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MOUNTAINS OF THE MOON UNIVERSITY

RESEARCH ETHICS COMMITTEE STANDARD OPERATING PROCEDURES (SOPs)

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Acronyms

MMU	Mountains of the Moon University
CIOMS	Council for International Organizations of Medical Sciences
CRF	Case Report Forms
DGSRI	Directorate of Graduate Studies, Research and Innovation
DSMB	Data Safety Management Board
GCP	Good Clinical Practice
ICH	International Council for Harmonization of technical requirements for registration of Pharmaceuticals for Human Use
IND	Investigational New Drug
IREC	Institutional Research Ethics Committee
MTA	Material Transfer Agreement
PI	Principal Investigator
REC	Research Ethic Committee
SAE	Serious Adverse Events
SOP	Standard Operating Procedures
ToR	Terms of Reference
UNCST	Uganda National Council for Science and Technology
VC	Vice Chancellor
WHO	World Health Organization

Definition of Terms

Research Ethics Committee (REC) is a committee established in or by an organization to conduct initial and continuing review of research projects with the primary goal of protecting the rights and welfare of research participants.

Research participant means a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information.

Research involving humans as research participants is defined as any study involving persons, and directed to the advancement of biomedical or other knowledge, that cannot be regarded as an element in established clinical management, public health or social practices and that involves either physical or psychological intervention or assessment, or generation, storage, and analysis of records containing biomedical or other information referable to identifiable individuals and communities. Research involving humans as research participants also includes research on any material obtained from a research participant, whether the participant is still living or has died.

Lay member /lay person from the community refers to an individual whose primary background is not in scientific research involving human participants or animal subjects, and who is capable of sharing his/her insights about the community from which research participants and or animal subjects are likely to be drawn.

MMU-REC SOPs means a set of guidelines and/or standard operating procedures that will be followed by the constituted and accredited Research Ethics Committee in approving new/reviewing research applications for topics involving human subjects in both science and non-science areas within MMU and for other external applicants.

1 BACKGROUND

1.1 Mountains of the Moon University Philosophy

Transforming minds to enhance community engagement

1.2 Mountains of the Moon University Vision

To be a center of excellence in teaching, research and community engagement for sustainable development

1.3 Mountains of the Moon University Mission

To provide Innovative and transformative education, Research and Community engagement for socio-economic transformation

1.4 Mountains of the Moon University core values

Professionalism: Adherence to high ethical principles; truthfulness, fairness, doing what you say you will do and speaking forth about why you do what you do.

Innovativeness: Applying solutions that make everything better every day and embracing change.

Integrity: Being honest and trustworthy in our works.

Teamwork: Working together to achieve the best possible outcomes for all.

Social Responsibility: Committed to added value in whatever we do and act in a manner that benefits the people within and outside the University.

1.5 Mountains of the Moon University Mandate

To teach, research, facilitate learning and undertake engagement with local communities for socio-economic transformation.

1.6 The Need for REC Policy and Standard Operating Procedures

During the process of conducting research, some people have to bear the burden as study participants and to ensure that their rights and welfare are not compromised in the process, the Uganda National Council for science and Technology (UNCST) came up with the national guidelines to regulate the conduct of research in Uganda.

In lieu of the above, Mountains of the Moon University is coming up with this policy and Standard operation procedures (SOPs) in order to guide its community developing the research scope, review, approval and monitoring of research involving human participants and all biomedical research.

2 PREPARATION OF POLICY AND SOPs DOCUMENT

2.1 *Purpose*

The purpose of this document is to outline the procedures that will be followed by MMU-REC in approving and monitoring research involving human subjects along the whole lifespan of the project, in conformity with the accreditation standards provided for by UNCST.

2.2 *Scope*

These SOPs will be implemented alongside other synergistic policies and guidelines approved by Mountains of the Moon University.

The MMU-REC works according to internal rules that are described in written standard operating procedures. The SOPs are confidential but may be disclosed to authorities upon request. However, in order to maintain a transparent relationship with non-members of the MMU-IREC, certain procedures will form guidelines for use by investigators, scientific experts and by the DGSRI/Faculty personnel.

2.3 *Responsibility*

It is the responsibility of MMU-REC secretariat or designated persons to prepare or amend the institutional guideline as and when the need arises. The designated persons will manage the preparation/amendment of the guideline with the assistance of the Secretariat.

2.4 *Detailed instructions*

2.4.1 Approval of new/updated Guideline

i. The members of the MMU-REC shall prepare new guidelines or update an existing one as and when need arises.
ii. The Chairperson of the MMU-REC and the Vice Chancellor or his/her designate should approve each new or updated guidelines.

The final version approved by the Chairperson of the MMU-REC and the Vice Chancellor or his/her designate **shall be the one to be used.**

2.4.2 Information for personnel

- All members of the MMU-REC must read and understand a new or updated guidelines.
- Each member will sign a form indicating that they have read and understood the new or updated guidelines.
- If the guideline is for investigators/students/University personnel then they should be given a copy of the guidelines after taking their

signature.

2.4.3 Distribution of guidelines

i. Guidelines are confidential and may be disclosed for use by investigators, scientific experts and MMU-REC members.
ii. A log of guideline distribution should be maintained for inventory records.

3 CONSTITUTING AN ETHICS COMMITTEE

3.1 Purpose

The MMU-REC is established to provide independent guidance, advice and decision on health research or other specific research protocols involving human subjects.

The MMU-REC is composed of both scientists and non-scientists. It is independent in its reflection, advice, and decision.

These Standard operating procedures describe the terms of reference (ToR) which provide the framework for constitution, responsibilities and activities of the institutional review committee.

3.2 Scope

The SOP applies to all activities under the MMU-REC.

3.3 Responsibility

It is the responsibility of the MMU-REC members and secretariat to read, understand and respect the rules set by MMU.

3.4 Detailed instructions

3.4.1 Ethical basis

i. MMU recognizes that the protocols it approves may also be approved by Uganda National Council for Science and Technology (UNCST) prior to their implementation in specific localities.
ii. In evaluating protocols and ethical issues, the MMU-REC is aware of the diversity of laws, cultures and practices governing research and medical practice in various Countries around the world.
iii. It attempts to inform itself where possible of the requirements and conditions of the various localities where a proposed MMU research is being considered.
iv. The MMU-REC also seeks to be informed, as appropriate, by national (UNCST)/local ethics committees and researchers of the impact of the research it has approved.
v. The MMU-REC is guided in its reflection, advice, and decision by the ethical principles expressed in the Declaration of Helsinki 1964 and subsequent revisions.
vi. It makes further reference to the national and international ethical guidelines for biomedical research involving human subjects; (CIOMS), the

Belmont Report, and the European convention on human rights and biomedicine.

vii. MMU establishes its own standard operating procedures based on the operational guidelines for ethics committees that review biomedical research (WHO), the WHO & ICH Guidelines for Good clinical practices and the local regulations.

viii. The MMUU-REC seeks to fulfill the requirements for international assurances and function in accordance with the national law and regulations.

3.5 *Compositions of the MMU-REC*

i. The MMU-REC will be composed of **at least 5 voting members**

ii. Sixty (60) percent of the members including the chairperson shall be from outside the University as prescribed by the UNCST guidelines (2022 as amended)

iii. The members should have various backgrounds to promote complete and adequate review of research activities commonly conducted by the University.

iv. Professional qualifications may include physician, pharmacist, nurse, social scientist, lawyers, statistician, paramedic and/or layperson.

v. The MMU-REC will have gender parity.

3.6 *Membership requirement and term of Office*

i. The Vice Chancellor will appoint members of the Committee and present their names to Senate and sent to council for noting.

ii. Members are selected in their personal capacities, based on the interest, ethical and or scientific knowledge and expertise, as well as on their commitment and willingness to volunteer the necessary time and effort for the MMU-REC's work.

iii. Members must disclose in writing any conflict of interest in a project or proposal under consideration.

iv. The MMU-REC will decide the extent to which members that might have a conflict of interest may participate in bringing out an advice/decision, confidentiality/conflict of interest agreement.

v. Members will be required to swear and sign an oath of secrecy at the start of their term

vi. The oath of secrecy protects the privacy and confidentiality of all parties whose information may be disclosed to the MMU-REC in the course of their work.

vii. Members appointed shall serve for a period of 3 years renewable.

viii. Their appointments may be renewed by the Vice Chancellor for up to two consecutive terms.

3.7 Resignation, disqualification and replacement of members

i. A Member may resign his/her position by submitting a letter of resignation to the chairperson of the MMU-REC, who shall communicate to the Vice Chancellor through the Director Graduate Studies, Research and Innovation.

ii. A Member may also be disqualified from continuing to serve on the Committee should the chairperson provide information to the other members in writing justifying the disqualification and there is unanimous agreement. The disqualification of such a member shall be ratified by Senate and presented to the University council for noting.

iii. Members that have resigned or have been disqualified may be replaced by new people using the standard procedures of appointing members to the committee.

3.8 Co-opted Members

i. The MMU-REC may be further supported in its reflections on specific protocols or requests for advice on specific ethical issues by co-opted members.

ii. Co-opted members are appointed by the Vice Chancellor on the recommendation of the MMU-REC chairperson through the Director Graduate Studies, Research and Innovation.

iii. Their professional qualifications shall be determined by the committee and based on the need at hand but not limited. Co-opted members shall be appointed for the duration of the need sought to be addressed.

3.9 Conditions of appointment

Members and co-opted members are appointed to the MMU-REC under the following conditions;

i. Willingness to publicize his/her full name, profession and affiliation.

ii. All financial accountability, reimbursement for work and expenses, if any, within or related to the MMU-REC should be recorded and made available to the public upon request.

iii. All MMU-REC members and co-opted members must sign confidentiality/conflict of interest agreements regarding meeting deliberations, applications, information on research participants and related matters.

3.10 Officers

i. The following shall be the officers of the MMU-REC and their respective responsibilities.

Designation	Responsibility
Chairperson	Chair the meetings and liaise directly with the Vice Chancellor, report the meeting outcomes to the Vice Chancellor, invite co-opted members to provide special expertise to the REC on proposed research protocol.
Vice-chairperson	Responsible to chair the meetings in the absence of the chairperson and act as Vice-chair during meeting with the chairperson,
Secretary	Responsible for the administrative aspect of the REC.

ii. Except for the Chairperson who is directly designated by the Vice Chancellor during appointment, the other officers are elected by the MMU-REC members for a **three-year term**. They may be re-elected but for not more than one term. Should they resign or be disqualified, MMU-REC members elect a replacement until the completion of the term.

3.11 Secretariat

a) The secretariat is composed of the REC secretary and the administrative supporting staff.
b) The supporting staff are the staff members of Mountains of the Moon University headed by the Deputy Director Grants.
c) The secretariat shall have the following functions:
   i. Organizing an effective and efficient tracking procedure for each proposal received.
   ii. Preparation, maintenance and distribution of study files.
   iii. Organizing the MMMU-REC meetings regularly.
   iv. Preparation and maintenance of meeting agenda and minutes maintaining the MMU-RECs documentation and archive.
   v. Communication with the MMU-REC members and applicants.
   vi. Arrangement of training for personnel and MMU-REC members.
   vii. Organizing the preparation, review, revision and distribution of SOPs and guidelines.
   viii. Providing the necessary administrative support for REC related activities to the chairperson of the committee (e.g. communicating a decision to the applicant).

ix. Providing updates on relevant and contemporary issues related to ethics in health research, as well as relevant contemporary literature to the committee members.

3.12 Roles and responsibilities of MMU-REC members

i. Participate in the REC committee meetings
ii. Review, discuss and consider research proposals submitted for evaluation.
iii. Monitor serious adverse event reports and recommend appropriate action(s)
iv. Review the progress reports and monitor ongoing studies as appropriate.
v. Evaluate final reports and outcomes.
vi. Maintain confidentiality of the documents and deliberations of MMU-REC meetings.
vii. Declare any conflict of interest.
viii. Participate in continuing education activities.

3.13 Quorum Requirements

i. A minimum of 3 voting members should be present at any meeting.
ii. Should the area under consideration lack an expert in the quorum, the committee shall co-opt an expert who will provide information that may be required by the committee for making an informed decision.

3.14 Dissolution of MMU-REC

i. At any point in time, should Mountains of the Moon cease to exist, the MMU-REC shall automatically be dissolved.
ii. The MMU-REC may also be dissolved at any time by the Vice Chancellor with approval from the Mountains of the Moon University Senate and it shall be followed by a written notification to each of the members.

4 CONFIDENTIALITY/ CONFLICT OF INTEREST AGREEMENT

4.1 Purpose

The purpose of this section is to introduce a form about confidentiality / conflict of interest Agreement and identify who should read, understand, accept, keep in mind, sign and date the form. The procedure provides details when and where to sign as well as how the signed document should be kept.

4.2 Scope

This SOP covers the Agreement on both confidentiality and conflict of interest concerning information and procedures followed by the MMU-REC.

4.3 Responsibility

It is the responsibility of the newly –appointed MMU-REC members to read, understand, accept and sign the Agreement contained in the confidentiality /Conflict of interest form before beginning their ethical review tasks with Mountains of the Moon University to protect the rights of study participants.

4.4 Detailed instructions

4.4.1 Read the text carefully and thoroughly

Newly appointed members obtain two copies of the agreement from which they will complete and sign

4.4.2 Sign with consent

a) Sign and date both copies at the document before a member of secretariat
b) Give the forms back to a compliance officer (in this case Deputy Director Grants or any other designated MMU staff) to countersign and date
c) The members keep a copy as their record.

4.4.3 Keep the agreement in mind

a) The compliance officer keeps a copy of the signed agreement as the University's record.
b) Keep the copies in a confidential/ conflict of interest agreement file
c) Store the file in a secure cabinet with restricted key holders.

5 TRAINING PERSONEL AND ETHICS COMMITTEE MEMBERS

5.1 Purpose

The purpose of this section is to inform the MMU-REC personnel and members where training is necessary and the members should seek to occasionally attend training or workshop programs to up-date themselves on progress of technology, information and ethics.

Mountains of the Moon University recognizes the importance of training and continuing professional development. Therefore, the University will allocate an annual budget for specific training and study visits for MMU-REC personnel and

members. New MMU-REC members are required to undergo training programs prior to joining the committee.

5.2 Scope

The SOP applies to all personnel of the MMU-REC.

5.3 Responsibility

It is the responsibility of the MMU-REC members and support staff to have themselves educated and trained periodically.

