1. Purpose

To describe and document the criteria for expedited review of applications submitted to FOMREC for ethical reviews that have been categorized as appropriate for such review by the chairman FOMREC, or by FOMREC administrative staff under SOP 004.

2. Scope

This SOP applies to the FOMREC members and FOMREC chairperson. Applies to all protocols and reports intended for expedited review.

3. Responsible Persons

FOMREC chairperson and FOMREC members appointed by the chairperson to expedite ethical review of application submitted to FOMREC.

4. Background

Expedited review is a procedure through which certain kinds of research can be reviewed and approved without convening a full committee meeting. The Uganda National Council for Science and Technology guidelines for research involving human subjects together with other international guidelines permit Ethics Review committees to review research through an expedited procedure if such research meets the following criteria:

A. For initial review, the research poses not greater than minimal risk.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Examples of research that may fall under this category may include but not be limited to:

- Research where no investigational drug is used.
- Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice excluding procedures involving radiation.
- Research involving materials (data or specimens) that have been collected solely for non-research purposes.
- Research involving materials (data or specimens) that are readily available to the public.
B. The research constitutes a minor change in previously approved research during the period for which approval is authorized;

Minor changes to previously approved research are those that meet all of the following criteria:

- Involve the addition of no more than minimal risk to participants.
- All added procedures are eligible for initial review using the expedited procedure if considered independently of the research.

Examples of minor changes include, but are not limited to:

- Addition of research activities that would be considered exempt or expedited if considered independently of the main research protocol;
- Amendments or modifications to a previously approved protocol that provide for a procedural change (if minor), are administrative, or decreased risks to a participant or patient.
- Minor increases or decreases in the number of participants;
- Amendments in remuneration to participants;
- Amendments to improve the clarity of statements in the informed consent form, research privacy form, or protocol to correct typographical errors, provided that such a change does not alter the content or intent of the statement.
- Changes in the Principal Investigator or Co-investigators

Examples of changes that may be considered major and may require full board review include, but not limited to;

- Broadening the range of inclusion criteria.
- Narrowing the range of exclusion criteria.
- Alterations in the dosage or route of administration of an administered drug.
- Extending substantially the duration of exposure to the test material or intervention.
- Deletion of laboratory tests, monitoring procedures, or study visits directed at the collection of information for safety evaluations.
- **Inclusion of new information regarding serious adverse events or other significant risks.**
- Changes which, in the opinion of the IRB chairperson or his/her designee, do not meet the criteria or intent of a minor modification.

C. Research previously approved by a full board committee will ideally be reviewed under full board committee. However if it falls under the categories below, such research may be reviewed under the expedited review process;

- Research is permanently closed to the enrollment of new subjects
- All subjects have completed all research-related interventions;
• Research remains active only for long-term follow-up of subjects
• Where no subjects/participants have been enrolled and no additional risks have been identified
• Where the remaining research activities are limited to data analysis.

Reviewers may exercise all the authority of FOMREC except to disapprove the research; if the reviewer decides that the request does not meet expedited review requirements, or if he or she feels the request needs to go before the full Board committee, the changes must be reviewed by the full Board committee meeting.

5. Procedures

I. The FOMREC administrative staff initially review the application to determine which review category the application falls under (expedited review or full board). The FOMREC administrative staff will then forward the protocol and the documentation to the FOMREC chairperson as in SOP 004.

II. The FOMREC chairperson will confirm the expedited review determination and may review the application or may designate a member(s) to review the application.

III. The expedited review may be carried out by the FOMREC chairperson or by one or more experienced reviewers designated by the chairperson from among FOMREC members.

IV. The FOMREC administrative staff initially review the application to determine which review category the application falls under (expedited review or full board). The FOMREC administrative staff will then forward the application and the documentation to the FOMREC chair.

V. The FOMREC chair will confirm the expedited review determination and may review the application or may designate a member(s) to review the application.

VI. If the expedited review is to be carried out by FOMREC members designated by the chairperson, FOMREC administrative staff in consultation with the chairperson will communicate in writing to the member(s) requesting him or her to review the application through an expedited review process. The communication will include all information that is deemed vital in helping the member to review the application.

VII. Using the background information in this SOP and other supporting forms, the reviewer will make recommendations regarding the science and ethics of the application protocol and any other issue(s) that may arise.
VIII. During the review process, the reviewer may consult the investigator for more information or clarification regarding the application.

IX. If the reviewer(s) approves the expedited research,
   a. His/her determination-recommendation will be noted in writing (letter).
   b. This will be given to the FOMREC chairperson and administrative staff who will make copies of the correspondence for the FOMREC files and the appropriate files of the study.

X. If the reviewer(s) decides that the research may not be expedited:
   a. They will notify the FOMREC administrative staff chairperson to place the research on the next FOMREC meeting agenda;
   b. FOMREC administrative staff, through the chairperson, will then notify the Investigator of the determination-recommendation in writing.
   c. FOMREC administrative staff will make copies of the correspondence for the FOMREC files and the appropriate file(s) of the study.
   d. The reviewer(s) will then present the decisions and reasons to the convened FOMREC meeting for discussion, approval, disapproval, or for revisions.

XI. The full Board-committee will be advised of all expedited review procedures at the next regularly scheduled meeting and these will be documented and filed as minutes of FOMREC meetings.