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| **STANDARD OPERATING PROCEDURE for Nigeria PreP Study** | | |
| **Study Site:** | | **SOPs Number** : DM-506 |
| **Title**  **DATA SECURITY** | | |
| **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** |
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1. **Introduction**

Data security means protecting data, such as a database, from destructive forces, and from the unwanted actions of unauthorized users. It is arguably the bedrock of all clinical studies. Data is considered to be *“sensitive”* where its misuse could actually harm the individual in question. Sensitive data also includes medical history, physical and mental health, plus any genetic profile – in other words, precisely the information needed when recruiting individuals for clinical studies.

Under Principle 7 of the EU’s 1988 Data Protection Act, data processors must implement *“adequate”* physical and technological safeguards to prevent data being used for purposes for which the owner has not given consent. They must also obey certain rules governing fair use, such as ensuring data is updated and is only held for as long as it is required.

1. **Objectives**

This SOP describes the process for internal and external protection of data in the Nigeria PreP Study

1. **Responsibility**

Principal Investigator, Data Manager

1. **Procedure**
2. Antivirus scan software will be installed on all computers used for data entry and analysis.
3. The data manager will update the virus protections every other week, and note the time and date completed on the data security log.
4. All study computers will be password protected, and used expressly for data management ie. Internet surfing, emailing, or Instant Messaging is prohibited if not work related.
5. All study computers will also be kept in fire and theft proof rooms.
6. On no account should study computers be taken outside the data management unit except with written approval from the PI.
7. The data manager will read and understand the pertinent definitions listed in this policy and procedure.

**Definitions**

**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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