CHICKEN SOUP FOR THE BUSY COORDINATOR

July 2020

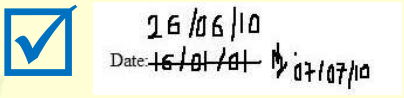
ENSURING DATA INTEGRITY WITH PRINCIPLES OF GOOD DOCUMENTATION

Scenario

During the routine monitoring for study ABC, the monitor noticed that the study team amended the source documents without initialing and dating the document. The monitor gave feedback to the study team on the need to follow proper documentation practice, and the responsibility of the PI and/or designated staff to ensure that the research study information (hardcopy or electronic) is recorded, handled and stored in a way that allows its accurate reporting, interpretation and verification.

What is the proper data correction method the study team should follow?

- Correction can be made by crossing out the original entry such as single line without obscuring the original data. E.g. correction fluid or tape should not be used (i.e. an audit trail should be maintained).
- Write the correct data beside the incorrect data.
- Correction should be Initialed and dated to show when and who made the adjustments.
  Refer to the example below:



How can the Clinical Research Coordinator (CRC) help ensure proper documentation by the study team moving on?

The CRC shared with the study team on the following principles of proper documentation practices, where the source data should meet the **ALCOA** standards:

- ✓ **A**ttributable –Data should be accountable and traceable by including appropriate identifiers (e.g. protocol number, subject number, date and time of study procedure / data entry, initials/signatures of study team member making the entry). A delegation log should be maintained to identify the signatures & initials.
- ✓ **L**egible – Data should be readable and permanent.
- ✓ **C**ontemporaneous – Documentation should be performed at the time the data becomes available/ as the event occurs / when procedures are performed (e.g. back-dating should not be done).
- ✓ **O**riginal – Documentation should be the first entry or record of the information collected. This could sometimes be referred to as source data or primary data.
- ✓ **A**ccurate – Documentation should be complete and correct. Editing should not be done without documenting and annotating the amendments.

The CRC also reminded the study team on the following documentation principles:

- ✓ Be complete – All recorded data needs to have an audit trail.
- ✓ Be consistent – Data reported on the DCFs / CRFs, which are derived from source documents, should also be consistent with the source documents and any discrepancies should be explained.
- ✓ Be enduring – The data must be maintained, intact, and accessible throughout their defined retention period.
- ✓ Be Available – The data must be accessible at any time during the defined retention period.

Other good documentation tips / habits for the study team

- The study team should document the date & time of the data collected in a contemporaneous manner.
- All handwritten documentations should be legible and written with permanent ink pens.
- Use of erasable ink pens are strictly prohibited *(i.e. Frixion pens uses a unique sensitive ink which is erasable by applying heat, thus making the data disappear. Therefore it should not be used to sign or create important documents).*

Reference: *NUH-IMU-SOP on MANAGEMENT OF SOURCE DATA AND SOURCE DOCUMENTS*
NHG Proper Conduct of Research SOP: 501-B05 Documentation

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