5.4 Detailed instructions

5.4.1 Topic for training

MMU-REC members should maintain competence by ensuring they keep updated of their knowledge of national guidelines for research including:

i. UNCST national guidelines for research involving humans as research participants (2022)
ii. Good clinical practice (GCP)
iii. Declaration of Helsinki
iv. Ethical issues
v. Relevant laws
vi. Development in relevant science, technical and environmental, health and safety aspect
vii. Relevant requirements of health, safety and environmental laws and regulations and related documents
viii. Audit procedures.

An interchange of ideas, information and experience with overseas Universities and organizations related to research ethic should also be carried out. International cooperation is also necessary to discuss ways of tackling harmful information distraction and joint effort to tackle such distribution patterns. Efforts are being made to collect information on overseas trends and to attend international specialist meeting organized for exchange of experience and information.

5.5 How to get trained

i. Get information about training courses, workshops, conferences, etc. Which are periodically announced on websites, bulletin boards and various media channels.
ii. Select the one you need.
iii. Register to attend.
iv. Keep the receipt.

5.6 Keeping the training records

i. Fill the form to record the training/workshop/conference activities in chronological order.
ii. Make a copy of the form.
iii. Keep the original form as your record.
iv. Give the copy to the administrative staff to keep in the MMU-REC file.

Members CVs should be updated with such information.

6 SOP FOR CO-OPTING MEMBERS

6.1 Purpose

The purpose of this SOP section is to provide procedures for engaging an expert from a given profession as a coopted member to the MMU-REC.

6.2 Scope

If the chairperson or the MMU-REC determines that a study will involve procedures or information that is not within the area of expertise of the MMU-REC members, he/she may invite nominations of individuals with competence in the identified area. The invitations will require receiving CVs of potential nominees.

6.3 Responsibility

Upon the advice or recommendation of the secretariat or any MMU-REC member, it is the responsibility of the MMU-REC to nominate and approve the name of the member to be co-opted.

6.4 Detailed instructions

6.4.1 Selection of co-opted members

a) Identify the experts by the MMU-REC member and secretariat.
b) Nominate the members.
c) Conduct a qualification review of the prospective members.
d) Make decision based on expertise, availability and independence criteria.
e) Get approval from the MMU-REC.
f) Contact the members.
g) The members provide:
    i. A curriculum vitae
    ii. A signed professional services Agreement
    iii. A signed confidentiality/conflict of interest agreement
    iv. Keep the documents in a member file.
h) Create a roster of members and the areas of their expertise.

6.4.2 Co-opted members' services.

i. MMU-REC provides study protocol documents to the appropriate co-opted members for review.
ii. The co-opted members must complete a consultative report to be reviewed by the MMU-REC at the time the study is reviewed.
iii. The co-opted members may attend the MMU-REC meeting, presents the report and participate in the discussion but cannot vote
iv. The report becomes a permanent part of the study file

6.4.3 Termination of the services.

i. Services of the co-opted members may be terminated by either the members themselves or by the MMU-REC.
ii. Upon termination of the Co-opted member's service, the secretariat ensures that all the qualifying documentations and the reasons for discontinuation of the member are filed with the administrative documents.

7 MANAGEMENT OF PROTOCOL SUBMISSION

7.1 Purpose

This standard operation procedure is designed to describe how the secretariat of the University review committee (MMU-REC) manages protocol submission to the MMU-REC.

7.2 Scope

Protocol submissions include:

i. Submission for initial review
ii. Resubmissions of protocols with corrections
iii. Protocol amendment
iv. Continuing review of approved protocols
v. Protocol termination

7.3 Responsibility

It is the responsibility of the MMU-REC secretariat to receive, record, distribute for review and get submission packages approved by the MMU-REC, as well as to deliver the review result to the protocol applicants.

7.4 Detailed instructions

7.4.1 Receive submitted packages

(a). **Initial Review Application**

- Go to 9.4

(b). **Resubmission of protocols with corrections**

Retrieve the previous receipt form from the secretariat's records.

- Go to step 7.5.2 (A) (ii).

(c). **Protocol Amendment**

- Retrieve the previous receipt form from the secretariat's records.
- Go to step 7.5.2 (A) (iii).

(d). **Continuing Review of Approved Protocols**

- . Retrieve the previous receipt form from the secretariat's records.
- Go to step 7.5.2 (A) (iv).

(e). **Protocol Termination**

- Retrieve the previous receipt form from the secretariat's records.
- Go to step 7.5.2 (A) (V).

7.4.2 Check for submission items

(A). **Get relevant forms:**

(i). Initial **Review Application.**

- A checklist for contents of submitted package
- A document receipt form and an application form for initial review.
- Go to step 7.5.2 (B).
- For e-submission, go to 6.5.2(C).

(ii) **Resubmission of protocols with corrections**

- A checklist form
- A document receipt form
- A review form
- Go to step 7.5.2 (B).

(iii). **Protocol Amendments**

- Checklist for contents of a submitted packaged
- A document receipt from

- A re-review report form
- Go to step 7.5.2(B).

(IV) **Annual Continuing Reviews of Approved Protocols**

- A checklist for the submitted packaged
- A document receipt form
- A re-review report form
- Go to step 7.5.2.2

(v) **Protocol Terminations**

- A checklist for content for a submitted packaged
- A document receipt form
- A re-review report form
- Go to step 7.5.2.2

(B) **Fill in the forms:**

- Gives the forms to the applicant to fill up the relevant information.

(C) **Verify contents of submitted package**

a) Use the checklist for content of a submitted package
b) Check the applicable documents to ensure that all required forms and the materials are contained within the submitted package.
c) Verify contents of protocols submitted package to include:
   i. Original application form for initial review
   ii. Summary sheet or memorandum of the study protocol

Study protocol and protocol-related documents.

d) Check completeness of necessary information in the application for initial review.

e) Check the summary sheet or memorandum of the study protocol for inclusion of the followings:

i. Abstract
ii. Type of protocols (screening, survey, trial and phase)
iii. Objectives
iv. Anticipated outcome
v. Inclusion /Exclusion criteria
vi. Withdrawal or discontinuations criteria
vii. Modes of treatments studied
viii. Methodology (synopsis of study design)
ix. Analysis(methods)
x. Activity plan/Timeline
xi. IND Number (if applicable)
xii. Schedule and duration of treatments
xiii. Efficacy or Evaluation criteria(response/outcome)
xiv. Safety parameters criteria (Toxicity)

f) Check the submitted Protocol and Related Documents for the following contents:

i. Subjects information sheets
ii. Inform consent form
iii. Case record form (CRF)
iv. Study budget and budget justification
v. Agreement of the study
vi. Curriculum vitae (CV) of investigators
vii. Investigators' Brochure

(D) Verify electronic documents (where applicable)

i. Place the electronic computer documents (protocol summary, protocol and protocol-related documents) on the MMU-REC server or the local area network at the time of submission for initial protocol review or protocol amendment packages in the drive and folder:
ii. Verify the electronic version and the contents of documents match the copy submitted by comparing a hard copy of electronic document with he submitted one.
iii. Printout the protocol documents.
iv. Verify the correctness of the documents.
v. Check that all pages of the documents have been included and submitted protocol and protocol-related documents do not have missing pages.
vi. Certify the printed hard copy in the same manner as the submitted document(s) with the dated signature.
vii. Stamp and assign a running number to received protocols, applying the system of 6 digits with running number of year in the first two boxes, then slash sign and the last two digits of the year, followed by a dash sign and the month.
viii. Count for correct number of copies.
ix. Store the hard copy of the electronic document with the submitted documents.
x. Use the assigned running number of the protocol as the labeled name.
xi. Identify clearly as the hard copy of the electronic document.

(E) Create a Protocol Specific File

i. Get the" **Protocol Submission**" file.
ii. Record the name and the number of the submitted protocol.
iii. Record the receiving date and name of the receiver

7.4.3 Complete the submission process

i. Get the form back from the applicants.
ii. Check the completeness of information.
iii. Notify the applicants if a package is incomplete.
iv. State clearly the items missing in the package.
v. Fill up the related parts and missing documents.
vi. Stamp the receiving date on the letter and the first page of the documents.
vii. Initial the receiver's name on the receiving documents.
viii. Make a photocopy of the completed form.
ix. Return the original copy of the form to the applicants for their records.
x. Attach the filled checklist with the copy of the form with a staple.
xi. Keep the copy of the document receipt form in the "**Protocol Receipt** "file
xii. Attach an initial review application form to the research protocol packages.
xiii. Keep the copy of the submitted documents with the original signatures in the "submission "file.

7.4.4 Store the received packages

i. Bind the packages together appropriately
ii. Store the dated and initial original protocol packages on the MMU-REC submission shelf for review in FIFO sequence.

8 USE OF ASSESSMENT FORM

8.1 Purpose

This SOP describes show the MMU-REC members use the assessment forms when reviewing the study protocols initially submitted for approval. The Assessment form is designed to standardize the review process and to facilitate reporting, recommendation and comments given to each individual protocol.

8.2 Scope

This SOP applies to the review and assessment of all protocol submitted for initial review and approval from the MMU-REC. The specific questions in the assessment form must be adequately addressed in the protocol itself and/or protocol-related documents under review.

8.3 Responsibility

It is the responsibility of the reviewers to fill the assessment form along with decision and comments they might have after reviewing each study protocol. The MMU-REC secretariat is responsible for recording and filing the decision, relevant points and deliberation about a specific protocol, including the reasons

for that decision. The chairperson of Mountains of the Moon University REC or his Vice (in the absence of the chairperson) must sign and date to approve the decision in the form.

8.4 Detailed instructions

8.4.1 Summarize the Protocol in an Application Assessment Form

(A). General Protocol Information

i. **Record general information about the protocol in the form such as:**

a) Title of the protocol
b) Protocol number and date
c) Principal investigators, license and contact number
d) Co-investigators and contact number
e) Funding agency and contact number
f) Study types
g) Duration of the study
h) Status of the protocol-New/Revised/Amended
i) Review status-Regular/Expedited/Emergency
j) Reviewers name
k) Objective and description of the study

8.4.2 Review the study protocol

i. Scientific merit
ii. Background of the study
iii. Need for human participants for study
iv. Objectives of the study
v. Review of Literature
vi. Sample size
vii. Methodology and date management
viii. Inclusions/exclusions criteria
ix. Control arms (Placebo, if any)
x. Withdrawal or discontinuation criteria

8.4.3 Examine the qualification of investigators and of study sites

i. Consider whether study and training background of the participating investigators relate to the study.
ii. Examine disclosure or declaration of potential conflicts of interest.
iii. Can facilities and infrastructure at study sites accommodate the study?

8.4.4 Review study participation

i. Voluntary, non-coercive recruitment/participation

ii. Procedures for obtaining informed consent
iii. Contents of the patient information sheet
iv. Contents and language of the informed consent document
v. Translation of the informed consents document in the local
vi. Language used-plain and easy to understand by general public
vii. Contact persons with address and phone numbers
viii. Privacy and confidentiality
ix. Risks-physical/mental/social
x. Benefits-to participants and to others
xi. Compensation - Reasonable/unreasonable
xii. Involvement of vulnerable participants
xiii. Provisions for medical/psychosocial support
xiv. Treatment for study related injuries
xv. Use of biological materials

8.4.5 Examine community involvement and impact

i. Community consultation
ii. Involvement of local researchers and University in the protocol design, analysis and publication of the results
iii. Contribution to development of local capacity for research and treatment
iv. Benefit to local communities
v. Availability of study results

8.4.6 The reviewer makes a decision

i. Get the assessment report form
ii. Record the decision by marking in the desired block any of the following:
iii. "Approved, Approved with recommendations, resubmitted, or disapproved"
iv. Check the completeness and correctness of the assessment form.
v. Sign and date the decision form.
vi. Give or send the complete forms to the MMU-REC secretariat.

8.4.7 Gather the assessment reports

i. Collect the assessment forms and the review result from each reviewer.
ii. Organize the form in order.
iii. Summarize the comments, suggestions, and opinions of each stud in the meeting agenda.
iv. Follow SOP preparation of meeting agenda and minutes.

8.4.8 Record the MMU-REC decision

i. Get the MMU-REC decision form

ii. Complete the information. (by the secretariat)
iii. List participating members and their votes.
iv. Summarize the guidance, advice and decision reached by the MMU-REC members.
v. Sign and date the document. (by the chairperson of the MMU-REC where applicable)
vi. Make a copy of the completed decision form.
vii. Keep the original copy in the file labeled "MMU-RECs decision".
viii. Keep the copy of the decision form with the study protocol
ix. Return the file and the protocol to the appropriate shelves.

9 INITIAL REVIEW OF APPLICATION PROTOCOL

9.1 Purpose

This standard operating procedure describes how the University REC manages to review an initially submitted protocol.

9.2 Scope

This SOP applies to the review process of the study protocol package submitted for the first time

9.3 Responsibility

It is the responsibility of the assigned reviewers to thoroughly review the study protocols delivered to them, give their decision, observation and comments to the MMU-REC in the Assessment Form and return to the secretariat office on the due date.

The MMU-REC secretariat is responsible for receiving, verifying and managing the contents of the both copies and the electronic version of the received packages. In addition, the secretariat should create a protocol specific file, distribute the packages and get them reviewed by the MMU-REC and deliver the review results to the applicants.

9.4 Detailed instructions

9.4.1 Receive the distributed protocol package

i. Check the distributed package

ii. Sign and date an acknowledgement form upon receiving the packages.
iii. Return the receipt form back to the delivery person/MMU-REC secretariat

9.4.2 Verify the contents of the package

i. Look for an Assessment form.
ii. Look for the due date for the review.
iii. Check the meeting date to see if he/she is available to attend the meeting.
iv. Notify the MMU-REC secretariat if there are documents missing, or the specified date cannot be met.

9.4.3 Review the protocol

(A). **Initial Review Application Form**

i. Check the form for completeness of the information and signatures of the principal investigator, the protocol chairperson (if applicable), the MMU-REC chairperson and secretariat.
ii. Check and attach the initial Review Application to the Research protocol.

(B). **Assessment Form**

a) Use the Assessment form to guide the review and deliberation process.

- **Note:** The completed Assessment Form is the official record of the decision reached by the MMU-REC for the specific protocol.

b) Consider the following criteria when performing the review:

i. Minimize risks to participants.
ii. Risks must be reasonable in relation to anticipated benefits.
iii. Participants are selected equitably.
iv. Informed consent is adequate, easy to understand and properly documented.
v. The research plan makes adequate provision for monitoring the date collected to ensure the safety of participants, where appropriate.
vi. There are adequate provisions to protect the privacy of participants and to maintain the confidentiality of date, where appropriate.
vii. Appropriate safeguards are included to protect vulnerable participants
viii. Make comments where appropriate.
ix. Sign and date the reviewer's name.

