

CHICKEN SOUP FOR THE BUSY COORDINATOR

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Investigator Site File (ISF) Management

Scenario:

Site ABC is managing a total of 50 investigator-initiated trials (IIT). During an internal monitoring, nearly half of the studies were found to have the same study findings:

- 1) The CVs of the study team members were not updated.
- 2) Doctors' medical licenses (ML) had expired.

Corrective Action:

Study administrators of Site ABC will be assigned to consolidate the documents needed from each of the affected study team members. Documents collected are then filed into the Investigator Site File (ISF) for all the affected studies.

Preventive Action:

To further prevent similar deficiencies, the study administrator of Site ABC has prepared a master file which contains the latest copy of CVs, MLs, CITI certificates and GCP Certificates of all the PIs. The study administrator will remind the study team to update their CVs & CITIs (if any) when they submit the Status Report Form (SRF) to Domain Specific Review Board (DSRB) yearly.

A note-to-file (NTF) will be created to indicate that all these essential documents are kept in a master file and will be accessible by auditors/monitors upon request. This NTF is kept in all the studies' ISF. The master file is kept in a locked cabinet and only delegated study team members such as clinical research coordinators have the right to access the locked cabinet.

Furthermore, a spreadsheet with coded formula will be created to track the renewal of these documents to make sure that these essential documents are updated regularly. The PI and/or designated staff is responsible for ensuring that essential documents are up to date.

Note: If electronic copies of essential documents are used, a qualified process should be in place and monitored to ensure the electronic copy is a complete and accurate representation of the original (i.e. certified true copy). The electronic copy should be placed in a validated electronic document management system.

References:

1. *NHG PCR SOP 501-B05 Documentation*
2. *NHG PCR SOP 501-A02 Responsibilities of the Research Team*

Additional Reference:

NHG 599-006 Guidance Document on Electronic Filing of Essential Documents, dated 1 Apr 20

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