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| **STANDARD OPERATING PROCEDURE for Nigeria PreP Study** | | |
| **Study Site:** | | **SOPs Number** : DA-501 |
| **Title**  **CRF COMPLETION AND CORRECTION** | | |
| **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**

Data collection tools are among the most important aspects of clinical study. They determine the amount and quality of data gathered during any research endavour. Adequate care should be employed in their design as inadequate data collection has the potential to ruin a well conducted study.

1. **Objectives**

This SOP describes the process for completing and correcting Case Report Forms (CRFs).

1. **Responsibility**

The Data Manager, Study Personnel.

1. **Procedure**
2. The data manager and study personnel will be trained to complete CRFs and study forms and documents in accordance with the following requirements.

* Complete all entries on CRFs, study forms and documents in blue or black ink only. No pencil or coloured pens. Never use correction fluid ie. “white out.”
* All fields should be completed according to the specific instructions on the form.

1. The data manager and study personnel will be trained to correct CRFs and study documents in accordance with the following requirements.

* Correct all entries on CRFs and study documents in blue or black ink only. No pencil or coloured pens. Never use correction fluid ie. “white out.”
* To make an error correction, draw a single line through the incorrect information, write the correct information, and then initial and date the change (except if error is on date, where only initial is sufficient). Never erase or obliterate entries that require correction.

1. CRF and study document entries that are not done according to procedure will result in incomplete or inaccurate research data, and inadequate source documentation.
2. All data corrected CRFs shall be entered in a timely manner using the appropriate program, and initialled and dated by the data manager (within 2 weeks of completion).
3. The data manager will read and understand the pertinent definitions listed in this policy and procedure.

**Definitions**

1. **Confidentiality**: Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a subject's identity.

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

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