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*

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O *riginal*

First record of the information or certified copy. The investigator should have the original source document.

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Accurate, consistent and real representation of facts.

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Research Documentation In-service

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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.