RUAREC Standard Operating Procedure

Monitoring of Active Projects that Received Animal Ethics Approval and Adverse Event Reporting

Drafted by: Rhodes University Animal Research Ethics Committee (RUAREC)

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Glossary of terms

Applicant – Person who wrote the application form and applied to the RUAREC for animal ethics clearance

EXCO – Executive Committee of the RUAREC

Facility – Facility that houses animals

Researcher – Person(s) undertaking the research / teaching activities

RU – Rhodes University

RUAREC – Rhodes University Animal Research Ethics Committee

SANS 10386:2008 – South African National Standards for the Care and Use of Animals For Scientific Purposes (number 10386 in the year 2008)

NSPCA – National Society for the Prevention of Cruelty to Animals

Vet – Registered veterinarian

1. Background of this Standard Operating Procedure (SOP)

Ethical review and clearance/approval processes of research and/or certain teaching activities involving animals as defined below (referred to as research and teaching in further text of this SOP), must follow rigorous procedures, adhere to stringent standards, as well as fulfil national and international legal/accreditation requirements and best practices. This SOP and all its parts apply to activities in research and teaching that are conducted in/by:

- All academic departments of Rhodes University;
- All institutes affiliated with Rhodes University;
- All investigations conducted by affiliated researchers working with animals at Rhodes University (these are academic and support staff, undergraduate and postgraduate students, postdoctoral fellows, research associates and senior research associates).

The above-mentioned academic units and/or individuals are referred to as RU stakeholders in further text of this SOP. Overall, all the unit operations and steps involved in the ethical review and clearance/approval processes of research and teaching at Rhodes University are aimed at achieving the following:

- To produce of new knowledge as part of the academic project at Rhodes University that involves animals;

- To validate, review and continuously update the subject matter and content that are taught as subject matter in all disciplines at Rhodes University which have animal ethics implications;
- To ensure that the knowledge produced and/or validated must be of high standard, as to withstand the peer-review and all other review standards in a given academic discipline in which results of studies that involve animals are published;
- To achieve comprehension and understanding of the necessary and prescribed knowledge of animal physiology, behaviour and other related aspects of curriculum outcomes and/or degree requirements in a particular academic discipline;
- To conduct research and teaching according the principles of academic integrity, fairness and with respect and with the view towards the protection of animal rights;
- To contribute to the preservation of the habitat and the protection of populations of higher primates in South Africa, on the African continent and internationally.

In light of the above principles and any other relevant ethical considerations, there are several stages to the animal ethics review process and ongoing monitoring of research and teaching. To ensure that the above-mentioned tenets are achieved, one of the steps in the ethical review and active process is the careful scrutiny to prevent unnecessary harm to all animals specifically in any and all research and teaching activities by RU stakeholders.

In conjunction with the above, it is stated clearly here that there is an urgent and ongoing need to maintain competence and familiarity by RU stakeholders with the necessary procedure to properly handle and to properly conduct research and teaching with all animals properly. To achieve this, this SOP is designed to achieve two main aims. Firstly, the SOP is aimed at outlining procedure(s) that is/are to be followed by all RU stakeholders with respect to the relevant research and teaching activities that involve animals. The second main aim of this SOP is to outline a procedure for the development of the ethical review expertise among the members of the Rhodes University Animal Research Ethics Committee (RUAREC) in terms of the knowledge and competencies to carry effective review and monitoring of research and teaching activities with animals and to maintain the necessary standards of animal welfare by RU stakeholders.

2. Philosophy and practical implementation/execution of the SOP

Philosophy of this SOP is derived from the principles of "*replacement, reduction, refinement and responsibility*". Therefore, the use of animals, as defined above, in research and teaching by RU stakeholders is only sanctioned and authorised, if no other alternatives are available to achieve the particular outcomes of research and teaching by RU stakeholders. These considerations must be based

on a very careful weighing of risks and benefits of such as research and teaching activities involving animals. In line with these facts, all activities in research and teaching by RU stakeholders with animals imply and are aimed at maintaining compliance and adherence to the following South African legislation and international standards that are aimed and protection of animal rights and welfare; and that take the specific consideration of animals into account

- South African National Standard no. 10386:2008
- Animals Protection Act no. 17 of 1962 as amended
- Performing Animals Protection Act no. 24 of 1935 as amended
- SPCA Act no. 169 of 1993
- Animal Matters Amendment Act of 1993
- Animal Protection Amendment Bill of 2017
- South African National Standard no. 10379:2005
- Professional Code of Ethics of the African Association of Zoos and Aquaria
- Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES, Available at: www.cites.org/eng/disc/text.php; website accessed on 18th June 2019).

Animal welfare must further be seen to include the freedom from "thirst and hunger", from "thermal and physical discomfort, pain, injury, distress" (SAAPAB, 2017). Unless otherwise stated in the text below, the following definitions for this SOP were extracted from section 1 of the Veterinary and Para-veterinary Professions Act no. 19 of 1982 (as amended; this act is designated as the Act in further text of this SOP). These definitions are as follows:

Veterinarian – any person who is registered or deemed to be registered in terms of the Act to perform the veterinary profession of a veterinarian. In addition, a veterinarian must be registered in the appropriate register operated by the (see section 18 subsections/paragraphs 1 and 2 of the Act). An extract of the register signed by the Registrar of the South African Veterinary Council (established in terms of sections 2-17 of the Act) or a certified copy thereof should be provided to RUAREC and filed by the Ethics Coordinator (currently Mr. Siyanda Manqele, email: s.manqele@ru.ac.za) for all the Veterinarians, who are trained and/or have experience in working with animals.

