| KCMC Clinical Trials Unit | STANDARD OPERATING PROCEDURE | Effective Date | SOP-Number CTU 001-02 |
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**Title:** INFORMED CONSENT PROCESS

**SOP References:** 45 CFR 46, 21 CFR 50, ICH E6.4.8 **Supersedes:** N/A

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| **Annual Review:** | | | |
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**PURPOSE:** To establish procedures for implementing the informed consent process.

**POLICY:** The Clinical Research Coordinator or Research Nurse are designated by the Principal Investigator to obtain consent from study participants. The Clinical Research Coordinator or Research Nurse designee is responsible for initiating and completing all components of the informed consent process in accordance with local, federal (both Tanzania and US), sponsor and institutional regulations and guidelines governing the recruitment of human subjects into clinical research trials. The informed consent process will be completed prior to initiating any study related procedures, including screening eligibility.

**RESPONSIBILITY:**

**Clinical Research Coordinator and Clinical Research Nurse designee:** Educated and trained to apply the Code of Federal Regulations governing clinical research in humans and International Conference on Harmonization (ICH) Guidelines Good Clinical Practice (GCP) & Clinical Safety Data Management when implementing the informed consent process.

**A. DEFINITIONS:**

**Assent:** Agreement. Based on ethical principle of respect for person and right to be left alone. Assent of children and permission of parents or legal guardians as determined by the IRB/IEC is required as per the provisions of 45CFR46. State/local law where the research is taking place defines the age of a

minor and requirements for emancipation. Local IRB/IEC determine the age for obtaining assen**t**

**Authorized Representative for Incapacitated Adult Subjects:** Federal 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 subject to the subject'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.

**Food and Drug Administration (FDA):** Public health agencies of the US and Tanzania that are 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 trials that provides assurance that the data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial subjects are protected.

**Human Subject:** An individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or patient.

**Informed Consent:** A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a signed and dated regulatory authority approved written informed consent form (ICF).

**Incapacitated Subjects:** An acutely ill or obtunded adult human subject that does not meet required decision making capacity in order to give informed consent. In the case of minors, procedures for obtaining consent

of minors supercede the procedure for obtaining consent from an incapacitated subject.

**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 trial.

**Oral Presenter:** The oral presenter gives an oral presentation to the subject or legal representative in the language that is understandable to him or her that describes the content of the written summary. The oral presenter is fluent in both English and the language that is understandable to the subject or legal representative. The oral presenter is not related to or a close associate of the study subject or legal representative. The oral presenter may serve as the person obtaining consent provided that he/she meets training requirements for person obtaining consent and is not related to the subject. The oral presenter cannot serve as their own witness. The oral presenter signs the written summary and the written short form.

**Vulnerable Subjects:** Individuals who may be at a disadvantage, whether real or supposed, compared to other prospective human subjects in their ability to voluntarily consent to whether or not to participate in a clinical trial. 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. Other examples of vulnerable subjects include: members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, persons kept in detention, patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

**Witness to the oral presentation:** The witness certifies that an oral presentation was made to the subject or legal representative in a language that is understandable to him/her and that it describes the content of the written summary and contains the basic elements of consent. The witness is fluent in both English and the language that is understandable to the subject or legal representative. The Witness can be related to, or a close associate of the subject or legal representative but should not be a member

of the study team. The witness signs the written summary and the written short form.

## B. PROCEDURES

### 1. THE INFORMED CONSENT PROCESS

a. **REVIEW/DISCUSSION:** The clinical coordinator or designee will be familiar with the contents of the current IRB/IEC approved version of the informed consent document for the assigned protocol. Subjects will be assessed for their ability to read either English or Kiswahili translation. Illiterate subjects 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.) Subjects will be given a copy of the IRB/IEC approved written informed consent to review in a language they understand. Contents of the informed consent will be reviewed in detail by the clinical research coordinator or designee and discussed with the potential study candidate and support (if present). The prospective subject and their support person(s) are encouraged to ask questions and clarification throughout this process.

b. **SIGNATURE:** After all questions are satisfactorily answered, subjects 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 Clinical Research Coordinator or designee obtaining consent will sign date the final page in dark ink.

c. **COPIES/FILING**: The Clinical Research Coordinator or designee will provide the subject with a copy of the consent form 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 subject screened for study will be filed in the study-specific informed consent binder located in the clinical research room regardless of whether the subject initiates study or not. The Clinical Research 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 Clinical Research Coordinator or designee will document eligibility as it becomes known on the study eligibility checklist.

