)	-	Application Form for Socio-Behavioural and Public Health Research
Annexure 5	*AX 05/SOP 05/V6*	Delegation of Responsibilities of Study team
Annexure 6	*AX 06/SOP 05/V6*	Document Receipt Form
Annexure 7	*AX 07/SOP 05/V6*	Guidelines for Investigators
Annexure 8	*AX 08/SOP 05/V6*	Sample format of an Informed Consent Document
Annexure 9	*AX 09/SOP05/V6*	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/V6*	Format for submission of an Informed Consent Document for Genetic Studies
Annexure 11	*AX 11/SOP 05/V6*	Departmental Review Board (DRB) Guidance Document
Annexure 12	*AX 12/SOP 05/V6*	Guidance document for IEC Admin

Annexure 1

Application Form for Initial Review.

Logo of the Institute

Application Form for Initial Review

..... *(Name of the Institution)* **EC Ref. No.** *(For office use):*

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

SECTION A - BASIC INFORMATION

1. ADMINISTRATIVE DETAILS

(a) Name of Organization: .....

(b) Name of Ethics Committee: .....

(c) Name of Principal Investigator: .....

(d) Department/Division: ..... (e) Date of submission: dd mm yy

(f) Type of review requested[1]:

Exemption from review ☐ Expedited review ☐ Full committee review ☐

(g) Title of the study: .....

.....

.....

Acronym/ Short title, (If any): .....

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

(i) Details of Investigators:

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

(j) Number of studies where applicant is a:

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

(k) Duration of the study: .....

[1] *Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017 on Page 36 Table 4.2. for types of review*
[2] *Include telephone/mobile, fax numbers and email id*

Version 1.0 *01*

2. FUNDING DETAILS AND BUDGET

(a) Total estimated budget for site: .....

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

.....

SECTION B - RESEARCH RELATED INFORMATION

3. OVERVIEW OF RESEARCH

(a) Lay summary[3] (within 300 words): .....

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(b) Type of study:

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

.....

4. METHODOLOGY

(a) Sample size/ number of participants *(as applicable)*

At site..... In India..... Globally .....

Control group..... Study group .....

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

.....

.....

.....

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.....

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

Version 1.0 *02*

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

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

Independent external review ☐ Review by sponsor/Funder ☐ Review within PI's institution ☐

Review within multi-centre research group ☐ No review ☐

Date of review: dd mm yy

Comments of scientific committee, if any (100 words)

.....

.....

.....

.....

SECTION C: PARTICIPANT RELATED INFORMATION

5. RECRUITMENT AND RESEARCH PARTICIPANTS

(a) Type of participants in the study:

Healthy volunteer ☐ Patient ☐ Vulnerable persons/ Special groups ☐

Others ☐ *(Specify)* .....

Who will do the recruitment? .....

Participant recruitment methods used:

Posters/ leaflets/Letters ☐ TV/Radio ads/ Social media/ Institution website ☐ Patients / Family/ Friends ☐ 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 yrs	☐	Pregnant or lactating women	☐
Differently abled (Mental/Physical)	☐	Employees/Students/Nurses/Staff	☐
Elderly	☐	Institutionalized	☐
Economically and socially disadvantaged	☐	Refugees/Migrants/Homeless	☐
Terminally ill (stigmatized or rare diseases)	☐		
Any other *(Specify)*:	☐	.....	

iii. Provide justification for inclusion/exclusion .....

.....

.....

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

.....

.....

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

Version 1.0 *03*

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

If yes, Monetary ☐ Non-monetary ☐ *Provide details*

.....

.....

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

If yes, Monetary ☐ Non-monetary ☐ *Provide details*

.....

.....

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

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

.....

.....

6. BENEFITS AND RISKS

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

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

Less than Minimal risk ☐ Minimal risk ☐

Minor increase over minimal risk or low risk ☐ More than minimal risk or high risk ☐

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

.....

.....

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

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

.....

.....

.....

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

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

If Yes, Specify .....

.....

.....

7. INFORMED CONSENT

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

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

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

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

Version 1.0 *04*

SECTION E: DECLARATION AND CHECKLIST [10]

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.
☐	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.
☐	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 confidentiality of 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 PI: .....

Signature: ..... dd mm yy

Name of Co-PI: .....

Signature: ..... dd mm yy

Name of Co-PI: .....

Signature: ..... dd mm yy

[10] *These formats are adaptable and can be modified by the Ethics Committee members depending on their needs and requirements*

Acknowledgement for Receipt of Application (Copy to be provided to PI)

Version 1.0 *07*

12. CHECKLIST

S. No	Items	Yes	No	NA	Enclosure No	EC Remarks (If applicable)
ADMINISTRATIVE REQUIREMENTS						
1	Cover letter	☐	☐	☐		
2	Brief CV of all Investigators	☐	☐	☐		
3	Good Clinical Practice (GCP) training of investigators in last 3 years	☐	☐	☐		
4	Approval of scientific committee	☐	☐	☐		
5	EC clearance of other centers*	☐	☐	☐		
6	Agreement between collaborating partners*	☐	☐	☐		
7	MTA between collaborating partners*	☐	☐	☐		
8	Insurance policy/certificate	☐	☐	☐		
9	Evidence of external laboratory credentials in case of an externally outsourced laboratory study QA/QC certification	☐	☐	☐		
10	Copy of contract or agreement signed with the sponsor or donor agency	☐	☐	☐		
11	Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs/Regulatory authorities for proposed study (whether in same location or elsewhere) and modification(s) to protocol	☐	☐	☐		
PROPOSAL RELATED						
12	Copy of the detailed protocol[11]	☐	☐	☐		
13	Investigators Brochure (If applicable for drug/biologicals/device trials)	☐	☐	☐		
14	Participant Information Sheet (PIS) and Participant Informed Consent Form (ICF)(English and translated)	☐	☐	☐		
15	Assent form for minors (12-18 years) (English and Translated)	☐	☐	☐		
16	Proforma/Questionnaire / Case Report Forms (CRF)/ Interview guides/ Guides for Focused Group Discussions (FGDs) (English and translated)	☐	☐	☐		
17	Advertisement/material to recruit participants (fliers, posters etc)	☐	☐	☐		

PERMISSION FROM GOVERNING AUTHORITIES

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

ANY OTHER RELEVANT INFORMATION/DOCUMENTS RELATED TO THE STUDY

	Item	YES	NO	NA	Enclosure no.	EC remarks
28						
29						

**For multicentric research.*
MTA-Material transfer agreement; CTRI-Clinical Trial Registry-India; DCGI-Drug Controller General of India; HMSC- Health Ministry's Screening Committee; NAC-SCRT- National Apex Committee for Stem Cell Research and Therapy; IC-SCR-Institutional committee for Stem Cell Research; RCGM- Review Committee on Genetic Manipulation; GEAC- Genetic Engineering Approval Committee; BARC- Bhabha Atomic Research Centre
[11] Refer to National Ethical Guidelines for Biomedical & Health Research Involving Human Participants 2017, section 4 Page no. 35 Box 4.4(b)

Version 1.0 *08*

(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 yrs parental/LAR consent ☐ Verbal assent from minor (7-12 yrs) along with parental consent ☐ Written assent from minor (13-18 yrs) along with parental consent ☐

Audio-Video (AV) consent ☐ Other ☐ *(specify)* .....

(c) Who will obtain the informed consent?

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

Any tools to be used .....

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

English ☐ Local language ☐ Other ☐ *(Specify)*.....

List the languages in which translations were done .....

If translation has not been done, please justify .....

.....

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

.....

.....

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

.....

.....

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

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

.....

8. PAYMENT/COMPENSATION

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

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

.....

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

If yes, then who will provide the treatment? .....

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

Sponsor ☐ Institutional/Corpus fund ☐ Project grant ☐ Insurance ☐

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

.....

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

[8]Enclose undertaking from PI confirming the same

Version 1.0 *05*

Annexure 2
Application form for Clinical Trials

(Annexure 8)

Application Form for Clinical Trials

Logo of the Institute

.....

(Name of the Institution) **EC Ref. No.** *(For office use):*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

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

   CTRI registration number: ..... NABH accreditation 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

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

   .....

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

   .....

   .....

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

   .....

   .....

Version 1.0

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

.....

.....

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

If yes, Name and Contact details: .....

.....

.....

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

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

.....

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

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

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.....

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

.....

.....

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

.....

.....

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

.....

.....

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

If yes, (100words).....

.....

.....

.....

.....

Version 1.0

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

   If Yes, provide details[22].....

   .....

   .....

   .....

10. Provide details of anticipated incidence, frequency and duration of adverse events related to the intervention.

    If yes, what are the arrangements made to address them ? Yes ☐ No ☐ NA ☐

    .....

    .....

    .....

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

    .....

    .....

    .....

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

    If no, please justify.

    .....

    .....

    .....

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

    .....

    .....

    .....

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

    .....

    .....

    .....

    .....

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

    .....

    .....

    .....

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

Version 1.0

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

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

.....

List the languages in which translations were done .....

Justify if translation not done.....

.....

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

18. Provide details of insurance coverage of trial Yes ☐ No ☐

.....

.....

.....

I. Medical Council of India (MCI) or the State Medical Council registration details of Principal Investigator

Yes ☐ No ☐

.....

.....

II. GCP training in last 3 years by investigators. Please enclose PI certificate Yes ☐ No ☐

Signature of PI: ..... dd mm yy

Version 1.0

Annexure 3
Application Form for Human Genetics Testing Research

(Annexure 10)

Application Form for Human Genetics Testing Research

Logo of the Institute

.....

(Name of the Institution) **EC Ref. No.** *(For office use):*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Describe the nature of genetic testing research being conducted.
   (e.g.- screening/gene therapy/newer technologies/human embryos/foetal autopsy)
   .....
   .....
   .....
   .....
2. 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 counseling)
   .....
   .....
   .....
5. Is there involvement of secondary participants? Yes ☐ No ☐ NA ☐
   If yes, will informed consent be obtained? State reasons if not. Yes ☐ No ☐ NA ☐
   .....
   .....
6. What measures are taken to minimize/mitigate/eliminate conflict of interest?
   .....
   .....
   .....
7. Is there 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 trial? If yes, is there approval from local EC and DBT[23] ? Yes ☐ No ☐ NA ☐

Signature of PI: ..... dd mm yy

[23] *Department of Biotechnology*

Version 1.0

Annexure 4

Application Form for Socio-Behavioural and Public Health Research

(Annexure 11)

Application Form for Socio-Behavioural and Public Health Research

Logo of the Institute

.....

(Name of the Institution) **EC Ref. No.** *(For office use):*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Data collection method used in the study

Focus group	☐	Questionnaire/Survey	☐	Observation	☐
Interviews	☐	Documents and records	☐	Ethnographies/Oral history/Case studies	☐
Others *(Specify)*	☐				

.....

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

.....

.....

.....

2. Type of informed consent 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.

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.....

.....

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 ☐

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Version 1.0

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

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

Invasive ☐ Potentially harmful ☐ Emotionally disturbing ☐ Involving disclosure ☐

Describe the risk minimization strategies.

.....

.....

.....

.....

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

.....

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.....

III. Describe how do societal benefits outweigh individual harm.

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.....

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

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.....

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.

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.....

.....

Signature of PI: ..... dd mm yy

Version 1.0

Annexure 5

AX 05/SOP 05/V6

Delegation of Responsibilities of Study team

Date: _____

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
		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/V6

Document Receipt Form for initial review

Protocol Number:	**Received number:**	**Project Submitted date:**
Protocol Title:	_____ _____	
Principal Investigator:		
Department		
Communication with the IEC :	**E-mail address** Phone Fax	
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) :		
Date on which documents received:		

Note:

For e-EC initial submission investigator will receive an acknowledgement email instead of document receipt form

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.

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

Annexure 7

AX 07/SOP 05/V6

Guidelines for Investigators

1. All the studies qualifying as 'clinical research' need to be submitted for the Institutional Ethics Committees review.
2. 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** and those funded by Research Society of KEM Hospital, Diamond jubilee Society trust will need an approval by the **Institutional Ethics Committee (IEC)** before commencing a study.
3. Location and Office Address (current):

   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 4.00 p.m.

   Saturday - 10.30 a.m. to 12.00 noon

   The office will remain closed on Sundays, all public holidays and last working day of every month.
4. There will be no meetings held in the month of May and November (during college vacations). 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.
5. 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.

6. General responsibilities of PI and Co-PI

   - **MMC/MCI :**

   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.

- **Updated CVs: (As per ICMR Annexure 13, kem.edu,** http://ethics.ncdirindia.org/Common_forms_for_Ethics_Committee.aspx)

Investigators responsible for conduct of clinical trials are adequately qualified, experience.

- **GCP:**

Investigators are knowledgeable in 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.

- **Investigators site specific SOPs for regulatory studies:**

Investigator should prepare the site specific SOPs which should be approved by the IEC and one copy should be handed over to the IEC for IEC records. Site specific SOPs should also cover the following elements related to the conduct of the clinical trial.

a. Updated investigators Brochure and clinical trial oversight plan
b. Work delegation log signed by the PI
c. SOP/Policy document to ensure continuity of trial in case of staff and investigator attrition
d. 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 the recruited subjects rights safety and wellbeing is not compromised.

6. The IEC is currently following the version 6 dated 15th July 2019 of the Standard Operating Procedures (SOPs), which are individual activity based and are 21 in number. The SOPs are available at our website www.kem.edu.
7. The following steps need to be followed by investigators while **submission of a New study proposal to** the IEC:

I Prior to approval of a research study

a) **e-EC software registration for the Principal Investigator:**

- **PI should keep ready following information and documents (in PDF versions) at the time of registration:**

1. Employee / Student ID Numbers of study team
2. Current Medical Council Registration certificate
3. Passport size photo
4. Biodata /CV
5. GCP training Certificate (within the preceding three years)

- **Follow the link as http://iecmanager.org**

1. Select institution as **Seth GS Medical College and KEM Hospital, Mumbai**.
2. Register
3. Submit the required information (registration) to get associated with institution for the project submission under following heads.
    a. Basic information
    b. Professional information
    c. Certifications
    d. Trainings
    e. Submit (Request)

- Principal Investigator registration request will for IEC Admin verification. After IEC admin approval, user will get the account activation link to his/her email. Through this he/she can set their own password to login to system as Principal Investigator (PI).

Note: Only PI can forward the Project to IEC Admin.
Project proposals submitted via e-EC **on or before 20th of every month till 24.00 am will** usually be taken up for discussion at the next month's IEC meeting.

b) The investigator should ensure that there is an 'Ethics Section' in the protocol which is in compliance with the ICMR 2017 Guidelines. The section should include the following aspects which may be stated in the Ethics Section or elsewhere in the protocol:

- 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.

c) Incompletely filled forms / forms without signatures / proposals will not be accepted and same will be conveyed to the PI.

d) 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-A)
b) Expedited Review (refer SOP 05-B)
c) Exempt from Review (refer SOP 05-C)

e) An investigator may refer to the SOP. No. 19 for 'Request for Waiver of Written Informed Consent' whenever necessary.

f) An investigator is required to refer to the format of an Informed Consent Document for genetic study whenever applicable AX 09/SOP 05/V6

The processing fees Details:

Projects Types	**The processing fees**
Pharmaceuticals sponsored project	Rs. 60,000/ project + TDS (10%)
Government sponsored projects	Rs. 7000/- + TDS (10%)
Thesis/ Dissertation	Rs. 1000/-(in hard cash).
All academic non- sponsored projects (**Including DNB, DM, Nursing, PhD Research**)	Rs. 1,500/-project (in hard cash).

The processing fees shall be collected only once at the time of submission of the project. The sponsored projects fees will be accepted by cheque / demand draft/NEFT which will include the tax, drawn in the name of 'Diamond Jubilee Society Trust, Seth G. S. Medical College'. The funds of the IEC are maintained in the Diamond Jubilee Society Trust (DJST) account,
PAN no. AABTS5336G.

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

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

h) Investigator will be able to track the status of the submitted project and respective meetings dates on PI's dashboard of e-EC software.

i) 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. The co-investigator appointed should be independent and he/she should not have a conflict of interest with the study, investigator or sponsor. This is in accordance with the ICMR 2006 guidelines.

j) An investigator is expected to submit reply to the letter of recommendations/ queries sent by the IEC within 180 days of date of receipt of the letter. In the absence of any response, the project will be declared closed for the IEC office records. The documents for these projects will be shredded by IEC staff and same will be recorded in the log book for shredded documents.

II **<u>Once approval for a study is granted</u>**

a) An approval will be granted for the entire duration of the study.

b) It is the responsibility of the principle 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 all projects sponsored by pharmaceuticals, the annual continuing review fees will be Rs. **10,000/**project + TDS (10%) (approved in 3rd September 2014 minutes), for the Government sponsored projects, the processing fees will be Rs. **1,000** /project (approved in 3rd September 2014 minutes). For academic (non- sponsored) projects (in hard cash) no continuing review fee will be charged (approved in 3rd September 2014 minutes). The continuing review fees shall be collected every 11 months from the date of approval (unless specified otherwise). The sponsored continuing review fees will be accepted by cheque / demand draft which will include the tax, drawn in the

name of 'Diamond Jubilee Society Trust, Seth G. S. Medical College'. The funds of the IEC are maintained in the Diamond Jubilee Society Trust (DJST) account, PAN no. AABTS5336G.

c) Submission of Study Related Documents for IEC review

Study related documents (protocol amendments, SAE reports, status reports, study completion reports, protocol deviations/ violations) will be accepted during the office hours specified above. Only one set of the above stated study related documents need to be submitted for the IEC review.

Agenda for the IEC meeting is prepared 3 days in advance before the date of meeting and is sent to the IEC members at least 2 days in advance. Hence the study related documents like answers to the IEC queries and amended study related documents (Protocol, ICD, CRF and IB) received within seven days and other types of documents 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 (**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).

d) 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.

e)Submission of Report of Protocol Deviations/ Violations in the study protocol Please use 1- Deviation /Non-Compliance/Violation Record AX 01/SOP 12/V6 for submitting report of Protocol Deviations/ Non-Compliance / Violations.

f) Submission of Report of Serious Adverse Events (SAEs)

The Principal Investigator should submit within 24 hours on site SAE report or the unexpected adverse event report as per the format specified in *AX 01/SOP 11-B/V6* (Appendix XI of Schedule Y) and *AX 02/SOP 11-B/V6 to* the IEC or by email. The report of SAE of death after due analysis shall be forwarded by the Investigator to chairman of the IEC and Chairman of the Expert Committee constituted by the Licensing Authority under
Appendix XII with a copy of the report to the Licensing Authority and the head of the institution where the trial is been conducted within 14 days of SAE of death. The report of the SAE other than death after due analysis shall be forwarded by the Investigator to Licensing Authority, chairman of the IEC and the head of the institution where the trial is been conducted within 14 days of occurrence of SAE.
The SAE report should be accompanied by detailed narrative of the SAE and CIOMS form.

It should be submitted as per checklist detailed by Licensing Authority in (Annexure A) and given in *SOP 11-B*

The sponsor or his representative shall pay the compensation in case of clinical trial related injury or death within 30 days of the receipt of such an order from Licensing Authority.

g) Any new information that may adversely affect the safety of the research participants or conduct of the trial should be informed to the IEC.

h) 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.

i) Submission of continuing review report in case of studies which continues for more than a year.

