University of Ghana Medical Center

Medical and Scientific Research Centre (MSRC)

Standard operating procedure and policy on *Expedited Review*

A. General Expedited Review

a) The Chairperson designates UGMC-IRB members to conduct expedited review in accordance with UGMC-IRB SOPs. Only research that meets the specific criteria will be reviewed by an expedited review process.
b) Designated reviewers may exercise all the authorities of the UGMC-IRB except that the reviewers may not disapprove the research. The research may only be disapproved after review in accordance with the non-expedited review procedure. When applicable, contingencies will be communicated to the PI in writing. If a PI does not agree to make the reviewer's requested revisions, research will be reviewed by the fully convened UGMC-IRB.
c) Requests for expedited review that, upon review, are determined not to meet the criteria for expedited review will be reviewed by the fully convened UGMC-IRB.
d) The fully convened UGMC-IRB will be kept apprised of expedited approvals of initial, continuing review, and minor modifications to previously approved research.
e) The UGMC-IRB or FDA may restrict, suspend, terminate, or choose not to authorize the UGMC-IRB's use of the expedited review procedure when necessary to protect the rights and welfare of participants.

B. Categories of research for expedited review

A. Applicability

1. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the UGMC-IRB through the expedited review procedure. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure.

2. The categories in this list apply regardless of the age of subjects, except as noted.

3. The expedited review procedure may not be used where identification of the subjects may be damaging to them in any way.

4. UGMC-IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review.

5. Categories one (1) through seven (7) pertain to both initial and continuing UGMC-IRB review.

B. Research Categories

1. Clinical studies of drugs and medical devices which have already been approved by the FDA.

1. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from healthy non-pregnant adults.
2. Prospective collection of biological specimens for research purposes by noninvasive means.
3. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
4. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical records, treatment or diagnosis).

5. Collection of data from voice, video, digital, or image recordings made for research purposes.

6. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

7. Continuing review of research previously approved by the fully convened UGMC-IRB if no significant changes are being made.

C. Expedited review of new project applications and continuing review applications should submit the same materials, and undergo the same processes as required for a full IRB review.

E. Review of changes in previously-approved research

1) Minor modifications in previously-approved research may be reviewed under expedited procedures. Expedited reviewers evaluate whether modifications represent a minor change. Minor modifications are defined as those that do not potentially adversely affect the overall assessment of the risks and benefits of the study and do not substantially change the specific aims/design of the study.

a. Examples of minor modifications include but are not limited to:
    i. A minor increase or decrease in the number of participants;
    ii. Adding or revising a study instrument or task condition;
    iii. Small changes in remuneration;
    iv. Changes to improve the clarity of statements or to correct typographical errors;
    v. Change in research team members;
    vi. Change in funding source; and
    vii. Change in or addition of research performance (study) sites operating under the same protocol where all procedures that are more than minimal risk have already been approved by the fully convened UGMC-IRB.

2) Review of proposed modifications that are not minor and/or do not qualify for an expedited category will be reviewed by the fully convened UGMC-IRB.
3) The UGMC-IRB will promptly notify the PI in writing of its decision regarding the proposed modification.