**2. <u>SPECIAL POPULATIONS</u> – a) Low literacy, illiterate, non-English or non-Kiswahili speaking patients; b) minors; c) incapacitated subjects**

**a) Low literacy, illiterate patients, or when IRB/IEC approved long form of primary language is not available:**

1) **REVIEW/DISCUSSION:** The process for obtaining informed consent in low literacy, illiterate, or patients whose primary language does not have an IRB/IEC approved long form consent is fulfilled by the combination use of an IRB/IEC written short form outlining the basic elements of consent, oral presentation in a language understandable to the subject that reads the basic elements of consent on the short form and summarizes the more detailed approved IRB/IEC consent form, and an impartial witness who is able to read and understand the written approved IRB/IEC version and language that the subject speaks.

2) **SIGNATURE: <u>Short form</u> -** After all questions are satisfactorily answered, subjects 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. Subjects 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 subject line will be left blank. The Clinical Research 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. **<u>IRB/IEC approved long consent form should be used as a template for the oral presentation</u>** – The person doing the oral presentation and the witness will sign and date in dark ink the signature lines on the final page of the long consent. The subject will not sign or mark this form.

3) **COPIES/FILING**: The short form will be stapled to the long form used as the template for oral presentation. The Clinical Research 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 subject screened for study will be filed in the study-specific informed consent binder located in the clinical research room regardless of whether the subject initiates study or not. The Clinical Research 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 Clinical Research Coordinator or designee will document eligibility as it becomes known on the study eligibility checklist.

**b) Minors**

1) **REVIEW/DISCUSSION:** The process for obtaining informed consent in minors is fulfilled by the combination of assent of the minor (signature from children 12 years or older and verbal or heading nodding agreement from those younger) and signature of the legal guardian granting permission for the minor to participate. An interactive discussion should be held with the child/minor and include reasonable potential discomfort associated with participation in the clinical trial. Whenever possible this discussion should be apart from the parent who may unduly influence the child, unless such separation would cause the child greater fear. The IRB/IEC approved consent form should be reviewed in detail with the legal guardian. If language or literacy problems exist, then the combination of these two special populations must be applied.

2) **SIGNATURE:** After the discussion with the child/minor, if the child agrees to participate, the person obtaining consent will review the consent form asking for guardian permission to let the child/minor participate. After all questions are satisfactorily answered, children/minors 12 years or older will sign the line designated for minor signature. The legal guardian will sign the legal guardian line and initial each page of the consent form to verify that this information has been reviewed. The Clinical Research Coordinator or designee obtaining consent will sign and date the final page in dark ink.

3) **COPIES, DOCUMENTATION AND FILING**: The Clinical Research Coordinator or designee will provide the legal guardian with a copy of the consent form for their own personal file. If the legal guardian does not wish to have a copy, documentation to that effect will be noted. All original signed informed consent forms for any subject screened for study will be filed in the study-specific informed consent binder located in the clinical research room regardless of whether the subject initiates study or not. The Clinical Research Coordinator or designee will document in a note or study-specific flow sheet the complete process used to obtain informed consent, including type of assent received from minor, permission from legal guardian, and whether or not the legal guardian received a copy. The Clinical Research Coordinator or designee will document eligibility as it becomes known on the study eligibility checklist.

**c. Incapacitated adult subjects:**

1) **REVIEW/DISCUSSION:**

The IRB/IEC may approve research on patients who are so acutely ill or obtunded as not to be able to give informed consent provided that: 1) the research not involve investigational drugs or devices; 2) the research carries

minimal risk for the patient, or the probability of benefit to the patient clearly outweighs the risks; 3) the information cannot be obtained in any way except by the use of this type of subject; 4) a consent form is signed by the subject's authorized representative; 5) the consent is explained to the subject as soon as feasible; and 6) reports of adverse reactions are sent immediately to the IRB/IEC so that the application to other patients can be stopped if indicated. The Clinical Research Coordinator or Designee will follow the same procedure as listed for literate or illiterate subjects when obtaining consent from the incapacitated subject's authorized representative as noted above. If the subject regains decision making capacity at any time during the clinical trial, the consent process will then be reviewed and followed through with the subject as if for any other clinical research subject. If the authorized representative is illiterate then the process for illiterate subjects will be followed but as applied to the authorized representative.

2) **SIGNATURE:** After the discussion with the incapacitated adult subject's authorized representative, if the representative agrees to the participation of the incapacitated subject in the clinical trial, 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 Clinical Research Coordinator or designee obtaining consent will sign date the final page in dark ink.

3) **COPIES, DOCUMENTATION AND FILING**: The Clinical Research 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 subject screened for study will be filed in the study-specific informed consent binder located in the clinical research room regardless of whether the subject initiates study or not. The Clinical Research 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 subject, and whether or not the legal guardian received a copy. Additionally, if at any time during the incapacitated subject's participation in study, capacity for decision making is restored, the Clinical Research Coordinator or designee will initiate the informed consent process with the subject and document the date that decision making capacity was restored. The Clinical Research 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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