- For studies which will continue for more than a year, a continuing review report as per the format *AX 02/SOP 07/V6* will need to be submitted for review
- If the Principal Investigator fails to submit the continuing review report within one month of the due date (i.e. 11th months from the date of approval, unless specified otherwise), the IEC secretariat will send a reminder as per the format *AX 01/SOP 07/V6* 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 which may consist of but not limited to

  a) A letter of reprimanding the Investigator

  b) Not reviewing future projects from the PI for a specified period of time

  c) A letter asking the Investigator to put recruitment of new participants on hold

III Once a study is over

Submission of Study Completion Report

For studies which are completed within the IEC approval period, a study completion report as per the format given in *AX 01/SOP 08/V6* should be submitted to the IEC, by the investigator. The study completion report is expected for review within 1 month of completion of the study at the site. A brief study report containing data analysis from all centres should be submitted once available from the sponsor.

IV In case a study is not initiated or terminated, the same should be communicated to the IEC stating reasons for the same. The format for submission of report of premature termination of the study is as per *AX 01/ SOP 09/V6* should be used

1. The IEC archives all the study related documents for a period of 5 years after the study is completed / terminated/ reported as not initiated at our site. In case, an investigator needs a copy of any document submitted to the IEC, a written request can be made for retrieval of the same using the form- Document Request Form *AX 01/SOP 16/V6*

Sponsor responsibilities

Any report of serious adverse event or death occurring in clinical trial after due analysis shall be forwarded by the sponsor to the chairman of the IEC and the head of the institution where the trial is been conducted within 14 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 Annexure 6.

Appendix I: Regulatory permissions

- **DC(I) approval**

  Studies which plan to use a new drug (as defined in 122-E of the Drugs and Cosmetics Act, 1945) require DC(I) permission. For such studies, a copy of the permission letter issued by the DC(I) to the pharmaceutical company/investigator 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.
- **Administration sanction** from the head of the Institution for sending the samples to laboratories outside KEM Hospital.
- It is mandatory as per the directive by the DC(I) (w.e.f.15th June 2009, which is applicable for clinical trials initiated after 15th June 2009) to register clinical trial at ICMR clinical trial registry at www.ctri.in before enrolling first patient in the study. (Registration is mandatory for interventional clinical trials)

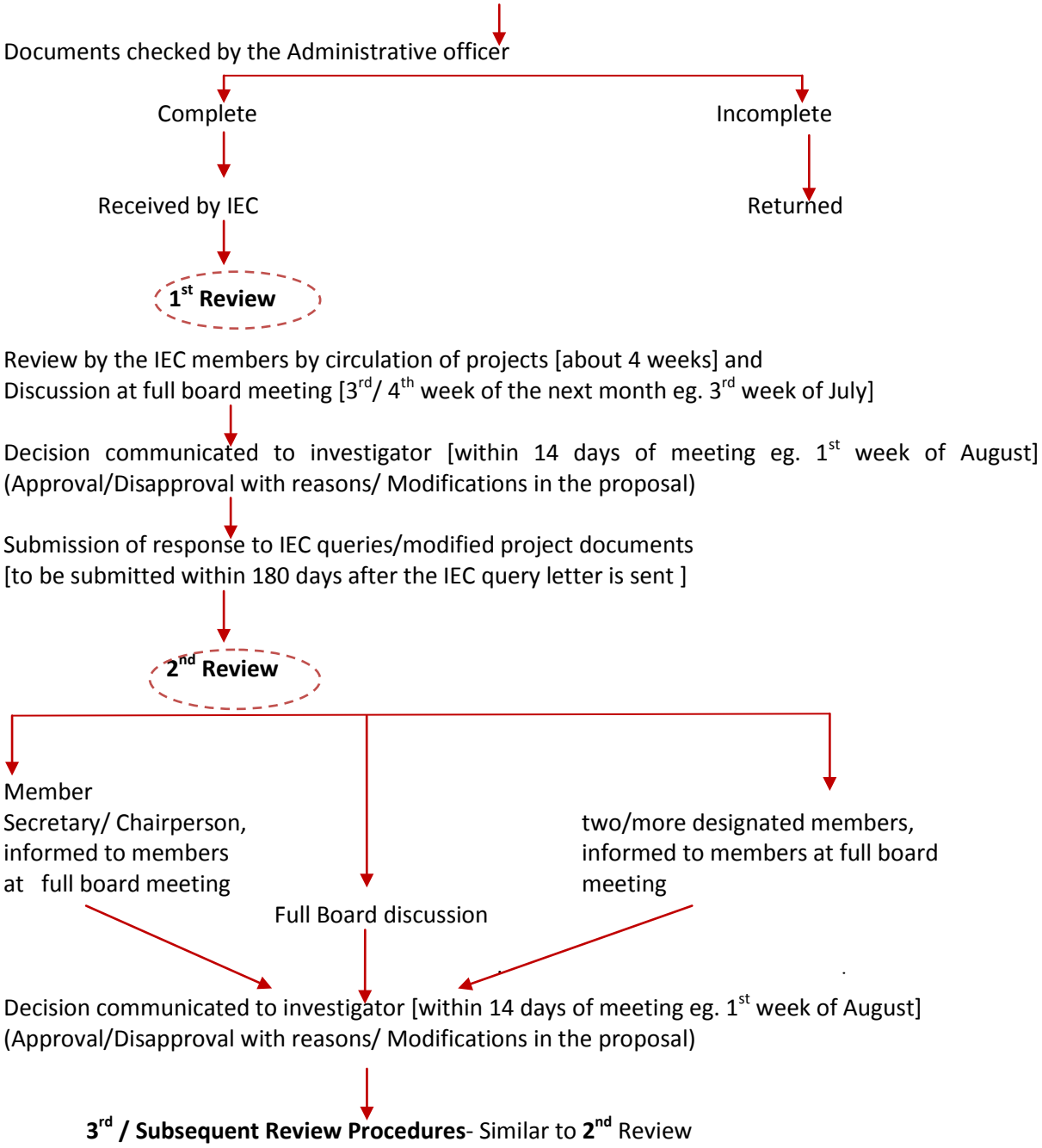
Appendix II: List of forms required for submission of study related documents

The following forms are available in the IEC office 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/V6*
- Deviation/Non-Compliance/Violation Record *AX 01/SOP 10/V6*
- Continuing Review Report Form *AX 01/SOP 07/V6*
- Study Completion Report *AX 01/SOP 08/V6*
- Premature Termination Report *AX 01/SOP 09/V6*
- Document Request Form *AX 01/SOP 16/V6*
- Guidance document for Department Review Boards (*AX 11/SOP 05/V6)*
- AV consent checklist for participants (SOP 12, AX02/SOP12/V6)
- Common Ethic Review of Multicentre Research (SOP 21)

Submission of Projects for IEC Review

Submission of project proposal by Investigator
(Sponsored by Pharmaceutical companies and Government Organizations)
[Till 20th of every month eg. 20th June]


Documents checked by the Administrative officer
Complete
Incomplete
Received by IEC
Returned
1st Review
Review by the IEC members by circulation of projects [about 4 weeks] and
Discussion at full board meeting [3rd/ 4th week of the next month eg. 3rd week of July]
Decision communicated to investigator [within 14 days of meeting eg. 1st week of August]
(Approval/Disapproval with reasons/ Modifications in the proposal)
Submission of response to IEC queries/modified project documents
[to be submitted within 180 days after the IEC query letter is sent]
2nd Review
Member
Secretary/ Chairperson,
informed to members
at full board meeting
Full Board discussion
two/more designated members,
informed to members at full board
meeting
Decision communicated to investigator [within 14 days of meeting eg. 1st week of August]
(Approval/Disapproval with reasons/ Modifications in the proposal)
3rd / Subsequent Review Procedures- Similar to 2nd Review

Annexure 8

AX 08/SOP 05/V6

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 company 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 2006 guidelines** –
Obligation of the sponsor to pay: The sponsor whether a pharmaceutical company, 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.]

[**As per the notification from the office of DC(I) (Notification GSR NO 53 (E) Dated 30-01-2013, 122 DAB),** it is mandatory for the sponsors to comply the following requirement :

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 XXXXXXX who is 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, 91 22 24122188 (Monday to Friday- 9:00am to 4:00pm; Saturday- 9:00am to 1:00pm).

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**

PLEASE NOTE THAT THE INFORMED CONSENT DOCUMENT SHOULD HAVE PAGE NUMBERS

Annexure 9

AX 09/SOP 05/V6

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/V6

Format for Informed Consent Document for Genetic Studies

This document will, in general, follow the format of the informed consent document contained in Annexure 4 of SOP no. 5 *AX 04/SOP 05/V6*. 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 4 of SOP no. 5 (*AX 04/SOP 05/V6*) 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, 2006. 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 company 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/V6
Departmental Review Board (DRB) Guidance Document

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 may be appointed amongst the members (The Co-chairperson will perform the functions of Chairperson in his/her absence).
- The DRB will be composed of at least 3 and a maximum of 7 members.

Details instructions:

The board should give opinion 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, 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 yrs PG teaching experience.
- It is the responsibility of Chairperson of the DRB to send the names of the DRB members to the IEC before 31st August 2013.
- **All thesis** (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. Incase DRB approval letter is being issued to the chairperson who is also a principal investigator for the study then the signature of the co-chairperson / any of the DRB member can be obtained on DRB approval letter.
- It is the responsibility of the DRB member to attend DRB 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.
- It is the responsibility of the DRB member to assist Chairperson in carrying out DRB work.

Annexure 12
AX 12/SOP 05/V6
Guidance Document for IEC Admin

Receive submitted packages by PI for initial review:

Project Overview

- Clicking on view link on Project list of Projects page, will take user to Project Overview.
- Tabs on Top enable IEC Admin to view and review submission under which the user (IEC Admin) will perform his actions against the project submission:

Project Summary Tab

- Under project summary tab, Project summary information on respective project submissions will be shown as following
    - Project Title
    - Project Status
    - Review Type
    - Latest Submission Status
    - Name of PI
    - Date of Submission
    - Insurance Expiry
    - Continuation submission date
    - Sponsor

Submission List Tab (Tab Next to Project Summary)

By selecting the appropriate submission user can view the list of submissions submitted for that Project.

- Following are the search filters on Submission list
    - Submission Type
    - Document(s) status
        - List of Submission (Following fields are shown)
    - Submission Type
    - Submitted By
    - Submitted On
    - Status

- Link to view (when the user clicks on the view link, user is navigated to the project documents, where submission related documents are displayed)
- Link to view details for the previous submissions of that particular project.

IEC Admin Review (Tab Next to Project Documents)

Upon review of submission by IEC Admin, if application found to be complete, IEC Admin will enter following details (depends on submission type):

- Processing Fee Paid (Yes/No)
- Hard copy of project for regulatory projects submitted (Yes/No)
- Reviewed by (IEC Staff / Admin Name)
- Project Number (textbox for entering allotted Project Number)
- Insurance Date (Renewal)

IEC Admin Review Actions

Upon Review of submission IEC Admin may choose one of the following action depends on his observations.

- Forward (to IEC MS)
- Return (to PI)
- Save (button)

Forward to IEC

- IEC Admin Review – Assign / Forward to IEC will have following sections:
- Ethic Committee (Dropdown with list of ECs)
  - For Project Initial Submission
    - Manual Assignment
    - If the Institution chooses to assign the project manually and update the required configuration during Institution setup, this will enable IEC Admin to assign the projects to IEC committees manually.
      - ❖ IEC Admin will select the Ethic Committee for the project and assign it
    - Auto / Random Assignment
    - If the Institution choose to assign the project automatically and update the required configuration during Institution setup, this will randomly assign project to IEC Committee and display the same to IEC Admin.
    - For the Reply to Queries or Any other submission of project (Ex: Amendments, Deviation, SAE etc.,)

❖ Ethic Committee already assigned to Project is shown

- Member Secretary (Auto fill depends on EC selection)
- Comments (textbox)
- Forward (button)
    - Upon forwarding, application will be shown to respective IEC MS project list (set for his review).
    - Upon forwarding the application to IEC, an acknowledgement email is sent to investigator.

Return to Principal Investigator

- IEC Admin Return Submission will have following:
- Comments
    - IEC Admin can enter the info on incomplete information that need to be submitted.
- Return
    - Upon Return, Message is sent to PI with comments entered for return of submission.

(Application status will be updated to Return (by IEC))

Institutional Ethics Committee (IEC)
Seth G.S. Medical College and K.E.M. Hospital, Parel,
Mumbai, Maharashtra ,India – 400 012.
Web: www.kem.edu

Title: Full Board Review of Submitted Protocol

SOP Code:

SOP 05-A/V6 dated 15th July 2019

1. Purpose

The IEC should review and must approve, every research study involving human participants and other forms of studies, before the research is initiated. The IEC should evaluate the scientific rationale, scope and, methodology, and the ethical aspects of the study. The committee should evaluate the possible risks to the participants with proper justification as well as the expected benefits to participants/community. The adequacy of documentation for ensuring privacy & confidentiality should 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 to identify the Primary Reviewer (PR) as per expertise and allocate the projects on e-EC software. All the IEC members can review all the protocols. However PR must review and give comments on e-EC software 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 and allocation of projects to IEC members on e-EC software	Member Secretary
3	Review of the assigned protocols on e-EC	IEC Member
4	Compile the comments of IEC members on e-EC software	Member Secretary

5. Detailed Instructions

5.1 Determine the protocol for full board review.

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

- Research involving vulnerable populations, even if the risk is minimal;
- Research with minor increase over minimal risk i.e.
- 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.
- Studies involving deception of participants
- Research proposals that have received exemption from review, or have undergone expedited review/undergone subcommittee review should be ratified by the full committee, which has the right to reverse/or modify any decision taken by the subcommittee or expedited committee;

- Amendments of proposals/related documents (including but not limited to informed consent documents, investigator's brochure, advertisements, recruitment methods, etc.) involving an altered risk
- Major deviations and violations in the protocol
- Any new information that emerges during the course of the research for deciding whether or not to terminate the study in view of the altered benefit–risk assessment
- Research during emergencies and disasters either through an expedited review/ scheduled or unscheduled full committee meetings. This may be decided by Member Secretary depending on the urgency and need
- Prior approval of research on predictable emergencies or disasters before the actual crisis occurs for implementation later when the actual emergency or disaster occurs.

5.2 Selection and allocation of projects to IEC members on e-EC software (Selection of PR)

- The Member Secretary, IEC 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, IEC 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 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 secretariat on the day of the meeting.
- The Member Secretary can invite an independent consultant or expert (if necessary) for comments during the full board meeting.

5.3 Review of the assigned protocols on e-EC

- The protocol will be reviewed by each member as per guidelines (how to review a study protocol described in *AX 04/SOP 05-A/V6*.)
- The IEC member will consider the following criteria when performing the review of the study protocol:

  - **5.3.1 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 Registration certificates and GCP training certificates (proceeding 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.

  - **5.3.2 Scientific Design and Conduct of the Study**

- Is the project original and innovative? e.g. Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools or technologies for this area?
- Is this an attempt to validate, prove or disapprove the validity of existing knowledge?
- Appropriateness of study design, work plan and structure to achieve the stated objectives: Are the conceptual or clinical framework, design, methods and analyses adequately developed, well integrated, well reasoned and appropriate to the aims of the project?
- Relevance of the work in the context of contemporary translation or clinical cancer research:
  - ❖ Does this study 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?
- Appropriateness of the study design in relation to the objectives of the study;
- The statistical methodology (including sample size calculation), and the potential for reaching sound conclusions with the smallest number of research participants;
- The justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities;
- The justification for the use of control arms;
- Potential of the work that would be conducted to lead into a larger and high impact study;
- Criteria for prematurely withdrawing research participants, and criteria for suspending or terminating the research as a whole;
- The adequacy of provisions made for monitoring and auditing the conduct of the research, including the constitution of a Data Safety Monitoring Board;
- Investigator's capability, availability of infrastructure and scientific environment to conduct the study within the time frame and carry it forward;
- The adequacy of the site, including the support staff, available facilities, and
- emergency procedures;
- Study Reporting and publication of the research.
- Regulatory permission for conduct of the study, HMSC clearance for international collaborative studies, MOU and CTA for national and international collaborative research.
  - ✓ minimize risks to participants;
  - ✓ risks must be reasonable in relation to anticipated benefits;
  - ✓ participants are selected equitably;
  - ✓ informed consent is adequate, easy to understand and properly documented;
  - ✓ the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants, where appropriate;
  - ✓ there are 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.

➢ **5.3.3 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 to review protocol and Informed Consent Document/Patient Information Sheet in *AX 04/SOP 05-A/V6.*

- 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

➢ **5.3.4 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
- Benefit to local communities
- Contribution to development of local capacity for research and treatment
- Availability of study results

5.4 Compile the comments of IEC members on e-EC software

The MS will compile the comments from each reviewer on e-EC software.

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 time 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.
Phase I studies	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.

7. Annexure

Annexure 1 *AX 01/SOP 05-A/V6* IEC Decision Form

Annexure 2 *AX 02/SOP 05-A/V6* Format of Project Approval letter (Interventional study)

Annexure 3 *AX 03/SOP 05-A/V6* Format of Project Approval letter (observational study)

Annexure 4 *AX 04/SOP 05-A/V6* Guidelines for reviewing a study protocol

Annexure 1

AX 01/SOP 05-A/V6

IEC Decision Form

Date of IEC meeting: _____

Protocol number: _____

IEC Protocol No. and Title:			
Principal Investigator:		Department:	
Final Decision at the meeting:	Approved		
	Revision with minor modification/amendments	MS	
		MS + PR	
	Revision with major modification	MS + PR	
		MS + PR+ FB	
	Not approved (Reason)		
	Monitoring required (Reason)		

No.	Names of Members present	Approved	Modification		Disapproved	Signature
			Major	Minor		

Comments:

No. of members voting for the decision:

No. of members voting against the decision:

No. of members abstaining from voting:

_____

Signature of Chairperson **Date:** _____

Annexure 2

AX 02/SOP 05-A/V6

Format of Project Approval letter (Interventional study)

Date XX/XX/XXXX

To,

Dr. xxxxxxxxxxxx,

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

Your absence during the decision making process for the above mentioned study did not have impact on the quorum for the meeting.

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

1. Xxx
2. Xxx
3. xxx

The IEC hereby approves the proposal entitled, "xxxxxxxxxxxxx".

It is understood that the study will be conducted under your direction, in a total of xxxx research participants, at 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. **IEC should be informed after the recruitment of first participant.**

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/V6 (Appendix XI of Schedule Y) and AX 02/SOP 11-B/V6 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 14 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 Annexure 6. (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.

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

A copy of the final report should be submitted to the IEC for review.

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

Sincerely yours

Member Secretary,
IEC
(Signed and dated by the IEC Member Secretary)

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

Annexure 3

AX 03/SOP 05-A/V6

Format of Project Approval letter (observational study)

Date XX/XX/XXXX

To,

Dr. xxxxxxxxxxxx,

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 hereby confirmed that neither you nor any of the study team members have participated in the voting/decision making procedures of the committee. Your absence during the decision making process for the abovementioned study do not have impact on the quorum for the meeting.

