NMU Research Ethics Committee (Animals): Standard Operating Procedures

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Revised by:	**Dr S Welman and Prof P Pistorius (with input from RECA members)**
Served at RECA meeting –	
(to be reviewed on an annual basis)	

1. Submission of applications

Purpose

This document sets out the process of submitting an animal ethics application to the Nelson Mandela University's Research Ethics Committee: Animal (REC-A). This is to clarify to the researchers and lecturers how the applications should be submitted, which application forms are needed and what documentation is required in the application. According to the South African National Standard for the Care and Use of Animals for Scientific Purposes (SANS 10386:2021), animals requiring ethics approval are defined as 'vertebrates, including eggs, foetuses and embryos, that is; fish, amphibians, reptiles, birds and mammals, and encompassing domestic animals, purpose-bred animals, farm animals, wildlife and higher invertebrates, such as the advanced members from the Cephalopoda and Decapoda. However, for REC-A purposes, studies involving lower invertebrates are advised to contact REC-A to seek clarity about whether ethics approval is required for their study before commencement of data collection.

Scope

This information is relevant for all applications for research and teaching purposes involving the use of animals at Nelson Mandela University. Applicants should ensure that they have consulted the South African National Standard: The care and use of animals for scientific purposes (SANS 10386:2021 or newer) before completing an application form.

Responsibilities

It is the responsibility of all researchers and lecturers to ensure that they obtain ethical approval for activities involving live or dead higher order invertebrates and vertebrates. Approval for animal use or manipulation cannot be granted retrospectively and it is therefore critical that RECA approval is sought prior to commencement of animal-use for teaching or research. The use of secondary data (data previously obtained from an external source) involving animals also requires REC-A approval. For example, researchers wanting to use biological samples or unpublished movement data that were originally collected by an external organisation (e.g. SANParks) for the organisation's own purposes and thus occurred independently of the researchers, must still apply for REC-A approval for their study.

Approval from REC-A is however not needed to use data from published literature or other freely accessible sources.

Procedures

1. All scientific activities related to use of animals conducted under the auspices of Nelson Mandela University must be submitted to REC-A. No scientific or teaching activity involving the use of animals shall start before written approval is given. Failure to obtain such permission shall result in projects not being recognised and disciplinary action may be instituted.

2. Research and lecturing protocols are reviewed from an ethical perspective and scientific and methodological aspects will be considered to ensure compliance with the highest ethical standards in the use and care of animals for scientific research and teaching activities, incorporating the core ethical principles of
   a) Replacement of the use of animals with alternative models where feasible.
   b) Reduction of the number of individual animals used to a level that is scientifically justifiable.
   c) Refinement of experimental design, procedures, care and husbandry, to minimise or eliminate the impact on individual animals in terms of actual or potential pain, suffering, stress, and lasting harm.
   d) Responsibility for the appropriate care and use of animals and maintaining compliance in accordance with the standards of the Institution.

3. The primary responsible person (PRP), typically the academic leader, must be a member of staff at Nelson Mandela University. Consideration will be given to Research Associates (RA's) as PRP's if they work on campus and not remotely or in cases where the animal welfare risks associated with the project are deemed to be minimal. The PRP assumes all responsibility for the ethical conduct of the project participants throughout the duration of the project.

4. Where permission from external stakeholders is required for research to commence, such documentation needs to accompany the REC-A application. For example, where research is to be conducted in areas under CapeNature or SANParks management or where the work involves a threatened or protected species, the relevant permits need to be attached.

5. In cases where the application involves a request for use of secondary data or samples previously collected (e.g. museum samples), then details of the original ethics permits need to be provided. If the original permit is not available, a letter of explanation and motivation must be submitted in support.

6. From August 2023, all applications are to be submitted electronically via the Mandela Ethics Online System (MEOS) accessible at http://meos-apply.mandela.ac.za/. Detailed instructions of how to use the system can be found on the REC-A website at https://rd.mandela.ac.za/Research-Ethics/Research-Ethics-Committee-Animal-(REC-A). A Nelson Mandela University affiliated email is required to access MEOS.

