Guidance on Good Study Documentation Practices

The purpose of this document is to provide Overall Principal Investigators and their research teams guidance on best practices for capturing source documentation.

How to capture:

What to capture:
- Maintain adequate records of all observations and other data pertinent to the research for each subject. The records and documents should clearly identify the subject to whom they are related.
- Remember that "source" documentation is where the information is first recorded. This includes signed and dated informed consent documents, clinic notes, medical records, lab reports, drug diaries, evaluation checklists, pharmacy dispensing records, X-rays, etc.
- Make sure all data are verifiable and all source documentation supports the audit trail. It should be possible to reconstruct the data in the case report form (CRF) from information recorded in the source documents.
- Maintain records of information sent and received, or used to verify information about a subject (e.g., shipping confirmations and receipts, patient obituaries).

How to capture:
Apply the ALCOA standard to ensure proper source documentation.
- **A**ttributable – Who created the information and when? (Signature/initials and date)
- **L**egible – Can it be read and clearly understood? (Print names if signatures are illegible.)
- **C**ontemporaneous – Is the information current? Was it captured in timely manner?
- **O**riginal – Has it been altered? Maintain original data even if changes need to be made later.
- **A**ccurate – Are conflicting data recorded elsewhere?

Edits and Changes to Source Documentation:

If source documentation is incorrect, incomplete, or otherwise deficient, it may be corrected/completed by making a notation in or addendum to the source documentation.

- Subsequent entries must be separately signed/initialed and dated.
- The signature/initials and date must be captured as it happens.
- Erroneous information should be crossed out with a single line to preserve legibility of the original data and initialed and dated. Changes to the information should be noted adjacent to the cross out along with the reason for the change.

What not to do:
- Never obliterate entries that require correction.
- Never destroy original documents.
- Never use whiteout.