

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES



INSTITUTIONAL ANIMAL CARE AND USE POLICY AND PROCEDURES

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1.0 PURPOSE AND CONTEXT

1.1 Purpose

The purpose of the Policy and Procedures for research involving Laboratory Animals is to assist units using animals for research at MUHAS, in caring for, and using animals for scientific purposes in ways judged to be scientifically, technically, and humanely appropriate, according to the ethical principles. This document is meant to assist scientists, researchers and other stakeholders to understand and apply ethics in research involving animals. The Policy and Procedures for research involving Laboratory Animals outline the responsibilities of MUHAS Institutional Animal Care and Use Committee (IACUC), staff, and investigators involved in the use of animals for scientific purposes. Research involving animals shall comply with the Tanzania Health Policy. The document will be reviewed from time to time to keep in pace with advancement of scientific knowledge and changes in societal perspective regarding animal morals.

1.2 Context

MUHAS has a Research Policy that guides the Institutional Review Board/Ethics Committee to ensure that animals involved in research are treated humanely. The University also a Quality Assurance policy which ensures that implementation of the various research projects constantly adheres to ethical and environmental considerations.

At MUHAS, animals are used for various purposes including drug discovery and teaching purposes. MUHAS has an animal house which is currently used with shared management from Institute of Traditional Medicine (ITM) through Departments of Biological and Pre-Clinical Studies, and School of Medicine (SoM) through departments of Clinical Pharmacology and Medicinal Chemistry. Each unit has personnel dedicated in taking care of animals including feeding, cleaning, and breeding. However, these personnel have no specialized training on laboratory animal care. In addition, despite being in operational for years, MUHAS lacks specific policy and procedures for care and use of animals in research.

A stakeholders workshop was conducted in March 2019 at MUHAS, involving researchers from different institutions in Tanzania to discuss the use of animal for research. It was realized that there is no single committee overseeing experiments involving laboratory animals despite the increase in number of animals used in these experiments. Moreover, the country has no similar guideline or standard operating procedures to be adopted for the same. Participants expressed a need to have a committee to evaluate and oversee care and use of laboratory animals for research, training and production of biologicals in Tanzania. Workshop participants agreed that MUHAS should spearhead the establishment of Institutional Animal Care and Use Committee (IACUC).

This document may also serve as a benchmark for developing Policy and Procedures for other research institutions and the country. The purpose of this document is also to provide ethical

guidelines for researchers and other people who are considering experiments on animals. The document will not only be useful during reviewing and approval of animal research proposals but also during post approval monitoring, reporting, and publishing results emanating from such research involving laboratory animals. Use laboratory animals is necessary in biomedical sciences to improve people and animal health, and the environment thereof. It is perceived that animals have a moral status, and their treatment should be subject to ethical considerations due to the following:

- (i) Animals have an intrinsic value which must be respected.
- (ii) Animals are sentient creatures with the capacity to feel and suffer from pain.

This policy and Procedures therefore reflect these situations and stipulate principles and considerations that reduce harm to animals under experiments while benefitting humans, animals, and the environment. These principles are grounded on the three Rs (Replace, Reduce, Refine).

1.3 Scope of application of the policy

This policy will be applicable to:

- a. MUHAS researchers
- b. MUHAS students
- c. MUHAS collaborators
- d. MUHAS Institutional Animal Care and Use Committee
- e. Reviewers of proposals related to laboratory animal experimentation
- f. MUHAS personel taking care of laboratory animals
- g. Any scientist affiliated with MUHAS working with laboratory animals within the country

1.4 Objectives of the Policy

The objective of Policy and Procedures for research involving Laboratory Animals is to ensure that experiments conducted in laboratory animals are justified, performed ethically and humanely to meet the demand of science for public good. Specifically:

- (i) To establish an Institutional Animal Care and Use Committee for Muhimbili University of Health and Allied Sciences.
- (ii) To provide policy and procedures for review, execution and monitoring of laboratory animal experimentation
- (iii) To provide guidance to Chair, SRPC on all matters concerning laboratory animal experimentation
- (iv) To provide conducive environment for scientists to acquire funding, perform laboratory animal experiment and disseminate results.

