Animal Research and Ethics Committee (AREC)

Standard Operating Procedures and Guidelines

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DEFINITION OF TERMS AND ABBREVIATIONS

Animal: For animal(s)" is defined as follows: 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)

Lasting Harm: Is inflicting suffering on an animal by causing it to experience pain, distress or negative sensations and by worsening its situation and this situation or result continues to exist or have an effect for a very long time. It is a situation that is detrimental to the quality of life of an animal. Example is a keeping a social animal, like a dog, locked up in solitary confinement for long periods. This may result in eating disorders, stereotypical and aggressive behaviour that may last for the whole lifespan of the dog.

PREAMBLE

The University of Limpopo (UL) recognises that a variety of academic activities require the use of animals of different species in research, teaching and learning. These activities come with the responsibility to ensure that all animals, i.e. 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" (SANS 10386:2008 or any amendment thereof), used in research, teaching and learning , are cared for and used in ways judged to be scientifically, technically and humanely appropriate.

To be in compliance with the prescriptive guidelines of ***SANS10386: 2008: "South African National Standard: Care and Use of Animals for Scientific Purposes***" (SANS10386 or any amendment thereof), UL has established an operational Animal Research Ethics Committee (AREC). The University has, set out terms of reference including the scope of its responsibilities, relationship to non-affiliated researchers, accountability, mechanisms of reporting, and remuneration (if any) for members. Furthermore,to be eligible for continued registration with the regulatory body, UL will ensure compliance with Section 73 of the "***National Health Act, Act No 61 of 2003***" (NHA). AREC should, therefore, be mandated by Senate, on behalf of the Institution, to function as an independent research ethics committee.

AREC must operate in a way to fulfil the legal and ethical responsibilities of University of Limpopo (UL) concerning the use of live, non-human vertebrates in research, teaching and learning. AREC must also ensure that the quality and operation of UL animal housing facilities, and the care and use of animals in research, teaching and learning are in accordance with guidelines established by SANS10386. Consequently, AREC's line of command is to the Deputy Vice-Chancellor (Research Innovation and Partnerships), to the relevant Faculty.

The jurisdiction of AREC extends to all research, teaching and learning activities of UL involving animals, irrespective whether such activities are conducted on or off-campus by any member of UL staff or students. It also includes teaching and/or research activities of UL where UL staff and/or students are involved in collaboration with another teaching or research institution or agency.

The main objective of AREC is to evaluate what should or should not be done when animals are proposed to be used for scientific purposes. The use of animals in scientific research and teaching can only be justified if the benefits to humans and/or animals are considered by an appropriately constituted structure to outweigh the potential harm to the individual animal subject. Therefore, all research and teaching programmes involving animals must be professionally evaluated and approved before the programme commences. AREC will not review proposals retrospectively.

Accountability and Responsibilities of AREC

The AREC is to function within the legislative framework of the National Health Act No. 61 of 2003 and the National Guidelines 2015, which requires a University at which research is being conducted to have an NHREC-registered AREC. The AREC is an independent body vested with the explicit authority and legal accountability for the final decision regarding the ethical acceptability of research, teaching and learning activities involving non- human vertebrates.

Name of the Committee

The name of the committee is "*Animal Research Ethics Committee (AREC)*"

1. PURPOSE

To ensure that scientific research, teaching and learning activities involving animals comply contextually with the relevant provisions of SANS10386 and other applicable legislations incorporating the "**Four R's**" core ethical principles of:

a) **Replacement:** Total replacement of either animals or techniques. Methods which directly replace or avoid the use of animals in experiments where they would otherwise have been used..

b) **Reduction:** Methods which minimize the number of animals used per experiment or study, either by obtaining comparable levels of information from fewer animals, or by obtaining more information from the same number of animals, thereby avoiding further experiments. Reduction benefits research by ensuring appropriately designed and considered animal experiments that are robust and reproducible.

c) **Refinement :** Methods that minimize the pain, suffering, distress or lasting harm that may be experienced by animals, and which improve their welfare, throughout their lifetimes and during all aspects of their use. Refinement benefits research by avoiding disturbances in the behaviour, physiology and immunology of animals which can lead to variation in experimental result.

d) **Responsibility:** Everyone using animals, whether for experimentation, testing diagnosis, teaching or sourcing of tissues or body fluids is responsible in their personal capacity for assuring that the animals which they use are afforded the highest levels of welfare and protection from abuse, and violations of the interests accorded to them.

i. For purposes of clarification, "animal(s)" is defined as follows: "*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*" (SANS10386:2008) or any amendment thereof).

