MAKERERE UNIVERSITY FACULTY OF MEDICINE

SOP 001: SOP for Submission of Protocols and Reports for review to FOMREC

1. **Purpose**
   To describe and document the procedure for submission of protocols and reports for review to the Faculty of Medicine Research and Ethics Committee (FOMREC)

2. **Scope**
   This SOP applies to all protocols and reports submitted for review to the Faculty of Medicine Research and Ethics Committee (FOMREC).

3. **Responsible Persons**
   The Chairman FOMREC, research office administrative staff, and investigators.

4. **Background**
   The Faculty of Medicine Research and Ethics Committee (FOMREC) has the mandate to perform the following functions:
   - Conduct initial and continuing review of any research activities involving drugs, devices, biological, behavioral, psychosocial, educational and other biomedical studies prior to the start of the research
   - Determine which studies need full committee or expedited review or those that need to be exempted
   - Ensure prompt reporting to FOMREC of changes in research activities, unanticipated problems or protocol violations that may cause increased risk to the research participants or others
   - Approve changes in research activities that happen after initial approval.
   - Review and ensure adequacy of the informed consent document and process
   - Suspend or terminate the research or revoke approval of any research under its review
   - Monitor publications arising from approved research

5. **Procedure**

1. The investigator(s) must fill the relevant form(s) available at the research administration office
2. The investigator(s) must pay the ethical review fees. Investigators should contact the research administration office, or check online for the charge structure detailing the FOMREC application fees

A) **Initial (New) Applications**

   The following must be submitted to the research administration office at the Faculty of Medicine;
   i. Filled REC Form 101 (2 copies) [See appendix I]
ii. Research Protocol (11 copies)
iii. Summary of protocol (11 copies) [See appendix I]
iv. Evidence of payment of application fees (Photocopy of receipt)
v. Soft copy of the submitted proposal
vi. Letter of approval from departments and/or the IRB of the collaborating institution(s) in case of collaborative research
vii. Minutes from departmental presentations
viii. Data collection instruments
ix. Curriculum Vitae(s) (CVs), copies of academic qualifications of the principal investigator(s), certificates, adverts, press releases, brochures, and copies of practicing licenses for relevant persons involved in the study or studies

B) Continuing Annual Review
i. Filled REC Form 102
ii. Annual progress report (Format to be indicated)
iii. Copy of letter of previous approval

C) Amendments Request
i. Filled REC Form 103
ii. Research proposal with track changes
iii. Soft copy of submitted proposal

D) Protocol Deviations/Protocol Violations
iv. Filled REC Form 103
v. Research proposal with track changes
vi. Soft copy of submitted proposal

E) Termination/Study Close out
i. Filled REC Form 105
ii. Full report

F) Adverse Event/Severe Adverse Event Report
i. Filled REC form 104

3. The research administration office will cross-check for completeness of the submitted application, acknowledge receipt and give a protocol number

4. The research administration office will, on weekly basis, present to the Chairman of the committee a summary of protocols received so as to schedule the next meeting(s) for either full committee review, expedited review, or exempted from review.
APPLICATION TO CONDUCT HEALTH/MEDICAL RESEARCH

This form must be completed by all persons/teams intending to conduct health/medical research in Uganda. Upon completion by the investigator(s) it should be submitted to the Faculty of Medicine Research and Ethics committee (FOM-REC). Upon completion of the relevant section by the REC, the form should be submitted to the Secretary, Research and Ethics committee Makerere Medical School P. O Box 7072, Kampala. The required registration fee should accompany each application. Cheques should be made payable to: 1) Makerere University Faculty of Medicine if they are in local currency or 2) Makerere University Faculty of Medicine Research for foreign currency (Dollars, Euros etc) in the accounts office.

Protocol Version Number: .....................

APPLICATION FORM CHECKLIST

This checklist was prepared in order to aid investigators in preparing a complete application and to help expedite review by the Ethical Review Committee. Your cooperation in completing it will be greatly appreciated.

PRINCIPAL INVESTIGATOR’S NAME:  
(SITE PRINCIPAL INVESTIGATOR)  

E-mail:  

Contact cell/telephone number:  

☐ Application form duly completed in duplicate.  

