

	<p align="center">Institutional Ethics Committee (IEC) Seth G.S. Medical College and K.E.M. Hospital, Parel, Mumbai – 400 012. Web: www.kem.edu</p> <p align="center">Constituting Institutional Ethics Committee</p>	<p align="center">SOP 02/V5</p> <p align="center">Effective from 1st Aug 2017 Valid up to 30th July 2019</p>
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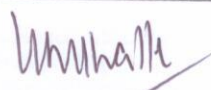

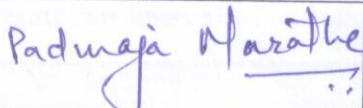
Title: Constituting Institutional Ethics Committee

SOP Code: SOP 02/V5 dated 26th July 2017

Authors:

Dr. Sharmila Jalgaonkar (Member Secretary, IEC-I)	
Dr. Snehalata Gajbhiye (Member Secretary, IEC-II)	

Reviewed by:

Dr. Urmila Thatte (Member, IEC-I)	
Dr. Yashashri Shetty (Member, IEC-I)	
Dr. Padmaja Marathe (Member, IEC-II)	

Approved by:

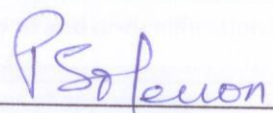
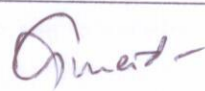

 Dr. Padmavathy Menon, Chairperson, IEC - I (Signature with Date)	 Dr. Alan Almeida, Chairperson, IEC - II (Signature with Date)
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1. Purpose

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. Flow Chart


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

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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 Research Society of KEM Hospital.
- The IECs will 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 two committees, Institutional Ethics Committee -I (IEC-I) and Institutional Ethics Committee-II(IEC-II). Both the committees are registered with the DCGI office as separate IECs, however they will follow same SOPs for uniform functioning.
- The committee 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 IEC 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 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.
- 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), Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005 and prevailing amendments from time to time), Indian GCP guidelines (2001) and Ethical Guidelines for Biomedical Research on Human Participants by ICMR (2006). The mandate will be


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- a. To ensure the protection of the rights, safety and wellbeing of human participants involved in a research project.
 - b. Provide public assurance of that protection.
- The IEC is established and functions in accordance with the relevant national law and regulations in force from time to time.
 - The IEC will review only those projects which are carried out in this institution by the staff members and students of the institution.
 - The IEC will also review projects which are carried out by institutional members in collaboration with other national or international institutions.

5.2 Composition of the Institutional Ethics Committee

- The IEC will be established by the **Head of the Institution (HOI)**.
- The IEC will be multidisciplinary and multi-sectoral in composition.
- The IEC will be composed of at least 7 and a maximum of 15 members. The members should be a mix of medical and non-medical, scientific and non-scientific persons including lay persons to represent the different points of view.
- The members will have differing backgrounds as this would promote complete and adequate review of research activities commonly conducted at Seth GS Medical College and KEM Hospital.
- The IEC will have representation that is varied in terms of gender, age and social background.
- 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 social scientist/ representative of non-governmental agency
 - ✓ One philosopher, ethicist or theologian
 - ✓ One or more lay person from community
- The IEC may 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 IECs 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/V5) 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

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- The Head of the Institute (HOI) is responsible for appointing new committee members.
The Chairperson and IEC members can suggest names of potential members but the final decision will remain with the HOI.
- Members will be selected in their personal capacities based on their interest, ethical and/or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the IEC work.
- Members must disclose in writing any interest or involvement-financial, professional or **otherwise- in a project or proposal under consideration (Refer to AX 01/SOP 03/V5 and AX 02/SOP 03/V5 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/V5 and AX 02/SOP 03/V5 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/V5 and AX 02/SOP 03/V5 Confidentiality / Conflict of Interest Agreements)

5.4 Tenure of Membership.

- The tenure of Institutional Ethics Committee members will be for a continuous period of two (2) 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.


5.5 Policy 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


- 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 IEC. 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.

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- 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.

