CHICKEN SOUP FOR THE BUSY COORDINATOR

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HOW TO ENSURE CONSISTENCY OF STUDY DOCUMENTS THROUGHOUT THE DURATION OF THE RESEARCH

Scenario:
Study A is conducted in Hospital X. After a recent study review audit, here are some of the findings to be addressed:

Finding (1): Latest approved version of the informed consent form and protocol are not kept in the investigator file
Finding (2): Study team member's essential documents were not up-to-date (i.e. training records)
Finding (3): Discrepancy between study documents and DSRB application form
Finding (4): Incorrect ICF version and language was used to obtain consent
Finding (5): Delegation log was not completed appropriately
Finding (6): Co-Investigators had been trained and delegated with study duties; but had not received approval from the IRB to be added into the study team

How can the Clinical Research Coordinator (CRC) assisted the Study A's Principal Investigator (PI) with a corrective action and preventive action (CAPA) to address the findings?

The CRC discussed with the PI to put in place the following measures.

i. Create an ICF tracking log to keep track of the latest approved ICF. This will help to ensure that only the current approved versions of the ICF will be used. Ensure sufficient copies of ICF are accessible to the PI and study team members delegated to obtain consent.
ii. To follow-up closely on the approval status of study amendments e.g. addition of study team members (i.e. Co-Is) prior to the commencement of their study involvement and update the delegation log.
iii. Plan for an internal monitoring of the study to:
    a. Ensure all study documents used tally with those submitted and approved by the ethics committee and/or regulatory authorities.
    b. Ensure essential documents such as the following (but not limited to) are up-to-date and maintained in the IF:
        - Study team members' Curriculum Vitae (CVs),
        - Training certificates (e.g. CITI, GCP etc.)
        - Logs (e.g. Study Responsibility/ Delegation Log, Subject Screening and Enrollment Log, Training Record Form etc.)

REMINDER: To ensure all study information are documented appropriately so as to prevent/reduce non-compliances and/or future findings, study team are to apply the **ALCOA** standards.

Attributable	Data should be accountable and traceable by including appropriate identifiers (e.g. protocol number, subject number, date and time of study procedure / data entry, initials/signatures of study team member making the entry).
Legible	Data should be readable by others.
Contemporaneous	Documentation should be performed at the time the data becomes available/ as the event occurs / when procedures are performed (e.g. back-dating should not be done).
Original	Documentation should be the first entry or record of the information collected.
Accurate	Documentation should be complete and correct.

References:

- NHG Proper Conduct of Research Policy, 501-A02: Responsibilities of the Research Team; 501-A03: Training and Education, 501-B03: Study Initiation, 501-B05: Documentation

Additional Reading: ICH GCP E6 (R2): Section 8 – Essential Documents for the conduct of a Clinical Trial

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