☐ I will submit a soft copy of my proposal at application
Eleven copies of complete research protocol in general/funding agency format.
Eleven copies of informed consent forms in English and local language of the study population.
Eleven copies of Drug Brochure or any supplementary information (if applicable).
Eleven copies of Questionnaire being administered during the study (if applicable).
I have made a copy of this entire application package for my files.
For clinical trials – I have also submitted an application to NDA (if applicable).

------------------------------------------
Signature: Principal Investigator (At Site)  Date
## Details of Research Team

<table>
<thead>
<tr>
<th>Details</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Principal Investigator (P.I)</td>
<td></td>
</tr>
<tr>
<td>Nationality of P.I</td>
<td></td>
</tr>
<tr>
<td>Current Qualifications</td>
<td></td>
</tr>
<tr>
<td>Academic Title</td>
<td></td>
</tr>
<tr>
<td>Institution &amp; Dept.</td>
<td></td>
</tr>
<tr>
<td>Postal address</td>
<td></td>
</tr>
<tr>
<td>E-mail address</td>
<td></td>
</tr>
<tr>
<td>Telephone No.</td>
<td></td>
</tr>
<tr>
<td>Is this research expected to lead to the award of a higher degree? (Yes/No)</td>
<td></td>
</tr>
<tr>
<td>If yes, what degree?</td>
<td></td>
</tr>
<tr>
<td>University/Institution where registered</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Co-investigators</th>
<th>Qualifications</th>
<th>Institution/Department</th>
</tr>
</thead>
<tbody>
<tr>
<td>Names/Supervisors</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Details of the Proposed Research

<table>
<thead>
<tr>
<th>Details</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Title of proposed research.</td>
<td></td>
</tr>
<tr>
<td>Proposed Starting &amp; Ending Dates</td>
<td></td>
</tr>
<tr>
<td>Performance site(s) in Uganda</td>
<td></td>
</tr>
<tr>
<td>Performance sites (outside Uganda)</td>
<td></td>
</tr>
<tr>
<td>Total number of study investigators</td>
<td></td>
</tr>
<tr>
<td>Budget (state currency)</td>
<td></td>
</tr>
<tr>
<td>Name and address of Funding agency:</td>
<td></td>
</tr>
<tr>
<td>Status of funding :</td>
<td></td>
</tr>
<tr>
<td>a)Submitted for funding</td>
<td></td>
</tr>
<tr>
<td>b)Pending</td>
<td></td>
</tr>
<tr>
<td>c)Funded</td>
<td></td>
</tr>
<tr>
<td>d)Self</td>
<td></td>
</tr>
<tr>
<td>Beginning &amp; Ending Dates of Funding</td>
<td></td>
</tr>
</tbody>
</table>
### Collaborating Institutions

<table>
<thead>
<tr>
<th>No</th>
<th>Name of Institution</th>
<th>Institutional Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>2nd</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3rd</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4th</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5th</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Population: Proposed inclusion criteria

*(Check all that apply)*

- Males
- Females
- Foetuses
- Children (Under 12 years of age)
- Adolescents (12 – 17 years)
- Pregnant women
- Elderly (over 65 years)
- Prisoners
- Cognitively impaired
- Hospital patients
- Refugees
- Institutionalized
- Other

### Type of study *(check all that applies)*

- Cross-sectional/Survey
- Secondary data
- Program/Project evaluation
- Clinical community trial
- Case control
- Longitudinal study
- Record review
- Course activity
- Other (specify) ........................................

### Consent Process *(Check all that applies)*

- Written: 
- Oral: 
- English: 
- Local Language: 
- Other: (Specify) ........
Proposed sample size: .................................................................

Reading level of consent document:
Primary ☐ Secondary ☐ Tertiary ☐ Other ☐ (Specify)

Determination of Risk (Check all that applies)

<table>
<thead>
<tr>
<th>Does the research involve any of the following</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human exposure to ionizing radiation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Human genetics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stem Cells</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fetal tissue or abortus</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Investigational new drug</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Investigational new device or technique (e.g. therapeutic, diagnostic)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Existing data available via public archives/sources</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Existing data not available via public archives</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Observation of public behaviour</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the information going to be recorded in such a way that subjects can be identified</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the research deal with sensitive aspects of the subjects behaviour, sexual behavior, alcohol use or illegal conduct such as drug use</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Could the information recorded about the individual if it became known outside of the research, place the subject at risk of criminal prosecution or civil liability</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Could the information recorded about the individual if it became known outside of the research, damage the subjects financial standing, reputation and employability?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Do you consider the proposed research
  A) greater than minimal risk ☐
  B) minimal risk ☐
  C) no risk ☐

