

**Category:** Study Conduct

**Title:** Continued interaction with the Institutional Ethics Committees

**SOP No:** D 17/06

**Date first effective:** 01 Jan 2024

**Review date:** 31 Dec 2024

Department of Clinical Pharmacology, First Floor, New MS Building,  
Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

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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 with the Institutional Ethics Committee (IEC).

### 2. **Scope:**

This SOP applies to the procedures to be followed during the conduct of a trial regarding continued communication with the IEC after approval is obtained from the IEC.

### 3. **Responsibilities**

The Principal Investigator (PI) will be primarily responsible for continued communication with the IEC, but can delegate this responsibility to the Study Co-Ordinator.

### 4. **Applicable rules, regulations and guidelines**

- New Drugs and Clinical Trials Rules 2019  
[https://cdsco.gov.in/opencms/export/sites/CDSCO\\_WEB/Pdf-documents/NewDrugs\\_CTRules\\_2019.pdf](https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf)
- National Ethical Guidelines for Biomedical and Health Research involving Human Participants ICMR, 2017  
[https://www.indiascienceandtechnology.gov.in/sites/default/files/file-uploads/guidelineregulations/1527507675\\_ICMR\\_Ethical\\_Guidelines\\_2017.pdf](https://www.indiascienceandtechnology.gov.in/sites/default/files/file-uploads/guidelineregulations/1527507675_ICMR_Ethical_Guidelines_2017.pdf)
- ICH-GCP E6 (R3) Draft Guidelines dated 19<sup>th</sup> May 2023  
[https://database.ich.org/sites/default/files/ICH\\_E6%28R3%29\\_DraftGuideline\\_2023\\_0519.pdf](https://database.ich.org/sites/default/files/ICH_E6%28R3%29_DraftGuideline_2023_0519.pdf)

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- IEC SOP, Guidelines and Checklists V6.1 <https://www.kem.edu/institutional-ethics-committee>

## **5. Reference to other applicable SOPs**

- SOP No. D 03/06: Responsibilities of the Study Team
- SOP No. D 04/06: Obtaining approval from the Institutional Ethics Committee
- SOP No. D 13/06: Dealing with protocol deviations.
- SOP No. D 15/06: SAE documentation and reporting
- SOP No. D 21/06: 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 Any communication with the IEC has to go as one soft copy (through pen drive or any other suitable storage device) and one hard copy.

6.3 Stamped acknowledgment (with IEC seal) should be taken on the copy of covering letter. (Refer SOP No: D 04/06 for the format of the covering letter)

6.4 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.)

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6.5 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 (<https://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).

6.6 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 and all public holidays.

6.7 To ensure inclusion in the agenda of the forthcoming meeting, any study related document should be submitted at least before 20<sup>th</sup> of every month, unless it is an SAE which should be sent to the IEC in the timelines specified in the IEC SOP.

6.8 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).

**6.9 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 in SOP No. D 15/06: SAE documentation and reporting and SOP No. D 14/06: Dealing with protocol deviation.

**6.10 Protocol amendments:**

- All amendments to the approved research proposal, case record forms and /or Informed Consent Document must be submitted to the committee (IEC-1/IEC-2/IEC-3) for review and approval.

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- Any planned changes in the protocol must not be initiated without prior written approval from the committee (IEC-1/IEC-2/IEC-3), except when necessary to eliminate immediate hazards to the subject, or when the change(s) involve only logistical or administrative aspects of the trial [e.g. change of monitor(s), telephone number(s)].
  - A covering letter, addressed to the Member Secretary of the respective IEC, with PI/Co-I's signature must be submitted mentioning reason(s) for amendments and summary of changes and the amended text must be highlighted in the revised protocol and protocol related documents.
- 6.11 Any new information that may adversely affect the safety of the subjects or conduct of the trial should be informed to the IEC.
- 6.12 If an appeal regarding rejection of a research proposal by the IEC has to be made, the Principal Investigator should make an appeal in writing to the Chairperson of the respective IEC with justification relevant to the issues/objections raised by the committee within twelve (12) weeks of the receipt of the committee's decision (Refer IEC SOP 09/V6.1).
- 6.13 Any change in the study team should be informed to the IEC and approval obtained.
- 6.14 Annual status report
- For studies which continue for more than a year, a status report mentioning the following details needs to be submitted in the 11<sup>th</sup> month after approval is granted. This is the responsibility of the Study Coordinator:
    - i. Number of participants approved by the IEC for recruitment at our site.
    - ii. Number of screened subjects, number of randomized subjects
    - iii. Number of enrolled participants
    - iv. Number of participants who have completed the study.

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- v. Number of participants who have dropped out/been withdrawn (stating reasons for dropouts/withdrawal)
  - vi. Number of participants at our site who had AE(s)
  - vii. If IEC has asked for AE reporting at specified timelines, this should be adhered to and referred to in the Annual Report
  - viii. Number of participants at our site who had SAE(s) giving reference to submission to the IEC.
  - ix. Report of an interim analysis (if available)
  - x. Report of the Data Safety and Monitoring Board (if available)
- 6.15 The annual continuing review fees are Rs. 10,000 for Pharmaceutical Industry sponsored studies and Rs. 1000/- for Government sponsored studies. Similarly, six monthly continuing review fees are Rs. 10,000 for Pharmaceutical Industry sponsored studies and Rs. 1000/- for Government sponsored studies.
- 6.16 Payment for the continuing review should be made *via* a cheque drawn in favor of "Seth GS Medical College & KEM Hospital, Diamond Jubilee Society Trust". The amount should be paid in full without tax deduction. (Refer IEC SOP: 05/V6.1).
- 6.17 The Study Coordinator has to submit the Continuing review report within one month of the due date [i.e. 11<sup>th</sup> months from the date of approval, unless specified otherwise] (Refer IEC SOP: 07/V6.1) after taking PI approval and signature.
- 6.18 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.
- 6.19 Study Completion Report
- For studies which are completed within the approval period, a study completion report should be submitted to the IEC, by the Study Coordinator. The study

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completion report form (IEC-AX 01/SOP 08/V6.1) should be used to submit the completion report.

- The study completion report should be submitted at the earliest for Govt. sponsored study and after obtaining report from sponsor for pharmaceutical industry sponsored study.

### 7. Abbreviations:

i.	AE	: Adverse Event
ii.	GCP	: Good Clinical Practice
iii.	ICH	: International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use
iv.	ICMR	: Indian Council of Medical Research
v.	IEC	: Institutional Ethics Committee
vi.	PI	: Principal investigator
vii.	SAE	: Serious Adverse Event
viii.	SOP	: Standard Operating Procedure

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Signature with date

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*21/06/2023*

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