MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES

STANDARD OPERATING PROCEDURE (SOP) FOR MUHAS INSTITUTIONAL ANIMAL CARE AND USE POLICY AND PROCEDURES

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LIST OF ABBREVIATIONS

SOP	Standard Operating Procedure
IACUC	Institutional Animal Care and Use Committee
MUHAS	Muhimbili University of Health and Allied Sciences
SRPC	Senate Research and Publications Committee
DRP	Director of Research and Publications
VC	Vice Chancellor
DVC-ARC	Deputy Vice Chancellor – Academic, Research and Consultancy
PI	Principal Investigator
FCR	Full Committee Review
DMR	Designated Member Review
COSTECH	Commission for Science and Technology
TVC	Tanzania Veterinary Council

1. INTRODUCTION

The Muhimbili University of Health and Allied Sciences (MUHAS) Institutional Animal Care and Use Committee, herein after referred to as IACUC, is tasked with the review and recommend of studies involving laboratory animal experimentation for research, training and product development so as to ensure that they are justified by their benefits and minimize pain or suffering that might occur. Standard Operating Procedure (SOP) document is necessary for a smooth operationalization of the IACUC specifically focusing on composition of membership, management and beneficiaries as well as how to carry out the oversight functions and how the Committee should operate in a step by step process of receiving and processing applications from researchers and scientists involved in laboratory animal experimentation. The SOP details the contents of studies involving laboratory animal experimentation and the format, timing of applications as well as the roles of the investigators and reviewers. Furthermore the SOP details in a step by step process of post approval monitoring. The SOP document is essential during inspections since the lack of written SOPs and/or non-adherence are the most frequently reported deficiencies during inspections.

2. THE COMMITTEE

The name of the Committee is MUHAS Institution Animal Care and Use Committee (IACUC).

2.1 Office Location

The office of the IACUC is located in the CHPE Building within the offices of the Directorate of Research and Publications.

Contact address:

Chairperson, Senate Research and Publications Committee (SRPC)
Muhimbili University of Health and Allied Sciences
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3. OFFICE STRUCTURE

The IACUC is the sub-committee of Senate Research and Publications Committee (SRPC). The IACUC will have an operational office composed of:

a. Chairperson (Director of Research and Publication, DRP)
b. Secretary to the Committee
c. Administrator
d. Office Secretary
e. IACUC members

4. COMPOSITION OF IACUC

The IACUC shall be composed of seven members drawn from MUHAS and elsewhere. Selection of committee members will consider gender balance, experience and competence in laboratory animal experimentation. The composition of the members shall be as follows: -

a. Chairperson (Director of Research and Publication, DRP)
b. Doctor of Veterinary Medicine or equivalent. Full or part time employee with training and/or experience in laboratory animals
c. Scientist external to MUHAS with experience and evidence of involvement in laboratory animal experimentation
d. A member from the general public with interest in animal welfare (e.g. animal keeper, member animal welfare society)
e. Three members from MUHAS SRPC (Bioethicist, 2 members from MUHAS Unit engaged with laboratory animals)

5. APPOINTMENT OF IACUC MEMBERS

5.1 Appointing Authority

Members will be recommended by SRPC Chairperson and approved by the Senate.

5.2 Tenure

The duration of appointment is for a period of one triennium (3 years). Thereafter, the Committee shall be reconstituted, where members can be reappointed once. The Chairperson represents the IACUC at the SRPC.

5.3 Resignation, Disqualification and Replacement of Members of IACUC

a. A member may resign to serve IACUC by submitting a letter of resignation to the Chairperson.
b. A member may also be disqualified from continuance should the Appointing Authority find him/her to have contravened the code of conduct.
c. The Chairperson shall request for replacement of any member under the following circumstances:
    i. Protracted illness for a period of more than six months, which does not permit him/her to participate in the deliberations of the Committee.
    ii. Non-attendance without reasonable cause for three consecutive meetings.
    iii. Voluntary withdrawal.
    iv. Disqualified member based on the violation of the code of conduct