2.0 DEFINITIONS

Animal experiment	Any scientific procedure involving animal(s)
Experimental animal	Non-human vertebrate used in animal experiment
Animal welfare	Is the well-being of non-human animal(s)
Humane care	Any human action(s) taken to ensure that animals are treated ethically
Laboratory animal	Any vertebrate animal used in the laboratory for scientific purposes including research, testing, training or production of biologicals
Pain	Physical, emotional or mental suffering caused by injury or illness
Research proposal	A document that contains information required for research stakeholders to decide to initiate a study
Suffering	The state of undergoing pain, distress, or hardship
Research	A systematic inquiry to describe, explain, predict and control the observed phenomenon
Reduction	A strategy for obtaining valid, reliable and reproducible scientific information from the use and/or re-use of least possible number of experimental animals
Refinement	Modifications of animal environment or experimental procedures to enhance animal well-being and minimize or eliminate pain, suffering and distress during animal experiment
Replacement	Refers to methods that avoid direct use of laboratory animals during experiment
Ethics	Moral principles that govern a person's behaviour or the conducting of an activity (philosophy that involves systematizing, defending, and recommending concepts of right and wrong conduct)
Ethical review	A formal evaluation of the moral grounding of a proposed scientific document before implementation
Distress	Extreme anxiety, sorrow, or pain
Biologicals	Involves animal cell cultivation techniques are viral vaccines (human and veterinary) monoclonal antibodies, cell surface antigens, enzymes, polypeptide growth factors, hormones, immunoregulators, viral bio-insecticides, tumor antigens, cell mass as a product and reconstitution of living skin.

3.0 POLICY STATEMENTS

3.1 Policy statement I: Establishment of the MUHAS Institutional Animal Care and Use Committee (IACUC)

The Muhimbili University of Health and Allied Sciences shall have Institutional Animal Care and Use Committee (IACUC). The IACUC is a regulatory requirement for the institutions that use laboratory animals in research, training, testing and production of biologicals. The IACUC has a key oversight role including the review and recommending activities and inspection of facilities for laboratory animal experimentation.

3.2 Policy statement II: Beneficiaries of Policy and Procedures for research involving Laboratory Animals

The beneficiaries of this policy and procedures shall include MUHAS staff, students and research collaborators, Muhimbili National Hospital (MNH), Muhimbili Orthopedic Institute (MOI), Ocean Road Cancer Institute (ORCI), Jakaya Kikwete Cardiac Institute (JKCI), other research institutions in the country and other stakeholders.

3.2.1 Procedures:

- a) All research proposals involving laboratory animals from the beneficiaries must be reviewed and approved by IACUC.
- b) MUHAS will make all necessary efforts to ensure that beneficiaries understand the policy and procedures pertaining to laboratory animal experiments.
- c) Ethical clearance of proposals will be granted to beneficiaries involved in research, training, biological testing, production of biologicals and other laboratory animal experiments conducted at the University or at another institution while complying with IACUC Policy and Procedures.
- d) The IACUC will inspect, at least once every 12 months, the beneficiaries' institutional animal facilities and advice on proper conduct of the facilities.
- e) The university will ensure that individuals involved in laboratory animal experiments comply with occupational health and safety procedures.
- f) Personnel actively working in laboratory animal facilities should be screened annually for potential zoonoses.

3.3 Policy statement III: Management of IACUC

MUHAS IACUC shall be a sub-committee of Senate Research and Publication Committee (SRPC) of MUHAS whose chair is Director of Research and Publications (DRP).

3.3.1 Procedures:

The Chair of MUHAS IACUC will:

- a) take overall responsibility for the MUHAS laboratory animal care and use policy and procedures
- b) be responsible for planning of resources for the IACUC.

- c) be responsible for ensuring that implementation of this policy and procedures is in line with MUHAS and National Development vision and mission.

3.4 Policy statement IV: Composition and appointment of the IACUC

The MUHAS Institutional Animal Care and Use Committee (IACUC) shall be composed of seven members, whose composition shall be as follows:

- I. Chair, Senate Research and Publication Committee
- II. Doctor of Veterinary Medicine with training and/or experience in laboratory animal science.
- III. A scientist experienced in research involving animals.
- IV. A member from the public to represent the interests of the community with regard to proper care and use of laboratory animals.
- V. Three members from MUHAS SRPC, one must be bioethist, the other from MUHAS Unit engaged with laboratory animals.

3.4.1 Composition:

- a) The members of the committee will be recommended by SRPC Chairperson and approved by the Senate.
- b) The tenure for this committee will be three years, and a member can be reappointed only once.
- c) The committee members will be required to be up to date regarding animal care and use in research

3.5 Policy statement V: Functions and responsibilities of the IACUC

The IACUC at MUHAS shall be responsible for review, approval and oversight of all activities involving laboratory animals' experimentation to ensure that research, training, testing and production of biologicals from laboratory animals at MUHAS and elsewhere in the country are designed and carried out in a humane manner that complies with IACUC Policy and Procedures, animal welfare regulations and agreed guidelines and principles.

3.5.1 Responsibilities:

The IACUC at MUHAS will be responsible for:

- a) Preparation of checklist for researchers and reviewers to use when developing and reviewing proposals for research, training, testing and production of biologicals involving laboratory animal experimentation.
- b) Reviewing and recommending for approval proposals for research, training, testing and production of biologicals involving laboratory animal experimentation at MUHAS and elsewhere.
- c) Assessing the contents of guidelines and standard operating procedures for research, training, testing and production of biologicals involving laboratory animal experimentation at MUHAS and elsewhere.