To ensure that research proposals involving the use of animals undergo rigorous, scientifically-informed ethical review processes, by using the 5 freedoms:

a) Freedom from hunger and thirst
b) Freedom from discomfort
c) Freedom from pain, injury and disease

Freedom to express normal behaviour
Freedom from fear and distress

ii. To ensure that animal usage takes place only where scientifically and ethically justifiable.

iii. To investigate, and take appropriate actions, in the event of deviations from approved protocols, and violations or allegations of unethical conduct concerning the use of animals in research, teaching and learning as well as animal housing facilities.

2. SELECTION AND APPOINTMENT OF REC MEMBERS

AREC will appoint occupationally diverse members who have knowledge and experience in animal research ethics. Members should have sound knowledge of ethical codes and guidelines, and must collectively have the ethical and scientific background as well as the expertise to competently review and monitor all protocols submitted to AREC.

2.1 Appointment process

Members are appointed through the office of the Deputy Vice-Chancellor (Research Innovation and Partnerships) and the executive deans of Faculties. The term of office for each member will be between two and four years, renewable twice, after which the person should stand down for at least one term.

This will ensure that both expertise and responsibility are fairly distributed and encouraged in a range of members, and that institutional memory is accumulated.

Exceptions to this are the consulting veterinarian and the animal care and welfare staff, all of whom serve for indefinite terms.

2.2 Appointment of the Chairperson and the Deputy Chairperson

2.2.1 Chairperson

a. The institutions shall appoint the chairperson of the AREC who holds a senior position in the institution. If the chairperson is an external appointee, the institutions shall provide the chairperson
b. with the necessary support and authority to carry out the role. The chairperson shall be appointed in

b) addition to categories A to D members .
c) The institutions should consider appointing the chairperson who is independent of the Care and use of animals for scientific purposes. In the cases where the independent chairperson
d) cannot be appointed, the institution needs to put in place adequate provision for conflict of interest.
e) In addition, the chairperson should have experience in research methodology and training in animal ethics (or should have served on the AEC for a period of a year).

The Chairperson and the Deputy Chair of AREC are appointed by the Deputy Vice-Chancellor (Research Innovation and Partnerships) from among recommended/elected members.

a. All members of AREC have full voting rights, except for ex-officio members.
b. No member of AREC shall be held personally liable for any act committed or omitted by the committee or member of the committee, in good faith in the course of his/her AREC duties.

2.2.2 Conflict of Interest

a. Actual or potential conflict of interest arises when a committee member is in a position to influence decisions made by AREC which will benefit, either financially

or personally, either that member or another person with whom the member has a relationship.

b. Such conflict of interest must be declared to the Chairperson of AREC before constitution of the meeting. The relevant member shall either:

b) withdraw from the meeting where the matter is being discussed;
c) abstain from taking part in any other discussion of the matter;
d) abstain from voting on the matter.

2.2.3 Confidentiality

Committee business is confidential so as to protect intellectual property, researchers' interests, and to permit committee members to speak freely and frankly, as well as to protect the public image of the University.

2.2.4 AREC is constituted as follows:

Composition of the University of Limpopo Animal Research and Ethics Committee (AREC).

As per prescribed SANS10386 or any amendment thereof).guidelines, Membership shall comprise at least four people, one from each of four categories of membership as defined below.

No.	Category	Name
Ex Officio Membership		
1.	Deputy Vice-Chancellor (Research Innovation and Partnerships)	
2.	Director: Research Development and Administration	
3.	Secretariat	
4.	Assistant secretariat	
Category A Member: person with qualifications in veterinary science, who is registered or authorized as a veterinarian in terms of the relevant national council (see foreword), and with experience relevant to the institution's activities or the ability to acquire relevant knowledge..		
6.	Animal Specialist	Available