7. Projects can fall under one of the following categories, each with their own application form:

a. 'Application for Approval (Research)': Any activity involving the acquisition, keeping or use of live animals or collection of animal parts primarily for a research study, requires completion of this form and submission for approval to REC-A.
b. 'Application for Approval (Practical)': Any activity involving the acquisition, keeping or use of live animals for practical work, requires completion of this form and submission for approval to REC-A.
c. 'Application for External sample collection': Application for the use of animal samples collected externally.
d. 'Application *to use External data*': Application for the use of existing research data that were collected externally.

Note that for c and d, samples/data should have been obtained in an ethical manner and the animal procedures that lead to the samples/data being collected should be known and explained (accompanied by an ethical clearance number for the project on the animals).

8. Applications will be sent electronically to all REC-A members at least a week prior to the following REC-A meeting. To facilitate the review process, the chairperson or delegated member may contact the applicant prior to the start of the review process to request additional information or clarification.

9. The chairperson may, at his/her discretion, consult an external reviewer for a particular protocol should he/she not believe the necessary expertise exists in the committee. The external reviewer will be requested to make a written report available to the chairperson prior to the meeting. To protect intellectual property, researchers' interests, and to permit committee members to speak freely and frankly, a confidentiality statement must be signed before access to information is granted to co-opted members or external consultants.

10. 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.

11. In extra-ordinary circumstances the Chairperson can request that an application be electronically circulated for consideration and approval outside of scheduled committee meeting dates. Once electronically approved, the resolution will be noted at the next scheduled REC-A meeting.

12. Should the animal use component of a project be conducted at another institution, the applicant will need to obtain ethical clearance from that institution, as well as from the RECA.

13. Amendments to accepted applications require a written motivation and changes to the original application should be made via MEOS. Such changes should clearly be closely aligned to the original application, alternatively a separate application will be required.

14. Researchers should inform the Chairperson as soon as possible of any adverse events or unforeseen deviation from the approved protocol. This should be done within one week of the

incident, otherwise researchers need to justify any delays. A detailed report also needs to be submitted via MEOS. Where deemed necessary, the Chairperson may temporarily suspend approval of the project pending investigation.

15. The REC-A Secretariat will notify applicants (PRP/PI) electronically of meeting resolutions.

2. Meeting procedures and REC-A membership

Purpose

To ensure that the meetings of the REC-A meet national standards and that all parties are aware of the processes followed.

Scope

All applications for research or teaching involving higher invertebrate and vertebrate animals must be discussed, and a decision made at quorate (see below) meetings. Progress on approved projects and any other aspects of animal-use for teaching or research are given consideration at REC-A meetings.

Responsibilities

Eight REC-A meetings are scheduled each year, with this being monthly except for January, April, July and December. Where need be, emergency meetings are held in the months where meetings are not scheduled. Meeting dates are set prior to the onset of a new calendar year and confirmed at the end of each preceding meeting.

Procedures

1. Meeting dates and deadlines are posted on the website of the Office of Research Development (https://rd.mandela.ac.za/).

2. The deadline for applications is approximately two weeks prior to the scheduled meetings.

3. Applications are made available to the REC-A members at least a week prior to each meeting. These are accompanied by the minutes of the previous meeting and agenda for the upcoming meeting compiled by the REC-A Secretariat.

4. Under special circumstances the Chairperson may include late applications to a given meeting, or circulate applications for review outside of scheduled meetings.

5. Meetings are held in person wherever possible and when not faced with COVID-19 or other health-related risks (during which times meetings are virtual). During normal conditions, if members cannot attend in person, they can do so virtually.

6. Unless on sabbatical or with the consent of the chairperson, if a member is unable to attend the meeting, the review comments should still be submitted timeously and apologies tendered.

7. A meeting quorum is at least 1 member of each category (Category A – Veterinarian, Category B – Animal Researcher, Category C – Animal welfare representative, Category D – Community member [layperson]). Membership is to adhere to SANS (2021) and the proposed updates to the DoH guidelines (2023).

8. New members to the Committee will be appointed through consultation and shall sign acceptance of a letter outlining the code of conduct. Any member wishing to resign from the Committee will send a formal letter of resignation to the Chairperson and ideally remain within the Committee for two months while a replacement is being recruited.

9. Should the Chairperson not be able to attend and chair a meeting or has recused themself from a portion of the meeting due to conflict of interests, the meeting will be chaired by the Vice-Chairperson preferably, or another experienced member.

