SOP 002: SOP for Submission of Protocols and Reports for review to HAUREC

Purpose

To describe and document the procedure for submission of protocols and reports for review to the Hospice Africa Uganda Research and Ethics Committee (HAUREC)

Scope

This SOP applies to all protocols and reports submitted for review to the Hospice Africa Uganda Research and Ethics Committee (HAUREC).

Responsible Persons

The Chairperson HAUREC, HAUREC administrative team and investigators.

Background

The Hospice Africa Uganda Research and Ethics Committee (HAUREC) has the mandate to perform the following functions:

- Conduct initial and continuing review of any research activities involving drugs, devices, biological, behavioral, psychosocial, educational and other biomedical studies prior to the start of the research
- Determine which studies need full committee or expedited review or those that need to be exempted
- Ensure prompt reporting to HAUREC of changes in research activities, unanticipated problems or protocol violations that may cause increased risk to the research participants or others
- Approve changes in research activities that happen after initial approval.
- Review and ensure adequacy of the informed consent document and process
- Suspend or terminate the research or revoke approval of any research under its review
- Monitor publications arising from approved research

Procedure

1. The investigator(s) must fill the relevant form(s) available at the research ethics committee administration office
2. The investigator(s) must pay the ethical review fees. Investigators should contact the HAUREC secretariat, or check online for the charge structure detailing the HAUREC application fees

A) Initial (New) Applications

The following must be submitted to the HAUREC secretariat at Hospice Africa Uganda;

i. Filled HAUREC Form 101 (2 copies) [See appendix I]
ii. Research Protocol (5 copies)
iii. Summary of protocol (5 copies) [See appendix I]
iv. Evidence of payment of application fees (Photocopy of receipt)
v. Soft copy of the submitted proposal
vi. Letter of approval from departments and/or the IRB of the collaborating institution(s) in case of collaborative research
vii. Minutes from departmental presentations/letter from head of department
viii. Data collection instruments
ix. Curriculum Vitaes (CVs), copies of academic qualifications of the principal investigator(s), certificates, adverts, press releases, brochures, and copies of practicing licenses for relevant persons involved in the study or studies

B) Continuing Annual Review

i. Filled HAUREC Form 102
ii. Annual progress report (Format to be indicated)
iii. Copy of letter of previous approval

C) Amendments Request

i. Filled REC Form 103
ii. Research proposal with track changes
iii. Clean copy of the changed protocol
iv. Soft copy of submitted proposal

D) Protocol Deviations/Protocol Violations

v. Filled REC Form 103
vi. Research proposal with track changes
vii. Soft copy of submitted proposal

E) Adverse Event/Severe Adverse Event Report

i. Filled HAUREC form 104

F) Termination/Study Close out

i. Filled HAUREC Form 105
ii. Full report

3. The HAUREC secretariat will cross-check for completeness of the submitted application, acknowledge receipt and give a protocol number

4. The HAUREC secretariat will, on weekly basis, present to the Chairperson of the committee a summary of protocols received so as to schedule the next meeting(s) for either full committee review, expedited review, or exempted from review.