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.		
7.	School of Agricultural and Environmental Sciences	Available
8.	School of Molecular and Life Sciences	Available
9.	School of Health Care Sciences	Unavailable
10.	School of Medicine	Unavailable
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. .		
11.	National Council of SPCA'S (NSPCA)	Available
12.	Additional Animal welfare/vet	Unavailable
Lay person:	Community Representative	Available
Biostatistician		
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.		
Additional members: The institutions should appoint to the AEC person(s) responsible for the routine care of animals within the institution, ensuring that the people have up-to-date information of all of the various facilities.: 13. Animal Unit (Department of Biodiversity) 14. Aquaculture Research Unit 15. UL Experimental Farm		
15.	Planning Branch Office of the Premier: Limpopo Province	
16.	Limpopo Department of Agriculture	
Category E member – Person with a legal background		
17.	School of Law Representative	Available
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		

3. FREQUENCY OF MEETINGS

a) The Committee will have a minimum of six meetings per year. Additional meetings may be called as necessary.

b) The presence of 50% plus one member will constitute a quorum. In addition, at least one member of each of categories A to D must be present (SANS10386:2008).
c) 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. If the need arises, members may send in electronic reviews of the protocols if unable to attend a meeting.
d) Minutes of each meeting will be taken outlining decisions, recommendations for revision and procedural and other issues related to the care and use of animals, with respect to each protocol under review.
e) In addition to normal meetings, members of the Committee will conduct, at least one site visit/inspection per quarter to each of the animal facilities.
   i. The observations from every inspection tour, together with any recommendations and/or commendations, will be discussed at the subsequent AREC meeting and included in the minutes. A report will be provided to the administration of each animal facility as required.
   ii. Monitoring of external applications

4. RESPONSIBILITIES AND FUNCTIONING OF AREC

4.1 Ethics Review Mandate

a) All research and teaching activities involving animals may not begin, and animals may not be acquired without prior ethics review and approval of a written animal use protocol.
b) To advise its appointing authority, the Deputy Vice-Chancellor (Academic and Research), on all matters pertaining to the ethics of research and teaching involving animals.
c) To ensure compliance with codes of ethics and procedures for the use and care of animals for teaching and research purposes and legislative norms and recommendations of SANS10386 best practice guidelines are met.
d) To review and approve or reject, after revision by the principal investigator/researcher (if needed), all applications for proposed research, teaching and learning activities involving animals to be carried out within the jurisdiction of UL.
e) Only activities for which animal usage is essential, and that are scientifically and ethically justifiable, are approved after due consideration of both animal ethical/ welfare aspects and the scientific and/or educational value of the proposed research.
f) To confirm that animal users are adequately qualified and/or trained to perform the research or activities involving animals.

g) To ensure that the proposed use, housing and care of animals for teaching, research and experimentation meets recommendations of SANS10386 and other international best practice animal care policies.
h) To confirm that applicants have necessary permits (where applicable) from the relevant authorities to capture, transport and/or work on animals.
i) To ensure that the particulars of the species, number and origin of the animals in each category of experiment are recorded in a register.
j) To monitor, at its discretion, the housing, care, euthanasia and disposal of animals in scientific studies and teaching activities.
k) To implement procedures for the submission, consideration and approval (or disapproval) of animal research and teaching protocols.

4.1.1 To review and revise, as appropriate, the AREC ethics guidelines and SOPs.

a. AREC has the authority, on behalf of the Deputy Vice-Chancellor (Research Innovation and Partnerships) to:

i. stop any intolerable procedure if it considers that unnecessary distress or pain is being experienced by an animal;
ii. Stop immediately any use of animals which deviates from the approved use.
iii. Have an animal killed humanely if pain or distress caused to the animal is not part of the approved protocol and cannot be alleviated.

4.2 Scientific and Educational Mandate

a) All research and/or teaching protocols involving the use of animals (projects which are conducted as an undergraduate or postgraduate level course or laboratory/teaching assignments), must undergo peer review for scientific and/or educational merit.
b) AREC does not conduct formal scientific and/or educational merit review of proposed research and/or teaching project protocols.
c) All submissions for evaluation by AREC of research and/or teaching protocols involving the use of animals must include written evidence of a peer review process of scientific and/or educational merit, conducted by other relevant faculty structures.

