University of Ghana Medical Center

Medical and Scientific Research Centre (MSRC)

Standard operating procedure and policy on IRB Review

Full Board Review

A. Convened Meetings

1. All studies that do not qualify for review by expedited procedure will be reviewed by the fully convened IRB. The studies will be individually presented, discussed, and voted on at a convened meeting.

2. Full Board review of studies will take place only when a quorum is achieved. Quorum should be defined as 1/3 of the entire IRB membership, including at least one IRB member whose primary concerns are in nonscientific areas. No official actions will be taken at a meeting where a majority of the members, including a non-scientist, are not present. If quorum is lost during a meeting, no official actions are taken until quorum is restored. Designated MSRC staff that attend the meeting are responsible for ensuring that quorum is achieved and maintained through the meeting. An attendance sheet that includes the names of IRB members that are attending, and their scientific designation is used to track quorum.

3. IRB meetings will take place either in person and/or by video conference with all participating members able to express themselves clearly to the hearing of all the other members.
   a. Before an IRB meeting, MSRC will ensure that all members have received all pertinent materials prior to the meeting.

4. All members' votes will be deemed equal and no proxy votes (written or by telephone) will be considered. The Chair will prompt each individual IRB member whether physically present, on phone or on video to verbalize their vote, when voting is needed for approval.

B. Full Board Review and Actions

1. Approval of a study at an IRB meeting requires the approval of a majority of members present at the meeting by vote or consensus. All votes shall be recorded in the meeting minutes.
2. The IRB's decision regarding approvability of new research, continuation of ongoing research, and modifications to previously approved research is based on national and international best practices for human research.
3. In general, materials are made available to IRB members at least seven days in advance of the meeting to allow adequate time for review. Urgent review

procedures may be invoked only under unusual circumstances by MSRC staff in consultation with the Chair.

4. Limits are placed on the number of studies that will be reviewed at a meeting to allow sufficient time for IRB deliberation. A maximum of three proposals shall be reviewed at a meeting.

5. The IRB will review all studies for scientific or scholarly validity to assess whether the research uses procedures consistent with sound research design and that research design is sound enough to yield the expected knowledge. This review is accomplished by at least one scientist IRB member of the IRB with the appropriate scientific or scholarly expertise.

6. All proposals may be subject to administrative scientific review by MSRC scientists. The MSRC scientist may work with the PI to bring the proposal to a level where it is deemed suitable for IRB review.

7. The IRB will review all new studies, modifications and continuing review applications to determine the appropriateness of the research in the local research context. Review and approval will be based on detailed applicable information provided in the myUGMC-IRB application.

8. The IRB may make one of the following determinations as a result of a full board review. In all instances, the approval date is the date of the convened meeting at which the IRB confirmed that the criteria for approval were met. The expiration date will be within one year of the approval date and represents the last date that the study is approved.
    a. Approve: The study and accompanying documents are approved with no changes required.
    b. Approve pending: The IRB requires specified changes to the study and/or accompanying documents,
        i. The IRB Chair or other individual designated by the IRB may review and accept these stated requirements for approval.
        ii. The PI should respond to the IRB's required actions in myUGMC-IRB.
    c. Revision required: When the IRB requests substantive changes or requirements, the study and accompanying documents cannot be approved without a response from the PI and subsequent reconsideration, discussion, and vote by the IRB.
    d. Disapprove: The study fails to meet one or more of the criteria for approval.

9. The IRB will promptly notify the PI in writing (via email) of its decision to approve, disapprove, or require modifications to proposed research. If the IRB decides to disapprove a research activity, it will include in its written notification a statement of the reasons for its decision. The PI is responsible for communicating the IRB decision to the Sponsor of the research (if applicable).

10. At the time of initial review and at continuing review, the IRB will make a determination regarding the frequency of review of the research studies. All studies will be reviewed by the IRB annually or more frequently depending on the level of risk.

11. At the time of initial, continuing review and modifications, the IRB will make a determination regarding the risks associated with the research studies. The meeting minutes will reflect the IRB's determination regarding risk levels.

