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

DCP/Ph1/015: Standard Operating Procedure (SOP) for Managing and Recording Data Related to Screen Failures and Participants Who Withdrew Consent

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

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Author: Dr. Sourav Mondal

DM Resident

Signature with date 27-Dec-2023

Reviewer: Dr. Bhaskar Krishnamurthy

Assistant Professor

Signature with date 29/DEC/2023

Dr. Bhaskar Krishnamurthy
Assistant Professor,
Department of Clinical Pharmacology,
Seth GSMC and KEMH,Mumbai -400 012.

Approved by: Dr. Nithya Gogtay

Professor & Head

Signature with date 30/12/23

Dr. Nithya Gogtay
Professor & Head
Department of Clinical Pharmacology
1st Floor, MS Building,
Seth GS Medical College & KEM Hospital,
Parel, Mumbai - 400 012.

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1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide guidelines for the management and recording of data related to screen failures and participants who have withdrawn their consent in a research study.

2. Scope

This SOP applies to all personnel involved in the research study who handle or manage data related to screen failures and participants who have withdrawn their consent.

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

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)

- Ph 1 SOP No. 14/35 Collection and review of screening data for selection of subjects/patients for a Phase I clinical trial with an Investigational product

6. Detailed instructions

S.No	Task	Person responsible
1.	If the participant does not meet the inclusion criteria or has exclusion criteria then the participant is declared as screen failure. Whenever a participants fails the screening process, the PI/CO-I should clearly document the reason for screen failure in the Participant's file and CRF.	PI/CO-I
2.	The documentation should include relevant details such as the date of screening, specific criteria that led to the screen failure, and any additional notes or comments from the screening team.	PI/CO-I
3.	Determine whether the participant needs any referral for management in the event of any abnormality in the screening tests.	PI/CO-I
4.	Call the participant and inform them regarding the screen failure and counsel them for further management or refer them to the appropriate clinical unit/department.	PI/CO-I
5.	If participant voluntarily decides to withdraw their consent and discontinue participation in the research study ask them the reason for withdrawal either face to face or telephonically.	PI/CO-I
6.	Attempt to address any fear or concerns that the participant expresses.	PI/CO-I

7.	If still participant wishes to withdraw, then document the date of withdrawal, the reason provided (if any), and any relevant details regarding the withdrawal process.	
8.	Document in the CRF, EDC then PI will review, and signature with date.	PI/CO-I/Study co-ordinator
9.	Verify the accuracy and completeness of the data entered in the CRF and EDC	PI
10.	File it in the participant file with stamp and date of screen failure or consent withdrawal.	Study co-ordinator

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
SOP	Standard Operating Procedure
PI	Principal Investigator

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Assistant Professor
Department of Clinical Pharmacology
Seth GSMC and KEMH, Mumbai

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