- d) Investigating, collecting, reviewing and advice corrective measures for all concerns for research, training, testing and production of biologicals involving laboratory animal experimentation at MUHAS and elsewhere.
- e) Conducting inspection of animal facilities and laboratories at least once a year to ensure that they comply with IACUC Policy and Procedures, animal welfare regulations and agreed guidelines and principles.
- f) Preparation of inspection reports and making recommendations regarding animal facilities, personnel and general conduct of experiments involving laboratory animals to the SRPC

3.6 Policy statement VI: Ethics in animal research

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

3.6.1 Procedures:

The scientists should show how they have considered replacing, reducing and refining the use of animals in their research, hereby;

- a) Replacement: The scientist(s) should show there is a lack of alternative methods
- b) Reduction: The scientist(s) should indicate the number of animals used is minimum. However, when thinking about ways to reduce the number of animals used, scientists also have to ensure that the design of their experiment is robust.
- c) Refinement: The scientist(s) should aim to alleviate or minimize potential pain, suffering or distress for laboratory animal welfare.

3.7 Policy statement VII: Submission procedures for proposals on research, training, testing and production of biologicals involving laboratory animal experimentation

Proposals for research, training, testing and production of biologicals involving laboratory animal experimentation shall be submitted to IACUC for review and approval before commencement of the experiments.

3.7.1 Procedures:

The procedures for submission of proposals to the IACUC at MUHAS will be:

- a) All applications for review and approval of proposals on research, training, testing and production of biologicals involving laboratory animal experimentation will be submitted to the Chairperson, SRPC, MUHAS.
- b) The application must be accompanied by evidence of payment of the application fees as per MUHAS guidelines.
- c) Application should clearly indicate the Principle investigator (PI) and the role of each investigator.
- d) Applicants should submit proposals following MUHAS or any other institutional guidelines for proposal development but the component involving animal experimentation must contain the following:

- i. Justification for using laboratory animals
 - ii. Significance/Rationale: Relevance of the results to humans or other animal species
 - iii. Materials and Methods: study design, materials and equipment required for the study, experimental animals used (type, species, strains, age, sex, weight, animal model) and reason for the choice, experimental design, sample size, procedures for assigning animals in different experimental groups, animal housing and husbandry, experimental procedures, variables to be collected (dependent and independent), collection, processing and analysis of any collected samples (e.g. body fluids, faeces, tissues etc.), data collection and statistical analysis.
 - iv. Source of laboratory animals to be used in the experiment(s)
 - v. Transportation of acquired and acclimatization of laboratory animals
 - vi. Disposal of the used animals
 - vii. Ethical statement: addressing animal welfare and humane use of animals and how the 3Rs were observed.
- e) All applications submitted should be accompanied by CV of each investigator indicating their scientific capacity and experience to carry out the proposed laboratory animal experiment(s).
 - f) The Chair, SRPC, will forward the submitted proposals to the IACUC for review and recommendations.
 - g) Decisions made by the IACUC will be submitted to the applicants through the Chair, SRPC

3.8 Policy statement VIII: Criteria for reviewing proposals on research, training, testing and production of biologicals involving laboratory animal experimentation

Proposals on research, training, testing and production of biologicals involving laboratory animal experimentation shall be reviewed by IACUC using the set criteria. The IACUC will assess whether the proposed research is designed and will be conducted in a manner that complies with IACUC Policy and Procedures, animal welfare regulations and agreed guidelines and principles.

3.8.1 Procedures:

Proposals on research, training, testing and production involving laboratory animal experimentation will be reviewed to ensure that the following set criteria are met;

- a) Proposals on research, training, testing and production of biologicals involving laboratory animal experimentation comply with this Policy and Procedures, animal welfare regulations and agreed guidelines and principles.
- b) There is a scientific justification and rationale for conducting the study which consider relevance to animal health, advancement of knowledge, the public good.
- c) There is a scientific justification and rationale for use of laboratory animals and not alternatives.
- d) The animals selected for a procedure are of an appropriate species, quality and standardization.

