

NELSON MANDELA UNIVERSITY RESEARCH
ETHICS COMMITTEE (ANIMAL) (REC-A)
TERMS OF REFERENCE and STANDARD OPERATING PROCEDURES

The Research Ethics Committee (Animal) (REC-A), is a sub-committee of the NMU RTI Committee, and has been appointed by the university Senate.

1. Scope of the REC-A

The NMU REC-A is charged with monitoring the treatment of animals used in research and teaching at NMU. The REC-A has been charged with the responsibility of reviewing all protocols involving animal use in order to ensure that they are in accordance with acceptable ethical and scientific standards. The REC-A must ensure that all aspects of the care and use of laboratory animals comply with national and international standards and norms. The REC-A assists the institution in complying with legislation and creating an awareness of ethical conduct in researchers and teachers.

2. Mission

The mission of the REC-A is to ensure the ethical use of animals in research and teaching.

2.1 In order to achieve this mission, the REC-A strives to:

- 2.1.1 Provide research ethics support to researchers and teachers working with animals
- 2.1.2 Promote animal welfare and to help resolve ethical issues which may arise from animal studies.
- 2.1.3 Promote the use of ethical analyses, so as to increase awareness of the interests of animals and their welfare needs.
- 2.1.4 Develop initiatives which will lead to the broadest application of the 'three R' principles, namely, replacement, reduction and refinement.
- 2.1.5 Ensure that the use of animals in experiments is justified by relevance of the problems being studied and the likelihood of successful outcomes.
- 2.1.6 Shape and influence public opinion in a positive way towards the justified use of animals in research and teaching.
- 2.1.7 Ensure that activities pertaining to the use of animals is in accordance with sound practise with regard to environment and biodiversity.

2.2 For the guidance of researchers, teachers and all those involved in the care and use of animals for scientific purposes. Integral to these principles is the need to strive for:

- 2.2.1 the replacement of animals with other methods;
- 2.2.2 the reduction in the number of individual animals used; and
- 2.2.3 the refinement of techniques used to reduce the impact on individual animals;
- 2.2.4 to ensure that scientific and teaching activities using live animals are performed only when they are **essential** in:
 - i. obtaining significant information and knowledge relevant to the understanding of humans and animals;
 - ii. the improvement of human or animal health and welfare;
 - iii. the improvement of animal management or production;
 - iv. to ensure that people who use animals for scientific purposes treat them with respect and ensure their welfare as an essential factor when planning and conducting studies;
 - v. to ensure that researchers, teachers and animal care-givers are aware that they have direct and ultimate responsibility for all matters relating to the welfare of the animals in their care.

3. Objectives

3.1 The following are the objectives of the REC-A:

- 3.1.1 to examine proposed experimental and teaching protocols submitted by institutional staff with reference to the likely harm that may be caused to the animals and likely benefits that may arise from such work and to determine how these considerations are weighted in relation to each other;
- 3.1.2 to examine hypotheses to ensure they are well considered, plausible, and have a reasonable prospect of yielding good results;
- 3.1.3 to approve applications that comply with the ethical principles for humane animal experimentation;
- 3.1.4 to propose amendments and modifications, seek clarifications and request revised submissions in the case of the applications that are not approved;
- 3.1.5 to reappraise applications that have not been completed within their proposed experimental period and reserve approvals for those in which there is no justification for time extensions;
- 3.1.6 to consider the sourcing, care and accommodation standards applied to all animals within the institution including breeding stocks, and monitor the humane killing of surplus animals;
- 3.1.7 to regularly consult and engage with recognized authorities, concern groups and reputable sources of information to ensure that they are abreast of developments in the field of ethical review and analysis;
- 3.1.8 to regularly review the establishment's managerial systems, procedures and protocols where these relate to the proper use of animals;
- 3.1.9 to establish that both the researchers, educators, animal caregivers and all individuals under their supervision have the competence, training and skills to ensure the comfort, health and humane treatment of animal subjects; and
- 3.1.10 to, from time to time, sponsor seminars and workshops on laboratory animal science, animal welfare and the ethics of animal experimentation, and make resources and material available to heighten ethical sensibility among researchers, educators and animal care-givers.

