University of Ghana Medical Centre (UGMC)

Medical and Scientific Research Directorate (MSRD)

Standard Operating Procedure and Policy for IRB Activities and Jurisdiction

Activities Subject to IRB Jurisdiction

A. All instances where the Organization (UGMC) engages in human research, it must be reviewed and approved by the IRB prior to initiation. Engagement encompasses all activities whereby any UGMC affiliates (including faculty or staff), agent, student, fellow, or post-doctoral appointee intervenes or interacts with living individuals for the purpose of research, obtains individually identifiable private information about living individuals for the purposes of research, or receives an award to conduct human research even when all activities involving human participants are carried out by a sub-contractor or collaborator. All Human Research at UGMC requires prior IRB approval in writing.

B. In the conduct of multi-site research, the UGMC-IRB must still review and approve the research. This review could be an administrative review depending on prior written reliance agreements with the other IRB(s).

C. When UGMC is the designated IRB of record or when UGMC defers its oversight to another IRB, the UGMC-MSRD is responsible for ensuring that a reliance agreement is in place and that appropriate documentation is maintained.

D. When UGMC is the coordinating center and/or the PI is from UGMC, the PI must ensure that IRB approval has been obtained at each participating site prior to initiation of the research at that site. Copies of the non-UGMC site's IRB approval must be provided to the IRB.

E. When an external organization or facility acts as a performance site only and is not engaged in research, the PI must obtain written permission from an authorized representative of the organization or facility acknowledging their agreement to serve as a site for the research activities. A copy of this documentation of permission must be provided to the IRB. The date of the permission document must be prior to the start of the conduct of human research subjects at the site.

F. The IRB will review research under its jurisdiction, as described in Section A above, to determine whether the research activities meet one or more of the exempt categories as detailed in the SOP for exempt research.

G. Definitions of Human Research: “Human research” is defined as any activity that represents “research” involving “human participants” defined by International Conference on Harmonization (ICH) recommendation or a “clinical investigation” of a “test article” involving one or more “human participants” as defined by FDA regulations as follows.

H. Determinations of the Conduct of Human Research

1. Investigators are expected to recognize when they are engaged in activities subject to IRB jurisdiction by complying with this Policy and other relevant organizational policies and procedures. If uncertain, an investigator may submit a written request to the IRB for a determination.
2. Applications for human research determinations will be reviewed according to the Expedited Review procedures described in expedited review standard operating procedure.
3. Determinations will be based on whether the activity meets the definitions of “human research” as outlined in Section G of this SOP.
4. Determinations will be communicated to investigators in writing, a copy of which will be retained by MSRD.
5. Changes in activity(ies) previously determined by IRB as not human research may be submitted for a determination of whether the change(s) continue to represent activities that are not human research.
6. If an investigator begins a non-research project that involves human participants and later finds that the data gathered could contribute to generalizable knowledge, the investigator must submit a proposal to the IRB for review and approval prior to using the data to develop the publication or presentation of the data (e.g., journal article, poster session, public speech, or presentation).

I. Failure to Submit a Project for IRB Review

1. The implications of engaging in activities that qualify as human research that is subject to IRB review without obtaining such review are significant. To do so would be in violation of applicable national laws and this Policy. Similarly, human research data collected to satisfy thesis or dissertation requirements without prior IRB approval is a violation of this Policy.
2. The IRB will not approve applications in which the investigator has attempted to circumvent IRB policies and procedures regarding human research by collecting data as non-human research and then submitting them as existing data. It is therefore in the investigator’s best interest to carefully consider the likelihood that the data will be used for research purposes in the future, and to err on the side of inclusion and seek IRB approval prior to commencing the work.

3. Violations of this Sub-section I may be considered serious or continuing noncompliance and will be handled according to the procedures described in Investigator Reporting Requirements and IRB Review of Reportable Events SOP.

J. UGMC subscribes to Open Research and Free Dissemination of Ideas and Information prohibits the conduct of classified research at UGMC.

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Standard operating procedure and policy on IRB Membership

Membership / IRBs

A. The UGMC-MSRD designates full board reviewing IRBs, the UGMC-IRB. The UGMC-IRB normally meets bi-monthly and as and when needed. Meetings of the UGMC-IRB may be cancelled if there are no studies ready for review.

