CRC Guidance: Good Clinical Practice Tips for Study Documentation

All original source documentation should be kept for each research participant. The records should include the consent form as well as information relevant to the participant's condition before, during, and after the conduct of the study.

Proper documentation practices are essential to ensuring compliant data. Following the below guidance when documenting study visits or adding to the regulatory file will help ensure that all data is verifiable and all documentation has an audit trail.

- Always document legibly and in black or blue ink
- Never discard previous versions of documents.
- Maintain records of all data and observations pertinent to the research participant. Document every phone call, every interaction with the study participant.
- Each page of the source documentation should be labeled by at least one unique identifier, such as the subject number.
- All source documentation should be signed and dated in real time by the person recording the data. For example, participant diaries and questionnaires should be signed/ dated by the participant, pharmacy dispensation records should be signed/dated by the individual dispensing.
- If source documentation is multiple pages, page numbers should be included at the bottom (ex. Page 1 of 4, Page 2 of 4…). Tip: If page numbers are included, only the final page needs to be signed/ dated.
- Never use white-out, write over, or completely scratch out data. To make a correction, draw a single line through the incorrect data, write your initials and date, then add the new data as necessary.
- If you need to add information at a later date, add the new information to the original source documents with the words ‘late entry.’ Include your initials and the current date.
- All blanks on source documents must be filled in – use leading zeros if needed and write ‘N/A’ or line through sections that are not applicable
- Always follow ALCOA PLUS guidance