12. Any changes in protocol either minor or major must receive IRB approval before being implemented by the PI. An exception is when a modification is needed for safety of participants. In that case, the PI must inform the IRB immediately after the modification. The expiration date of IRB approval remains unchanged after approval of a modification, unanticipated problem, or report of new information unless otherwise voted upon and approved by the IRB that the study should be reviewed again prior to the current expiration date.

C. Full Board Review of New Submissions

1. In order for the IRB to determine whether the proposed research meets the requirements for approval, the PI must submit sufficiently detailed materials regarding the research.

2. Primary Reviewers: MSRC in consultation with the Chair will assign at most three (3) primary reviewers to each study. The primary reviewer(s) will be assigned studies based on related expertise. When making reviewer assignments, MSRC staff will take into consideration the vulnerable populations involved in the research and ensure at least one individual who has experience with this population is scheduled to be present at the meeting. Primary reviewers are responsible for conducting an in-depth review of all pertinent documentation and presenting the research at the convened IRB meeting.

3. Materials provided to all IRB members are:
   a. Complete myUGMC-IRB application including the signature of the PI.
   b. Full protocol;

c. Proposed informed consent document(s);
d. A copy of FDA or other regulatory body approved documents where applicable.
e. Investigator's Brochure (if one exists);
f. Copies of surveys, questionnaires, study tools, or instruments;
g. Recruitment materials and advertisements intended to be seen or heard by potential participants.
h. Documents pertaining to approvals conducted by UGMC ancillary committees (when applicable).

4. Complete documentation of the study is available to all members for review at or prior to the convened meeting via the myUGMC-IRB system.

5. All IRB members are expected to review materials in enough depth to discuss the information when they are present at the IRB meeting.

6. Review of recruitment materials/advertisements and participation payments: The IRB will review the advertisement as well as the mode of communication to assure that it is not coercive or unduly influential and does not promise a benefit beyond what is outlined in the consent and study materials.

D. Continuing Review by the Full Board

1. The PI must submit sufficiently detailed updated materials regarding the research in order for the IRB to determine:
   a. whether the proposed research continues to meet the requirements for approval.
   b. the studies that need verification from sources other than the investigators that no material changes had occurred since the previous IRB review,
   c. that the current consent document is still accurate and complete, and
   d. that any significant new findings that arise from the review process and that may relate to participants' willingness to continue participation will be provided to participants.

2. Continuing review will follow the same procedure as initial review outlined in Section C of this SOP.
   A. Materials provided to all IRB members are:
      a. Complete continuing review application which includes:
         i. Study summary;
         ii. Status report on the progress of the research;
         iii. Number of participants consented;
         iv. Summary of any adverse events, listing of unanticipated problems involving risks to participants or others, summary of withdrawal of

participants from the research and the reasons for withdrawals, and complaints about the research since the last IRB review;

v. Most recent data/safety monitoring report (when applicable);
vi. Summary of any relevant recent literature, interim findings obtained thus far, modifications to the research since the last IRB review, any relevant multi-center trial reports;
vii. Any other relevant information (especially information about risks associated with the research); and

B. Complete protocol (may be a separate document) including any modifications previously approved by the IRB;
C. Granting agency progress report, if applicable and available (The grant progress report will be reviewed for consistency with the study);
D. A copy of the current consent document(s) and any newly proposed consent document.
E. Recruitment materials and advertisements intended to be seen or heard by potential participants.
F. Documents pertaining to scientific reviews conducted by UGMC ancillary committees (when applicable) and;
G. If modifications are submitted at the time of continuing review, a revised myUGMC-IRB application and any revised and/or supporting documents
H. Study tools or instruments (when applicable); and
I. Based on subject experiences or study results the current risks and potential benefits assessed for the study.

J. Complete documentation (including the study file) and relevant IRB minutes are available to all IRB members for review via the myUGMC-IRB system.

K. All IRB members are expected to review materials in enough depth to discuss the information when they are present at the convened meeting.

L. All continuing review submissions that do not qualify for review by expedited procedure will be individually presented, discussed, and voted on at a fully convened IRB meeting.

M. All continuing reviews that meet the criteria for expedited review as described in the list of research activities which may be reviewed through expedited review procedures will be reviewed by qualified IRB members who have been designated by the Chair to conduct expedited review. All expedited reviews of studies will be reported to the Full Board.

N. Expiration of IRB Approval: 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.