4.3 Animal Welfare Mandate

National practices and guidelines emphasise the active monitoring role Animal Research Ethics Committees must play in ensuring that all animal research and teaching activities that are

conducted under the jurisdiction of UL, comply with guidelines for humane animal use by also applying the five freedoms as a guide for ensuring effective animal welfare:

a. Freedom from hunger and thirst
b. Freedom from discomfort
c. Freedom from pain, injury and disease
d. Freedom to express normal behaviour
e. Freedom from fear and distress

AREC shall, therefore, ensure that:

Animals are housed or maintained only in areas that have been inspected and approved for this purpose;

a. all animal facilities are inspected and the facilities and animal care provided, meet provincial and national standards;
b. the level of security in animal facilities is adequate for the protection of the animals housed therein and the staff working with the animals;
c. a written report will be compiled and tabled at the next AREC meeting. The report, with AREC recommendations and/or commendations, will be presented to the manager of the animal facility.

AREC, or the chairperson on its behalf, can suspend or terminate an objectionable procedure, which results in an animal experiencing unnecessary distress or pain.

a) Any use of animals for purposes other than those already approved or use of non-approved procedures shall be stopped.
b) Any animal that is in pain or distress that cannot be alleviated shall be humanely killed. This may be decided at the discretion of the veterinarian.
c) AREC shall ensure that adequate veterinary care is provided to all animals kept in husbandry facilities and/or during laboratory experimentation.
d) A set of standard operating procedures shall be developed and regularly reviewed for:
   i. animal husbandry;
   ii. animal handling
   iii. Bio security
   iv. animal housing

v. alleviation of pain or distress through proper and effective use of anaesthesia and analgesia where necessary.
vi. Acceptable and humane euthanasia methods
vii. facility and equipment management and
viii. any other area(s) as required.

1. AREC will monitor that all staff, whether involved in research, teaching and learning or in the care and maintenance of animals, are competent to do so and have received adequate training in the use of animals in this context.
2. A risk management programme for the animal husbandry facilities shall be established in conjunction with the University's risk management plan.

5. REVIEW CRITERIA

The reviewer/s will check if the following information has been provided:

a) the title
b) description of the project
c) species, number of animals, and use category
d) judicious use of animals
e) sources, husbandry, and location of animals
f) experimental protocol
g) personnel involved in project
h) occupational safety and hazardous materials

6. MECHANISMS FOR REPORTING BY AREC

- The AREC is managed and supported by the University of Limpopo and function directly under the DVC: Research Innovation and Partnerships.
- The AREC will report annually on their activities to the NHREC and UL Senate research ethics committee (SREC) in the form of an annual report.

7. ADMINISTRATIVE SUPPORT

AREC has a fulltime Research Ethics Officer and an assistant who provide administration and secretariat support to the committee and are supported by the DVC Research Innovation and Partnerships. Additional assistance is sought from time to time when a need arises.

8. APPLICATION, REVIEW AND APPROVAL PROCESS

a) Research protocols are reviewed primarily from an ethical perspective although the scientific and methodological aspects are also taken into account.

b) The application forms and guidelines for submission of a research protocol or teaching programme will be made available by AREC.

The following documents must be submitted:

- Application Form
- Research proposal
- Relevant Permits, where applicable.
- Informed consent or letter of approval from individual or private facilities, where applicable
- Proof of training records

a) Applications must be submitted two weeks before the next meeting
b) No retrospective ethics approval can or will be granted.
c) The Chairperson or delegated member will allocate the application to a primary and a secondary reviewer. However, all members will receive the proposals for review.
d) The Chairperson may, at his/her discretion, consult an external reviewer for a particular proposal, if he/she feels the committee does not have the necessary expertise to adequately evaluate it.The external reviewer will be requested to make a written report available to the Chairperson prior to the meeting.
e) For studies where lower order invertebrates, carcasses or biological specimen ethically sourced, a full application may not be required, such applications will be approved in an expedited process.

Upon review by the AREC, an application will be given one of the following categories grades:

a) **Approved** – An ethical clearance certificate or permission letter will be issued and the researcher can commence with the study.
b) **Modifications required** - The researcher/supervisor must correct certain changes/recommendations to the protocol. The corrected proposal will be verified by AREC and a letter of approval will be issued.
c) **Deferred** - The application requires major changes or the committee has major concerns. The resubmitted protocol must be reviewed at a convened meeting.
d) **Rejected** - The application cannot be accepted in its current form.

