

Research Compliance Awareness TIPS “ALCOA+”

(Attributable, Legible, Contemporaneous, Original and Accurate *plus* Complete, Consistent, Enduring and Available)

Q: What does the acronym “ALCOA+” stand for? One of the most common federal inspection findings in investigator site inspections is lack of reliable, accurate and adequate source documentation. This also happens to be the most common pitfall identified during sponsor audits. The importance of good documentation practice needs to be emphasized to researchers to ensure that the study results are built on the foundation of credible and valid data.

A: The acronym “ALCOA+” stands for the fundamental elements of data integrity. These are:

A Attributable- Does the documentation clearly demonstrate:

- The link to its source (who it’s about)
- Who observed and recorded the information
- When the data was observed and recorded (date and time stamped)

L Legible

- Can the information be easily understood?
- Is it recorded permanently on durable medium?
- Have original entries been preserved? (not obscured)

C Contemporaneous – Was the information recorded with timeliness?
Complete –

O Original – Is the source information accessible and preserved in its original form?

- Source is “where it’s written down first”

A Accurate

- Does the recorded information describe what took place during the study without error?
- Did the conduct of the study conform to the protocol?
- Who made corrections and when corrections were made?

RESEARCH COMPLIANCE

PLUS

C Complete

- Does the documentation include all of the necessary information?
- Is all of the data available? Are changes any included?

C Consistent

- Are good documentation practices complete throughout the course of the study?
- Are the dates and timestamps recorded in the expected sequence?

E Enduring

- Is the data recorded in a permanent, maintainable format for the required retention time (10+ years)?

A Available

- Is the data available and accessible for review, audit and/or inspection throughout the required retention time (10+ years)?

We encourage you to contact our office to explore the training and education opportunities.

I CARE | **Protect**

 RUSH