NEW

Clinical Research Documentation

ALCOA-C CHECKLIST

"If it wasn't documented, it wasn't done."

Having its roots in the federal regulations governing good laboratory practice for non-clinical laboratory studies, or 21 CFR 58.130 (e), "ALCOA" remains the practice of FDA auditors and quality assurance professionals regarding clinical practices. This checklist reflects the recently updated guidelines (ICH GCP E2 Rev2) and how clinical research professionals should apply them to their study.

A L C O A C

Attributable

- It should be obvious who created a record, and when it was created
- If a record was changed, it should be obvious who made the change, when the change was made, and why

Legible

- The research record should be easily read

Contemporaneous

- Study evidence/results should be recorded as they are observed
- All signatures/initials should be attached to a date indicating when the signature was added to the document

Original

- Study records should be originals, not photocopies

Accurate

- Study records should have a high level of integrity and honesty to what was truly observed; give a full accounting of the research process
- Study records should be thorough and correct; work should be double checked for unintentional errors

Complete

- Investigators and institutions should maintain adequate, accurate and complete source documents

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*ICH GCP E6 Rev2

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