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2.1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to describe frequency of Ethics Committee Meeting and the terms of reference (TOR) of members, which provide the framework for constitution, selection, roles and responsibilities of the Institutional Ethics Committee (IEC) and procedures for maintaining confidentiality of all activities and documents.

2.2. Scope

This SOP applies to the constitution of the IEC, selection, roles and responsibilities of members of the IEC and maintenance of confidentiality of all activities and documents.

2.3. Responsibility


The Head of the Institution will appoint the Chairperson, Member Secretary and IEC members in consultation with the Chairperson of IEC. The letter issued by the Chairperson will specify the Terms of Reference especially about the role and responsibility specific to each member, duration and conditions of appointment. It is the responsibility of all the Chairperson, Member Secretary and IEC members and the Secretariat to read, understand, follow and respect this SOP.

2.4. Detailed Instructions

2.4.1 *Composition of the Institutional Ethics Committee*

The IEC will be established by the Chairman, AVP Research Foundation. The Chairperson and IEC members can suggest names of potential members but the final decision will remain with the Chairman, AVP Research Foundation.


- EC Committee has to declare that its functioning and decision making is independent.
- It is the responsibility of the chairperson and Member Secretary to assess that the functioning of Ethics Committee is independent and as per current ethical guidelines and regulatory guidelines.

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2.4.2 Introduction.

It is necessary for all research proposals on biomedical, social and behavioral science research for health involving human participants, their biological material and data to be reviewed and approved by an appropriately constituted EC to safeguard the dignity, rights, safety and well-being of all research participants. ECs are entrusted with the initial review of research proposals prior to their initiation, and also have a continuing responsibility to regularly monitor the approved research to ensure ethical compliance during the conduct of research. The EC should be competent and independent in its functioning.

- The Institution is responsible for establishing an EC to ensure an appropriate and sustainable system for quality ethical review and monitoring.
- The Institution is responsible for providing logistical support, such as infrastructure, staff, space, funds, adequate support and protected time for the Member Secretary to run the EC functions.
- The EC is responsible for scientific and ethical review of research proposals. Although ECs may obtain documentation from a prior scientific review, they must determine that the research methods are scientifically sound, and should examine the ethical implications of the chosen research design or strategy.
- All types of biomedical and health research (whether clinical, basic science, policy, implementation, epidemiological, behavioral, public health research, etc.) must be reviewed by an EC before it is conducted.
 - Its hierarchical position in the organization and authority under which it is established will be clearly indicated (AX 02/SOP 02/V1)
 - The IEC will be multidisciplinary and multisectoral in composition.
 - The IEC will be composed of at least 7 members and a maximum of 15 members as per current requirement of CDSCO i.e. GSR 72 of Drugs & Cosmetics Act (D&C) Rules 1945, amendments.

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- The members will
 - Include a combination of medical and non-medical, scientific and non-scientific persons including laypersons to represent the different points of view to promote adequate review of research.
 - Have the required qualifications as prescribed by applicable regulations and guidelines from time to time
 - Have the expertise, time and commitment to perform all functions
- The IEC will have representation that is varied in terms of gender, age and social background to safeguard the interests and welfare of all sections of the community / society’.
- The committee should include at least one member whose primary area of expertise is in a non-scientific area, a clinician and at least one member who is independent of the institution/ research site.
- The IEC may invite member(s) of specific patient 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 02/V1) and declare in writing, conflicts of interest, if any prior to attending the meeting. They will attend the meeting in the capacity of ‘Guest/ Observer’ and will not have right to vote. (See SOP 05/V1)
- The Composition shall be as follows:
 - Chairperson (must not be affiliated to the institution)
 - Co-Chairperson (if appointed, must not be affiliated to the institution)
 - One Member Secretary (must be affiliated to institution)
 - One Joint Member Secretary (if appointed, must be affiliated to institution)
 - One or more Basic Medical Scientist having post graduate qualification in biological sciences (preferably clinical Pharmacologist for reviewing proposals on drugs, devices, vaccines and others included under the definition of new drug as per D&C Act)/ Pathology/ Microbiology/

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Anatomy/ Physiology/ Biochemistry and adequate experience (may or may not be affiliated to institution).