9.4.4 MMU-REC meeting

i. The primary reviewer presents a brief oral or written summary of the study design and his/her comments.
ii. The chairperson entertains discussion on each document under consideration (e.g., protocol, informed consent, investigators and site qualifications, advertisements).
iii. Recommendations for modifications to the protocol, consent form, and/or advertisements as requested by the committee are noted in the meeting minutes as with modifications made by MMU-REC' and will be communicated to the investigator.
iv. The chairperson calls for a separate vote on each element in review. The committee votes to either:
v. Approve the study to start as presented with no modifications
vi. Approve the study to start with committee approved modifications to the consent = Approved with recommendation.
vii. Require modifications to items noted at the convened meeting and follow-up by the chairperson, after receipt of the requested modifications = Approved with recommendation
i. Require modifications to the items and full committee review of the materials = Approved with stipulation or resubmission
ii. Request further information regarding the item and full committee re-review of the material = Approved with stipulation or resubmission for re-review.
iii. Not approve the study, stating the reason for disapproval = Disapproved

If the study is approved, the committee determines the frequency of continuing review from each investigator.

i. The secretariat sends action letter along with the approved document to the investigator.
ii. The letter contains, at a minimum, a listing of each document approved, the date set by the committee for frequency of continuing review, and a review of other obligations and expectation from the investigator throughout the course of the study.
iii. A computer-generated approval and expiration date is stamped/placed on every page of each consent form approved by the Mountains of the Moon University.

If the votes are not to approve the study, the secretariat immediately notifies the investigator in writing about the decision and not to approving the study.

If the investigator wishes to appeal to the decision, he/she may do so by contacting the MMU-REC secretariat.

i. The appeal process is stated by the action latter to the investigator.

If the committee requires modification to any of the documents,

i. the secretariat either generates the revisions to the documents, or sends the written request of the specific changes to the investigator asking him or her to make the necessary changes and resubmit the documents to the MMU-REC or chairperson.

9.4.5 Preliminary communication of the Decision

(a) **communication of the decision**

i. The chairperson sends an electronic version of the completed Assessment form to the secretariat of the University within one working day whenever possible, but not later than 5 working days after the review has taken place.
ii. The secretariat, in turn forwards the committee decision to the principal investigator (e.g. via e-mail) and files sent or received e-mail messages in the protocol file.

9.4.6 Final communication of the Decision

(a) **Signature of Approval**

i. Obtain and complete the appropriate forms, after a decision has been reached by the MMU-REC.
ii. Get signature from the chairperson
iii. Date the form.

(b) **The Assessment form**

i. Complete the Assessment form.
ii. Get signature of the chairperson.
iii. Maintain the completed Assessment form and the minutes of the meeting relevant to the protocol review.
iv. Process the above tasks within 5 working days after the meeting.

(c) **The Application Review Form**

i. Get the chairperson to sign and date the original version of this form within 5 working days and return this to the secretariat.
ii. Assign the Mountains of the Moon University members at the bottom boxes on the last page of the form by filling in the boxes with numbers in

sequential order, the approval sequence in the first three boxes, the current month after the slash and the current year after the dash sign.

Example:

A protocol, submitted in January of the year 2024 and it is the 12 protocol approved by the MMU-REC in that year, would be numbered as MMU-REC 012/01-24.

- Sign and date the form by the secretariat.

(d) **The Action letter**

i. Prepare an action letter to inform the investigator or the project manager about the committee's decision.
ii. State clearly the actions that need to be taken by the investigator.
iii. For the decision disapproval, a notifying letter to the investigator or the project manager should state the followings.
iv. If you wish to appeal to this decision, please contact the MMU-REC and submit your appeal in writing, addressed to the MMU-REC chairperson with justification as to why the appeal should be granted.
v. Verify the correctness of the wordings and spelling.
vi. Send the action letter to the applicant within 7 working days.

9.4.7 Storage of the Documents

- Keep a copy of the Action Letter in the Correspondence file.
- Place the original documents of the application review and the Assessment forms in sequence of approval number in the Approved file.
- Store the file on an appropriate shelf in the designated cabinet.
- Documents should be kept for a period of 5 years after completion of the research project.

10 EXPEDITED REVIEW

10.1 Purpose

The purpose of this SOP is to provide criteria for determining which study protocols can be reviewed through **expedited** process as well as instructions on management, review and **Approval of the expedited** review.

10.2 Scope

This SOP applies to the review and approval of study proposals with minimum risk to participants, protocol amendments or informed consent changes of currently approved studies.

10.3 Responsibility

It is the responsibility of the MMU-REC members to define which study protocols should be reviewed and approved through expedited channel.

10.4 Detailed instructions

10.4.1 Receive the submitted documents

i. Receive the application documents submitted by investigators.
ii. Get content of submitted package (checklist) form, to check items received.
iii. Stamp the receiving date on the letter and the documents.
iv. Sign the receivers name on the receiving documents.
v. Hand the received documents to the MMU-REC secretariat.

10.4.2 Determine protocols for expedited review

- MMU-REC Secretariat determines whether a study is qualified for expedited review according to the following criteria:

(a) Modification /amendment of protocol

i. ***Administrative revisions,*** such as correction of typing errors
ii. Addition or deletion of ***non-procedural items***, such as the addition of study personal names, laboratories, etc.
iii. ***Non-significant risk*** research activity.
iv. The research activity includes only minor changes from previously approved protocol.

(b) Proposals involve interviewing of a non-confidential nature (not of a private e.g. related to sexual preference etc), not likely to harm the status or interest of the individual and not likely to offend the sensibility of the people involved.

(c) Those that involve collection of small amount of blood samples (and not too frequent) e.g. by finger, heel or ear stick.

(d) Those that involve collection of biological specimen for research by non-invasive means (e.g. collection of body fluids or excreta non-invasively, collection of hair or nail clippings in a non-disfiguring or non-threatening manner).

(e) Collection of data for research purposes through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice and using medical devices which have been already approved for use. Examples of such procedures include collection of data through application of EEG or ECG electrodes, acoustic testing, tests using the Doppler principal, non-invasive blood pressure and other routine clinical measurements, exercise tolerance etc. however procedures involving the use of x-rays or microwaves are not recommended for expedited review.

(f) Research involving data, documents or specimens that have been already collected or will be collected for ongoing medical treatment or diagnosis.

(g) Continuing review of research previously approved with no modifications to the original protocol and studies taken place and no additional risks have been identified.

If the protocol satisfied any of the criteria for expedited review, the secretariat will send the protocol to Chairperson.

10.4.3 Expedited Process

i. Chairperson nominates 2 or more MMU-REC members to review the received protocol.
ii. The selected members are normally those who received and recommended the previous version of that protocol, if it is not submitted for the first time.
iii. The secretariat sends the revised protocol to the selected members.
iv. Carryout the expedited review on the complete proposal (study protocol with all the attached documents as mentioned in the guidelines for submission of proposals.
v. The review may be made either by circulation of comments, telephone discussion or meeting.
vi. If consensus cannot be reached, the chairperson will refer the proposal back to the MMU-REC for a full review.
vii. The expedited review should not take longer than 2 weeks.
viii. Inform the MMU-REC of the proposals approved by expedited review at its regular meetings.
ix. If any committee member raises concern about any of the proposals presented to it as expedited review, then that proposal shall undergo a regular review.

10.4.4 Communicate with the MMU-REC and the investigator

i. The reviewers forward their comments to the Secretariat.
ii. Full Board notification of items approved through expedited review by the Chairperson or the designee is accomplished by providing notification and source documentation of the items in the meeting agenda / notes.
iii. The MMU-REC Secretariat communicates the decision to the investigator.

11 REVIEW OF PROTOCOL AMENDMENTS

11.1 Purpose

The purpose of this procedure is to describe how protocol amendments are managed and reviewed by the MMU-REC.

11.2 Scope

This SOP applies to previously approved study protocols but later being amended and submitted for approval by the MMU-REC. Amendments made to protocols may not be implemented until the MMU-REC.

11.3 Responsibility

It is the responsibility of the MMU-REC Secretariat to manage protocol amendments.

Investigators may amend the contents of protocols from time to time. Protocol amendments may be submitted for either "expedited" review by the Chairperson /Secretariat/ reviewers or full MMU-REC review.

11.4 Detailed instructions

11.4.1 Manage the Amendment package

a) The amendment package is prepared by the PI.

b) Upon receipt of the package, the secretariat of the MMU-REC should follow the receiving procedure in (management of protocol submission) and.

c) Procedure for maintaining confidentiality of MMU-REC documents.

d) **Request for Amendment Memorandum of the protocol by the principal investigator on an existing and previously approved protocol.**

The memorandum should:

i. State/describe the amendment
ii. Provide the reason for amendment
iii. State any untoward effects with original protocol
iv. State expected untoward effects because of the amendment.

Original Amendment submission form

a. Check for completeness and for presence of the required signatures (principal investigator or medical Advisor of the institute, if applicable).

Protocol and related documents

b. The amended version of the protocol and related documents should be provided.
c. The changes or modification should be underlined or highlighted.

11.4.2 Notify the chairperson of the MMU-REC

a. Upon receipt of the amendment package, the Secretariat should inform the Chairperson of the MMU-REC verbally or in writing.
b. Keep "Sent" or "Received" mail related to the notification of the Chairperson in the protocol file under the Correspondence section.
c. Send the request for amendment memorandum and the protocol and the related documents to the Chairperson within one working day of receipt by the Secretariat.
d. Follow MMU-REC in preparing and distributing the documents.
e. After review of the materials, the Chairperson will determine whether the protocol requires expedited or full review.

11.4.3 Determine whether expedited or full review

a. Refer to Expedited Review.
b. Refer to Full Review.
c. Protocol amendment which increase risk to study participants, as judged by the Chairperson, such as change in the study design, which may include but is not limited to:
   i. additional treatments or the deletion of treatments
   ii. any change s in inclusion/exclusion criteria
   iii. change in the method of dosage formulation, such as, oral changed to intravenous
   iv. significant change in the number of subjects (Increase: If there are <20 subjects enrolled, change of 5 is significant, if there are > 20 subjects enrolled, a change of 20% is significant- Decrease: if decrease in the number of subjects is alters the fundamental characteristics of the study, it is significant)
   v. significant decrease or increase in dosage amount
   vi. If the Chairperson decides the protocol requires full MMU-REC approval, the Chairperson will indicate this decision on the Checklist, sign and date the form.
   vii. The Secretariat places the protocol amendment request on the agenda for the next convened meeting.

viii. The following documents are distributed to each MMU-REC member:

- The amendment's revision documents to clearly identify each change
- Requested changes to the consent form, if applicable
- If an amendment is received just prior to the MMU-REC meeting, the Chairperson may decide to review the amendment in full MMU-REC, even though the amendment may be expedited.

11.4.4 Expedited Review

- Refer to expedited review procedure.

11.4.5 Full Review by the MMU-REC

- Refer to full Board Review.
- See section 9.4.

11.4.6 Protocol Amendment Review Process

i. Use the process outlined in the Application Assessment Form to review amended protocol-related documents.

ii. Note recommendations for changes to the protocol and/or informed consent requested by MMU-REC Members in the minutes as "with modifications made by Mountains of the Moon University" and will be communicated to the trial office or investigator.

iii. The Chairperson calls for a vote on the proposed amendment to:

a) Approve the protocol amendment with no modification of the informed consent.

b) Require a modification to the proposed amendment or informed consent documents, stating the reason and action required to sustain the study with follow-up by the Chairperson.

c) Require a modification to the proposed amendment or informed consent documents, stating the reason and action required to sustain the study with a follow-up full MMU-REC review.

d) Suspend the study, until further information is obtained.

e) Not suspend the study as currently approved, but request further information regarding the amendment and the effects of the amendment son the approved study.

f) Not approve the amendment request, stating the reason-but allow the study to continue as previously approved.

g) If the MMU-REC approves the protocol amendment, Secretariat staff communicates this decision to the investigator.

h) If the MMU-REC does not approve the protocol amendment, the Chairperson immediately notifies the investigator in writing of the decision and the reason for not approving the amendment.

i) If the MMU-REC votes to require modifications to any of the documents, or protocol amendment, the Secretariat sends a written request about the

specific changes to the investigator asking him or her to make the necessary changes and submit the documents to *Mountains of the Moon University* Review Committee.

j) The Chairperson completes a decision form after the MMU-REC has reached its decision.

k) Keep the forms, minutes of the meeting relevant to the discussion and the decision reached by the MMU-REC as the official records of the amendment review process.

(B) Communication of the Decision

The Chairperson notifies the Principal Investigator after the MMU-REC meeting and in writing as soon as possible, but not later than 7 working days following the review.

The Chairperson must send an electronic version a copy of the Amendment Submission Form with her/his signature and date of approval to the Secretariat not later than one day or whenever possible, but no later than 3 working days after the review has taken place.

(C) Completion of the Amendment Submission Form

i. The Chairperson must sign and date original version of this form and return this to the Secretariat no later than 5 working days after the review.

ii. Addition of amendment to the protocol Number.

a) The Secretariat assigns a letter to the protocol number that corresponds to the number of the amendment. For example:

b) The amendment to Mountains of the Moon University 012/01-24 would be formatted as: Mountains of the Moon University 012/01-24 **C.**

iii. Record the amended protocol number on the form.

iv. The Secretariat signs and dates the original version of the form.

11.4.7 Notifying the Principal Investigator

- Send a signed and dated Amendment Submission Form to the Principal Investigator (P.I) for their records no later than 7 working days.
- The Clinical Trials or the P.I. should then provide a "clean" copy *(underlining and highlighting re moved)* of the protocol and related documents as well as the "clean electronic version (where applicable). To the Secretariat of the MMU-REC.

11.4.8 Store documents

- Place the original completed documents, the "clean" version of the protocol and related documents in the protocol file with the other documents pertaining to the documents.

12 REVIEWS OF RESUBMITTED PROTOCOLS

12.1 Purpose

This procedure describes how resubmitted study protocols are managed, re-reviewed and approved by the MMU-REC.

12.2 Scope

This SOP applies to study protocols that have been reviewed earlier with recommendations from MMU-REC for some corrections in the initial review process.

12.3 Responsibility

It is the responsibility of the MMU-REC Secretariat to ensure the completeness of the resubmitted documents and to notify the Chairperson that a protocol previously approved with conditions for revision has been resubmitted to the MMU-REC for reconsideration.

A re-submitted protocol will be reviewed and approved by either the Chairperson or some MMU-REC members/reviewers, or full MMU-REC. How the protocol will be reviewed should have been determined by the MMU-REC at the time of the initial review. This information can be found on the Decision Section of the Assessment Form.