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

1. Xxx
2. Xxx
3. xxx

The IEC hereby approves the proposal entitled, "xxxxxxxxxxxxx".

It is understood that the study will be conducted under your direction, in a total of xxxx research participants, at 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 4

AX 04/SOP 05-A/V6

Guidelines for reviewing a study protocol

Reviewers should think about and try to find answers to the following questions:

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

5. Does the study design have adequate built-in safeguards for risks?
   - ❑ Appropriate screening of potential 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.
6. Is pre-clinical and/or early clinical studies sufficiently performed before this study?
   - ❑ The animal study and *in vitro* testing results?
   - ❑ Previous clinical results, if done?
   - ❑ Whether the proposed study is appropriately built on the pre-clinical and/or early clinical results.
     - ❑ The selected dose based on adequate prior results?
     - ❑ Monitoring tests designed to detect expected possible risks and side effects?
7. 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?
8. 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 if recruitment of study participants include:

- A consent form
- 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, diagrams 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)

Guidelines to 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.

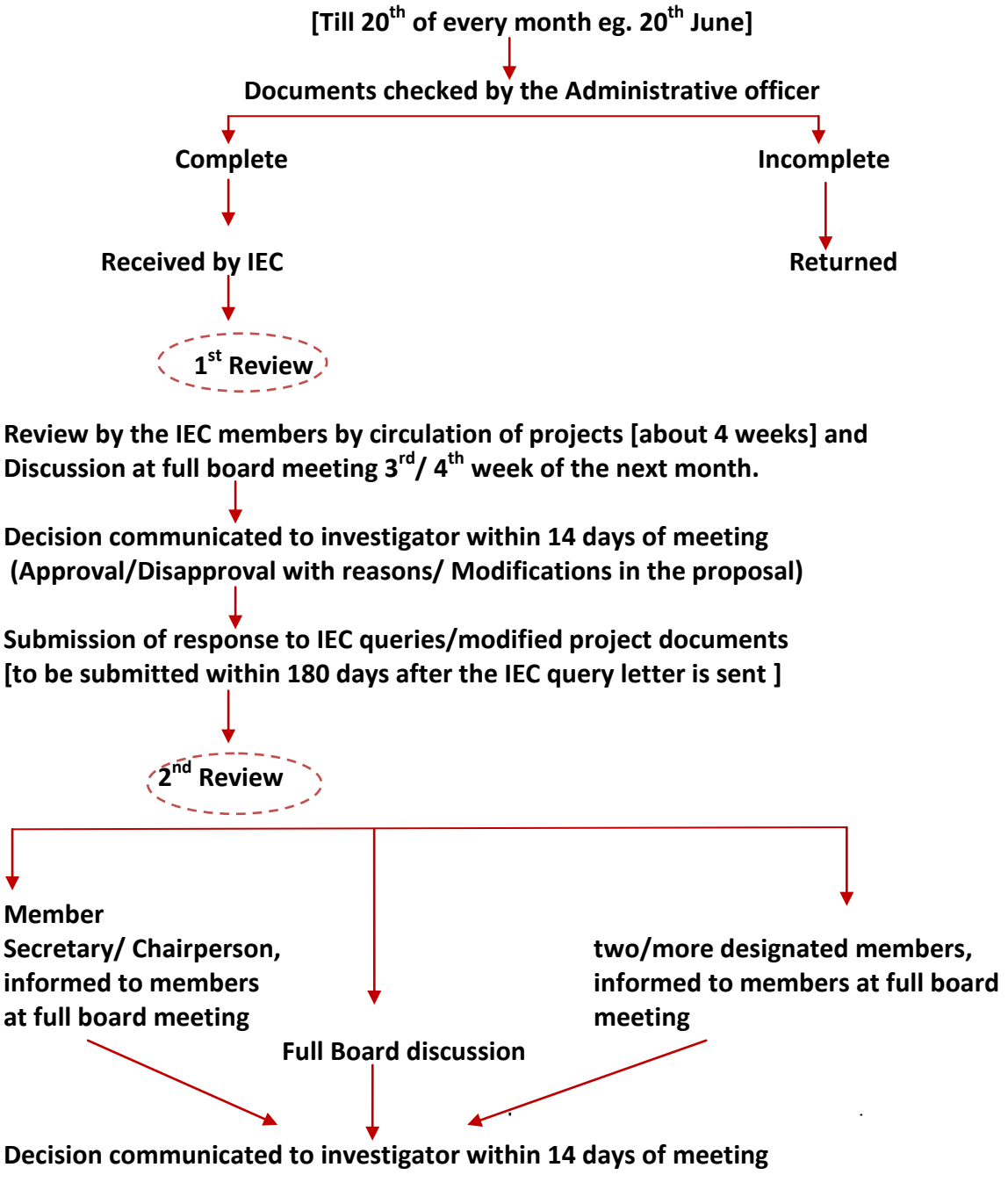
☐ Risks are adequately disclosed in the consent form.

Full Board Review

Initial Submission of Projects for full board Review

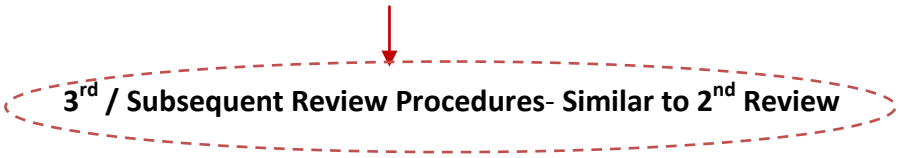
Submission of project proposal by Investigator [as per checklist – www.kem.edu / http://ethics.ncdirindia.org/Common_forms_for_Ethics_Committee.aspx

Clinical trials, academic clinical trial and pharmaceutical sponsored, government sponsored and academic projects studies submit as per **www.kem.edu / http://ethics.ncdirindia.org/Common_forms_for_Ethics_Committee.aspx**



(Full Board Review of Submitted Protocol)

(Approval/Disapproval with reasons/ Modifications in the proposal)



Institutional Ethics Committee (IEC)
Seth G.S. Medical College and K.E.M. Hospital, Parel,
Mumbai, Maharashtra ,India – 400 012.
Web: www.kem.edu

Title: Expedited Review

SOP Code:

SOP 05-B/V6 dated 15th July 2019

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-B/V6)** 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 recommendation 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	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 Secretariat will check and receive documents and forward it to member secretary.

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 stating the reasons in the covering letter 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 regarding whether a study with 'not more than minimal risk' qualifies for an expedited review.
IEC may do expedited review only if the protocols involve -

- 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);
- 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 (See Section 12 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 date of receipt of the protocol.

5.4 Decision of IEC

- The comments of the Primary reviewers will be discussed by the Member Secretary with the Chairperson and decision about approval will be taken by the member secretary in consultation with 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 to the Principal Investigator, if the Project/ Protocol amendment are approved.
- If project is disapproved or requires resubmission after certain modifications, this will be informed to the Principal Investigator. The reasons for disapproval of a project will be specified in the letter sent to Principal Investigator.

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 proposal* with *minimal risk in nature*.

7. Annexure:

Annexure 1	*AX 01/SOP 05-B/V6*	Application form for expedited review.
Annexure 2	*AX 02/SOP 05-B/V6*	Approval letter format in case of Expedited Review for prospective observational study
Annexure 3	*AX 03/SOP 05-B/V6*	Approval letter format in case of Expedited Review for retrospective observational study

Annexure 1

AX 01/SOP 05-B/V6

Application form for expedited review.

(Annexure 1)

Logo of the Institute

Application Form for Expedited Review

.....

(Name of the Institution) **EC Ref. No.*** *(For office use):*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Choose reasons why expedited review from EC is requested[12] ?
   - i. 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 proposal. ☐
   - 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 multicentre 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[13] ? Yes ☐ No ☐

   If Yes give details: .....

   .....

   .....

Signature of PI: ..... dd mm yy

Comments of EC Secretariat: .....

Signature of Member Secretary: ..... dd mm yy

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

Version 1.0

Annexure 2

AX 02/SOP 05-B/V6

Approval letter format in case of Expedited Review for prospective 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.
This 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/V6 (Appendix XI of Schedule Y) and AX 02/SOP 11-B/V6 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 in SOP 5 Annexure 6.

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

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

A copy of the final report should be submitted to the IEC for review.

Sincerely yours

xxxxxxxxxxx
Chairperson

Date of approval of the study: xxxxxx

Annexure 3

AX 03/SOP 05-B/V6

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.
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 research participants and
about any new information that may affect adversely the safety of the research participants or the conduct of the trial.

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

A copy of the final report should be submitted to the IEC for review.
Sincerely yours
xxxxxxxxxxx
Chairperson

Date of approval of the study: xxxxxx

Expedited Review

Proposal by Investigator [as per checklist – www.kem.edu / http://ethics.ncdirindia.org/Common_forms_for_Ethics_Committee.aspx

↓

Documents checked by the Administrative officer

Complete	Incomplete
↓	↓
Received by IEC	**Returned**

PROCEDURE WITHIN 14 WORKING DAYS

The proposal submitted for initial review satisfying any of the following criteria as per SOP 05-B/V6

- **Involving data, documents or specimens that have been already collected or will be collected for ongoing medical treatment or diagnosis.**
- **Research on Research interventions in emergency situations.**
- **Collection of data for research purposes through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice and using medical devices which have been already approved for use. Examples of such procedures include collection of data through application of EEG or ECG electrodes, acoustic testing, tests using the Doppler principle, non-invasive blood pressure and other routine clinical measurements, exercise tolerance etc. However procedures involving the use of x-rays or microwaves are NOT recommended for expedited review.**
- **Clinical studies of drugs and medical devices only when**
  - i. **research is on already approved drugs except when studying drug interaction or conducting trial on vulnerable population or**
  - ii. Adverse Event (AE) or unexpected Adverse Drug Reaction (ADR) of minor nature is reported.
- **Research on Disaster management.**

After determining that the Protocol / Project qualifies for an expedited review, the Chairperson / Member Secretary will nominate two or more IEC members to review the protocol / project.

↓

Review by the nominated IEC members
Decision communicated

To the investigator within 14 working days]	The Secretary will inform the
decision at its	
(Approval/Disapproval with reasons / Modifications in the proposal)	upcoming full board meetings.

Institutional Ethics Committee (IEC)
Seth G.S. Medical College and K.E.M. Hospital, Parel,
Mumbai, Maharashtra ,India – 400 012.
Web: www.kem.edu

Title: Exemption from the Ethics Review for Research Projects

SOP Code:

SOP 05-C/V6 dated 15th July 2019

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-C/V6* 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 should be taken by the Member Secretary in consultation with the Chairperson and should be informed to the Members in the forthcoming IEC meeting.

3. Responsibility

It is the responsibility of the Member Secretary to record the decision in the Exemption Form with reasons. The IEC Secretariat is responsible for recording and filing the decision including the reasons for that decision. The Chairperson/ Member Secretary must sign and date letter conveying the decision *AX 01/SOP 05-C/V6*.

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-C/V6,* Protocol and other documents 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 programmes by Govt. agencies such as programme evaluation where the sole purpose of the exercise is refinement and improvement of the programme or monitoring (where there are no individual identifiers).

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.

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 records 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 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

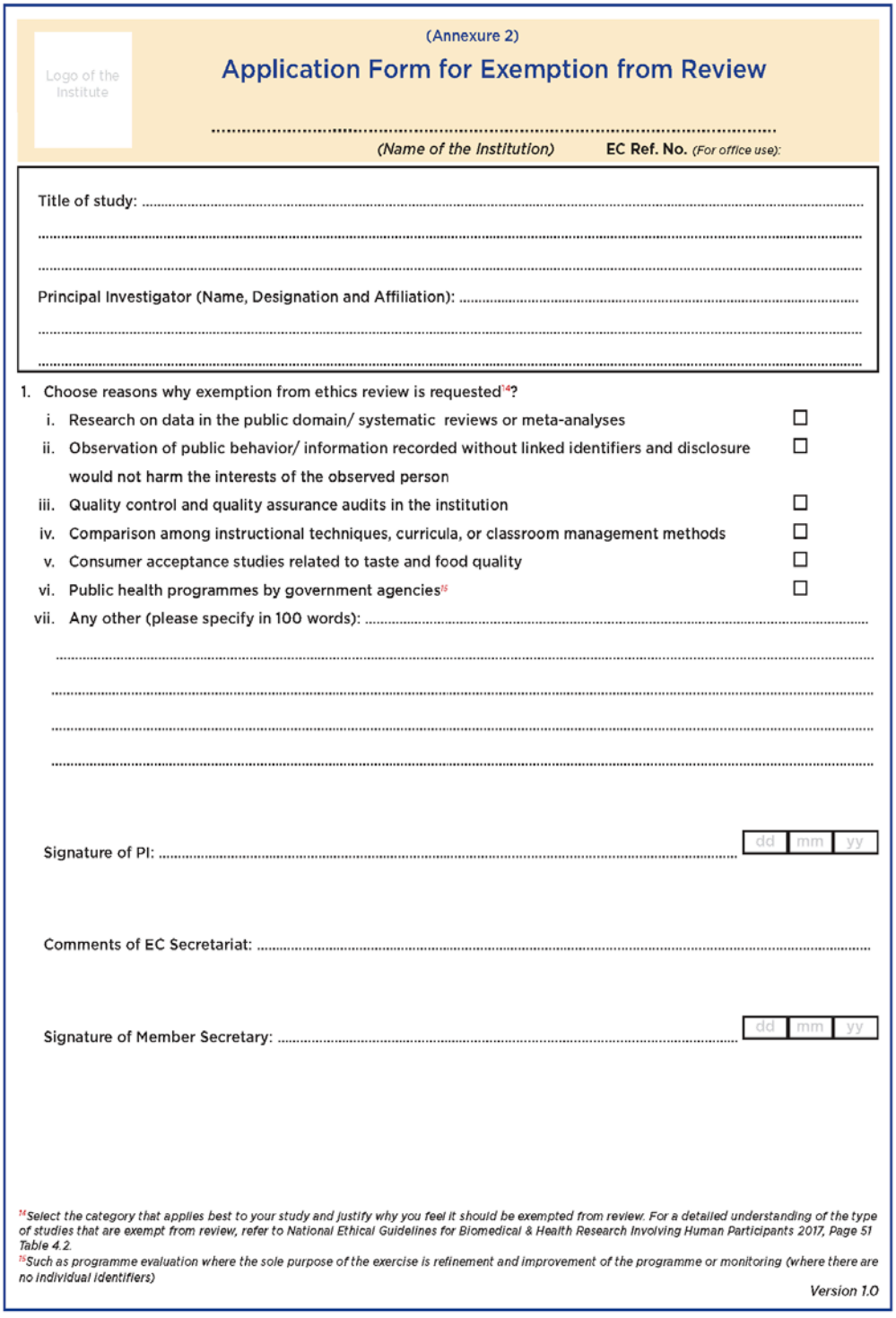
Annexure 1 *AX 01/SOP 05-C/V6* Review exemption application form

Annexure 2 *AX 02/SOP 05-C/V6* Approval for Exemption from Review

Annexure 1

AX 01/SOP 05-C/V6

Review Exemption Application



(Annexure 2)

Logo of the Institute

Application Form for Exemption from Review

..... *(Name of the Institution)* **EC Ref. No.** *(For office use):*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

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

.....

.....

.....

.....

Signature of PI: ..... dd mm yy

Comments of EC Secretariat: .....

Signature of Member Secretary: ..... dd mm yy

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

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

Version 1.0

Form

Annexure 2

AX 02/SOP 05-C/V6

Approval for 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-C/V6; ICMR 2006 chapter I Ethical review procedures page no.11). 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

Exemption From Review

Submission of project proposal by Investigator [as per checklist – www.kem.edu / http://ethics.ncdirindia.org/Common_forms_for_Ethics_Committee.aspx with Review Exemption Application form (Annexure 1, SOP 05-C)

↓

Documents checked by the Administrative officer

Complete	Incomplete
↓	↓
Received by IEC	**Returned**

↓

The IEC Member Secretary will determine whether a protocol qualifies for exemption from review based on the following criteria as per SOP 05-C/ V6

↓

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.

↓

Final decision will be made by the Chairperson as per SOP.

↓

Decision communicated

To the investigator within 14 days] the decision (Approval/Disapproval with reasons) meeting.

→ Member Secretary will inform at its upcoming full board

→ Member Secretary may keep the application for review and decision regarding exemption at the next full board meeting.

Institutional Ethics Committee (IEC)
Seth G.S. Medical College and K.E.M. Hospital, Parel, Mumbai,
Maharashtra ,India – 400 012.
Web: www.kem.edu

Title: Review of Resubmitted Protocols

SOP Code:

SOP 05-D/V6 dated 15th July 2019

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 of a protocol; which is previously reviewed earlier with recommendations from IEC for some changes.

A re-submitted protocol may be reviewed by either the two or more IEC members designated by the Chairperson/ Member secretary, or all the IEC members 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 01/SOP 05-A/V6*).

4. Activity Table

No.	Activity	Responsibility
1	Receive resubmitted protocol package, check contents, ensure completeness of the documents submitted and distribution of protocol and study-related documents	IEC Secretariat
2	Review 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 the letter of comments by the IEC.
- 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 complete package along with all the required documents.
- The Secretariat will refer to the IEC Decision Form *AX 01/SOP 05-A/V6* on the given protocol and distribute this package containing the reply to the query letter, revised protocol and related documents for resubmitted protocol to the Member Secretary

For Minor modifications

The protocol land 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 land related documents will be reviewed by either one / two designated primary reviewers or after review by the designated primary reviewers will be discussed in the upcoming full board 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/ Member Secretary/ Chairperson will refer to the query letter/ comments as guidance for the review and consider 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 designated primary reviewers should complete the review process within seven / eight 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 letter of permission 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 which may or may not be discussed in next full board meeting depending on the comments of the reviewers. If the response and changes are approved in the full board, letter of permission can be issued to the Principal Investigator.

5.3 Written communication of the IEC decision.

The decision will be communicated to the PI within 14 days and for the projects which will be discussed in the full board meeting the decision will be communicated within 14 days of the meeting. Response from the PI to the IEC communication is expected within 180 days of date of receipt of the letter and in the absence of any response, the project will be declared closed for the IEC office records.

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

Institutional Ethics Committee (IEC)
Seth G.S. Medical College and K.E.M. Hospital, Parel,
Mumbai, Maharashtra ,India – 400 012.
Web: www.kem.edu

Title: Review of Amended Protocol /Protocol related documents

SOP Code:

SOP 06 /V6 dated 15th July 2019

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 will not 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 protocol package, 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 package, 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 Secretariat.

  The 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/V6*.

- 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 Administrative Officer will confirm that the:

- ✓ amended version of the protocol and related documents are present
- ✓ Changes or modifications in the amended version are highlighted.

- The 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 Secretariat will forward the amendment to the Member Secretary/ Chairperson.
- The 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 package with the Protocol Amendment Assessment Form *AX 01/SOP 06/V6.*
- The member secretary or chairperson will categorized the amendments as minor or major amendment as per section 5.2.

