Version 1.0 dated 24th of December 2024
Effective date: 1st of January 2025
Revision due date: 31st of December 2025

Title: Ph.1 SOP 00: Preparing a Standard Operating Procedure (SOP)

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Signature with date: 31~1C 26/DEC/2024

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Ph.1 SOP 00: Preparing a Standard Operating Procedure (SOP)

1. Purpose: The purpose of this SOP is to describe the steps for preparation of SOP for any activity in the Department of Clinical Pharmacology, Seth GSMC and KEMH, Mumbai.

2. Scope: This SOP is limited to preparation of any SOP in the above department.

3. Responsibilities: The responsibilities for ensuring implementation of this SOP lies with the Principal Investigator (PI). The SOP can be prepared by any member of the Department (medical and non-medical).

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
- Medical Devices Rules, India, 2017
- New Drugs and Clinical Trials Rules, India, 2019

5. References (to other SOPs)

None

6. Detailed instructions

S.No	Task	Person responsible
1	Write the header for the SOP containing the following: • SOP number • Title of the SOP • Version number with date • Effective date (Date the SOP shall be	Person preparing the SOP

	effective from) • Due date for revision	
2	Insert page numbers	Person preparing the SOP
3	Prepare the first page of the SOP as follows: • Title of the SOP • Version number with date • Effective date • Due date for revision • SOP prepared by • SOP reviewed by • SOP authorized by	Person preparing the SOP
4	Prepare the table of contents on the second page of the SOP	Person preparing the SOP
5	Prepare SOP under the following headings: • Purpose • Scope • Responsibilities • Applicable rules, regulations and guidelines • Reference (to other SOPs) • Detailed instructions • Abbreviations	Person preparing the SOP
6	Under 'Purpose', state the reason why the SOP is being prepared	Person preparing the SOP
7	Under 'Scope', describe the limitations of the SOP, i.e. where it shall be applicable	Person preparing the SOP
8	Under 'Responsibilities', mention the persons responsible for ensuring compliance with the SOP	Person preparing the SOP
9	Under 'Applicable rules, regulations and guidelines', enlist the guidelines and regulations, which shall be adhered to while performing the tasks	Person preparing the SOP

	/activities outlined in the SOP (The most recent version of the guidelines should be referred with their date of release)	
10	Under 'References (to other SOPs)', provide references to all other departmental (including Phase I) SOPs, which might have to be referred to while performing the tasks outlined in the SOP, along with the SOP number and the version number	Person preparing the SOP
11	Under 'Detailed Instructions', construct a table with the following columns: • Serial number • Task / Activity • Person responsible	Person preparing the SOP
12	Outline each individual task that is to be performed in the activity with absolute clarity	Person preparing the SOP
13	Use active voice, as in giving instructions, while outlining the tasks	Person preparing the SOP
14	Mention the persons responsible for performing the task (along with any back-ups if required)	Person preparing the SOP
15	Under 'Abbreviations', enumerate the full form of all the abbreviations used in the SOP	Person preparing the SOP
16	Internally discuss the SOP and get it reviewed and vetted by a senior member in the Department	Person preparing the SOP
17	Make the necessary corrections and modifications suggested during the internal discussion	Person preparing the SOP
18	Fill up the appropriate page numbers in the Table of Contents on the second page	Person preparing the SOP
19	Sign off the SOP along with the date and the appropriate stamps* – • Person preparing the SOP • Person reviewing the SOP	Person preparing the SOP

	• Person authorizing the SOP	
20	Scan the signed off copy of the SOP and maintain the soft copy in a pen drive	Person preparing the SOP / Study co-ordinator
21	File the signed off copy of the SOP in the Departmental SOP file**	Person preparing the SOP / Study co-ordinator

* The due date from which the SOP shall become effective should be on or after the date the person authorising the SOP has signed off.

** While preparing for any clinical trial, photocopies of all the SOPs relevant to the trial should be maintained in the Trial Master File (TMF).

Note: The SOP shall contain all the tasks that are to be routinely done in that activity. Any task applicable under specific scenarios can be added as a footnote at the end of the 'Detailed instructions'

For example: In a SOP for Ethics Committee submission, filling of duty delegation log and preparation of cover letter are two of the routinely performed tasks. They shall be included in the table in the Detailed Instructions. However, filling the annexure for exemption of informed consent is applicable only in specific scenarios. This shall be included as a footnote.

7. Abbreviations

ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICMR	Indian Council of Medical Research
PI	Principal Investigator
SOP	Standard Operating Procedure
TMF	Trial Master File