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

DCP/Ph1/019: Evaluation of readiness of a Phase I clinical trial facility for conduct of a study in participants

Version 1.2
Effective date: 1st of January 2024
Revision due date: 31st of December 2024

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Signature with date 29/Dec/2023

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1. **Purpose:** The purpose of this SOP is to outline the procedure for evaluating the readiness of conducting a Phase I clinical trial study. This evaluation ensures that all necessary preparations are in place before the study begins, thereby minimizing risks and ensuring the safety and efficacy of the trial.

2. **Scope:** This SOP applies to all personnel involved in the planning, preparation, and conduct of Phase I clinical trials.

3. **Responsibilities:** The 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)**

- Ph1 SOP No. 20 /45: Preparation of Trial Master File (TMF)

6. Detailed instructions

S.No	Task	Person responsible
1.	Ensure that the following documents are in place: • Administrative approval • Regulatory approval • Signed Clinical Trial Agreement (CTA) • Institutional Ethics Committee (IEC) approval • Trial Master File • CTRI Registration • All applicable MoUs • All applicable SOPs	Study Coordinator under the supervision of PI/ CO-I
2.	Ensure that the following minimum facilities are available: • Restricted access to (Phase 1 unit, Consent room, Archival room, Pharmacy room) • Maintenance of temperature and drug accountability log for IP • Adequate number of beds (As per Visits) • SOPs for handling common medical emergencies e.g. syncope, hypotension, anaphylaxis, cardiac arrest, etc. • 24x 7 medical cover with duty delegation • 24 x 7 contact with sponsor or persons responsible for Investigational Medicinal Product [IMP] • Procedures for handling immediate maintenance of life support (i.e. resuscitation and stabilization of participants in an acute emergency) • Maintenance of Emergency trolley	Medical study team (PI /CO-I) , Anesthetist or Emergency medicine expert and Study Nurse.

	• Transfer of study participant to intensive care unit (ICU) if required. • All machineries like Multipara Monitor, ECG Machine, Defibrillator, Ventilator etc are calibrated.	
3.	• Ensure that adequate qualified staff is available for conduct of the study.	PI
4.	• All staff members have undergone GCP training and there is documentation of the training.	PI
5.	• Ensure two rounds of protocol readings are completed and are documented in the training log before site initiation.	PI / Co-I
6.	• All evaluations and findings related to the readiness assessment should be documented, signed, and dated.	Study Coordinator under the supervision of PI/ CO-I
7.	• The documentation should be retained as part of the study records and made available for regulatory inspections and audits.	Study Coordinator under the supervision of PI/ CO-I
8.	• If any facility or anything is not ready, take appropriate steps to ensure it is in place before Study initiation.	Study Coordinator under the supervision of PI/ CO-I

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
SOP	Standard Operating Procedure
PI	Principal Investigator

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