NHG RESEARCH EDUCATION

Qualité

Education to facilitate high standards of research conduct

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Good Practices for Maintaining Essential Documents

Background

The National Healthcare Group (NHG) Research Quality Management (RQM) team regularly conducts study reviews on research carried out in NHG and its partner institutions.

Through the study reviews, RQM seeks to educate researchers and team members and raise awareness on proper research practices and documentation techniques. Ultimately, the review process contributes towards safeguarding the rights, safety and well-being of research subjects.

At recent study reviews, essential documents were found to be poorly maintained. Findings include:

• Having incomplete essential documents

• Maintaining essential documents in electronic systems that lack an audit trail and security access.

What are Essential Documents?

Essential documents are those documents which individually and collectively permit evaluation of the conduct of research and the quality of data produced. Examples of essential documents include, but not limited to: IRB and/or regulatory documents, information provided to research participants, subject screening and enrolment logs, study team training records and research agreements.

Why are Essential Documents important?

Essential documents serve to demonstrate compliance during the conduct of research to applicable regulatory requirements and institutional policies.

Tips and Recommendations

A) Use an Investigator File Checklist

The study team should maintain the essential documents in an Investigator File. An Investigator File checklist (E.g. Proper Conduct of Research Document 507-002) may be used to ensure required documents are available in the study files. Documents that are required but not available for filing (E.g. master randomization list kept by the Collaborator and blinded to the study team) should be explained using a "Note-to-File".

B) Set controls to prevent unauthorized alterations, access and data loss

With the advancement in technology and shift to a paperless environment, the study team should ensure:

• There are suitable controls to ensure that electronic documents could not be altered without authorization.

• There should be an audit trail for any changes made to the documents.

• To maintain confidentiality of data, there should be appropriate security measures (e.g. password protection) to limit access of the electronic files by authorised personnel only.

• There should be a backup system in place to prevent accidental data loss.

C) Adhere to retention guidelines

When the study is completed, appropriate measures should be taken to ensure that the essential documents are retained in accordance to applicable guidelines.

• For clinical trials, retention period are stated in the Clinical Trial Agreement and/or as per Section ICH-GCP 4.9.5.

• For all other research, the documents should be retained for at least 6 years after completion of the research study. The study team may also sub-contract the archival of essential documents to a suitable commercial vendor through a written agreement.

It is imperative to maintain essential documents adequately in accordance to the applicable guidelines and regulations to ensure that the research information are recorded, handled and stored in a way that allows its accurate reporting, interpretation and verification.

References

- Proper Conduct of Research SOP 501-B05 Documentation
- ICH-GCP E6 R2 Sections 4.9 and 8
- European Medicines Agency: Guideline on GCP compliance in relation to trial master file (paper and/or electronic) for content, management, archiving, audit and inspection of clinical trials

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