



UNIVERSITY OF LIMPOPO

**Animal Research and Ethics Committee (AREC)
Terms of Reference (TOR)**

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1. INTRODUCTION

The University of Limpopo has established an Animal Research Ethics Committee (“AREC”) under the terms of the National Health Act 61 of 2003 (“National Health Act”) and the Department of Health, Ethics in Health Research: Principles, Processes, and Structures, 2nd ed. 2015 (“National Guidelines 2015”). The Terms of Reference (“ToR”) are designed to ensure that the AREC is compliant with the requirements of the National Health Act, South African National Standard(SANS10386) or any other amendment thereof) and other related Acts and guidelines.

2. PURPOSE OF THE TOR

The TOR is to provide guidelines and minimum standards for the AREC operational management of the research process within the University.

- The primary ethics guidance for the AREC will be the South African National Standard 10386:2008 (“SANS 2008 or any other amendment thereof) and the National Guidelines 2015.
- Where relevant, major international guidelines (including, but not limited to International Guiding Principles for Biomedical Research (“CIOMS and ICLAS”) will apply. When strict compliance of a particular requirement of these declarations and codes is impossible, AREC will ensure that the proposed research is nonetheless in keeping with the spirit of the declarations and codes.
- The fundamental purpose of the AREC in reviewing research is to contribute to safeguarding the welfare, safety, and well-being of all animals in research, teaching and learning conducted by the University and its researchers. The AREC will do this through independent, prospective and ongoing ethics review of all research projects involving animal participants undertaken by members of staff, registered students and affiliates of the University, and external applicants.
- Research to be reviewed by the AREC will be in accordance with the legislative guidelines listed below.

2.1 LEGISLATIVE, POLICY FRAMEWORK/ GUIDELINE

- The Animal Protection Act, 1962 (Act 71 of 1962)
 - The Animal Diseases Act, 1984 (Act 35 of 1984)

- The Veterinary and Para-Veterinary Professions Act, 1982 (Act 19 of 1982) and all subsequent notices relating to the practicing of these professions
- The Animal Health Act, 2002 (Act 7 of 2002)
- The Medicine and Related Substances Control Act, 1965 (Act 101 of 1965)
- The Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947)
- The South African National Standard for the care and use of animals for scientific purposes SANS10386 10386:2008 or any amendment thereof
- All applicable standards prescribing normal farming practices and transport, including, national and industries standards, as well as standards published as Regulations in terms of any of the applicable Acts, such as wildlife and aquaculture.

3. SCOPE

- Any research involving animals must be submitted for review by the AREC.
- When reviewing research proposals, special attention will be given to research that includes live, non-human vertebrate, including fertilized eggs, fetuses and embryos, i.e. fish, amphibians, reptiles, birds and mammals, and encompassing domestic animals, feral animals, purpose-bred animals, farm animals, wildlife and higher invertebrates, such as the Cephalopoda and Decapoda (for example, octopus, squid, cuttlefish)
- The AREC will uphold all the University's necessary rules and regulations and in so doing review applications for degree and non-degree purposes, including procedures applicable to the maintenance of animals, and approve only activities that are ethically acceptable and conform to the approved standards.
- The AREC will under no circumstances consider any applications for retrospective review.
- The AREC will issue a waiver letter where secondary data will be used, or when the research involves invertebrate species.

4. RESPONSIBILITIES

4.1. AREC

The main responsibility of the AREC is to conduct rigorous ethics reviews of all research proposals involving animals to safeguard the welfare, safety, and well-being of all animals in teaching and research. The other responsibilities include but are not limited to the following:

- a) Promote the four R's of research (Replace, Refine, Reduce, and Responsibility); hold researchers accountable for their research actions;
- b) The AREC must confirm that research proposals stand up to ethical scrutiny as is appropriate to the discipline or field concerned.
- c) The review must ensure the maintenance of ethical standards.
- d) Inspect animal facilities
- e) Monitor animal studies
- f) Advise the institution
- g) Protect animals from harm by weighing the risk of harm against the prospect of benefits; Promote the highest ethical standards and best available techniques or approaches for optimal wellbeing of participating animals; and
- h) Promote important environmental, social and ethical values to the research community.
- i) AREC must review research proposals prospectively and not retrospectively, to ensure that the research proposal meets the accepted ethical norms and standards before research commences, using the guidelines indicated in the National Guidelines 2015 as a minimum benchmark, of which one important aspect is, but which is not limited to:
- j) The primary responsibility of each AREC member is to decide independently whether the proposed research study protects the interests of animals adequately and upholds the highest of standards.
- k) In reviewing ethics applications, allocate a suitable level of severity classification for research studies whilst reviewing ethics applications which can be found as AREC Research Classification of Severity Categories in Animal Research
- l) follow-up site and study inspections confirm that the AREC Guidelines for the Use and Care of Animals in Teaching and Research at the University of Limpopo
- m) ensure that all AREC members sign the research ethics Code of Conduct
- n) The AREC will uphold the necessary University's rules and regulations.

