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| **STANDARD OPERATING PROCEDURE for Nigeria PreP Study** |
| **Study Site:**  | **SOPs Number** :SA-104 |
| **Title****ROLES, RESPONSIBILITIES AND DELEGATION OF DUTIES** |
| **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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1. **Introduction**

Appropriately qualified and trained staff are required to ensure the satisfactory conduct of research studies at a site. For a study to adhere to Good Clinical Practice (GCP) guidelines, Study Protocol and applicable regulatory requirements, it is essential that all staff involved are aware of their roles and responsibilities and that they are appropriate for the duties delegated to them by the PI.

1. **Objective**
* To outline the division and delegation of responsibilities and clarify boundaries of responsibility within the research study team and how they should be documented.
1. **Responsibility:**
* It is the responsibility of all staff to sure that they are appropriately qualified and skilled to performance roles assigned to them. The Principal Investigator and Study must ensure that staff engaged in the study is qualified and competent to perform assigned task and responsibility.
1. **Definitions**

International conference of Harmonisation GCP (ICH GCP) guidelines defines an investigator as “*A person responsible for the conduct of the clinical trial at a trial site.”*

The investigator is responsible for protecting the integrity, health and welfare of the research participants. The investigator must be:

* + Qualified by education, training and experience
	+ Thoroughly familiar with the study protocol and any investigational product(s)
	+ Aware of, and compliant with Good Clinical Practice and any applicable regulatory requirements

The investigator responsible for leading the team is referred to as the PI. Other investigators are referred to as co-investigators.

The Sponsor takes responsibility for the initiation, management and financing (or arranging the financing) of the study.

1. **Procedures**

***Who?***

* Before the study initiation the PI, Site coordinator and study staff must discuss and agree on the study requirements and the delegation of duties. The delegation of duties will depend on the qualifications and experience of the individuals in the team.
* Evidence of appropriateness to perform the delegated duties is generally in the form of up to date Curriculum Vitae (CV), and evidence of GCP training (certificate). The PI must be assured by these and knowledge of the study team that all team members are able to perform their delegated duties appropriately.

***When?***

* The delegation of duties and roles within the study team should be discussed and documented as part of study set up and initiation. Further training and competency may be required by some members of the team which should be undertaken before commencing work on the study.
* The Principal Investigator may be required to sign off their team on the delegation of duties log as part of the official initiation visit, if appropriate.

***How?***

***Roles of the study team***

The PI has overall responsibility for the conduct of the study at their site. The responsibilities of a PI are summarised in Appendix A and include:

* Ensuring the welfare and medical care of study participants
* Obtaining approval of and continued communication with regulatory bodies
* Conduct of the study in compliance with the protocol and required governance regulations and guidelines, as well as local policies/procedures
* Administration, management, storage of investigational product
* Safety reporting
* The accurate and timely completion of study data
* Archiving

**Evidence of appropriateness of research team**

The ICH GCP state that the Principal Investigator is responsible for ensuring that; “Each member of the research team, including those at collaborating sites, is qualified by education, training and experience to discharge his/her role in the study, and their qualifications are documented.” A current CV for each member of the study team will fulfil this requirement for qualifications to be documented. The CV should be updated every 2 years or when there is a relevant change. Superceded versions should be maintained in the site file. This training will include study specific required training and experience. Good Clinical Practice (GCP) training should be attended and certificate of attendance will be evidence of this. These documents are essential documents and must be maintained as such within the study site file.

The frequency of GCP training must satisfy the Sponsor and Trust requirements. For this study, the suggested timeframe for this is every years. Clarification should therefore be sought from the study Sponsor.

**Delegation of duties**

The clinical trials regulations state: “*A sponsor of a clinical trial, in accordance with this regulation may delegate any or all of his functions under these regulations to any person but any such arrangement shall not affect the responsibility of the sponsor”.*

The principle of delegation of duties is that the duty can be delegated but not the responsibility. This delegation may be from Sponsor to PI; PI to site coordinator/Co Investigator; PI; PI to members of the site study team.

At a study site, any duties that are delegated to the study team remain the responsibility of the PI. Each member of the team should perform their delegated duties adhering not only to research guidance and relevant legislation but also to local Trust and professional body requirements.

Other key staff involved in the study may be delegated duties by the PI. A summary of some of these duties is shown in Appendix A however the protocol team may as need be add more responsibility and duty. These people must be appropriately experienced and qualified to assist in the management of the study for the task that they have been delegated. The PI can delegate duties, but never the responsibility for the study at the site. The allocation of duties to appropriately qualified persons should be recorded in a study specific delegation of duties log (Appendix B) with specimen signatures and the initials of all involved.

Documentation of delegated duties is an on-going process as circumstances may change, e.g. different members of staff may become involved in the study. The log must:

* List the names and roles of all staff involved and outline which duties have been delegated to them
* Confirm the start and end dates for each member of staff performing their delegated duties
* Be signed and dated by the PI – they should sign off each individual member of staff, considering their evidence of training, education and experience prior to the staff member carrying out any duties for the trial. By delegating duties the PI confirms that the team member is appropriate for their delegated duties and, maintains the responsibility. Therefore active involvement in the study is not permitted for staff until they have been signed off by the PI.
* Be updated throughout the study. This may include new staff and staff who leave. Superseded versions must not be destroyed in order to allow an audit trail of who was performing which duties at any time point in the conduct of the study for future inspection
* Be filed appropriately in the Investigator Site File. If archived by a sponsor, a copy must remain at the site.
* Be supplied to the sponsor as requested, with updated versions being supplied when updated. Contact names and roles of other individuals involved in the study should also be notified to the sponsor.

The delegation of duties log is an essential document and must be maintained as such within the study site file.

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

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