PURPOSE: To establish the process for reading and implementing a clinical research protocol.

POLICY: The Principal Investigator and all research staff involved with the performance of a protocol are responsible for reading and implementing the clinical research protocols once approved by all necessary regulatory authorities [the Sponsor, Duke Medical Center (DUMC) Institutions Review Board (IRB), Kilimanjaro Christian Medical Centre (KCMC) Institutional Ethics Committee (IEC), National Institute of Medical Research (NIMR) of Tanzania, and any other required regulatory officials], in accordance with Federal, International, Sponsor and Institutional guidelines and regulations.

RESPONSIBILITY: The Principal Investigator and all research personnel involved with the execution of the research trial.

A. DEFINITIONS:

Approval: The affirmative decision of the IRB and IEC (IRB and IEC defined below) that the clinical trial has been reviewed and may be conducted at the institution's site within the constraints set forth by the IRB/IEC, the Institution, Good Clinical Practice (GCP [defined below]), and the applicable regulatory requirements.

Clinical Trial/Study: Any investigation in human subjects intended to discover, prevent, control, diagnose or treat illness, including: verify clinical, pharmacological, and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.

Multi-Center Trial: A research trial conducted according to a single protocol at more than one site, and, therefore, with more that one site Investigator.

Protocol: A document that describes the objective(s), design, methodology, statistical considerations, and organization of a clinical trial. The protocol usually also gives the background and rationale for the clinical trial, but these could be provided in other protocol referenced documents.

Protocol Amendment: A written description of a change(s) to a protocol or formal clarification of a protocol.

Subject/Trial Subject: An individual who participates in a clinical trial..

Trial Site: The location(s) where trial-related activities are actually conducted.

Clarification Memo: A memo designed to clarify a specific part of the protocol. A clarification memo does not officially change the protocol (see protocol amendment).

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.

Institutional Review Board (IRB) and Institutional Ethics Committee (IEC): An independent body constituted of medical, scientific, and nonscientific members, whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trials, of protocols and amendments, and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

Investigational Product: A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

B. THE RESEARCH PROTOCOL

1. READING THE PROTOCOL: The clinical research coordinator will be responsible for reading the assigned research protocol in its entirety including but not limited to the schema, study design,
study treatment, inclusion/exclusion criteria, required evaluations, laboratory tests/procedures, toxicity management, clinical/laboratory endpoints, the schedule of events, appendices and the informed consent.

2. INFORMED CONSENT DOCUMENT: The clinical research coordinator will be

responsible for reading and understanding the informed consent document prior to reviewing it with a potential study candidate.

3. INFORMATION: The clinical research coordinator will be responsible for reviewing all communication and documents pertaining to the protocol, including but not limited to correspondence, clarification memos, and protocol amendments.

4. COMMUNICATION: The clinical research coordinator will communicate with the protocol team regarding all questions, issues or problems with the research protocol.