

## **STANDARD OPERATING PROCEDURE [SOP-2]**

### **DEVELOPMENT, REVIEW AND REVISION OF SOPS**

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#### **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 Committees – CHARUSAT (IEC-CHARUSAT). The SOPs provide clear, unambiguous instructions so that the related activities of the committee are conducted in accordance with existing Indian regulations and relevant, national and international ethical guidelines.

#### **2. Scope**

This SOP covers the procedures of writing, reviewing, distributing and amending the SOPs of the IEC by members of IEC-CHARUSAT

#### **3. Procedures for the development, review and revision of SOPs**

##### **Development**

It shall be the responsibility of the Chairperson of the IEC to appoint an SOP team to formulate a new SOP or to revise existing SOP. The SOP team shall do this by following the standard procedures and formats while drafting or editing any SOP of the IEC.

Office of the IEC will co-ordinate activities of writing, reviewing, distributing and amending SOPs. It shall:

- 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 IEC members
- maintain a file of all current SOPs and the list of SOPs

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- maintain a file of all past SOPs of the IEC

SOP team will:

- Assess the request(s) for SOP/s revision in consultation with the IEC Office, Member Secretary and Chairperson
- Propose new / modified SOP/s as needed
- Draft the SOP/s in consultation with the IEC members and involved administrative staff
- Review the draft SOP
- Submit the draft for approval to Chairperson
- Get it released by Appointing Authority

*Chairperson of the IEC will appoint two or more members of IEC as SOP Team and approve the SOPs with sign and date. Similarly, IEC members and involved administrative staff will sign and date the approved SOP when they receive it and maintain a file of all SOPs received*

**Detailed instructions for development**

Identifying the need for new or amendment of current SOP

- Any member of the IEC or its office that will 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/her request by writing to the IEC Chairperson either as an email/ letter/ verbal request in a meeting or otherwise.
- The Secretary will inform all the IEC members about this request at a regular full-board IEC meeting/ through email/ letter to which they will have to respond appropriately in timely manner.
- If the IEC members agree to the request, an appropriate SOP team 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 Secretary will inform the member of the IEC who made the request for modification of the SOP regarding the Committee's decision as well as to the IEC Office.

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Appointing an SOP Team

- The Chairperson will constitute an SOP Team consisting of the Member Secretary and two or more members of the IEC who have a thorough understanding of the ethical review process and are trained in preparation of SOPs.
- The SOP writing team will carry out the subsequent steps as described below.

**Review, approval and distribution**

Writing and reviewing a new/ revised SOP

- When the need for a new/ revised SOP/ an amendment 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 will be given a number and a title that is self-explanatory and easily understood. A unique number will be assigned to each SOP item by the IEC Office. The first SOP of the current version would be SOP v1-1.
- Each SOP may have annexures, which are formats to be filled in by various stakeholders [IEC or Principal Investigator (PI)]. Each annexure will be given a unique digital number with SOP name.
- Each SOP will be prepared according to the standard template [as above].
- Each page of the SOP will bear the footer which will have page number, the effective date i.e. the date of release of the SOP by the Appointing Authority and the SOP number. Header will bear the title of SOP and Name of IEC [*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 [sent either in hard copy or on email].
- 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.
- The new SOPs will be prepared with reference and guidelines of ICMR guidelines 2017 as per committee constituted by Chairperson. A new version will then be brought forth subject to the nature of change; if there is a minor administrative addition/ deletion or change, an amendment will be added instead of coming out with a new version. But if the Committee is of opinion that a new version needs to be brought out considering the importance of changes, instead of an amendment, a new

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version shall be brought forth.

*Preparing and submitting final draft (applicable for both new and existing Sops)*

- The suggestions that are agreed upon by the all IEC members will be incorporated in the revised draft SOP and it will be finalized in a formal full committee meeting, wherever possible.

The SOP team would stand automatically dissolved once the IEC takes final decision regarding the SOP.

*Approving the new / revised SOP*

- The final version will be presented to the Chairperson for review and approval
- The authors, 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 Appointing Authority (*as per the institutional policy*) as releasing authority [both for amendments as well as new version].

*Implementing, distribution and filing of 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.
- One complete original set of current SOP will be filed in the SOP Master file, by the IEC Coordinator in the IEC office.
- The approved SOP will be notified to the Registering Authority and also uploaded on institute's website [[www.charusat.ac.in/ethicalcommittee.php](http://www.charusat.ac.in/ethicalcommittee.php)] for everybody's access.
- Only one copy of the earlier version will be filed in the file entitled 'Past SOPs of the IEC' by the IEC Coordinator in the IEC office.

**Revision interval**

- The IEC members and the Office will review the SOPs generally at least once in every 2 years and also when needed.