5.6 Resignation and Disqualification of Members.

- Resignation: An IEC member may resign from membership by submitting a letter of resignation to the Chairperson. The member may or may not assign reasons for resignation. The resignation will become effective from the day it is accepted by the Chairperson.
- Disqualification for conduct unbecoming of an IEC member: A member may be disqualified from continuance should IEC determine by a three-fourth majority specifically called for the purpose that the member's conduct has been unbecoming of an IEC member.
 - (i) The process will be initiated if IEC Chairperson or Member-secretary receives a communication in writing (provided by IEC member or a member of the public) alleging misconduct by a member.
 - (ii) The Chairperson will satisfy himself/ herself that a prima facie case exists before initiating action. If, in the opinion of the Chairperson, the matter is of grave significance where integrity of IEC could be questioned, the Chairperson may suspend the membership of the concerned IEC member till final decision is taken by IEC. During the period of suspension, the concerned individual will not have any rights, privileges or responsibilities of an IEC member and will not perform any duties of IEC member.
 - (iii) The Chairperson may call for a meeting of the IEC specifically to discuss this issue or the matter will be taken up for discussion. The meeting convened will follow the usual rules of quorum. The allegation will be discussed at the IEC meeting and the member alleged of misconduct will be provided adequate opportunity to defend himself / herself.
 - (iv) The member would stand disqualified if members present approve of disqualification by voting (voting by 2/3rd of majority of members present in the meeting and voting). The Chairperson will convey the disqualification to the concerned member through a written communication.
- Disqualification for not attending IEC meetings: A member may be disqualified from IEC membership if the member fails to attend more than 3 regular consecutive IEC meetings without prior intimation. The process conducted will be as follows:
 - (i) The member-secretary will inform Chairperson, in writing, if a member has not attended more than three consecutive regular meetings of the IEC.
 - (ii) The Chairperson will initiate the process of review of membership of such a member by including the matter in the Agenda of the next regular IEC meeting
 - (iii) A written communication will be sent to the concerned IEC member informing him/ her that the issue of disqualification would be discussed at the meeting inviting the member to be present at the meeting to put up his/ her case. Alternately, the concerned IEC member will be allowed to state his/ her arguments regarding unauthorized absence in writing by a letter addressed to the Chairperson

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

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

5.7 Conditions of appointment

Members and Independent consultants will be appointed to the IEC if they accept the following conditions.

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

5.8 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 IEC
- Member-secretary or an IEC member 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.

5.9 Hierarchy

- There will be one Chairperson, one Member Secretary. A Joint Member Secretary may be appointed amongst the members if necessary.
- The Chairperson will be the head of the committee.
- The Member Secretary and the Joint Member Secretary (whenever applicable) will be the guardian of all documents and funds in the possession of the committee.
- Other IEC members will be 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 2 years term. These may be re-elected any number of times. Should they resign or be disqualified, the IEC members will elect a replacement for another term.

5.10 Chairperson

- The Chairperson will be appointed by the Head of the Institute,

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- 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 IEC functioning.
- The Chairperson will delegate his/ her responsibilities to appropriate individuals in accordance with IEC SOPs
- In case of anticipated absence, the Chairperson will nominate a committee member as Acting Chairperson. 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, IEC Joint Member Secretary (where applicable), the administrative Officer/s 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 IEC and they will be supervised by the Member Secretary.
- [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 IEC members 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 IEC related 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.

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15. To delegate various responsibilities to appropriate and authorized individuals

16. To ensure adherence of IEC functioning 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 (AX 01/SOP 02/V5)**

1. To support the Member Secretary in executing functions of the IEC.


2. To perform any other functions as instructed by Member Secretary/ Chairperson.

5.12 Roles and Responsibilities of IEC members

- To attend IEC Meetings and participate in discussions and deliberations so that appropriate decisions can be arrived at.
- To review, discuss and consider research Proposals submitted for evaluation.
- 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 IEC work as per SOPs

5.13 Quorum Requirements

- The full board meeting will be held as scheduled provided there is quorum. For the IEC meeting, a quorum will consist of at least 5 members one regular member (preferably one pharmacologist), the social worker, a clinician, the lay person and the legal expert besides Member Secretary and Chairperson. (As per the Schedule Y – version dated 20th January 2005, 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

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agency/Philosopher/ethicist/theologian or a similar person, one Lay person from the community).

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.

5.15 Responsibilities of the Institutional Ethics Committee


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

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

- 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. (AX03/SOP02/V5)
- Annual Evaluation of IEC members/Member Secretary will be done by Chairperson(AX04/SOP02/V5).The individual feedback will be provided by email to the members.
- Annual Evaluation of IEC staff will be done by Member Secretary (AX05/SOP02/V5).
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

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6. Glossary


Confidentiality	Prevention of disclosure, to other than authorized individuals, of IEC/ information and documents
IEC	Institutional Ethics Committee is an independent body whose responsibility is 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 Schedule Y) 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. References

- [1] World Health Organization, Operational Guidelines for IEC that Review Biomedical Research, 2000. (Geneva 2000 www.who.int/tdr/publications/publications/- last accessed 31st July 2017) International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) 1996- <http://www.ich.org/LOB/media/MEDIA482.pdf> (last accessed 31st July 2017)
- [2] CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects http://www.cioms.ch/frame_guidelines_nov_2002.htm (last accessed 31st July 2017)
- [3] ICMR's Ethical Guidelines for Biomedical research on Human Participants, ICMR (2006) - http://www.icmr.nic.in/ethical_guidelines.pdf (last accessed 31st July 2017)
- [4] Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005) [http://www.cdsco.nic.in/html/Schedule-Y%20\(Amended%20Version-2005\)%20original.htm](http://www.cdsco.nic.in/html/Schedule-Y%20(Amended%20Version-2005)%20original.htm) (last accessed 31st July 2017), amendment 30th January 2013)
- [5] European Convention on Human rights and Biomedicine (1997). <http://conventions.coe.int/treaty/en/treaties/html/164.htm> (last accessed 31st July 2017)