- One or more clinicians from various institutes (at least one should be affiliated to institution)
- One legal expert or retired judge (must not be affiliated to institution)
- One social scientist/ representative of non-governmental agency/ One philosopher, ethicist or theologian, intellect, educationist (must not be affiliated to institution)
- One or more lay person (non-scientific person) from the community and should be literate and aware of local, social and cultural norms of the particular area (must not be affiliated to institution).


2.4.3 Composition of SAE subcommittee under IEC

- The IEC Chairperson will delegate SAE review to subcommittee members constituted by some members of IEC. Primarily clinician, basic medical scientist (preferably pharmacologist), will be part of the sub-committee along with member secretary. The Chairperson or Co-chairperson may delegate some responsibility to any other ethics committee member e.g. legal expert (if required). This subcommittee will review the SAEs submitted by PI (on site) and will take decision regarding reporting to DCGI, reimbursement and compensation etc.

Members

Following points are applicable for Chairperson, Co-chairperson, Member Secretary, and additional Member Secretary as well

- Members will be selected in their personal capacities based on their qualification, experience in domain field, interest, ethical and/or scientific knowledge and expertise, as well as have commitment and willingness to volunteer the necessary time and effort for the IEC activity. They should not have any known record of professional misconduct.
- Basic Medical scientists and clinicians should have post graduate qualifications

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and adequate experience (minimum 2 years).

- Conflict of interest will be avoided, but where unavoidable, there will be transparency with regard to such interests (See SOP 03/V1).

2.4.5 Agreement regarding Maintenance of Confidentiality


- It is the responsibility of each IEC member, reviewing research project or attending IEC meetings, to read, understand, accept and sign the agreement contained in the confidentiality Form (AX 03/SOP 02/V1).
- The staff of the secretariat will sign confidentiality agreement which should be filed with the IEC.(AX 03B/SOP 02/V1)
- The Secretariat will obtain the signature of the IEC Chairperson on the Confidentiality form
- The secretariat will provide IEC member a photocopy of the Confidentiality Form for their records (duly signed and dated by them and IEC Chairperson) and acknowledge the receipt of agreement with their signature and date.
- The Secretariat will keep the original copies of the signed Agreements in the IEC office in the file entitled ‘Confidentiality Agreement’ file for members and photocopies of the agreement in the individual members files.

2.4.6 Tenure of Membership

- The tenure of IEC will be for a continuous period of 3 years for members and not more than 6 years for Chairperson from the date of appointment. All members shall serve a maximum of six-year term on the committee, beyond which under exceptional circumstances there may be two incremental extensions for three years at a time. Extension of membership may be considered due to non-availability of members of similar stature, qualification and intent to contribute to ethical human research.

2.4.7 Appointment of New Members

- a) The IEC members will be appointed by the Chairman of AVP Research Foundation


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- b) New members will be appointed under the following circumstances:
1. When a regular member completes her/his 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.
- c) The membership requirements as stated in this SOP should be fulfilled
- d) New members shall be identified by the Chairperson according to the membership requirement (i.e. as per the composition specified in Section 4.1 of this SOP), provided the potential member fulfills the conditions of appointment. The names of new members to be appointed may be suggested by the IEC members as well. The final decision regarding appointment of members will be taken by the Chairman, AVP Research Foundation.

2.4.8 Conditions to be fulfilled by a member after appointment

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

- Members must submit
 - a recent signed CV
 - Training certificates in Ethics and/ or GCP. In case training certificates are not available at time of induction as member in the IEC, the member must submit these within 6 months of appointment.
- Members must be willing to
 - Publicize his/her full name, profession and affiliation.
 - Sign the Confidentiality Agreement (as per Annexure 3/SOP 02/V1) and maintain confidentiality regarding meeting, deliberations, applications, information on research participation and related matters.
 - Read, understand, accept and follow the Conflict of interest policy and sign the Conflict of interest agreement/form (See SOP 03/V1).


