

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

SOP No: D 04/07
Date first effective: 01 Jan 2025
Review date: 31 Dec 2025
Department of Clinical Pharmacology, First Floor, New MS Building,
Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

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

SOP No.: D 04/07
Total pages: 10

Date first effective: 01 Jan 2025
Next Review date: 31 Dec 2025

Version: 07

SOP Team:

Author: Dr. Ananya Rakshit
DM Resident

Signature with date

Anu.
30/Dec/2024

Reviewer: Dr. Mahesh Belhekar
Associate Professor

Signature with date

Belk
31 Dec 2024

Dr. Mahesh N. Belhekar
Associate Professor
Department of Clinical Pharmacology
New MS Building, First Floor,
Seth GS Medical College and KEM Hospital
Acharya Donde Marg, Parel,
Mumbai - 400 012, India

Approved by: Dr. Nithya Gogtay
Professor and Head

Signature with date

N
30.12.24

Dr. Nithya Gogtay
Professor & Head
Department of Clinical Pharmacology
1st Floor, MS Building,
Seth GS Medical College & KEM Hospital,
Parel, Mumbai - 400 012.

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

SOP No: D 04/07

Date first effective: 01 Jan 2025

Review date: 31 Dec 2025

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

Table of Contents

No.	Contents	Page No.
1	Purpose	3
2	Scope	3
3	Responsibility	3
4	Applicable rules, regulations and guidelines	3
5	Detailed instructions	4
6	Appendices	8
7	Abbreviations	10

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

SOP No: D 04/07

Date first effective: 01 Jan 2025

Review date: 31 Dec 2025

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

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 (IEC) 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 or IEC-2 or IEC-3) before commencing a study.

3. **Responsibilities**

Principal investigator (PI) will be responsible for obtaining the institutional ethics committee approval.

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

- ICMR's Ethical Guidelines for Biomedical and Health research involving Human Participants, ICMR(2017) http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf (last accessed 20 Dec 2024)
- New Drugs and Clinical Trials Rules, 2019
https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf (last accessed 20th Dec, 2024)

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

SOP No: D 04/07

Date first effective: 01 Jan 2025

Review date: 31 Dec 2025

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

- **Indian GCP Guidelines 2001**
https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MzM5NQ== (last accessed 20th Dec, 2024)
- **International Conference on Harmonization, Guidance on Good Clinical Practice ICH GCP E6 (R3)**
https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf (Adopted on 06 January 2025)
- **Standard-Operating-Procedures of Institutional Ethics Committee, Seth GS Medical College and KEM Hospital, Mumbai**
[https://www.kem.edu/wp-content/uploads/2024/12/institutional-ethics-committee/Standard-Operating-Procedures\(SOPs\)V7-effective-from-9th-Dec-2024_.pdf](https://www.kem.edu/wp-content/uploads/2024/12/institutional-ethics-committee/Standard-Operating-Procedures(SOPs)V7-effective-from-9th-Dec-2024_.pdf) (last accessed 20th Dec, 2024)

Reference to other applicable SOPs

SOP No D 03/07: Responsibilities of the Study Team

SOP No. D 17/07: Continued interaction with the Institutional Ethics Committee (IEC-1/ IEC-2/ IEC-3)

5. 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.

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

SOP No: D 04/07

Date first effective: 01 Jan 2025

Review date: 31 Dec 2025

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

3. The IEC has defined projects that are exempted from review. (Refer to <https://www.kem.edu/wp-content/uploads/2013/08/SOP-05-C-Exemption-from-the-Ethics-Review-for-Research-Projects.-1.pdf> for IEC SOP 05-C/V5“Exemption from the Ethics review for research projects”).
4. The institute has three 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 [https://www.kem.edu/wp-content/uploads/2024/12/institutional-ethics-committee/Standard-Operating-Procedures\(SOPs\)V7-effective-from-9th-Dec-2024_.pdf](https://www.kem.edu/wp-content/uploads/2024/12/institutional-ethics-committee/Standard-Operating-Procedures(SOPs)V7-effective-from-9th-Dec-2024_.pdf)
6. The charges for review of projects by the three institutional ethics committees as follows:

Sr. No	Project Type	Initial Processing fees in INR		Periodic Review Processing fees in INR- 6 monthly Review		Annual Review Processing fees in INR	
		Gross Amount less 10% TDS	Net Amount	Gross Amount less 10% TDS	Net Amount	Gross Amount Less 10% TDS	Net Amount
1.	Pharmaceutical Sponsored Study	94,445 Less 9,444.50	85,000.50	11,112 Less 1,111.20	10,000.80	22,223 Less 2,22.30	20,000.70
2.	Government	11,112		2778		5,556	

