**Clinical Research Documentation Standards, “If it was not documented, it was not done.”**

To achieve data quality the ALCOA-C principle should be applied to source documentation, which specifies, the data should be:

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| **A** | Attributable | Is it obvious who wrote/did it and when?  If changes were created, is it obvious who, when, and why changes were made? |
| **L** | Legible | Can it be read easily? |
| **C** | Contemporaneous | Are the study information/results recorded as they are observed current and in the correct time frame? |
| **O** | Original | Is it a copy? Has it been altered? |
| **A** | Accurate | Are conflicting data recorded elsewhere? |
| **C** | Complete | Has the information been recorded in its entirety? |

At a minimum, the following general standards must be followed:

* Keep handwritten notes and signatures legible. If necessary, the individual’s name may be printed underneath the signature.
* Sign and date all entries in real time.
* Make error corrections by 1) drawing a single line through the incorrect information, 2) initialing, dating, and stating a reason for the change (if necessary), and 3) inserting the correction. If the change is obvious, i.e., a transcription error that can be verified with the original source, then a rationale for the change is not required. If the change is not obvious, i.e., a diagnosis or symptom that was deleted after initial entry, then there should be a rationale for the change.
* Never obliterate entries that require correction.
* Never destroy original documents, even if they require error correction.
* Keep subject records secure yet accessible.
* Do not alter past-dated notes, chart notes/progress notes, e.g., by writing alongside or adding to prior entries.
* Only use dark ink.
* Never use whiteout.
* Never use pencil.