5.2 Review the amended protocol and related documents
For Minor amendment

The Minor amendments of the protocol and related documents will be reviewed by either member secretary or chairperson.

For Major amendment

The protocol and related documents will be reviewed by either one / two designated primary reviewers or after review by the designated primary reviewers will be discussed in the upcoming full board meeting. In case the decision is to discuss the amendment 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 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)
- Primary reviewers will send the comments to the member secretary
- Following aspects of the Protocol amendment which may include but is not limited to:
    a. Change in study design
    b. additional treatments or the deletion of treatments
    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 final decision regarding the amendments shall include one of the following:

- ✓ If the IEC decision is 'Approved', it implies the approval of the amendment as it is presented with no 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 and if response from the PI found satisfactory 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 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 to decide if 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 with the PI giving reasons for disapproval

5.3Written communication of the IEC decision to investigator

- ✓ The decision will be communicated to the PI within 14 days and for the amendments which will be discussed in the full board meeting the decision will be communicated within 14 days of the meeting.
- ✓ The 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/V6* Protocol Amendment Request and Assessment Form

ANNEXURE 2 *AX 02/SOP 06/V6* Project Amendment/Document Amendment Approval letter

Annexure 1

AX 01/SOP 06/V6

Protocol / Protocol related documents Amendment Request and Assessment Form

(Annexure 4)

Logo of the Institute

Application/Notification form for Amendments

..... *(Name of the Institution)* **EC Ref. No.** *(For office use):*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Date of EC approval: dd mm yy Date of start of study dd mm yy

2. Details of amendment(s)

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

3. Impact on benefit-risk analysis Yes ☐ No☐

If yes, describe in brief: .....

.....

4. Is any re-consent necessary? Yes ☐ No☐

If yes, have necessary changes been made in the informed consent? Yes ☐ No☐

5. Type of review requested for amendment:

Expedited review (No alteration in risk to participants) ☐

Full review by EC (There is an increased alteration in the risk to participants) ☐

6. Version number of amended Protocol/Investigator's brochure/ICD: .....

Signature of PI: ..... dd mm yy

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

Version 1.0

Annexure 2

AX 02/SOP 06/V6

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 above mentioned 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 Review Board.

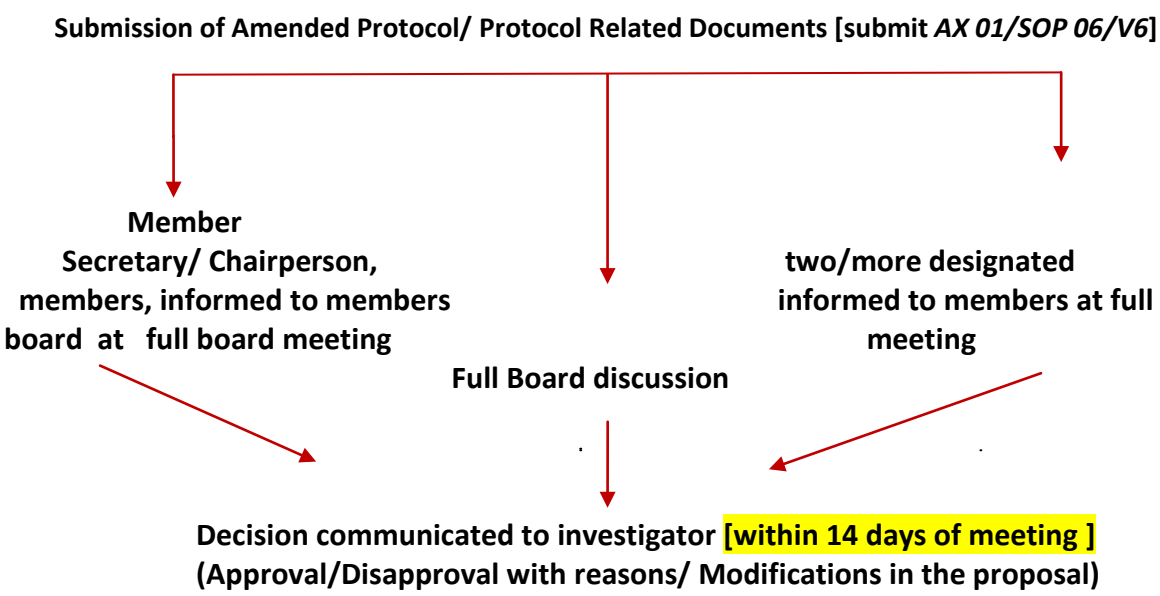
OR

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

Review of Amended Protocol / Protocol Related Documents



Institutional Ethics Committee (IEC)
Seth G.S. Medical College and K.E.M. Hospital, Parel, Mumbai, Maharashtra, India – 400 012.
Web: www.kem.edu

Title: Continuing Review of Study Protocols

SOP Code:

SOP 07 /V6 dated 15th July 2019

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 projects approved by the Institutional Ethics Committee will be reviewed at least once a year. Depending upon the degree of risk to the participants, the nature of the studies, the vulnerability of the study participants and duration of the study, the IEC may choose to review or monitor the protocols more frequently.

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. All the approved protocols will be reviewed annually (at least once a year). 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 meeting wherein the project is finally approved or can be taken subsequently based on the SAE reports, monitoring reports, adequacy documentation procedures followed by the investigators 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.	Assign reviewers and review the annexure/ related documents of continuing review	Chairperson /Member Secretary/ IECMembers
4.	Written communication of the IEC decision to investigator	IEC Secretariat

5.Detailed Instructions

5.1. Determine the date of continuing review and Notify the Principal Investigator or study team

a. Determining the date of continuing review

- The Administrative Officer will look through the document archives/master chart of projects approved by the IEC for the due date of continuing reviews.
- The Secretariat will plan for continuing review of annual progress reports to be reviewed as close as possible to the due date or the anniversary of the effective date (date of original approval) of the protocol.

***b. Notifying the Principal Investigator or the study* team**

- If the Principal Investigator fails to submit the Continuing review report within one month of the due date (i.e. 11th months from the date of approval, unless specified otherwise), the IECsecretariat will send a reminder as per the format mentioned in *AX 01/SOP 07/V6*within 7 working days of this due date. If there is no response within 15 days after the date of reminder, the IEC, BHR I & II secretariat will put up the matter for discussion at the forthcoming full board meeting for appropriate action which may consist of but not limited to

a) A letter of reprimanding the Investigator.

Not reviewing future projects from the PI for a specified period of time / till the submission of status report of the previous study.

b) A letter asking the Investigator to put recruitment of new participants on hold.

5.2 Managing the continuing review package upon receipt.

- The Secretariat will receive a package (soft and hard copy) submitted by the Study Team of continuing review for each approved protocol. The Secretariat will make sure that the contents of the package include the following documents:
  - Continuing Review Application Form (*AX 02/SOP 7/V6)*duly filled with an explanation for any "yes" (ticked on the Continuing Review Application Form (*AX 02/SOP 07/V6)*answers on the application form and a discussion of scientific development, either through the conduct of this study or similar research that may alter risks to research participants. The changes in the selection criteria of participants, protocol/Informed consent Document amendments, changes in the study team, any unexpected complications etc. have to be discussed in the attached narrative.
  - The 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 secretariat will ensure the payment of Rs 10,000 for Pharma sponsored studies and Rs 1000/- for Government sponsored studies. The Secretariat will forward the continuing review report to the Member Secretary/ Chairperson.

5.3 Assign reviewers and review the annexure/ related documents of continuing review

The Chairperson /Member Secretary will review the Continuing Review Application Form (*AX 02/SOP 07/V6)*.The Chairperson / member secretary can designate 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.

Review of Continuing Review Application

- The Continuing review submission may undergo expedited review (as per the procedure described in SOP 05-B/V6) or full board review (as per the procedure described in SOP 05-A/V6) 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/V6*)
  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.

5.4 Written communication of the IEC decision to investigator

- ✓ The decision will be communicated to the PI within 14 days and for the continuing review reports which will be discussed in the full board meeting the decision will be communicated within 14 days of the meeting.
- ✓ The 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/V6* Reminder letter by the IEC to investigator

Annexure 2*AX 02/SOP 07/V6* Continuing Review Application Form

Annexure 3 *AX 03/SOP 07/V6* Continuing Review report Approval Letter

Annexure 1

AX 01/SOP 07/V6

Reminder letter by the IEC to Investigator

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 Annual 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/V6*)**

b) If completed – status report in the format as per form no. **(*AX 01/SOP 08/V6*)**

c) If terminated / not initiated – status report in the format as per form no. **(*AX 01/ SOP 09/V6*)**

Signature with date _____

Member Secretary_____

Annexure 2

AX 02/SOP 07/V6

Continuing Review/ Annual report format

(Annexure 3)

Continuing Review / Annual report format

Logo of the Institute

.....

(Name of the Institution) **EC Ref. No.** *(For office use):*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Date of EC Approval: dd mm yy Validity of approval: dd mm yy
2. Date of Start of study: dd mm yy Proposed date of Completion: dd mm yy

   Period of Continuing Report: dd mm yy ---- to ------ dd mm yy
3. Does the study involve recruitment of participants? Yes ☐ No ☐

   (a) If yes, Total number expected..... Number Screened: ..... Number Enrolled: .....

   Number Completed:..... Number on followup:.....

   (b) Enrolment status – ongoing / completed/ stopped

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

   (d) Any other remark.....

   .....

   (e) Have any participants withdrawn from this study since the last approval? Yes ☐ No ☐

   If yes, total number withdrawn and reasons: .....

   .....

   .....
4. Is the study likely to extend beyond the stated period ?[17] Yes ☐ No ☐

   If yes, please provide reasons for the extension. .....

   .....

   .....
5. Have there been any amendments in the research protocol/Informed Consent Document (ICD) during the past approval period?

   If No, skip to item no. 6 Yes ☐ No ☐

   (a) If yes, date of approval for protocol and ICD : dd mm yy

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

   If yes, when / how: .....

   .....

   .....

[16] *In case there is a Data Safety Monitoring Board (DSMB) for the study provide a copy of the report from the DSMB. If not write NA.*

[17] *Problems encountered since the last continuing review application with respect to implementation of the protocol as cleared by the EC*

Version 1.0

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

If yes, discuss in detail: .....

.....

.....

7. Have any ethical concerns occurred during this period? Yes ☐ No ☐

If yes, give details:.....

.....

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

Describe in brief: .....

.....

.....

(b) Have any SAE's occurred since last review? Yes ☐ No ☐

If yes, number of SAE's :..... Type of SAE's: .....

.....

.....

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

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

.....

.....

9. Has there been any protocol deviations/violations that occurred during this period?

If yes, number of deviations .....

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

.....

.....

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

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

.....

.....

Any other comments:.....

.....

Signature of PI: ..... dd mm yy

Version 1.0

Annexure 3

AX 03/SOP 07/V6

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 reviewed in the IEC meeting held on XXXXXXXX and was noted.

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:

Institutional Ethics Committee (IEC)
Seth G.S. Medical College and K.E.M. Hospital, Parel,
Mumbai, Maharashtra ,India – 400 012.
Web: www.kem.edu

Title: Review of Study Completion Reports

SOP Code:

SOP 08 /V6 dated 15th July 2019

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 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.	Assign reviewers and review the annexure/ related documents of completion report	Member-Secretary
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 Secretariat will receive 1 copy (soft and hard) of Study Completion Report filled as per the format – *AX 01/SOP 08/V6* 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 Secretariat shall forward the Study Completion Report along with Study Completion Report Form- *AX 01/SOP 08/V6* and sends it to the Member secretary.

5.2 Assign reviewers and review the annexure/ related documents of completion report

- The completion report submission may undergo expedited review (as per the procedure described in SOP 05-B/V6) or full board review (as per the procedure described in SOP 05-A/V6) as deemed appropriate by the IEC Chairperson/ Member Secretary
- The Chairperson and the Member Secretary will review the report, Study Completion Report Form and Study Completion statement and notify it to the other IEC members at the forthcoming full board meeting or the Chairperson / member secretary can designate two other IEC members to review the Study report and related documents. If deemed necessary, the

Chairperson/member secretary may keep the report for discussion at the forthcoming IEC meeting.

- The Secretariat will send the Study Completion Report Form *AX 01/SOP 08/V6* and Study Completion statement *AX 02/SOP 08/V6 for regulatory studies* 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 Written communication of the IEC to investigator

5.3.1 During the Board meeting

- The 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 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 report is accepted by IEC the decision will be communicated to the PI within 14 days of the date of the receipt from the investigator / full board meeting. The Administrative Officer will archive the entire study protocol for a period of 5 years from the date of completion of the project if the decision is noted and closed.
- For thesis / dissertations no dues certification will be stamped only after confirming the submission of study completion report.
- If PI fails to submit the CSR within 1 year from date of completion notification, then IEC will dispose of the master file once the archival period over. (IEC will archive the master file for five years from the completion notification. 1st Reminder for CSR will be sent at 5th Month & 2nd Reminder will be sent at 7th months)

7. Annexure

Annexure 1	*AX 01/SOP 08/V6*	Study Completion Report Form
Annexure 2	*AX 02/SOP 08/V6*	Study Completion Statement for regulatory studies

Annexure 1

AX 01/SOP 08/ V6

Study Completion report Form

(Annexure 12)

Logo of the Institute

Study completion/Final report format

.....

(Name of the Institution) **EC Ref. No.** *(For office use):*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Date of EC approval: dd mm yy
2. Date of start of study: dd mm yy Date of study completion: dd mm yy
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 withdrawal of participants[24] : .....

   .....

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

   .....

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

   .....

   .....

   .....

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

   Deviations: ..... Violation: ..... Amendments: .....
7. Describe in brief plans for archival of records / record retention:.....

   .....

   .....

   .....

   .....

[24] *Explanation for the withdrawal of participants whether by self or by the PI*

Version 1.0

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 [25] : .....

.....

.....

.....

.....

12. Number of SAEs that occurred in the study: .....

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

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

If yes, provide details.....

.....

.....

.....

.....

Signature of PI: ..... dd mm yy

[25] *For sponsored studies, if the final report is not available from sponsor, it may be submitted later to the EC once it is ready.* *Version 1.0*

Annexure 2

AX 02/SOP 08/V6

Study Completion Statement for regulatory studies

Project no. and title:
Principal Investigator:
Department:
Date of project approval:

Status report/s received so far						
Dates of meeting						

Documents approved after the first approval:

1.
2.

SAE at our sites (details)

Sr. No.	Date	SAE

_____

Signature with date
Member Secretary

Institutional Ethics Committee (IEC)
Seth G.S. Medical College and K.E.M. Hospital, Parel,
Mumbai, Maharashtra ,India – 400 012.
Web: www.kem.edu

Title: Management of Premature Termination / Suspension / Discontinuation of the study / Withdrawal of study before site initiation

SOP Code:

SOP 09 /V6 dated 15th July 2019

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 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 receiving premature termination/ Suspension / Discontinuation of the study / Withdrawal of study before site initiation of a research study report as per (AX 01/SOP 09/V6) 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 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 of a research study.

The Secretariat will receive 1 copy (soft and hard) of premature termination/ Suspension / Discontinuation of the study / Withdrawal of study before site initiation of a research study filled as per the format – AX 01/SOP 09/V6 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 Secretariat shall forward the premature termination/ Suspension / Discontinuation of the study / Withdrawal of study before site initiation of a research study Form- AX 01/ SOP 09/V6 and sends it to the Member secretary.

5.2 Review the report and take the decision.

- The member secretary / Chairperson shall review the results, reasons and accrual data and discuss the report at the regular 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/ SOP 09/V6*
- If the Premature termination/ suspension/discontinuation Report is unclear or more information is required from the PI, the Chairperson shall instruct the 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 days and Secretariat will record the decision reached on the Premature Termination / Suspension / Discontinuation of the study / Withdrawal of study before site initiation in the minutes of the meeting.

5.4 *Store the protocol documents.*

- The Secretariat will keep the original version of the Premature Termination Report *AX 01/ SOP 09/V6* in the Protocol file and send the file to archive.
- The protocol documents will be stored for a period of 5 years from the date of project Termination.

6. Annexure

ANNEXURE 1 *AX 01/ SOP 09/V6* Premature Termination Report

Annexure 1

AX 01/ SOP 09/V6

Premature Termination Report

(Annexure 7)

Logo of the Institute

Premature Termination/Suspension/ Discontinuation Report Format

.....

(Name of the Institution) **EC Ref. No.** *(For office use):*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Date of EC approval: dd mm yy Date of start of study: dd mm yy
2. Date of last progress report submitted to EC: dd mm yy
3. Date of termination/suspension/discontinuation: dd mm yy
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[21] (if any): .....

   .....

   .....

6. Details of study participants:

   Total participants to be recruited: ..... Screened: ..... Screen failures:.....

   Enrolled:..... Consent Withdrawn:..... Reason (Give details): .....

   .....

   .....

   Withdrawn by PI:..... Reason(Give details): .....

   .....

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

Version 1.0

Institutional Ethics Committee (IEC)
Seth G.S. Medical College and K.E.M. Hospital, Parel,
Mumbai, Maharashtra ,India – 400 012.
Web: www.kem.edu

Title: Protocol Deviation/Violation

SOP Code:

SOP 10 /V6 dated 15th July 2019

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

1. It is responsibility of IEC secretariat to receiving deviation /violation reports as per (AX 01/SOP10/V6) submitted by the Principal Investigator and forwards it to the member secretary / chairperson with required documents if needed.
2. It is responsibility of the member secretary / chairperson to categorized the submitted protocol deviations as minor and major and assign one/ two primary reviewers accordingly.
3. It is responsibility of the designated reviewers to review the protocol deviations and take the decision regarding the same.
4. 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	Secretariat
2	categorized the protocol deviations and assign one/ two primary reviewers	Member Secretary /Chairperson
3	To review the protocol deviations	IEC members
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):

1. Protocol deviation/ non-compliance/ violation may be reported by Investigator/ study site/ sponsor/ Contract-Research Organization to the IEC
2. 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.

3. The Secretariat may detect protocol deviation/non-compliance/violation from failure to comply with statutory requirements/failure to respond to requests from IEC within reasonable time limit/failure to respond to communication made by IEC.
4. The IEC members may detect protocol deviation/non-compliance/violation when scrutinizing annual/ periodic reports/ SAE reports/ any other communication received from the Investigator/ trial site/ sponsor/ study monitor/ contract research organization/ethics committee monitor.
5. 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.
6. Communication/ complaint/ information received from research participant who has been enrolled or any individual who has been approached for enrollment
7. Any report/ communication brought to the notice of Member, Secretary/ Jt. Secretary/ Chairperson of IEC by an independent person
8. Communication received from the Head of the Institution informing IEC about an alleged protocol violation/ non-compliance/ protocol deviation

5.1 Receiving deviation /violation reports and forward it to the member secretary / chairperson

The Secretariat will receive 1 copy (soft and hard) of protocol deviation Report filled as per the format – *AX 01/SOP 10/V6* 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 Secretariat shall forward the protocol deviation Report along with protocol deviation Form-*AX 01/SOP 10/V6* and sends it to the Member secretary.

