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| **STANDARD OPERATING PROCEDURE for Nigeria PreP Study** | | |
| **Study Site:** | | **SOPs Number** :SA-106 |
| **Title**  DOCUMENTATION AND RECORDS RETENTION | | |
| **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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**Document History**

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| **Version number** | **Reason for change** | **Date** |
| 1.0 | Initial release | 28th March 2015 |
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**Distribution List**

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1. **Introduction**

Clinical studies are conducted according to international and local regulations including ICH GCP to protect the safety and welfare of study participants. These regulations require that the Staff who conducts research be conversant, knowledgeable and skilled in their delegated responsibilities and duties. While it is recognised that research staff are professionals and experts in their fields, it is important to note that training and retraining is necessary to update the staff knowledge and skill. Initial and ongoing training regarding the responsible conduct of research is essential for participants’ safety, efficient data collection, satisfactory data analysis and generation of credible results.

1. **Objective**

To describes the process and documentation required for the initial and ongoing education of study staff in study protocol, Good Clinical Practices (GCPs) and the ethical conduct of research.

1. **Responsibility:**

It is the responsibility of all staff to ensure that they are appropriately trained and educated on study protocol, Good Clinical Practices (GCPs) and the ethical conduct of research. The Principal Investigator must ensure that staff engaged in the study have going through training and education on study protocol, Good Clinical Practices (GCPs) and the ethical conduct of research.

1. **Definitions**

The following definitions from the International Conference on Harmonisation, Good Clinical Practice: Consolidated Guideline apply to this SOP.

**Good Clinical Practice (GCP):** A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

1. **Education and Documentation of Education description**
2. **Protecting Human Research Participants Training**

The PI will direct all staff to the NIH Office of Extramural Research website to complete web-based training in “Protecting Human Research Participant,” where a certificate of completion can be provided at the conclusion of the program. <https://phrp.nihtraining.com/>

All staff involved in study will be required to submit to PI the NIH Office of Extramural Research certificate of completion OR other such written evidence of training in the protection of human subjects.

1. **Good Clinical Practice Training**

The PI or the Sponsor should organise GCP training for all study staff after engagement but before participating in any trial related activities. A signed certificate of attendance by the PI or Designee will be the evidence that the said Staff has fulfilled this requirement. A certified GCP training by any other body approved by the PI or Sponsor is acceptable in lieu of above training.

1. **Study Protocol Training**

All study staff should be trained on the study protocol before performing any study related activities. The training could be centrally or individual but must be certified by the PI or the Sponsor. A post training score of at least 75% should be accepted as adequate understanding and only then can the PI or Sponsor certify the staff as having received adequate training. A singed certificate of attendance with post training result sheet attached is to be taking as evidence of training completion.

Study staff will maintain a log of completed training. (Attachment A Training Compliance Form)

The PI should determine that each member of the study staff provides appropriate documentation that he/she has fulfilled the training requirement.

The PI or designee should maintain a record of participants in all initial and ongoing educational activities and certifications that the study provides and/or requires of all study Staff.

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

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