10. At the start of each meeting, the attendees should sign the register and declare any conflicts of interest that they may have with respect to the agenda presented. The Chairperson should remind all Committee members that the meeting discussions are confidential and that by signing the register, the Committee members acknowledge this. The Chairperson should also remind Committee members attending online when the meeting is being recorded for their permission which can include acknowledging confidentiality.

11. In all instances where there is a legitimate conflict of interest, members shall recuse themselves from discussions pertaining to the matter and would have no vote on its outcome.

12. Applications tabled for approval will be discussed by all Committee members present, excluding any recused members, and the process by which decisions are made shall be fair, consistent and transparent to Primary Responsible Investigators (PRP), Principle Investigators (PI), and all REC-A members. Decisions in meetings are by consensus, and if consensus cannot be reached, then decisions are based on majority votes. All effort should be made to resolve any conflicts and members can have it noted in the minutes that they disagree with a decision.

13. Decisions are classed as follows:

    a. Approved – The Committee approves the application as is and requires no clarification or corrections. The clearance letter can be awarded as soon as possible.
    b. Approved with minor modification – The Committee has approved the application pending minor technical clarification, ethical or design concerns. On receipt of a revised application, the REC-A member that serves as the liaison contact for the application will assess whether these issues were resolved. If so, the clearance letter can be awarded as soon as possible.
    c. Approved with major modification– The Committee is concerned that there are ethical or design concerns that will require substantial revision of the application. On receipt of a revised application, the REC-A member that serves as the liaison contact for the application will, in consultation with the Chairperson, assess whether these issues were resolved. If so, the clearance letter can be awarded as soon as possible.
    d. Rejected/resubmission – The Committee is of the view that the research is either unethical

or not clearly enough articulated to allow assessment of the content. Where the proposed research is deemed to be unethical (or animal welfare concerns outweigh the benefits of the study) the application is rejected. Where modification of the application, in terms of content or animal use, seems possible to resolve concerns raised by REC-A, then a resubmission is encouraged.

14. Minor amendments and modification to projects, as well as applications for use of secondary data, can be approved via round robin if the request is very well motivated (eg. when an urgent but minor change needs to be made to a student project to allow continuation of study).

15. Decisions are communicated to the applicant via institutional e-mail (ie, university email address unless explicitly specified otherwise) within one week of the meeting.

16. All matters relating to REC-A meetings, including all applications, meeting minutes, agendas, application outcomes will be kept on record for long-term storage.

3. Animal holding facility inspections

Purpose

To ensure that all animal housing facilities are managed and maintained according to the South African National Standard: Research and Teaching using animals. Through Active Monitoring, to ensure that research and teaching activities at the animal housing facilities are conducted according to the SANS 10386:2021 (or updated version).

Scope

All facilities under the auspices housing live vertebrate and higher invertebrate animals for research purposes must be inspected regularly by REC-A member/s and annually in the presence of the NSPCA REC-A member (as described in the SANS 10386:2021 (or updated version)). Active Monitoring of projects making use of the facilities will allow confirmation that animal use is conducted in an ethical manner.

The facilities inspection checklist (including cleanliness; adherence to SOP's posted at the facility access door (eg, regarding food and chemical storage); food and water availability for experimental animals; presence of monitoring sheets and project information for active experiments) will be completed by the inspection team when conducting the inspection. Evidence (including photographic) of any shortcomings will be kept on record.

Responsibilities

Annual inspections of the Animal Facilities will include a minimum of three committee members, of which one must be a category A (veterinarian) and one a category C (NSPCA) member. The facility manager/technician will accompany the inspection team.

A copy of each inspection report will be attached as an annexure to REC-A meeting documentation and discussed under agenda standing item 'Animal Holding Facility'.

Procedure

1. Although the facility manager/technician and PRPs/PI's with active projects will generally be informed in advance of planned inspections, they may be conducted unannounced. In the case of the latter, where it involves active animal rooms, it is imperative that the inspection team contact the PRP/PI (contact details on door of active rooms) prior to entering these rooms and potentially compromising experiments.

2. The inspection will be conducted using the annual facilities review checklist adhering to the standards set forth in the SANS 10386:2021 or newer version.