*Minimal risk is a risk where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical, psychological examinations or tests. For example the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examinations.*

- Do any of the participating investigators and or their immediate families have conflict of interest with the sponsor of the project or the manufacturer or owner of the drug or device under investigation or serve as a consultant to any of the above? YES ☐ NO ☐ (If yes, please submit a written statement of disclosure to the Chairman of the FOM-REC)
RESEARCH PROPOSAL SUMMARY

It is the REC requirement that the composition of the Institutional Review Board (IRB) include individuals with varied backgrounds and education. Investigators are therefore required to attach four (4) copies of a 2-3 page (maximum 4 pages) Research Proposal Summary using the headings provided below in terminology that is understandable across disciplines.

1. RESEARCH QUESTION TO BE ADDRESSED BY THIS PROPOSAL

2. RATIONALE FOR RESEARCH
   - Describe briefly the background of the study, and state reasons for conducting it.
   - State objectives of study.

3. METHODS
   - Study design and rationale for that design. Explain how the study will be performed.
   - Population: Sample size, selection and exclusion of subjects, gender. For larger sample sizes on greater than minimal risk studies, provide justification of the sample size.
   - Subject's state of physical health. Indicate if healthy, ill, seriously ill or terminally ill.
   - Does the study involve any special populations: Subjects will include, minors, fetuses, abortuses, pregnant women, prisoners, mentally retarded, mentally disabled, or none of the above.
   - If subjects are from one of the above special populations explain the necessity for including them.
   - Specify source of participating subjects, e.g. hospitals, clinics, institutions, prisons, industry, unions, schools, general population, etc. NOTE: If you plan to advertise for patients, the ad must be submitted to the FOM-REC for review and approval prior to its publication and/or posting.
   - List all research procedures and/or interventions involving human subjects (when applicable) including tests to be conducted and the analysis of samples (where applicable including where the analysis is to be done – if outside the country please justify including how the samples are to be shipped).
   - Distinguish procedures which are part of routine care from those that are part of the study.
   - Questionnaire/Interview instrument (when applicable)
     If the study includes either of these, a copy of the instrument is to be appended to this application. If the instrument is in development stages, provide an outline of the types of questions to be asked and the expected date of completion and submission to the MUREC.
   - Methods of intervention: Will any new drugs or biologic agents be administered to the subjects, or will previously used agents be used in a new manner? If yes, please note that you are also required to file a separate application with the National Drug Authority (NDA) and may not conduct your study without the approval of both the NDA and the FOM-REC. You are also required to complete the relevant part in this application titled “Studies involving the testing of drugs and medical devices”.
   - Methods for dealing with adverse events
   - Methods for dealing with illegal, reportable activities (e.g. child abuse)

RISKS / BENEFITS TO SUBJECTS
   - Highlight any potential risks - physical, psychological, social, legal, ethical (e.g. confidentiality), or other and assess the likelihood and seriousness of such risks (none, low, moderate, and high). Include the incidence of complications if known. You may use a narrative description if more appropriate or a table with 3 columns (potential adverse effects, seriousness and likelihood of complications. Incidence if known.)
   - Highlight procedures for protecting against or minimizing potential risks.
   - If the activity involves women who could become pregnant and is potentially harmful to a fetus, describe steps that will be taken to prevent pregnancy or exclude pregnant women.
   - Assess potential benefits to be gained by the individual subject and explain why the benefits outweigh the risks.
   - Assess benefits which may accrue to society in general as a result of the planned work.
COMPENSATION/REIMBURSEMENT

- Will subjects receive any compensation, monetary or other? If monetary, how much? Will subjects be asked to assume any out-of-pocket costs for participating in the research? If yes, what? Identify expenses such as additional transportation, laboratory tests, supplies, cost of study drug if it becomes commercially available, etc.

