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

DCP/Ph1/011: Identification (and advertisement) for potential subjects for a Phase I trial with an investigational product (IP) – both healthy participants and patient participants

Version 1.1
Effective date: 1st of January 2024
Revision due date: 31st of December 2024

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TABLE OF CONTENTS:

S. No	Content	Page no
1	Purpose	3 of 7
2	Scope	3 of 7
3	Responsibilities	3 of 7
4	Applicable rules, regulations and guidelines	3 of 7
5	References (to other SOPs)	3 of 7
6	Detailed instructions	4-6 of 7
7	Abbreviations	6 of 7

DCP/Ph1/011: Identification (and advertisement) for potential subjects for a Phase I trial with an investigational product (IP) – both healthy participants and patient participants

1. Purpose: The purpose of this SOP is to provide instructions for identification and advertisement for potential participants for a Phase I trial with an investigational product (IP).

2. Scope: This SOP is limited to identification and advertisement for potential participants for a Phase I trial with an IP at our institute.

3. Responsibilities: The responsibilities for ensuring implementation of this SOP lies with the Principal Investigator (PI).

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, 2017
- New Drugs and Clinical Trials Rules, 2019

5. References (to other SOPs)

- Ph. 1 SOP A9: Managing submission of protocol and associated documents for approval of Ethics Committee / Institutional Review Board

6. Detailed instructions

S.No	Task	Person responsible
1	Confirm / ensure that the study has received approval from the institutional ethics committee (IEC) prior to initiating the task of participant identification	Study co-ordinator [medical]
2	Confirm / ensure that the study has received the final CTRI number	Study co-ordinator [medical]
3	Confirm / ensure that the final CTRI number has been informed to the institutional ethics committee	Study co-ordinator [medical]
4	Confirm / ensure that any advertisement material to recruit participants has received institutional ethics committee (IEC) approval	Study co-ordinator [medical]
5	Ensure that a register / note book and a functional pen is at hand prior to initiating the process of identifying potential healthy participants	Study co-ordinator [non-medical]
6	Identify a minimum of 50 potential healthy participants from those who have participated in previous studies and available with the department and list them in the notebook [mentioned in point 5] along with telephone numbers	Study co-ordinator [non-medical]
7	Make a call one by one to all 50 healthy participants and document this in the notebook	Study co-ordinator [non-medical or medical]
8	Inform the healthy participants who pick up about the Phase I study and give an overview, especially the	Study co-ordinator [non-medical or medical]

	eligibility criteria of the study, and ask if they would be interested in participating. Ask them for permission to speak to them and if the time is not convenient ask for a time to call them back	
9	Make a list of those healthy participants where the phone numbers are wrong, have changed or those who decline, or those who do not pick up the call	Study co-ordinator [non-medical or medical]
10	If the number of participants who consent in principle is less than the sample size planned, make a new list of participants from 51-100 from the existing database and document this in the same notebook	Study co-ordinator [non-medical or medical]
11	Stop calling potential participants only when the total number willing is at least 30 more than the planned sample size and sign the list with date	Study co-ordinator [non-medical or medical]
12	If an advertisement that is IEC approved is being used to recruit healthy participants, paste the advertisement within the institution outside the canteen and library	Study co-ordinator [non-medical or medical]
13	Once the Study co-ordinator receives calls on his / her phone from potential healthy participants in response to the advertisement, document this in the notebook and explain the eligibility criteria to the participant	Study co-ordinator [non-medical or medical]
14	If the study involves patient participants, the Study co-ordinator will after due permissions sit in the outpatient clinic, in wards or ICU as appropriate and work with the clinical in charge to identify potential patient participants	Study co-ordinator [medical]

15	Record the names and phone numbers of all those patients who say yes in principle for participation in the notebook with the identifier "list of patients who have said yes in principle" and sign the list with date	Study co-ordinator [medical]

7. Abbreviations

CTRI	Clinical Trials Registry of India
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICMR	Indian Council of Medical Research
ICU	Intensive Care Unit
IEC	Institutional Ethics Committee
IP	Investigational product
PI	Principal Investigator
SOP	Standard Operating Procedure

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