3. During all inspections, attention will be given to ensuring that PRPs/PIs are compliant with regards to ensuring monitoring forms are visible and current (these forms are available from the Office of Research Development's website ('Draft Monitoring Forms' https://rd.mandela.ac.za)).

4. Problems will be characterized as either minor, generally in the case where the wellbeing of animals is not compromised, or significant. In the case of the latter, involving a threat to the safety and wellbeing of animals, correction plans will be discussed with the facility manager when involving the general facility or the PRP when it relates to a specific experiment/project. A report detailing the problems, including the correction dates, will be sent to the PRP/facility manager. This will warrant a response by the due date including reasons for the problems and a corrective action plan for each problem. It is the responsibility of the PRP/facility manager to ensure that all problems identified in the inspections are corrected.

5. REC-A will be notified of all problems and take the appropriate actions, as needed.

4. Reporting of deviations, adverse events and whistle blowing

Purpose

This document is for the purpose of identifying animal welfare incidents related to animal research procedures, treatments, and the care and wellbeing of research animals at Nelson Mandela University. As such, relevant information can be recorded, referenced and filed with the protocol case history.

Scope

The process applies to all University affiliates conducting animal research. The implementation and management of this process shall be at the discretion of the REC-A. All research and teaching activities involving the manipulation and use of animals at Nelson Mandela University need to be done under the auspices of an approved REC-A project and as such all activities related to animals will be dictated by the approved protocol activities.

Responsibilities

It is the responsibility of all researchers to ensure that they report to REC-A any deviation from the approved protocol or any adverse or unexpected incidents. Adverse events are any events that have a negative impact on the well-being of an animal within the scope of the approved protocol. Unexpected incidents are those events or incidents that are not planned or expected during experiments as laid out by the approved protocol, which may or may not lead to a deviation from the approved protocol.

Procedures

1. It is the responsibility of the applicant of the ethical clearance to report any deviations, adverse events or incidents that occur during the course of a research study or teaching activity (Including unexpected deaths) to REC-A.

2. Animal welfare and mortality events should be reported ASAP but no later than a week of occurrence. An 'Unexpected mortality/Adverse Events Report' should be submitted via MEOS, researchers should also inform the REC-A Chairperson or Vice-Chairperson of the incident. If neither the Chairperson or Vice-Chairperson is available, the researcher should inform any available REC-A member.

3. The member of the Committee that received the report should forward the report to the Chairperson for further engagement with the rest of the Committee.

4. The Chairperson (as a representative of the Committee) has the authority to take immediate appropriate action (i.e. to suspend all further study-related activities) or refer the case to the Institute for possible further action (i.e. disciplinary action) if circumstances indicate that such action is warranted.

5. Following corrective actions, the committee reserves the right to request frequent reports (at the Committee's discretion) to monitor and evaluate the situation to assess the adequacy of the corrective action applied.

6. Where any members of the public or research community observe research misconduct, this should be reported to either the RECA Chairperson or any member of theCommittee or University Senior Management. If deemed necessary, the Chairperson of REC-A can, with immediate effect, terminate the relevant study.

5. Annual and final reports

Purpose

Approved projects need to report annually on progress and this document provides the standard processes and instructions for such reporting which is guided by the SANS10386:2021 document.

Scope

Annual progress reports need to be submitted by all University affiliates that have active and approved animal research projects or teaching involving practical work on live or dead animals that require REC-A approval. The implementation and management of this process shall be at the discretion of the REC-A.

Prerequisites

Reporting is done on all approved animal projects. For a project to be approved it needs to be reviewed by the REC-A. For this purpose, please see 'Submission of applications' and 'Meeting procedures' which outline how applications can be submitted and how the Committee functions in terms of approving animal ethics projects.

Responsibilities

It is the responsibility of all researchers and lecturers to ensure that they provide annual progress reports. An additional motivation is required in cases where the project requires renewal. At completion of a project, a final closure report is to be submitted to the REC-A.

Procedures

1. Researchers and lecturers must submit annual and final reports using the 'Annual Progress Report' and 'Completion of Project Report' forms via MEOS, or for approved studies pre-dating MEOS, the forms are available on the website of the Office of Research Development (https://rd.mandela.ac.za). Manual submission of annual and final reports should be submitted to the Ethics Manager at Research Development or if unavailable to Mr Imtiaz Khan; Imtiaz.Khan@mandela.ac.za.