12.4 Detailed instruction

12.4.1 Receive protocol resubmitted package

a) Check the distributed package for:

i. Memorandum addressing the corrections.

ii. Initial Review Application form

iii Revised version of protocol and related documents such as the informed consent document, date collection or case report forms, diary sheets, etc are included as part of the package.

v. Change made to the documents should be underlined or highlighted.

c) Sign and date an acknowledgement form upon receiving the packages.

d) Return the receipt from back to the delivery person, MMU-REC secretariat.

12.4.2 Review the revised protocol

i. Refer to the meeting minutes as guidance for the review.

ii. Consider whether the recommendation of the MMU-REC has been followed.

iii. Make further comments where appropriate.

iv. Sign and date the reviewer's name.
v. Notify the MMU-REC secretariat.

12.4.3 REC meeting

i. The secretariat receives the review report and informs the chairperson.
ii. If no MMU-REC meeting is necessary, then go to step 12.4.4.
iii. If the MMU-REC previously decided to see the new revision, then proceed with the following steps:
iv. The primary reviewer presents a brief oral or written summary of the study design and his/her comments to the MMU-REC members.
v. The chairperson entertains discussion on the protocol revision.
vi. Further recommendations for modifications to the protocol, consent form, and/or advertisements as requested by the committee are noted in the meeting minutes as with modifications made by MMU-REC and will be communication to the investigator.
vii. The chairperson calls for a vote on the revision to either:
viii. Approve the study to start as the presented with no modifications, Approved
ix. Approve the study to start with committee approved modifications to the consent, Approved with minor modification.
x. Require modifications to items noted at the convened meeting and follow-up by the chairperson, after receipt of the requested modifications, approved with major modification.
xi. Disapproved.

12.4.4 Document the MMU-REC decision

i. Place the original completed documents along with the completed re-review report, the Assessment form and the initial review application form as well as the others in the protocol package.
ii. Prepare an approval letter.
iii. Send an approval letter to the principal investigator
iv. Get the chairperson's signature.

12.4.5 Communication of the decision

i. The chairperson notifies the Principal Investigator of the review decision and the reason for the decision as soon as possible after the re-review.
ii. For protocols requiring full MMU-REC review, the notification will be as soon as possible after the re-review has taken place, but no later than the next working day.
iii. For protocol reviewed by partial MMU-REC, the notification will be as soon as possible after the review has taken place, but no later than 5 working days after the members/reviewers have received the re-submission package.

iv. For protocol reviewed by the chairperson, the notification will be as soon as possible after the review has taken place, but not later than 5 working days after the chairperson has received the resubmission package.
v. The secretariat notifies the principal investigator about the decision of the MMU-REC through an e-mail or telephone and files the sent and received e-mail messages in the protocol file.
vi. The secretariat then prepares the approval/action letter and gets the chairperson's signature
vii. If the study is approved, the committee determines the frequency of continuing review for each study site.
viii. The secretariat sends an action latter to the investigator notifying the MMU-RECs decision and schedule of continuing review.
ix. The latter contains, at a minimum, a listing of each document approved, the date set by the committee for frequency of continuing review, and a review of other obligations and expectations from the investigator throughout the course of the study.
x. A computer-generated approval and expiration date is placed on every page of each consent from approved by the MMU-REC.
xi. If the committee requires modification to any of the documents, the secretariat either generates the revisions to the documents or sends a written request of the specific changes to the investigator to make the necessary changes and resubmit the documents to the MMU-REC.

13 MANAGEMENT OF PROTOCOL CONTINUING REVIEWS

13.1 Purpose

This protocol describe how continuing review of previously approved Mountains of the Moon University protocols are managed by the review committee.

The purpose of the continuing review is to monitor the progress of the entire study, not just the changes in it, to ensure continuous protection of the rights and welfare of research participants. Continuing review of the study may not be conducted through an expedited review procedure, unless 1) the study was eligible for, and initially reviewed by, an expedited review procedure; or 2) the

study has changed such that the only activities remaining are eligible for expedited review.

13.2 Scope

This SOP applies to conducting any continuing review of the study protocols involving human subjects at intervals appropriate to the degree of risk but not less than once a year. Depending upon the degree of risk to the participants and duration of the study, the MMU-REC may choose to review or monitor the protocols more frequently.

13.3 Responsibility

It is the responsibility of the MMU-REC secretariat to remind the MMU-REC and the principal investigators regarding study protocols that should be continuously reviewed. The chairperson is responsible for determining the date of continuing review.

The MMU-REC is responsible for reviewing the process made in the protocol, the occurrence of unexpected events or problems, and the rate of the accrual of participants. The protocol informed consent documents and assent documents are examined to ensure that the information remains accurate.

The MMU-REC has the same options for decision making on a continuing review package as for an initial review package. The decision is made as *approval; approval with recommendations; approval with stipulations, pending, or disapproval.*

13.4 Detailed instructions

13. 4. 1 Determine the date of continuing review

i. Look through the document archives for the due date of continuing reviews.
ii. Plan for continuing review meeting at least two months ahead and as close as possible to the due date or the anniversary of the affectivity date. (Date of original approval) of the protocol.
iii. Consult the chairperson for scheduling the Board meeting date.

13.4.2 Notify the principal investigator or the study team

i. Inform the study team at least **two months in advance** of the due date for the continuing review by post, e-mail or other appropriate means.
ii. Mail or e-mail also a continuing review application forms to the study team to fill up.
iii. Keep the informed notice in the correspondence file.
iv. Allow the study team sufficient time to collate the information and to prepare a report package required for the continuing review.

13.4.3 Manage continuing review package upon receipt

i. Receive a package of continuing review for each protocol prepared and submitted by the study team.

ii. Upon receipt of the package, the secretariat of the MMU-REC should perform the following;

(a) **Initial and date the submission package.**

- Check on procedures of receipt of submitted packages.

(b) **Verify the contents of the package.**

- Make sure that the contents of the package include:
- **Continuing Review Application Form**
- Check for complete information and for the presence of the required signatures (protocol chairperson, if applicable, Mountains of the Moon University medical advisor and medical and scientific director of the Mountains of the Moon University).
- See continuing review application form
- **Continuing review memorandum** with progress report
- Summarize the progress of the protocol since the time of the last review.
- Include information about the number of participants enrolled to date and since the time of the last review, an explanation for any "yes" answers on the application form and a discussion of scientific development, either through the conduct of this study or similar research that may alter risks to research participants.
- **Current informed consent document**
- Both the printed and electronic copies in the local area network (where applicable) in the following drive:
- Verify electronic informed consent documents (where applicable).
- Check if the electronic copy for matches the hard copy submitted by the study team.
- Store the hard copy with the submitted documents.
- Clearly identify the document as the hard copy of the electronic informed consent document.
- Ensure that the version of the informed consent document is the most recently approved informed consent document.

(c) Photocopy the package.

- Make sufficient copies (for both members and reviewers) of the original continuing review package in accordance with MMU-REC procedures for maintaining confidentiality of MMU-REC documents.

(d) **Store the continuing review package.**

- Store the original package in the protocol specific file.

13.4.4 Notify the Members of the MMU-REC

- Distribute the protocol progress report and the informed consent document to the MMU-REC.

13.4.5 Prepare meeting agenda

- See procedures on the preparation of the meeting agenda
- Place the review on the agenda for the meeting of the MMU-REC which coincides with the anniversary of the protocol effective date (original approval date).
- Distribute the materials to the MMU-REC members by the electronic mail(e-mail), fax or by post, according to (procedures for maintaining confidentiality of MMU-REC Documents) at least one and a half to two weeks in advance of the scheduled meeting
- Keep copies of "sent" e-mail, cover memos and/or letter accompanying posted materials in the correspondence section of the protocol specific file.
- Record and keep the MMU-REC members' response upon receipt of the agenda in the member correspondence file.

13.4.6 Protocol Review Process

(i). Continuing Review Application Form

- Use the continuing review application form to guide the review and deliberation process.
- Sign and date the continuing review application form by the chairperson of the MMU-REC after a decision has been reached.
- The completed continuing review application form is the official record of the decision reached by the MMU-REC for the protocol.
- Maintain and keep the form and minutes of the meeting relevant to the continuing review as part of the official record of the review process.

(ii). Communication of the Decision

- Communication of the decision
- The chairperson notifies the PI of the decision and the reasons for the decision as soon as possible after the meeting. But no later than one working day.
- Preliminary written communication of the Decision
- The chairperson must send an electronic version of the completed continuing review application form to the secretariat and to the medical and scientific Director within one working day whenever possible, but no later than 5 working days after the review has taken place.
- The secretariat, in turn, forwards this to the study team (by e-mail). "send" or "received" e-mails are filed in the protocol file under "correspondence".

- Complete the printed version of the continuing review application/assessment form by the chairperson of the MMU-REC:
- Sign and date the printed version of the form containing the decision and return this to the secretariat.
- Complete the process within the 5 working days of the MMU-REC meeting
- Complete the original version of the continuing review application form by the chairperson.
- Sign and date the original version of the form.
- The secretariat must sign and date the form.

13.5 Store original documents

- Place the original completed documents with the other documents in the continuing review package in the protocol file.

13.6 Distribute documents to the study team

- Distribute copy version of the completed continuing review application/Assessment form to the principal investigator within 7 working days.

14 REVIEW OF FINAL REPORT

14.1 Purpose

The purpose of this SOP is to provide instructions on the review and follow-up, if appropriate, of final reports for any study previously approved by Mountains of the Moon University REC.

14.2 Scope

This SOP applies to the review and follow-up of the final report which is an obligatory review of each investigator activities presented as a written report of studies completed to the MMU-REC.

Although Mountains of the Moon University provides a study report form to the investigator, any mechanism (letter format, form provided by the sponsor, etc.) may be used, provided that the information submitted is sufficient.

14.3 Responsibility

It is the responsibility of the MMU-REC secretariat to review the report for completeness before making copies for the Board meeting.

14.4 Detailed instructions

14.4.1 Before each Board meeting

i. The secretariat receives and checks the report packages.
ii. The secretariat reviews the submitted report and briefs to the chairperson.
iii. Make a sufficient number of copies.

14.4.2 During the Board meeting

i. Each Board member reviews a copy of the final report.
ii. The chairperson entertains any discussion of the study.
iii. If appropriate to the discussions, an MMU-REC member may call for consensus on whether to request further information or to take other action with the investigator.
iv. Summarize what action should be taken.

14.4.3 After the board meeting

i. Notify the investigator of the decision.
ii. Accept and file the final report, if no action is taken.
iii. Note the decision in the meeting minutes.
iv. Consider the study as closed.
v. Get a copy of the final report signed by the chairperson.
vi. Send an acknowledged letter to the investigator.
vii. Archive the entire study protocol and the report.

15 INTERVENTION IN PROTOCOL DEVIATION/NON-COMPLIANCE/VIOLATION

15.1 Purpose

This SOP provides instructions for taking action and maintaining records that identify investigators/institutes who fail to follow the procedures written in the approved protocol or to comply with national/international guidelines for the conduct of human research, including those who fail to respond to the MMU-REC's requests.

15.2 Scope

This SOP applies to all MMU-REC approved research protocols involving human subjects.

15.3 Responsibility

The designated member of the secretariat is responsible for collecting and recording the non-compliance list.

15.4 Detailed instructions

15.4.1 Whenever protocol deviation/non-compliance/violation has been observed

i. Ensure that the issues as well as the details of non-compliance involving research investigators are included in the agenda of the MMU-REC meeting.

ii. Maintain a file that identifies investigators who are found to be non-compliant with national/international regulations who fail to follow protocol approval stipulations or fail to respond to the MMU-REC request for information/action.

iii. **Note:** the REC may elect to suspend or terminate approval of current studies or refuse subsequent applications from the investigators cited. Such decisions are recorded in the minutes.

15.4.2 The MMU-REC's Decision

i. The chairperson notifies the investigator of the MMU-REC's action in written when the Board
ii. Suspends or
iii. Terminates approval of a current study or
iv. Refuses subsequent applications from an investigator cited for non-compliance.

15.4.3 Notify the investigator

i. The MMU-REC secretariat members record the MMU-REC's decision.
ii. Draft and type a notification letter.
iii. Get the chairperson to sign and date the letter.
iv. Make four copies of the notification letter.
v. Send the original copy of the notification to the investigator.
vi. Send a copy of the notification to the relevant national authorities and institutes.
vii. Send the third copy to the sponsor or the sponsor's representative of the study.

15.4.4 Keep records and follow up

i. Keep the last copy of the notification letter in the "non-compliance" file.
ii. Store the file in the shelf with an appropriate label.

iii. Follow up the action after a reasonable time.

16 MANAGEMENT OF STUDY TERMINATION

16.1 Purpose

The procedure describes how MMU-REC proceeds and manages the termination of a research study. Protocols are usually terminated at the recommendation of the MMU-REC, Data safety monitoring board (DSMB), scientific director, sponsor or other authorized bodies when subject enrollment and subject follow-up are discontinued before the scheduled end of the study.

16.2 Scope

This SOP applies to any study approved by Mountains of the Moon University that is being recommended for termination before its scheduled completion.

16.3 Responsibility

It is the responsibility of the MMU-REC chairperson to terminate any study that the MMU-REC has previously approved when the safety or benefit of the study participants is doubtful or at risk. The secretariat is responsible for management of the termination process.

16.4 Detailed instruction

16.4.1 Receive recommendation for study termination

a) Receive recommendation and comments from DSMB, MMU-REC members, scientific Director, Sponsor or other authorized bodies for study protocol termination
b) Inform the principal investigator or the study office to prepare and submit a protocol termination package.
c) Receive the study protocol termination package prepared and submitted by the principal investigator or the study office.
d) Verify the contents of the package for inclusion of:
i. Request for termination memorandum of this SOP.
ii. The request for termination memorandum should contain a brief written summary of the protocol, its results, and accrual date.
iii. Original continuing review application form.
iv. Termination is indicated under "Action Request"
v. Completeness of the information, including accrual date since the time of the last continuing review.
vi. Presence of the required signatures (principal investigator).
vii. Initial and date the package upon receipt.

16.4.2 Review and discuss the termination package

i. Notify the chairperson regarding the recommendation for study protocol termination.
ii. Send a copy of the termination package to the chairperson within one working day upon receipt.
iii. The chairperson calls for an emergency meeting to discuss about the recommendation.
iv. The chairperson signs and date the continuing review application form in acknowledgment and approval of the termination.
v. The chairperson returns the form back to the secretariat within 5 working days of the receipt of the package.
vi. The secretariat reviews, signs, and dates the continuing review application form indicating that the termination process is complete.

