Category : Study conduct
Title : Source documentation
SOP No. : D 12/07
Date first effective: 01 Jan 2025 **Review date:** 31 Dec 2025

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

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1. Table of Contents

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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

- ICMR's Ethical Guidelines for Biomedical and Health research involving Human Participants, ICMR(2017) http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
- International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) ICH E6 (R3) https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf (Adopted on 06 January 2025)
- Indian GCP guidelines 2001 https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MzM5NQ (Last accessed 20 Dec 2024)

5. Reference to other applicable SOPs

SOP No: 18/07 Archiving documents.

SOP No: 19/07 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.

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 19/07 on preparing for monitoring and audits)

13. Upon study completion, the source documents should be archived for the specified duration in the archival room of ward 24 (Refer to SOP 18/07 on archiving documents)

7. Glossary

Source document: International Conference on Harmonization, Guidance on Good Clinical Practice (ICH GCP) ICH E6 (R3) https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Step4_FinalGuideline_2025_0106.pdf (Adopted on 06 January 2025)

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).

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