University of Ghana Medical Centre
Medical and Scientific Research Centre (MSRC)
Standard Operating Procedure and Policy for IRB Records Keeping

A. MSRC will prepare and maintain adequate documentation of IRB activities, including the following:
   - All available and applicable documents related to submission of a research study including, but not limited to, the IRB application, protocol, scientific evaluations (including evaluations provided by IRBs other than the IRB), Investigator's Brochure, consent form(s), modifications to the previously approved research, progress reports submitted by the PI, recruitment and advertisement materials, study tools and instruments, reports of unanticipated problems involving risks to participants or others, reports of noncompliance, and new information.

   - Minutes
     - Minutes of the IRB meetings shall document all deliberations, decisions and justification for the decisions including those for expedited and exempt review
     - Attendance and reasons for non-attendance by members, consultants and non-affiliated members
     - Minutes are distributed to the Chair of the meeting and to the attending IRB members. Approval of the minutes by the Chair will be communicated and approval by the IRB members is indicated by their absence of response within five days of the request for comments.
     - Modifications to the minutes that materially change the content of the minutes will be communicated to the Chair and attending IRB members. Approval of the revised minutes by the Chair and attending IRB members is indicated by their absence of response within five days of the request for comments.

B. Continuing Review: Records of continued reviewed activities including all associated document shall be kept by the MSRC.

C. Correspondence: Copies of all relevant correspondence between the IRB and study team will be included in myUGMC-IRB.

D. Membership Lists
   - A list of IRB members which includes demographic information and area of expertise, as applicable

E. Policies and Procedures: MSRC will keep records of the policies and procedures that IRB will follow to fulfill its mandate. This can be found in the various standard operating procedures.

F. New Findings: Statements that the PI will inform the participants of significant new findings developed during the course of the research which may affect the participant's willingness to continue participation (see SOPs on full board review, expedited review, Informed Consent and Investigator Reporting Requirements and IRB Review of Reportable Events).

G. Emergency Use Reports:

- All documents related to Emergency Use of an FDA regulated test article including, but not limited to, the IRB application, protocol and Investigator's Brochure (if available), and consent form.
- The above administrative records and records relating to research will be retained by the IRB for a minimum of 7 years after the research is completed, for a minimum of 7 years if the research is cancelled without participant enrollment, or longer as required by law.
- Records are accessible for inspection and copying at a reasonable time and in a reasonable manner by authorized regulatory authorities.

- The IRB system is a comprehensive electronic IRB data management and documentation system. Key functions include:
  - Study submission and review through both expedited and convened board workflows with documentation of communication with study teams and of all required determinations.
  - Automated reminder system to PIs and research teams for continuing review submission.
  - Provision of approval documentation and access to review information for PIs and study teams.
  - Documentation of IRB member recruitment, training, IRB membership and roster information.
  - A module for IRB members to schedule themselves to attend meetings and to provide tracking and documentation of attendance and quorum requirements for each meeting including attendance by scientists, nonscientists, and unaffiliated IRB members.
  - Full Board meetings: The Chair, attending IRB members and MSRC staff (Administrative representative, IRB review analyst and IRB coordinator) have computer to access myUGMC-IRB.
    - The primary reviewer(s) complete electronic reviewer sheets automatically customized to the study under review.

- Continuing education is available to IRB members through a dedicated page in the myUGMC-IRB system. Education is provided at the beginning of each monthly meeting. Previous monthly presentations remain available for review at any time.
- The Chair, MSRC staff and IRB members are provided with a reference manual in myUGMC-IRB (and hard copy format) that includes the regulations and other guidance to aid in the reviews.
- An electronic agenda is available for use prior to and during the meetings.
- After the meeting the motion and number of votes for, against or abstaining are recorded in myUGMC-IRB for each study that is reviewed.