NHG RESEARCH EDUCATION

Qualité

Education to facilitate high standards of research conduct

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Monitoring Observations On Essential Document

Purpose of essential documents

Essential documents are important. They:

- Individually and collectively permit an evaluation of the research conduct and quality of research data produced
- Serve to demonstrate compliance to applicable regulatory requirements and institutional policies
- Assist successful management of research study at the site
- Assist monitors, auditors and inspectors to confirm compliance and integrity of collected data

Expectations of how essential documents should be managed

- Essential documents must be maintained with an audit trail and the PI and study team should ensure they are up to date.
- The study team should ensure that a list of essential documents are identified and adapted according to protocol requirements.
- Prior to study initiation, these essential documents should be prepared in the Investigator File.

Essential documents include CVs, study delegation logs, IRB and regulatory documents. For a list of essential documents that are commonly required, please refer to the PCR 507-002 Investigator File Contents Template.

Common Errors

Two common errors associated with essential documents are highlighted here

Essential documents were not filed in the investigator file.

Example 1: Study team members' CVs, CITI certificates and annual DSRB Financial Conflict of Interest (FCOI) forms were either outdated or not filed in the investigator file.

Study team members should file up-to-date CVs that indicate their current appointment. In addition, they should also file CITI or GCP certificates, where applicable, to demonstrate that minimum training requirements for each study team member is met. FCOI forms which are submitted annually between 01 December to 31 January should also be filed in the investigator file.

Example 2: Laboratory accreditation certificates and calibration/maintenance certificates for equipment used in the study were not filed in the investigator file.

In situations where documents such as calibration or maintenance certificates may not be available, a note-to-file should be included in the investigator file to confirm if preventive maintenance had been performed and where the documentation could be found.

Study delegation logs were not maintained appropriately.

Example 1: New study team members were assigned to the study team, but they were not listed in the study delegation log.

The PI should ensure that delegation of study responsibilities to new study team members are documented on the study delegation log before they perform study related procedures. The start date should be clearly documented and endorsed by the PI by signing/initializing on the study delegation log.

Example 2: The clinical research coordinator had left the institution. However, the end date was not indicated in the study delegation log.

The PI should ensure that the end date is documented for study team members who have ceased involvement in the study. The PI should endorse the removal of the study team member on the study delegation log.

For further help or clarity on essential documents, you may send your enquiries to researchquality@nhg.com.sg

References

1. NHG Proper Conduct of Research Standard Operating Procedures - *PCR SOP 501-B05: Documentation*
2. NHG Proper Conduct of Research Standard Operating Procedures - *PCR SOP 501-B03: Study Initiation*
3. NHG Proper Conduct of Research Standard Operating Procedures - *Template 507-B02: Investigator File Contents*

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