16.4.3 Notify the principal investigator

i. Make a copy of the completed continuing review application form
ii. Send the copy to the principal investigator for their records within 7 working days

16.4.4 Store the protocol documents

- Keep the original version of the request memorandum for termination and the original version of the continuing review application form in the protocol file.
- Send the file to archive.
- Store the protocol documents indefinitely

16.4.5 Inactivate the protocol documents

Place the study protocol into the inactive protocol folder.

17 REVIEWS OF SERIOUS ADVERSE EVENTS (SAE) REPORTS

17.1 Purpose

The purpose of this SOP is to provide instructions on the review and follow-up reports of serious adverse experience and unexpected events for any active study approved by the MMU-REC. The SAE must be reported by the investigators or sponsors within 10 working days after the incident occurred and unexpected events should be included in the continuing review report submitted to MMU-REC.

Unanticipated risks are sometimes discovered during the course of studies. Information that may impact on the risk/benefit ratio should be promptly reported to and reviewed by the MMU-REC to ensure adequate protection of the welfare of the study participants.

The unanticipated risks may as well include any event that in the investigator's opinion, may adversely affect the rights, welfare or safety of subjects in the study.

17.2 Scope

This SOP applies to the review of SAE and unexpected events reports submitted by investigators, date safety monitoring board (DSMB), sponsor, local safety monitor, MMU-REC members or other concerned parties.

17.3 Responsibility

The primary responsibility of the MMU-REC is to review and address SAE and unexpected events involving risks to subjects or others as well as ethics complaints. In addition, the committee is authorized to offer mediation under appropriate circumstances.

MMU-REC should also make sure that researchers are made aware of the policies and procedures concerning reporting and continuing review requirements.

The MMU-REC secretariat is responsible for first screening the assessment of the reports and seeing whether they need a review of full board, chairperson, other qualified BU-IREC members or experts.

17.4 Detailed instructions

17.4.1 Before each MMU-REC meeting

(a). **Review and determine the review channel**

- MMU-REC secretariat or members review the report assessment to determine whether the report requests review by the full Board or by the chairperson or other qualified MMU-REC member(s).

(b). **Criteria for the review**

i. Assessment of the adverse experience is unknown or unlikely.
ii. Report is forwarded to the chairperson for review and determination if report should be reviewed at the convened meeting by full Board.
iii. Assessment of adverse experience is possibly caused by, or probably caused by the investigational product.
iv. The report is added to the agenda for review at a convened meeting by full Board.

v. An adverse experience/IND safety report has been previously seen by full Board but being resubmitted by another investigator participating in the multi-study site (as part of a multi-center/site study).
vi. This notification does not require full Board review.
vii. Reviewed by the chairperson or other qualified MMU-REC members and secretariat.

17.4.2 During the MMU-REC meeting

(I). **Review and discuss**

- After reading and reviewing the report, the chairperson entertains discussion on the study and similar adverse experiences or advisories.
- If appropriate to the discussions, the chairperson or another board member may call for a consensus on whether to: *Request an amendment to the protocol or the consent form. Request further information. Suspend or terminate the study.*

(ii) **Decide what action should be taken.**

- If any of the above actions are taken, the MMU-REC secretariat notifies the investigator of the action taken.
- If the MMU-REC takes on action, a notation is made in the minutes and the study is allowed to continue.

(iii). **Inform investigator or clinical trial office.**

- The MMU-REC secretariat member drafts a formal letter to the investigators or the clinical trial office to notify them of the action they should take according to the MMU-REC decision.
- Get the chairperson to approve, sign and date the letter.
- Send the letter and record the delivery date.

18 SITE MONITORING VISITS

18.1 Purpose

The purpose of this SOP is to provide procedures as to when and how a study site should be visited and monitored of its performance or compliance to GCP.

18.2 Scope

This SOP applies to any visit and/or monitoring of any study sites as stated in the MMU-REC approved study protocols that identify the place(s) where the study and/or laboratory procedures are being carried out or performed.

18.3 Responsibility

It is the responsibility of the MMU-REC to perform or designate some qualified agents to perform on its behalf on-site inspection of the research projects it has approved.

The MMU-REC members or secretariat in consultation with the chairperson may initiate an on-site evaluation of a study site for cause or for a routine audit.

18.4 Detailed instructions

18.4.1 Selection of study sites

i. Review periodically the database files of the submitted/approved study protocols.
ii. Select study site needed to be monitored based on the following criteria.
iii. When the MMU-REC has never approved the principal investigator for a research project, a study visit should be planned for at the appropriate time after the study starts.
iv. New study sites
v. Reports of remarkable serious adverse events.
vi. Numbers of study carried out at the study sites.
vii. Frequency of protocol submission for MMU-REC review.
viii. Non-compliance or suspicious conduct
ix. Frequently fail to submit final reports

18.4.2 Before the visit

The MMU-REC representatives will

i. Contact the site to notify them that they will be visiting them. At that time, the monitor and the site will coordinate a time for the site evaluation visit.
ii. Make the appropriate travel arrangements.
iii. Review the MMU-REC files for the study and site.
iv. Make appropriate notes, or
v. Copy some parts of the file's comparison with the site files.

18.4.3 During the visit

i. Get a checklist.
ii. The MMU-REC representatives will
iii. Review the informed consent documents to make sure that the site is using the most recent version.
iv. Review randomly the subject files to ensure that subjects are signing the correct informed consent.
v. Observe the informed consent process, if possible,

vi. Observe laboratory and other facilities necessary for the study at the site.
vii. Review the MMU-REC files for the study to ensure that documentation is filed appropriately.
viii. Collect views of the study participants.
ix. Debrief the visit report/comments.
x. Get immediate feedback.

18.4.4 After the visit

i. The MMU-REC representative will:
ii. Write a report/comment within 2 weeks describing the finding during the audit.
iii. Forward a copy of the site visit to the "site monitoring" file for full Board review.
iv. Send a copy of the report to the site for their files, and
v. Place the report in the correct site files.

18.4.5 Present the inspection results to the committee

i. Consult with the MMU-REC secretariat.
ii. Schedule the presentation in the meeting agenda.
iii. Present the results of on-site inspections to the committee.

19 AGENDA PREPARATION, MEETING PROCEDURES AND MINUTES

19.1 Purpose

The purpose of this procedure is to identify the administrative process and provide instructions for the preparation, review, approval and distribution of meeting agenda, minutes and action, invitation, and notification letters of Mountains of the Moon University MMU-REC meetings.

19.2 Scope

This SOP applies to administrative processes concerning the preparation of the agenda for all regular MMU-REC meetings, divided into three stages: before, during and after the meeting.

19.3 Responsibility

It is the responsibility of the Secretariat staff to prepare the agenda for the MMU-REC meeting and to ensure the quality and validity of the minutes after the meeting is over. The Chairperson should review and approve the agenda and the minutes sent to him/her.

19.4 Detailed instructions

19.4.1 Before each meeting

(A) Check for filled up forms for completeness.

i. An administrative staff member:

a) Reviews the new study application for completeness.

b) Documents the review by completing the appropriate checklist. If incomplete, the staff member attempts to obtain the information from the person who submitted the application package.

19.4.2 Consider the appropriate review channel of each protocol.

i. Use the criteria and the procedures as described in the corresponding SOPs when deciding the review channel.

a) Expedited Review.

b) Initial Review of Submitted Protocols

c) Review of Resubmitted Protocols.

d) Review of Protocol Amendments

e) Continuing Review of Study Protocols

f) Review of Protocol Terminations

g) Review of Final Reports

19.4.3 Assign protocol reviewers.

i. Assign at least two reviewers (for technical and ethical review) for initial review of each submitted protocol by the MMU-REC Secretariat.

ii. *The technical reviewer prepares a brief protocol summary, including a statement of the purposes, the evaluation parameters, and the methodology of the protocol. The ethical reviewer examines the consent form for completeness of information and protection of human subjects.*

iii. The assignment should be based on the information provided.

19.5 Prepare meeting agenda

i. Schedule the review as soon as possible after submission, either at the time of the next scheduled meeting or *within 4 weeks after submission.*

ii. Arrange extra MMU-REC meetings to accommodate protocol reviews.

iii. Consult the Chairperson to schedule the meeting date.

iv. Prepare the meeting agenda, according to the format shown.

v. Schedule protocols on the agenda on a first-come first-serve basis.

vi. Include "request to appeal items in the agenda, upon receipt of the correspondence, preferably during the next convened Board meeting.
vii. Prepare invitation letters to the reviewers and the members.
viii. Allow at least 3 weeks for the review process.
ix. Specify the due date for the return of comments.
x. Include a protocol assessment form with the protocol package along with the invitation letter, a response form and the meeting agenda.
xi. Write down the running member of the protocol in the square boxes at the bottom right corner of the form.
xii. Sign the second page of the form.
xiii. Prepare the package for delivery.
xiv. Record the names of the assigned reviewers in the appropriate database or the review assignment file.

19.5.1 Distribution of Protocol Packages to the MMU-REC Members.

i. Keep in mind Procedure for Maintaining Confidentiality of REC documents when preparing and distributing documents.
ii. Distribute copies of the protocol submission packages to the assigned reviewers and MMU-REC members by either electronic mail (if electronic submission protocols), or by post *two weeks in advance of the scheduled meeting.*
iii. Keep copies of "sent" e-mail, fax cover memos and/or letters accompanying posted materials in the Correspondence section of the respective protocol file.
iv. Verify (verbally, by e-mail, fax or by mail) with the members whether the protocol packages are received.

19.5.2 Prepare for the meeting.

i. Make a room reservation on the schedule meeting date and time.
ii. Make sure that the room, equipment and facilities are available in good running condition and cleaned for the meeting day.

19.5.3 During the meeting.

i. The MMU-REC may allow investigators, projectors managers, sponsors, etc., to attend the portion of the Board meeting related to their studies.
ii. At the discretion of the Chairman, may be allowed to observe the Board meetings.
iii. These guests may include a potential client, students, etc.
iv. Guests are required to sign a confidentiality agreement.
v. The Secretariat reports on the minutes of the previous meeting presents the agenda for discussion.
vi. The Secretariat records the discussions and decisions made during the meeting.

vii. The Chairperson may inform members and attendees of the rules being followed during the meetings.
viii. The meeting proceeds in the order organized in the agenda; however, the Chairperson may allow some switching depending on the situation.
ix. The approval process starts when one of the reviewers gives a brief about the study and presents his/her observations and comments.
x. In case the reviewer cannot be present during the meeting, a member of the Secretariat or an MMU-REC member may give the briefing about the study by reading the comments and evaluation of the reviewers.
xi. The other members give their comments right after the presentation and the discussion about the study takes place.
xii. Investigators may be allowed to present their projects in brief and clarify any questions the MMU-REC members may have.

19.5.4 Voting

i. In order to avoid conflict of interest, only those Board members who are independent of the investigator and the sponsor of the trial will vote on the research-related matters.
ii. All voting will take place after the observers/presenters/Board members with a conflict of interest leave the room.
iii. The chair determines if the number of voting Board members is sufficient to constitute a quorum and proceeds accordingly.
iv. A Board makes a motion to recommend action on a protocol or issue being discussed.
v. The motion is seconded and the voting takes place.
vi. A motion is carried out once the majority of MMU-REC members vote in favor of the motion.

19.5.5 After the Board meeting.

i. As soon as possible after every meeting, a copy of the minutes is sent to a senior administrative staff member for quality control and review.
ii. The senior administrative staff member indicates review by signing and dating the minutes.
iii. Following staff review, the minutes are given to the Chairperson or designee for review and approval.
iv. The Chairperson indicates approval by signing and dating the minutes.
v. A member of the administrative staff maintains the official copies of the minutes in accordance with departmental archiving procedures.

19.6 Preparing the Minutes and the Decision Forms.

19.6.1 Assembling the meeting minutes and the decision form.

i. Use the format as shown above to write the minute.

ii. Compose the summary of each discussion and decision in a concise and easy-to-read style.
iii. Make sure to cover all contents in each category.
iv. Check spelling, grammar and context of the written minutes.
v. Finish the minutes within two weeks after the meeting.

19.6.2 Contents of the MMU-REC Meeting Minutes.

a) The official minutes of the Committee meeting consist of, but are not limited to the following:

i. Name of person preparing the minutes
ii. Venue where the meeting was held
iii. Meeting date
iv) Attending committee members and guests
v. Agenda items
vi. Individual serving as Chairperson of the meeting
vii. Determination of a duly constituted quorum by the Chairperson to proceed with the meeting

b) Requirements for each study or activity requesting Approval:

i. Sponsor's name
ii. Protocol number/date/version of protocol, when available
iii. Investigator's name
iv. Advertisements
v. Name of board member presenting study materials
vi. Discussion as deemed appropriate by the Chairperson
vii. Number of members voting "yes", "no", or "abstention"
viii. Number of abstentions and the reason for the abstention
ix. Reference to the investigators approval letter that lists all changes requested by the board
x. Determination of the next requested continuing review.

c) Requirements for each study or activity requesting Expedited Review:

i. Sponsor's name
ii. Protocol number, if applicable
iii. Investigator's name
iv. Lists of expedited approval requests and outcomes.

d) Required for each continuing Review Report:
i. Sponsor's name;
ii. Protocol number, if applicable;

iii. Investigator's name;
iv. Indication of the Board's determination to continue, terminate, or amend the study;
v. Lists of recommendations or actions to be taken up with the investigator, if applicable.

e) Required for each Adverse Event notification and Final Report:

i. Sponsor's name;
ii. Protocol number, if applicable;
iii. Investigator's name;
iv. Actions deemed appropriate by the board's review.

f) Required for Termination of Approval:
i. Sponsor's name;
ii. Protocol number, if applicable;
iii. Investigator's name; reason for termination

19.6.3 Approval of the minutes and the decision

i. Check the correctness and completeness of the minutes.
ii. Get the Chairperson of the MMU-REC to sign and date the relevant sections of the minutes of the MMU-REC meeting and the decision form.

19.6.4 Filling the minutes.

i. Place the original version of the minutes and the signed decision form in the MMU-REC files for the specific protocol.
ii. Place all correspondence in the appropriate file.
iii. Place a copy of the approval letter in the "minutes" file to inform the Board Members of the Expedited approval.
iv. Document the appeal requests in the meeting minutes.

19.6.5 Distributing the minutes and the decision.

i. Send a copy of the relevant sections of the minutes and the decision form to the applicants for their records by mail or other means.
ii. Send the approved minutes to the MMU-REC members.
iii. Send the decision of the MMU-REC for an appeal request to the person concerned in writing.
iv. Record the receivers and the delivery date.

20 MAINTAINING CONFIDENTIALITY OF MMU-REC DOCUMENTS

20.1 Purpose

The sources of violation of confidentiality are usually found in the day-to-day use of copies of original documents. This SOP therefore describes how to handle the original documents and copies of the documents in order to protect confidentiality of documents.

