University of Ghana Medical Centre
Medical and Scientific Research Centre (MSRC)
Standard Operating Procedure and Policy for the MSRC Office

A. MSRC physical office space includes adequate resources (meeting area, filing space, equipment, research commons and computers with internet service) to support the research mission. The Director reviews resources and budget needs and presents requests to the UGMC CEO on an annual basis as part of the fiscal budget process.

B. MSRC staff
   1. MSRC employs required number of staff who are responsible for supporting and managing the research activities at UGMC. Specific staff responsibilities are outlined in job descriptions on file in the MSRC office.
   2. Staff have a description of the responsibilities expected of their positions and their performance is evaluated at least annually by their immediate supervisor.
   3. In addition to the intensive training at the time of hire which is tracked on an orientation checklist, staff members are provided and expected to participate in ongoing educational opportunities such as attendance at regional and national research management, conferences and MSRC sponsored events (e.g. Question and Answer sessions, IRB retreats, and MSRC staff in-services). All continuing education activities are tracked through monthly reports that are compiled into a quarterly educational report. Attendance at monthly staff meetings and bi-weekly team meetings is required to fulfill continuing education requirements. Staff who fail to attend all such meetings, unless appropriately excused by their immediate supervisor, the Deputy Director, or Director will be subject to UGMC disciplinary action in accordance with UGMC Human Relations policies. A copy of current yearly training modules can be found on file.
   4. All staff members must pass the required training modules which is tracked through the Director's office

C. IRB Policies and Procedures
   1. MSRC will maintain and follow up-to-date policies and procedures that adhere to regulatory mandates and ethical principles in line with the Ghana FDA and International Council for Harmonization (ICH) guidelines. These policies and procedures are made available to the research community through the MSRC public website.
   2. Changes to regulations, guidelines, organizational policy, or best research practices may require a new policy or a revision to the existing policy. Such new policies or revisions will be reviewed and approved by the Director prior

to implementation and will be documented in the appropriate policy and/or procedure manual.

3. New policies or procedures or a modification to existing polices or procedures will be disseminated to the appropriate individuals and departments through website updates, listserve announcements and/or presentations as applicable. When applicable, training for UGMC staff and PIs, IRB members, or the research community will be provided.

D. The IRB will ensure that patient safety and privacy is always protected when research involves human subjects in accordance with ICH good clinical practices and local guidelines.

E. IRB Function in relation to other UGMC Committees/Offices:
The IRB functions independently of, but in coordination with, the following Committees/Offices.

1. UGMC Legal Representative: The IRB and MSRC staff communicate regularly with legal representative on issues related to national law, interpretations of the regulations, policies and procedures and development of grants and other agreements (e.g., IRB Authorization Agreements, Individual Investigator Agreements).

2. Department Heads: The Chairperson of IRB and MSRC staff communicate with Department heads informally when responding to inquiries or recruiting new IRB members and formally when reporting instances of noncompliance and at the Chairpersons presentation for the UGMC Management Committee. Additionally, the Chairperson or MSRC staff may consult with Department heads regarding specific studies if there are questions related to adequacy of resources, expertise, or other matters for which the Department has jurisdiction.

3. Committee on Research Integrity (CRI): The CRI investigates allegations of research misconduct as defined in UGMC Research Integrity Policy and includes "…knowing, serious or continuing violations of national, international and institutional rules and regulations governing the conduct and dissemination of research…"
4. Conflicts of Interest Review Committees (CIRC): The IRB relies on the CIRC to review, make recommendations, and, if applicable, manage financial conflicts of interest.

5. Human Subject Research Monitoring Committee (HSRMC): The HSRMC monitors studies after IRB approval has been granted and research participants have been enrolled/recruited. The goal of the committee is to

ensure the safety of human research participants by monitoring compliance with the research study, UGMC policies, ICH-GCP, FDA and national regulations. The IRB may communicate any issues of concern to HSRMC in order to request review of a particular study. Monitoring results of the HSRMC will be shared with the IRB Chair and MRSD Director.

6. UGMC Biosafety Committee (UBC): Research involving the deliberate transfer of DNA (or DNA of RNA derived from recombinant DNA) into one or more human participants requires initial and continuing review by the UBC. The IRB will not review submissions requiring approval from the UBC until the UBC has reviewed and approved the study. Severe Adverse Events that occur in these studies require reporting to the UBC.

7. Investigational Drug Service: Pharmacists dispensing investigational drugs for inpatient research studies verify that the study has current IRB approval and that the patients signed an IRB-approved consent form prior to dispensing the drug. Copies of active IRB-approved studies involving investigational drugs are available in the Pharmacy Department.

8. MSRC grants management accounts: MSRC establishes accounts in the UGMC financial system for extramural research awards. MRSD will only release funds for expenditure on research awards involving human research upon certification of IRB approval of the research. MSRC may freeze funds at any time during the sponsored project period, upon notification by the IRB of a PI's noncompliance with human participant research policies and procedures. Funds may continue to be frozen until the issue is resolved.

9. Intellectual property management: MSRC manages intellectual properties arising from research programs at UGMC in coordination with the UGMC Legal representative. These areas range from patents, copyrights, know-how, and proprietary materials. MSRC assists faculty with consulting agreements and research contracts. MSRC works with UGMC Legal representative with regard to material transfer agreements.

F. MSRC Function in Relation to Regulatory Bodies and National Committees/Offices:
MSRC functions in compliance with FDA requirements (as described in this document) and, additionally, adheres to the standards recognized by the ICH.