

Category : Study conduct
Title : Source documentation
SOP No. : D 12/06
Date first effective: 01 Jan 2024 Review date: 31 Dec 2024

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

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SOP No.: D 12/06 Total pages: 06
Date first effective: 01 Jan 2024 Next Review date: 31 Dec 2024
Version: 06

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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

- New Drugs and Clinical Trial Rules 2019
https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf (last accessed 20th Dec, 2023)
- Ethical Guidelines for Biomedical and Health research involving Human Participants, ICMR 2017
http://www.icmr.nic.in/guidelines/ICMR_Ethical_Guidelines_2017.pdf
(last accessed 20 Dec 2023)
- ICH-GCP E6 (R3) Draft Guidelines dated 19th May 2023
https://database.ich.org/sites/default/files/ICH_E6%28R3%29_DraftGuideline_2023_0519.pdf

5. Reference to other applicable SOPs

- SOP No: D 18/06 Archiving documents.
- SOP No: D 19/06 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

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administered including dose, route of administration, batch number, manufacturing/expiry date, Electrocardiogram (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.

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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 D 19/06 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 D 18/06 on archiving documents)

7. Glossary

- **Source document:** ICH-GCP E6 (R3) Draft Guidelines dated 19th May 2023
https://database.ich.org/sites/default/files/ICH_E6%28R3%29_DraftGuideline_2023_0519.pdf

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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8. Abbreviations:

- i. **CBC:** Complete Blood Count
- ii. **Co-I:** Co-investigator
- iii. **CPU:** Clinical Pharmacology Unit
- iv. **ECG:** Electrocardiogram
- v. **MRD:** Medical Records Department
- vi. **PI:** Principal investigator
- vii. **SOP:** Standard Operating Procedure

Reviewer: Dr. Mahesh Belhekar
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