

Category: Pre study procedures
Title: Obtaining approval from the Institutional Ethics Committee(s)

SOP No: D 04/05

Date first effective: 01 January 2023

Review date: 31 December 2023

Department of Clinical Pharmacology, 1st 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 for making a submission and obtaining permission from the Institutional Ethics Committee for all clinical studies.

2. Scope:

An Investigator planning to conduct a research study involving human participants at the Dept. of Clinical Pharmacology, Seth G.S. Medical College & K.E.M. Hospital, should seek permission of the Institutional Ethics Committee (IEC-1, IEC-2 or IEC-3) before commencing a study.

3. Responsibilities

Principal investigator will be responsible for obtaining ethics committee approval.

4. Applicable rules, regulations and guidelines

- 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-1 and IEC-2, IEC-3 SOPs, Guidelines and Checklist
- New Drugs and Clinical Trials Rules, 2019

5. Reference to other applicable SOPs

SOP No D 03/05: Responsibilities of the Study Team

SOP No. D 17/05: Continued interaction with the Institutional Ethics Committee (IEC-3, IEC-2, IEC-1)

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6. Detailed instructions

1. All studies which involve research on human participants require approval of the Institutional Ethics Committee (IEC-I for pharma sponsored study, IEC-II&III for biomedical and health research). Clinical studies are defined as "Research conducted with Human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual".
2. Retrospective studies, for example, (but not limited to) analysis of patients' records, X rays, ECGs, also require IEC approval.
3. The IEC has defined projects that are exempted from review. (Refer to IEC SOP 05-C/V5 "Exemption from the Ethics review for research projects")
4. The institute has two ethics committees which review and accord approval for different projects. Projects are randomly divided amongst the three Institutional Ethics Committees (IEC-1 or IEC-2 or IEC-3).
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 intranet at the IEC site and at <http://www.kem.edu>. The relevant portions are also enclosed as appendices with this SOP.

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6. The charges for review of projects by the three institutional ethics committees as of 20th April 2022 are as follows

- Rs 2000/- for postgraduate student's thesis
- Rs 2500/- for other academic projects (institutional academic)
- Rs 10000/- for government sponsored projects
- Rs 85,000/- for studies funded by the pharmaceutical industry
- Rs 10,000/- for annual review of sponsored projects
- Rs 10,000/- for the continuing review of sponsored projects (6 monthly)

7. Payment should be made *via* a cheque drawn in favor of "Diamond Jubilee Society Trust, Seth GS Medical College & KEM Hospital." The amount should be paid in full without tax deduction. In case of academic and government sponsored studies, an online payment can be made to the IEC. The payee details can be accessed from: <https://www.kem.edu/wp-content/uploads/2021/04/Circular-Revised-Mode-of-payment-Revised.pdf>

8. Project submission should be done via e-EC software
(<https://iecmanager.org/institution/42>)

9. The Project Submission Application Form for IEC are available on <http://www.kem.edu/institutional-review-boards>

10. Two sets of the project proposal (one original hard copy and one soft copy) should be submitted to the concerned IEC after getting confirmatory email from the concerned IEC.

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11. The project proposal should be submitted to the office of the IEC-1/ IEC-2 on or before 20th of every month and the meeting is held once a month.
12. If the study requires a consent waiver, a separate letter needs to be sent to the Member Secretary, requesting for a consent waiver, giving reasons in the format recommended by IEC (Refer IEC SOP 19/V5).
13. Enclose along with the submissions, a letter of administrative approval from the Director of the Institute.
14. If the study is a collaborative one, enclose a letter of written consent from the collaborator as well as permission from the Director/Dean/Head of the collaborating institute.
15. For studies funded by the pharmaceutical industry, a tripartite clinical trial agreement (CTA) is to be submitted to the IEC. The three parties are – the Principal Investigator, the sponsor and the Director of the Institute (who signs on behalf of the Municipal Corporation of Greater Mumbai, MCGM). The CTA needs to be ratified by the legal department of the MCGM, Fort, Mumbai 400001.
16. Application form to be submitted to the ethics committee should be as per Appendix 1.
17. Submissions are to be made to the IEC-1/IEC-2/ IEC-3 Secretariat, situated in the UG-PG hostel (ground floor). The timings are:

Monday to Friday: 1.30 p.m. to 4.00 p.m.

Saturday: 10.30 a.m. to 12.00 noon

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The office will remain closed on Sundays and all the public holidays.

18. IEC decisions will be received within 14 days after the meeting (Refer IEC SOP 05-A/V5).
19. Discuss the queries with the sponsor as appropriate and get their inputs.
20. Respond objectively to the queries in a reasonable time frame and ensure that the replies reach the IEC in time prior to the next meeting (as per announced on the intranet).
21. Once approval is received,
 - a) Keep the original in the Trial master file of the project
 - b) Send a copy to the collaborator(s) and sponsor as appropriate.
 - c) Keep a copy in the IEC approval master file of the office.
22. Refer to SOP D 17/05 for continued communications needed with IEC-1/IEC-2/IEC-3 during conduct and at the end of study.

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6. Appendices to the SOP

Appendix 1 Format of the application for documents submission to the institutional ethics committee

Documents submission letter for Institutional Ethics Committee approval

<< On Department's Letterhead >>

Date:<<DD/MM/YY>>

The Member Secretary,
Institutional Ethics Committee,
<<Insert the Institute Address>>

Reference: <<<<STUDY TITLE>>>>

Study Number/ Protocol No:

Subject: Submission of Clinical Study Documents for your review and approval

Dear Sir/Madam,

Please find enclosed EC package (<<<No. of copies>>>) with following documents for your review and approval:

Sr.No.	Document	Version and Date

As per the requirement of Schedule Y of Drugs and Cosmetics Act, kindly provide your approval for the above documents.

I request you to acknowledge the receipt of all the above-mentioned documents by signing this letter.

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Looking forward to hearing from you soon.
Thanking you

Yours sincerely

Principal Investigator

Acknowledgement:

Received By:

Signature and date:

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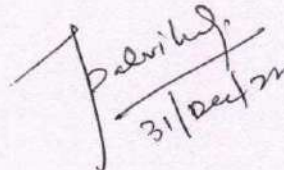
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
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