

SOP 005: SOP for Taking Minutes and Communicating Decisions to Investigators

Purpose

To describe and document the procedure for recording HAUREC meeting minutes and communicating HAUREC decisions to investigators

Scope

Recording of minutes and communicating decisions to investigators.

Responsible Persons

HAUREC administrative team, HAUREC members assigned to review protocols and investigators

Background

Both national and international regulations require HAUREC to maintain adequate documentation of its activities. These minutes along with any other documents must provide sufficient detail about the deliberation, decisions and actions of HAUREC and its members.

Minutes will be taken at all HAUREC meetings including emergency meetings. Both soft and hard copies of the minutes and other HAUREC documents will be securely kept for a minimum of 10 years and then archived.

Procedures

- I. The minutes of HAUREC meetings will include but not be limited to the following:
 - II. Attendance of research and ethics committee members, co-opted members, HAUREC administrative team, investigators and other researchers present
 - III. Separate deliberations, actions and decisions made on each of the applications being reviewed including amendments and protocol deviations
 - IV. Report from expedited reviewer and discussion
 - V. Circumstances in which members with conflict of interest did not participate in deliberation and voting
 - VI. Any other discussions and decisions taken by HAUREC
- The HAUREC administrative team will prepare the minutes of the meeting in conjunction with the committee secretary and copies of which will be provided to HAUSREC members in a period of 1 week

- Investigators whose protocols were reviewed will receive communication in writing, within two (2) weeks, about HAUREC decisions detailing why the decision was made.
 - i. In case the decision made was; passed with minor changes, the reviewer of the corrections will be indicated. The investigator(s) will submit the corrected version of the protocol directly to the research administration office which will relay it to the designated reviewer
 - ii. In case major changes are required, the investigator shall be advised to resubmit the corrected version of the proposal/protocol.
 - iii. In case of a rejection, the investigator shall be given a summary of the reasons for the rejection
- An investigator who is dissatisfied with the decisions of the IRC may appeal to Uganda National Council of Science and Technology.
- Minutes will be kept on file at the HAUREC secretariat
- Approved proposals and consent forms shall be stamped and archived
- Approval letters shall contain protocol version and protocol number