

STANDARD OPERATING PROCEDURE [SOP - 8]

Administrative Support

Table of contents		
Sr. No.	Content	Page No.
1	Purpose	1
2	Scope	1
3	Ensuring adequate finance, human resource allocation and secretariat for administrative work and record keeping	1
4	Financial dealings of Ethics Committee activities and functioning	2
5	Procedure for communication between ethics committee, investigator/ relevant site staff, institution and regulatory authority	3
6	Procedure post Accreditation& Registration	4

1. Purpose

To provide instructions for establishment and maintenance of IEC-CHARUSAT Office for its day to day functioning

2. Scope

This SOP applies to IEC-CHARUSAT Secretariat, investigators and IEC-CHARUSAT Members

3. Ensuring adequate finance, human resource allocation and secretariat for administrative work and record keeping

- It shall be the duty of the Appointing Authority to provide a separate office and record room for regular functioning of the committee
- An Office Co-ordinator/ Assistant shall be appointed to manage daily work of the IEC-CHARUSAT. As per existing regulatory requirements, IEC-CHARUSAT shall have sufficient members to maintain quorum.
- Additional staff may be appointed and duties assigned; as and when deemed necessary by the IEC-CHARUSAT.
- 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 leaves may be

Institutional Ethics Committee – CHARUSAT
Charotar University of Science and Technology, Changa -388421

recommended by IEC-CHARUSAT members and discussed during regular IEC-CHARUSAT meeting and will be recorded in minutes.

- The administrative staff will report to the Chairperson and/or Member Secretary.
- A separate room within the institution shall be identified for meeting [s] of the committee.
- Office of the IEC-CHARUSAT shall be well equipped with tables, chairs, computer [with required software], printer, telephone, internet facility, shredders and steel lockable cupboards for its efficient functioning. Any additional requirement too shall be fulfilled depending upon the need.
- Preferably, a separate room shall be provided to facilitate archival and retrieval of documents. Regular pest control measures shall be undertaken in accordance with regulatory requirements with ensured fire safety measures. Steel lockable cupboards shall be used to store the documents.

4. Financial dealings of Ethics Committee activities and functioning

Incomes and Expenditures towards functioning of the committee

1. Standard fee will be charged for the review of research proposals submitted by the investigators of CHARUSAT for review in case of Industry Sponsored Clinical Trials.

a. IEC-CHARUSAT fees for Clinical trials: Fees for review clinical trials would be decided as and when required as prevailing norms.

2. Research projects initiated and submitted by investigators outside CHARUSAT but to be conducted within CHARUSAT will be accepted only after written permission granted by CHARUSAT Research Cell [on hard copy of the research proposal]

3. Research projects initiated and submitted by investigators outside CHARUSAT for research to be conducted outside CHARUSAT will not be accepted for review EXCEPT when there is a research collaborator from CHARUSAT as a co-principal investigator (Co-PI).

4. Research proposal review fees should be deposited in favour of “**Charotar University of Science and Technology**”, payable at Anand, Gujarat.

5. No member is expected to receive any remuneration, in either cash or kind, from any investigator or industry involved in the research proposal to be reviewed. Conflict [s] of interest, if any, will be declared prior to review as mentioned earlier and if required, depending upon the conflict of interest, will not be part of decision making during review process.

6. Expenses towards conduct of the meeting [s] will be borne by CHARUSAT.

Institutional Ethics Committee – CHARUSAT
Charotar University of Science and Technology, Changa -388421

7. A statement of all income and expenditure [including honorarium to internal as well as external members] will be made available for records purposes at the end of each financial year by IEC-CHARUSAT Office.

Honorarium to the Members

Reimbursement of travelling expense and/or reasonable honorarium for attending the IEC-CHARUSAT meetings will be given to the Chairperson, External Members and Member Secretary as decided by the appointing authority.

5. Procedure for communication between ethics committee, investigator/ relevant site staff, institution and regulatory authority

- Any new project shall be submitted to IEC-CHARUSAT in **Annexure [s] 4, 4.1, 4.2, 4.3, 4.4, 4.5 or 5, 5.1, 5.2, 5.3, 5.4**. This includes application, protocol, informed consent documents in English as well as vernacular language. Apart from them, an investigator may submit checklists as per relevant annexures.
- All projects need to be uploaded into the designated folder/ drive as circulated by the Member secretary.
- Only the PI can upload the necessary documents into the drive. At the same time, one hard copy of all the relevant documents too shall be submitted to IEC-CHARUSAT as Master file.
- Upon submission, an inward number will be generated. The inward number should be noted for future communication regarding the research proposal. Member Secretary should forward the submitted proposal to all the IEC-CHARUSAT Members for review.
- Online system facilitates the receipt of suggestions from IEC-CHARUSAT Members after review. These suggestions will then be combined and passed on to the PI through email.
- This process shall routinely be completed at least a week before the scheduled meeting.
- After the meeting, PI shall be intimated of IEC-CHARUSAT decision on both email and hard copy.
- The response from PI again has to be through online as well as one hard copy.
- Apart from PI, all communications to all other stake holders [Appointing authority/ Regulatory Authority etc. shall be made via email/ hard copy.
- Principal Investigator shall update/ communicate IEC-CHARUSAT for any amendments, adverse events, serious adverse events, 1st recruitment in a new trial,

Institutional Ethics Committee – CHARUSAT
Charotar University of Science and Technology, Changa -388421

sponsor's site visit report, interim/ yearly updates, compliance to monitoring visits etc. in one hard copy as well as in soft copy.

[Annexure 8, 9, 13, etc.]

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

The Member Secretary will make a yearly activity report for submission to the Registrar of CHARUSAT that will include the following elements:

1. Number and dates of the IEC-CHARUSAT meetings
2. Number of SAE subcommittee and any other subcommittee (as applicable)
3. Number and type of proposals (Pharma/ Government sponsored/ Registry/ investigator initiated collaborations with foreign universities or international organizations) reviewed in a year, status of each study proposal whether completed / ongoing / terminated
4. Number of approvals for full board review/ expedited review with decisions
5. Brief details about workshops, training programmes and other activities undertaken by the IEC-CHARUSAT and those attended by IEC-CHARUSAT members
6. Monitoring reports [if any relevant]
7. Self-assessment report [s]
8. Any other relevant matter/ suggestions

6. Procedure post accreditation and registration

- IEC-CHARUSAT shall undertake assessment for Accreditation, when necessary.
- All communications with Accreditation Authority shall be done by Member Secretary, in consultation with the Chairperson and the Registrar
- Expenses for Accreditation shall be borne by CHARUSAT
- Once accredited, IEC Office shall ensure timely communication with Accreditation Authority for Surveillance Assessment or Re-Accreditation
- Same procedure would apply for Re-registration with DHR/ CDSCO.
- All documents pertaining to Accreditation and Registration shall be archived at IEC-CHARUSAT office.