3. Post-approval passive monitoring of protocols

- Post-approval passive monitoring specifically refers to the passive monitoring of projects and their associated activities that have received ethical clearance from the RUAREC.
- Ethical approval for a project is for one year, with an option to renew the approval for up to two times; i.e., a particular project can only be approved for up to a maximum of three years. An Annual Report must be submitted for each approved project, during which a renewal can be requested. The Annual Report will consist of sections where amendments to the original approved protocols can be requested or it can be stated that the project is ending (i.e., Closure of Project is stated). The Annual Report will also provide sections where adverse events and unexpected injuries or mortalities have occurred during the project activities.
- Amendments to project activities, protocols, researchers or applicants can be done during the year. Request for the amendment to an approved project can be done by submitting the request to the RUAREC, via contacting the Ethics coordinator, the Chair of the RUAREC or by filling in the Amendment Request form. For amendments that are changes in researchers or minor changes to protocols (e.g., reduction in sample sizes, change in vet on the project), the Chair may approve the amendment to the approved project, and report the approval to the RUAREC at the next committee meeting. For those amendments that would constitute a major change to the approved project activities (e.g., changes to the approved methods, increase in sample sizes, change in Principal Investigator, additional project activities), the amendment request will be reviewed by the RUAREC at the next committee meeting.

4. Post-approval active monitoring

- Post-approval active monitoring specifically refers to the active monitoring of projects and their associated activities that have received ethical clearance from the RUAREC.
- Applicants will indicate on the animal ethics application form whether animals will be housed onsite ("onsite" defined as within the Grahamstown/Makhanda region) for the project work.
- Should there be animals housed onsite, inspection of the facilities may be undertaken by the RUAREC or the EXCO. Inspections could include inspecting the animal housing setup (prior and/or during the project activities) and observing the project procedures to ensure competence of the researcher in the approved procedures.
- If procedures are being done that were not in the approved ethical clearance application, the project will be instructed to cease any and all activities until an investigation can be carried out into the project activities up to that date and a determination will be made as to whether the project will be shut down entirely or whether the project may continue.
- If the housing setup is deemed inadequate or not in accordance with the standards outlined in the SANS 10386:2008, the project will be instructed to cease any and all activities until an investigation can be carried out into the project activities up to that date and a determination will be made as to whether the project will be shut down entirely or whether the project may continue.

5. Routine inspection of animal care and use facilities

- Facilities that house animals on campus of Rhodes University for the use in Research or Teaching activities must comply with the standards outlined in the SANS 10386:2008.
- Activities involving animals (such as housing, euthanasia, husbandry etc) that are carried out in these facilities should comply with the SOPs of the RUAREC and the SANS 10386:2008.

- Routine inspection of the facilities can be carried out by the RUAREC and by animal welfare organisations (e.g. NSPCA). Inspections will include observation of procedures done to animals at the facility and inspection of the housing conditions of the animal enclosures. It is highly recommended that an inspection is done while animals are present in the enclosures and that inspections are done at least once annually.
- Inspections can be carried out by the RUAREC or the animal welfare organisation at the request of the facility or at the request of interested parties (e.g., due to a report by a whistle-blower) or at the request of the RU.

6. Reporting of monitoring activities, including problems encountered, to the RUAREC and the institution

Project activities that are approved by the RUAREC must be the only activities done during the project's activities. However, adverse events or unexpected incidents may occur during a project's activities. Researchers must report any adverse events or unexpected incidents that occur within one week of the event to the RUAREC. Users of animals for scientific purposes should provide details of the type and extent of possible adverse events in their application to the RUAREC. If the events happen as expected, they do not have to report them separately, unless additional reporting is a condition of RUAREC approval.

An unexpected adverse event may result from different causes, including but not limited to:

- death of an animal, or group of animals, that was not expected (e.g., during surgery or anaesthesia, or after a procedure or treatment),
- adverse effects following a procedure or treatment that were not expected (e.g., unexpected reaction to an anaesthetic, injury sustained as a result of the project activities),
- adverse effects in a larger number of animals than predicted during the planning of the project or activity, based on the number of animals actually used, not the number approved for the project or activity,
- a greater level of pain or distress than was predicted during the planning of the project or activity,
- power failures, inclement weather, emergency situations, or other factors external to the project or activity that have a negative impact on the welfare of the animals.

Examples of situations that require reporting include, but are not limited to:

- deaths of animals not described in the approved application,
- complications not described in approved application (e.g., a type of anaesthetic doesn't provide adequate pain relief),
- more deaths or complications than described in approved application (e.g. higher mortality number than the expected fatality rate applied for in the application),

- facility or equipment failure that compromises animal welfare or the success of the activity (e.g., power loss to facility means ventilated fish enclosures do not receive air bubbled into the enclosure, leading to a reduction in oxygen provision to the fish housed in the enclosure),
- facility or management practices or investigator monitoring that are not meeting the animals' needs (e.g. birds have sore feet due to the type of flooring),
- facility, management, or experimental procedures are having a greater negative welfare impact than was described and approved.

Detailed unexpected adverse event reports should include:

- the description of the event
- how the event and welfare of the animals are monitored and addressed
- the actual and potential impacts of the event on animal welfare
- the actual and potential impacts of the event on the aims and outcomes of the activity
- what immediate and long-term steps are being taken or considered to investigate causes and develop future prevention strategies.

An unexpected adverse event report is not required if:

- the RUAREC knows that the adverse event may happen
- the event happened as expected and has been approved by the RUAREC.

Examples of situations that do not require reporting include:

- expected deaths of animals as described and approved in the proposal
- outbreak and response to treatment of a disease or complication as described and approved in the proposal.

For those interested parties that are not directly involved in the research, but would like to report project activities that are negatively impacting the welfare of animals used in a particular project's activities, please refer to the RUAREC SOP for whistleblowers.

7. References

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