5.2 categorized the protocol deviations and assign one/ two primary reviewers

- The member secretary or chairperson will categorized the protocol deviations as minor or major.

For Minor protocol deviations

The **Minor** protocol deviations and related documents will be reviewed by either member secretary or chairperson.

For Major protocol deviations

Major protocol deviations and related documents will be reviewed by either one / two designated primary reviewers or after review by the designated primary reviewers will be discussed in the upcoming full board meeting. In case the decision is to discuss the **Major** protocol deviations at the full board meeting, the Primary reviewer / Secretary will present a brief oral summary of the major protocol deviations and the comments of the IEC members/Chairperson in the IEC Full Board meeting.

- **Definitions**

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 subject received the wrong treatment or incorrect dose.
- A research subject met withdrawal criteria during the study but was not withdrawn.
- A research subject received an excluded concomitant medication.

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

- A research subject was enrolled but does not meet the protocol's eligibility criteria.
- Failure to treat research subjects 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 subject 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 subject 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 or CC 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.

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

5.3 To review the protocol deviations

- The Chairperson / 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 that IEC has noted the deviation / violation
  - ✓ Direct the PI to ensure that deviations/violations do not occur in future and follow IEC recommendations.
  - ✓ Enlist measures that the PI would undertake to ensure that deviations/violations do not occur in future
  - ✓ Reprimand the PI.
  - ✓ Call for additional information.
  - ✓ Suspend the study till additional information is made available and is scrutinized.
  - ✓ Suspend the study till recommendations made by the IEC are implemented by the PI and found to be satisfactory by the IEC.
  - ✓ Suspend the study for a fixed duration of time.
  - ✓ Inform the Institutional Head/ Director/Dean.
  - ✓ Revoke approval of the current study.
  - ✓ Inform DCI/ Other relevant regulatory authorities.
  - ✓ Keep other research proposals from the PI/ Co-PI under abeyance.
  - ✓ Review and/ or inspect other studies undertaken by PI/Co-PI.
  - ✓ 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 that the IEC will be based on:

[1] The nature and seriousness of the deviation / violation

[2] Frequency of deviation / violation in the study in the past

[3] Frequency of deviation / violation in previous studies conducted by the same PI/ Co-PI or in the same department.

- 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 Secretariat will record the decision reached on the protocol deviation / violation in the minutes of the meeting.

6. Annexure

Annexure 1 *AX 01/SOP 10/V6* Déviation/Violation Record

Annexure1

AX 01/SOP 10/V6

Deviation / Non-Compliance / Violation Record

(Annexure 5)

Protocol Violation/Deviation Reporting Form (Reporting by case)

Logo of the Institute

..... *(Name of the Institution)* **EC Ref. No.** *(For office use)*:

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

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

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

6. Provide details of Deviation/Violation: .....

.....

.....

.....

7. Corrective action taken by PI/Co-PI: .....

.....

.....

.....

8. Impact on (if any): Study participant ☐ Quality of data ☐
9. Are any changes to the study/protocol required? Yes ☐ No ☐

If yes, give details.....

.....

Signature of PI: ..... dd mm yy

Version 1.0

(Protocol Deviation/Violation)

Sr. No	**Patient initials & Patient ID.**	**Protocol deviation/violation**	Impact of the deviation/violation		**Corrective measures by PI/Co-PI**	**Are any changes to the project/protocol Required. Specify**
			Safety or wellbeing of the participants	Quality of data /Data integrity		
1.						
2.						

Institutional Ethics Committee (IEC)
Seth G.S. Medical College and K.E.M. Hospital, Parel,
Mumbai, Maharashtra ,India – 400 012.
Web: www.kem.edu

Title: Constituting SAE Subcommittee

SOP Code:

SOP 11-A/V6 dated 15th July 2019

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 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	Head of the Institute, Chairperson, IEC Members and Secretariat.
2	Membership requirements	Head of the Institute, Chairperson.
3	Tenure of Membership	Chairperson, IEC Members and Secretariat.
4	Initiation of the process of appointment	Secretariat.
5.	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.	Selection and appointment of Head of the SAE subcommittee	Head of the Institute.
9.	Quorum requirements	IEC Members and 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 SAE Subcommittee is guided in its reflection, advice and decision by the ethical principles expressed in Declaration of Helsinki (Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964, and amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975; 35th World Medical Assembly, Venice, Italy, October 1983; 41st World Medical Assembly, Hong Kong, September 1989; 48th World Medical Assembly, Somerset West, Republic of South Africa, October 1996; and the 52nd World Medical Assembly, Edinburgh, Scotland, October 2000; Note of Clarification on Paragraph 29 added by the World Medical Assembly, Washington 2002; Note of Clarification on Paragraph 30 added by the World Medical Assembly, Tokyo 2004), 59th WMA General Assembly, Seoul, October 2008, 64th WMA General Assembly, Fortaleza, Brazil October 2013.
- 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), draft CIOMS guidelines 2015.
- The SAE Subcommittee will work according to its established Standard Operating Procedures based on the Operational Guidelines for Ethics Committees that review Biomedical Research (WHO, 2000), International Conference on Harmonization- Good Clinical Practices (ICH-GCP) Guidelines (1996), (New Drugs and Clinical Trials, Rules 2019, G.S.R 227 (E) 19th March 2019) and Ethical Guidelines for Biomedical Research on Human Participants by ICMR (2006), ICMR guidelines 2017. 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.
  c. To ensure appropriate compensation as per New Drugs and Clinical Trials, Rules 2019, G.S.R 227 (E) 19th March 2019 is provided to the research participants.
- The SAE Subcommittee is established and functions in accordance with the relevant national law and regulations in force from time to time.

5.2 Composition of the SAE Subcommittee:

- The SAE Subcommittee will be appointed by the Chairperson of Ethics Committee.
- 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).
  - ✓ One Executive Secretary (who is a member of the IEC).
  - ✓ Any IEC member with post graduate qualifications in the discipline of Medicine.
  - ✓ Atleast one member possessing post graduate degree in the subject of Pharmacology (who is the member of the IEC).
  - ✓ Atleast one member possessing post graduate degree in the subject of General Medicine (who is the member of the IEC).
  - ✓ IEC Secretary will be Ex-Officio members of the SAE Subcommittee.
  - ✓ 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 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.
- The IEC secretariat will initiate the process of filling up the forthcoming vacancies two months prior to the end of tenure of a member of SAE Subcommittee. 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. The retiring member will be eligible to be appointed for the new tenure consecutively three times.

5.5 Appointment of new members:

a) The SAE Subcommittee members will be appointed by the Chairperson. New members will be appointed under the following circumstances:

1. When a regular member completes his/ her tenure.
2. If a regular member resigns before the tenure is completed.
3. If a regular member ceases to be a member for any reason including death or disqualification.
4. To fulfill the membership requirements as per 5.3 of this SOP.

b) 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 provided the potential member fulfils the conditions of appointment as defined in 5.8 of this SOP after discussion by the IEC. The names of new members to be appointed may be suggested by the IEC members to the Chairperson. 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.

  (i) 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.

  (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 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.

(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 him/ her.

(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 SAE Subcommittee member may be disqualified from SAE Subcommittee membership if the member fails to attend more than 5 regular consecutive SAE Subcommittee meetings without prior intimation. The process conducted will be as follows:

(i) The Head of SAE Subcommittee will inform Chairperson, in writing, if a member has not attended more than five consecutive regular meetings of the SAE Subcommittee.

(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 SAE Subcommittee 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 SAE Subcommittee 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 respective 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 Head of SAE Subcommittee will inform the IEC members about the cessation of membership by a confidential written communication to other members of IECs or at the next meeting of IECs.

5.7 Conditions of appointment:

Members will be appointed to the 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.

5.8 Hierarchy:

- There will be one SAE Subcommittee-Head, one executive Secretary of SAE Subcommittee.
- The executive Secretary 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 elected 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.

5.9 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.

5.10 Functions of the Executive secretary of the SAE Subcommittee:

1. To receive All type of adverse event reports (SAE, UAE, AE, SUSAR's).
2. To organize an effective and efficient tracking procedure for each onsite adverse event report received.
3. To inform the adverse events (serious and unexpected) reports to other members of the SAE Subcommittee.
4. To schedule and organize the SAE Subcommittee meetings.
5. To prepare and maintain meeting agenda and minutes.
6. To prepare the communication letters related to the adverse event reports.
7. To communicate with the IEC members and applicants/ investigators.
8. To provide necessary administrative support for SAE Subcommittee related activities.
9. To ensure adherence of the SAE Subcommittee functioning as per SOPs.

5.11 Functions of the IEC Secretariat:

- The IEC Secretariat will perform the functions as mentioned in **SOP11-B/V6** for the SAE Subcommittee.

1. Functions of the Administrative Manager, Officer/s, Executive Assistant.

2. To support the Executive Secretary in executing functions of the SAE Subcommittee.
3. 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

4. The agenda will also include information about onsite AE reports and SAE/UAE reports for the SAE /UAE occurring at other trial sites.

5. 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	Recommendation (s) by the SAE Sub Committee

The minutes will also include the notification /recommendation on the onsite AE reports and other site SAE/UAE reports

4. To perform any other functions as instructed by Executive Secretary/ Head of the SAE Subcommittee.

5.12 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, discuss and consider adverse event reports submitted for evaluation.
- 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 2019, G.S.R 227 (E) 19th March 2019. The SAE subcommittee while reviewing may solicit opinion of one or more independent consultant(s) 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 cause and abide by the rules and regulations of IEC or the necessary confidentiality documents are signed. The

independent consultant would be requested to provide an opinion in writing within 2-3 working days, depending upon the gravity and seriousness.

- The following decisions/actions including the following but not limited to, are listed below:

1. Note the information about the SAE in records for future reference.
2. To opine on compensation entitled to research participants (as per New Drugs and Clinical Trials, Rules 2019, G.S.R 227 (E) 19th March 2019) experiencing Serious Adverse Event and unexpected adverse events and adverse events and recommend appropriate action(s).
3. 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.
4. Provide periodic follow-up of the research participant till SAE is resolved or till death occurs (whichever is earlier).In case of pregnancy as SAE to send follow up reports of the child in utero and post delivery of the baby till 1 year.

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 IEC 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.

5.13 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.

5.14 Minutes of the SAE subcommittee meeting:

Minutes of SAE subcommittee meeting will be prepared by SAE subcommittee Executive secretary. These minutes will then be presented in the next Full Board meeting of IEC-I and IEC-II by respective member secretaries.

5.15 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 the each adverse event report.
- The SAE Subcommittee will review the serious adverse event, unexpected adverse event and non serious 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 2019, G.S.R 227 (E) 19th March 2019).

Institutional Ethics Committee (IEC)
Seth G.S. Medical College and K.E.M. Hospital, Parel, Mumbai, Maharashtra ,India – 400 012.
Web: www.kem.edu

Title: Review of Serious Adverse Events (SAE) Reports and Unexpected Adverse Events (UAE)

SOP Code:

SOP 11-B/V6 dated 15th July 2019

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe procedures for the review of initial and follow-up reports of adverse events (AE), serious adverse events (SAE) and unexpected adverse events (UAE) reported to the IEC by our sites and other site reports at Seth GS Medical College and KEM Hospital for any study under the oversight of the Institutional Ethics Committee (IEC).

2. Scope

This SOP applies to the review of AE, SAE and UAE reports submitted to the IEC.

3. Responsibility

It is the responsibility of the IEC to review AEs, SAEs and UAEs reported to the IEC. These could be AEs, SAEs and UAE occurring at Seth GS Medical College and KEM Hospital or other sites for the given project/related project.

4. Activity Table

No.	Activity	Responsibility
1	Receipt of AE, SAE and UAE report.	Secretariat.
2.	Submission of AE, SAE and UAE report to the Subcommittee.	Secretariat.
3	Agenda and Minutes of the Subcommittee.	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.	Communication of the IEC decision about SAE review to the principal investigator.	Secretariat.
7.	Communication of the IEC decision about SAE review to DCI.	Member Secretary / Chairperson of the IEC.
8	Discussion/Information at the full board IEC meeting	Member Secretary of the IEC.

5. Detailed Instructions

5.1 Onsite SAE and UAE:

5.1.1 Receipt of SAE/UAE report :

- The IEC Secretariat will receive the following documents within the specified time frame pertaining to SAE /UAE experienced by the research participants ON SITE for research proposals approved by the IEC:
  - i. On site SAE or UAE report to be submitted by the Principal Investigator within 24 hours of their occurrence as per the format specified in *AX 01/SOP 11-B/V6 & AX 03/SOP 11-B/V6 (SAE Reporting format for Biomedical Health Research)* (as per Appendix XI of Schedule Y)
  - ii. In the case of SAE, the report with due analysis will be submitted by the Principal investigator within 14 days along with the format specified in *AX 02/SOP 11-B/V6*
  - iii. In the case of SAE, the report with due analysis will be submitted also by the sponsor within 14 days along with the format specified in *AX 02/SOP 11-B/V6*
  - iv. On site SAE / Unexpected AE close out report for SAE at the site to be submitted by the Principal Investigator with the format specified in *AX 04/SOP 11-B/V6.*
- 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 violation.
- The IEC Secretariat will sign and write the date and type of report on which the report is received.
- For all the onsite SAE/ UAE reports received at the IEC office, the Administrative Officer will forward these reports to the executive secretary of the SAE Subcommittee within two working days.

5.1.2 Review of SAE, UAE Reports:

- Secretary of the SAE Subcommittee will review the SAE /UAE report and arrange a meeting depending on the timelines.
- SAE and UAE reports submitted to the IEC will be reviewed by the SAE subcommittee at least weekly or more often (as needed).
- The constitution and functioning of the SAE subcommittee is described in SOP 11-A/V6
- At the meeting, the members of the SAE subcommittee will review all the SAE/UAE reports received in the earlier week and submit a report stating the recommendations on the SAE/UAE report discussed in the meeting to IEC.

5.1.3 Communication to the IEC:

i. The IEC Secretariat will receive the minutes within 5 working days of the meeting of the SAE subcommittee and recommendation taken on the onsite SAE /UAE report.
ii. This report will be circulated to the IEC members *via* email and approval/ objection will be sought from the members in a period of 2 days.
iii. If approval is obtained from all the IEC members the decision will be communicated to the Licensing authority (DCI) within 30 days of the occurrence of the SAE.
iv. If the SAE is death then the decision will be communicated to DCI within 30 days of the occurrence of the SAE- Death.

v. If decision is that research participant is entitled for financial compensation an emergency IEC meeting will be scheduled within 7 days for the same (refer SOP 14/ V6)

vi. If objection is received from more than 2 IEC members an emergency IEC meeting will be scheduled within 7 days for the same.

- The decision taken at the emergency IEC meeting regarding the onsite SAE/UAE report will be communicated to the Licensing authority (DCI) within 30 days of the occurrence of the SAE. If the SAE is death then the decision will be communicated to DCI within 30 days of the occurrence of the SAE-DEATH.

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 / Chairperson (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/UAE, 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 principal investigator will be requested to forward follow-up reports after due analysis of the SAE/unexpected AE report to the IEC within 14 days of the occurrence of the SAE/unexpected AE report.
- The Administrative Officer will file a copy of the query letter in the study file.

5.1.5 Inform Licensing authority (DCI):

- The Member-Secretary / Chairperson (IEC) of the IEC will forward the letter describing the opinion on the SAE report death, along with the opinion on financial compensation, to the Chairperson of the Expert Committee constituted by the Licensing authority (DCI) and also a copy to DCI within 30 days of the occurrence of the SAE-death.
- The Member-Secretary / Chairperson (IEC) of the IEC will forward the letter the decision taken on the given SAE report (other than death)/unexpected adverse event report along with the opinion on financial compensation to the Licensing authority (DCI) within 30 days of the occurrence of the SAE/ unexpected adverse event.
- 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:
    1. On site AE reports to be submitted by the Principal Investigator annually.
    2. 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 Administrative Officer will forward these reports to the executive secretary of the SAE Subcommittee within two working days.

5.2.2 Review of AE Reports:

- AE reports submitted to the IEC will be reviewed by the SAE subcommittee at the scheduled meetings as per procedures described in SOP 11A and minutes communicated to IEC Secretariat.

5.2.3 Inform Investigator:

- The SAE/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/-Chairperson (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 AE 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 AE report, 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.

5.2.4 Further action:

- The Administrative Officer will file a copy of these letters in the study file.
- If deemed necessary Licensing Authority will be informed.

Custodian:

5.3 SAEs occurring at other sites:

The investigator will need to submit the SAEs occurring at other sites (CIOMS, SUSARS and Appendix XI) 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]
- 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 During the Full board IEC meeting:

- The IEC Member Secretary will read out the minutes of all the weekly SAE Sub-committee meetings including the recommendations/decisions of the SAE sub-committee.
- In case of the AE/ SAE/UAE occurring at the site to be discussed at the full board meeting, the member secretary will also provide the relevant information including updates on AE/ SAE/ UAE that have occurred earlier at the site. The Chairperson will invite members to voice their opinions and ensure free and frank discussion.
- If appropriate to the discussions and any issues put forth by SAE subcommittee, the issue can be re-discussed and decision can be arrived at by voting (a majority vote for a decision is 2/3rd majority of the members present and voting) or by consensus.