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2.4.9 Resignation and Disqualification of Members

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

- **Disqualification for conduct unsuitable of an IEC member:**
 - (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 as 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 during full committee review meeting. 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 herself/ himself.
 - (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 EC membership if the member fails to attend more than 3


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consecutive EC 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 without prior intimation to the IEC.
- (ii) The Chairperson will initiate the process of review of membership of such a member by including the matter in the Agenda of the next IEC meeting.
- (iii) A written communication will be sent to the concerned IEC member informing her/him that the issue of disqualification would be discussed at the meeting inviting the member to be present at the meeting to clarify her/his position. Alternately, the concerned IEC member will be allowed to explain uninformed absence in a letter addressed to the Chairperson, which will be read and reviewed at the meeting.
- (iv) The Chairperson or Member-Secretary will inform the other IEC members about the cessation of membership of the member by written communication or during the next meeting of IEC.

2. 4.10 Training of the IEC Members in Research Ethics

- An individual selected as a new member of the IEC will be required to attend one meeting as an ‘Observer’ before being inducted as a member of the IEC.
- Member Secretary or an IEC member may provide introductory training in Research Ethics, GCP to the new member.
- Other alternative for training certificate in ethics and GCP could be by online or by attending workshops.
- Training in SOP will have to be in-house by member secretary or an IEC member.
- A newly inducted member should submit certificate of training in 6 months.
- All members including Chairperson and Member Secretary will be encouraged to receive continued training by participating in a workshop, conference and/or re-training program related to research ethics, as a delegate, faculty,

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facilitator, etc.

- The IEC will conduct workshops on ethics in clinical research, GCP and SOPs from time to time to impart training and update or assess the IEC Members and Institutional faculty members.
- The IEC may nominate and/ or sponsor the expenses of (as applicable) an IEC member or prospective members for attending conference, continuing education session workshop and/ or training program etc.

2.4.11 Hierarchy


- Chairperson, Co-chairperson, Member Secretary and Alternate Member Secretary may be appointed from amongst the members.
- The Chairperson will head the committee. Co-chairperson will head the committee in absence of chairperson.
- The Member Secretary and the Alternate Member Secretary (whenever applicable) will be in-charge of all documents and funds in the possession of the committee.
- Other IEC members will be regular committee members with equal ranking.

2.4.11a Additional Functions of Chairperson

- The Chairperson will be responsible for conducting committee meetings, leading all discussions and deliberations pertinent to the review of research proposals.
- The Chairperson will preside over all elections as well as administrative and financial matters pertinent to the committee’s functions. The Chairperson will represent the IEC at various meetings and forums.
- The Chairperson will sign documents and communications related to IEC functioning.
- The Chairperson will delegate her/his responsibilities to the Co-Chairperson in accordance with IEC SOPs.

2.4.11b Functions of Co- Chairperson

- To act as Chair in the absence of Chairperson and to perform all functions of

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Chairperson.

2.4.12 Additional Functions of the Member secretary


- Sign documents and communications related to IEC functioning
- Communicate with the IEC members and applicants/ investigators
- Notify the Principal Investigator regarding IEC decisions related to the submitted research proposal
- Provide necessary administrative support for IEC related activities to the Chairperson
- Provide updates on relevant and contemporary issues to ethics in health research as well as relevant contemporary literature to the committee members
- Receive ethics committee review processing fees and issue official receipts for the same
- Delegate various responsibilities to appropriate and authorized individuals
- Ensure adherence of IEC functioning as per SOPs
- Prepare and make available for scrutiny by auditors/ inspectors annual reports/ annual financial statements of the IEC

2.4.13 Functions of the Joint/ Associate/ Alternate Member Secretary (whenever appointed)

- The Joint Member Secretary will perform the same functions of Member Secretary in his/her absence

2.4.14 Functions of IEC members

- Attend IEC Meetings and participate in discussions and deliberations so that appropriate decisions can be arrived at
- Review, discuss and consider research Proposals submitted for evaluation
- Monitor Serious Adverse Event reports and recommend appropriate action(s)
- Review the progress reports and monitor ongoing studies as appropriate
- Do onsite visits wherever needed
- Evaluate final reports and outcomes

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- Maintain confidentiality of the documents and deliberations of IEC meetings
- Declare any conflict of interest in writing to the Chairperson, if any, at each meeting
- Participate in continuing education activities in bioethics and biomedical and health research and provide the certificate related to the training to the IEC secretariat.
- Provide an updated CV when requested for by the IEC secretariat
- Carry out the work delegated by Chairperson, Member-secretary and Jt. Member-secretary
- Assist Chairperson, Member-secretary and Jt. Member-secretary in carrying out IEC work as per SOPs
- Be updated on relevant laws and regulations


