SOP 006: SOP for Expedited Review of Research Protocols

Purpose

To describe and document the criteria for expedited review of applications submitted to HAUREC for ethical reviews that have been categorized as appropriate for such review by the chairperson HAUREC, or by HAUREC administrative team under SOP 003

Scope

Applies to all protocols and reports intended for expedited review

Responsible Persons

HAUREC chairperson and HAUREC members appointed by the chairperson to expedite review of application submitted to HAUREC

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 no 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.
- 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 HAUREC chairperson or his/her designee, do not meet the criteria or intent of a minor modification.

C. Research previously approved by a full committee will ideally be reviewed under full 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 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 HAUREC 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 committee, the changes must be reviewed by the full committee meeting.

Procedures

I. The HAUREC administrative team initially review the application to determine which review category the application falls under (expedited review or full board). The HAUREC administrative team will then forward the protocol and the documentation to the HAUREC chairperson as in SOP 003.

II. The HAUREC 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 HAUREC chairperson or by one or more reviewers designated by the chairperson from among HAUREC members.

IV. If the expedited review is to be carried out by HAUREC members designated by the chairperson, 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

V. Using the background information in this SOP and other supporting forms, the reviewer will make recommendations regarding the science and ethics of the protocol and any other issue(s) that may arise.

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

VII. If the reviewer (s) decides that the research may not be expedited:
    a. They will notify the chairperson to place the research on the next HAUREC meeting agenda;
    b. The chairperson will then notify the Investigator of the recommendation in writing.
    c. HAUREC administrative team will make copies of the correspondence for the HAUREC files and the appropriate file(s) of the study

d. The reviewer (s) will then present the decisions and reasons to the convened HAUREC meeting for discussion, approval, disapproval, or for revisions.

VIII. The full 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 HAUREC meetings