

**MOGADISHU UNIVERSITY
INSTITUTIONAL REVIEW BOARD
MU-IRB**

Mogadishu University Institutional Review Board is a committee that handles research proposals by staff and students and also from partners.

Those intending to submit proposals to MU for review should read this information before submission to acquaint themselves with the requirements and the process.

A. Requirements for Initial Review

- Certificate of Humans Subjects Protection from the Principal Investigator/Co-investigator, attached to each application, this is compulsory.
- A submission form MU-IRB (Research Proposal submission form /form 301A) has to be filled in by the principal investigator and signed by the supervisor if the PI is a student. (please request the Forms from this email: mu.irb@mu.edu.so).
- The investigator submits 08 hard copies of the proposal and attaches (staples) the submission form to appear at the front of each copy of the proposal.
- Send a soft copy of the submissions to mu.irb@mu.edu.so.
- Insert a version number and Version date on the protocol, consent forms and data collection tools. This is essential for version control and monitoring document use. Include page numbers on the proposal as well for easy review and provision of feedback.
- Proposal should be submitted three (3) weeks before the date of the meeting (preferably the early weeks of the month); meetings are usually held every last Saturday of the month, so for one to be considered for this meeting they should submit before the 5th of every month, the mode of operation is first come first serve basis.
- All research activities should include a local Investigator (Somalian) to be part of the study. A written approval from the home institution must be submitted with the IRB application for International students and they should also have Somalian Supervisor on the proposal preferably from the Mogadishu University.
- As regards Mogadishu University's higher degree research, two copies of the proposal should be submitted with the IRB submission form signed by their supervisors should be attached to both proposals at the front page. Submissions should be delivered to the MU Administrative Block, MU-IRB Secretary (Refer to Fees Structure) Where applicable.
- For PhD candidates seeking registration from Mogadishu University, their proposals must be signed by their supervisors (Refer to Fees Structure).

Note FOR EMPHASIS: A complete submission should entail the listed items accordingly:

Submission Requirements for Initial Review (Checklist)

- Except for Mogadishu University registered students, CV of the Investigators on the study is required.
- MU-IRB Research Proposal submission form, appropriately signed (form 301A) (available on request).
- A CERTIFICATE IN HUMAN SUBJECTS PROTECTION BY ALL THE INVESTIGATORS IS REQUIRED

- Research Protocol, Investigator brochure, or device specifications (where applicable)
- Questionnaires & assessment instruments, plus copies of these documents translated to the appropriate local language.
- Proposed informed consent document(s); plus, copies of these documents translated to the appropriate local language, “thumbprint” should be provided for illiterate participants. (CONTACTS FOR THE IRB HOTLINE: +252-613997777. Which will be held always by Chairperson or designated Vice-Chair for participants to contact in case they have any questions concerning their rights while they participate in the study and this should be clearly stated in the consent form).
- Proposed subject instruction; plus, copies of these documents translated to the appropriate local language.
- Any other supporting material, such as advertisements for recruitment of Research participants.
- A description of the consenting process or a copy of the investigative site’s Standard Operating Procedures for obtaining informed consent.
- You need to be physically available for presentation on the day of the meeting, using the power point unless exempted.

B. Requirements when responding to IRB Comments;

Usually after review by the IRB, the Research team will receive comments and or suggestions that require them to address or respond to before approval is granted.

This is how you should go about it:

1. A cover letter addressed to the IRB Chair providing itemized responses to IRB comments and guidance for the changes made to the protocol if any
2. (02) copies of the revised protocol with track changes
3. A clean copy of the revised protocol.

C. Requirements for continuing Review

1. Investigators are required to submit the Continuation or Termination of Approved Protocol form to the IRB before the expiration date of the study
2. MU IRB template for continuing review should be followed, (Available on request)
3. A cover letter addressed to the chairman of the IRB requesting for renewal of approval should be submitted to the IRB.
4. Previously approved protocol (02) copies should be submitted together with the request.
5. The Investigator pays the fees (refer to fees structure) to accounts Officer and brings the Photocopy of the receipt when submitting the documents. Or through bank account after getting clearance from the IRB Administrator.

D. Requirements for Amendment of the protocol

An amendment refers to any made to the previously approved proposal, and any change/ amendment requires IRB approval before implementation even the change of a question in a questionnaire or change in title would require IRB review, as long as the change is being made to the protocol that has already been approved.

Requirements:

1. Cover letter requesting for approval of the amendment and a description of the changes proposed indicating the rationale.
2. Submit 03 copies of the previously approved protocol, study instruments and consent forms.
3. 03 copies of the amended protocol, study instruments and consent forms with track changes (highlighting proposed changes) should also be submitted
4. The Investigator pays \$200 to accounts Officer and brings the photocopy of the receipt when submitting the documents.

E. Requirements for Expedited Review of a Protocol

An expedited review, refers to review of a proposal in the quickest way possible, there's no requirement for a meeting, the chairman can either review the submitted proposal or assign it to any other designated MU-IRB reviewer (s), the P.I should expect to get IRB comments within a week which they have to respond to before approval is granted. However not all studies can fit the criteria for expedited review, the MU-IRB chairman and Administrator have to review the proposal in line with the MU-IRB SOPs to determine if it meets the criteria for expedited review.

List of requirements:

1. A cover letter addressed to the IRB Chairman requesting for expedited review, explaining why you think the study qualifies for expedited review.
2. A submission form should be attached to (03) copies of the proposal to be submitted for review.
3. The Investigator should wait to hear from the Committee confirming to them if their study qualifies for expedited review, (the Investigator can be notified within 3 days)
4. The Investigator pays the fees (refer to fees structure) to accounts Officer and brings the Photocopy of the receipt when submitting the documents. Or through bank account after getting clearance from IRB Administrator.

F. Requirements for Exemption from IRB Review

Requests for exemption are also reviewed expeditiously and only apply to proposals which don't involve human subjects, studies that only employ document review and many other specifications in the SOP (Send summary of proposed study).

1. The Investigator Requests MU-IRB SOPs from the Mogadishu University for exemption. SOPs will be available soon on Website www.mu.edu.so the SOPs can be downloaded then from the IRB section (Review Board) in the website.
2. Once the MU-IRB SOPs are (sent to the investigator) or downloaded, the Investigator can review and see if their study complies with the guidelines and then drafts a cover letter addressed to IRB Chairman requesting for exemption from IRB Review basing on the SOPs they've reviewed.
3. Investigator submits 3 Copies of the proposal and fills in Exemption screening questions extracted from the MU-IRB SOPs and submits it as well.
4. This kind of review is charged \$100 which should also be paid to accounts.