MAKERERE UNIVERSITY FACULTY OF MEDICINE

SOP 002: SOP for Convening and Conducting FOMREC Meetings

1. **Purpose**
   To describe and document the procedure for convening and conducting FOMREC meetings

2. **Scope**
   This SOP applies to all FOMREC administrative staff, FOMREC members and Investigators who have submitted their applications to FOMREC

3. **Responsible Persons**
   Chairman FOMREC, Administrative staff, FOMREC members and Investigators

4. **Background**
   Generally, FOMREC meetings will be held once every week except during examination period of the university or public holidays. Schedule of meetings will be dictated by the number of submitted applications, and at the discretion of the chairperson.

   FOMREC meetings will be conducted in the Dean’s conference room unless it is not available. In this case, alternative space will be communicated to the investigators, supervisors and FOMREC members two (2) days before the scheduled time of the meeting.

   FOMREC meetings will be chaired by the designated chairperson and when absent, some body will, in writing, be delegated to chair the meeting. In case the chairperson or any other member of the committee has conflict of interest in the application under review, this will be documented and the individual will excuse himself/herself in the consensus process. If the conflict of interest is with the chairperson, another individual will be delegated to chair the meeting during deliberation involving such applications

5. **Procedures**
   - **Meeting invitations:** the research administrator or his/her designee will invite members of FOMREC in writing for the meeting. The invitation will include the agenda of the meeting. The agenda will at least include one or more of the following:
     a) Review of minutes of previous meeting
     b) A list of new protocols to be discussed
     c) A list of applications for renewal of approval
     d) A list of research status reports, AEs and SAEs, amendments and protocol deviations presented to FOMREC
     e) Any other business
Together with the invitation letter, FOMREC members will receive full protocols and reports to be reviewed and any other document that will facilitate them in effectively participating in the meeting at least one week before the meeting.

Principal investigators will also be invited to the review meetings by phone calls, email, in writing, or by short messages (sms). This will also involve the use of notice boards. For students, the invitation letter will clearly indicate that their supervisors must be present when their applications are being discussed.

- **Quorum**: the chairperson will call the meeting to order when at least five members of FOMREC including the chairperson (or any designated chairperson) are present. All members present including the investigators will record their names indicating the capacities in which they are attending the meeting. Meetings should start within 30 minutes after the time indicated in the invitation letter. If quorum is not raised after 30 minutes, the meeting will be postponed.

- **Conducting the meeting**:
  - Initial applications for review will be presented first and students will be given priority. Investigators will be required to make a 10 minute PowerPoint presentation and another 10 minutes for the committee to discuss the application. Decisions will be made by consensus. Where this fails, the issues will be brought to a vote. In case of a stalemate, the chairperson will give the casting vote.
    - One of the following decisions may be made:
      - Passed without changes
      - Passed with minor changes; in such a case, a FOMREC member will be nominated to review the revised protocol;
      - Major changes required i.e. change in the title, methodology or major changes in the informed consent. In this case, the proposal shall require a resubmission and presentation to the committee.
  - After all the initial (new) applications have been reviewed, applications for renewal will be discussed by the committee. These may not require presence of the investigator. However, at the discretion of the chairperson, the investigator may be called upon.
  - Status reports, AEs and SAEs reports will then be presented to the committee.
  - Administrative issues and any other business will then be discussed after the investigators have left the meeting.
  - A single sitting should not last beyond 3 hours. However, the chairman may extend the meeting beyond the three hours upon prior request and consensus of the members of the committee. Any unresolved business should be referred and discussed at the next meeting.