Research Compliance Awareness

RESEARCH COMPLIANCE

TIPS

**“ALCOA”**

**(Attributable, Legible, Contemporaneous/Complete,** **Original, and Accurate)**

**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.

**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 – Does the documentation include all of the necessary information?

**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?

We encourage you to contact our office to explore the training and education opportunities.  Please contact Rita Tharpe at ext. 2-4485 or Renee Reber at ext. 2-8314 for more information.