4.2. THE CHAIRPERSONPERSON

The Chairperson is responsible for impartially guiding the operations of the AREC, resolving conflicts of interest related to the business of the AREC, and representing the AREC in any negotiations with the institution's management. This includes:

- a. ensuring that the Committee operates in accordance with the principles and requirements of the Code, the relevant policies of the University, and the agreed Committee procedures
- b. ensuring that proposals are considered by the Committee and the outcomes conveyed to investigators in a timely manner
- c. advising University management regarding the level of resourcing required by the Committee
- d. representing the committee in any negotiations with management
- e. overseeing all requirements of the committee to report and review its operation
- f. ensuring committee records are maintained and made available for review by the institution and authorised external reviewers.

4.2.1 DELEGATED AUTHORITIES

The Chairperson shall have delegated authority to:

- a) Consult with any other members of the committee and any other parties to seek advice and assistance in addressing matters arising from any report of adverse occurrence or unforeseen event.
- b) Any delegated authority decisions made by the chairpersonperson must be reviewed at the next quorate meeting of the committee, and in the absence of the Chairperson, the members present will elect one of their member as Chairperson of that meeting.
- c) Delegated powers for dealing with proposals: The chairpersonperson, secretariat, and at least one member from category C or D (as a sub-committee) will have delegated power to approve minor modifications, such as short extensions of time, to approved projects and to deal with emergencies, and
- d) any decisions made by the sub-committee in relation to minor modifications to approved projects must be reported to and reviewed by the committee at its next meeting and the Committee must be provided with: a) a copy of the documentation related to each proposal considered, and b) any resolutions requiring formal ratification by the committee.

5. MEMBERSHIP AND TERMS OF OFFICE

Each appointment shall normally be for a term of three years. It is recognised that in some circumstances, the availability of suitably qualified potential members will require some members to serve for longer periods.

Prior to the expiry of the current term of office, members will be invited in writing, to serve an additional term of office. On written acceptance, members will be deemed to have been re-appointed. Where members decline this invitation, a vacancy will be declared. On declaration of a vacancy, the DVC Research Innovation and partnerships will be notified, and the Director of Research Administration and Development will facilitate the process of filling the vacancy.

6.1 The membership of this Committee shall be:

- **Ex Officio Membership**
 - a) Deputy Vice-Chancellor (Research Innovation and Partnerships)
 - b) Director: Research Administration and Development
- **Category A Member:** A person(s) with qualifications and experience to provide comparable expertise. Person with qualifications in veterinary science, who is registered or authorized as a veterinarian in terms of the relevant national council , and with experience relevant to the institution's activities or the ability to acquire relevant knowledge.
- **Category B members** – suitably qualified person with substantial and recent experience in the use of animals for scientific purposes relevant to the institution and the business of the AEC. This shall include possession of a higher degree in research or equivalent experience. If the business of the AEC relates to the use of animals for teaching only, therefore, the teacher with substantial and recent experience may be appointed.
- **Category C member** – A person who demonstrates commitment to, and established experience in, furthering the welfare of animals, not employed by or otherwise associated with the institution, and not currently involved in the care and use of animals for scientific purposes. Veterinarians with specific animal welfare interest and experience may meet the requirements of this category. In the cases where a veterinarian acts as category C member, there shall be an additional category A veterinarian (i.e. one veterinarian cannot act as both categories A and C members). The person should be selected on the basis of active membership of, and endorsement by an animal welfare organization. This member should bring an animal welfare perspective to the AEC deliberations. While all members of the AECs shall consider the welfare of the animals, the category C member brings to

the committee a special awareness of current community and broader animal welfare concerns.

- **Secretary**

The Ethics Officer shall be the secretary to the Committee and shall provide support and advice to the Chairperson.