INFORMED CONSENT

- Any kind of contact with human subjects requires a disclosure/consent process.
- Attach a copy of the consent form. Indicate how (verbal or written) informed consent will be obtained (please request for guidelines for implementing informed consent from the MUREC Offices).
- If subjects are minors or mentally disabled, describe how and by whom permission will be granted.
- Where will the record of consent be stored? (Consent forms must be kept for three years after the completion of the investigation, unless otherwise stipulated by the MUREC).

CONFIDENTIALITY ASSURANCES

Describe any means by which the subject’s personal privacy is to be protected and confidentiality of data maintained. Include information on the following:

- Any sensitive information that will be gathered.
- Plans for record keeping
- Location of the data
- Data security
- Person responsible and telephone number
- Who will have access to the data
- Plans for disposal of the data upon completion of the study

CONFLICT OF INTEREST (real or apparent)

- Other than the normal scholarly gains, are there any other gains you might receive from taking part in this study?

COLLABORATIVE AGREEMENTS

- Provide letters of approval from collaborating institutions’ IRBs and from other local IRBs from other sites.

INTENDED USE OF RESULTS

- Include plans for dissemination and utilization of study results

OTHER INFORMATION:

- Any other information.

Please note: Attach 11 COPIES of the full research proposal. The full proposal should include the following: Title, objectives, background and literature review; methodology (to include research design, subjects and methods, ethical considerations, timetables etc. references, budget etc.). Investigators may submit the full proposal in the funding agency format as long as it covers the above headings.

Please also attach copies of curriculum vitae for the Principal Investigators and all Co-investigators. The CVs should include the following: Name, Postal address, Employers name and address, Qualifications, Present Position, past research experience (relevant) and Published Papers (relevant). Principal Investigators or co-investigators who would have already submitted their CVs during the current year are exempted from this requirement.
STUDIES INVOLVING THE TESTING OF DRUGS AND DEVICES

DRUG / DEVICE INFORMATION FORM

PROVIDE DOSSIER OR BROCHURE OF INVESTIGATIONAL DRUG/DEVICE
SIGNATURE ASSURANCE SHEET

Principal Investigator's Assurance Statement:

I certify that the information given by me is correct to the best of my knowledge; I am familiar with and understand the REC's policy concerning research involving human subjects (CIOMS Guidelines or Helsinki Declaration) and I agree:

(Please check all that applies)

1. To accept responsibility for the scientific and ethical conduct of this research study;
2. To obtain prior approval from the FOM-REC as well as the UNCST before amending or altering the research protocol or implementing changes in the approved consent form;
3. To immediately report to the FOM-REC and the UNCST any serious adverse reactions and/or unanticipated effects on subjects which may occur as a result of this study;
4. To complete and submit the Continuing annual Review Form annually (when due) as well as the Final/Study termination form at the end of the proposed study (if applicable).
5. To submit the final study report to the FOM-REC using a standard form.

<table>
<thead>
<tr>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Print name</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Signature of Co-investigator</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Print Name</td>
<td></td>
</tr>
</tbody>
</table>

SUBMIT APPLICATION PACKAGE TO THE FOM-REC OFFICES (The entire application package includes the application form, research proposal summary (2-3 pages), full research proposal (even in funding agency format), consent form and other relevant documents).

*******
RESEARCH AND ETHICS COMMITTEE REVIEW AND ENDORSEMENT REQUIRED

Statement from the Institutional Ethical Review Board:
The REC will only accept for review and approval research proposals that have been found both scientifically and ethically acceptable in accordance with the Guidelines on Institutional Ethical Review Boards.
We the Institutional Ethical Review Committee established by

..................................................................................................................
(Name of Institution conducting the research/in which the research is to be conducted)

do certify that we have reviewed the research proposal titled

..................................................................................................................

..................................................................................................................
submitted by

..................................................................................................................
We attest to the scientific and ethical merit of this study and the competency of the investigator(s) to conduct the project and do hereby recommend the proposal to the UNCST for approval.

SIGNATURES

<table>
<thead>
<tr>
<th>Signature: Head of Ethics Committee (or other authorized signatory)</th>
<th>Name (Please Print)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signature: Ethics Committee representative</td>
<td>Name (Please Print)</td>
</tr>
</tbody>
</table>

Contact Tel. Number : .................................................
..............................
E-mail address : ...................................................

OFFICIAL STAMP OF INSTITUTION
*Institution includes Universities, Hospitals, Research Institutes or Companies.