

SOP 003: SOP for Determining Review Category of Protocols and Reports for Ethical Review

Purpose

To describe and document the procedure for determining the review category of protocols and reports submitted to Hospice Africa Uganda Research and Ethics Committee (HAUREC) for ethical review.

Scope

Applies to all protocols and reports submitted to HAUREC

Responsible Persons

HAUREC administrative team and HAUREC chairperson

Background

HAUREC has authority to conduct initial review, continuing review, protocol amendments and protocol deviations reviews of any research activities involving the use of human participants conducted by, in collaboration with or at the Hospice of Africa Uganda. The review process can be by full committee review, expedited review, or exempted from further IRC review. The Chairperson of the committee, vice chair, a designated HAUREC member, or HAUREC administrative team shall decide which review category a particular application for ethical review will take, basing on information provided on the application form.

Procedures

After receiving and checking for completeness of a new application for ethical review, HAUREC administrative team will evaluate the application to determine which category of review process the application will take using the information indicated on the application form and advise the chairperson accordingly

a. Full committee review

In determining applications that will be reviewed by a full committee, attention will be given to the following;

- i. Significant risk studies (more than minimal risk studies)
- ii. The research intends to use vulnerable participants or the population to be involved in research warrants additional protection
- iii. Use of placebo
- iv. Deviation from standard of care
- v. Use of existing data, documents, records, pathological specimens or diagnostic specimens with personal identifiers
- vi. All clinical and non clinical trials

b. Expedited Review

Under the expedited review process, the review may be carried out by the HAUREC chairperson or by one or more experienced reviewers designated by the chairperson from among HAUREC members.

The reviewer may exercise all the authorities of HAUREC except disapproving/rejecting the application under review. Disapproving/rejecting an application after review shall only be done in a full committee review. Where the reviewer does not recommend approval of an application, the protocol or report shall be referred for review to the full committee

The following kinds of research may be reviewed through expedited review:

- i. Undergraduate research
- ii. Research that involves no more than minimal risk
- iii. If there are minor changes in the previously approved research during the period for which approval was authorized

c. Exempted from further HAUREC review

At the discretion of the chairperson of HAUREC, research may be exempted from further review. The following categories may be exempted:

- i. Research conducted in an educational setting on regular or special instructional strategies, curricula and classroom management methods
- ii. Research involving use of existing data, documents, records, pathological or diagnostic specimens if the sources of such materials are publicly available or if the information cannot be linked to the subjects