  Actions 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, fax or 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/SOP 11-B/V6*	Checklist for Serious Adverse Event & Unexpected Serious Adverse Event Submission.
Annexure 2	*AX 02/SOP 11-B/V6*	Serious Adverse Event Analysis Report (**For SAE at the site)**
Annexure 3	*AX 03/SOP 11-B/V6*	Serious Adverse Event Report (Biomedical Health Research)
Annexure 4	*AX 04/SOP 11-B/V6*	Serious Adverse Event close out Report **(For SAE at the site)**
Annexure 5	*AX 05/SOP 11-B/V6*	Serious Adverse Event at other site

Annexure 1

AX 01/SOP 11-B/V6

Checklist for Serious Adverse Event & Unexpected Serious Adverse Event submission

Sr. No.	**Details**		
1.	**Country (Name of the country should be specified)**		
2.	**SAE report of death or other than death, Please tick (✓)**	**Death** ☐	**Other than Death** ☐
		Yes / No	**Page No.**
3.	**In case of Serious Adverse Event(SAE), please specify if there is any injury to the participant (Please specify Yes/No) in the box**		

4.	Protocol Title		
5.	Protocol Study No./ ID /Code		
6.	Copy of Clinical Trial permission obtained from CDSCO		
7.	CTRI Registration No. (Mandatory for Clinical Trial Permitted after 15/06/09)		
8.	Sponsor(Address with contact no and Email)		
9.	CRO (Address with contact no and Email)		
10.	Initial / Follow-up (FU)		
11.	In case of follow-up: Date & Diary no of initial or recently submitted report information		
12.	**Patient Details**		
a)	Initials & other relevant identifier (hospital/OPD record number etc.)		
b)	Gender		
c)	Age and/or date of birth		
d)	Weight		
e)	Height		
13.	**Suspected Drug(s)**		
a)	Generic name of the drug.		
b)	Indication(s) for which suspect drug was prescribed or tested.		
c)	Dosage form and strength.		
d)	Daily dose and regimen (specify units - e.g., mg, ml, mg/kg).		
e)	Route of administration.		
f)	Starting date and time of day.		
g)	Stopping date and time, or duration of treatment		
14.	**Other Treatment(s)**		
	Provide the same information for concomitant drugs (including non prescription/OTC Drugs) and non-drug therapies, as for the suspected drug(s).		
15.	**Details of the events**		
a)	Full description of event (s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction.		
b)	Start date (and time) of onset of reaction.		
c)	Stop date (and time) or duration of reaction.		
d)	Dechallenge and rechallenge information.		
e)	Setting (e.g., hospital, out-patient clinic, home, nursing home).		
16.	**Outcome**		
a)	Information on recovery and any sequelae; results of		

	specific tests and/or treatment that may have been conducted.		
b)	For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; any post-mortem findings.		
c)	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.		
17.	**Details about the Investigator**		
a)	CT Site Number, if any		
b)	Name		
c)	Address		
d)	Telephone/Mobile Number & Email		
e)	Profession (speciality)		
f)	Date of reporting the event to Licensing Authority:		
g)	Date of reporting the event to Ethics Committee overseeing the site:		
h)	Signature of the Investigator		
18.	**Details about the Ethics Committee**		
a)	Name & Address		
b)	Name of Chairman & Address		
c)	Telephone/Mobile Number		
d)	Email		
19.	Adverse Event Term / Details of SAE		
20.	Causality Assessment (Related/Unrelated) by Investigator.		
21.	Causality Assessment (Related/Unrelated) by Sponsor/CRO		
22.	Details of compensation provided for injury or death. In case no compensation has been paid, reason for the same :		
23. a)	Duly filled SAE Form as per Appendix XI of Schedule Y		
b)	Laboratory investigations report /Discharge summary (if available and applicable)		
c)	Post-mortem report (if applicable)/ Any additional documents)		

Note: Information not relevant to a particular SAE should be marked with NA

Annexure 2

AX 02/SOP 11-B/V6

Serious Adverse Event analysis Report

(For SAE at the site)

Sr. No.	Details		
14.	**Country (Name of the country should be specified)**		
15.	**SAE report of death or other than death, Please tick (✓)**	**Death** ☐	**Other than Death** ☐
		Yes / No	**Page No.**
16.	**In case of Serious Adverse Event(SAE), please specify if there is any injury to the participant (Please specify Yes/No) in the box**		
17.	Protocol Title		
18.	Protocol Study No./ ID /Code		
19.	Copy of Clinical Trial permission obtained from CDSCO		
20.	CTRI Registration No. (Mandatory for Clinical Trial Permitted after 15/06/09)		
21.	Sponsor(Address with contact no and Email)		
22.	CRO (Address with contact no and Email)		
23.	Initial / Follow-up (FU)		
24.	In case of follow-up: Date & Diary no of initial or recently submitted report information		
25.	**Patient Details**		
f)	Initials & other relevant identifier (hospital/OPD record number etc.)		
g)	Gender		
h)	Age and/or date of birth		
i)	Weight		
j)	Height		
26.	**Suspected Drug(s)**		
a)	Generic name of the drug.		
b)	Indication(s) for which suspect drug was prescribed or tested.		
c)	Dosage form and strength.		
d)	Daily dose and regimen (specify units - e.g., mg, ml, mg/kg).		
e)	Route of administration.		
f)	Starting date and time of day.		
g)	Stopping date and time, or duration of treatment		
14.	**Other Treatment(s)**		

	Provide the same information for concomitant drugs (including non prescription/OTC Drugs) and non-drug therapies, as for the suspected drug(s).		
15.	**Details of the events**		
a)	Full description of event (s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. In addition to a description of the reported signs and symptoms, whenever possible, describe a specific diagnosis for the reaction.		
b)	Start date (and time) of onset of reaction.		
c)	Stop date (and time) or duration of reaction.		
d)	Dechallenge and rechallenge information.		
e)	Setting (e.g., hospital, out-patient clinic, home, nursing home).		
16.	**Outcome**		
a)	Information on recovery and any sequelae; results of specific tests and/or treatment that may have been conducted.		
b)	For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction; any post-mortem findings.		
c)	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.		
17.	**Details about the Investigator**		
a)	CT Site Number, if any		
b)	Name		
c)	Address		
d)	Telephone/Mobile Number & Email		
e)	Profession (speciality)		
f)	Date of reporting the event to Licensing Authority:		
g)	Date of reporting the event to Ethics Committee overseeing the site:		
h)	Signature of the Investigator		
18.	**Details about the Ethics Committee**		
a)	Name & Address		
b)	Name of Chairman & Address		
c)	Telephone/Mobile Number		
d)	Email		
19.	Adverse Event Term / Details of SAE		
20.	Causality Assessment (Related/Unrelated) by Investigator.		
21.	Causality Assessment (Related/Unrelated) by		

	Sponsor/CRO		
22.	Details of compensation provided for injury or death. In case no compensation has been paid, reason for the same :		
23. a)	Duly filled SAE Form as per Appendix XI of Schedule Y		
b)	Laboratory investigations report /Discharge summary (if available and applicable)		
c)	Post-mortem report (if applicable)/ Any additional documents)		

Details of payment for medical management of SAE? (please give information who paid how much was paid, to whom, with evidence of the same)

What is the investigator's assessment for the amount of compensation to be paid?

What is the sponsor's assessment for the amount of compensation to be paid?

Has the participant made a claim? Yes No

If yes, for how much amount _____

If no, please ensure that the participant / nominee have been made aware of his/her' rights regarding compensation. Please submit documentation regarding the same

_____

_____

_____

Signature of the Principal Investigator : Date:_____

For IEC office use only

Verified by:

Name: _____

(Signature with date of IEC administrative staff) _____

Note: Information not relevant to a particular SAE should be marked with NA

Annexure 3

AX 03/SOP 11-B/V6

Serious Adverse Event Report
(For Biomedical Health Research)

(Annexure 6)

Serious Adverse Event Reporting Format (Biomedical Health Research)

Logo of the Institute

..... *(Name of the Institution)* **EC Ref. No.** *(For office use):*

Title of study: .....

.....

.....

Principal Investigator (Name, Designation and Affiliation): .....

.....

.....

1. Participant details :

Initials and ID	Age at the time of event	Gender	Weight:.....(Kgs)
.....	.....	Male ☐ Female ☐	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 [19]:

.....

.....

.....

.....

.....

.....

.....

4. Details of suspected intervention causing SAE [20]

.....

.....

.....

.....

.....

.....

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 ☐

.....

.....

.....

.....

[19] *Duration, setting, site, signs, symptoms, severity, criteria for regarding the event serious*

[20] *Refers to research intervention including basic, applied and operational research or clinical research, except for investigational new drugs. If it is an academic clinical trial, mention name, indications, dosage, form and strength of the drug(s)*

Version 1.0

7. In case of a multi-centric study, have any of the other study sites reported similar SAEs ?

   (Please list number of cases with details if available)

   .....

   .....

8. Tick whichever is applicable for the SAE: (Kindly note that this refers to the Intervention being evaluated and NOT disease process)

   A. Expected event ☐ Unexpected event ☐

   B.

Hospitalization	☐	Increased Hospital Stay	☐	Death	☐	Congenital anomaly/ birth defect	☐
Persistent or significant disability/incapacity	☐	Event requiring intervention (surgical or medical) to prevent SAE	☐	Event which poses threat to life	☐	Others	☐

   .....

   In case of death, state probable cause of death.....

   C. No permanent/significant functional/cosmetic impairment ☐

   Permanent/significant functional/cosmetic impairment ☐

   Not Applicable ☐

9. Describe the medical management provided for adverse reaction (if any) to the research participant. (Include information on who paid, how much was paid and to whom).

   .....

   .....

10. Provide details of compensation provided / to be provided to participants (Include information on who pays, how much, and to whom).....

    .....

11. Outcome of SAE

    Resolved ☐ Ongoing ☐ Death ☐ Others *(specify)* ☐

    .....

12. Provide 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 PI: ..... dd mm yy

Version 1.0

Annexure 4

AX 04/SOP 11-B/V6

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?	

Signature of Principal Investigator: _____ Date _____

For IEC office use only
Verified by:
Name: _____
(Signature with date of IEC administrative staff) _____

Annexure 5

AX 05/SOP 11-B/V6

Serious Adverse Event

(For SAE at other site)

Checklist for Serious Adverse Event at other site

Sr. No.	**Details**	
1	Project No.	
2	Project Title	
3	Serial No.	
4	Patients Initial	
5	Country	
6	Age	
7	Sex	
8	Weight	
9	SAE-Onset date	
10	SAE criteria	
11	SAE Term –I,II,III…..	
12	Suspected drug name	
13	Suspected drug dose	
14	Suspected drug ROA(Route Of Administration)	
15	Indication	
16	Therapy start date	
17	Therapy end date	
18	Therapy duration (days)	

19	Sponsor	
20	MFR No.	
21	SAE- reporting Date	
22	Report source	
23	Report Type	
24	Causality by PI	

Signature of Principal Investigator: _____ Date _____

For IEC office use only

Verified by:

Name: _____

(Signature with date of IEC administrative staff) _____

Institutional Ethics Committee (IEC)
Seth G.S. Medical College and K.E.M. Hospital, Parel, Mumbai, Maharashtra ,India – 400 012.
Web: www.kem.edu

Title: Site Monitoring Visit

SOP Code:

SOP 12 /V6 dated 15th July 2019

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide the procedures to select 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 agent to perform on-site inspection of selected study site(s) of relevant projects it has approved.

The IEC members or Secretariat in consultation with the Chairperson may initiate an on-site evaluation of a study site for a routine audit.

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, Secretariat
3	During the visit	IEC members / representative
4	After the visit	IEC members /representative, 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 01/SOP 05-A/V6*.
- The Chairperson will identify and designate one or more IEC members or independent monitor to carry out routine monitoring of the study site.
- The reason for identifying a particular site for 'monitoring' will be provided to an IEC member. This cause could include any one or more of the following:
  - Routine monitoring
  - High number of protocol violations, or
  - Large number of studies carried out at the study site or by the investigator, or
  - 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.

- After discussion at an IEC meeting, decision regarding conducting 'monitoring' will be taken. The Chairperson will identify and select one or more IEC members or independent monitor who along with IEC members will conduct monitoring of a site.

5.2 Before the visit

- The IEC Chairperson will designate an IEC member or appoint an Independent monitor who along with IEC members will perform the task of monitoring. The selected member or independent monitor will be provided with an appointment letter in this regard. A copy of the appointment letter along with the agenda for monitoring (mentioned in SOP 12 Version 6 point no. 5.3) will be forwarded to the Principal Investigator of the site to be monitored. The IEC members and independent monitor (if designated) will sign a Confidentiality/ Conflict of Interest Agreement Form prior to accessing documents related to study and visiting the study site.
- The Secretariat will inform the Principal Investigator in writing about the date/time of monitoring visit and request for confirmation from the Principal Investigator or Co-investigator to be available for the monitoring visit.
- The 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/V6 from the 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 possible,
  - ✓ Review randomly selected participants files to ensure that participants are signing the correct informed consent,
  - ✓ Observe laboratory and other facilities necessary for the study at the site, if possible.
  - ✓ Review the project files of the study to ensure that documentation is filed appropriately.
  - ✓ Review the source documents for their completeness.
  - ✓ Collect views of the study participants, if possible.
  - ✓ Fill the Site Monitoring Visit Report Form- *AX 01/SOP 12/V6*, sign and date it.

5.4 After the visit

- The IEC member/ Independent monitor will submit the completed Site Monitoring Visit Report Form- *AX 01/SOP 12/V6 to* the IEC secretariat within *14 days* of conducting a site monitoring visit.
- The report should describe the findings of the monitoring visit. The member-secretary will present the monitoring report at the next full board IEC meeting and the concerned IEC member/ independent monitor will provide additional details/ clarifications to members, as required.
- The IEC will discuss the findings of the monitoring process and take appropriate specific action by voting or combination of actions, some of which are listed below:
  - Continuation of the project with or without changes,
  - Restrictions on enrollment,
  - Recommendations for additional training,
  - Recruiting additional members in the study team,
  - Revising the **protocol or ICD or CRF** / providing qualifications/ experience criteria for members of the study team, termination of the study,
  - Suspension of the study, etc. (It can happen in situations where the investigator has not replied to monitoring visit findings letter within 60 days, corrective actions had been requested at previous reviews and were not implemented, major violations in conduct of the study)
- The final decision taken at the full board IEC meeting by the Chairperson is recorded in the Site Monitoring Visit Report Form- *AX 01/SOP 12/V6*
- The Secretariat will convey the decision to the Principal Investigator in writing within 14 days of the meeting.
- The Secretariat will place the copy of the report in the protocol file.

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/V6*	Site Monitoring Visit Report
Annexure 2	*AX 02/SOP 12/V6*	Checklist for Monitoring of Audiovisual recording of AV consent Process
Annexure 3	*AX 03/SOP 12/V6*	Guidance document for audio visual recording of AV consent Process

Annexure 1

AX 01/SOP 12/V6

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)	**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**
16)	**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**
17)	**Any Protocol Deviations/Violations noted? ☐ Yes ☐ No ☐ NA** **Have all the deviations/violations notified to IEC? ☐ Yes ☐ No ☐ NA**

	Comments (If Any)
18)	**Have the eligibility, inclusion exclusion criteria been adhered to? ☐ Yes ☐ No ☐ NA**
19)	**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 DSMU within 7 working days and deaths within 24hrs of the knowledge of PI?** **☐ Yes ☐ No ☐ NA** **Comments (If Any)** **_____**
21)	**Are the Investigational drugs accountability and prescription procedures performed and documented?** **☐ Yes ☐ No ☐ NA** **If 'Yes' kindly state the issues:** **_____** **_____**

22)	**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:** _____ _____
23)	**No of participants monitored during this visit:_____**
24)	**Duration of the visit:_____**
25)	**Any outstanding tasks/action items from the visit?** _____ _____ _____ _____

Monitoring visit conducted by:

Name of Lead Monitor _____

Signature and Date _____

Name of monitor_____

Signature and Date _____

Name of study team member present:_____

Signature and Date:_____

Annexure 2

AX 02/SOP 12/V6

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 Schedule Y 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 IC 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:_____

(Site Monitoring Visit)

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_____
    Remarks:_____

(Site Monitoring Visit)

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 and date of PI /Co-inv _____

Annexure 3

AX 03/SOP 12/V6

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 (eg to go to the bathroom or answer a phone). In such a case, the AV recording shall be stopped mentioning the time of stopping. It will be resumed/ restarted by stating the date and time of restarting the recording. YES /NO
7. The medically qualified authorized member of the research team administering the consent shall use the checklist to ask the potential participant/ LAR questions to document the authenticity of the informed consent process. Translation will be done as applicable. The answers of the participant/ LAR shall be recorded for each point. YES /NO
8. The actual signing process by all concerned parties should also be recorded. YES /NO

Post recording checklist:

1. The memory card/ storage device used in the camera for video recording will be the source document. Check the file for clarity regarding the audio and video recording. YES /NO
2. The memory card/ storage device used in the camera for video recording will be the source document. Check the file for clarity regarding the audio and video recording. YES /NO

3. Rename the file with the unique number for the patient on this research protocol. YES /NO

4. Make backup one by copying that file onto the dedicated external HDD that shall be used to document all consent AV recording for a specific research protocol. YES /NO

5. This external HDD should be suitably labeled and password protected. YES /NO

(Site Monitoring Visit)

6. Store the external HDD in a secure location to ensure confidentiality. YES /NO

7. Make backup two by copying that file onto a remote cloud storage with encryption using the computer with internet access. YES /NO

8. This should also be suitably located, labeled and password protected. YES /NO

Institutional Ethics Committee (IEC)
Seth G.S. Medical College and K.E.M. Hospital, Parel,
Mumbai, Maharashtra ,India – 400 012.
Web: www.kem.edu

Title: Agenda Preparation, Meeting Procedures and Recording of Minutes

SOP Code:

SOP 13/ V6 dated 15th July 2019

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe the administrative process and provide instructions for the preparation, review, approval and distribution of meeting agenda, 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 regular Full Board IEC meetings, divided into three stages: before, during and after the meeting.

3. Responsibility

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

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 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

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 (n =00)

B] Projects Exempted from review: (n =NIL)

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 (n =NIL)

E] Continuing review report/ completion report/ final clinical trial report reviewed and approved by The IEC member Secretary and Chairperson.

- **Continuing review report (n=NIL)**

- **Completion report:- (n=NIL)**

- **Termination report:- (n =NIL)**

F] Protocol deviations reviewed and noted by the IEC member Secretary and Chairperson (n =NIL)

G] IEC Site monitoring reports (n = NIL)
H] Other letters reviewed and noted by the IEC member Secretary / Chairperson (n = NIL)

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(n =NIL)

B. Minor Protocol / ICD amendments and other project related documents reviewed and approved by the IEC member Secretary and Chairperson (n =NIL)

C. Continuing review report/ completion report/ final clinical trial report reviewed and approved by the IEC member Secretary and Chairperson.

- **Continuing review report (n=NIL)**

- **Completion report:- (n=NIL)**

- **Termination report:- (n =NIL)**

F] Protocol deviations reviewed and noted by the IEC member Secretary and Chairperson (n =NIL)

G] IEC Site monitoring reports (n = NIL)

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. 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 Secretariat will collect and verify all forms/documents for completeness to keep all these papers in the meeting.
- The Secretariat will prepare the meeting agenda, according to the above mentioned format.
- The 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 Secretariat will send the agenda of the meeting to members via e-mail at least 1 day in advance of the scheduled meeting.
- The Secretariat will make a meeting room reservation for the scheduled meeting date and time.
- The 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 closes for vacation. Meeting will be held as scheduled provided there is quorum. For the IEC meeting, a quorum will consist of:

- 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

  besides the Member Secretary and the Chairperson.

- 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/V6* prior to attending the meeting.
- The Secretariat will obtain signatures on the Confidentiality /Conflict of Interest Agreement Form *AX 03/SOP 03/V6* from newly appointed members/ Guests/ observers/ Subject Expert prior to the start of the meeting.
- The Secretariat will obtain the signatures of all the IEC members on the attendance register.
- The Secretariat will obtain from members the written conflict of interest *AX 01/SOP13/V6* 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-A/V6– 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.

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 01/SOP 05-A/V6 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.
- 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 Secretariat will obtain the signature of all the members and of the Chairperson of the IEC on the IEC Decision Form *AX 01/SOP 05-A/V6*.
- If the study is approved, the Committee will determine the frequency of Continuing Review from each investigator.

