Category: Study Conduct

Title: Training of investigators / co-investigators, scientist(s), pharmacist(s), nurses, technicians and other trial staff for a Phase I clinical trial with an Investigational product.

SOP No.: DCP/Ph1/021 **Total pages:** 6

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

Version: 02

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DCP/Ph1/021: Training of investigators / co-investigators, scientist(s), pharmacist(s), nurses, technicians and other trial staff for a Phase I clinical trial with an Investigational product

1. **Purpose:** The purpose of this Standard Operating Procedure (SOP) is to outline the process and requirements for training investigators, co-investigators, scientists, pharmacists, nurses, technicians, and other trial staff involved in a Phase I clinical trial with an investigational product.

2. **Scope:** This SOP is limited to understanding study team responsibilities for all clinical studies involving human participants.

3. **Responsibilities:** Principal investigator, Co-investigator, Study Coordinator or any other appropriately qualified staff in the team, as delegated by the Principal Investigator, will be responsible for implementation of this SOP.

4. Applicable rules, regulations and guidelines:

- Ethical Guidelines for Biomedical and Health Research involving Human Participants, ICMR (2017)
- ICH E6 (R2) Integrated Addendum to ICH E6 (Rl), Current Step 4 version dated 9th November, 2016
- Medical Devices Rules, 2019
- New Drugs and Clinical Trials Rules, 2019

5. References (to other SOPs)

- Departmental SOP No. 03/29 Responsibilities of the study team.

6. Detailed instructions

S.No	Task	Person responsible
1.	• Ensure that all personnel involved in the trial receive appropriate training. • Oversee and coordinate the training process. • Document and maintain records of training activities.	PI
2.	• Provide training materials, resources, and expertise. • Ensure compliance with applicable regulations and guidelines. • Review and approve training plans and documentation.	Trial Sponsor / Clinical Research Organization (CRO)
3.	Training Plan Development • General training on Good Clinical Practice (GCP) guidelines, relevant regulations, and trial-specific protocols. • Specific training on the investigational product, handling, administration, adverse event reporting, storage requirements, obtaining informed consent, conducting study visits, collecting, recording data and managing trial-related documents.	PI, in collaboration with the trial sponsor or CRO
4.	Training Updates • Regular updates and refresher training should be provided to personnel involved in the Phase I clinical trial to ensure their knowledge and skills remain current and in line with any protocol amendments, evolving regulatory landscape, or new safety information.	PI, in collaboration with the trial sponsor or CRO

5.	Deviations and Non-Compliance • Any deviations from the training plan or non-compliance with training requirements should be documented, investigated, and addressed promptly. • Corrective actions should be implemented to prevent future deviations or non-compliance.	PI and the study team
6.	• Training records should be archived in a secure and organized manner for a predefined period, as required by applicable regulations and site specific.	Study Co-ordinator under the supervision of PI
7.	• Temperatures recorded must be audited regularly at least annually. • Calibration of temperature monitoring device and refrigerator should be maintained & updated as per requirement, desired frequency 3 moths – 6 months. • Ascertain the temperature requirements of the IP as per the protocol provided by the sponsor. • Ensure that the refrigerator for storing of IPs in Pharmacy room of ward no.24 of the Department of Clinical Pharmacology, is calibrated. • Access to the refrigerator in which IP is stored should be restricted. • If the IP is to be stored at room temperature, it should be stored in Pharmacy room located at ward no. 24 of Department of Clinical Pharmacology, or in Residents Room in Phase 1 unit, 2nd Floor, New MS Building, KEM Hospital depending on the temperature requirement.	Pharmacist under the supervision of PI

	• Refrigerator must be labeled with the name of the study, storage temperature for which the IPs are housed, with the date and due date of calibration. • Data logger should always be kept with the IP to keep a track of temperature round the clock	

7. Abbreviations

Co-I	Co-investigator
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICMR	Indian Council of Medical Research
ID	Identity number
IEC	Institutional Ethics Committee
SOP	Standard Operating Procedure
PI	Principal Investigator

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