Category : Study conduct-All studies (Government funded/NGO funded/Regulatory

Title : Source documentation

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Version: 08

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1.1.26

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1. Table of Contents

1.1.26
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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:

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

4. Applicable rules, regulations and guidelines

- National Ethical Guidelines for Biomedical and Health Research involving Human Participants (2017), https://ethics.ncdirindia.org/ICMR_Ethical_Guidelines.aspx, last accessed on 20th March 2026.
- New Drugs and Clinical Trials Rules (2019), https://cdsco.gov.in/opencms/opencms/en/Acts-and-rules/New-Drugs/, last accessed on 20th March 2026.
- ICH HARMONISED GUIDELINE GOOD CLINICAL PRACTICE (GCP) E6(R3), https://database.ich.org/sites/default/files/ICH_E6%28R3%29_DraftGuideline_2023_0519.pdf, last accessed on 20th March 2026.
- India GCP guidelines (Draft, September 2024), https://ethics.ncdirindia.org/asset/pdf/Indian_GCP_guideline.pdf, last accessed on 20th March 2026.
- National Ethical Guidelines for Biomedical Research Involving Children.https://ethics.ncdirindia.org//asset/pdf/National_Ethical_Guidelines_for_BioMedical_Research_Involving_Children.pdf last accessed on 20th March 2026.
- Standard-Operating-Procedures of Institutional Ethics Committee, Seth GS Medical College and KEM Hospital, Mumbai

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https://www.kem.edu/wpcontent/uploads/2025/03/SOPs_V7_effective_from_9th_Dec_2024_Seth_GSMC_&_KEMH_Mumbai.pdf V7-effective-from-9th-Dec-2024_.pdf (last accessed 20th March, 2026)

5. Reference to other applicable SOPs

SOP No/ Version No: 18/08 Archiving documents.

SOP No/ Version No: 19/08 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, reports of radiological investigations and Payment Vouchers.

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 signed with date stamp /written date 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).

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7. All source 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 with "True copy" stamp by Head of Department prior to submitting them to the medical records department (MRD) for any inpatient study.

9. All source documents should be maintained in a restricted access 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 with "True copy" stamp by Head of Department immediately and countersigned with date stamp /written date by the person in charge and these copies will serve as source documents since thermal recordings will fade over time.

11. PI signature with date stamp /written date should be taken on all source documents and true copy written where appropriate.

12. All source documents should be made available to the monitor, auditors or inspectors as appropriate (Refer to SOP 19/08 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 18/09 on archiving documents) or 3rd party archiving based on the clinical trial agreement (CTA).

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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 Last accessed 20th March 2026. 2026 (Adopted on 06 January 2025)

Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, participant' 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).

Reviewer as appropriate:

Signature with date 01/Jan/26

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Approved by Head of Department: Dr. Nithya Gogtay
Professor and Head

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