- The 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 Secretariat will compose the summary of each meeting discussion and decision in a concise and easy-to-read style in the minutes within 7 working days of the meeting day.
- The Secretariat will make sure to cover all contents in each particular category to include the following as in annexure 2

5.4 Approval of the minutes

- The Secretariat will check the correctness and completeness of the minutes and forward the minutes to the IEC members/Chairperson for review within 7 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 Secretariat will place the original 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/V6* Conflict of Interest form
Annexure 2 *AX 02/SOP 13/V6* Sample format for minutes of the meeting

Annexure 1
AX 01/SOP 13/V6
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/V6
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	
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

- **<u>To discuss continuing review report</u>**
- **<u>Reminders already sent to PI for continuing review report not yet received</u>**
- **<u>To discuss Completion report</u>**
- **<u>To discuss termination report</u>**

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: (n =NIL)

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 (n =NIL)

E] Continuing review report/ completion report/ final clinical trial report reviewed and approved by The IEC member Secretary and Chairperson.

- **Continuing review report (n=NIL)**

- **Completion report:- (n=NIL)**

- **Termination report:- (n =NIL)**

F] Protocol deviations reviewed and noted by the IEC member Secretary and Chairperson (n =NIL)

G] IEC Site monitoring reports (n = NIL)

H] Other letters reviewed and noted by the IEC member Secretary / Chairperson (n = NIL)

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

D. Responses forwarded by the Principal Investigator to the query letter/resubmitted protocols(n =NIL)

E. Minor Protocol / ICD amendments and other project related documents reviewed and approved by the IEC member Secretary and Chairperson (n =NIL)

F. Continuing review report/ completion report/ final clinical trial report reviewed and approved by the IEC member Secretary and Chairperson.

- **Continuing review report (n=NIL)**

- **Completion report:- (n=NIL)**

- **Termination report:- (n =NIL)**

F] Protocol deviations reviewed and noted by the IEC member Secretary and Chairperson (n =NIL)

Period 5:

D. Other points for discussion (n =0)

e.g

3. Policy decisions of the meeting of IEC-I /II/III.
4. Report of any other subcommittee or group appointed/ designated by Chairperson for any specific or general purpose.

E. Next Meeting to be scheduled on xxxxxx (19, 20, reserved for staff society)

F. 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**

Institutional Ethics Committee (IEC)
Seth G.S. Medical College and K.E.M. Hospital, Parel,
Mumbai, Maharashtra ,India – 400 012.
Web: www.kem.edu

Title: Conduct of Emergency Meeting

SOP Code:

SOP 14 /V6 dated 15th July 2019

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 Secretariat will endeavor to contact each and every IEC member and inform about the date, time and venue of the meeting as well as the reason for calling for the meeting. For the purpose of calling an emergency meeting, contact by telephone or email to the email address provided by the member would be considered as sufficient.
- The Secretariat/ Administrative Officer will prepare packets for distribution to the members containing the information and documents about the matter(s) for which Emergency Meeting is scheduled or send the relevant details (incase the documents are too many) via email.
- The Administrative Officer 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 Administrative Officer 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 without a quorum provided 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 must be maintained throughout the entire discussion. Emergency meetings may be held via teleconference, if applicable.

Institutional Ethics Committee (IEC)
Seth G.S. Medical College and K.E.M. Hospital, Parel, Mumbai,
Maharashtra ,India – 400 012.
Web: www.kem.edu

Title: Maintenance of Active Project Files

SOP Code:

SOP 15 /V6 dated 15th July 2019

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 Secretariat will:

- Submission receive in the IEC office. Preserve soft copy and one original set (hard copy for regulatory studies and if needed non regulatory studies) 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.)
- All documents related to the study file are gathered, classified and combined together appropriately.
- The Administrative Officer will save the submissions which will be stored separately for IEC-I & II on e-EC software cloud based, on Google drive and on 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.

5.2 Maintain the active study files

The Administrative Officer will:

- Combine related documents of the approved study files appropriately.
- Attach an identity Label to the package.

- Keep all active and potential study packages 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 active study files will be password protected and will be accessible only to the IEC secretariat.
- The cupboard where hard copies of the active study files are kept will be kept in a lock and key and will have controlled access only to the secretariat.
- 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 secretariat after the permission of chairperson.
- Annual subscription of appropriate anti-virus and malware protector will be availed for the soft copy submissions.
- Annual maintenance of fire proof service provider and paste control provider will be availed for the protection of hard copies.
- Send all closed study files to the archive.

6. Glossary

Active Study File	Any approved protocol, supporting documents, records containing communications and reports that correspond to each currently approved study.

Institutional Ethics Committee (IEC)
Seth G.S. Medical College and K.E.M. Hospital, Parel, Mumbai, Maharashtra ,India – 400 012.
Web: www.kem.edu

Title: Archiving and Retrieving Documents

SOP Code:

SOP 16 /V6 dated 15th July 2019

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide instructions for storage/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.

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 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 secretariat.

- 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 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.

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/V6*
- The requestor must also sign and date the log of request. (*AX 02/SOP 16/V6)*
- Retrieval of documents can only be done when a request is made in the request form (*AX 01/SOP 16/V6)* that is approved (signed and dated) by the IEC Chairperson/Member Secretary.
- For administrative purpose and while discussing / keeping the study completion report , 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 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 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/ Secretariat retrieving the file, Date and time of returning the file.
- The 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.\

6. Glossary

Administrative Documents	Documents include official minutes of Board meetings and the Standard Operating

	Procedures, both historical files and Master Files 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/V6*	Document Request Form
Annexure 2	*AX 02/SOP 16/V6*	Log of Requested IEC Documents

Annexure 1

AX 01/SOP 16/V6

Document Request Form

Name of Document requested:
Requested by: Name: ----------
☐ Chairperson ☐ Secretariat ☐ IEC Member
☐ 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/V6

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)

Institutional Ethics Committee (IEC)
Seth G.S. Medical College and K.E.M. Hospital, Parel,
Mumbai, Maharashtra ,India – 400 012.
Web: www.kem.edu

Title: Responding to Research Participant's Request or Complaint

SOP Code:

SOP 17 /V6 dated 15th July 2019

1. Purpose

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

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/ 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 request, complaint or query, from a research participant will be accepted by the Secretariat and forwarded to the IEC Member Secretary after entering into the Participant's Request/ Complaint Record Form **(**AX 01/ SOP 17/V6**)**
- The Member Secretary may receive a request, complaint or query directly from the participant. He/she will record it in the request record form AX 01/SOP 17/V6 and notify the Secretariat.
- The Member Secretary will additionally ascertain details of the request/ complaint by examining any relevant documents and by interviewing the participant if necessary. If required, the Member Secretary will call for additional relevant information and documents from the Principal Investigator (PI).
- The Secretariat will inform the Chairperson about the request, query or complaint received from the research participant.

- In case of a request for additional information or clarification, the Member Secretary in consultation with the Chairperson will provide the information himself / herself or will designate one or more IEC member(s) to provide such information.
- In case of a complaint received from a research participant, the Member Secretary, in consultation with the Chairperson will initiate a process to address any injustice that may have occurred. Depending on the seriousness of the matter, the Chairperson will direct the Member Secretary to:
  - Appoint a subcommittee of two or more IEC members for enquiry in order to resolve the matter.
  - Call an emergency meeting of two or more IEC members for discussion or
  - Consider the matter for discussion at the next full board meeting
  - The Member Secretary/ designated IEC members will assess the situation and mediate a dialogue between the research participant and PI in an attempt to resolve the matter.
  - The IEC will insist on factual details to determine gap, if any, between truth and individual perception.
- The final decision will be taken by the Member Secretary in consultation with the 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 Secretariat.
- The information including any action taken or follow-up and final decision will be recorded in the form AX 01/ SOP 17/V6 and the form is signed and dated.
- The IEC members will be informed about the action taken and the outcomes in the forthcoming IEC meeting (in case of requests/ complaints not discussed in full board meeting) and will be minuted.
- The Secretariat will place all documents in the relevant study file.

6. Annexure

Annexure 1 *AX 01/ SOP 17/V6* *Participant's Request/ Complaint Record Form*

Annexure 1

AX 01/SOP 17/V6

Participant's Request/ Complaint Record Form

Date	
Received by :	
Request received through:	❑ Telephone call No _____ ❑ Fax No _____ ❑ 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 _____

(Responding to Research Participant's Request or Complaint)

Institutional Ethics Committee (IEC)
Seth G.S. Medical College and K.E.M. Hospital, Parel,
Mumbai, Maharashtra ,India – 400 012.
Web: www.kem.edu

Title: Management of complaints by investigators

SOP Code:

SOP 18 /V6 dated 15th July 2019

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide guidelines for dealing with the appeal/complaint made by investigator (principal investigator, co-investigator) against the IEC office/members.

2. Scope:

This SOP applies to handling of appeal/complaint made by 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/ Members/ to the Head of the Institution

3. Responsibility:

It is the responsibility of the IEC to adhere to the principals of fairness, confidentiality, integrity and prevention of detriment while addressing appeal/ investigating the complaints by investigators.

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/ Secretariat/ Members
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/ 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, complaint or appeal by the investigator through Via Letter to Head of the Institution, Telephone call, fax, email or Walk-in etc.
- The annexure 1, *AX 01/SOP 18/V6* will filled and forwarded by the secretariat to the member secretary / chairperson.

5.2 Initiating process to identify the problem

- The Member Secretary /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 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 of Head of the institution/ Chairperson/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/V6* and the form is signed and dated.

5.4 Communication with the investigator

- The final decision will be informed to the investigators by the 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 Secretariat will place all documents in the relevant study file.

6. Annexure

Annexure 1	*AX 01/SOP 18/V6*	Complaint/ Appeal Record Form

Annexure 1

AX 01/SOP 18/V6

Complaint / Appeal Record Form for Investigators

Date	
Received by :	
Complaint/ Appeal received through:	❑ Letter to Head of the Institution ❑ Telephone call No _____ ❑ Fax No _____ ❑ 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 _____

Institutional Ethics Committee (IEC)
Seth G.S. Medical College and K.E.M. Hospital, Parel,
Mumbai, Maharashtra ,India – 400 012.
Web: www.kem.edu

Title: Request for Waiver of Written Informed Consent

SOP Code:

SOP 19 /V6 dated 15th July 2019

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/V6* is designed to standardize the process of applying for consent waiver.

2. Scope

This SOP applies to the all protocols with a request of granting consent waiver submitted for review by the IEC. The decision should be taken by the IEC members 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 responsibility of the 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/V6* 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/SOP 19/V6)*.
- ✓ 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/SOP 19/V6*	Application form for requesting waiver of consent

Annexure 1

AX 01/SOP 19/V6

Application form for requesting waiver of consent

1. **Principal Investigator's name:** _____
2. **Department:** _____
3. **Title of project:**

   _____

   _____

   _____
4. **Names of other participants, staffs and students:**

   _____

   _____

   _____
5. **Request for waiver of informed consent:**

- Please check the reason(s) for requesting waiver (Please refer the back of this annexure for criteria that will be used by IEC to consider waiver of consent).

  [1] Research involves 'not more than minimal risk'

  [2] There is no direct contact between the researcher and participant

  [3] Emergency situations as described in ICMR Guidelines (ICMR 2017 Guidelines- http://www.icmr.nic.in/ethical_guidelines.pdf)

  [4] Any other (please specify)

  _____

- Statement assuring that the rights of the participants are not violated

  _____

- State the measures described in the Protocol for protecting confidentiality of data and privacy of research participant

  _____

Principal Investigator's signature with date: _____

Final decision at full board meeting held on: _____

Waiver granted Yes ☐ No. ☐

If not granted, reasons _____

_____

_____

Signature of the Chairperson with Date: _____

Type of research projects which may qualify for consent waiver:

A request to waive written informed consent must be accompanied by a detailed explanation. The investigator is also required to provide assurance regarding protection of identity of research participants and maintenance of confidentiality about the data of the research participants. The following criteria (ICMR 2017 guidelines) 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,* 45CFR 46*)* 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 2017 guidelines)*

   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)

4. Research on anonymised 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)
5. In emergency situations when no surrogate consent can be taken. *(ICMR 2017 guidelines)* 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.

Institutional Ethics Committee (IEC)
Seth G.S. Medical College and K.E.M. Hospital, Parel,
Mumbai, Maharashtra ,India – 400 012.
Web: www.kem.edu

Title: Reviewing proposals involving vulnerable Populations.

SOP Code:

SOP 20 /V6 dated 15th July 2019

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 Secretariat of the Institutional Ethics Committee will

- Maintain on file the update checklist (1-5) 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, 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 patriarchical 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 (1-5). 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.

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 (for e.g. critically/terminally ill or socially/economically disadvantaged/HIV/Leprosy patients/marginalized population) the investigators wants to include the above mentioned population in the study .They have to mention in the protocol details regarding justification of including the vulnerable population for the study, risk and benefits to the study participants along with mechanism of minimizing risks , measures to protect their autonomy, measures for recruitment of such participants along with measures taken for protection of privacy and confidentiality .
- IEC can recommend for written / verbal Informed consent /audio –visual consent /audio consent (leprosy patients) in the vulnerable population . 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 locate such material related to vulnerable populations when specifically requested for, by a reviewing member

5.3 Review the protocol

Reviewers responsibility

- IEC Members will review the protocol and the informed consent document or assent form.
- The reviewers comments will be discussed in the IEC meeting and the final comments will be sent to the PI.
- The discussion will be documented in the minutes.
- 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

Approval of the protocol

- The final version of the protocol will be approved by the board with the appropriate checklist as given in annexure (1-5).
- 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 Review Board. The Committee has been constituted in accordance with the EC membership requirements set forth in Schedule Y (20th January 2005)
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	*AX 01/SOP 20/V6*	Checklist – Requirements for Research Involving Children
Annexure 2	AX 02/*SOP 20/V6*	Checklist – Requirements for Research Involving Pregnant Women & Fetuses
Annexure 3	AX 03/*SOP 20/V6*	Checklist- Research Involving Cognitively Impaired Adults
Annexure 4	AX 04/*SOP 20/V6*	Checklist-Research Involving Students, Employees or Residents
Annexure 5	AX 05/*SOP 20/V6*	Checklist- Considerations for Genetic Research
Annexure 6	AX 06/*SOP 20/V6*	Checklist- Requirements for Research involving terminally ill patients
Annexure 7	AX 07/*SOP 20/V6*	Checklist- Considerations for Research in HIV participant
Annexure 8	AX 08/*SOP 20/V6*	Checklist- Requirements for Research involving economically/socially backward/illiterate patients

Annexure 1

AX 01/ SOP 20/V6

Checklist –Requirements for Research Involving Children

Investigator: _____ IEC :
Study Title:_____

For the principal investigator		IEC Office
RISK DETERMINATION	BENEFIT ASSESSMENT	IEC ACTION
☐ Minimal *	☐ Direct benefit	Approvable
	☐ No direct benefit	
☐ Greater than minimal risk	☐ Potential to child	Approvable
☐ Greater than minimal risk	☐ No direct benefit to individual offer general knowledge about the child's condition or disorder.	Approvable case –by-case **

* Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or occurring during the performance of routine physical or psychological examinations or tests.

** Risk may not be more than a minor increase over minimal risk, consent of both parents is required under normal circumstances.

	Yes	No	NA
Does the research pose greater than minimal risk to children?	☐	☐	☐
If yes: Are convincing scientific and ethical justifications given?	☐	☐	☐
If yes: Are adequate safeguards in place to minimize these risks?	☐	☐	☐
Does the study involve normal volunteers?	☐	☐	☐
If yes: Is the inclusion of normal volunteers justified?	☐	☐	☐
Are the studies conducted on animals and adults, appropriate and justified?	☐	☐	☐
If No: Is the lack of studies conducted on animals and adults justified?	☐	☐	☐
Will older children be enrolled before younger ones?	☐	☐	☐
Is permission of both parents necessary?	☐	☐	☐
If Yes: Are conditions under which one of the parents may be considered: "not reasonably available" described?	☐	☐	☐
If Yes: Are the conditions acceptable?	☐	☐	☐
Will efforts be made ensure that parents' permission to involve their children in research studies is free from coercion, exploitation, and /or unrealistic promises?	☐	☐	☐
Are provisions made to obtain the assent of children over 7 and, where appropriate, honoring their dissent?	☐	☐	☐
Are provisions made to protect subjects' privacy and the confidentially of information regarding procedures?	☐	☐	☐
Are there special problems that call for the presence of a monitor or IEC member during consent procedures?	☐	☐	☐
Are special needs of adolescents such as counseling and confidentiality accounted for in the research design?	☐	☐	☐
Are there any special problems such as confidentiality and reporting that might arise in sensitive research about child abuse or sexual practices of teenagers?	☐	☐	☐
Does the research involve implications for other family member ?(for example, genetic risk , HIV infection , Hepatitis C)	☐	☐	☐
If Yes: Are there adequate mechanisms in place to deal with other members of the family?	☐	☐	☐
Are parents required to be present during the conduct of the research? (Are proposed participants to be very young? Are the procedures involved painful? Must the subject stay overnight in the hospital when they otherwise would not have to?)	☐	☐	☐

- Approval to proceed with this category of research must be made by the Administrator of the IEC, with input from selected experts

Signature of Principal Investigator: _____ Date _____

IEC Office use only	
Comments:	
Primary Reviewer Signature & Date	

Annexure 2

AX 02/ SOP 20/V6

Checklist – Requirements for Research Involving Pregnant Women & Fetuses

Investigator: ***IEC #:***

Study Title:

SECTION 1

☐ **THIS RESEARCH INVOLVES PREGNANT WOMEN OR FETUSES PRIOR TO DELIVERY**

	Yes	**No**	**NA**
Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;	☐	☐	☐
The risk to the fetus is not greater than minimal, or any risk to the fetus which is greater than minimal is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus;	☐	☐	☐
Any risk is the least possible for achieving the objectives of the research;	☐	☐	☐
The woman's consent or the consent of her legally authorized representative is obtained in accord with the informed consent provisions, unless altered or waived.	☐	☐	☐
The woman or her legally authorized representative, as appropriate, is fully informed regarding the reasonably foreseeable impact of the research on the fetus	☐	☐	☐
No inducements, monetary or otherwise, will be offered to terminate a pregnancy;	☐	☐	☐
Women's participation in the research will not have an effect on the decisions by investigator with respect to the timing, method or procedures used to terminate a pregnancy; and	☐	☐	☐
The decision of investigator determining the viability of a fetus will not have an effect if the women participates in the research	☐	☐	☐

If the response to any of the above is No, the research is not approvable by the IEC at this time. See section 3

SECTION 2

☐ **THIS RESEARCH INVOLVES FETUSES AFTER DELIVERY**

	Yes	No	NA
1. Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to fetuses	☐	☐	☐
2. The individual(s) providing consent is fully informed regarding the reasonably foreseeable impact of the **research** on the fetus	☐	☐	☐
3. No inducements, monetary or otherwise, will be offered to	☐	☐	☐

terminate a pregnancy;			
4. 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	☐	☐	☐
5. The decision of investigator determining the viability of a fetus will not have an effect if the women participates in the research	☐	☐	☐

AND

A. Fetuses of uncertain viability	**Yes**	**No**	**NA**
1. Does the **research** hold out the prospect of enhancing the probability of survival of the particular fetus to the point of viability, and any risk is the least possible for achieving the objectives of the **research;**	☐	☐	☐
OR			
The purpose of the **research** is the development of important biomedical knowledge which cannot be obtained by other means and there will be no risk to the fetus resulting from the **research**;	☐	☐	☐
2. The legally effective informed consent of either parent of the fetus or , if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's legally authorized representative is obtained.	☐	☐	☐

And/or

B. Nonviable fetuses	Yes	No	NA
1. Vital functions of the fetus will not be artificially maintained;	☐	☐	☐
2. There will be no risk to the fetus resulting from the research;	☐	☐	☐
3. The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and	☐	☐	☐
4. The legally effective informed consent of both parents of the fetus will be obtained except that the waiver and alteration provisions do not apply. However, if either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable fetus will suffice to meet the requirements of this paragraph. The consent of a legally authorized representative of either or both of the parents of a nonviable fetus will not suffice to meet the requirements of this paragraph.	☐	☐	☐

If the response to any of above is **No,** the research is not approvable by the IEC at this time. See section 3.

