University of Ghana Medical Centre
Medical and Scientific Research Centre (MSRC)
Standard Operating Procedure and Policy for IRB Activities and 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-MSRC 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 MSRC.
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.