Research Good Documentation Practices

"If it is not documented, it didn't happen"

ALCOA+C =

***A**ttributable*

It should be obvious who documented or did what; traceable to a person, date, time, and participant visit or contact. The document should also show who made any changes and the reason for the change.

***L**egible*

The record should be easy to read with identifiable signatures (if not, a name should be printed in addition to the signature). Changes to source data should not obscure the original entry.

***C**ontemporaneous*

Study documentation or results should be documented in real-time. If a clinical observation cannot be entered when made, chronology should be recorded. Acceptable amount of delay (within one month) should be defined and justified. E.g., "late entry". All signatures or initials should be attached to a date indicating when the signature was added to the document.

***O**riginal*

First record of the information or certified copy. The investigator should have the original source document. Changes to source data should be traceable.
A signature on a worksheet or other written documentation means personal completion or verification of completion for a required procedure/ test/ assessment/ etc. in a clinical trial.

***A**ccurate*

Consistent and real representation of facts.

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Complete

The information should answer who, what, when, where, why, and how. Do not leave blank pages or remove blank pages, unless instructed by Sponsor.

*As per ICH GCP 4.9.0, all the elements of the acronym ALCOA must be applied to both paper and electronic source data, and the records that hold that data. Serving as evidence of the events that took place during a study, source documents need to paint the full picture of what happened. Using ALCOA as a guide to collect quality data in clinical trials can help justify that a test article is safe and effective.

RESEARCH DOCUMENTATION 101:

Documentation – When errors occur

- Document what happened
- Document why it happened
- Document how to prevent the same error from happening again
- Implement the changes needed to prevent recurrences, in a policy if applicable
- Educate staff about the new policy implemented, if applicable
- Communicate to the staff that the error occurred (to prevent repeat occurrences)
- If the error is a protocol deviation or violation fill out the appropriate forms and submit to the REB in a timely manner (annually for minor deviations and immediately for violations.)
- It is recommended that all research documents should be legible and that any corrections made are done by striking a single line through the error, the correct value is placed adjacent to it, and the correction is initialed and dated by the individual making the correction.
- All research documents should be completed in non-erasable blue or black ink. No pencil or brightly colored pens as they can fade and become illegible over time.
- Copies of original source data should be certified if being kept in a research chart as source documentation.
- Original source data on thermal sensitive recording paper (example: EKG or blood pressure reading printout) should be saved as a certified copy.
    - As per 1.63 of ICH-GCP, a certified copy is, irrespective of the type of media used, a copy of the original record that has been verified (i.e. by a dated signature or generation through a validation process) to have the

same information including data that describe the context, content, and structure as the original.

- An attestation should include a statement the certified copy is exactly as the original document. EXAMPLE:
  I, NAME, attest this is as an exact copy having all of the same attributes and information as the original. (Followed by signature and date)

Documentation – General Practices

Do's

• Check that you have the correct chart before you begin writing.
• Make sure your documentation reflects your professional capabilities.
• Write legibly.
• Chart the time you administered an injection (or drew blood), the administration route (or phlebotomy site), and the patient's response
• Record each phone call, email or text you make (to a monitor, to a study participant, etc.) including exact time, message, and response.
• Chart patient care at the time you provide it
• Record all facts (Be objective- no speculation or guessing).
• Chart only for yourself.
• Begin each entry with date (and time if applicable) and end with your signature and title.
• If you remember an important point after you've completed your documentation, chart the information with a notation that it's a "late entry". Include the date and time of the late entry.
• Document often enough to tell the whole story.

Don'ts

• Don't chart a symptom, an event, etc. without also charting what you did (or are going to do) about it.
• Don't alter a subject record.
• Don't use shorthand or abbreviations that aren't widely accepted (Policy NSHA MM-SR-005).
• Don't write imprecise descriptions (e.g. "long time" or "various attempts").
• Don't chart what someone else said, heard, felt or smelled unless the information is critical. In that case, use quotations and attribute the remarks appropriately.
• Don't attribute thoughts, feelings, or intentions, to other persons (includes subjects, providers, spouses, parents, etc.).
• Don't write retaliatory or critical comments about clients or care by other health care professionals (including sponsors).
• Don't add dates to documents or chart care ahead of time- something may happen, and you may be unable to actually give the care you've charted on the date you anticipate. Charting care that you have not done is considered fraud.

Examples of Don'ts

1. "Patient angry because of long wait and decided to leave"
2. "Blood draw not done because husband would not let us"
3. "Monitor didn't tell us until today that existing subjects have to sign new consents"

Better Alternatives

1. 2 May 2022 1930 "Subject left the office prior to completion of 30 minute wait time. Subject verbalized understanding of protocol and states that she is unable to comply due to personal commitments." [and then state what, if any, action is taken as a result].
2. 2 May 2022 1930 "Venipuncture attempt X 1 in left antecube and X 1 in left antecube without success. Subject's mother refuses additional attempts." [and then state what, if any, action is taken as a result).
3. 2 May 2022 1930 "Site informed by monitor of process for updating patient consents; patient currently out of compliance according to this protocol and will sign the updated consent according to process as outlined per monitor".

Or in other words:

o "Subject anxious about ..... " should be "Subject states: 'I worry that….
o "Subject doing fine .... " should be "Mom states that subject is doing well per baseline and without AEs or SAEs except where noted."
o "Left another message for subject .. " should be "2 May 2022 19:30 Left message #3 on subject's cell#, explained that subject is now one day out of window per protocol and requested return phone call urgently."

References:

Medi-Smart (2005). Nursing Legal Issues. http://medi-smart.com/documentation.htm.
Potter, P.A. & Perry, A.G. (2001). Fundamentals of Nursing (5th ed). St. Louis, MO: Mosby, Inc.
University Hospitals (2011) Clinical Research Good Documentation Practices (https://www.uhhospitals.org/-/media/Files/For-Clinicians/Research/alcoac-documentation.pdf