2.4.15 Quorum requirements as per ICMR Guidelines

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

2.4.16 Secretariat

- The Secretariat will be composed of the administrative supporting staff
- The Secretariat will support the Member Secretary and Joint Member Secretary (if applicable) in all their functions
- All the staff of the Secretariat will sign confidentiality agreement which should be filed with the IEC (*AX 03/SOP 02/V1*)
- The working rules for the Secretariat are stated in (*AX 01/SOP 02/V1*)

2.4.17 Types of projects reviewed by IEC

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The IEC will review scientific and ethical aspects of all types of research studies involving human participants; sponsored by pharmaceutical companies, sponsored by Government of India/ NGOs, studies in collaborations with international organizations/universities, all dissertation projects (postgraduate students: MD, MS, MCh, DM, Mch, DNB, PhD, MSc, MPTh, MOTh, Nursing, dental and any other course run by recognised Institutions as applicable), research projects of undergraduate students carried out under the guidance of faculty (e.g. Central Council for Research in Ayurvedic Sciences, Indian Council for Medical research studentship or any other) and investigator initiated research studies which are self-funded/ funded by institutional funding bodies.

2.4.18 Quorum Requirements

- The full board meeting will be held as scheduled provided there is quorum as indicated above in Box 4.2.
- For regulatory trials, a quorum will consist of at least 5 members specific in composition with representation of 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 Layperson from the community, apart from Member Secretary and Chairperson as mandated by ICMR Guidelines.
- Without satisfying this condition, any decision taken by the committee shall remain null and void
- In absence of the Chairperson, Co-Chairperson will chair the meeting

2.4.19 Honorarium to the Members

Reimbursement of travelling expenses and /or reasonable honorarium for attending the IEC meetings may be given to the IEC members.

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2.4.19 Preparing an annual activity report of the IEC for submission to the Head of the Institute

The Member Secretary will make a yearly activity report for submission to the Head of the Institute, which will include the following elements:


- a. Number and dates of the IEC meetings of full committee
- b. Number of SAE subcommittees and any other subcommittee, as applicable)

Number and type of proposals (Pharma/ Government sponsored/ Dissertations/ investigator initiated) reviewed in a year, status of each study proposal whether completed/ ongoing / terminated
- c. Number of approvals for full board review/ expedited review with decisions
- d. Brief details about workshops, training programs and other activities undertaken by the IEC and those attended by IEC members
- e. Any other matter

2.5. Reference to other applicable SOPs

SOP 03/V1 - Conflict of Interest Policy for Institutional Ethics Committee

SOP 08/V1 - Agenda Preparation, Meeting Procedures and Recording of Minutes

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2.6. Annexure

Annexure 1 AX 01/SOP 02/V1 - IEC Administrative Staff: Working rules

Annexure 2 AX 02/SOP 02/V1 - Organizational Chart of the Institution

Annexure 3 AX 03/SOP 02/V1 - Confidentiality Agreement Form for IEC members/
Staff of Secretariat


Annexure 4 AX04/SOP 02/V1- Conflict of Interest Declaration Form for IEC
members /Guests/Observer/Expert

Annexure 5 AX 05/SOP 02/V1 - Confidentiality and Conflict of Interest Agreement
Form for Guest/ Observer Attendees to IEC/ IEC Meetings

Annexure 6 AX 06/SOP 02/V1 - List of Ethics Committee Members

Annexure 7 AX07/SOP02/V1 – List of SAE Subcommittee Members



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Annexure 1: AX 01/SOP 02/V1

The IEC Secretariat/ Administrative Staff: Working Rules

There will be employees in the IEC secretariat to assist Member Secretary for smooth functioning of IEC. Administrative officers/ assistants with support staff of attendants/helpers may be appointed as and when deemed necessary by the IEC. This staff will help the IEC Chairperson and Member-Secretary. The eligibility criteria for new staff to be appointed will be laid down depending on the required job profile. The need for appointment of administrative staff, job profile and qualifications, office timing, salary structure and number of eligible leaves may be recommended by IEC members and discussed during regular IEC meeting and will be recorded in minutes.

