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| **STANDARD OPERATING PROCEDURE for Nigeria PreP Study** | | |
| **Study Site:** | | **SOPs Number** : QA-602 |
| **Title**  **THIRD PARTY AUDITS** | | |
| **Version Number**: | **Version Date:** | **Effective date**: |
| **Approval name Signature Date** | | |

**Annual Review**

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| **Review date** | **Revision Date** | **Signature** |
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1. **Introduction**

Independent GCP audits provide an insight into the quality of your clinical research at a point in time. They facilitate the monitoring of how well your quality management system is working and whether your SOPs are adequate and meet regulatory authority expectations.

1. **Objectives**

This SOP describes the steps followed by auditors from the time the audit or inspection is scheduled until all follow-up activities associated with the audit or inspection has been completed. For the purposes of this document the term ‘audit’ addresses both audits and regulatory inspections and the term ‘auditor’ includes both auditors and regulatory inspectors.

1. **Responsibility**

This SOP applies to Nigeria PreP leadership, study staff and consultants involved in arranging, managing, or participating in a third party audit and/or monitoring a site that is being audited by a third party.

1. **Procedure**

**A. Preparing for the audit**

* The central PI should notify the sponsor, when notified of a third party audit as soon as possible
* Work with the auditor to develop a proposed schedule (estimated number of days, times) for the audit (to the extent possible) and ensure that all key personnel will be available before confirming a date
* Ensure that records of staff qualifications and training are available for review by the auditor
* The Site coordinator ensures that all study documentation, including the regulatory binder, study templates, study communication records and electronic records maintained by Nigeria PreP Study are accurate, complete and available for review by the auditor
* The PI review with study staff who will be involved in the audit all study documents, both technical and financial
* All auditors request must be reviewed and agreed to by the PI
* PI must approve all auditor requests for copies of documents and records and review the copies of documents and records before handing them to the auditor in order to be satisfied that appropriate measures have been taken to ensure the protection of proprietary or confidential information contained in those documents and records
* The PI must be consulted if the auditor requests that an affidavit or any other document be signed, initialled or otherwise ratified
* The PI should designate a staff to take notes of activities and discussions during the audit. He should also designate a staff to make copies and obtain documents and records as requested.
* The PI Identify adequate space for the auditor to use to review documents and records
* The Site coordinator ensure that the Investigator, Subinvestigator and site staff are to notify the PI if they are notified by a third party that their site will be audited
* The PI or designee should review the following with the site staff prior to a scheduled audit to ensure that:
  + all key study personnel will be available for the audit before the audit date is confirmed
  + all study documentation, including informed consent forms, source documents, electronic records, CRFs, and the regulatory binder for the study identified as the focus of the audit are accurate, complete and available for review by the auditor.
  + Standard Operating Procedures are available
  + study drug dispensing records should be accurate, complete and available for review.
  + study drug accountability records are accurate, complete and available for review
  + records of staff qualifications and training are available for review by the auditor.

1. **During the audit**

The PI should do the following;

1. Meet with the auditor. Request to see identification and notice of Inspection/audit and ascertain the purpose of the inspection
2. Review the policies and guidelines for the conduct of the audit with the auditor
3. Provide orientation and access to the study records and files
4. Ensure that the auditor is not left unattended and arrange for appropriate staff to be available to answer questions, retrieve documents, and facilitate completion of the audit
5. Document all relevant discussion and requests
6. Provide copies of requested study-related documents; ensuring a second copy of each document is made and kept in Nigeria PreP study audit file
7. Review the copies to redact any proprietary or confidential information before the copy is given to the auditor
8. Ensure that questions posed by the auditor are answered by appropriate personnel and request additional time to respond if necessary
9. Request an opportunity to immediately correct objectionable observations
10. Ensure that the auditor does not remove an original document or record from study premises, nor makes any copies him/herself nor makes any marks on original documents and records
11. Request that a summary of audit findings be provided at the end of each day
12. Meet with all relevant key personnel to discuss and summarize the day’s events after the auditor has departed
13. **Following up after the audit**
14. The PI should participate in the exit interview with the auditor; include all relevant personnel at the meeting.
15. If observations can be corrected before the end of the audit, attempt to do so and the auditor may annotate the report
16. Ask the auditor to clarify any items and provide as much detail as appropriate for items that need such clarification
17. Express explanations or disagreements about any items or issues clearly, assertively and respectfully
18. The PI or designate respond to the audit report as soon as possible after its receipt, within any required deadlines. Retain copies of any audit documents in the appropriate file
19. The site coordinator;
    1. participate in the exit interview with the auditor,
    2. Meet with the Investigator and/or Subinvestigator and relevant site staff after the exit interview with the auditor to discuss required next steps
    3. Request that the site send draft responses to audit reports to the PI prior to formal submission to the auditor.
    4. Review draft and provide feedback to the appropriate site staff member within one business day.
    5. Notify PI of all audit findings and follow up, as applicable
    6. Confer with the PI about reporting audit results to other relevant regulatory authorities or funding sponsors

**This SOP has been read and understood by**

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