- **Category D member** – An independent person(s) who does not currently and has not previously conducted scientific studies or teaching activities using animals, either in their employment or beyond their undergraduate education, and who is not an employee of the institution, except under defined circumstances (for example, tenured academic staff from non-animal scientific departments). If such an employee is appointed, the individual shall be in a senior position, and shall not be supervised by other committee members or by anyone involved in the animal research at the institution. The institution shall provide clear reasons for the necessity to appoint an employee in this category.

- Research & Development Planning Branch
- Office of the Premier: Limpopo Province
- Limpopo Department of Agriculture Representative
- Category E member – Law person
- School of Law Representative
- At least one Layperson.
- One senior representative from each husbandry facility:
- Animal Unit (Department of Biodiversity)
Aquaculture Research Unit
- UL experimental Farm

In addition to the above, membership may include:

- Representatives from relevant Government Departments,
- co-opted member(s), as external experts, to assist with the review of particular protocols, if and when necessary.
- Culture, religion and environmental specialist

6.2 Access to expertise

The AEC may invite people with specific expertise to provide advice, as required.

7. QUORUM

The Committee shall have a quorum 50% plus 1 which must include at least one member from each Category A, B, C and D at all times throughout the duration of the meeting, including after the withdrawal of any members with a conflict of interest. If the Committee has more than four members, Categories C plus D must represent no less than one third of the members.

8. CONFLICT OF INTEREST

Committee members are required to declare to the Chairperson any real, perceived or potential conflict of interest they may have with any item on the Committee's agenda. If the Chairperson or Committee deems a member to have a conflict of interest in a matter before the Committee, the member must not be present when the Committee considers that matter.

The Committee will require that all members and any experts approached to provide advice to the AREC, declare any interests with respect to AREC business and its operation:

- i. prior to their appointment - by making a signed declaration of all real or potential conflicts of interest as part of the member application process as matters arise
- ii. by declaring all real or potential conflicts of interest and the nature of that interest to either the Chairperson or subcommittee of AREC as soon as is reasonable after they become aware of the conflict at each meeting
- iii. by declaring as an early item of the meeting agenda all real or potential conflicts of interest and the nature of that interest.
- iv. This must include all real or potential conflicts with any items on the meeting agenda or any other matter relating to membership of the Animal Ethics Committee, and all declarations of real or potential conflicts of interest (as part of the appointment process, between or at meetings) are to be recorded in the relevant meeting minutes

9. MEETINGS

The Code requires that Committee meetings must be held face-to-face where practical, with video or web conferencing, as a first preference used where necessary to establish quorum. In exceptional circumstances the use of teleconferencing is permissible. Committee meetings shall be held at least six times per year. Decisions should be based on a thorough, fair and inclusive process of discussion and deliberation by AREC members, and should be made only by those present throughout the discussion. Decisions should be made on the basis of consensus. Where consensus cannot be reached after reasonable effort to resolve differences, the AREC should explore with the applicant/s ways of modifying the project or activity that may lead to consensus.

If consensus is still not achieved, the AREC should only proceed to a majority decision after members have been allowed a period of time to review their position followed by further discussion. Committee members are required to fully prepare for each meeting, read the documentation in advance, and make every reasonable effort to attend each meeting.

10. ACCESS TO RESOURCES

External Committee members will be provided with access to any resources they reasonably require to fulfill their duties.

11. OBSERVERS

- Observers are welcome with the Chairperson's prior permission and provided they advise the Secretary in advance.
- Observers are entitled to see and hear the proceedings of the meeting but have no voting rights and no right to speak at meetings, unless invited to do so by the Chairperson.
- Observers must leave the meeting when requested by the Chairperson, or if any matters are to be considered in closed session.

12. AGENDAS AND MINUTES

- Agendas and associated documentation will be distributed 10 calendar days before the meeting. Members will be notified by email of the location and availability of material. Members are encouraged to bring laptops, to the meetings and view the agenda online during the meeting.
- The Chairperson will review the draft minutes and action sheet of each meeting, after which the Secretary will circulate the documents to all Committee members and include them in the agenda papers for the next meeting.
- The minutes of the meeting will be comprehensive

13. REFERRAL OF MATTERS

The Committee may refer any item to the Deputy Vice-Chancellor (Research Innovation and Partnerships) or the Senate Research Committee(SREC)for discussion, consideration, and/or action, and may refer relevant matters for action or noting to other senate Committees.