Category: Study conduct-All studies (Government funded/NGO Regulatory)

Title: Continued Communication and interaction with the Institutional Ethics Committees(IECs)

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1. Purpose:

This standard operating procedure (SOP) describes the responsibilities of the research team towards procedures to be followed during the conduct of a trial regarding continued communication and interactions with the Institutional Ethics Committees.(IECs)

2. Scope:

This SOP applies to the procedures to be followed during the conduct of a trial regarding continued communication and interactions with the Institutional Ethics Committee(IEC) after approval is obtained from the Institutional Ethics Committee.(IECs). We have 3 Institutional Ethics Committees (IEC-I for Pharma sponsored study, IEC-II&III for biomedical and health research).

3. Responsibilities

The Principal Investigator will be primarily responsible for continued communication and interactions with the Institutional Ethics Committee, but can delegate this responsibility to the Study Coordinator.

4. Applicable rules, regulations and guidelines

- National Ethical Guidelines for Biomedical and Health Research involving Human Participants (2017), https://ethics.ncdirindia.org/ICMR_Ethical_Guidelines.aspx, last accessed on 26th March 2026.
- New Drugs and Clinical Trials Rules (2019), https://cdsco.gov.in/opencms/opencms/en/Acts-and-rules/New-Drugs/, last accessed on 26th March 2026.
- ICH HARMONISED GUIDELINE GOOD CLINICAL PRACTICE (GCP) E6(R3),https://database.ich.org/sites/default/files/ICH_E6%28R3%29_DraftGuideline_2023_0519.pdf, last accessed on 26th March 2026.

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- India GCP guidelines (Draft, September 2024), https://ethics.ncdirindia.org/asset/pdf/Indian_GCP_guideline.pdf, last accessed on 26th March 2026.

- National Ethical Guidelines for Biomedical Research Involving Children.https://ethics.ncdirindia.org//asset/pdf/National_Ethical_Guidelines_for_BioMedical_Research_Involving_Children.pdf last accessed on 26th March 2026.

- Standard-Operating-Procedures of Institutional Ethics Committee, Seth GS Medical College and KEM Hospital, Mumbai https://www.kem.edu/wpcontent/uploads/2025/03/SOPs_V7_effective_from_9th_Dec_2024_Seth_GSMC_&_KEMH_Mumbai.pdf V7-effective-from-9th-Dec-2024_.pdf (last accessed 26th March, 2026)

5. Reference to other applicable SOPs

- SOP No / Version No. 03/08: Responsibilities of the Study Team
- SOP No / Version No. 04/08: Obtaining approval from the Institutional Ethics Committee
- SOP No / Version No. 13/08: Dealing with protocol deviations
- SOP No / Version No. 15/08: SAE documentation and reporting
- SOP No / Version No. 21/08: Communication with sponsor

6. Detailed instructions

6.1 The Institutional Ethics Committees (IEC-1, IEC-2 and IEC-3) grant approval for a study for its entire duration.

6.2 Stamped acknowledgment (with IEC stamp and seal) should be taken on the copy of covering letter. (Refer SOP 04/08 for the format of the covering letter)

6.3 During study conduct, study-related documents, including but not limited to the following, will have to be submitted to the Institutional Ethics Committee (IEC) for review and approval. Only one set of these Study Related Documents need to be submitted for the IEC-1/ IEC-2/ IEC-3 review.

- Protocol amendments (including amendments to informed consent documents or investigator's brochure),

- SAE reports,
- Status reports,
- Study completion reports,
- Protocol deviations/ violations
- Administrative/logistic changes to the protocol (e.g. change in study team members, change in address of sponsor etc.)

6.4 Before making the submission, ensure that you have read and understood all the procedures for IEC submission. The IEC SOPs are available as a hard copy in the department as well as a soft copy on the institutional website (http://www.kem.edu/institutional-ethics-committee) at the institutional ethics committee site. (IEC SOP 07/V6.1: Standard Operating Procedures for Continuing review of study protocols).

6.5 These documents will be accepted during the specified office hours.

- Monday to Friday: 1.30 p.m. to 4.00 p.m.
- Saturday: 10.30 a.m. to 12.00 noon

The office will remain closed on Sundays, bank holidays and all the public holidays as approved by the institution.

6.6 To ensure inclusion in the agenda of the forthcoming meeting, any study related document should be submitted at least 10 days prior to the date of the meeting unless it is an SAE which should be sent to the IEC in the timelines specified in the IEC SOP.

6.7 In case a study is not initiated or terminated, this has to be communicated to the respective IEC stating reasons for the same, using the format for submission of report of premature termination of the study (Refer IEC SOP 09/V6.1 – AX 01/ SOP 09/V6.1).

6.8 SAE:

- In case of an SAE report which has direct bearing on the safety of the research participants, the reporting should be done within the stipulated time limits as described

otherwise] (Refer IEC SOP: 07/V6.1) after taking PI approval and sign. The six monthly report is to be submitted.

6.17 In case of delay in submitting annual report, the IEC secretariat will send a reminder which has to be responded within 15 days from the date of reminder to avoid actions viz. not reviewing future projects from the PI for a specified period of time or till the submission of status report and/or withholding the recruitment of new participants.

6.18 Clinical Study Report (CSR)

- For studies which are completed within the approval period, a study completion report should be submitted to the IEC, by the Study Coordinator. The Clinical study Report form (IEC-AX 01/SOP 08/V6.1) should be used to submit the completion report.
- The Clinical study Report should be submitted at the earliest for Govt. sponsored study and after obtaining report from sponsor for a pharmaceutical industry-sponsored study.

Reviewer as appropriate:

Signature with date 01/Jan/26

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