MAKERERE UNIVERSITY FACULTY OF MEDICINE

SOP 004: SOP for Determining Review Category of Protocols and Reports for Ethical Review

1. Purpose
   To describe and document the procedure for determining the review category of protocols and reports submitted to FOMREC for ethical review.

2. Scope
   Applies to all protocols and reports submitted to FOMREC.

3. Responsible Persons
   FOMREC administrative staff and FOMREC chairperson.

4. Background
   FOMREC has authority to conduct initial review, continuing review, protocol amendments and protocol deviations reviews of any research activities involving the use of human subjects conducted by, in collaboration with or at Makerere University Medical School. The review process can be by full board committee review, expedited review, or exempted from further IRB review. The Chairperson of the committee, or a designated FOMREC staff member, or FOMREC administrative staff are mandated to decide which review category a particular application for ethical review will take, basing on information provided on the application form.

5. Procedures
   After receiving and checking for completeness of a new application for ethical review, FOMREC administrative staff or the Chairperson will evaluate the application to determine which category of review process the application will take using the information indicated on the application form and advise the chairperson accordingly.

a. Full board committee review
   In determining applications that will be reviewed by a full board committee, attention will be given to the following:
   i. Significant risk studies (more than minimal risk studies)
   ii. The research intends to use vulnerable participants or the population to be involved in research warrants additional protection.
   iii. The research intends to use vulnerable subjects or FOMREC feels the population to be used warrants additional consideration.
   iv. Use of placebo.
   v. Deviation from standard of care.
   vi. Significant risk studies (more than minimal risk studies).
vii. Use of existing data, documents, records, pathological specimens or diagnostic specimens with personal identifiers

viii. **All clinical and nonclinical trials**
b. Expedited Review

Under the expedited review process, the review may be carried out by the FOMREC chairperson or by one or more experienced reviewers designated by the chairperson from among FOMREC members.

The reviewer may exercise all the authorities of FOMREC except disapproving/rejecting the application for review. Disapproving/rejecting an application for ethical review may only be done in a full board committee review. Where the reviewer does not recommend approval of an application, the protocol or report shall be referred for review to the full committee.

The following kinds of research may be reviewed through expedited review:

i. Undergraduate research
ii. Research that involves no more than minimal risk
iii. If there are minor changes in the previously approved research during the period for which approval was authorized

c. Exempted from further FOMREC review

At the discretion of the chairperson of FOMREC, research may be exempted from further review. The following categories may be exempted:

i. Research conducted in an educational setting on regular or special instructional strategies, curricula and classroom management methods
ii. Research involving use of existing data, documents, records, pathological or diagnostic specimens if the sources of such materials are publicly available or if the information cannot be linked to the subjects