6. FUNCTIONS OF THE CHAIRPERSON, SECRETARIAT AND IACUC

6.1 Functions of the Chairperson

The Chairperson shall:

a. Chair Committee meetings.
b. Review and accept revisions that were made as per the Committee recommendation pending proposal approval.
c. Assign responsibilities and duties to any other member.
d. Have the oversight of Committee documents, records and archives.
e. Perform a pre-review of each submission of the Committee to ensure adherence to administrative submission requirements.
f. Undertake all administrative procedures in providing training and educational programs to new and continuing IACUC members.
g. Design and disseminate templates for Committee submission documents, including research proposal, informed consent materials, agreements and periodic and final reports.
h. Design and maintain a system for collecting and filing all IACUC documents, including meeting minutes, member qualifications, proposal submission versions, deviations from approved proposals, and periodic and final reports.
i. Assist MUHAS management to recruit new IACUC members

j. Prepare and submit annual IACUC operational budgets and plans to MUHAS management in consultation with the Deputy Vice Chancelor for Academic, Research and Consultancy (DVC-ARC).
k. Receive, verify and distribute all submitted documents to the appropriate members for IACUC review. Ensure that all required materials for submission are present and complete.
l. Create and distribute meeting agendas, and arrange meeting logistics.
m. Correspond with Principal Investigator (PI) and/or Co-PI throughout the submission and review process, while safeguarding independence of the review process.
n. Advise submitting investigators on preparing and submitting proposals for review according to relevant Standard Operating Procedures (SOP).
o. Be available for and attend any external investigations or audits of the IACUC.
p. Provide updates on relevant and contemporary issues related to laboratory animal experimentation to IACUC members.

6.2 Functions of the Secretariat

The Secretary to the Committee shall be responsible for the daily activities of the Secretariat. The Secretariat shall:

a. Organize effective and efficient tracking procedures for each proposal received.
b. Prepare, maintain, and distribute study files.
c. Organize IACUC meetings regularly.
d. Prepare, maintain and distribute meeting agenda and minutes.
e. Maintain the IACUC's documentations and archives.
f. Communicate with the IACUC members and applicants.
g. Arrange logistics for training of personnel and IACUC members.
h. Organize logistics for preparation, review and distribution of SOPs to stakeholders.
i. Provide the administrative support for the IACUC- related activities.

6.3 Functions of IACUC

The IACUC at MUHAS shall:

a. Safeguard the rights, safety, and well being of laboratory animals used for research, training, testing and production of biologicals.

b. Provide independent, competent, and timely review of the proposed laboratory animal experimentations.
c. Advise the Senate through SRPC on all matters of research, training, testing and production of biologicals using laboratory animals.
d. Develop and establish monitoring procedures for laboratory animal experimentations.
e. Submit the report to SRPC

7. APPLICATION AND PROCESSING OF CLEARANCE FOR LABORATORY ANIMAL EXPERIMENTATIONS

7.1 Domain

The IACUC shall receive applications for clearance for laboratory animal experimentations of proposals and approval from the following domain, regardless of whether the study is cleared by other institutions outside MUHAS, if the study:

a. Is sponsored by MUHAS,
b. Is conducted by, or under the direction/supervision of an employee of MUHAS, that may or may not use any property or facility of MUHAS,
c. Involves the use of MUHAS name,
d. Involves student studies (such as; undergraduate, postgraduate, visiting students).

7.2 Application

a. The application is made by the Principle investigator (PI) or Co-PI on behalf of the research team.
b. PI or Co-PI shall submit all required application documents (such as cover letter, application form, proposal, CV, evidence of payment).
c. PI shall submit both hard and soft copies of the application documents to the office of Director of Research and Publications (DRP), MUHAS.
d. Postgraduate students shall submit both hard and soft copies of the application documents to the office of the Director of Postgraduate Studies who will subsequently forward it to the office of DRP.
e. Animal experimentation involving undergraduate students will be under custodian of their supervisors who will be responsible for the review of their work and submission to DRP for ethical clearance.

7.3 Processing of Application

a. Upon receipt of the application, office of DRP will validate if the application meets the application criteria.
b. The PI or Co-PI is informed immediately on the receipt of the application and if there are any deficiencies they are communicated for immediate attention.
c. Applications meeting the criteria are registered in the database and forwarded to the IACUC for review.
d. IACUC Chairperson shall choose one or more independent reviewers for each proposal who shall review it and submit report within ten (10) working days.
e. The report will be discussed by the IACUC that will subsequently make decision and recommendations regarding the proposal to the DRP
f. The DRP will subsequently communicate the decisions to the PI/Co-PI.