20.2 Scope

This SOP applies to all kinds of handling, distribution and storage of submitted study protocol s, MMU-REC documents, and correspondence with experts, auditors and the general public.

20.3 Responsibility

Confidentiality of study protocols, MMU-REC documents, and correspondence with experts and auditors is mandatory. MMU-REC members and staff have signed confidentiality with the institute that enforces confidentiality.

If non-members of the MMU-REC need copies of documents, it is the responsibility of the MMU-REC member/staff requesting a copy on behalf of the non-members to maintain confidentiality of documents.

20.4 Detailed instructions

20.4.1 Access to MMU-REC Documents

The MMU-REC members and the staff of the Secretariat of the REC, who must read, understand and agree to the following:

i) Members of the MMU-REC sign a confidentiality agreement with Mountains of the Moon University Institutional Research Ethics Committee (IREC) before the start of any activity for the MMU-REC.

- Shall have access to all MMU-REC documents.
- Are free to request and to use original documents or copies of original documents.

ii) Secretariat of the MMU-REC

- The Secretary of the MMU-REC is a staff member of the *Mountains of the Moon University*. Have access to any document issued by or to the MMU-REC, according to (Maintaining Confidentiality of MMU-REC's Documents).

20.4.2 Classify confidential documents

a)**Types of documents**

The types of documents reviewed by MMU-REC members include:

i. Study protocols and related documents (case report forms, informed consent documents, diary forms, scientific documents, expert opinions or reviews)

ii. MMU-REC documents (SOPs, meeting minutes, advice and decisions)

iii. Correspondence (experts, auditors, study participants, etc.)

Note: *Copies of all versions of documents, including draft and sequential definitive versions are to be kept private and confidential with the exception of those made according to the following sections.*

20.4.3 Copy confidential documents

Copies of documents, including drafts and sequential versions, are considered to be confidential and not permitted to be brought out *except when a document is needed for day-to-day operations.*

i) Copy Authorization.

a) Only members of the MMU-REC are allowed to ask for copies.
b) Only staff members of the Secretariat of the MMU-REC are allowed to make such copies.
c) The Secretary of the MMU-REC may ask for help, but is responsible for maintaining confidentiality of all documents.

ii) Log of Copies.

a) A Log of Copies must be kept by the Secretariat.
b) The log should include: the name and signature of the individual receiving the copy; the initial of the MMU-REC Secretary who made the copy; the number of copies made and the date that the copies were made.

iii) Copies requested by non-members of the MMU-REC.

a) Copies of MMU-REC's documents requested by non-members of the MMU-REC (including the Secretary) can only be given after the permission from the Chairperson of the IRC and the person requesting for the document signs a confidentiality agreement form.
b) Copies made for non-members of the MMU-REC must be recorded in both the Log of Requests for Copies of MMU-REC's documents and the log of Copies of the Original Documents

iv) File Log of Copies.

a) The Log of Copies of Original Documents must be stored with the original documents.
b) The Log of Copies of Original Documents is *not* a confidential document and can be reviewed upon request.
c) A Log of Copies of Original Documents must be maintained.

21 AUDITING AND INSPECTION OF THE MMU-IREC

21.1 Purpose

The purpose of this procedure is to guide how to prepare for an audit or inspection of the MMU-IREC processes.

21.2 Scope

This SOP applies to every unit of the *Mountains of the Moon University–MMU-REC* Office.

21.3 Responsibility

It is the responsibility of the Secretariat, the Members, and the chairperson of the MMU-REC to perform all tasks according to the SOPs and to be well-prepared and available to answer questions during evaluation, audit or inspection visits of authorities and guests.

i. Call for an Audit/Inspection
ii. Receive a notice of inspection visit.
iii. The Chairperson informs the Secretariat/Director/Vice Chancellor.
iv. The Chairperson alerts every unit to get ready.
v. Prepare for the visit.
vi. Go through all steps on the list.
vii. Note and comment on each part.
viii. Emphasize on the studies with problems.
ix. Check if all documents are labeled and kept in the right order for easy and quick search.
x. Background and training records of MMU-REC members.
xi. Application Submission Records.
xii. Protocol Assessment Records.
xiii. Communication Records.
xiv. Amendment Approval.
xv. Meeting Agenda, Minutes, and Action letters.
xvi. Active files.
xvii. Continuing and Final reports.
xviii. Reserve a meeting room and all necessary facilities.

xix. Review the MMU-REC SOPs.
xx. Make sure that no omission or deviation exists.
xxi. Make sure to have good reasons for any omission or deviation.
xxii. Inform MMU-REC members about the inspection date if they are able to attend the audit/inspection meeting.

21.4 Welcome Auditor/ Inspector

i. The Chairperson or the Secretariat welcomes and accompanies the auditors/inspectors to the reserved meeting room.
ii. Members and some key staff must also be present in the meeting room.
iii. The conversation starts with the auditor/ inspector stating the purpose of the visit and what kind of information and data are needed.
iv. Answer questions of the auditors/inspectors clearly, politely and truthfully with confidence and straight to the point.
v. Find and get all information and files requested by the auditors/inspectors.

21.5 Correct the mistakes

i) Review comments and recommendations of the auditors/inspectors.
ii) Write a report and have it approved by the Chairperson.
iii) The Chairperson calls for the correction.
iv) Allow appropriate time for correction and improvement process.
v) Carry an internal follow-up audit.
vi) Evaluate the outcome.
vii) Report the outcome to the Chairperson.

21.6 Record the Audit/Inspection Event.

i) Keep record of the report on the audit/inspection meeting in the audit/inspection file.
ii) Record also the findings from the internal follow-up audit in the internal audit file.

22 GLOSSARIES

22.1 Glossary one: The Guideline

Guideline	Any suggestion, rules, etc, intended as a guide for Specific practice

22.2 Glossary two: Understanding the MMU-IREC

Confidentiality	Prevention of disclosure, to other then authorized Individuals, of MMU-REC's information and documents
MMU-IREC	Institutional Research Ethics Committee (IREC) is an Independent body (or committee) whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects and other materials (Plant, Animal) involved in research and to provide public assurance of that protection.
Scientists	Professionals with advanced training and expertise in the medical or non-medical areas related to the protocol being reviewed.

22.3 Glossary three: Confidentiality/Conflict of Interest Agreement Form

Confidentiality	**The nonoccurrence of unauthorized disclosure of information;**
Confidentiality Agreement	Sometimes called secrecy or nondisclosure agreements an agreement designed to protect trade secrets, information and expertise from being misused by those who have learned about them. The type of information that can be included under the umbrella of confidential information is virtually unlimited. Most confidentiality agreements exclude certain types of information from the definition of confidential information. It is very important that the recipient include these exceptions in the confidentiality agreement. An important point that must be covered in any confidentiality agreement is the standard by which the parties will handle the confidential information. The agreement must establish a time period during which disclosures will be made and the period during which confidentiality of the information is to be maintained.
Conflict of interest	A situation in which a person, such as a public official, an employee, or a professional, has a private or personal interest sufficient to appear to influence the objective exercise of his or her official duties.

	There are three key elements in this definition; financial interest; official duties; professional interest. A conflict of interest occurs when: ▪ An individual's private interest differs from his or her professional obligations to the institute. ▪ Professional actions or decisions occur that an independent observer might reasonably question. ▪ A conflict depends upon situation and not on the character or actions of the individual. ▪ Potential conflicts of interest must be disclosed and managed as per policy.

Confidentiality/Conflict of Interest Agreement Form

In recognition of the fact that I ..... (Members name and his /her affiliation.....) herein referred to as the "Undersigned", has been appointed as a member of Mountains of the Moon University - MMU-REC and requested to assess research studies involving human subjects in order to ensure that they are conducted in a humane and ethical manner, with the highest standards of care according to the applied national (UNCST), local regulations, University policies and guideline;

Whereas, the appointment of the undersigned as a member of MMU-REC is based on individual merits and not as an advocate or representative of a home province /territory/community /district nor as the delegate of any organization or private interest;

Whereas, the fundamental duty of the MMU-REC member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, MMU-REC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects;

The undersigned, as a member of Mountains of the Moon University- REC, is expected to meet the same high standards of ethical behaviour to carry out its mandate.

This agreement thus encompasses any information deemed confidential or proprietary provided to the undersigned in conjunction with the duties as a member of MMU-REC. Any written information provided to the undersigned that is of a confidential, proprietary, or privileged nature shall be identified accordingly.

As such, the undersigned agrees to hold all confidential or proprietary trade secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes, shall not be used for any other purpose or disclosed to any third party. Written confidential information provided for review shall not be copied or retained. All confidential information (and any copies and notes thereof) shall remain the sole property of the MMU-REC.

The undersigned agrees not to disclose or utilize, directly or indirectly, any confidential or proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the undersigned confirms that his/her performance of this agreement is consistent with the University's policies and any contractual obligations they may have to third parties.

Conflict of Interest

It is recognized that the potential for conflict of interest will always exist but has faith in Mountains of the Moon University REC and its chairperson to manage the conflict issues so that the outcome is the protection of human subjects.

It is the policy of MMU-REC that no member may participate in the review; comment or approve of any activity in which he/she has a conflict of interest except to provide information as requested by the MMU-REC.

The undersigned will immediately disclose to the chairperson of MMU-REC any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the committee, and to abstain from any participation in discussions or recommendations in respect of such proposals.

If any applicant submitting a protocol believes that and MMU-REC member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol.

The request must be in writing and addressed to the chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the REC member (s) in question. The committee may decide to investigate the applicant's claim of the potential conflict.

When a member has a conflict of interest, the member should notify the chairperson and may not participate in the MMU-REC review or approval except to provide information requested by the committee.

Examples of conflict of interest cases may be of the following:

- A member is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.

- A member's personal biases may interfere with his or her impartial judgment.

Agreement on confidentiality and Conflict of interest

Please sign and date this Agreement, if the undersigned agrees with the terms and conditions set forth above. The original (signed and dated agreement) will be kept on file in the custody of Mountains of the Moon University REC. A copy will be given to you for your records.

In the course of my activities as a member of the MMU-REC, I may be provided with confidential information and documentation (which we will refer to as the "confidential information"). I agree to take responsible measures to protect the confidential information; subject to applicable legislation, including the Access to information Act, not to disclose the confidential information to any person; not to use the confidential information for any purpose outside the committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all confidential information (including any minutes or notes I have made as part of my committee duties) to the chairperson upon termination of my functions as a committee member.

Whenever I have a conflict of interest, I shall immediately inform the chairperson not to count me toward a quorum for voting.

I, ..., have read and accept the aforementioned terms and conditions as explained in this Agreement.

_____ _____

Undersigned Signature Date

_____ _____

VC - MMU Date

Confidentiality Agreement Form for Guest Attendees to MMU-REC Meetings

I,....., undersigned that I am allowed to attend the MMU-REC, some confidential information may be disclosed or discussed. Upon signing this form, I agree to take reasonable measures to keep the information as confidential.

Indicate the details (date and number) of the MMU-REC Meeting attended:

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

_____ _____

Signature of the Guest Attendee/Observer Date

_____ _____

Chairperson of MMU-REC Date

Confidentiality Agreement Form for Non-members Requesting Copies of IREC's Documents

I, ..., as a non-member of MMU-REC, understand that the copy(ies) given to me by the MMU-REC is (are) confidential. I shall use the information only for the indicated purpose as described to the MMU-IREC and shall not duplicate, give or distribute these documents to any person(s) without permission from the MMU-REC. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

I have received copies of the following MMU-REC documents:

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

_____ _____

Signature of recipient Date

_____ _____

Chairperson of MMU-REC Date

22.4 Glossary Four: Training Record Form

Conference	A meeting of individuals or representatives of various organizations for the purpose of discussing and/or acting on topics of common interest.
Meeting	Deliberations between at least two (2) persons where such deliberations determine or result in the joint conduct or disposition of business.
Workshop	A group of people engaged in study or work on a creative project or subject

Training Record Form

First name:	Last name:
Staff/Membership since:	Status:
Education Background:	
Work Experience:	

Training Experience:

#	Courses/Workshops/Conference/ Meetings Attended	Organized by:	Where?	Duration	Source of Funding
1					
2					
3					
4					
5					
6					
7					
8					
9					

22.5 Glossary Five: Co-Opted Membership

Co-opted Member	An expert who gives advice, comments and suggestion upon review of the study protocols with no affiliation to the institutes or investigators proposing the research protocols.

22.6 Glossary Six: Contents of Submitted Protocol

FIFO	First In First Out Sequence

CONTENTS OF A SUBMITTED PACKAGE

Initial Review Submitted Package

- Protocol Summary Sheet or Memorandum
- Original Initial Review Application Form
- Protocol and Protocol-Related Documents

☐ Information for subjects ☐ informed consent form
☐ Case report forms (CRF) ☐ study budget
☐ Investigator's brochure ☐ others .....

☐ **Resubmission for Re-review Submitted Package**

- Resubmission or "Correction" Memorandum
- Revised Protocol Summary Sheet (if submitted initially)
- Original Initial Review Application Form
- Protocol and Protocol-Related Documents

☐ Information for subjects ☐ informed consent form
☐ Case report forms (CRF) ☐ study budget
☐ Investigator's brochure ☐ others .....

Note: Changes made to the protocol and protocol-related documents should be clearly marked either with the underlining or highlighting feature of the document or the software package used to prepare the documents.

Protocol Amendment Submitted Package

- Request for Amendment Memorandum
- Original Amendment Submission Form
- Protocol and Protocol-Related Documents

Note: Changes made to the protocol and protocol-related documents should be clearly marked either with the underlining or highlighting feature of the software package used to prepare the document.

Annual Continuing Review Package

- Request for Annual Continuing Review Memorandum
- Original Continuing Review Application Form
- Current Informed Consent Document (last approved by the MMU-REC)

Protocol Termination Package

- Request for Termination Memorandum
- Original Continuing Review Application Form (Termination Submissions are contained on this form).

