Category: Pre study procedures

Title: Obtaining approval from the Institutional Ethics Committee(s)

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Table of Contents

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 2023)
- 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, 2023)
- 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, 2023)
- ICH-GCP E6 (R3) Draft Guidelines dated 19th May 2023 https://database.ich.org/sites/default/files/ICH_E6%28R3%29_DraftGuideline_2023_0519.pdf(last accessed 20th Dec, 2023)

- IEC-1 and IEC-2 SOPs, Guidelines and Checklist https://www.kem.edu/institutional-ethics-committee, https://www.kem.edu/wp-content/uploads/2023/01/IEC-Circular.pdf, https://www.kem.edu/wp-content/uploads/2020/10/Standard-operating-procedures-V6.1-dated-29th-June-2020.pdf(last accessed 20th Dec, 2023)

Reference to other applicable SOPs

SOP No D 03/06: Responsibilities of the Study Team

SOP No. D 17/06: 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.
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/2023/01/IEC-Circular.pdf, and https://www.kem.edu/wp-content/uploads/2020/08/Standard-operating-procedures-V6.1.

6. The charges for review of projects by the three institutional ethics committees as of 2nd Jan 2023 are 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 Sponsored Projects	11,112 Less 1,111.20	**10,000.80**	2778 Less 277.80	**2,500.20**	5,556 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		N/A		N/A	

		Charge – Rs 10,000/- per project. Above 25 lakh for every 5,00,000 in addition – Charges are Rs 1,000/- + TDS 10%		

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/2023/03/Protocol-review-processing-fees-follow-addendum-2section-4.pdf
9. The Project Submission Application Form for IEC are available on https://www.kem.edu/public/institutional-ethics-committee
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.
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 17/06 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

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>>>

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

Signature with date

23/DEC/2023.

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