8. CRITERIA FOR REVIEWING AND APPROVING PROPOSALS ON RESEARCH, TRAINING, TESTING AND PRODUCTION OF BIOLOGICALS INVOLVING LABORATORY ANIMAL EXPERIMENTATION

All proposals on research, training, testing and production of biologicals involving laboratory animal experimentation shall abide to the 3R principles:

a. The investigator should indicate the need for use of animals other than alternatives, stating why non-sentient experimental systems are not suitable for the proposed study.
b. The investigator should show potential benefits of the proposed experimental animal studies to the human and animal health, advancement of knowledge and the public goods.
c. The selected animals (species, breeds, strains) appropriately meet the intended output of the study.
d. The investigator should show how the number of laboratory animals is kept to the minimum through use of appropriate animal species, standardization, selection of specific models and appropriate experimental design that provide valid results and adequate statistical power.
e. The investigator should show that experimental procedures are conducted by a trained, skilled or experienced personnel.

f. The author should show how the experiment will avoid and minimize discomfort, pain, distress and suffering to animals by appropriate transportation, acclimatization, husbandry, restraining, sedation, analgesia, or anaesthesia.
g. The investigator should show that experimental procedures (e.g. administration of drugs and other materials, collection of body fluids, biopsies, stool) are conducted according to prevailing guidelines.
h. The investigator should show how the collected laboratory animal samples (e.g. body fluids, biopsies, stool) are properly handled, transported, stored, processed and analysed.
i. The investigator should show clearly how humanely the experiment is terminated and animals disposed. This manner of disposing animals should include those exiting the experiment before termination.
j. Safe disposal; animals should be disposed in a manner that will take precaution to prevent any spread of disease from animal s to humans

9. POST APPROVAL MONITORING OF LABORATORY ANIMAL EXPERIMENTATION

a. The duration of the projects involving animal experiment studies should be specified in the proposal and application form.
b. Time frame for laboratory animal experimentation should be clearly indicated to allow planning for monitoring
c. Laboratory animal experimentation should start within six months of stipulated time frame otherwise written explanation for the delay should be given.
d. Failure to start laboratory animal experimentation within one year of stipulated time frame will require resubmission of the animal experimentation component of the study for review and approval.
e. Approved ongoing animal experiments are subject to annual renewal of their approval. The PI/Co-PI shall apply for the renewal one month before expiry of the active date.
f. IACUC will determine the levels of risk for particular animal experimentation and decide on frequency of monitoring.
g. Progress reports shall be submitted to the DRP at least every six months, or more frequently if the level of risk is high.

h. Investigators are required to obtain laboratory animal experiment clearance before implementing amendment to previously approved study.
i. Serious adverse events resulting from the laboratory animal experiments should immediately be notified to DRP by the PI/Co-PI.
j. For non-compliance concerns, SRPC may decide to carry out adhoc visits of study site and facilities to check compliance to the approved laboratory animal experiments.
k. The decision to suspend or terminate approved laboratory animal experimentation shall be made by Senate upon recommendation by SRPC.
l. PI/Co-PI shall declare confidentiality of data of which IACUC shall support data safety monitoring.
m. PI/Co-PI should ensure safety to all personnel involved in laboratory animal experimentations.
n. PI/Co-PI should clearly show how to handle accidents, emergencies and infections to animals and personnel involved in laboratory animal experiments.
o. A summary of the final report on the laboratory animal experimentation should be submitted to the DRP within one year of conclusion of the study.

10. MEETINGS OF THE IACUC

10.1 Schedule of the meetings

a. The IACUC shall hold meetings as needs arise.
b. The schedule and agenda of Committee meetings shall be prepared by the Secretariat and communicated to the IACUC members at least a week before the meeting.

10.2 Agenda

The Chairperson and administrator shall prepare the "standard agenda" for the meeting which will include at least the following:

a. Date, time and venue of the meeting
b. Declaration of conflict of interest relating to items on the agenda
c. Confirmation of minutes of the previous Committee meeting
d. Matters arising from previous meetings
e. Application for laboratory animal experimentation clearance

f. Application for laboratory animal experimentation clearance for studies which have undergone amendments.
g. Report(S) of serious adverse events and complaints on/from laboratory animal experimentation, personnel involved and the community.
h. Any other report to be reviewed by the IACUC
i. Any Other Business

