1.1 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). The SOPs provide clear, unambiguous instructions so that the related activities of the committee are conducted in accordance with Indian regulations and relevant, national, and international ethical guidelines.

1.2. Scope

This SOP covers the procedures of writing, reviewing, distributing and amending the SOPs of the IEC.

1.3. Responsibility

It is the responsibility of the Chairperson of the IEC to appoint a SOP team to formulate a new SOP or to revise existing SOP. The SOP team shall do this by following the standard procedures, format and coding system as per the contents in the checklist provided earlier that is used while drafting or editing any SOP of the IEC. All members of IEC will review the SOPs and approval will be given by **Chairperson of IEC**. The SOPs shall then be accepted by the **Chairman.**

1.3.1 Secretariat of the IEC will

- Assist Chairperson to formulate a SOP Team
- Co-ordinate activities of writing, reviewing, distributing and amending 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 an up-to-date distribution list for each SOP distributed to the EC members.
- Maintain a register to record the names of investigators to whom SOPs are distributed
- Maintain a file of all current SOPs and the list of SOPs
- Maintain a file of all past Master SOPs of the IEC.

	Institutional Ethics Committee	**SOP 01/V1**
		Effective from
		September 2019
	Title: Preparing Standard Operating Procedures	**Valid till**
	(SOPs): Writing, Reviewing, Distributing and Amending	September 2022
	SOPs	

1.3.2 SOP team will

- Assess the request(s) for SOPs revision in consultation with the Secretariat, Member Secretary and Chairperson

- Propose new / modified SOPs as needed

- Draft the SOPs giving step by step process details in consultation with the designated IEC members and involved administrative staff

- Make a list of SOPs with coding reference

- Review the draft SOPs

- Submit the draft for approval to Chairperson

1.3.3 Chairperson of the IEC will

- Appoint one or more SOP Teams

- Approve the SOPs

- Sign and date the approved SOPs

1.3.4 IEC members and involved administrative staff (if any) will

- Sign and date the approved SOPs when they receive it

- Maintain a file of all SOPs received

1.4. Detailed instructions

1.4.1 Identify the need for new or amendment of current SOP

Any member of the IEC or Secretariat who would feel the requirement of a revision or notices an inconsistency/ discrepancy/ has any suggestions on how to improve the existing SOPs or requests to design an entirely new SOP can put forth his request by writing to the IEC Chairperson either as an email/letter/verbal request in a meeting. The Chairperson will inform all the IEC members about this request at a regular full-board IEC meeting. If the IEC members agree to the request, an appropriate SOP team(s) will be appointed by the Chairperson to proceed with the revision process of the SOP. If the IEC members do not agree, no further action will be taken. The Chairperson will inform the member of the IEC or Secretariat who made the request for modification of the SOP.

1.4.2 Appoint the SOP Team(s)

- The Chairperson will constitute a SOP Team(s) consisting of the member-secretary and two or more members of the IEC who have a thorough understanding of the ethical review process.

- The SOP writing team will carry out the subsequent steps as described in sections *1.4.3-1.4.7.*

1.4.3 List all relevant procedures

- Write down step by step all the procedures of the IEC that are to be standardized in the form of a SOP

- Organize, divide and name each process

1.4.4 Write and review a new SOP

- When the need for a new SOP has been identified and agreed upon, a draft will be written by one or more designated members of the SOP team, appointed by the Chairperson.

- Each SOP should be given a number and a title that is self-explanatory and 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, e.g. the first SOP of the current version would be *SOP 01/V1* i.e. it is SOP number 01 with version 1.

- Each SOP may have annexure(s), which are forms to be filled in by various stakeholders [IEC or Principal Investigator (PI)]. Each annexure will be given a unique code number with the format AX pp/SOP xx/Vy. AX refers to annexure form; pp is a two-digit number identifying the number of the annexure, while xx/Vy refers to the SOP number and its version. For example *AX 01/SOP01/V1* means annexure form number 1 belonging to SOP 01/V1.

- Each SOP will be prepared according to the standard template in *AX 01/SOP01/V1*. Each page of the SOP will bear the header which will have the effective date (*aa/bb/cccc*) i.e. the date of approval of the SOP by the Chairperson. The SOP number will be on the right hand corner with the title of the SOP while the footer will bear the page number as page p of q (total) pages. The logo of the Institution/ Hospital may be put in the header if required.

- The draft SOP written by one or more members of the SOP team will be reviewed by the remaining members of the SOP team/UEC members. 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.

1.4.5 *Write and review a revised SOP*

- If a SOP supersedes a previous version, the latter will be indicated in the Document History Form (*AX 02/SOP01/V1*) along with description of the main change(s).
- The rest of the steps are as described in **Section *1.4.4***.

1.4.6 *Prepare and submit final draft*

- The SOP Team will submit the reviewed SOP to the IEC Members who will review it at a meeting.
- The suggestions that are agreed upon by the IEC members present at the meeting will be discussed and incorporated in the revised draft SOP and it will be finalized.
- The SOP team would stand automatically dissolved once the IEC takes final decision regarding the SOP.

1.4.7 *Approve the new / revised SOP*

- The final version will be presented to the Chairperson for review and approval.
- The authors (SOP team members), reviewers and the Chairperson will 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 which the SOP will be implemented. The face page may also contain signature of Head of the Institution as having accepted the document.

