

**INSTITUTIONAL ETHICS COMMITTEE**  
**H. M. PATEL CENTRE FOR MEDICAL CARE & EDUCATION**  
**KARAMSAD, GUJARAT -388325**

[Reg. No. ECR/ 331/ Inst/ GJ/ 2013/ RR-16]

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**STANDARD OPERATING PROCEDURE [SOP]**

**ADMINISTRATIVE SUPPORT**

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**1. Purpose**

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

**2. Scope**

This SOP applies to IEC Secretariat, investigators and IEC 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. As per existing regulatory requirements, IEC shall have sufficient members to maintain quorum.
- Additional staff may be appointed and duties assigned; as and when deemed necessary by the IEC.
- 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 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.
- A separate room within the institution shall be identified for meeting [s] of the committee.

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- Office of the IEC 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 review of research proposals submitted by the investigators of the institution [HMPCMCE] for review in case of Industry Sponsored Clinical Trials.
  - a. IEC fees for Clinical trials:
    - Rs. 50,000/- for initial review of each protocol
    - Rs. 5,000/- for review of each amendment
      - The revised fee structure will be applicable to new clinical trials submitted on or after 1<sup>st</sup> August 2017
2. Research projects initiated and submitted by investigators outside the institution [HMPCMCE] but to be conducted within the Centre will be accepted only after written permission granted by Institutional Research Group [on hard copy of the research proposal]
3. Research projects initiated and submitted by investigators outside the institution [HMPCMCE] and also to be conducted outside the institution will not be accepted for review EXCEPT when the participant [s] to be recruited are from HMPCMCE institutions.
4. Research proposal review fees will need to be deposited in favour of “**Charutar Arogya Mandal**” having PAN No: AAATC 1264G, 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 the Centre.
7. A statement of all income and expenditure [including honorarium to internal as well as external members] will be made available to IEC Office for records purposes at the end of each financial year by the Centre.

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Honorarium to the Members

Reimbursement of travelling expense and /or reasonable honorarium for attending the IEC 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 in Annexure [s] 5, 5.1, 5.2, 5.3, 5.4, 5.5. 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 IEC Software [www.iecmanager.org/institution/15](http://www.iecmanager.org/institution/15) after PI getting duly registered with it.
- Once registered, a PI can upload the necessary documents into the online software. At the same time, one hard copy of all the relevant documents too shall be submitted to IEC as Master file.
- Upon submission, an inward number gets generated. On uploading the inward number into the system, MS can forward it to all the IEC Members for review.
- Online system facilitates the receipt of suggestions from IEC Members after review. These suggestions are then 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 decision on both, IEC Software as well as hard copy, after generating outward number.
- The response from PI again has to be through online software 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 be required to update/ communicate IEC for any amendments, adverse events, serious adverse events, 1<sup>st</sup> recruitment in a new trial, 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]**

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 that will include the following elements:

1. Number and dates of the IEC meetings of full committee

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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 and those attended by IEC 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 shall undertake assessment for Accreditation, when necessary.
- All communications with Accreditation Authority shall be done by Member Secretary, in consultation with Chairperson and Head of Institution
- Expenses for Accreditation shall be borne by the institution
- 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 CDSCO
- All documents pertaining to Accreditation and Registration shall be archived at IEC office.