10.3 Meeting process

a. The Chairperson or administrator appoints one member as lead (secondary) reviewer for each proposal. Two weeks prior to the meeting information is given to the reviewer. The agenda indicates the lead reviewer for proposal.
b. The Chairperson/Secretary may invite the PI or Co-PI to attend the meeting at which his/her application is reviewed.
c. The Chairperson/Secretary may invite a person who has relevant expertise to the proposal being discussed or representatives of communities, or special interest group.
d. A member who is unable to attend a meeting may submit comments in writing on any agenda item.
e. The quorum for meetings of the IACUC at least four members.
f. Conflict of interest in the Agenda items is expressed by signing a form of declaration of conflict of interest, and the member has to excuse himself/herself from the meeting room when the respective proposal is being discussed.
g. The Chairperson is responsible for conduct of the business. All members present are given reasonable time to express their views. The meeting is held in privacy and members are required to exercise confidentiality with regard to the business of the IACUC.

10.4 Decision making

a. Decision is reached by consensus
b. One of the following decisions is taken by the IACUC:
    i. Recommended as presented
    ii. Provisionally recommended, subject to revisions
    iii. The Committee decides that further expert consultation is needed

iv. Not recommended

c. The Chairperson ensures that one of the above decisions is made on every application
d. The IACUC decision for further information or clarification is delegated to the chairperson or designated review committee for considering the information and recommend issuing of clearance.
e. Decision on laboratory animal experimentation clearance is made within a period of 60 days of the date of receipt of application by IACUC.

10.5 Minutes

a. The minutes of the IACUC meetings are prepared by the Secretariat and approved for circulation by the Chairperson.
b. The minutes are confirmed in the next meeting and signed by both Secretary and Chairperson.
c. The minutes are confidential.

10.6 Communicating decision to applicants

a. After approval by the VC, the DRP shall send notification of the decision to the PI/Co-PI in writing within one week of receipt of the VC's approval.
b. Research teams involving foreign nationals doing research in Tanzania require research permit by the Commission for Science and Technology (COSTECH).
c. Research teams involving foreign nationals may require veterinary professional certification from Tanzania Veterinary Council (TVC).

11. EDUCATION AND TRAINING OF IACUC MEMBERS AND SUPPORTIVE STAFF

a. The office of the DRP shall support seminar(s) to IACUC members and supportive staff at least once a year.
b. Seminar facilitators will be invited from within and outside MUHAS.
c. Training curricula for the seminars shall be predetermined by the IACUC Secretariat, but may be flexible to accommodate specific needs for participants.
d. The IACUC members are encouraged and supported to attend research ethics workshops and conferences.

12. ESSENTIAL READINGS FOR IACUC MEMBERS

a. MUHAS Research Policy 2009
b. Guidelines on Ethics for Health Research in Tanzania. Publication of the Tanzania Health Research Forum, 2001
c. Tanzania Animal Welfare Act, 2008
d. MUHAS quality assurancy policy, November 2017
e. IRAC 1985 agreed principles

13. FEES, REIMBURSEMENT FOR MEMBERS AND OPERATIONAL BUDGETS FOR THE IACUC

13.1 Fees for Laboratory Animal Experimentation Clearance

a. Review of new proposals and amendments by the IACUC are subject to a fee.
b. The IACUC administrator, upon receipt of application, shall send the invoice to the PI, Co-PI or Sponsor.
c. Invoices must be paid to MUHAS finance department prior to dispatch of approved letters.
d. A fee of $100 shall be paid for each new application whereas $50 and $25 shall be paid for major and minor amendments respectively.
e. Fees for proposals emanating from students are subject to MUHAS regulations
f. The following categories are exempted from fees:
    i. Proposals funded by MUHAS small grants (e.g. Departmental support).
    ii. Small, self and in-kind sponsored proposals involving MUHAS staff.

13.2 Honoraria for IACUC Members

a. Reviewers of proposals will be paid according to the prevailing MUHAS rates and regulations.

13.3 Budget for IACUC

a. The IACUC Administrator/Secretary shall prepare an annual operational budget and send it to the appropriate institutional authority for approval.
b. The total budget will depend on a number of items that require funding to adequately maintain a fully operational IACUC.

14. STANDARD LETTERS AND FORMS

Wherever necessary the following standard letters and forms will be used.

a. Acknowledgement of receipt of valid /invalid application
b. Application forms
c. Approval of laboratory animal experimentation letter
d. Checklist form for applicants
e. Annual report forms
f. Guidelines for reviewing proposals involving laboratory animal experimentation
g. Confidentiality/Conflict of interest agreement form