CHICKEN SOUP FOR THE BUSY COORDINATOR

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ESSENTIAL DOCUMENTS - SETTING UP AND MAINTAINING THE INVESTIGATOR FILE

Principal Investigator (PI) and Study Team would be starting a study after securing grant funding and obtaining ethics approval for a protocol. What would they need to know and do pertaining to the setting up and maintaining the essential documents in the Investigator File (IF)?

Purpose: "Essential Documents are those documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor and monitor with the standards of Good Clinical Practice and with all applicable regulatory requirements." *(ICH GCP E6 R2, Section 8.1)*

The essential documents also serve a number of important purposes such as:

a) Assist successful management of research at the study site.
b) Assist monitors, auditors and inspectors to confirm compliance and integrity of data collected.

The minimum list of essential documents are segregated into three sections according to the stage of the study (refer to ICH GCP E6 (R2) Section 8 for the full list of essential documents required during the stages of the study/trial):

Stages of the study	Examples of Essential Documents (but not limited to)
Before the study commences	IRB approval letter, IRB approved protocol, IRB approved informed consent forms, Regulatory authority approval letter (for clinical trials)
During the conduct of the study	IRB approved protocol amendments, informed consent forms, study delegation log, biological specimen log, documentation of investigational product (for clinical trials involving investigational product)
After completion or termination of the study	Final report

Responsibilities: The PI is responsible for maintaining the study's essential documents in their IF. However, this responsibility would usually be delegated to the study's clinical research coordinators (CRC). Therefore it is pertinent for the CRC to be knowledgeable and well versed on the different types of essential documents that would be required to set up the IF.

During a monitoring visit/ audit, the IF would be checked and inspected. If the IF is not maintained or set up properly, some of the common findings related to essential documents may arise:

- Missing informed consent forms (ICFs) or data collection forms.
- Missing Data and insufficient information for Audit trail.
- Study team members performing procedures that they have not been delegated to perform.
- Study team members not updated with the latest approved informed consent form and outdated informed consent form still being used.

Best practice: To prevent/ minimize the above findings, the CRC may use the NHG Investigator File Contents Template to ensure that essential documents are maintained with an audit trial and are up to date. Maintaining the essential documents in the IF in a timely manner, would greatly assist and facilitate the team members to prepare for any monitoring or audits.

References:

- ICH GCP E6 (R2), Section 8 Essential Documents For The Conduct of A Clinical Trial
- NHG Proper Conduct of Research SOP 501-B05: Documentation

Additional Readings:

- NHG Proper Conduct of Research SOP 501-A02: Responsibilities of the Research Team
- NHG Proper Conduct of Research SOP 501-B09: Study Completion Activities

Recommended course on essential documents, principles of good documentation and common documentation pitfalls:
(PCR300) Study Conduct II: Documentation, Safety Reporting and Investigational Products

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