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

SOP No: D 04/07

Date first effective: 01 Jan 2025

Review date: 31 Dec 2025

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

	Sponsored Projects	Less 1,111.20	10,000.80	Less 277.80	2,500.20	Less 555.60	5,000.40
3.	Thesis Dissertation	1,500		N/A		N/A	
4.	Academic non-sponsored projects	2,500		N/A		N/A	
5.	Funded studies	Budget ranging from 5,00,000/- to 25,00,000/- IEC Charge – Rs 10,000/- per project. Above 25 lakh for every 5,00,000 in addition – Charges are Rs 1,000/- + TDS 10%		N/A		N/A	

7. Payment should be made *via* a cheque/ demand draft/ NEFT 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.
8. The payee details can be accessed from: [https://www.kem.edu/wp-content/uploads/2024/12/institutional-ethics-committee/Standard-Operating-Procedures\(SOPs\)V7-effective-from-9th-Dec-2024_.pdf](https://www.kem.edu/wp-content/uploads/2024/12/institutional-ethics-committee/Standard-Operating-Procedures(SOPs)V7-effective-from-9th-Dec-2024_.pdf)
9. The Project Submission Application Form for IEC are available on <https://www.kem.edu/public/institutional-ethics-committee>

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

SOP No: D 04/07

Review date: 31 Dec 2025

Date first effective: 01 Jan 2025

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

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.
11. The project proposal should be submitted to the office of the IEC-1/ IEC-2/IEC-3 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 <https://www.kem.edu/wpcontent/uploads/2018/07/SOP-05-C-Exemption-from-the-Ethics-Review-for-Research-Projects.pdf>, IEC SOP 05-C Version 6.1 dated 29th June 2023).
13. Enclose along with the submissions, a letter of administrative approval from the Dean / 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, funder and the Dean / Director of the Institute (who signs on behalf of the Municipal Corporation of Greater Mumbai, MCGM).
16. The legal person of the IEC will review and finalize the CTA.
17. Application form to be submitted to the ethics committee should be as per Appendix 1.
18. 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 4.30 p.m.
Saturday: 10.30 a.m. to 12.30 noon
The IEC office will remain closed on Sundays and all the public holidays.

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

SOP No: D 04/07

Date first effective: 01 Jan 2025

Review date: 31 Dec 2025

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

19. IEC decisions will be received within 14 days after the meeting (Refer IEC SOP05-A/V5.1 5.1 dated 2nd April 2018, <https://www.kem.edu/wp-content/uploads/2019/04/SOP-05-Management-of-Initial-Protocol-Submissions.pdf>).
20. Discuss the queries with the sponsor as appropriate and get their inputs.
21. 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). Only Principal Investigator and study team shall communicate with IEC.
22. Once IEC approval is received,
 - a) Take Principal Investigator's signature on all the pages of the approval.
 - b) Keep the original in the Trial master file of the project
 - c) Send a copy to the collaborator(s) and sponsor as appropriate.
 - d) Keep a copy in the IEC approval master file of the office (DCP/R).
23. Refer to SOP D 17/07 for continued communications needed with IEC-1/IEC-2/IEC-3 during conduct and at the end of study.

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

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

SOP No: D 04/07
Date first effective: 01 Jan 2025
Review date: 31 Dec 2025
Department of Clinical Pharmacology, First Floor, New MS Building,
Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

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 New Drugs and Clinical Trials Rules - 2019, 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.

Looking forward to hearing from you soon.
Thanking you

Yours sincerely

Principal Investigator

Acknowledgement:

Received By:

Signature and date:

Contents: <<<No. of copies>>>

<<< Footer >> Page No. __ of __

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

SOP No: D 04/07

Date first effective: 01 Jan 2025

Review date: 31 Dec 2025

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

7. Abbreviations:

- i. CTA: Clinical Trial Agreement
- ii. CTRI: Clinical Trial Registration India
- iii. GCP: Good Clinical Practice
- iv. IEC: Institutional Ethics Committee s
- v. PI: Principal Investigator
- vi. SOP: Standard Operating Procedure

Reviewer:

Dr. Mahesh Belhekar
Associate Professor

Dr. Mahesh N. Belhekar
Associate Professor
Department of Clinical Pharmacology
New MS Building, First Floor,
Seth GS Medical College and KEM Hospital
Acharya Donde Marg, Parel,
Mumbai - 400 012, India

Signature with date

Bel
30/12/2024

Approved by:

Dr. Nithya Gogtay
Professor and Head

Signature with date

NG
30/12/24

Dr. Nithya Gogtay
Professor & Head
Department of Clinical Pharmacology
1st Floor, MS Building,
Seth GS Medical College & KEM Hospital,
Parel, Mumbai - 400 012.