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| **STANDARD OPERATING PROCEDURE for Nigerian PreP Study** | | |
| **Study Site:** | | **SOPs Number** :CA-204 |
| **Title**  **OBTAINING INFORMED CONSENT** | | |
| **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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1. **Introduction**

Obtaining an Informed consent during research not only ensure that individual are not forced to participates in research endavour, but respects the individual autonomy and as well protect those with developing/diminished autonomy. Informed consent is not a one of activity but an ongoing collaboration and partnership between the PI and the study participants. Study participants may wish to withdraw this consent at any time during the study without any consequence thereof.

The Site Coordinator or Study Nurse is often designated by the Principal Investigator to obtain consent from study participants. The PI designee is responsible for initiating and completing all components of the informed consent process in accordance with local, international, sponsor and institutional regulations and guidelines governing the recruitment of human subjects into clinical research. The informed consent process is completed prior to initiating any study related procedures, including screening eligibility.

1. **Objectives**

To establish procedures for implementing the informed consent process.

1. **Responsibility**

The PI designee iseducated and trained to apply the code, regulations governing clinical research in humans and International Conference on Harmonization (ICH) Guidelines Good Clinical Practice (GCP) & when implementing the informed consent process.

1. Definitions

Authorized Representative for Incapacitated Adult Subjects**:** Local and International regulations that govern research involving human subjects define a legally authorized representative as an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective participant to the individual's participation in the procedure(s) involved in the research. Individuals entitled to authorize consent to medical treatment generally have the authority to provide consent on behalf of another adult for participation in clinical research presenting the prospect of therapeutic benefit to the subject. These include: 1) Court-approved guardian; 2) health care agent; 3) spouse; 4) adult son and/or daughter; 5) parent; 6) adult brother and/or sister; 7) uncle and/or aunt; or 8) other adult kin.

* **NAFDAC:** Public health agencies of Nigeria charged with protecting its citizens by enforcing related public health laws that include use of biological agents in clinical research in human subjects and approval of medications for consumers.
* **Good Clinical Practice (GCP):** A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical studies that provides assurance that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of study participants are protected.
* **Human Participants:** An individual who is or becomes a subject in research, either as a recipient of the test article or as a control. A Participant may be either a healthy human or patient.
* **Informed Consent:** A process by which an individual voluntarily confirms his or her willingness to participate in a particular study, after having been informed of all aspects of the study that are relevant to the individual’s decision to participate. Informed consent is documented by means of a signed and dated HREC approved written informed consent form (ICF).
* **Incapacitated Participants:** An acutely ill or obtunded adult human that does not meet required decision making capacity in order to give informed consent.
* **Legally Acceptable Representative/Guardian:** An individual, juridical or other body authorized under applicable local law to grant permission on behalf of a prospective subject (such as a minor or incompetent adult) to participate in a clinical study.
* **Vulnerable Participants:** Individuals who may be at a disadvantage, whether real or supposed, compared to other prospective human participants in their ability to voluntarily consent to whether or not to participate in a clinical study. This may include individuals who are unduly influenced by the expectation, whether justified or not, of benefits associated with participation or of a retaliatory response from senior members of a hierarchy if they refused to participate.

1. **Process**
2. **The informed consent process**

* **Review/discussion:** The Site coordinator or designee will be familiar with the contents of the current HREC approved version of the informed consent document for the study. Participants will be assessed for their ability to read either English or local language (Igbo, Hausa and Efik). Low lettered participants or those with other disadvantages that cannot comprehend the approved written informed consent will be consented via oral presentation with witness present, except in the case of incapacitated subjects whose legal guardian and their ability to comprehend and provide consent must be determined. (Details on these types of consent follow later.) Participants will be given a copy of the HREC approved written informed consent to review in a language they understand. Contents of the informed consent will be reviewed in detail by the Site coordinator or designee and discussed with the potential study candidate and support (if present). The prospective participant and their support person(s) are encouraged to ask questions and clarification throughout this process.
* **Signature:** After all questions are satisfactorily answered, participants who choose to participate in the study will initial each page of the approved written consent form in dark ink to verify that contents of each page were discussed and sign and date the final page. The Site Coordinator or designee obtaining consent will sign date the final page in dark ink.
* **Copies/filing**: The Site Coordinator or designee will provide the participant with a copy of the consent form for their own personal file. If the participant does not wish to have a copy, documentation to that effect will be noted. All original signed informed consent forms for any participant screened for study will be filed in the study-specific informed consent binder located in the study office regardless of whether the participant initiates study or not. The Site Coordinator or designee will document in a note or study-specific flow sheet the complete process used to obtain informed consent, including whether or not the patient received a copy. The Site Coordinator or designee will document eligibility as it becomes known on the study eligibility checklist.