The decisions of AREC, and any recommendations for revision, shall be communicated in writing to the respective researchers.

a. Subsequent to receiving an AREC-approved protocol, the principal investigator/researcher may apply for minor changes to AREC. Minor changes would include an increase in the number of animals required, staff/student additions

to the project, minor change in experimental protocol, etc. Such minor changes can be approved by the chair of AREC or his/her delegate.

b. Any major proposed changes to the approved proposal (change of species, change of doses and the number of animals used) will require a re-submission for consideration by AREC.
c. All principal investigators/researchers of approved research protocols will be required to submit a signed final report for each completed protocol for review and approval by AREC.

9. ADMINISTRATIVE PROCESSING OF APPLICATIONS, POST MEETING AND RECORD KEEPING

a) Decisions taken at the AREC meeting will be communicated in writing to the applicant. Only once these requirements are fulfilled can a formal certificate or letter of approval be issued. The applicant may not start the project until a final letter of approval has been issued.
b) Copies of all approved protocols and ethical clearance certificates will be submitted electronically to the researcher, supervisor, the School Research and Ethics Committee.
c) All applications reviewed electronically will be stored by the secretariat of the AREC for a minimum period of 5 (five) years after completion of the project.
d) The original application form (electronic), the ethical clearance certificate and other records will be stored by the secretariat of the AREC for a minimum period of 5 (five) years after the completion of the project.
e) The secretary of the AREC shall keep an accurate record of meeting attendance, apologies, recusals and whether or not a quorum was maintained throughout each meeting; main discussion points and decisions taken.

10. APPLICATIONS FOR AMENDMENTS

a. For minor or major amendments, there is a standard ethics application form for amendments to projects that should be used by the principal investigator/researcher to formally request the amendment to the study protocol.
b. For urgent cases of minor amendments such as an additional minor procedure (e.g. change of co-investigator, where only one or two procedures are currently approved, can be approved by category A and B members, and later be ratified by the full committee during the next AREC meeting. However, major amendments

(e.g. change in the housing, change in objectives of the study and etc.) will be reviewed at a full quorate meeting.

c. AREC reserves the right to decide if the changes made to the protocol are minor or major.

11. REPORTING OF ADVERSE EVENTS

Adverse events are unanticipated or atypical events that occur to an animal because of routine husbandry, experimental manipulation, or diseases. Where unexpected adverse incidents or outcomes occur during research, rapid reporting is essential, primarily from the point of view of animal welfare. Understanding incidents and how to respond to them may require specialised knowledge, so it is important that key information is recorded and reported promptly to those responsible for the work and the AREC, and a collective response made. This may be, for example, isolation of affected or potentially affected animals, closer monitoring, changes to routine husbandry or experimental procedures, or suspension or termination of the work. The SOP to guide researchers on reporting adverse events and a form to fill in are accessible on the website.

12. EXPEDITED REVIEW PROCESSES

The expedited review refers to situations in which a research proposal is urgently reviewed without convening an ordinary AREC meeting.

a) Expedited review should apply, in principle, only to research that poses no more than minimal risk of harm, such as studies utilising secondary data.
b) Expedited review and approval may apply to new research applications or amendments, and may apply only when no more than minimal risk is incurred by the study or the amendment that is being reviewed, or in case of an amendment for which animal welfare may be compromised if, review and approval are not expedited.

12.1 Responsibilities of the AREC in handling expedited reviews

Whether a study or amendment is suitable for expedited review is at the discretion of the chairperson, a deputy chairperson or the Preliminary Subcommittee.

12.2 Expedited review process

An Ad Hoc process will be initiated by the Chairperson or Deputy Chairperson and resulting expedited decision will be for ratification by the AREC at its next meeting. Reviewer comments will be requested from AREC members for consideration at the Preliminary Subcommittee meeting.

a) The chairperson allocates the review to a minimum of two reviewers and notifies the Research Ethics Officer.
b) The Research Ethics Officer (within two days) sends the application to the identified reviewer who have three working days to review.
c) As soon as the reviewer reports are received, the chairperson of the AREC prepares a consolidated response and forwards it to the Research Ethics Officer.
d) A formal letter of decision of the AREC with feedback is sent to the applicant (always the supervisor or PI) as soon as possible (approximately three working days) after the decision.
e) If corrections are needed, they are done by the applicant and sent back to (arec@ul.ac.za) A proposal resubmission tool should be included indicating what, how and where in the documentation the corrections were addressed (Corrections should be highlighted in the application document as well).
f) The updated application is re-sent to the same reviewers for the review of the corrections (three working days).
g) Corrections are either approved by reviewers or further corrections are requested.
h) If additional corrections are requested they should be corrected (as previously indicated) and re-submitted by the primary investigator.

