DEPARTMENT OF CLINICAL PHARMACOLOGY
SETH GSMC AND KEMH, MUMBAI – 400012

Ph.1 SOP A09: Managing initial submission of protocol and associated documents for approval by Institutional Ethics Committee

Version 1.1 dated 30th of December 2024
Effective date: 1st of January 2025
Revision due date: 31st of December 2025

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Signature with date: 30/DEC/2024

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1. Purpose: The purpose of this SOP is to describe the responsibilities of the study team towards procedures to be followed for making the initial submission to the Institutional Ethics Committee (IEC) for approval for all phases of clinical trials with an investigational product (IP).

2. Scope: This SOP is limited to making the initial submission to the Institutional Ethics Committee for approval (IEC-I for pharmaceutical company sponsored studies, IEC-II & III for biomedical and health research including academic studies) for all phases of clinical trials with an IP at our institute.

3. Responsibilities: The responsibilities for ensuring implementation of this SOP lies with the Principal Investigator (PI)

4. Applicable rules, regulations and guidelines:

- Ethical Guidelines for Biomedical and Health Research involving Human Participants, ICMR (2017)
- International Council on Harmonization (ICH); Good Clinical Practice Draft Guidelines: (R3) dated 19th May, 2023
- ICH Good Clinical Practice Guidelines: 1996
- Medical Devices Rules, India, 2017
- New Drugs and Clinical Trials Rules, 2019
- Seth GSMC and KEMH, Mumbai, IEC-1, IEC-2, and IEC-3 SOPs, Guidelines and Checklists

5. References (to other SOPs)

- SOP Ph1 A03: Preparation, review, and finalisation of protocol for a Phase I clinical trial with an Investigational product
- SOP Ph1 A04: Preparation, review, and finalisation of case record form for a Phase I clinical trial with an Investigational product
- SOP Ph1 A05: Preparation, review, and finalisation of informed consent document for a Phase I clinical trial with an Investigational product
- SOP Ph1 A05a: Preparation, review, and finalisation of informed consent document for a Phase I clinical trial with an Investigational product in vernacular languages
- SOP Ph1 A06: Managing regulatory submission for a Phase I clinical trial with an Investigational product

6. Detailed instructions

S.No	Task	Person responsible
1	Ensure that all the procedures for IEC submission have been read and understood (The IEC SOPs, guidelines and checklists are available on the institutional website [http://www.kem.edu] under Institutional Ethics Committee, as well as hard copies are available in the department)	PI / Co-I / Study co-ordinator
2	Fill Annexure 1 of IEC – Application Form for Initial Review for all types of trials	PI / Co-I / Study co-ordinator
3	Fill Annexure 2 of IEC – Application Form for Clinical Trials	PI / Co-I / Study co-ordinator
4	Fill Annexure 5 of IEC – Delegation of Responsibilities of Study team	PI / Co-I / Study co-ordinator
5	Fill Annexure 6 of IEC – Documents Receipt form for initial review	PI / Co-I / Study co-ordinator

6	Fill Undertaking by the Investigator	PI
7	Prepare cover letter (application to the Member Secretary of the IEC)	PI / Co-I / Study co-ordinator
8	Obtain relevant signatures wherever required on the above documents	PI / Co-I / Study co-ordinator
9	Arrange all documents for IEC submission as per the IEC checklist (including administrative approval from the head of the institution)	PI / Co-I / Study co-ordinator
10	If the study is a collaborative one, enclose a letter of collaboration (Memorandum of Understanding / Statement of Agreement) with the collaborating party	PI / Study co-ordinator
11	For studies receiving external funding, 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 Director of the Institute (who signs on behalf of the Brihanmumbai Municipal Corporation, BMC). (The CTA needs to be ratified by the legal department of the BMC, Fort, Mumbai 400001).	PI
12	Scan all documents and obtain the soft copies on a pen drive	PI / Co-I / Study co-ordinator
13	Submit both hard copies (in a labelled file) and soft copies (in a pen drive) to the IEC office on or before the 20th of every month in the designated office hours as below: • Monday to Friday: 1.30 p.m. to 4.00 p.m. • Saturday: 10.30 a.m. to 12.00 noon	PI / Co-I / Study co-ordinator
14	Obtain receiving of the IEC on the Document	PI / Co-I / Study co-

	Receipt form and file the receiving in the Trial Master File (TMF)	ordinator
15	Once an email is received from the IEC assigning the study to one of IEC-I, IEC-II, or IEC-III, and instructing for payment; make the necessary payment as per the IEC fee structure mentioned below: • Rs 85,000/- + 10% TDS for studies sponsored by the pharmaceutical industry • Rs 10,000/- + 10% TDS for government sponsored projects • Rs 2500/- for other academic projects • Rs 10,000/- + TDS for the continuing review of pharmaceutical company sponsored projects (6 monthly) • Rs 2,500/- + TDS for the continuing review of Government sponsored projects (6 monthly)	PI
16	Make the payment online into the account of 'Seth GS Medical College & KEM Hospital, Diamond Jubilee Society Trust'	PI
17	Obtain screenshot of the successful transaction and e-mail the same to the concerned IEC email id as follows: • IEC-1: iec-1@kem.edu • IEC-2: iec-2@kem.edu • IEC-3: iec-3@kem.edu	PI

7. Abbreviations

Co-I	Co-investigator
CTA	Clinical Trial Agreement
GSMC	Gordhandas Sunderdas Medical College
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICMR	Indian Council of Medical Research
IEC	Institutional Ethics Committee
IP	Investigational product
KEMH	King Edward–VII Memorial Hospital
BMC	Brihanmumbai Municipal Corporation
PI	Principal Investigator
SOP	Standard Operating Procedure
TDS	Tax Deducted at Source
TMF	Trial Master File