1. **Special populations – i) Low literacy, non-English or non-main language speaking participants; ii) incapacitated participants**

**i) Low literacy, or when HREC approved long form of primary language of the participant is not available:**

* **Review/discussion:** The process for obtaining informed consent in low literacy, or participants whose primary language does not have HREC approved consent is fulfilled by the combination use of an oral presentation in a language understandable to the participant, and the presence of an impartial witness who is able to read and understand the written approved HREC version and language that the participant speaks.
* **Signature:** After all questions are satisfactorily answered, participants who choose to participate in the study will initial or allow an ink fingerprint of their right index finger at the bottom of each page and on the final page. Participants who are able to write the date will date next to their signature or fingerprint on the final page. If unable to write, the line for date on the participant line will be left blank. The Site Coordinator or designee obtaining consent will sign date the final page in dark ink and document all parts of this process. The witness present throughout this process will sign and date in dark ink as well. **HREC approved consent form should be used as a template for the oral presentation**.
* **Copies/filing**: The Site Coordinator or designee will provide the subject with a copy of the complete process for their own personal file. If the subject does not wish to have a copy, documentation to that effect will be noted. All original signed informed consent forms for any participant screened for study will be filed in the study-specific informed consent binder located in the study office regardless of whether the particiapnt initiates study or not. The Site Coordinator or designee will document in a note or study-specific flow sheet the complete process used to obtain informed consent, including whether or not the individual received a copy. The Site Coordinator or designee will document eligibility as it becomes known on the study eligibility checklist.

1. **Incapacitated adult participants:**

* **Review/discussion:** The Site Coordinator or Designee will follow the same procedure as listed for low literate participants when obtaining consent from the incapacitated participant’s authorized representative as noted above. If the participant regains decision making capacity at any time during the study, the consent process will then be reviewed and followed through with the participant. If the authorized representative is low literate then the process for low literate participants will be followed but as applied to the authorized representative.
* **Signature:** After the discussion with the incapacitated adult participant’s authorized representative, if the representative agrees to the participation of the incapacitated individual in the study, the person obtaining consent will review the consent form asking for the authorized representative’s permission to let the incapacitated adult participate in the research study. After all questions are satisfactorily answered, the authorized representative will sign the line designated for the legal representative and indicate relationship to the incapacitated subject. The authorized representative will initial each page of the consent form to verify that this information has been reviewed. The Site Coordinator or designee obtaining consent will sign date the final page in dark ink.
* **Copies, documentation and filing**: The Site Coordinator or designee will provide the authorized representative with a copy of the consent form for their own personal file. If the authorized representative does not wish to have a copy, documentation to that effect will be noted. All original signed informed consent forms for any individual screened for study will be filed in the study-specific informed consent binder located in the study office regardless of whether the individual initiates study or not. The Site Coordinator or designee will document in a note or study-specific flow sheet the complete process used to obtain informed consent, including type of process used in obtaining consent, the relationship between the authorized representative and the incapacitated adult participant, and whether or not the legal guardian received a copy. Additionally, if at any time during the incapacitated participant’s participation in study, capacity for decision making is restored, the Site Coordinator or designee will initiate the informed consent process with the individual and document the date that decision making capacity was restored. The Site Coordinator or designee will document eligibility as it becomes known on the study eligibility checklist.

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

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