SECTION 3
THIS RESEARCH CAN BE CONDUCTED ONLY AFTER:

(a) The IEC finds that the research presents a reasonable opportunity to further the understanding, prevention or alleviation of a serious problem affecting the health or welfare of pregnant women or fetuses **and,**

(b) The secretary, after consultation with a panel of experts in pertinent disciplines (for examples: science, medicine, ethics, law) to determine either:
   (1) That the research in fact satisfies the conditions of Schedule Y , as applicable, or
   (2) The following:
      (i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women or fetuses;
      (ii) The research will be conducted in accord in sound ethical principles; and
      (iii) Informed consent will be obtained in accord with informed consent provisions of Schedule Y and other applicable subparts, unless altered or waived in accord.

Signature of Principal Investigator: _____ Date _____

IEC Office use only	
Comments:	
Primary Reviewer Signature & Date	

Annexure 3

AX 03/ *SOP 20/V6*

Checklist- Research Involving Cognitively Impaired Adults

- The purpose of this checklist is to provide support for IEC members or the Designated Reviewer when reviewing research involving cognitively impaired adults as subjects.
  1. For review using the expedited procedure this checklist is to be completed by the **Designated Reviewer** to document determinations required by the regulations and protocol specific findings justifying those determinations and retained.
  2. For review using the convened IEC is to document determinations required by the regulations and protocol specific findings justifying these determinations.

1. **Research Involving Cognitively Impaired Adults in which there is Anticipated Direct Benefit to the subject** (All items must be "Yes")		
☐ Yes	☐ No	One of the following is true (Check the box t-hat is true) ☐ The risk to the participants is presented by an intervention or procedure that holds out prospect of direct benefit for the individual subject. ☐ More than minimal risk to participants is presented by monitoring procedure that is likely to contribute to the participants well – being.
☐ Yes	☐ No	The risk is justified by the anticipated benefit to the participants.
☐ Yes	☐ No	The relation of anticipated benefit to the risk is at least as favourable to the participants as that presented by available alternative approaches.
☐ Yes	☐ No	The proposed plan for the assessment of the capacity to consent is adequate.
☐ Yes	☐ No	Assent is required of: (One of the following must be **"Yes")** One of the following is true (**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.
2.Research Involving Cognitively Impaired Adults in which there is No Anticipated Direct Benefit to the subject (All items must be "Yes")		
☐ Yes	☐ No	The proposed plan for the assessment of the capacity to consent is adequate.
☐ Yes	☐ No	The objectives of the trial cannot be met by means of study of participants who can give consent personally.
☐ Yes	☐ No	The foreseeable risks to the participants are low.
☐ Yes	☐ No	The negative impact on the participants well-being is minimized and low.
☐ Yes	☐ No	The trial is not prohibited by law.
☐ Yes	☐ No	Participants have a disease or condition for which the procedures in the research are intended.
☐ Yes	☐ No	Participants will be particularly closely monitored.
☐ Yes	☐ No	Participants will be withdrawn if they appear to be unduly distressed.
☐ Yes	☐ No	The proposed plan for the assessment of the capacity to consent is adequate.
☐ Yes	☐ No	Assent is required of (One of the following must be **"Yes")** One of the following is true **(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.

Signature of Principal Investigator: _____ Date _____

IEC Office use only	
Comments:	
Primary Reviewer Signature & Date	

Annexure 4

AX 04/SOP20/V6

Checklist-Research Involving Students, Employees or Residents

Participants who are students, employees or residents require special considerations.

Does the employer or supervisor of the research participant need to be aware of the research project?	☐ No	☐ Yes
Is there a letter of support and/ or internal services checklist?	☐ No	☐ Yes
Have the participants been assured that their status (education, employment, and/or promotion) will not be affected by any decision to participate or not?	☐ No	☐ Yes
Have the risks to participants been minimized?	☐ No	☐ Yes
Have participants been assured that participation is voluntary (no signs of coercion)?	☐ No	☐ Yes
Have participants been assured that confidentiality will be protected or maintained?	☐ No	☐ Yes

Signature of Principal Investigator: _____ Date _____

IEC Office use only	
Comments:	
Primary Reviewer Signature & Date	

Annexure 5

AX 05/SOP 20/V6

Checklist - Considerations for Genetic Research

Investigator: _____ ***IEC #:*** _____
Study Title:_____
_____
_____
_____
_____

	Yes	No
1. Will the samples be made anonymous to maintain confidentiality? If yes, stop here	☐	☐
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/V6

Checklist - Requirements for Research involving terminally ill patients

Principal Investigator Name: _____

Proj. No of IEC.-_____

Study Title:_____

RISK DETERMINATION	BENEFIT ASSEMENT	IEC ACTION
☐ Minimal	☐ With direct benefit ☐ Without direct benefit	☐ Approved ☐ Not Approved
	☐ Potential benefit	☐ Approved ☐ Not Approved
	☐ No direct benefit to individual but offer general knowledge about the child's condition or disorder and may benefit to the society or future generations are likely to benefit.	☐ Approved case by case (with special safeguards ☐ Not Approved
☐ Less than minimal risk	☐ With direct benefit ☐ Without direct benefit	☐ Approved ☐ Not Approved
	☐ Potential benefit	☐ Approved ☐ Not Approved
	☐ No direct benefit to individual but offer general knowledge about the child's condition or disorder and may benefit to the society or future generations are likely to benefit.	☐ Approved case by case (with special safeguards ☐ Not Approved
☐ Minor increase over minimal risk or Low risk	☐ With direct benefit ☐ Without direct benefit	☐ Approved ☐ Not Approved
	☐ Potential benefit	☐ Approved ☐ Not Approved
	☐ No direct benefit to individual but offer general knowledge about the child's condition or disorder and may benefit to the society or future generations are likely to benefit.	☐ Approved case by case (with special safeguards ☐ Not Approved
☐ More than minimal risk or High Risk	☐ With direct benefit ☐ Without direct benefit	☐ Approved ☐ Not Approved
	☐ Potential benefit	☐ Approved ☐ Not Approved
	☐ No direct benefit to individual but offer general knowledge about the child's condition or disorder and may benefit to the society or future generations	☐ Approved case by case (with special safeguards

(Reviewing proposals involving vulnerable Populations.)

	are likely to benefit.	☐ Not Approved

Minimal risk- Probability of harm or discomfort anticipated in the research is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population or during the performance of routine tests where occurrence of serious harm or an adverse event (AE) is unlikely

	Yes	No	NA
Does the research pose greater than minimal risk to patients?	☐	☐	☐
If yes: Are convincing scientific and ethical justification given?	☐	☐	☐
If yes: Are adequate safeguard in place to minimize these risks?	☐	☐	☐
Are appropriate studies that have been conducted on animals and adults justified?	☐	☐	☐
If No: Is the lack of appropriate studies conducted on animals and adults justified?	☐	☐	☐
Do the anticipated benefits justify requiring the subjects to undertake the risks	☐	☐	☐
Is inclusion of vulnerable population warranted?	☐	☐	☐
Can the research question be answered by using a non-vulnerable population?	☐	☐	☐
Will efforts be made ensure that participants are free from coercion, exploitation, and /or unrealistic promises?	☐	☐	☐
Are provisions made to obtain the consent?	☐	☐	☐
Are provisions made to protect participant's privacy and the confidentially of information regarding procedures?	☐	☐	☐
Are there special problems that call for the presence of a monitor or IEC member during consent procedures?	☐	☐	☐
Are special needs of counseling and confidentiality accounted for in the research design?	☐	☐	☐
Are there any special problems such as confidentiality and reporting that might arise in this research	☐	☐	☐

Comments-

Name & Sign of Primary Reviewer :

Date:

Annexure 7

AX 07/SOP 20/V6

Checklist - Considerations for Research in HIV participant

Investigator: _____ ***IEC #:*** _____

StudyTitle:_____

_____

_____

	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 requires family members/caretakers permission ?	□	□
10.Would the confidentiality will be maintained ?	□	□
11.Will family members / care takers will 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.Would the participant provided with effective referral to appropriate follow-up services as indicated, including long term prevention and treatment support?	□	□

Signature of Principal Investigator: _____ Date _____

IEC Office use only	
Comments:	
Primary Reviewer Signature & Date	

Annexure 8

AX 08/SOP 20/V6

Checklist –Requirements for Research involving economically/socially backward/illiterate patients

Principal Investigator
Proj. No.-
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	☐	☐	☐

Comments-
_____
_____
_____
_____

Name & Sign of Primary reviewer :
Date:

Institutional Ethics Committee (IEC)
Seth G.S. Medical College and K.E.M. Hospital, Parel,
Mumbai, Maharashtra ,India – 400 012.
Web: www.kem.edu

Title: Common Ethic Review of Multicentre Research

SOP Code:

SOP 21/V6 dated 15th July 2019

1. Purpose

In case of multicentric studies wherein IEC have BEEN GIVEN the responsibility of designated IEC (DEC), will undertake a common review of the study proposal with mutual agreement of all the ECs of participating centres (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 on e-EC software	Member Secretary
3	Review of the assigned protocols on e-EC	Designated IEC Members
4	Compile the comments of IEC members on e-EC software	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 Determine the protocol submitted by coordinating PI for common ethical FULLBOARD 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. 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 on e-EC software (Selection of PR)

- The Member Secretary, IEC 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 a position to review due to some reason, he/she should inform the Member Secretary, IEC at the earliest, so that the research study can be assigned to another member.
- 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 independent consultant or 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 04/SOP 05-A/V6*.)

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 Scientific Design and Conduct of the Study

- Is the project original and innovative? e.g. Does the project challenge existing paradigms or clinical practice; address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools or technologies for this area?
- Is this an attempt to validate, prove or disapprove the validity of existing knowledge?
- Appropriateness of study design, work plan and structure to achieve the stated objectives: Are the conceptual or clinical framework, design, methods and analyses adequately developed, well integrated, well reasoned and appropriate to the aims of the project?
- Relevance of the work in the context of contemporary translation or clinical cancer research:
  - ❖ Does this study 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?
- Appropriateness of the study design in relation to the objectives of the study;
- The statistical methodology (including sample size calculation), and the potential for reaching sound conclusions with the smallest number of research participants;
- The justification of predictable risks and inconveniences weighed against the anticipated benefits for the research participants and the concerned communities;

- 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 sites, including the support staff, available facilities, and emergency procedures;
- Study Reporting and publication of the research.
- Regulatory permission for conduct of the study, HMSC clearance for international collaborative studies, LoU and MoU for national and international collaborative research.
  - ✓ minimize risks to participants;
  - ✓ risks must be reasonable in relation to anticipated benefits;
  - ✓ participants are selected equitably;
  - ✓ informed consent is adequate, easy to understand and properly documented;
  - ✓ the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants, where appropriate;
  - ✓ there are 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.

5.3.3 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 to review protocol and Informed Consent Document/Patient Information Sheet in *AX 04/SOP 05-A/V6.*

- 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.

5.3.4 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
- Benefit to local communities
- Contribution to development of local capacity for research and treatment
- Availability of study results

5.4 Compile the comments of IEC members on e-EC software

The MS will compile the comments from each reviewer on e-EC software.

6. Discussion of the comments in FB meeting.

The proposal will be discussed in FB meeting by all IEC members. 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)

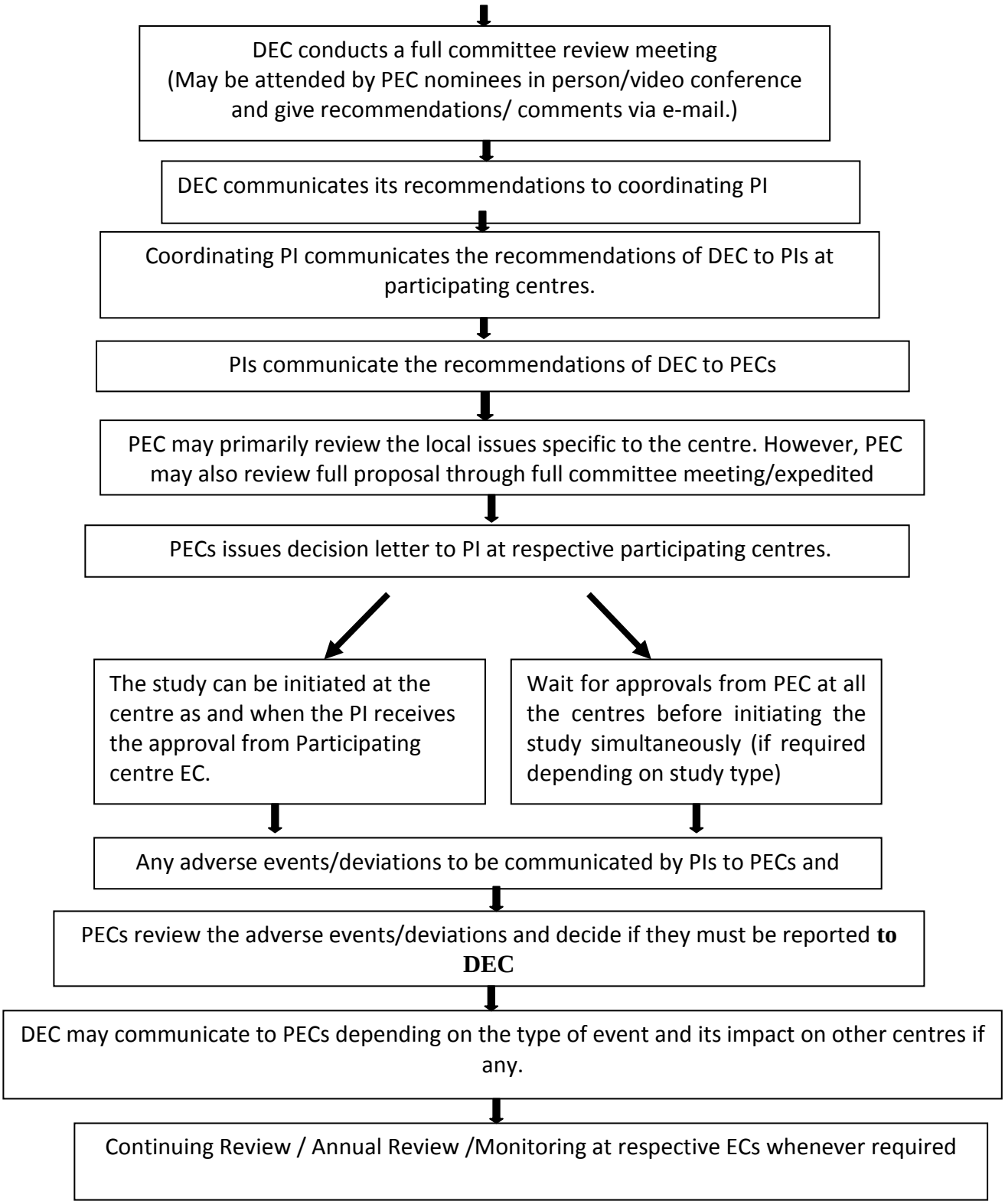
7. Annexure

Annexure 1	*AX 01/SOP 21/V6*	Flowchart for common review process of multicentric study
Annexure 2	*AX 02/SOP 21/V6*	Draft - LoU format for Common Review of multicenter research

Annexure 1

AX 01/SOP 21/V6

Flow chart for Common Review Process of Multicentre Research



Annexure 2

AX 02/SOP 21/V6

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: ……
……
……
……

References:

1. New Drugs and Clinical Trials Rules, 2019 – cdsco [Internet] 2019 June. [updated 2019 March ;cited 2019 June 5]Available from https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf.
2. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), INTEGRATED ADDENDUM TO ICH E6(R1): GUIDELINE FOR GOOD CLINICAL PRACTICE E6(R2) [updated 2016 Nov 9 ;cited 2019 June5]Available from https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4_2016_1109.pdf.
3. Good Clinical Practices for Clinical Research in India, CDSCO, 2005 [updated 2015 ;cited 2019 June 5]Available fromhttps://www.ncbi.nlm.nih.gov/pmc/articles/PMC3612334/
4. 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.
5. 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.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf
6. 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
7. Information Brochure for Ethics Committee Accreditation Program –Dec 2016 [updated 2016 ;cited 2017 July 31]Available from https://www.nabh.co/Images/PDF/CT_Brochure.pdf
8. 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
9. 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
10. 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/
11. "CFR Title 21". US Food and Drug Administration.[Internet] 2019 July [updated 2018 1st April; cited 2019 June 5] Available from https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
12. 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

13. European Convention on Human rights and Biomedicine (1997).[Internet] 2019 July [updated 1999 1st Dec]; cited 2019 June 5] Available from http://conventions.coe.int/treaty/en/treaties/html/164.htm
14. 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=0798FF5E5B7F02D04B4906BAFA8E2196?sequence=1
15. International Ethical Guidelines for Health-related Research Involving Humans-CIOMS and WHO2016 [Internet] 2016 [updated 2011]; cited 2019 June 5] Available from https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf
16. NATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL AND HEALTH RESEARCH INVOLVING HUMAN PARTICIPANTS .ICMR 2017 [Internet] 2017 [updated 2017]; cited 2019 July 23] Available from https://www.icmr.nic.in/sites/default/files/guidelines/ICMR_Ethical_Guidelines_2017.pdf
17. Development of Standard Operating Procedures for Ethics ... – FERCAP [Internet] 2002 [updated 2017]; cited 2019 July 23] Available from http://www.fercap-sidcer.org/events.php?Events_Show_Form=dev_of_SOP
18. Assessment of risk and potential benefit-[Internet] 2017; cited 2019 July 23] Available from https://bioethicsarchive.georgetown.edu/nbac/capacity/Assessment.htm
19. Bernabe et al.: The risk-benefit task of research ethics committees: An evaluation of current approaches and the need to incorporate decision studies methods. BMC Medical Ethics 2012 13:6.
20. Audio visual recording of informed consent is now mandatory in India (Order dated 19 Nov 2013) [cited 2019 July 23]. Available from:http://www.inclinition.com/manage/pages/files/1739670688_AV%20Recording%20of%20informed%20consent.pdf .
21. FERCI Draft Template: SOP for AV Recording of Informed Consent Process: (cited on 2019 July 23) Available from http://ferci.com/wp-content/uploads/2014/01/AV-Consent-FERCI-template_06_01_14-Final-1.doc
22. NACO Operational guidelines 2019. [Internet] updated 2015(cited on 2019 July 23) Available fromhttp://naco.gov.in/operationalguidelines
23. 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/
24. 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/