2. As a means of Passive Monitoring of accepted projects, annual progress reports are required for each calendar year that ethics approval is active. The period of activity will be stipulated in the application and the duration of approval will be provided in the approval letter.

3. Annual progress reports need to be submitted no later than the 15th of January, covering all project activities in the previous calendar year. REC-A will send a call for submission of Annual Progress Reports in November/early December.

4. Annual progress reports will include at least the following information:

    a. List of animals used in the study
    b. Numbers of animals per species used in the study
    c. What progress has been achieved
    d. Any deviations from approved protocol
    e. Any adverse events or unanticipated problems
    f. Whether the project is continuing, has been completed, or discontinued

5. REC-A reserves the right, as per the SANS 10386:2021, to request a more frequent reporting schedule for projects that have been identified as high risk.

6. REC-A has the authority to suspend or terminate research that does not comply with annual reporting requirements.

7. Final reports are to be submitted when the use of animals is complete, ethics approval has expired, or the project has been discontinued.

8. Use of animal holding facilities

Purpose

Approved projects needing to make use of the animal holding facilities need to comply to certain conditions set out by the REC-A and guided by the SANS10386:2021 document.

Scope

All researchers making use of the animal holding facilities need to be familiar with the conditions set out below.

Procedures

1. No unauthorised entry into the animal facilities.

2. Facilities to be kept clean and tidy at all times.

3. Personal Protective Equipment (PPE) to be used by all staff/visitors working on animals (including lab coats and masks).

4. Keep noise levels as low as possible and cell phones on silent mode when entering animal holding rooms.

5. No eating, drinking or smoking in the animal holding facility.

6. Make sure to use dedicated storage facilities for feed, bedding and chemicals.

7. Please liaise with the Animal Holding Facility Manager prior to intake of any animals and supply details of where animals are arriving from and when they will be arriving, supplying REC-A letter of project approval. In the event that the Facility Manager is unavailable, please liaise with the nominated proxy or with the Zoology Senior Technician.

8. Animals received are to be brought through the back door to the environmental rooms through the clean corridor and not through the main entrance of the building.

9. All new animals to the facility are to be kept in isolation during a quarantine period in accordance with SANS (2021) guidelines.

10. Unless required as part of the approved study, all captive animals to receive appropriate, uncontaminated and nutritionally adequate food in accordance with acceptable requirements for the species and REC-A approved protocol.

11. Unless required as part of the approved study, all captive animals to have access to uncontaminated clean drinking water.

12. Monitoring sheets (including water and food provisioning schedules) and details of REC-A approved protocol to be posted on the door (in envelope) at the entrance of the relevant environmental room/s. REC-A may require photographic evidence of animals and their holding conditions at short notice.

13. Please make sure housing conditions are consistent with descriptions in REC-A approved protocol.

14. Cold-room and freezer facilities are available outside of environmental rooms. Items stored here need to be clearly labelled and signed.

15. Ensure prompt and sanitary disposal of animal carcasses and waste material in accordance with the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993). Contact Mfundo Mpinga (041 5042428) Mfundo.Mpinga@mandela.ac.za for assistance.

16. Before making use of ablutions, please ensure the following: your lab coat is left on the appropriate hooks, not to be worn into the ablutions and to ensure that your hands are sanitised.

17. All surgical procedures to be performed by a qualified vet or person with appropriate para-veterinary certification, or under the supervision of these professionals, if so approved by REC-A.

18. Cage washing can be done within the rooms making use of the dedicated sinks. Rooms to be kept clean during experiments and to be thoroughly washed after each experiment.

19. All cleaning chemicals to be kept in the lockable cabinet outside of the environmental rooms. Cabinet to be found in corridor clearly labelled as cleaning chemical storage.

For queries/ assistance with environmental rooms contact **Pieter du Toit Phone:** 0823429215/0415042168 **Email:** Pieter.dutoit@ mandela.ac.za

References

South African National Standard: The care and use of animals for scientific purposes (SANS 10386: 2021).

Some SOPs adapted from University of Fort Hare.