8. Annexure

Annexure 1	AX 01/SOP 02/V5	Policy statement of the institution
Annexure 2	AX 02/SOP 02/V5	IEC Administrative staff: Working rules
Annexure 3	AX03/SOP02/V5	IEC Evaluation Form of Chairs & Co- chairs
Annexure 4	AX04/SOP02/V5	IEC Evaluation Form of IEC Member Secretary/Members
Annexure 5	AX05/SOP02/V5	IEC Evaluation Form of Staff
Annexure 6	AX 06/SOP 02/V5	Organizational Chart of the Institution

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Annexure 1

AX 01/SOP 02/V5

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' (IEC-I) and 'Institutional Ethics Committee-II' (IEC-II) will continue to review scientific and ethical aspects of all types of research studies involving human participants. It is resolved that IEC-I and IEC-II are reconstituted on _____ and the new committee will serve for a 2 years term from _____ to _____.

The IEC-I and IEC-II have been registered with the Central Drug Standard Control Organization [Registration nos. _____ and _____]. The IEC-I and IEC-II will work according to the revised Standard Operating Procedures (SOPs) which have been formulated for this purpose and are effective from _____

The mandate will be:

- a. To ensure the protection of the rights, safety and well-being of human subjects involved in a research project.
- b. To provide public assurance of that protection.
- c. To function independently without any interference in the review and decision making process from the Head of the Institute and administrative department of the Institute.
- d. The IEC shall adhere to existing applicable rules & regulation for its formation and functioning which includes the registration of IECs, criteria for selection, tenure, resignation, schedule of meeting, reporting to regulatory authority and other administrative process.
- e. The IEC at present follow International Conference on Harmonisation – Good Clinical Practices (ICH-GCP) Guidelines (1996), Indian GCP guidelines (2001), Schedule Y (Drugs and Cosmetic Act 1940; amendment 20th January 2005, Declaration of Helsinki and the prevailing amendments from time to time), Ethical Guidelines for Biomedical Research on Human Participants by ICMR (2006)

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- f. The IEC-I and IEC-II will 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 IECs.

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

- a. XXXXXXXXXXXX
- b. XXXXXXXXXXXX

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

Date


Annexure 2

AX 02/SOP 02/V5

The IEC Administrative Staff: Working Rules

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

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

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[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 IEC accounts shall be sought every time a new administrative staff member is to be appointed.


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

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

[4] Duties of the Administrative Manager:

- Overall management of both the IECs.
- Supervising the duties of the deputy Manager.
- Supervising the duties of Executive assistant to Member secretary of SAE subcommittee.
- Attending the meetings of both the 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 both the committees and maintaining the details of the account and communication regarding the same with the DJST.
- All communication to the investigators in case of change in any policy of IEC.
- All correspondence to the regulatory authorities in regards to SAE/ compensation issue.
- Overall co-ordination of the activities related to audits/registrations 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.
- To co-ordinate 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.
- 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 IECs
- Performance of other duties assigned by the Chairperson/Member Secretary.

[5] Duties of the Deputy Manager/s:

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- 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/Administrative 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/Administrative 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.

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- 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/Administrative 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/Administrative Manager/Deputy Manager/Executive assistants.


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

[8] The office timing for the Administrative 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 can not 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 IEC members.

[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.

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Annexure 3
AX03/SOP02/V5

IEC Evaluation Form of Chairs & Co- chairs

1. Mention (v) 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 (v) 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

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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 4

AX04/SOP02/V5

IEC Evaluation Form of IEC Member Secretary/Members

1. Mention (v) 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 (v) in the column)

Yes: ☐ No: ☐

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

Yes: ☐ No : ☐

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

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Regular: ☐ Irregular: ☐

11. Number of educational sessions conducted: ☐

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

Good: ☐ Average: ☐ Poor: ☐

13. Contribution to IEC meetings: (Make tick (v) in the column)

Good: ☐ Average: ☐ Poor: ☐

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

Good: ☐ Average: ☐ Poor: ☐

15. Communication with IEC staff : (Make tick (v) in the column)

Good: ☐ Average: ☐ Poor: ☐

Annexure 5
AX05/SOP02/V5
IEC Evaluation Form of Staff

1. Mention (v) 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 (v) 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 (v) in the column)

Yes: ☐ No: ☐

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

Yes: ☐ No: ☐

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

Yes: ☐ No: ☐


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

Yes: ☐ No: ☐

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

Yes: ☐ No: ☐

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

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Yes: ☐ No: ☐

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

Yes: ☐ No: ☐

12. Number of educational sessions conducted : ☐

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

Good: ☐ Average: ☐ Poor: ☐

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

Good: ☐ Average: ☐ Poor: ☐

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

Good: ☐ Average: ☐ Poor: ☐

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

Good: ☐ Average: ☐ Poor: ☐

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

Good: ☐ Average: ☐ Poor: ☐


18. Ability to help investigator :

Good: ☐ Average: ☐ Poor: ☐

Feedback-

Signature:

Date:

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Annexure 6

Organizational Chart