   Each IRB member is charged with ensuring the protection of the welfare and safety of research participants by assuring that researchers adhere to ethical, regulatory, and organizational requirements.

B. IRB Make-up: The IRB;
   1. Is comprised of at least five members with varying backgrounds and expertise to promote complete and adequate review of research activities overseen by UGMC.

   2. Is qualified through the experience and expertise of its members.

   3. Is qualified through the diversity of its members including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes. The IRB does not consist of entirely men, women, or members of one profession.

   4. Is competent to review specific research activities and able to ascertain the acceptability of proposed research in terms of organizational commitments and regulations, applicable law, and standards of professional conduct and practice.

   5. Includes at least one member whose primary concerns are in a scientific area, at least one member whose primary concerns are in a non-scientific area who will represent the general perspective of the participant, and at least one member who is not otherwise affiliated with UGMC and who is not part of the immediate family of a person who is affiliated with UGMC.

C. If the IRB is reviewing research involving a population vulnerable to coercion or undue influence, including but not limited to, prisoners, children, pregnant women, cognitively or decisionally-impaired, and economically or educationally disadvantaged, the IRB will ensure that the study is reviewed by one or more individuals who are familiar with the population. The IRB will regularly examine its local research context for other vulnerable populations that should be

represented to ensure that the research is reviewed by an IRB member or consultant who is knowledgeable about or experienced in working with that population. The review of initial and continuing review of research, or modifications of research, involving prisoners will include review by a prisoner representative to confirm that the research meets or continues to meet the regulatory criteria for inclusion of prisoners.

D. Conflicts of Interest

1. Conflicting interests include both financial and non-financial interests which might interfere with the review process either by competing with an IRB member's obligation to protect participants or by compromising the credibility of the research review process. Both financial and non-financial conflicts of interest are defined in the conflict of interest policy.

2. As a requirement of IRB membership, each IRB member will sign the MSRD Confidentiality and Conflict of Interest Agreement as an initial membership requirement and every two (2) years thereafter. An IRB member may not participate in the review of any study (including the review of reportable events) in which he or she has a conflicting interest, except to provide information requested by the IRB.

3. If a submitted proposal involves an IRB member, he/she shall not be part of the review process.

4. When acting as a primary reviewer the IRB member must verify that they do not have a conflict of interest before reviewing the study.

5. Consultants and guests attending meetings will review the meeting agenda prior to the meeting to identify any conflict of interest. Guests and consultants (that are not also IRB members) will sign the MSRD Confidentiality and Conflict of Interest Agreement.

6. IRB members who have conflict of interest and therefore not part of the review process shall be noted as absent due to conflict of interest in the IRB meeting minutes. In meetings where there are several studies to be reviewed members with a conflict of interest related to a particular proposal shall be excused.

7. When a Chair leaves the meeting due to a conflict of interest, the meeting shall appoint one of the members as chair.

8. All MSRD staff shall sign the MSRD Confidentiality and Conflict of Interest Agreement when hired and on an annual basis thereafter.

9. The IRB maintains documentation that all IRB members and MSRD staff are aware of and committed to compliance with the IRB policy regarding conflicts of interest.

E. When necessary, the IRB may invite individuals with competence in special areas to assist in the review process as a consultant.

1. **Full Board Review**: The need for a consultant may be identified prior to the review by the IRB, by MSRD staff, an IRB member or requested by the IRB during the review.
   a. If identified prior to the meeting, MSRD staff or the Chair will identify and contact an individual with appropriate expertise.
   b. If requested by the IRB, the IRB may recommend an appropriate individual or request that MSRD staff or the Chair identify an appropriate individual.
   c. The consultant's findings will be presented to the IRB for consideration either in person, by an IRB member or by MSRD staff. Consultants may attend the IRB meeting but do not have voting rights. Information provided by consultants is retained in myUGMC-IRB and use of a consultant is documented in the meeting minutes.
   d. Ad hoc or informal consultations requested by individual IRB members (rather than the full board) will be requested in a manner that protects the researcher's confidentiality when possible, and is in compliance with the IRB conflict of interest policy (unless the question raised is generic enough to protect the identity of the particular PI and research study).
   e. Studies involving administration of radioactive materials to human subjects must be reviewed by an expert in the field of radiation therapy before being submitted to the IRB. The expert's written opinion should accompany the submission.