3.2 In the light of this, the REC-A is tasked to

- 3.2.1 monitor, inspect and assess the acquisition, transport, production, housing, care, use and disposal of animals;
- 3.2.2 evaluate and approve, subject to possible modification, or reject written proposals for animal studies submitted for ethical review;
- 3.2.3 regularly review operating standards and the REC-A's managerial systems, procedures, policies and protocols which relate to the proper care and treatment of research animals;
- 3.2.4 report annually to the management of the institution;
- 3.2.5 advise how staff involved with animal production, care and teaching may be appropriately trained and how competence can be assured;
- 3.2.6 withdraw approval for any approved project and/or authorise the humane killing formally of any animal which is being subjected to unnecessary deprivation, fear, distress and pain;
- 3.2.7 maintain a register of approved projects and receive reports on their outcome, and
- 3.2.8 recommend to the institution any measures needed to ensure that the standards of the National Code are maintained;
- 3.2.9 prepare written procedures, which are agreed to by the institution, to deal with non-compliance, research misconduct, and any grievance related to the AEC process. The written procedures shall clearly define the reporting mechanisms and responsibilities of all parties to ensure fair and effective processes;
- 3.2.10 initiate investigation into any suspected or alleged non-compliance with the Code, institutional policies or the said Animal Protection Act;
- 3.2.11 advise management where appropriate.

4. Membership

The REC-A shall have membership that will allow it to fulfil the terms of reference. It shall comprise at least four persons. The following categories must be represented:

Category A: A person(s) with qualifications in veterinary science.

Category B: A person(s) with substantial recent experience in the use of animals in scientific or teaching activities. This shall include two representatives (academic and technician) from each of the departments of Biochemistry and Microbiology, Pharmacy, Zoology and George Campus.

Category C: A person(s) with commitment to and experience in the welfare of animals who is not associated with the institution, and who is not involved in the care and use of animals for scientific purposes.

Category D: An independent person(s) who does not currently and has not previously conducted scientific or teaching activities using animals.

An individual may represent more than one category. Membership extends for three years and is renewable. The REC-A may co-opt experts or persons from a specific discipline to provide expertise on specific issues or seek written advice.

5. Operating Procedures

- 5.1 All members of the REC-A should acknowledge in writing their acceptance of the Terms of Reference.
- 5.2 The committee shall elect a chairperson who will have a three year term of office.
- 5.3 No member of the committee shall be held personally liable for any act committed or omitted by the committee.
- 5.4 A quorum for meetings shall include at least one member from each category, i.e. A, B, C and D.
- 5.5 A representative from the discipline must be present when a protocol serves for approval.
- 5.6 Minutes shall be maintained, which record decisions and all other aspects of the REC-A's operation.
- 5.7 Meetings should be scheduled as frequently as the volume of business demands, but not less than quarterly.
- 5.8 The process by which decisions are made shall be fair, consistent and transparent to researchers and teachers, and acceptable to REC-A members.
- 5.9 Standard operating procedures (SOPs) covering all operational activities shall be developed and made available for reference and inspections.
- 5.10 Only research or teaching activities that conform to the requirements of legislation may be approved.
- 5.11 Where possible, decisions on approval of proposals should be made on the basis of consensus at quorate meetings.
- 5.12 The REC-A shall ensure that adequate records are kept on the acquisition, breeding, health, care, housing, use and disposal of animals.
- 5.13 Approved projects of long duration and long-term continual use of individual animals shall be reviewed at least annually. Any project may be reviewed, if warranted, by the emergence of new information.
- 5.14 The REC-A shall report in writing at least annually to the governing body of the institution on its activities.
- 5.15 The continuation of all projects shall be subject to the receipt of a duly completed affirmation form.
- 5.16 The REC-A shall develop a system to categorise proposals to help identify areas of special concern.
- 5.17 The REC-A may be approached by individuals or organisations, which do not have direct access to an institutional REC-A.
- 5.18 For amendments to a protocol: Any amendment request should be emailed by the PRP/PI to the Secretariat with changes clearly highlighted in the original application form.
- 5.19 The REC-A appoints a designated member to be available for consultation with the PRP/PI in order to advise regarding the implementation of the recommendations.
- 5.20 In extra-ordinary circumstances the Chairperson can request that an application be electronically circulated for consideration and approval. Once electronically approved, the resolution will be noted at a REC-A meeting.
- 5.21 The Chair (senior position in institution) shall have the power to immediately suspend any experiment that the committee considers to be in contravention of the relevant legislation.

