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Category: Study Conduct

Title: Continued interaction with the Institutional Ethics Committees

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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.

2. Scope:

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

3. Responsibilities

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

4. Applicable rules, regulations and guidelines

- New Drugs and Clinical Trials Rules 2019
- Ethical Guidelines for Biomedical and Health Research involving Human Participants, ICMR 2017
- International Conference on Harmonization; Good Clinical Practice Guidelines: 1996
- ICH E6(R3) EWG Draft Guidelines dated 19th April, 2021.
- IEC SOP, Guidelines and Checklists V6.1

5. Reference to other applicable SOPs

- SOP No. 03/05: Responsibilities of the Study Team
- SOP No. 04/05: Obtaining approval from the Institutional Ethics Committee
- SOP No. 13/05: Dealing with protocol deviations
- SOP No. 15/05: SAE documentation and reporting

- SOP No. 21/05: 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 a soft copy (uploaded in e-EC) and one hard copy. Submission should be done *via* e-EC software (https://iecmanager.org/institution/42)

6.3 Stamped acknowledgment (with IEC seal) should be taken on the copy of covering letter. (Refer SOP 04/03 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.)

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 (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).

6.6 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 the public holidays.

6.7 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.

6.8 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.15/05: SAE documentation and reporting and SOP No.13/03: Dealing with protocol deviation.

6.10 Protocol amendments:

- All amendments to the approved research proposal, case record form and /or Informed Consent Document must be submitted to the committee (IEC-1 / IEC-2/ IEC-3) for review and approval.
- 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 Ethics Committee 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 11th 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
v. Number of participants who have dropped out/been withdrawn (stating reasons for drop-outs/ 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. 11th months from the date of approval, unless specified otherwise] (Refer IEC SOP: 07/V6.1) after taking PI approval and sign. The six monthly report is to be submitted

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 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.

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