Document Receipt Form

		Received number:	☐☐☐ ☐☐ ☐☐
Protocol Number		**Submitted date:**	
Type of submission	☐ Initial ☐ Resubmission ☐ Protocol Amendments	☐ Continuing Review of Approved protocols ☐ Protocol Termination	
Protocol Title:			
Principal Investigator:			
Telephone number:		Fax:	
E-Mail		Preferred Contact	☐ Phone ☐ Fax e-mail
Institute/organization			
Delivery route:	☐ Post ☐ E-Submissid ☐ In person		
Documents submitted:	☐ Post ☐ E-Submission ☐ In person		
Documents to be submitted later:	☐ information for subjects ☐ informed consent form ☐ case report forms ☐ study budget ☐ investigator's brochure ☐ others	Check what documents are received later on: ☐ information for subjects ☐ informed consent form ☐ case report forms (CRF) ☐ study budget ☐ investigator's brochure ☐ others.....	
Received by:			

Date received:		

Note: *Please bring this receipt with you when contacting Mountains of the Moon University MMU-REC*

22. 7 Glossary Seven: Study Assessment Form

Study Assessment Form	An official record that documents the protocol review process.
Document	Document may be of any forms, e.g., paper, electronic mail (e-mail), faxes, audio or video tape, etc.
Vulnerable subjects	A vulnerable category of subjects includes children, prisoners, pregnant women, handicapped or mentally disabled persons, refugees, displaced persons and economically or educationally disadvantaged persons, who are likely to be vulnerable to coercion or undue influence.

Study Assessment Form

Protocol Number:		Date (D/M/Y)	
Protocol Title:			
Principal Investigator:		License: No:	
Institute:		Contact No.	
Co- Investigator (s):			Contact No.
Total No. of participants:		No. of study site:	
Funding Agency:			Contact No.
Duration of the study:	Status:	☐ New ☐ Revised ☐ Amended	
Reviewer's name		Contact No.	
Type of the study:	☐ Intervention ☐ Document based ☐ Social survey.	☐ Epidemiology ☐ Individual based ☐ Others, specify	☐ Observations ☐ Genetic
Review status:	☐ Regular Emergency	☐ Expedited	☐

Description of the Study in brief: Mark whatever applied to the study.

☐ Randomized ☐ Stratified Randomized ☐ Open-labeled

☐ Double blinded ☐ Placebo Controlled ☐ Treatment Controlled

☐ Cross-over ☐ Parallel ☐ Interim Analysis

☐ Use of Tissue samples ☐ Use of blood samples ☐ Use of genetic materials

☐ Multicenter study ☐ Screening ☐ Descriptive

Brief the study design and the statistic used:

Study objectives:

.....

.....

Mark and comment on whatever items applicable to the study.

1	Objectives of the study ☐ Clear ☐ unclear	What should be improved?
2	Need for Human Participants ☐ Yes ☐ No	Comment:
3	Methodology: ☐ Clear ☐ unclear	What should be improved?
4	Background Information and Data ☐ Sufficient ☐ insufficient	Comment:
5	Risks and Benefits Assessment ☐ Sufficient ☐ insufficient	
6	Inclusion Criteria ☐ Appropriate ☐ inappropriate	Comment:
7	Exclusion Criteria ☐ Appropriate ☐ inappropriate	Comment:
8	Withdrawal Criteria ☐ Appropriate ☐ inappropriate	Comment:
9	Involvement of vulnerable participants ☐ Yes ☐ No	Comment:
10	Voluntary, Non-Coercive Recruitment of participants ☐ Yes ☐ No	Comment:
11	Sufficient number of participants? ☐ Yes ☐ No	Comment:
12	Control Arms (placebo, if any) ☐ Yes ☐ No	Comment:

13	Are qualification and experience of the participating investigators appropriate? ☐ Yes ☐ No	Comment:
14	Disclose or Declaration of Potential Conflicts of Interest ☐ Yes ☐ No	Comment:
15	Facilities and infrastructure of participating sites ☐ Appropriate ☐ inappropriate	Comment:
16	Community consultation ☐ Yes ☐ No	Comment:
17	Involvement of Local Researchers and University in the protocol Design, Analysis and Publication of Results. ☐ Yes ☐ No	Comment:
18	Contribution to Development of Local Capacity for Research and Treatment . ☐ Yes ☐ No	Comment:
19	Benefit to Local Communities ☐ Yes ☐ No	Comment:
20	Availability of Similar Study/Results. ☐ Yes ☐ No	Comment:
21	Are blood/tissue samples sent abroad?. ☐ Yes ☐ No	Comment:
22	Are procedures for obtaining Informed Consent appropiate?. ☐ Yes ☐ No	Comment:
23	Contents of the informed Consent Document	Comment:

	☐ Clear ☐ unclear	
24	Langauge of the Informed Consent Document ☐ Clear ☐ unclear	Comment:
25	Contact Persons for Participants ☐ Yes ☐ No	Comment:
26	Privacy & Confidentiality ☐ Yes ☐ No	Comment:
27	Inducement for Participation ☐ Unlikely ☐ Likely	Comment:
28	Provision for Medical/Psychosocial Support ☐ Appropriate ☐ inappropriate	Comment:
29	Provision for Treatment of Study- Related Injuries ☐ Appropriate ☐ inappropriate	Comment:
30	Provision for Compensation ☐ Appropriate ☐ inappropriate	Comment:

Assessment Report

Review Date (D/M/Y): ..... Protocol number .....

Protocol Title:		
Elements Reviewed	☐ Attached ☐ Not attached	
Review of Revised Application ☐ Yes ☐ No	Date of previous review:	
DECISION	☐ Approved ☐ Approved with Recommendation ☐ Resubmission ☐ Disapproved	
Comment:		
Signature:		
		Date:

Meeting No...../..... Date (D/M/Y):.....

Protocol number..... Assigned No.....

Protocol Title:				
Principal Investigators:				
Institute:				
Elements Reviewed		☐ Attached ☐ Not Attached		
Review of Revised Application ☐ Yes ☐ No				
Decision of the meeting:	☐ Approved Recommendation ☐ Resubmission	☐ Approved with ☐ Disapproved		

No.	Voting MMU-IREC	Decision			
		AP	AR	RES	DA

Note: AP- Approved; AR – Approved with recommendation; RES – Resubmission for re-review; DA – Disapproved

Signature:

.....
Chairperson
Date:.....

.....
Secretary
Date: .....

22.8 Glossary Eight: Application Form for Initial Review

Initial Review	The first-time review of that protocol made by two or three individual reviewers (MMU-REC members or non- members) in advance of the full Committee meeting, and comments of the reviewers will be reported to the full Committee meeting.
Phase 1 studies	Initial introduction of an investigational new drug (IND) into humans, studies designed to determine the metabolism and pharmacological actions of drugs in humans, and studies designed to assess the side effects associated with increasing doses.
Phase II study	A Study of drug metabolism, structure-activity relationships, and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes.
Phase III study	A Study expands controlled and uncontrolled trials performed after preliminary evidence suggesting effectiveness of the drug has been obtained. They are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling.
Phase IV study	A study that seeks to expand an approved medication's use into a new population, new indication, or new dose.
Stipulation	Specify as terms of or condition for an agreement, contract, etc. state, put forward for a necessary condition.

APPLICATION FORM FOR INITIAL REVIEW

Protocol Title:	
Protocol number:	Total Participants to be included:

STUDY TYPE: (Mark "√" whichever apply to the study)

☐ Survey ☐ Social ☐ Medical ☐ Community based ☐ Individual based

☐ Screening ☐ Observational ☐ Epidemiology ☐ Intervention study
☐ Clinical Trial: ☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV

☐ Genetic Study ☐ Retrospective ☐ Prospective ☐ Others .
STUDY POPULATION:

☐ Healthy ☐ Patient ☐ Vulnerable groups

CHARACTERISTICS OF PARTICIPANTS PARTICIPATED:
Age Range: ☐ 0 -17 yrs ☐ 18 - 44 yrs ☐ 45 - 65 yrs ☐ ≥66 yrs

Pediatric: ☐ None ☐ < 1 yr ☐ 1-3 yrs ☐ 4 -14 yrs

Impaired: ☐ None ☐ Physically ☐ Cognitively ☐ Mentally

REQUESTED EXCLUSION OF PARTICIPANTS:

☐ None ☐ Male ☐ Female ☐ Children ☐ Other (specify)

SPECIAL RESOURCE REQUIREMENTS (check all that apply):

☐ Intensive Care ☐ Isolation unit ☐ Surgery

☐ Pediatric Intensive Care ☐ Transfusion ☐ CAT scan

☐ Gene therapy ☐ Controlled substances (Narcotics/Psychotropics)

☐ Prosthetics ☐ Gynecological services ☐ Others, specify .

☐ Organ transplantation, specify.

IONIZING RADIATION USE (X-rays, radioisotopes, etc):

☐ None ☐ medically indicated only

INVESTIGATIONAL NEW DRUG (IND)/DEVICE (IDE):

☐ None ☐ IND ☐ IDE

FDA No..... FDA No. .....

Name .....Name .....

Sponsor ..... Sponsor .....

Holder ..... Sponsor .....

PROCEDURE USE: ☐ Invasive ☐ Non-Invasive

MULTI-SITE COLLABORATION: ☐YES ☐ No
FINANCIAL DISCLOSURE: ☐YES ☐ No.
INSTITUTE RESEARCH CONTACT

Name: .....

Address: .....

Telephone: .....

Email: .....

APPLICATION FORM for INITIAL REVIEW
PARTICIPATING INVESTIGATORS:

First/Last Name	License No.	University/Organization	Telephone /Email
1			
2			
3			
4			

TYPE OF REVIEW:

☐ Initial Review	☐ Emergency
☐ Resubmission Review	☐ Continuing Review
☐ Amendment Review	☐ Report Review
☐ Expedited Review	☐ Protocol Termination

SIGNATURES:

_____ Date: .....
Principal Investigators

_____ Date: .....
Protocol Chairperson (if application)

COMPLETION:

_____ Date: .....

Secretary, MMU-IREC, Mountains of the Moon University
APPLICATION NUMBER: ☐☐/☐☐/☐☐

22.9 Glossary Nine: Administrative Documents

Administrative Documents	Documents include official minutes of Board meetings as described in Standard Operating Procedures, both historical and Master Files.
Expedited approval	An MMU-REC approval granted only by the Chairman of the Mountains of the Moon University -MMU Committee or a designated Mountains of the Moon University committee member (not the full Board) for minor changes to current MMU-REC approved research activities and for research which involves no more than minimal risks.
Expedited review	A review process by only two or more designated MMU-REC members who then report the decision to the full Committee meeting. An expedited review is a *speedy* one for minor changes to the approved protocol and for research proposal with minimal risk in nature.

22.10 Glossary Ten: Protocol Amendment Form

Amendment protocol package	A package of the amended parts and related documents of the protocol, previously approved by the MMU-REC. In the course of the study, the PI may decide to make changes in the protocol.
Clinical trial office	An institute or an office where the study takes place and where the principal investigator and/or his/her staff may be reached.
Expedited approval	A MMU-REC approval granted only by the Chairperson of the Mountains of the Moon University MMU-REC or a designated *Mountains of the Moon*

	University MMU-REC member (not the full MMU-REC) for minor changes to current MMU-REC approved research activities and for research which involves no more than minimal risk.

Protocol Amendment Submission Form

PROTOCOL NUMBER	SUBMITTED DATE:
PROTOCOL TITLE:	
PRINCIPAL INVESTIGATOR:	
INSTITUTE:	Telephone:
APPROVED DATE:	NO. OF AMENDMENT:
REASON FOR THE AMENDMENT:	
PROPOSED AMENDMENT	

TYPE OF AMENDMENT REQUESTED:

☐ EXPEDITED (Minor changes)

☐ FULL REVIEW BY REC (More than minor changes or that amendment "materially" affects risks to subjects")

SIGNATURES:

_____ Date: .....
Principal Investigator

COMMENTS: EXPEDITED (Minor changes) FULL REVIEW

APPROVALS

_____ Date: .....
Chairperson, MMU-REC

COMPLETION

_____ Date: .....
Secretary, MMU-REC

PROTOCOL NUMBER: Mountains of the Moon University ☐☐☐ ☐☐ ☐☐

22.11 Glossary Eleven: Review of Resubmitted Protocol

Document	All kinds of evidence to include paper documents, electronic mail (e-mail), fax, audio or video tape.
Completed Assessment Form	An official record of the review decision along with comments and dated signature of the reviewer.

Review of Resubmitted Protocol

Protocol No.	Application No.: ☐☐☐ ☐☐ ☐☐	
Protocol Title:		
Total participants:	☐ 2nd Review ☐ 3rd Review ☐ 4th Review	
Principal Investigator:		Tel:
Initial Review Date:		Last Review Date:
MMU-REC Decision recorded in the meeting minute:	☐ Approved with minor changes or recommendation ☐ Major changes or recommendation need to be reconsidered	
Opinion of the reviewers: • Revision or modification according to the recommendation • What need to be further revised:	☐ Yes ☐ No. Explain:	

SIGNATURES: _____ **Date:** .....
APPROVAL: _____ **Date:** ..... **Chairperson, MMU-REC, Mountains of the Moon University** **COMPLETION:** _____ **Date:** ..... Secretary, MMU-REC, Mountains of the Moon University

22.12 Glossary Twelve: Review Application Form

Approved protocols	Protocols that have been *approved without stipulations* or *approved with recommendations* by the MMU-REC may proceed. Protocols that have been *approved with stipulations* by the MMU-REC may not proceed until the conditions set by the MMU-REC in the decision have been met. Protocols should be amended and submitted to the MMU-REC within *one* month for re-review.

Continuing Review Application Form

PROTOCOL No.:	ASSIGNED NO. ☐☐☐ ☐☐☐ ☐☐
PROTOCOL TITLE:	
INSTITUTE MEDICAL ADVISOR: REC	
ACTION REQUESTED: ▪ Renew - New participant accrual to continue ▪ Renew - Enrolled participant follow up only ▪ Terminate - Protocol discontinued HAVE THERE BEEN ANY AMENDMENTS SINCE THE LAST REVIEW? NO YES (Describe briefly in attached narrative)	HAS ANY INFORMATION APPEARED IN THE LITERATURE, OR EVOLVED FROM THIS OR SIMILAR RESEARCH THAT MIGHT AFFECT THE IRCIIRB'S EVALUATION OF THE RI SKIBENEFIT ANALYSIS OF HUMAN SUBJECTS INVOLVED IN THIS PROTOCOL? ▪ NO ▪ YES (Discuss in the attached narrative) HAVE ANY UNEXPECTED COMPLICA TIONS OR SIDE EFFECTS BEEN NOTED SINCE LAST REVIEW? ▪ NO ▪ YES (Discuss in the attached

SUMMARY OF PROTOCOL PARTICIPANTS:

__ Accrual ceiling set by IEC/IRB

__ New participants accrued since last review

__ Total participants accrued since pr

ACCRUAL EXCLUSIONS

- NONE
- MALE
- FEMALE
- OTHER

IMPAIRED PARTICIPANTS

- None
- Physically
- Cognitively
- Both

HAVE THERE BEEN ANY CHANGES IN THE PARTICIPANT POPULATION, RECRUITMENT OR SELECTION CRITERIA SINCE THE LAST REVIEW?