6. Ethics Codes of Conduct

- 6.1 Any research or teaching project is expected to comply with the following:
 - 6.1.1 It is recognised that laboratory animals are protected by law in South Africa, and that their use for education, teaching and research must be justified.
 - 6.1.2 It is accepted that sentient, non-human animals have the capacity to experience a range of physical sensations and emotions and are therefore subject to moral concern.
 - 6.1.3 It is accepted that the use of animals in science critically depends on maintaining public confidence in the mechanisms and processes used to ensure that animal experiments are justified and humane.
 - 6.1.4 Integrity should be promoted by honesty and fairness. Researchers, educators, animal care staff and REC-A members should be honest about their own limitations, competence, belief systems, values and needs, and be prepared to respect views contrary to their own.
 - 6.1.5 Special care should be taken not to treat animals as mere objects. Research objectives shall always be subordinate to the humane treatment of animals.
- 6.2 The following legislation is of critical importance and all experimental projects must be compliant with the legislation.
 - 6.2.1 South African National Standard. The care and use of animals for scientific purposes SANS 10386.
 - 6.2.2 Animals Protection Act, 1962 (Act 71 of 1962).
 - 6.2.3 Veterinary and Para veterinary Act, 1982 (Act 19 of 1982).
 - 6.2.4 Animal Health Act, 2002 (Act 7 of 2002).
 - 6.2.5 Medicines and Related Substances Control Act, 1965 (Act 101 of 1965).
 - 6.2.6 Fertilisers, Farm Feeds, Agricultural Remedies and Stock Substances Control Act, 1947 (Act 36 of 1947).
 - 6.2.7 Other relevant provincial and national legislation.

7. Application

- 7.1 Written proposals shall be submitted to the REC-A on the appropriate form.
- 7.2 Proposals should contain sufficient information to satisfy the REC-A that the proposed use of animals is justified and complies with the principles of replacement, reduction and refinement.
- 7.3 Proposals shall identify the impact of all sections of the project on animals used and means by which the impact will be minimised.
- 7.4 Further appropriate information:
 - 7.4.1 The project title.
 - 7.4.2 Names and qualifications of researchers and other personnel directly involved.
 - 7.4.3 An explanation of how qualifications and experience are appropriate to procedures and protocols to be used in the project.
 - 7.4.4 Clear description of the scientific or educational objective and expected results of the project.
 - 7.4.5 Justification of the project that should address how it will:
 - i. increase our understanding of humans or animals;
 - ii. improve human or animals' health and welfare;
 - iii. improve animal management or production; or,
 - iv. achieve the ecological or educational objectives;
 - 7.4.6 reasons why techniques which do not use animals have been rejected as unsuitable;
 - 7.4.7 details of what happens to the animals from the time they are obtained until the time the project is completed;
 - 7.4.8 justification of all aspects which might impact on the animals' well-being with detailed methods to minimise distress or pain;
 - 7.4.9 details of how animals will be monitored with accompanying records;

- 7.4.10 justification of number and species of animal required based on experimental design and statistical consideration;
- 7.4.11 planned end-point and reasons for this choice. If death as end-point cannot be avoided it shall be justified and measures to minimise pain and distress shall be detailed;
- 7.4.12 expected start and completion dates and duration of experiments;
- 7.4.13 any health risks to other animals or staff, including biohazards;
- 7.4.14 expected commencement and completion dates of the project;
- 7.4.15 a brief review of relevant literature;
- 7.4.16 a declaration signed by the responsible researcher(s) and/or teacher(s) that they are aware of the responsibilities set out in the National Code.

8. Sources

This document was prepared with reference to the following:

- 8.1 South African National Standard : SANS 10386. The care and use of animals for scientific purposes.
- 8.2 Guidelines on ethics for medical research : use of animals in research and training of the SA Medical Research Council.
- 8.3 Guidelines for ethical conduct in the care and handling of animals used for research and education at the NMU.
- 8.4 Draft Terms of Reference : REC-H at NMU.