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

DCP/Ph1/014: Collection and review of screening data for selection of participants for a Phase I clinical trial with an Investigational product

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

Title: **DCP/Ph1/014:** Collection and review of screening data for selection of participants for a Phase I clinical trial with an Investigational product

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1. Purpose: The purpose of this SOP is to outline the procedures for the collection and review of screening data to select participants for participation in a Phase I clinical trial with an investigational product (IP).

2. Scope: This SOP applies to all personnel involved in the screening process of Phase 1 clinical trials with IPs conducted at our institute.

3. Responsibilities:

Principal investigator, Co-investigator, Study Coordinator (preferably medical) or any other appropriately qualified staff in the team, as delegated by the Principal Investigator, will be responsible for screening participants for taking part in any study.

4. Applicable rules, regulations and guidelines:

- Ethical Guidelines for Biomedical and Health Research involving Human Participants, ICMR (2017)
- ICH E6 (R3) Integrated Addendum to ICH E6 (Rl), Current Step 4 version dated (May 2023)
- Medical Devices Rules, 2017
- New Drugs and Clinical Trials Rules, 2019

5. References (to other SOPs)

- Ph1 SOP No. 13/45: Screening of subjects for participation in a Phase I clinical trial with an Investigational product
- Ph1 SOP No. 15/45: Managing and recording of data related to screen failures and subjects who withdrew consent

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6. Detailed instructions

S.No	Task	Person responsible
1.	Read and thoroughly understand the eligibility criteria and all the screening procedures as per the study protocol.	PI / Co-I/ Medical study co-ordinator
2.	Screening Data Collection and Documentation: Obtain all the results for the screening tests within the screening window period.	Study Coordinator
3.	Review of the Screening results by comparing with the normal reference ranges/ value	PI / Co-I
4.	Determine whether the participant is eligible or not for enrolment into the study based on the eligibility criteria as defined in the study protocol.	PI/ CO-I
5.	Call the Participant and inform them regarding their eligibility for enrolment into the study.	Study Coordinator
6.	If the participant is eligible enter the participant details in the enrolment log, assign a study identification number, schedule participant visits as per the protocol.	Study Coordinator
7.	File the Screening results and the screening outcome in the participant file with date and signature.	CO-I / Study Coordinator
8.	If the participant does not meet the inclusion criteria or has exclusion criteria then the participant is declared as screen failure (refer to SOP 15)	PI/ CO-I
9.	Document in the CRF, enter relevant data in the eCRF and EDC then PI will review, verify and signature with date.	Study Coordinator
10.	Verify the accuracy and completeness of the data entered in the CRF and EDC	PI

11.	Document any deviations from the SOP and report them to the PI for resolution.	PI /CO-I/Study team

Note : Even after the participant is not enrolled, and IP not administrated, participant has consented for screening or participating in the study in case of any AE, SAE, PD has to be notified to IEC within due time.

7. Abbreviations

AE	Adverse Event
Co-I	Co-investigator
CRFs	Case Record Form
EDCs	Electronic Data Capture
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
PD	Protocol Deviation
PI	Principal Investigator
SAE	Serious Adverse Event
SOP	Standard Operating Procedure

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Assistant Professor

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