CHICKEN SOUP FOR THE BUSY COORDINATOR

NOV 2023

ALCOA Principles for Source Documentation

Source documentation in research should meet the ALCOA standards:

- ✓ **Attributable**: Data should clearly state who performed the action and when.
- ✓ **Legible**: Data should be easy to understand, recorded permanently and preserved in its original form.
- ✓ **Contemporaneous**: Data should be recorded at the same time the trial-related activity is performed.
- ✓ **Original**: Data should be preserved in its original form or a certified true copy.
- ✓ **Accurate**: Data should be free from error. Amendments should be scored, amended, initialed and dated.

Scenario

The following observations relating to source documentation were noted from a recent Site Monitoring Visit. *(refer to 1st column in the table below)*

1. For each observation, what should be the recommended corrective actions and preventive actions?
2. What are the applicable ALCOA principles that should be adhered to for each observation?

OBSERVATION	CORRECTIVE ACTION AND PREVENTIVE ACTION PLAN	ALCOA PRINCIPLES
It was not possible to ascertain who had completed the questionnaire for Trial Participant 001, as the entry had not been initialed and dated.	• The CRC should document in the questionnaire / Note to File to clarify who had completed the questionnaire and when it had been completed, and initial and date the entry with the current date. • The CRC should ensure that all source documents are attributable, moving forward.	 ATTRIBUTABLE
It was not possible to ascertain when the CRC had dispensed the Investigational Product to Trial Participant 002, as the IP dispensing date had been completed as '10 Jan 2023' but the study visit had occurred on '19 Jan 2023'.	• The CRC should amend the dispensing date to 19 Jan 2023, and initial and date the amendment with the current date. A Note to File should be created to explain the delayed amendment. • The CRC should ensure that all source data are legible, moving forward.	 LEGIBLE
The CRC did not complete the IP Dispensing Log at the time of dispensing for Trial Participant 003 at Study Visit 5. She completed it when the trial participant had returned the unused IP at Study Visit 6.	• The CRC should document the reason for the delayed entry on the IP Dispensing Log, and initial and date the entry with the current date. • The CRC should ensure that source documents are completed in a contemporaneous manner, moving forward.	 CONTEMPORANEOUS
The CRC did not certify photocopies of the Investigational Product Storage Temperature Logs as true copies.	• The CRC should certify the photocopies of the IP Storage Temperature Logs as true copies. • The CRC should ensure that all photocopies of source documents are certified as true copies, moving forward.	 ORIGINAL
The Investigational Product temperature had been monitored using a min-max thermometer, which had displayed the temperature readings to one decimal place. However, the CRC had rounded off the temperature readings to the nearest whole number on the IP storage temperature logs.	• The CRC should generate a Note to File to document the inaccurate documentation of the IP storage temperatures and report the non-compliance to the IRB. • The CRC should ensure that the IP storage temperature is documented accurately, in accordance with the min-max thermometer.	 ACCURATE

References:

- Section 4.9.0 ICH E6 (R2) Guideline for Good Clinical Practice

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