|  |  |  |
| --- | --- | --- |
| **STANDARD OPERATING PROCEDURE for Nigeria PreP Study** | | |
| **Study Site:** | | **SOPs Number** :SA-101 |
| **Title**  **SOPS PREPARATION, MAINTAINANCE AND TRAINING** | | |
| **Version Number**: | **Version Date:** | **Effective date**: |
| **Approval name Signature Date** | | |

**Annual Review**

|  |  |  |
| --- | --- | --- |
| **Review date** | **Revision Date** | **Signature** |
|  |  |  |
|  |  |  |

**Document History**

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

**Distribution List**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name/Location** | **No of copies** | **Name/Location** | **No of copies** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

1. **Introduction**

The International Conference on Harmonisation recommends that a detailed, written instruction to achieve uniformity of the performance of a specific function be developed for all GCP compliant studies. The instruction is to be used across all sites involved in a specific study.

1. **Objectives**

This standard operating procedure describes the preparation, review, approval, and maintenance of the written procedures for clinical study to ensure compliance with the relevant regulations and guidelines. This SOP also describes procedures for training on SOPs and documentation of training.

1. **Responsibility**

It is the responsibility of the Principal Investigator, Site Principal Investigator and Site Coordinator to review and approve SOPs. The Principal Investigator assume ultimate accountability for all SOPs. It is the responsibility of all Nigeria PreP study staff and consultants involved in supervising, managing, or conducting study-related activities to understand and follow the SOPs. This includes the following: PI, Site PI, Site Coordinator, Study Physician, Study Nurse, counsellors and other study Staff.

1. **Definitions**

The following definitions, from the International Conference on Harmonisation apply to this SOP.

**Standard Operating Procedures (SOPs):** Detailed, written instructions to achieve uniformity of the performance of a specific function.

**4. Process overview**

A. Procedure for preparing new SOPs or revising previously issued SOPs

B. Procedure for reviewing and approving SOPs

C. Procedure for providing training on implementing SOPs

**5. Procedures**

**A. Procedure for preparing new SOPs or revising previously issued SOPs**

Based upon changes to the regulations, guidelines, or to NACA policies and procedures*,* write a new SOP or revise a previously issued SOP that describes the new or revised procedures.

Each SOP includes the following in the header:

* The abridged study title (Nigeria Prep Study)
* Name of study site
* The SOP number, version and effective date
* Approval name, signature and date

Each SOP includes the following in the footer:

* The National Agency for Control of AIDS name
* The page number of total number of pages

New SOP numbers will be sequential within the appropriate category code (eg SA= Study Administration; CA= Clinical Activities; LP= Laboratory Procedures; DA= Drug Administration; DM= Data management and QA= Quality Assurance), Category number (SA =1; CA=2; LP=3, DA=4, DM=5 and QA= 6) and the specific SOP number within the category (eg 01,02 etc). Example of an SOP number is DA-401 for first SOP in Drug Administration category.

Site Coordinator/Designee: Write the SOP, using the following format:

* Introduction
* Objective
* Applicable Regulations and Guidelines (if any)
* References to Other Applicable SOPs (if any)
* Attachments (if any)
* Responsibility
* Definitions
* Process Overview
* Procedures
* History of Changes

Maintain a Table of Contents by number and title of the SOPs.

Site PI:

* Review draft SOP to ensure accuracy and completeness.

Study PI:

* Approve, sign, and date each new SOP after it is finalized.

Site coordinator/Administrator:

* Distribute the new/revised SOP to specified study staff members and consultants. The SOPs will be available in one controlled paper manual at the study headquarters in Abuja, Nigeria (generic) and 3 study sites (Sites specific Versions). Collect the superceded SOP, if appropriate. Also maintain an historical archive of copies of all previous versions of SOPs to be available in the event of an audit.

**B. Procedure for reviewing SOPs**

Site Coordinator or Designee:

* All SOPs will be reviewed for accuracy and/or obsolescence at least once every year from the approval date, and upon new issuance of new regulations and guidelines.
* If revisions or additions are required, follow the procedure described above.
* If no changes are required, document review date on the title page and note in Document History that no change was necessary, file appropriately.

**C. Procedure for providing training on implementing SOPs**

* Provide training to all specified staff members within 14 days prior to the effective date of a new or revised SOP.
* Ensure that each specified employee documents (Attachment A, Training Compliance Form) the date of training and the SOPs reviewed.
* Ensure that each new employee reviews all applicable SOPs prior to undertaking any responsibilities for which SOPs apply.
* Ensure that each new employee documents (Attachment B, Training Compliance Form) the date of review *(or training, if appropriate)* and the relevant SOPs.
* Maintain a record of SOP training and review for all study staff.

**Attachment A**

**Title Page Template**

|  |  |  |
| --- | --- | --- |
| **STANDARD OPERATING PROCEDURE for Nigerian PreP Study** | | |
| **Study Site:** | | **SOPs Number** : |
| **Title** | | |
| **Version Number**: | **Version Date:** | **Effective date**: |
| **Approval name Signature Date** | | |

**Annual Review**

|  |  |  |
| --- | --- | --- |
| **Review date** | **Revision Date** | **Signature** |
|  |  |  |
|  |  |  |

**Document History**

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

**Distribution List**

|  |  |  |  |
| --- | --- | --- | --- |
| **Name/Location** | **No of copies** | **Name/Location** | **No of copies** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**Attachment B**

**TRAINING COMPLIANCE FORM**

**Name of Study staff…………………………………………………………............................**

|  |  |  |  |
| --- | --- | --- | --- |
| **SOP Number** | **SOP Title** | **Initials** | **Date reviewed** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

Reviewed by:

Date: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_