12.3 Responsibilities of researchers

i. Researchers should submit the necessary documentation as required to accompany the expedited review request.
ii. Formulate a clear and systematic cover letter guiding the AREC.
iii. Clearly indicate:

a) the title of the research
b) the researcher(s)
c) what it is that is being requested
d) if changes were made to a previously approved application, the researcher need to outline the nature thereof and where the change has been effected.
e) which documents are attached to the application, and
f) add any explanation to clarify the application
g) Attach all the required documents separately and submit the application to the: Research Ethics Officer (arec@ul.ac.za)

12.4 Expedited review for Amendments

The Preliminary Subcommittee of the AREC may approve an amendment to a study as an expedited approval when all of the following criteria are met:

a. The amendment poses no more than minimal risk; and
b. No ethical and animal welfare concerns have been raised by reviewers
c. The preliminary subcommittee of the AREC may approve an annual renewal and progress reports to a study as an expedited approval when all of the following criteria are met:
d. The annual renewal or progress report brings about no substantive additional risk; and
e. No ethical and animal welfare concerns have been raised by reviewers

13. PILOT STUDIES

Pilot studies, where proposed should be regarded as integral to the overall study or studies. These enable the assessment of the feasibility and value of the study, and the potential for Replacement, Reduction and Refinement. Pilot studies should be carried out before the main study to allow for the definition of various elements and parameters in the study. Pilot studies for setting humane endpoints in an experiment are needed when:

a) the effects of the treatment are unknown, so that morbidity, time course of effects, and specific clinical signs still have to be more narrowly defined,

b) the identification of humane endpoints on the basis of specific parameters (for example, telemetrically obtained data) is possible, and

c) the pathological changes observed can be used later to set humane endpoints.

14. EXTERNAL APPLICATIONS

Researchers with no affiliation to the University of Limpopo or are considered to be external applications to the University can approach AREC to review and approve their research proposals. Where AREC may on a case-by-case basis decide whether it is the appropriate REC to deal with the matter and whether the REC is willing and has proper expertise and capacity to evaluate the application.

A cost (“Review Fee”) will be levied for such service only for researchers who are non-affiliated to the University of Limpopo and external applicants to the amount of R15 000,00 (fifteen thousand Rand) plus VAT as per the Value Added Tax Act as amended from time to time, which

Review Fee is payable upon submission. The Review Fee is subject to the AREC Chairperson's discretion, in consultation with the Secretariat and the Research Office.

15. MONITORING: PASSIVE MONITORING, ACTIVE MONITORING, FACILITY INSPECTION

AREC has the right to monitor the research they approve. The National Health Research Ethics Council (NHREC) perceives this monitoring role of AREC as very important. The South African National Standard: The Care and Use of Animals for Scientific Purposes (SANS10386 10386:2008) also makes specific reference to monitoring. Monitoring is an important part of the role of AREC. Firstly, to provides means of ensuring that the welfare of animals used (i.e. research, testing and teaching) meets the standards required by the regulatory bodies.

The Animal Welfare regulations (SANS10386 and NHREC) require animal ethics committees to monitor:

a) compliance with the conditions of project approvals and
b) animal management practices and facilities to ensure compliance with the Animal Protections Acts.

AREC will ensure that investigators, at all stages of their project/s remain compliant to the approved protocol. Investigators are required to maintain records of monitoring and assessment of animal wellbeing, and as required, take prompt action in accordance with intervention points and humane endpoints (as endorsed by the AREC).

AREC may recommend and adopt any additional appropriate mechanism for monitoring, including:

   a. announced and unannounced inspection of research sites;
   b. monitoring of data and signed informed consent documentation;

b) inspection to verify that researchers adhere to SOPs and other approved experimental procedures;
c) inspection of the scoring of welfare monitoring sheets (animals);
d) The AREC should ensure that adequate records are kept on the acquisition, breeding, health, care, housing, use and disposal of animals (SANS10386:2008 section 5.2.7)or any other amendments thereof)
e) The frequency and type of monitoring should reflect the degree and the extent of risk of harm to animals.

f) Researchers should provide comprehensive and appropriate information to the AREC to facilitate the monitoring process.

