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 00a: Amending a Standard Operating Procedure (SOP)

Version: 1.0 dated 24th of December 2024

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Signature with date: 26/DEC/2024

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

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

2. Scope: This SOP is limited to amending an existing 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 amended 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	Change the version number of the SOP to the latest one with the current date	Person amending the SOP
2	Change the effective date of the SOP*	Person amending the SOP
3	Make the necessary amendment(s) in the appropriate section(s) of the SOP	Person amending the SOP
4	Highlight the changes in yellow	Person amending the SOP
5	Internally discuss the SOP and get it reviewed and	Person amending the SOP

	vetted by a senior member in the Department	
6	Make the necessary corrections and modifications suggested during the internal discussion	Person amending the SOP
7	Check whether there are any changes in the page numbers and accordingly update the table of contents if required	Person amending the SOP
8	Sign off the SOP along with the date and the appropriate stamps* – • Person preparing the SOP • Person reviewing the SOP • Person authorizing the SOP	Person amending the SOP
9	Scan the signed off copy of the SOP and maintain the soft copy in a pen drive	Person amending the SOP / Study co-ordinator
10	File the signed off copy of the SOP in the Departmental SOP file**	Person amending 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).

7. Abbreviations

GSMC	Gordhandas Sunderdas Medical College
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICMR	Indian Council of Medical Research
KEM	King Edward VII Memorial
PI	Principal Investigator
SOP	Standard Operating Procedure
TMF	Trial Master File