University of Ghana Medical Centre
Medical and Scientific Research Centre (MSRC)
Standard Operating Procedure and Policy for Principal Investigators (PIs)

A. ***Qualifications***

1. All personnel performing any procedures associated with a research study must have appropriate training and expertise.
2. Individuals performing specific functions or procedures should have the necessary licensure and/or credentials to conduct the activity in accordance with the research study.
3. Medications administered as part of a research study should be administered in accordance with the applicable licensure requirements as applicable by law based on where the research is conducted.
4. For research conducted by an undergraduate or graduate student, the IRB requires that the research be supervised by a full-time faculty member.
   a. This faculty member may not be on leave. If he/she must go on leave, a replacement faculty should be appointed in consultation with the head of department to oversee the conduct of the research. The IRB should be informed of this change in an amended protocol.
   b. The faculty member must be in good standing with his/her academic organization during the IRB submission, IRB review, and conduct of the study.
5. The PI's qualification to conduct research is documented by virtue of his/her faculty, staff, or student status.
   a. UGMC PIs must provide a signed assurance from their Department Head
   b. If the UGMC PI is an undergraduate or graduate student the faculty supervisor must also provide a signed assurance.
   c. Researchers from an outside institution must have a co-PI from UGMC or the University of Ghana.
6. The PI must have adequate resources including funding, facilities, staff, the time to conduct and complete the research, and equipment to conduct proposed research.

B. ***Education Requirements***

1. The IRB requires that PIs and research personnel comply with their organizational policy regarding education related to the protection of the rights and welfare of research participants.
2. It is the responsibility of the PI to ensure that research personnel are qualified and adequately trained in the protection of the rights and welfare of human participants.

3. PIs and their research staff can avail themselves for educational modules offered by the MSRC.
4. Individuals who serve as research supervisors or advisors are expected to understand the regulatory and ethical considerations for research with human participants.

C. ***Financial Conflicts of Interest***

1. The PI and research team members must comply with the conflict of interest policies from their organization. If an organization does not have a conflict of interest policy the UGMC-MSRC conflict of interest policy apply.
2. The IRB requires all individuals engaged in the research to disclose in the IRB application form any financial interests that the individual, individual's spouse, domestic partner, or dependent children have with the sponsor of the study, the supporting organization, or company that owns or licenses the technology being studied.
3. When a financial interest exists, the financial interest will need to be reviewed, approved, and, if necessary, managed in accordance with the conflict of interest policy applicable to the PI and the study team.
4. Where a conflict of interest exist, documentation of the review by the conflict of interest committee is required in order for the IRB to approve the research.
5. The IRB may require disclosure of the financial interest to participants in the consent form if a financial conflict of interest is identified.

D. ***IRB Approval***

1. The IRB approval will be obtained before implementation of any research involving human participants, including review of identifiable data, records, tissues, or other derived materials.
2. Prior IRB approval must be obtained before initiating any change to previously approved research except when necessary to eliminate apparent, immediate hazards to participants.
3. Changes in approved research may be initiated without IRB approval only to eliminate apparent, immediate hazards to the participant. These changes should be immediately reported to the IRB after the occurrence as a reportable event.

E. ***Change in the PI***

1. Changes in PI are treated as modifications to previously approved research and must be approved by the IRB before implementation of the change.
2. Requests to change the PI must be approved by the IRB after prior approval is obtained from the original PI and the authorized Dean, Head of Department, or assurance from an organizational official or other designee.

3. Student-conducted research requires additional prior approval of the Faculty supervisor.
4. In studies where active participation is ongoing, participants should be notified about the change in PI immediately.

F. ***Premature completion of the study***

1. If a study is ending prematurely, the IRB must be notified:
   a. If the study is ending due to a safety issue the information should be submitted as an unanticipated problem involving risks to participants or others.
   b. In all cases, participants should be notified if they are still actively involved in the study, such as receiving the intervention or continue to interact with the study team. This notification will require IRB approval prior to distribution to the participant unless notification is necessary to eliminate an immediate hazard.

G. ***Responsible Conduct of Research***

1. All individuals engaged in the conduct of human subject research are expected to comply with the highest standards of ethical and professional conduct in accordance with national, organizational and MSRC regulations and policies.
2. Failure on the part of the PI, or any member of the study team to comply with these policies may result in the IRB approval being revoked.

H. ***Review of grant applications***

1. For sponsored research, the PI will ensure that the research described in the grant application or proposal is consistent with what is submitted to the IRB.
2. Any deviations from the original sponsored project should have the approval of the sponsor

I. ***Protected Health Information Minimum Necessary Standard***

1. The research team will only collect information essential to the study and in accordance with this policy.
2. To the greatest extent possible, access to the information will be limited within the research team.
3. If protected health information is used or created, it will not be re-used or disclosed to any other person or entity, except as required by law, research oversight, or those uses outlined in the myUGMC-IRB application.