15.1. Passive monitoring

In general, AREC will require project leaders to submit interim reports at least annually. The nature of certain studies can, however, require the submission of progress reports at shorter intervals e.g. quarterly or bi-annually. A final report should be submitted on completion of a study.

15.2 Active monitoring

AREC will have subcommittees to carry out announced or unannounced visits to facilities where approved protocols involving animals are taking place. Inspections of fieldwork conducted at extremely remote sites or where access is difficult, may be performed by a delegate and can be facilitated or corroborated with photographic or video imaging.

Notice will be given to the animal facility managers and researchers of an intended inspection. Where practicable up to 48 hours' notice will be given

15.3 Facility Inspections

a) AREC members will carry out regular inspections of the institutional animal housing facilities.
b) Notice will be given to the animal facility managers and researchers of an intended inspection. Where practicable up to 48 hours' notice will be given. Notwithstanding the section above, the Committee reserves the right to carry out random unannounced inspections of approved research projects.
c) The inspection team will consist of a member from each category. The committee may delegate to other independent persons the authority to inspect remote sites and monitor projects.
d) The inspection team will report its findings in writing within 7 days after the inspection to the facility managers, chairperson and the secretariat, the report will be discussed at the next scheduled committee meeting.
e) The Committee Secretariat will maintain a register of inspection visits and reports.

The inspection will cover:

i. Biosecurity
ii. Species & Numbers
iii. Health, behavior, appearance
iv. Housing

v. General environment
vi. Enrichment
vii. Feeding
viii. Documentation
ix. Vet care
x. Euthanasia

16. HANDLING OF COMPLAINTS, WHISTLEBLOWING AND VIOLATION OF GOOD RESERCH CONDUCT

16.1 Complaints

A researcher or an academic involved in teaching and training, who is in disagreement with decisions/recommendations of AREC, may appeal this decision/recommendation in writing to the Chairperson of AREC.

a) Complaints should be received in the form of a written letter, e-mail or phone call. It should be clear on the nature of the complaint and providing the necessary facts. When such a complaint is received, the AREC secretariat should be contacted immediately and a plan of action devised in agreement with the Chair of the AREC.
b) In cases where the researcher/supervisor disagrees with the suggestions, recommendations or decision of the AREC, a written appeal (at least two weeks before the next AREC meeting) may be made directly to the AREC.
c) The item will be placed on the agenda, discussed at AREC and the decision of AREC communicated to the researcher in writing within two weeks. The letter will be copied to the HOD, the director of the school, the Dean and SREC. If a mutual agreement regarding a workable solution is reached, the matter will be considered resolved.
d) If the researcher is still not satisfied with AREC's decision, he or she may appeal with SREC.
e) SREC may appoint a subcommittee of outside reviewers to re-examine the decisions made by the AREC. The decision derived from the outside reviewer's report will be communicated in writing to the researcher within seven (7) days of the report having been received.
f) The SREC will make the final internal decision.
g) The complainant shall be advised about his/her right to contact the NHREC. The procedure is available on the webpage of the NHREC and all necessary contact information shall be provided to the complainant.

17. WHISTLEBLOWING

The institution is committed to the highest standard of ethics and integrity in research. Any member of the AREC, staff member or student of the institution who has a reasonable belief that any act of misconduct, fraud, maladministration, or non-adherence to approved research procedures, guidelines or policies has been committed, is obligated to report any such unethical research practices at the institution using the correct procedure. Any whistleblowing should be done in a bona fide and non-vindictive manner. AREC will ensure the confidentiality to all members of the AREC, staff members or students of the University, and furthermore ensures that nobody is exposed for disclosing in good faith information that would assist the Chairperson of the AREC in meeting their obligation in terms of the guiding principles and regulations. Research non-compliance entails:

i. Animal welfare violations, such as:
   a. Evidence of poor feeding
   b. Poor Housing (e.g. no environmental enrichment)
   c. Overcrowding
   d. Neglect of sick animals
ii. Violation of good research practice and misconduct, such as:
   a. Fabrication (making up research data or results and recording or reporting the fabricated material).
   b. Falsification (manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research records).
   c. Plagiarism (the appropriation of another person's research idea, processes, results, or words without giving appropriate credit).
iii. Any conduct that may be deemed as fraudulent
iv. Maladministration (e.g. mismanagement or inefficient administration of research resources negatively affecting the welfare of animals)
v. Non-adherence to approved research procedures, guidelines or policies.

