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

Ph.1 SOP B13: Screening of potential participants for a Phase I clinical trial with an Investigational Product

Version 2.0 dated 1st January2026
Effective date: 3rd of January 2026
Revision due date: 31st of December 2026

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1. Purpose: The purpose of this SOP is to describe the procedures to be followed by the study team for screening of potential participants for participation in a Phase I clinical trial with an investigational product (IP).

2. Scope: This SOP is limited to screening of potential participants for a Phase I clinical trial with an IPconducted at our institute.

3. Responsibilities: The responsibilities for ensuring implementation of this SOP lies with the Principal Investigator (PI). The responsibilities for the individual tasks are mentioned under the Section 6. 'Detailed Instructions'.

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, 2017
- New Drugs and Clinical Trials Rules, 2019

5. References (to other SOPs)

- Ph. 1 SOP A01: Feasibility to conduct a Phase I clinical trial with an Investigational product
- Ph. 1 SOP B11: Identification (and advertisement) for potential participants for a Phase I clinical trial with an Investigational product

- Ph. 1 SOP B12: Obtaining informed consent from participants for participation in clinical trials
- Ph. 1 SOP B14: Collection and review of screening data for selection of participantsfor a Phase I clinical trial with an Investigational product
- Ph. 1 SOP B15: Managing and recording of data related to screen failures and participants who withdrew consent
- Ph. 1 SOP C25: Collection of samples after Check-in / admission of participants for a Phase I clinical trial with an Investigational product
- Ph. 1 SOP C 26 Medical examination of participants after check-in / admission for a Phase I clinical trial with an Investigational product

6. Detailed instructions

S.No	Task	Person responsible
1	Ensure that the study has been approved by the IEC, and the CTRI registration of the study has been completed and notified to the IEC	PI / Co-I / Study co-ordinator
2	Ensure thoroughness of the study team with the study protocol with respect to eligibility criteria and screening investigations. Document a minimum of two protocol trainings	PI / Co-I / Study co-ordinator
3	Confirm the identity of the potential participant by cross checking with his / her screening ID	PI / Co-I / Study co-ordinator
4	Obtain written informed consent from the participant and / or LAR as per Ph. 1 SOP B12: Obtaining informed consent from participants for participation in clinical trials*	PI / Co-I
5	Explain to the participant why you are asking	PI / Co-I

	him/her to undergo screening. Explain all the relevant tests that need to be done as per the protocol.**	
6	Give the participant sufficient time to arrive at a decision as to whether or not to participate in the screening process. Note down this time taken in the consent narrative.	PI / Co-I
7	Ensure that the potential participants who agree to be screened have an OPD paper (or an IPD paper if admitted)	PI / Co-I
8	Once the participant agrees to be screened, document the contact details (address and telephone number) of the participant in the source notes	PI / Co-I
9	Fill the participant's detailed demographic information, medical history, present illness, concomitant medications and other details, as per the protocol requirements, in the source notes (and hospital notes, if admitted)	PI / Co-I
10	Perform the general and systemic examination of the participant as required in the protocol and document these in the source notes#	PI / Co-I
11	Perform all the required laboratory investigations as specified in the protocol# • For drawing of a blood sample, refer Ph.1 SOP C25: Collection of samples after Check-in / admission of Subjects / patients for a Phase I clinical trial with an Investigational product	PI / Co-I / Laboratory technician

	• For obtaining an ECG, refer Ph. 1 SOP C 26Medical examination of participants after check-in / admission for a Phase I clinical trial with an Investigational product	
12	Collect the results of the screening tests as per SOP B14: Collection and review of screening data for selection of participants for a Phase I clinical trial with an Investigational product	PI / Co-I / Study co-ordinator
13	Once the results of screening are available, assess whether the subject is eligible to participate in the study## Follow Ph. 1 SOP B14: Collection and review of screening data for selection of participants for a Phase I clinical trial with an Investigational product	PI / Co-I
14	If found to be eligible, assign a participant identification number to the participant	PI / Co-I / Study co-ordinator
15	In the event that the screening results show that the subject is not eligible, inform him/her and exclude him / her from the study. Follow Ph. 1 SOP B15: Managing and recording of data related to screen failures and subjects who withdrew consent	PI / Co-I / Study co-ordinator
16	Refer the participant to the appropriate clinical unit/department in the event of an abnormality in the screening tests, which requires medical attention	PI / Co-I / Study co-ordinator
17	Review and sign the screening laboratory reports	PI
18	Give a photocopy of the signed screening laboratory reports to the participant	Study co-ordinator

19	File the original screening laboratory reports and the CRF in the participant file at the trial site	PI / Co-I / Study co-ordinator
20	Reimburse the participant for the study visit as per the provisions made for the same in the study protocol and as per Institutional Ethics Committee approval/ recommendation	Study co-ordinator
21	Maintain a departmental ledger recording details of all individuals who were counselled about the study and the number that actually consented to participate in the screening process. Document the reasons, if possible, for why subjects declined to participate in the screening	Study co-ordinator

* If the protocol requires two consent forms to be used, i.e. the screening consent form and the study participation informed consent form, ensure that the screening consent form is used first.

**If the protocol requires HIV testing to be done, ensure that the participant is counselled regarding the same as per National Aids Control Organization (NACO) Guidelines

Ensure that the study clinician is present at the time of any study related procedure

The review of screening results to assessment the eligibility for recruitment of potential participants must be done by a medical person

Note: If PI plans to recruit participants from among employees, colleagues, or students, this must be explained and justified in the protocol, reviewed and approved by the IEC, and appropriate measures to protect the vulnerable population should be in place.

7. Abbreviations

Co-I	Co-Investigator
CRF	Case Record Form
CTRI	Clinical Trials Registry of India
ECG	Electrocardiogram
HIV	Human Immunodeficiency Virus
ICD	Informed Consent Document
ID	Identification number
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICMR	Indian Council of Medical Research
IEC	Institutional Ethics Committee
IP	Investigational product
IPD	In-patient department
LAR	Legally acceptable representative
NACO	National AIDS Control Organization
OPD	Outpatient department
PI	Principal Investigator
SOP	Standard Operating Procedure

Reviewed by: Dr RoopaParida
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Signature with date 01/Jan/2026

Authorized by: Dr Nithya Gogtay
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Signature with date 1.1.26

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