- NO
- YES (Explain changes in attached narrative)

HAVE THERE BEEN ANY CHANGES IN THE INFORMED CONSENT PROCESS OR

DOCUMENTATION SINCE THE LAST

REVIEW?

- NO
- YES (Explain changes in attached narrative)

narrative)

HAVE ANY PARTICIPANTS WITHDRAWN FROM THIS STUDY SINCE THE LAST MMU-REC APPROVAL?

- NO
- YES (Discuss in the attached narrative)

INVESTIGATIONAL NEW DRUG/DEVICE

☐ NONE ☐ IND

☐ FDA

Name: .....

Sponsor: .....

Holder: .....

IONIZING RADIATION USE (X-rays,

radioisotopes, etc)

☐ None

☐ Medically indicated only

HAVE ANY PARTICIPATING INVESTIGATORS BEEN ADDED OR DELETED SINCE LAST REVIEW?

- NO
- YES (Identify all changes in the attached narrative)

HAVE ANY NEW COLLABORATING SITES (UNIVERSITY) BEEN ADDED OR DELETED SINCE THE LAST REVIEW?

- NO
- YES (Identify all changes and provide an explanation of changes in the attached narrative)

CHANGE IN MEDICAL ADVISOR / INVESTIGATOR? ▪ NONE ▪ DELETE ..... ▪ ADD.....	HAVE ANY INVESTIGATORS DEVELOPED EQUITY OR CONSULTATIVE RELATIONSHIP WITH A SOURCE RELATED TO THIS PROTOCOL WHICH MIGHT BE CONSIDERED A CONFLICT OF INTEREST? ▪ NO ▪ YES (Append a statement of disclosure)

SIGNATURES:

Date: .....
Protocol Chairperson (if applicable)
Date: .....
.....Institute Medical Advisor
.....Vice Chancellor or a Designated Officer

MMU-REC Commend/Decision:

APPROVALS

_____ Date: .....
Chairperson, MMU-REC, Mountains of the Moon University

COMPLETION:

_____ **Date:** .....
Secretary, MMU-REC, Mountains of the Moon University

22.13 Glossary Thirteen: Non-Compliance Record

Deviation / Non compliance Violation	The MMU-REC monitors whether investigators do not perform the study in compliance with the approved protocol, ICH GCP, FDA regulations and/or fail to respond to the MMU-REC's request for information/action.

Deviation / Non-Compliance / Violation Record

Application Numb☐☐☐ ☐☐/☐☐ -	**Date:**.....
Study Title:	

Investigator:	Contact No:
University:	Contact No:
Sponsor:	Contact No:
☐ Deviation from protocol	☐ Non-compliance
☐ Major ☐ Minor	☐ Violation
Description:	
MMU-IREC's Decision:	
Action taken:	Outcome:
Founded by: ..... Date:	Reported by: ..... Date: .....

Study Report Form

Protocol No.:	**Assigned No.:**
Protocol Title:	
Principal Investigator:	
Phone number:	E-mail address:
Sponsor's Name:	
Address:	
Phone:	E-Mail:
Study site(s):	
Total number of study participants:	No. of study Arms:
Number of participants who received the test articles:	
Study materials:	

Treatment form:	
Study dose (s):	
Duration of the study	
Objectives:	
Results: (use extra blank paper, if more space is required).	
Signature of P.I.:	Date:

22.14 Glossary Fourteen:Termination of Study

Study Termination Memorandum

PROTOCOL NUMBER:			
PROTOCOLTITLE:			
PRINCIPAL INVESTOR:			
PHONE:		E-MAIL:	
INSTITUTE:			
SPONSOR:			
MMU-REC APPROVAL DATE:		DATE OF LAST REPORT:	
STARTING DATE:		TERMINATION DATE:	
NO. OF PARTICIPANTS		NO. ENROLLED:	
SUMMARY OF RESULTS			
ACCRUAL DATA:			
P.I. SIGNATURE:		DATE:	

22.15 Glossary Fifteen: Reporting of Adverse Events

Adverse Event	Any unforeseen medical occurrence in a patient or clinical investigation participant administered an investigational product and which does not necessarily have a causal relationship with this treatment. The adverse event can therefore be any unfavorable or unintended sign or experience associated with the use of the investigational product, whether or not related to the product.
Adverse Drug Reaction	In the pre-clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not established all noxious or unintended responses to the product related to any dose should be considered adverse drug reactions. The phrase "responses to a medicinal product" means that a causal relationship between the product and the adverse event is at least a reasonable possibility, i.e., the relationship cannot be ruled out. Regarding marketed products, a response to a product which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of diseases or for modification of physiological function.
IND	Investigational New Drugs means substances with potential therapeutic actions during the process of scientific studies in human in order to verify their potential effects and safety for human use and to get approval for marketing
SAE (Serious Adverse Event)	The adverse event is SERIOUS and should be reported when the Adverse patient outcome is: **Death** - Report if the patient's death is suspected as being a direct outcome of the adverse event. **Life- Threatening** - Report if the patient was at substantial risk of dying at the time of the adverse event or it is suspected that the use or continued use of the product would result in the patient's death.

	Examples: Pacemaker failure; gastrointestinal hemorrhage,' bone marrow suppression; infusion pump failure which permits uncontrolled free flow resulting in excessive drug dosing. Hospitalization (initial or prolonged) - Report if admission to the hospital or prolongation of a hospital stay results because of the adverse event. *Examples: Anaphylaxis,' pseudomembranous colitis; or bleeding causing or prolonging hospitalization.* Disability - Report if the adverse event resulted in a significant, persistent, or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities or quality of life. Examples: Cerebrovascular accident due to drug-induced hypercoagulability; toxicity," peripheral neuropathy. **Congenital Anomaly** - Report if there are suspicions that exposure to a medical product prior to conception or during pregnancy resulted in an adverse outcome in the child. Examples: Vaginal cancer in female offspring from diethylstilbestrol during pregnancy," malformation in the offspring caused by thalidomide. **Requires Intervention to Prevent Permanent Impairment or Damage** - Report if suspect that the use of a medical product may result in a condition which required medical or surgical intervention to preclude permanent impairment or damage to a patient. Examples: Acetaminophen overdose-induced hepatotoxicity requiring treatment with acetylcysteine to prevent permanent damage; burns from radiation equipment requiring drug therapy; breakage of a screw requiring replacement of hardware to prevent malun ion

	of a fractured long bone.
Unexpected ADR	Unexpected Adverse Drug Reaction is an adverse reaction, the nature or severity of which is not consistent with the informed consent / information sheets or the applicable product information (e.g., investigator's brochure for the unapproved investigational product or package insert / summary of product characteristics for an approved product.

Serious Adverse Event Report

Principal Investigator:			Application No: ☐☐☐ ☐☐ ☐☐
Study Title:			Protocol No.
Name of the study medicine/device			Reported Date: ..... ☐ Initial ☐ follow-up Onset date:.....
Sponsor			Date of first use:.....
Subject's initial/number:	Age:	☐ Male ☐ Female	
Subject's History			Laboratory findings:
SAE:	Treatment outcome: ☐ resolved ☐ on-going		
Seriousness: ☐ Death ☐ Life Treatment ☐ Hospitalization – O initial O prolong ☐ Disability/Incapacity ☐ Congenital Anomaly	Relation to O Drug O Device O study ☐ Not related ☐ Possibly ☐ Probably ☐ Definitely related		

☐ Other	☐ Unknown	
Changes to the protocol recommended?		☐ No ☐ Yes, attach proposal
Changes to the informed consent form recommended?		☐ No ☐ Yes, attach proposal

22.16 Glossary seventeen: Monitoring Visits

MMU-IREC representatives	Many MMU-REC members rarely find time to perform monitoring visit themselves. They may ask outside experts or the staff of Ethics Committees to perform the tasks on their behalf and later report their findings to MMU-REC
Monitoring visit	An action that MMU-REC or its representatives visit study sites to assess how well the selected investigators and the institutes are conducting researches, taking care of subjects, recording data and reporting their observations, especially serious adverse events found during the studies. Normally monitoring visit will be arranged in advance with the principal investigators.

Checklist of a monitoring visit

Application No. ☐☐☐ ☐☐ ☐☐	Date of the visit:
Study Title:	
Principal Investigator:	Phone:
Institute:	Address:
Sponsor:	Address:
Total number of expected subjects:	Total subjects enrolled:
Are site facilities appropriate? ☐ Yes ☐ No	Comment:
Are informed consents recent? ☐ Yes ☐ No	Comment:
Any adverse found? ☐ Yes ☐ No	Comment:

Any protocol non-compliance/violation ? ☐ Yes ☐ No	Comment:
Are all Case Record Forms up to date? ☐ Yes ☐ No	Comment:
Are storage of data and investigating products locked? ☐ Yes ☐ No	Comment:
How well are participants protected? ☐ Good ☐ Fair ☐ Not good	Comment:
Are outstanding tasks or results of visit? ☐ Yes ☐ No	Comment:
Duration of visit: ..... hours	Starting from: Finish:
Name of MMU-REC member/	
Representative and a companion:	
Completed by:	Date:

22.17 Glossary Seventeen: MMU-REC Meetings

Agenda	A list of things to be done; a program of business at a meeting
Minutes	An official record of the business discussed and transacted at a meeting, conference, etc.
Quorum	Number. of MMU-REC members required to act on any motion presented to the Board for action
Majority vote	A motion is carried out if one half plus one member of the required quorum vote in its favor.

Format of an Agenda
Agenda of the MMU-REC Meeting
No...../year

Venue of the meeting
Meeting Date
Meeting Time
****

The Board meeting will proceed in the following sequences:

Period 1	Issues to be informed to the members.
Period 2	Approval of the last meeting minute
Period 3	Protocol Presentation, Review, Discussion and Voting
Period 4	Issues to be reported for Consideration
Period 5	Other issues of interest to the members

Program of Studies Protocol to be considered

Time	**Project**	**Investigator/Institute**	**Reviewers**

Form of MMU-REC Meeting Minutes

Meeting No.:		Meeting date:
☐ Regular meeting		☐ Emergency meeting
Location where the meeting is held (city, state)		
Agenda items:		
Starting time:		Adjourned time:

Attending committee members and guests:

1. 8.
2. 9.

3.

4.

5.

6.

7.

10.

11.

12.

13.

14.

Individual serving as Chairman of the meeting:

Determination of a duly constituted quorum by the Chairman to proceed with the meeting.

Prepared by:	Reviewed by:.....
Date:	Date: .....
Approved by:..... Date:.....	

22.18 Glossary Eighteen: Request of MMUREC Document(s)

Document	Documents mean the followings: Study Protocols and related documents (such as case report forms, informed consents, diary forms, scientific documents, reports, records, expert opinions or reviews) MMU-REC documents (SOPs, meeting minutes, advice and decisions) Correspondence (experts, auditors, study participants, etc.) of any forms, such as printed or written papers, hard copies, electronic mails (e-mail), faxes, audio or video tapes, etc.
Non-members of the MMU-REC	Any relevant person/persons who presently is/are not a member/members of the MMU-REC such as authorities, monitors, auditors, subjects, etc.

Log of Requests for Copies of MMU-REC's Documents

#	Documents requested	# of copies	Name of Recipient	Signature of Recipient	Secretariat Initials	Date

Log of copies of original Documents

Title of the document.....

.....

.....

#	Name of Recipient	# of copies	Reason of the request	Signature of Recipient	Secretariat Initials	Date

Note: *This log should be attached to the original documents.*

22.19 Glossary Nineteen: Audit and Inspection

Audit	A systematic and independent examination of research trial approval activities and documents to determine whether the review and approval activities were conducted and data were recorded and accurately reported according to the SOPs, GCP, Declaration of Helsinki and applicable regulatory requirements
Inspection	The act by regulatory authorities of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authorities to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and/or contract research

	organization's (CRO) facilities, Office of Ethics Committees, or at other establishments deemed appropriate by the regulatory authorities

Audit and Inspection Checklist

☐ Internal Audit ☐ External Audit ☐ Inspection	Date:
The date(s) which the audit/inspection has been agreed for	☐ Yes .....☐ No.
Will an interpreter be required? If yes, what arrangements has been done?	
Review the SOPs and note details of any omissions or deviations, with reasons	
Check the files for the presence of all signed documents. Note any that are missing and actions taken.	
Background and training records of MMU-REC members Application Submission Records Protocol Assessment Records Communication Records Amendment Approval Meeting Agenda, Minutes, Action letters Active files Continuing and Final reports	
Are any documents known to be missing form the study master file?	
Which personnel and members will be available? Give details of times and dates.	
What arrangements are there in the event the auditor/inspection needs to make copies of Documents	
Completed by:.....	Date:.....

BIBLIOGRAPHY

1. National Guidelines for Research Involving Humans as Research Participants; (UNCST), 2022.
2. Guidelines for the Conduct of Health Research involving Humans Subjects in Uganda; 1997.
3. Forum for Ethical Review Committees In Asia and the Western Pacific; August 2003.
4. World Health Organization, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000.
5. International Conference on Harmonization, Guidance on Good Clinical Practice (ICH, GCP) 1996.
6. World Health Organization, Surveying and Evaluating Ethical Review Practices, Feb. 2002
7. BU-REC, 2020

LIST OF SIGNATURES

Title of the Guideline (SOPs): MMU-REC Standard Operating Procedures
Number of SOPs: 01 - 21

The following listed persons with their signatures have read this guideline

No.	Full Name of MMU-REC Member	Signature	Date

ETHICS REVIEW CHARGES

The following charges to be reviewed after every five years shall be paid before a protocol is reviewed:

S.NO	Researcher category	First review		Annual renewal	
		Individual	Collaboration	Individual	Collaboration
1.	Mountains of the Moon University Student	USD 20	USD 50	USD 20	USD 50
2.	Mountains of the Moon University Staff	USD 50	USD 80	USD 30	USD 55
3.	Ugandan Student (not 1)	USD 50	USD 80	USD 30	USD 50
4.	Ugandan non-student researcher (not 2)	USD 100	USD 150	USD 50	USD 100
5.	East African Student (not 1 or 3)	USD 200	USD 300	USD 50	USD 100
6.	East African researcher (not 2 or 4)	USD 300	USD 400	USD 50	USD 100
7.	International student	USD 300	USD 400	USD 50	USD 100
8.	International researcher	USD 400	USD 400	USD 50	USD 100
9.	International research collaboration	USD 500	USD 500	USD 50	USD 100

Prayer

The DGSRI requests the CGSREP to receive and consider the SOPs for MMU-REC for onward approval.