17.1 Procedure for Whistleblowing

a) A disclosure should be made in writing and submitted to the AREC secretariat, who will forward to the chairperson as soon as possible.
b) When a member of the AREC, a staff member, a student or an external person makes a disclosure to the secretariat, it must be done in a responsible and honest manner.
c) If the notification is made to the AREC secretariat, they must as soon as possible acknowledge receipt of the disclosure directly to the whistleblower and immediately (within three days) notify the chairperson of the committee by forwarding the disclosure.
d) The chairperson will immediately upon receipt of the disclosure set up an appointment with the whistleblower, the applicable legal representative of the AREC within 14 (fourteen) working days of the acknowledging of the disclosure.
e) The aim of this appointment is to allow the investigating team to conduct an initial investigation in order to establish whether there is a *prima facie* case to address.
f) If the investigating team considers that there is no *prima facie* case to be addressed and that no further action will be taken, this decision will be explained to the whistleblower.
g) If the investigating team considers that there is a *prima facie* case to be addressed, the way forward is discussed to the satisfaction of all members.
h) If disciplinary measures are required, the research director will be notified and the appropriate University procedure followed.
i) Investigations will be dealt with sensitively, on an impartial basis and within a reasonable time frame.
j) Details of the allegation, the identity of the person making the allegation and against whom the allegation is made will remain confidential.
k) The chairperson and legal representative of the AREC can request the assistance of an independent person. Those requested to assist in the investigation will be chosen on the basis of being independent from the issues/events from which the allegation has been initiated.
l) The Senate Research Ethics Committee (SREC) is notified of the reporting and the actions taken. If necessary, the SREC is included in the actions.
m) If the whistleblower is not satisfied with the outcome of the investigation they should raise their concerns with the secretariat to find another solution or to refer them to NHREC.

18. VIOLATION OF GOOD RESEARCH CONDUCT

a) Where inspections detect activities of non-compliance with the code or approval conditions, the inspecting committee members must report immediately to the committee Chair.

b) When projects or activities in breach of the code are detected, the committee must ensure that actions are taken to ensure that animal wellbeing is not compromised, the issue is addressed promptly, and activities that have the potential to adversely affect animal wellbeing cease immediately. Actions may include suspending or withdrawing approval for the project or activity.

The following steps will be taken:

(i) the Chair will contact the chief investigator to address the issues

(ii) details of the non-compliance will be circulated to the full committee via email, ahead of a meeting of the full committee being convened to consider the non-compliance

(iii) where the non-compliance can be rectified without compromising animal wellbeing, the researcher or student will be advised that the project or activity may proceed following confirmation of rectification being effected

(iv) when considered necessary, recommend to the DVC (Research innovation and partnerships) that a project or activity be suspended, discontinued or that other necessary steps be taken

(v) if satisfied that appropriate action has been taken to ensure that a non-compliance does not re-occur, the committee may restore approval for a research project/teaching activity and advise the researcher or student, DVC (Research innovation and partnerships) and any other formal parties to the project to this effect in writing.

In the event that the Committee has determined that a project is not being conducted or cannot be conducted in accordance with the approved protocol and that the welfare of animal/s is not or will not be protected, the committee will:

a. formally advise the researcher or student of specified steps to be taken to allow the project to continue suspend the project until the committee is satisfied that the welfare of the animal/s is/are protected and that the approved protocols will be followed, or

b. recommend to the DVC (Research innovation and partnerships) that the project be suspended or discontinued.

19. LEGISLATIVE, POLICY FRAMEWORK/ GUIDELINES

- 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.

20. Review of SOP

As the scientific body of knowledge underpinning animal management practices is constantly expanding, there is a need to periodically review the adequacy of SOPs being used by animal carers and users. This is an activity in which researchers, animal carers, and the AREC all have an interest as there are implications for animal welfare and, consequently, the robustness of experimental data. This SOP will be regularly updated to ensure relevance and adherence to the mandate of the regulatory bodies.