CHICKEN SOUP FOR THE BUSY COORDINATOR

May 2021

How to Prepare for a Study Review or Audit?

Scenario

Dr. Wong, a new Principal Investigator (PI) of a research study, received an email from NHG Research Quality Management (RQM) team informing him that his study was selected for Study Review / audit in the next month. Dr. Wong is unsure of the preparations for the audit and consulted his study team's lead Clinical Research Coordinator (CRC) whom advised the following.

Preparing for Audit

Upon receiving the audit notification, the PI should inform the Sponsor / Director / designee of Research as appropriate, the purpose, time, and date, of the audit. The PI should also inform all individuals and groups involved in the conduct of the study, if any, as soon as possible.

The PI or designated staff should confirm the Agenda with the auditor or Inspector, arrange a private room for the audit and ensure that key study team members are available for meeting with the auditor on the day of the audit.

The PI or designated staff should ensure that all documentation, including informed consent forms, source documents, Data Collection Forms (DCFs) / Case Report Forms (CRFs), and the Investigator Files for the study are accurate, complete and available for review by the auditor or inspector.

The PI or designated staff should review the study's activities, processes and prepare the essential documents for the auditor or inspector's review and verification such as:

Site Operations

- PI should ensure that the delegated study team members are performing the specified clinical research study functions in accordance with the latest approved study protocol and any other written agreement between the sponsor and the investigator/institution.
- The equipment maintenance / calibration is done at minimum per manufacturer's recommendations and maintenance / calibration documents are maintained in the investigator file, where required.
- Relevant written laboratory procedures (e.g. study laboratory manual / work flow) are accessible.

Informed Consent

- Only current IRB-approved consent forms were used.
- Informed consent was obtained appropriately per ethical guidelines and applicable regulatory requirements before each subject's participation in the research study.
- Proper documentation of informed consent process in the source documents.

Essential Documents

- The PI and/or designated staff is responsible for ensuring that essential documents are maintained with an audit trail and are up to date.
- The PI or designated staff should ensure that records of staff qualifications and training and research SOPs are available for review by the auditor. These include updated CVs, training records for applicable CITI and IRB recognised Good Clinical Practice (GCP) minimum trainings, protocol and study procedures training.
- Safety Events (e.g. Serious adverse events, Unexpected serious adverse drug reactions (USADR), UPIRTSOs) are appropriately reported to the relevant parties within the time periods specified by the protocol, IRB and applicable regulatory requirements.

Biological Specimen *(If applicable)*

- The PI or designated staff should ensure that documentation on collection, shipment, receipt and storage of biological specimens is accurate, complete and available for review.

For GCP Inspection by HSA and the related Inspection processes and activities, you may refer to more information on HSA Website https://www.hsa.gov.sg/clinical-trials/good-clinical-practice or the HSA's Guidance on GCP Compliance Inspection Framework https://www.hsa.gov.sg/clinical-trials/regulatory-guidances for your preparation.

REFERENCES

1. 501-B05 Documentation
2. 501-B10 Handling Audits
3. 501-C01 Informed Consent Form and Process
4. 501-C04 Biological Specimen Collection and Handling
5. 501-C05 UPIRTSO

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