University Hospitals
Clinical Research Center

Clinical Research Good Documentation Practices

"If it is not documented, it did not happen"

ALCOA + C to achieve data quality:

A *ttributable*

It should be obvious who documented or did what; traceable to a person, date, and subject visit.

L *egible*

The Record should be easy to read and signatures identifiable (if not then print name also).

C *ontemporaneous*

The information should be documented as it happens. 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.

A *ccurate*

Accurate, consistent and real representation of facts.

+

C *omplete*

The information should be complete (i.e., to answer who, what, when, where, why, and how).

- All of 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 collecting quality data in clinical trials can help justify that a test article is safe and effective. -

References:
ICH GCP E6R2 4.9.0 and ICH GCP E6R2 4.9.1
(Sources: Woollen, 1999; Lopienski, 2014)

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Research Documentation In-service

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
- Communicate to the staff that the error occurred (in order to prevent repeat occurrences)
- If the error is a protocol deviation or violation fill out the appropriate IRB forms and submit to the IRB in a timely manner
- Educate staff about the new policy implemented if applicable
- It is recommended that all research entries 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 indelible blue or black ink. No pencil or brightly colored pens as they can fade and become illegible over time. Any documents that are not completed in indelible ink should have certified copies made. Please see the link here: UH Clinical Research SOP SC-410: Certified Copies of Research Regulatory Documents for details about how to make certified copies of research documents

Documentation > General Practices

Do's	Don'ts
• 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 you make (to a monitor, to a parent, 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'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. • 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. o 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 chart care ahead of time- something may happen and you may be unable to actually give the care you've charted. Charting care that you have not done is considered fraud.

Research Documentation In-service, cont.

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. 11 Nov 2011 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. 11 Nov 2011 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. 11 Nov 2011 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:

- "Subject anxious about ..... " should be "Subject states: 'I worry that
- "Subject doing fine .... " should be "Mom states that subjects is doing well per baseline and without AEs or SAEs except where noted.”
- "Left another message for subject .. " should be "11 Nov 20111930 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.