

Category : Study conduct

Title : Source documentation

SOP No. : 12/05

Date first effective: 01 Jan 2023

Review date: 31 Dec 2023

Department of Clinical Pharmacology, 1st Floor, New MS Building, Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

Category: Study conduct

Title: Source documentation

SOP No.: 12/05

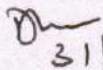
Total pages: 6

Date first effective: 01 Jan 2023

Next Review date: 31 Dec 2023

Version: 05

Author: Dr. Dhruve Soni
DM Resident

Signature with date  31/DEC/2022


Reviewer: Dr Vijaya Gunjal
Assistant Professor

Signature with date  31/DEC/2022

Department of Clinical Pharmacology
Seth GS Medical College & KEM Hospital,
Parel, Mumbai - 400 012.

Approval: Dr Nithya Gogtay
Professor & Head

Signature with date

 31-12-22
Dr. Nithya Gogtay
Professor & Head
Department of Clinical Pharmacology
1st Floor, MS Building,
Seth GS Medical College & KEM Hospital
Parel, Mumbai - 400 012.

Category : Study conduct

Title : Source documentation

SOP No. : 12/05

Date first effective: 01 Jan 2023

Review date: 31 Dec 2023

Department of Clinical Pharmacology, 1st Floor, New MS Building, Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

1. Table of Contents

No.	Contents	Page No.
1	Purpose	3
2	Scope	3
3	Responsibility	3
4	Applicable rules, regulations and guidelines	3
5	Reference to other applicable SOPs	3
6	Detailed instructions	4
7	Glossary	5

Category : Study conduct
Title : Source documentation
SOP No. : 12/05
Date first effective: 01 Jan 2023 Review date: 31 Dec 2023
Department of Clinical Pharmacology, 1st Floor, New MS Building, Seth GS Medical
College & KEM Hospital, Parel, Mumbai 400012.

1. Purpose:

This standard operating procedure (SOP) describes the responsibilities of the research team towards procedures to be followed for source documentation.

2. Scope

This SOP is limited to describing procedures for source documentation of clinical studies.

3. Responsibilities:

Every member in the study team will be responsible for source documentation.

4. Applicable rules, regulations and guidelines

- New Drugs and Clinical Trial Rules 2019
- Ethical Guidelines for Biomedical and Health research involving Human Participants, ICMR 2017
- ICH E6(R3) EWG Draft Guidelines dated 19th April, 2021.

5. Reference to other applicable SOPs

SOP No: 18/05 Archiving documents

SOP No: 19/05 Preparing for monitoring and audits

6. Detailed instructions

1. Source documents refer to all original data related to the participant which includes clinical notes, results of laboratory tests, urine output chart, details of drugs administered including dose, route of administration, batch number, manufacturing/expiry date, ECG report and reports of radiological investigations.
2. Source documents should include the details of the informed consent process [Narrative] and it should be signed by the person who conducted the consenting process.

Category : Study conduct

Title : Source documentation

SOP No. : 12/05

Date first effective: 01 Jan 2023

Review date: 31 Dec 2023

Department of Clinical Pharmacology, 1st Floor, New MS Building, Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

3. Source documents should be used for collecting information onto the case record form.
4. All the source documents should be countersigned by the PI.
5. Source document should contain similar information as mentioned in the case record form.
6. Maintain a master file of all source documents per participant (One file per participant for filing all source notes/documents).
7. All information should be kept confidential and confidentiality should be maintained throughout.
8. Source information that is directly recorded on the hospital case sheets (for example pulse, blood pressure etc.) that need to be sent back to the hospital records for archiving should be photocopied prior to submitting them to the medical records department (MRD) for inpatient study.
9. All source documents should be maintained in a secured cupboard in the clinical pharmacology unit (CPU) of ward 24.
10. Source documents printed on thermal paper such as ECG recordings and CBC reports should be photocopied immediately and countersigned by the person in charge and these copies will serve as source documents since thermal recordings will fade over time.
11. PI signature should be taken on all source documents.
12. Source documents should be made available to the monitor, auditors or inspectors as appropriate (Refer to SOP 19/05 on preparing for monitoring and audits)

Category : Study conduct

Title : Source documentation

SOP No. : 12/05

Date first effective: 01 Jan 2023

Review date: 31 Dec 2023

Department of Clinical Pharmacology, 1st Floor, New MS Building, Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

13. Upon study completion, the source documents should be archived for the specified duration in the archival room of ward 24 (Refer to SOP 18/05 on archiving documents)

7. Glossary

- **Source document:** ICH E6(R3) EWG Draft Guidelines dated 19th April, 2021.

Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories, and at medico-technical departments involved in the clinical trial).

Category : Study conduct

Title : Source documentation

SOP No. : 12/05

Date first effective: 01 Jan 2023

Review date: 31 Dec 2023

Department of Clinical Pharmacology, 1st Floor, New MS Building, Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

Reviewer: Dr. Vijaya Gunjal
Assistant Professor


Signature with date



31/DEC/2023
Department of Clinical Pharmacology
Seth GS Medical College & KEM Hospital,
Parel, Mumbai - 400 012.

Approved by: Dr. Nithya Gogtay
Professor and Head

Signature with date



31.12.22

Dr. Nithya Gogtay

Professor & Head

Department of Clinical Pharmacology

1st Floor, MS Building,

Seth GS Medical College & KEM Hospital,

Parel, Mumbai - 400 012.