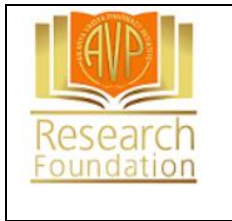
The administrative staff will report to the Chairperson and/or Member Secretary.

Duties of IEC Secretariat

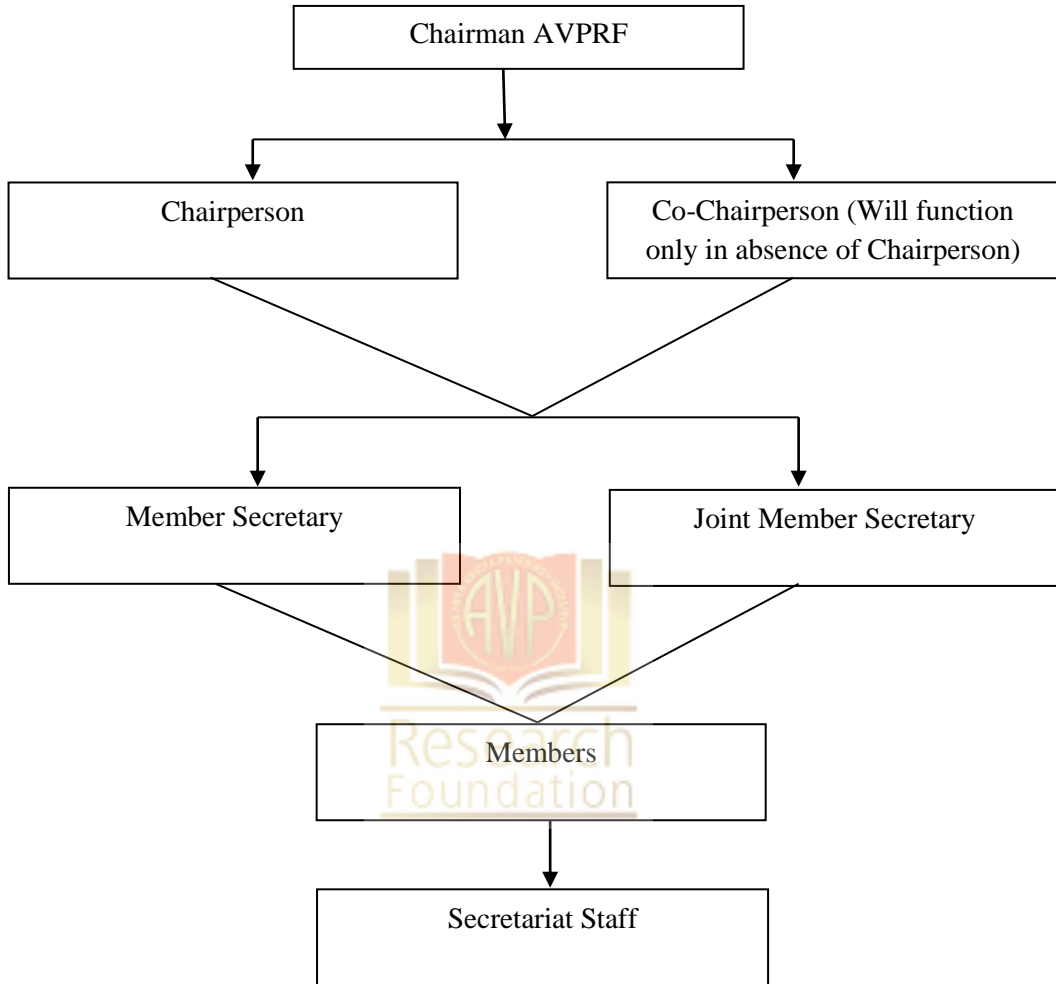
- Correspondence with IEC members and external experts
- Correspondence with the investigators
- Preparing agenda and minutes of the IEC meetings
- Answering queries of the investigators
- Filing study related documents
- Archiving and maintaining the study files, SOPs, all correspondences
- Maintaining electronic database of the IEC records with access limitation.