- e) The minimum number of laboratory animals required to obtain valid results are used according to experimental study design and statistical power.
- f) There is proper execution of laboratory animal experiment(s), including the avoidance and minimization of discomfort, pain, distress and suffering to the animals.
- g) Appropriate experimental procedures (e.g. administration of drugs and other materials, collection of body fluids, biopsies, stool) are conducted.
- h) Collected laboratory animal samples (e.g. body fluids, biopsies, stool) are properly handled, transported, stored, processed and analysed.
- i) Appropriate sedation, analgesia, or anaesthesia is used for procedures that may cause pain or distress to laboratory animals.
- j) The animals that will suffer severe or chronic pain, distress or disability that cannot be relieved by medication are humanely euthanized at the end of the procedure or, if appropriate, during the procedure.
- k) The living conditions of laboratory animals during experimentation are appropriate for their species and numbers and contribute to their health and comfort.
- l) Researchers and other personnel handling laboratory animal experiments are appropriately qualified and experienced for conducting the procedures.
- m) Procedures for termination and disposal of laboratory animals exiting or at the end of the experiments should be humane.

3.9 Policy statement IX: Post approval monitoring of approved proposals

The IACUC shall conduct regular oversight of all approved proposals on research, training, testing and production of biologicals involving laboratory animal experimentation in a form of post approval monitoring that will help to ensure the well-being of the laboratory animals and which may provide opportunities to refine the conduct of the experiment(s).

3.9.1 Procedures:

The primary goal of the post approval monitoring is to foster a positive culture on research, training, testing and production of biologicals by striving to establish partnerships with investigators in order to promote and ensure animal welfare, proposal compliance (i.e. accurate and consistent adherence to the approved proposal) and high quality research and exchange of information (e.g. new policies, regulations, and guidelines that may affect proposal compliance and/or laboratory best practice).

Monitoring will find out whether the procedures and activities described in the proposal are implemented accordingly. The procedures for monitoring will be:

- a) Ethical clearance will be given for a duration of one year, and has to be renewed before expiring.
- b) Monitoring will be done where need arises (based on specific proposal activities, on a random basis, for-cause monitoring due to animal welfare or non-compliance concerns) and the frequency will be subject to the sensitivity of the experiment(s).

- c) Coordinate a visit for monitoring of facilities and personnel involved in laboratory animal experimentation at least once per year.
- d) Work with the investigators and personnel involved in laboratory animal experiments to review proposals and observe if animal experiments comply with this Policy and Procedures document, animal welfare regulations and agreed guidelines and principles.
- e) Provide appropriate recommendations and support to investigators and personnel involved in laboratory animal experimentations to ensure compliance with these Policy and Procedures, animal welfare regulations and agreed guidelines and principles. Recommendations may include additional monitoring, training, and/or an amendment to the protocol.
- f) Non-compliance with these Policy and Procedures, animal welfare regulations and agreed guidelines and principles will be reported to the Chair, SRPC.
- g) Failure to comply with these Policy and Procedures, animal welfare regulations and agreed guidelines and principles will result into recommendation of termination of the laboratory animal experiments.

4.0 REVIEW OF REPORTS

4.1 Policy Status

This is the new Policy and Procedures for Institutional Animal Care and Use and subject to approval by Council may be changed from time to time as experience and body of knowledge increases in this field.

4.2 Key Stakeholders

The following list of stakeholders have been consulted during the development of this Policy and Procedures for Institutional Animal Care and Use. Key stakeholders included members of the external community as well as university staff.

- i. MUHAS management
- ii. MUHAS faculty
- iii. Scientists and faculty in other Universities in Tanzania who attended conference on ethics of animal research, at MUHAS.
- iv. Other institutions and regulatory authorities (SUA, NIMR, COSTEC, TVLA, HKMU)
- v. Associated hospitals (Muhimbili National Hospital, Muhimbili Orthopedics Institute, Ocean Road Cancer Institute, Jakaya Kikwete Cardiac Institute)
- vi. MUHAS collaborators (Dartmouth College and University of Penn, USA)
- vii. Researchers
- viii. Adjunct staff
- ix. Students

5.0 APPROVAL DETAILS

The University Senate approved the policy on the agenda itemin the minutes of the Senate meeting numberon

6.0 ENDORSEMENT DETAILS

The University Council endorsed the policy on the agenda itemin the minutes of the Council meeting numberon

7.0 RELATED LEGISLATION

MUHAS Charter of Incorporation, February 2007;4 (ii), (k), (q)

8.0 RELATED POLICIES

- A. Research Policy Guidelines (2017)
- B. Research Agenda (2012)
- C. MUHAS Welfare Act (Y)

9.0 RELATED DOCUMENTS

- A. Understanding Animal Research, 2017
- B. Animal Welfare and the 3Rs
- C. Medical Advances and Animal Research
- D. How is animal research regulated?

10.0 EFFECTIVE DATE FOR THE POLICY

Unless otherwise determined by the approving body, the policy shall become effective from the date it is approved by the University Senate/Council.

11.0 NEXT REVIEW DATE

Three years after approval and when deemed necessary.

12.0 POLICY OWNER

Muhimbili University of Health and Allied Sciences Council.

13.0 POLICY AUTHOR

The Directorate of Research and Publications of the University.

14.0 CONTACT PERSON

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