

SOP 009: SOP for Reporting Adverse Events

Purpose

This SOP provides a procedure for the accurate and timely reporting of certain adverse events from the sites carrying out research approved by HAUREC. It also provides the necessary definitions and reporting period as recommended by the Uganda National Council for Science and Technology and other international Guidelines.

Scope

This SOP applies to all personnel involved in the review and conduct of studies by HAUREC

Personnel responsible

HAUREC administrative team, Chairperson HAUREC and HAUREC members

Background

After initiation of a study intervention, the study intervention should be closely monitored for its clinical safety. According to the Uganda National Council for Science and Technology Guidelines and other regional and international guidelines, all serious adverse events including events related to the underlying disease or the suspected intervention should be reported. The site investigator should promptly provide written/electronic reports to the Sponsor, HAUREC and the Data Safety Monitoring Board. Adverse Event reporting generally includes the reporting of any adverse event observed during an investigation, regardless of causality or severity.

Definitions

Adverse Events: Unfavorable and unintended diagnosis, symptom, sign (including an abnormal laboratory finding), syndrome or disease that occurs during a study, if absent at baseline, or if present at baseline, appears to worsen

Expected adverse event: An adverse event that is known to have occurred and is reported in the Investigator's brochure and as such, this event is included in the informed consent document

Unexpected Adverse Experience: any adverse experience which is not mentioned in the current investigator's brochure or consistent with the risk information described in the protocol. .

Serious Adverse Event: an adverse experience with a test article that results in any of the following: death, a life threatening experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, congenital birth defect or anomaly, or any other experience that may require medical or surgical intervention to prevent one of the serious outcomes.

Unanticipated Device Effect: any serious adverse effect on health or safety or any life threatening event or death caused by or associated with a device, if that effect, problem or death was not previously identified in the protocol or any problem associated with a device that relates to the rights safety or welfare of subjects.

Procedure

1. The Sponsor and principal investigator are responsible for reporting all unexpected adverse events and serious adverse events related to a test intervention to HAUREC. Fatal or life threatening events should be reported to the IRC within 3 working days of discovery. All other unexpected serious adverse events should be reported no later than ten working days from the day the Sponsor or Investigator becomes aware of the event.
2. The Investigator will use the Adverse Event Reporting Form for HAUREC for this reporting. Information should include the facts of the case, including the date of event, medical history of the subject, the event relationship to the test intervention or underlying condition, the likelihood of reoccurrence, and whether the event provides new risk information that should be added to the informed consent.
3. The principal investigator will be responsible for reporting serious adverse experiences to trial sponsors and HAUREC. However, he/she may delegate the data collection and communication of such events to appropriate clinical site research personnel. The principal investigator or another investigator on the clinical study will sign the SAE report prior to submission to HAUREC
4. Assignment of cause and effect of an adverse experience may not be clear. In order to assure that review of all serious adverse events is systematically undertaken, all studies that involve intervention with a diagnostic or therapeutic drug, biologic agent, device or procedure will have all serious unexpected adverse events reported to the HAUREC regardless of the probability of cause.

5. For reported deaths, the principal investigator or designee should supply the sponsor and HAUREC with any additional requested information (e.g., hospital records and autopsy reports).
6. The investigator must notify HAUREC of any safety reports, study monitor's reports, DSMB reports or reports from the Sponsor concerning safety from other research sites as received from sponsors by submitting such reports to HAUREC within 10 working days of receipt.
7. In the case of investigational drugs, if upon further evaluation of the SAE, the sponsor determines that the investigational drug presents an unreasonable and significant risk to subjects the sponsor may require the principal investigator to:
 - a. Discontinue the investigation
 - b. Notify HAUREC and clinical site research personnel that the study is being discontinued
 - c. Return all outstanding stock of Clinical Trial Materials (CTM)
8. The principal investigator is responsible for immediately discontinuing a trial upon receipt of notification from the sponsor in the event that the sponsor determines that an unanticipated adverse device event presents an unreasonable risk to study subjects. In order to resume a previously terminated study of a significant risk device, the principal investigator must submit a request to HAUREC and copy all HAUREC correspondence / approval to the sponsor.

How to Submit an Adverse Event Form

- a. Investigators should use the HAUREC Adverse Event Reporting Form 104 while reporting adverse events
- b. Each event should be reported on a separate form.
- c. Incomplete forms will be returned to the investigator for completion.
- d. Upon receipt of a serious adverse event report, the HAUREC administrative team will log the report into the database for the study and send a copy of the report to the Chairperson of HAUREC who may review it or designate a HAUREC member to review it.
- e. If designated HAUREC member is used, he will review the Adverse Event and may approve continuation of the study without modification to the protocol or Informed Consent, or approve continuation with minor changes to the protocol or Informed Consent on behalf of the HAUREC. The Reviewer may request a temporary suspension of a study if in his or her opinion continuation is likely to further expose participants to undue risk yet suspension will reduce such risk. However, the Reviewers cannot terminate a study. This action is reserved to a properly convened meeting of the HAUREC.

- f. The reviewer will prepare a report on the review which will be presented at the next convened HAUREC meeting.
- g. Should HAUREC require additional information, a letter will be sent to the investigator requesting additional information.
- h. All serious adverse events not reviewed by designated Reviewers will be reviewed by the full Board.
- i. A copy of all correspondence / reports will be kept in the appropriate HAUREC files and study files