

**Ph.1 SOP B12a**

DEPARTMENT OF CLINICAL PHARMACOLOGY  
SETH GSMC AND KEM HOSPITAL, MUMBAI 400012

Ph.1 SOPB12a: SOP for protection of privacy and confidentiality of study participants

Version 2.0 dated 26<sup>th</sup> December 2025  
Effective date: 1<sup>st</sup> of January 2026  
Revision due date: 31<sup>st</sup> of December 2026

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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
	Annexure 1	7 of 7

  
1.1.26

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**1.Purpose:** The purpose of this SOP is to outline the procedure for maintaining the privacy and confidentiality of participants in clinical trials while conducting them.

**2.Scope:** This SOP is limited to both regulatory and non-regulatory (academic) clinical studies conducted in the Department of Clinical Pharmacology, Seth GSMC and KEMH, Mumbai.

**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 B12: Obtaining written informed
- Ph. 1 SOP B20: Preparation, review, and finalisation of informed consent document for a Phase I clinical trial with an Investigational product in vernacular languages

  
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**6.Detailed instructions:-**

S.No	Task	Person responsible
During the conduct of the clinical study		
1	<p>When the participant is enrolled in a clinical study, generate a unique ID (identifier number or alphanumeric code) in sequence with any previous enrolled participant.</p> <p>The unique ID may be provided by the sponsor or generated at the study site.</p> <p>The ID may contain one or more of the following:</p> <ul style="list-style-type: none"> <li>• Abbreviation of the study name</li> <li>• Abbreviation of the name of the study site (KEM)</li> <li>• Three-digit Number in sequence (001, 002,... and so on)</li> </ul> <p>Use this ID to refer to the participant throughout the course of the trial</p>	PI/ Co-I/ Study co-ordinator
2	<p>Conduct the informed consent process in private, in a separate room (consent rooms are on the first and second floor in the department) with access only to study team members</p>	PI/Co-I
3	<p>In case of audio-visual consent, the face of the participant shall be clearly visible in the recording. Ensure that these recordings (CDs) are stored in a secure cupboard under lock and key with restricted access as mentioned below in Points 5 and 6</p>	PI/Co-I
4	<p>Ensure that all trial records including the CRF, ICD, and other trial documents contain only the ID generated as before. None of these should contain the name, or any other identifier or the participant (Exceptions to break confidentiality enlisted in Annexure I)</p>	PI/Co-I/ Study Coordinator

  
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5	Store the files of the participant documents (and CDs of audio-visual contents wherever applicable) in a secure area that is kept under lock and key (such as a study cupboard)	Study ordinator
6	Ensure that the access to these documents (cupboard) is restricted* (Prepare a list of people with access to the cupboard with 'effective from' date and place it over the cupboard)	Study ordinator
7	In case of electronic storage of data, ensure that the computer be opened with a password and provide the password to only authorized persons**	
After the conduct of the trial		
1	Express the results as summary statistics. Do not divulge individual participant information the results/ study completion report	PI/ Co-I
2	Avoid any participant identifiers in the manuscript to be sent for publication or in the updated results on CTRI	PI/ Co-I

\*Institutional Ethics Committee (IEC) members during monitoring, sponsor-appointed monitors, and external regulatory inspectors shall have unrestricted access to all document and shall be provided any document whenever asked for.

Page 5 of 7

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7. Abbreviations

Co-I	Co-Investigator
CRF	Case Record Form
GSMC	Seth Gordhandas Sunderdas Medical College "
HIV	Human Immunodeficiency Virus
ICD	Informed Consent Document
ICH	International Council for Harmonisation Technical Requirement for Pharmaceuticals Human Use
ICMR	Indian Council of Medical Research
ID	Identifier code
KEM	King Edward-VII Memorial Hospital
PI	Principal Investigator
SOP	Standard Operating Procedure

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**Annexure 1**

**Exceptions to break confidentiality:**

1. When the laboratory reports of the participant reveal that the participant is suffering from HIV, the results should be disclosed to him/her with appropriate counselling. Confidentiality will have to be broken in case of any notifiable disease as specified by the Government of India.
2. When the laboratory test results reveal any genetic abnormality, referral to the concerned department shall be provided with a note for counselling and/or treatment to the participant and the family members.
3. Reporting to the appropriate person(s)/department (e.g. Psychiatry) is needed when the participant is found to be harbouring suicidal / homicidal tendencies

  
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