Duties of the attendant/s /helper/s

- 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
- Assisting the Secretariat during the meetings



Annexure 2: AX 02/SOP 02/V1
Organizational chart of the institution



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Annexure 3: AX 03 /SOP 02/V1

Confidentiality Agreement Form for IEC Members/ Secretariat Staff

I _____ (IEC Member's name) have been appointed as a member of the IEC based on my individual merit and have been asked to assess research involving human 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 guidelines/regulations (international regulations in addition, if applicable) and institutional policies.

I agree to hold all the information deemed Confidential, Proprietary or privileged in trust or confidence. This information provided to me for research review whether explicit or implied, verbal or documentary, incorporated in computer software or held in electronic storage media/device or otherwise shall be used only for contemplated purposes and not for any other purpose. As written confidential information including any copies and notes thereof, provided for review is sole property of the IEC it shall not be copied or retained, and promptly returned or properly handled in the manner required by the IEC, including destruction of the same.

I agree to take reasonable measures to protect the information from use by third parties including access to it under Right to Information Act; not to use the Confidential Information for any purpose outside the Committee's mandate or which would result in a benefit to me or any third party; and upon termination of my functions as a Committee member to destroy all Confidential Information including any minutes or notes I may make or keep as reference as a IEC member. Furthermore, I confirm that my performance of this agreement is consistent with the institutional policies and any contractual obligations they may have with third parties.

Legal compulsion to disclose

In the event that the member becomes legally compelled to disclose any Confidential Information the member shall give prompt notice in writing of such facts to the IEC so



Annexure 04: AX 04/SOP 03/V1

Conflict of Interest Declaration Form for IEC members

/Guests/Observer/Expert

I _____ declare (actual or potential COI) in relation to the proposal entitled “ _____ ” submitted for review to the IEC. The reason for COI is personal/professional/financial (describe).....

I will refrain from the review process and/or discussion at the IEC meeting and also not take part in ongoing and periodic review and monitoring of this project.

_____ Signature of IEC Member/Guests/Observer/Expert

_____ Date

_____ Chairperson’s Signature

_____ Date

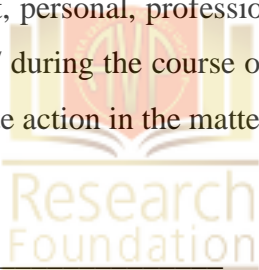


Annexure 5: AX 05/SOP 03/V1

Confidentiality and Conflict of Interest Agreement Form For Guest/ Observer Attendees to IEC/ IEC Meetings

I, _____ (name), understand that I am being allowed to visit IEC office facility / attend the IEC meeting on _____ at _____ am/pm as a Guest/Observer at _____ (Venue). I understand that I may become aware of some confidential information during my visit to IEC office/ during the course of the IEC meeting. Upon signing this form, I agree to take full responsibility to keep the information strictly confidential unless I am legally compelled to disclose only that portion of the Confidential Information as may be necessary as part of my duty.

I do not have conflict of interest, personal, professional or financial, but in the event of my having it related to my visit/ during the course of IEC meeting I will inform IEC of the same for it to take appropriate action in the matter accordingly.



 Signature of the Guest/ Observer attendee with date

 Chairperson of IEC with date

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

 Signature of the Guest/Observer attendee with Date




Annexure 6: AX 06/SOP 02/V1

Ethics Committee Membership List

S. No.	Member Name	Area of Expertise	Affiliation With Institution	Gender
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				

Note: The Ethics Committee membership list is current date.


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Annexure 7: AX 07/SOP 02/V1

SAE Sub-Committee Members List

S. No.	Member Name	Role In SAE Subcommittee	Highest Degrees Earned	Gender	Specialty	Affiliation with Institution
1						
2						
3						
4						



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7. Flowchart

S. No.	Activity	Responsibility
1.	Composition of the Institutional Ethics Committee	Head of the Institute
2.	Selection and appointment of Chairperson	Head of the Institute
3.	Appointment and conditions of appointment of new members	Head of the Institute
4.	Initiation of the process of appointment	Secretariat
5.	Tenure of Membership	Head of the Institute
6.	Resignation and disqualification of members	Chairperson and IEC Members
7.	Quorum requirements	Member Secretary and Secretariat