2. **Expedited Review**: If an expedited reviewer determines they do not have the appropriate expertise to conduct the review of a study, a consultant may be utilized. The consultant may provide an expert review of an entire study or only a specific issue associated with a study. The consultant may be identified and contacted by the expedited reviewer, other MSRD staff or the Chair. Information provided by consultants is documented in myUGMC-IRB.

F. Recruitment and Conditions of IRB Membership
1. IRB members are sought by MSRD through recommendation from Department Heads, officials from related institutions, recommendations from other IRB members, or on a volunteer basis. IRB members may be recommended but are not selected by Investigators and Investigators may not specify which IRB members review their submissions.

2. Members of the community may serve as unaffiliated members of the IRB who may attend and observe proceedings. Unaffiliated members do not have voting rights. Not more than three unaffiliate members may attend a particular meeting.

3. IRB members serve as volunteers (without payment) except for consultants outside the UGMC and its related institutions.

4. IRB members are covered for their good faith service on the IRB as provided in the UGMC self-insured liability program.

5. IRB members designated as alternates may represent the primary member in their absence and are included on the IRB membership lists on file at MSRD. Meeting minutes will document when an alternate attends a meeting for a primary member. If an alternate attends a meeting at which the primary member is present, the alternate and primary member will not vote on the same study and only one will count towards quorum.

6. IRB membership will be monitored to ensure there are a sufficient number of unaffiliated members to achieve a goal of having at least one unaffiliated member present at a majority of the convened meetings.

7. The Chair is responsible for periodic evaluation, including providing feedback of the performance of IRB members and for the periodic evaluation of IRB composition to confirm adherence to regulatory and organizational requirements. MSRD conducts IRB member surveys at least once every two years to evaluate IRB member performance and satisfaction, and to identify continuing education topics.

8. The Chair is evaluated on a periodic basis through a survey provided to the IRB members. The Director – MSRD provides results of the survey to the Chair.

9. Each IRB member will serve an initial two-year appointment. Following initial appointment and at the time of evaluation, upon mutual agreement of the IRB member, the Chair and the IRB member may be reappointed for another term. An IRB member may be considered for removal from membership if he/she is not acting in accordance with the IRB's mission or policies and procedures after consultation with the chairperson.

10. Chair is selected on the basis of their commitment, knowledge of research and regulatory affairs, personal integrity, and ability to conduct an effective meeting.

11. The Chairperson is a voting member at the meeting and, as appropriate for their expertise, is assigned studies for review. Chairperson responsibilities include:
    a. Identify issues with studies scheduled for review before the meeting and facilitate discussions with the reviewers and/or PI to resolve the issues
    b. Serve as the leader in the meeting and engage the IRB members in the discussion and keep the discussion focused on the criteria for approval.
    c. Provide guidance on questions about the regulations and organizational policies.
    d. If there are required actions, determine if the study may be approved pending completion of the required actions or if the study must return to the IRB for additional consideration.
    e. Summarize the motion and call for the vote.
    f. Review and approve the minutes, and; communicate with the PI after the meeting, as necessary, to address questions about the IRB determinations.

G. IRB Member Education (for the purposes of this Policy, the term "members" includes Chair)
    1. New IRB members who have no IRB experience are required to attend an introductory training session organized by MSRD and observe at least one IRB meeting prior to formally reviewing studies and voting at an IRB meeting.

    2. Training sessions focus on educating IRB members in the responsibilities and obligations of IRB members regarding the protection of human participants, applicable regulations and guidance documents, local IRB requirements, and on the regulatory requirements for approval of new and continuing review of human research.

    3. Ongoing education for IRB members includes educational materials presented during IRB meetings; MSRD lectures, educational sessions, or retreats held throughout the year; and other local, regional, or national meetings when appropriate.

    4. When possible, MSRD will fund IRB members' and/or Chair's attendance at regional or national conferences.

5. MSRD has a library of educational materials available for checkout by IRB members.

H. All IRB members including the Chairperson are expected to comply with the highest standards of ethical and professional conduct in accordance with national regulations and applicable organizational and IRB policies.