1.4.8 *Implement, distribute and file SOPs*

- The approved SOP will be implemented from the effective date.
- The Member Secretary will discuss the approved SOP with the administrative staff and instruct them to implement it accordingly.
- A copy of the approved SOP (termed controlled copy) will be distributed to the IEC members and a log will be maintained as per the annexure - *AX 03/SOP 01/V1*.
- The IEC members and Secretariat will review the SOPs at least once in every 3 years.
- One complete original set of current SOPs will be filed in the SOP Master file by the IEC Secretariat in the IEC office.

- Photocopies made from the official paper versions of the SOP can be considered current or official as controlled copies, if stamped and signed by Member Secretary or authorized individual for distribution to IEC members.

- SOPs are made available to all Investigators on Institute website.

- When the revised version is distributed, all the IEC members will be requested to destroy their copy of earlier version.

- Only one copy of the earlier version will be clearly marked 'Superceded' and filed in the file entitled 'Past SOPs of the IEC' by the IEC Secretariat in the IEC office.

- The process of evolution of previous SOPs of the IEC will be documented in defined format as per *AX 04/SOP01/V1*.

- The IEC members and Secretariat will review the SOPs at least once in every 3 years.

5. Annexure

Annexure 1 *AX 01/SOP01/V1*- Template for SOPs

Annexure 2 *AX 02/SOP01/V1*- Documentation of History of the SOPs

Annexure 3 *AX 03/SOP01/V1*- Log of the IEC members receiving

Annexure 4 *AX 04/SOP01/V1*- Template for SOP

Annexure 5 *AX 04/SOP01/V1*- List of SOPs of the IEC

Annexure 1: AX 01/SOP01/V1

Templates for SOP'S

Main Text:

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

2. **Scope:** S*tates the range of activities that the SOP applies to.*

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

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

5. **Annexure**: *Forms to capture information pertaining to the SOP instructions*

6. **Flow chart:** *Simplifies the procedures in step by step sequence and states clearly the responsible person(s) or position for each activity*

Annexure 2: AX 02/SOP01/V1

Documentation of History of the SOPs Details of superseded SOP

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

Annexure 3: AX 03/SOP01/V1

Log of the IEC members receiving SOPs

No.	Name of Recipients	Designation	SOP code number	No. of Copies	Signature	Date

Annexure 4 AX 04/SOP01/V1

Template for SOP

	Institutional Ethics Committee
	Title: *Title which is self-explanatory and is easily understood*
	SOP No: SGSOPxx/Vy **Page:** a of b
	Code : SGSOP xx/Vy
	Effective date: DD/MM/YYYY
	Authors: xxxxxxxxx **Reviewed by**: xxxxxxx **Approved by**: xxxxxxxxx **Accepted by:** xxxxxxxxx

Annexure 5: AX 04/SOP 01/V1

List of SOPs of the -Institutional Ethics Committee (IEC)

No	Title of the Standard Operating Procedures (SOPs)	SOP No.
1	*Preparing Standard Operating Procedures (SOPs): Writing, Reviewing, Distributing and Amending SOPs*	*SOP 01*
2	*Constitution of Institutional Ethics Committee (IEC), Selection, Roles and Responsibilities of Members of the IEC*	*SOP 02*
3	*Handling Conflict of Interest among Ethics Committee Members*	*SOP 03*
4	*Selection and Responsibilities of Independent Consultants*	*SOP 04*
5	*Procedures for allowing Guest/ Observer to visit Institutional Ethics Committee or attend IEC meeting*	*SOP 05*
6	*Management of Submission of Research Study Protocol and Study Related Documents*	*SOP 06*
7	*Categorization of Submitted Protocols for Ethics Review*	*SOP 07*
7A	*Initial Full-Board Review of Research Study Protocols*	*SOP 7 A*
7B	*Expedited Review of Research Study Protocols*	*SOP 7 B*
7C	*Exemption from Ethics Review of Research Study Protocols*	*SOP 7C*
8	*Agenda Preparation, Meeting Procedures and Recording of Minutes*	*SOP 08*
9	*Review of Amended Protocol, Protocol-related Documents and Resubmitted protocol*	*SOP 09*
10	*Continuing Review of Study Protocols*	*SOP 10*
11	*Review of Protocol Deviations / Violations/ Non-compliance*	*SOP 11*
12	*Review of Serious Adverse Events (SAE) Reports*	*SOP 12*
13	*Review of Study Completion Reports*	*SOP 13*
14	*Management of Premature Termination / Suspension / Discontinuation of the Study*	*SOP 14*
15	*Request for Waiver of Written Informed Consent and Waiver of Consent*	*SOP 15*
16	*Site Monitoring and Post-Monitoring Activities*	*SOP 16*
17	*Dealing with Participants' Requests and Complaints Coming to Ethics Committee*	*SOP 17*
18	*Maintenance of Active Study Files, Administrative Records of the Ethics Committee, Archival of Closed Files and Retrieval of Documents*	*SOP 18*
19	*Reviewing Proposals involving Vulnerable Populations*	*SOP 19*
20	*Preparing for Ethics Committee Audit/ Inspection*	*SOP 20*
21	*Training and Assessment of Ethics Committee Members*	*SOP 21*

6. Flow Chart

No.	Activity	Responsibility
1	Identify the need for new or amendment of current SOP	Any member of UEC, secretariat or administrative staff
2	Appoint the SOP Team(s)	Chairperson
3	List all relevant procedures	SOP Team
4	Write a new/ revised SOP	SOP Team
5	Review a revised SOP	SOP Team and/UEC members
6	Prepare and submit final draft	SOP Team
7	Approve the new/revised SOP	Chairperson
8	Acceptance of the new/revised SOP	Head of the institution (Chairman, AVPRF)
9	Implement, distribute and file SOPs	IEC members and Secretariat