J. ***Informed Consent:***

The rights and welfare of human participants and the methods for obtaining their voluntary consent to participate in research should be carried out in accordance with IRB policies and procedures, and the policies of the UGMC-MSRC. This

includes the information listed below, along with the information in SOP on informed consent:

1. Information provided during the consent process should be discussed with participants to ensure that they understand the nature of the research and can voluntarily decide to participate, without risk of coercion or undue influence.
2. If any language barriers or other impediments to communication exist, measures should be taken to ensure the participant's understanding. When consenting non-English speaking participants, consent should occur in the native language in the format approved for the study.
3. Discussions regarding the research and each participant's desire to continue to participate should continue throughout their participation in the study.
4. When children participate in research, their assent should be obtained in accordance with the provisions approved by IRB.
5. When written documentation of consent is required, the consent form should be signed and dated by both the research participant and the individual who obtained the consent. A signed copy should be provided to the participant.
6. The individual obtaining consent must be a member of the study team and appropriately trained and qualified.
7. Any information provided to participants in the form of consent and written assent documents, scripts, and debriefing forms (as may be required by the IRB) should bear UGMC-MSRC stamp of approval.
8. Contact information for the PI or appropriately designated research team member, IRB should be provided to research participants.
9. Participants should be aware of whom to contact for information and or complaints concerning the study.

K. ***Referrals***: If during the course of the research study, it becomes apparent that the participant needs to be referred for further services, the PI should make such referral(s).

L. ***Continuing Review***

1. All research involving human participants shall be reviewed by the IRB annually.
2. As a courtesy to PIs, MSRC issues continuing review notices before the study is due to expire. To allow adequate time for review, it is very important that the PI submits continuing review applications 6 weeks prior to the date of IRB approval expiration.
3. If IRB approval expires all research activities must stop and new participants may not be enrolled. PIs have a grace period of 4 weeks to submit a continuing review application. During this period till the continuing review is approved participants enrollment is not allowed.

4. The IRB approval will be expired after 4 weeks grace period, at which point MSRC will close the study. Once MSRC closes a study it will not be re-opened under the previous approval. A new submission is required.

M. ***Verification of information related to ongoing research***

1. The IRB has the right to audit an ongoing project based on
   a. Its policy of random audits for quality assurance purposes
   b. Complaints from research participants or other sources about the conduct of the study
2. The IRB may conduct this audit by itself or ask the committee on research integrity to do the same and report findings to the IRB.

N. ***Appeal Process***

1. Full Board Reviews: The PI has the right to respond in person or in writing if the IRB disapproves a research activity by contacting the Chairperson or MSRC staff. The IRB will consider any new information that was not previously presented to the board during any subsequent review.
2. Expedited Reviews: If a PI does not agree to contingencies recommended by the expedited reviewer, the study is referred to the full board review.

O. ***Record Retention***

1. All research records, including signed consent forms, must be kept in their original form or a certified scanned electronic form for at least seven years beyond close of the study.
2. Additional retention requirements may be required under national laws and regulations. It is the responsibility of the PI to retain these records.
3. Protected Health Information must be stored in accordance with national laws and regulations and UGMC-MSRC policies.

P. ***Close Form***

1. The PI is required to submit a Close Form at the conclusion or discontinuation of all IRB approved projects.
2. Studies may be closed when the following conditions apply:
   a. interventions and interactions with the research participant have been completed and
      i. the data have been stripped of all identifiers (including codes) with which individual identities of participants could be ascertained; or
      ii. The data remain identifiable but will no longer be used for the current research study.

b. After a study has been closed a new application must be submitted and approved by the IRB before any identifiable or coded data may be used, even by the same PI.

3. A study may be closed by MSRC as described in Section P of this SOP. Repeated failure to submit final reports may be considered noncompliance with the UGMC-IRB policies.

Q. ***Ownership of Research Property***

1. Unless an exception applies or permission has been granted by UGMC, UGMC owns all intellectual property, including lab notebooks, cell lines and other tangible research property for studies conducted by UGMC researchers. This includes original research documents, lab notebooks (in any format), interview tapes and transcripts, electronic databases, and all other data and specimens.
2. For studies conducted by non-UGMC researchers their organization's policies or applicable contractual agreements regarding ownership of research property will apply.

R. ***When a PI leaves the UGMC***

1. When a UGMC PI leaves UGMC, all such research property will stay at UGMC in the custody of a collaborator or the appropriate Dean or Department Head unless prior arrangements have been made and the appropriate organizational approvals have been obtained.