

STANDARD OPERATING PROCEDURE [SOP-10]

Training & Self-Assessment

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1. Purpose

The purpose of this SOP is to describe requirements and methodology for training and performance assessment of the Institutional Ethics Committee-CHARUSAT (IEC) members and the IEC-CHARUSAT Office.

2. Scope

The SOP applies to all the IEC-CHARUSAT members and the IEC-CHARUSAT Office.

3. Conduct of training of IEC-CHARUSAT Member[s]

It will be the responsibility of the IEC-CHARUSAT Chairperson with the assistance of Member Secretary to ensure that there is adequate initial and continued training of the IEC-CHARUSAT members and the IEC-CHARUSAT Office. IEC members should have knowledge of the following:

- Relevant research ethics and regulatory guidelines
- Roles and Responsibilities of IEC-CHARUSAT members
- Review of protocol and related documents, including concepts of Risk Benefit assessment, Equity in recruitment, Autonomy, Confidentiality and Privacy
- Recent Developments in relevant health science specialities
- SOPs of the IEC-CHARUSAT

IEC Office bearers should have knowledge and relevant skills for conducting the following activities:

- Competency in working on Microsoft word, Excel, IEC-CHARUSAT office software
- Maintenance of IEC-CHARUSAT Database

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- Communication skills- written and verbal
- Knowledge about the SOPs

Training of new IEC-CHARUSAT Members

- Every time a new committee is constituted/ re-constituted, the members will undergo initial training on ethics in clinical research and good clinical practices and SOPs. One training every year at the minimum should be acquired by each member as part of continuous development program.
- An individual selected as a new member of the IEC-CHARUSAT will be required to attend one meeting as an 'Observer' before being inducted as a member of the IEC-CHARUSAT [no voting rights].
- An IEC-CHARUSAT member [preferably Member Secretary] will provide an introductory training to the new members. The new IEC-CHARUSAT member[s] would be encouraged to undergo online EC training program [preferably by ICMR or CDSCO] or training sessions as organized by the IEC-CHARUSAT.
- The IEC-CHARUSAT Member Secretary, Member[s], 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.
- IEC-CHARUSAT will conduct workshop[s] on ethics in clinical research and good clinical research practices at least once a year to impart training by the IEC-CHARUSAT Members to the Institutional faculty members [current/ potential investigators].
- The Appointing Authority will sponsor or reimburse the expenses of an IEC member or prospective members for attending conference, continuing education session workshop and/ or training program (if applicable).

Training of the IEC-CHARUSAT Office

- The IEC-CHARUSAT Member Secretary along with other members will train the IEC-CHARUSAT Office [Co-ordinator] on SOPs.
- There will be initial training and at least one training session per year on SOPs.
- The competency of staff in computers and communication skills will be evaluated and ensured initially at the time of appointment by the Member Secretary and Chairperson.

4. Implementation of corrective and preventive actions (as required)

All in-house trainings will be followed by evaluation of its effectiveness with a test. As indicated by the results, retraining shall be undertaken for members found deficient. Apart

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from this, the Member Secretary will be responsible for assessment of all IEC-CHARUSAT members with a self-assessment exercise at least once a year. During such an exercise, if the performance is not found to be satisfactory [$<80\%$], the member will be subjected to training again for the same and again re-evaluated on the same.

Maintenance of training records of the IEC-CHARUSAT Members and the Administrative Staff

The IEC-CHARUSAT Office will maintain copies of the certificates of all training workshops and conferences in research ethics attended by the individual IEC-CHARUSAT members. The copies will be filed in the individual members' files. The records regarding training material [s] will also be maintained in their respective files. For all in-house trainings, all details regarding schedule, resource persons, delegates and training material will be archived [both in hard copies as well as in electronic form].

5. Periodic self-assessments [including corrective and preventive actions]

The Committee will undertake periodic self-assessment, at least 1 every financial year. For the same, Chairperson will form a committee of Member Secretary along with one or two members. If required, member from Quality Improvement Group of institute may also be included for his/ her inputs.

The Committee shall scrutinize the types of research projects reviewed & number of projects approved/ rejected, review monitoring reports from members submitted, analyse minutes of meeting for lacunae, peruse SAE review and participant interview process and whether adequate steps were taken to ensure continuous training of the members in order to evaluate the working of Ethics Committee as a whole unit.

Report of the same will be furnished to the Appointing Authority. Based on the assessment report, corrective measures [if any suggested] will be implemented within 30 days, depending upon their feasibility. In case the recommendations cannot be implemented, a report on the same will be submitted to the Appointing Authority, declaring the reasons for the same and will be asked for assistance, in case of a vital recommendation.