1. **Purpose**

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

2. **Scope**

   Applies to all research approved by FOMREC

   This SOP applies to the FOMREC administrative staff, FOMREC chairperson, FOMREC members, and investigators whose research has been approved by FOMREC.

3. **Responsible Persons**

   FOMREC administrative staff, FOMREC chairperson and FOMREC members

4. **Background**

   FOMREC 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 FOMREC. However, FOMREC is required to continuously monitor progress of research and to notify investigators when the reports are due. This is through passive monitoring—otherwise—FOMREC 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 FOMREC and duration of the study, but at least once a year. All studies approved by FOMREC 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 For investigators who do not comply with the reporting requirements, ethical approval will be withdrawn until their reports are submitted and the studies re-approved.

5. **Procedures**
FOMREC will passively or actively carry out its monitoring function. Passive monitoring will be performed through updating and scrutinizing its research database 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 FOMREC members visiting research sites to physically assess compliance to guidelines for research by the study site.

a) Passive Monitoring: Non-field Oversight

1. FOMREC administrative staff 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 FOMREC administrative staff will in the last week of every month generate a list of studies approved by FOMREC whose approvals are due to expire in the following month.

3. In collaboration with the Chairperson, the administrative staff 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 IRB Administrator or designee will send repeat notices at approximately two weekly intervals.

5. The site-principal investigator may also be contacted if no response is received. The FOMREC 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 FOMREC form together with all the necessary review materials. When these are received, the administrative staff and the chairman FOMREC will schedule them for continuing review either through expedited or full board review or exempted according to SOP 004.

Active Monitoring: 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 FOMREC approves the research. Scheduled site inspections will depend on the amount of attention FOMREC 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 FOMREC reporting requirements
- Failure to manage investigational articles/samples/materials
- **Serious Adverse events**
- **Report of Scientific Misconduct**

1. **Routine Monitoring**
   
   I. The chairperson of FOMREC in consultation with the IRC members and the administrative staff will randomly select sites that are to be visited for routine monitoring at least a month before the date of the visit.

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

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

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

2. **Monitoring after Reported Deficiencies**

   I. When the chairperson of FOMREC 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 Chairman or his/her designee, together with at least two other FOMREC members will conduct the site inspection.

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

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

VI. The inspection team will visit the site and make an assessment.
3. **Scheduled site Inspections**

Monitoring visits may be scheduled at the time of approval of the research if the research presents more than minimal risk to the participants. The frequency of such visits will depend on the magnitude of risk such research presents.

I. The administrative staff will generate a list of studies that have scheduled site inspection visits and present it to the chairman of the FOMREC.

II. The chairperson of the FOMREC will write to the PI informing him/her about the intended visit indicating the date and areas the visit is likely to focus on.

III. The chairman will nominate two FOMREC members to carry out the monitoring visit.

IV. At least one of the members selected must have attended the meeting where the research study being conducted was approved.

V. During the inspection, the monitoring team will carry the following:
   a. a copy of the minutes of the meeting where the study was approved
   b. the version of protocol approved together with its appendices

VI. The chairman of the FOMREC will write to the PI informing him/her about the intended visit indicating the date and areas the visit is likely to focus on.

**Action to be taken after Monitoring Visits**

After the monitoring visit, the following will be done:

I. The monitoring team will make a report to the chairperson of the FOMREC.

II. The chairperson shall schedule discussion of the report at the next FOMREC meeting.

III. The report will be discussed and a decision will be made by the committee.

IV. The administrative staff will communicate the decision of the committee to the site not more than two weeks after it has been made.
V. Depending on the gravity of the site deficiencies, in consultation with the chairperson in consultation with the monitoring team and other FOMREC members may temporarily make decisions during the visit that they reasonably deem fit to confer protection to research participants.