QUICK GUIDANCE

Late or Missing Source Documentation

What to do when source records are incomplete, late, or cannot be located

WHAT IS IT?

Source Documentation:

Original records or certified copies of clinical findings, observations, or other activities in a clinical trial — the foundation for verifying study data.

Late or Missing Source:

Records not created contemporaneously with the activity, or records that cannot be located or were never created.

WHEN DOES THIS APPLY?

- Visit notes, laboratory results, or assessment records were not completed at the time of the visit
- Source documents cannot be located in the subject's file
- A sponsor monitor or auditor identifies missing or late source records
- EDC data cannot be verified against source because source is unavailable

PROCESS AT A GLANCE

1. Identify the Gap

- Review the subject's source file against the protocol Schedule of Events and EDC data
- Identify specifically what is missing: visit notes, lab reports, AE records, assessment forms, etc.
- Determine whether the documentation is missing entirely or simply late

2. Notify the PI

- Inform the PI of the missing or late source documentation promptly
- Document PI awareness and any instructions provided

3. Reconstruct or Locate Documentation

- Search all possible locations: EMR, paper files, lab systems, imaging systems

- If documentation exists elsewhere (e.g., hospital EMR), obtain a certified copy
- If documentation must be created late, clearly date it with the actual creation date, note it is a late entry, and include the reason for the delay

4. Create a Note to File

- Write a detailed note-to-file explaining what was missing, why, when it was discovered, and what corrective action was taken
- Include the PI's signature on the note-to-file
- File the note-to-file in the subject's source record

5. Complete a Reportable New Information Report (if applicable)

- Initiate a Protocol Deviation form (RNI) if the missing documentation reflects a procedural failure (e.g., a required assessment was not performed) Reportable New Information
- Report to the sponsor and IRB as required

6. Implement Corrective Actions

- Identify the root cause of the missing or late documentation
- Implement corrective measures: visit checklists, post-visit source review, delegation of documentation tasks
- Conduct a look-back review of other subjects to identify similar gaps

KEEP IN MIND

x Avoid: Do not backdate source documents or create records to appear contemporaneous when they are not. Never alter original records.

✓ **Best practice:** Create late entries transparently with the actual date. Use certified copies when originals exist elsewhere. Document the root cause and corrective actions.

REFERENCES

- ICH E6(R2) Good Clinical Practice Guidelines
- Reportable New Information https://research.arizona.edu/sites/default/files/2025-08/Reportable-New-Information-v2025-07.pdf
- Applicable Study Protocol