SOP 007: SOP for Monitoring and Tracking of Research progress

Purpose

This SOP is to describe and document the operations taken by HAUREC in monitoring and tracking research activities at research sites. It also documents notification requirements and procedures regarding progress reports to HAUREC.

Scope

Applies to all research approved by HAUREC

Responsible Persons

HAUREC administrative team, HAUEC chairperson and HAUREC members

Background

HAUREC is mandated to protect human participants in research by conducting the initial and continuing review, and by carrying out passive and active monitoring of research activities. This process ensures that research activities comply with stipulated laws, regulations, guidelines and institutional policies right from the formative stage of research to its completion. After the initial approval of research, investigators are expected to comply with the reporting requirements of HAUREC. However, HAUREC is required to continuously monitor progress of research and to notify investigators when the reports are due. This is through passive monitoring otherwise HAUREC may actively do so by randomly selecting a study and visiting the study site for monitoring.

Monitoring and tracking of research activities during the course of the study is a dynamic process that should take place at defined intervals depending on the degree of risk as determined by the HAUREC and duration of the study, but at least once a year. All studies approved by HAUREC must comply with the reporting requirements until the study is completed. For investigators who do not comply with the reporting requirements, ethical approval will be withdrawn until their reports are submitted and the studies re-approved.

Procedures

HAUREC will passively or actively carry out its monitoring function. Passive monitoring will be performed through updating and scrutinizing its research data-base to identify studies whose reports are due and notify investigators accordingly. The reports will be reviewed and may trigger active monitoring. Active monitoring will involve HAUREC members visiting research sites to physically assess compliance to guidelines for research by the study site.

a) Non-field Oversight

1. HAUREC administrative team will be responsible for entering and maintaining a list of all studies approved by it. Communication of approval to the investigator will indicate the reporting requirement for the specific research.

2. The HAUREC administrative team will in the last week of every month generate a list of studies approved by HAUREC whose approvals are due to expire in the following month.

3. In collaboration with the Chairperson, the administrative team will generate and send notification letters reminding the investigator to submit the report 4 weeks before the report is due i.e. 4 weeks before expiry of approval and for closing studies 60 days before closure. The communication will be sent along with the required forms and instructions for submission.

4. If no response is obtained, the administrative team or designee will send repeat notices at approximately two weekly intervals.

5. The principal investigator may also be contacted if no response is received. The HAUREC Chairperson, Administrator or designee may perform this function.

6. A copy of the written requests, email copies, faxes and fax confirmations will be kept in the files of the study.

7. The expected response will include a completed HAUREC form together with all the necessary review materials. When these are received, the administrative team and the chairperson HAUREC will schedule them for continuing review either through expedited or full board review or exempted according to SOP 003

8. The investigator will then be notified following procedures in SOP 005

Field Oversight

Study sites may be selected randomly for routine monitoring or may be selected after deficiencies have been reported, or by site inspection following scheduled visits at the time HAUREC approves the research. Scheduled site inspections will depend on the amount of attention HAUREC intends to give to that specific research site which in turn will depend on the risk attributed to the research. It is helpful for monitors to be aware of where problems are most likely to arise during the conduct of a study. The following are the most likely areas;

- Non compliance to protocol
- Inadequate or inaccurate record keeping
- Problems with the informed consent process
- Failure to comply with HAUREC reporting requirements
- Failure to manage investigational articles/samples/materials
- Serious Adverse events
- Report of Scientific Misconduct

Routine Monitoring

I. The chairperson of HAUREC in consultation with the HAUREC members and the administrative team will randomly select sites that are to be visited for routine monitoring at least a month before the date of the visit.

II. The chairperson will then assign to each of the sites two members of HAUREC to carry out the site monitoring

III. The chairperson HAUREC will then inform, in writing, the PI of the site about the intended visit indicating the date

IV. The two selected HAUREC members will then visit the site and carry out the monitoring

Monitoring after Reported Deficiencies

I. When the chairperson of HAUREC receives a report of likely deficiencies at particular research sites either from whistle blowers or research participants, or problems identified from submitted reports, he or she will initiate a site inspection not more than 14 days from the day such a report was received.

II. The Chairperson or his/her designee, together with at least two other HAUREC members will conduct the site inspection

III. The inspection team will hold a meeting prior to the visit to discuss the reported deficiency and come up with a site inspection plan

IV. Depending on the gravity of the deficiency and the time available, the PI may or may not be notified about the intended visit

V. The inspection team will visit the site and make an assessment