CHICKEN SOUP FOR THE BUSY COORDINATOR

JANUARY 2025

Study Audit or Inspection – The Activities Involved Before, During and After

Study audits or inspections are carried out to ensure that research studies are conducted according to the study protocol, standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).

To make sure a study audit or inspection is conducted smoothly, the research team will cooperate with the auditors or inspectors in providing the necessary documents and information required for the conduct of the audit or inspection .
All necessary follow up activities associated with the audit or inspection will have to be completed. The PI is responsible for ensuring that there is adequate preparation for the audit or inspection and cooperate with the inspector or auditor, including follow up activities.

Before	During	After
• PI should inform all individuals and groups involved in the conduct of the study, including Sponsor / Research director or designee as appropriate of the inspection or audit details. • Ensure all study source documents and investigator files with essential documents are in place and readily available. • Booked suitable venue for the study inspection or audit. • All study team members are informed and available for study inspection or audit.	• PI or designated staff should meet with the inspector or auditor and provide orientation and access to the facility, study records and files and provide copies of requested study related documents. • PI or designated staff should ensure that any issues or concerns raised by the inspector or auditor should be clarified immediately with supporting materials where applicable. • All study related documents and medical records to be accessible by inspector or auditor.	• Within stipulated timeline, PI or designated staff must respond to the inspection or audit report. • Each finding or item in the report should be replied by PI or designated staff and provide clarification or steps to be taken to institute corrective action and preventive action. • Once the submitted CAPA is accepted, site is to implement the action plan and make it a gold standard across all similar studies.

References:
PCR SOP 501-B10 Handling Audits / Inspections
Other Resources:
- *Guidance on Good Clinical Practice Compliance Inspection Framework*
- *NHG PCR-400: Monitoring, Audits and Inspections online course.*

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