

UCT POLICY AND STANDARD OPERATING PROCEDURES REGARDING SCIENTIFIC USE OF NON-HUMAN PRIMATES

[Last updated 16 September 2015]

The University recognizes the important contribution that research involving Non-Human Primates (NHPs) has made, and may continue to make, to our scientific and biomedical knowledge. The University is also cognisant of the ethical considerations that arise with regard to NHP research and of the concomitant public sensitivity surrounding the use of NHPs.

This document must be read in conjunction with the UCT RESEARCH POLICY and the UCT RESEARCH ETHICS CODE FOR USE OF ANIMALS IN RESEARCH AND TEACHING and the Faculty AEC TERMS OF REFERENCE, the AEC APPLICATIONS FOR ETHICS AUTHORISATION, STANDARD OPERATING PROCEDURES, AND AEC REPORTING OF PROTOCOL DEVIATIONS UNANTICIPATED PROBLEMS AND WELFARE VIOLATIONS IN ANIMAL RESEARCH STANDARD OPERATING PROCEDURES.

A GENERAL CONSIDERATIONS

The University commits itself to developing and encouraging a sensitization process designed to foster an attitude of respect and compassion towards all sentient animals, including the needs and general well-being of non-human primates in science.

As per the guidelines contained in the UCT Research Ethics Code for Use of Animals in Research and Teaching, the University requires that the use of experimental animals be governed by strict criteria based on the principles of **replacement, reduction and refinement**. This means that all efforts must be made to reduce the use of NHPs to a minimum, that NHPs may not be used if a reasonable and viable alternative exists, and that discomfort, pain, suffering, stress and distress must be avoided if possible or kept to a minimum.

Prior authorisation must be obtained from the relevant Faculty Animal Ethics Committee before any NHPs are subject to scientific use. A *decisional analysis system* (e.g. as provided in the MRC handbook #3 Appendix 3, *Use of Animals in Research and Training 2004*) is used in addition to conventional evaluation of such protocols. Following authorisation by the Faculty AEC, authorisation must also be obtained from the Senate Animal Ethics Committee before any NHPs are used.

The scientific use of NHPs can be justified only when the good that can reasonably be expected to be derived from the use is comparable to or exceeds the harm inflicted on the animal. "Scientific use" includes but is not limited to use in research, testing, teaching, validation and observation.

The species represented by the families Pongidae and Hylobatidae (Great and Lesser Apes respectively) are considered to be particularly closely related to humans in evolutionary terms. Use of these species poses particular moral concerns. Consequently, proposals involving these species should be approved only in exceptional circumstances.

Replacement

The use of NHPs should only be approved in circumstances where a non-animal method or different animal model is not feasible

Reduction

Only the smallest number of NHPs possible, consistent with the aims of the research, should be used. Statistical analysis and factual evidence must justify the number of animals requested

Refinement

Every effort must be made to refine all aspects of the use of NHPs including

- Source, capture and transport of the animals.
- husbandry and environmental enrichment of the animals
- trained and competent staff, sensitised to the needs of NHPs
- experimental design, materials and techniques used
- care of the animals before, during and after each procedure
- adequate analgesia where pain may be involved
- end-points of the procedure, including humane and intervention endpoints
- re-use, re-homing or other fate at the end of the procedures
- method of killing animals

B SPECIFIC CONSIDERATIONS

1. *Acquisition*

The University accepts responsibility for ensuring that NHPs are acquired only from legal (authorized) sources registered with the appropriate provincial authority or recognized research institution. Note: UCT has disallowed the scientific use of wild-caught baboons in research.

2. *Emergencies*

A detailed contingency plan should be in place, prior to admission of a NHP to a captive setting (e.g. laboratory or breeding facility), to deal with any medical emergency or environmental hazard.

3. *Export*

In principle, NHPs may not be exported from the Western Cape to another province or country, unless for a specific approved purpose, in which case approval by the Senate Animal Ethics Committee and relevant permits must be obtained. Possible purposes include maintenance of genetic diversity or provision of overseas researchers with a model of a primate disease. Where an exemption is considered, evidence must be presented that the NHPs will be exported only to institutions with standards of NHP care at least as good as those of UCT.

4. *Housing and Care*

The housing and care of NHPs should be in accordance with best practices as embodied in SANS 10386:2008 and/or internationally accepted standards.

Environmental enrichment should be prioritised for the period of stay and adequate experienced and trained staff, sensitised to the needs of NHPs, should be available.

NHPs housed at NHP facilities should be housed singly in cages for as short a period as possible, with reference to the experimental requirements.

5. Reporting

All members of the University have the responsibility to report animal welfare violations, protocol violations, and any unanticipated problems related to animal research procedures, treatments, and the care and well-being of research animals, so that they may be investigated and corrected. The responsibility of reporting as established in a cooperative research agreement shall extend to colleagues and collaborators not affiliated with UCT and who may participate in and/or observe, monitor, audit or otherwise be aware of UCT research being conducted off-campus and outside of UCT facilities. Failure to report incidents may be construed as an irresponsible act and lead to negative consequences.

6. Zoonoses

All staff handling NHPs, or otherwise coming into contact with NHPs, must act in accordance with applicable standard operating procedures in this regard, including but not limited to those providing for health screenings of animal workers and compliance with occupational health and safety standards.

C STANDARD OPERATING PROCEDURE

I New non-human primate (NHP) protocol applications

1. Prior authorisation must be obtained from the Faculty Animal Ethics Committee (AEC) before any NHPs are used for scientific purposes. This applies to all NHP studies and research including protocols for which a Faculty AEC formally delegates oversight and monitoring responsibility to the AEC of another institution. Formal delegation under this policy requires a written cooperative research agreement specifying that full information and copies of all reports (protocol monitoring reports, incident reports, etc.) be promptly submitted to the Faculty AEC, and prepared in accordance with SANS Code Section 5.2.11. Terms of delegation may include cooperative, announced, unannounced and other types of inspection, monitoring, and audit activities to which UCT and another institution may agree.
2. Applicants must complete the Faculty AEC appropriate application form(s), paying particular attention to the detail required for NHP use.
3. The review process shall be consistent with Faculty AEC Terms of Reference for the reviewing AEC, and applicable standard operating procedures.
4. A *decisional analysis system* (e.g. as provided in the MRC handbook #3, *Use of Animals in Research and Training* 2004) shall be used in addition to conventional evaluation of such protocols by the Faculty AEC. The minutes must reflect the decisions in terms of the analysis.
5. Immediately following a *decision to approve a protocol*, and *prior to initiation of the protocol*, the Chair of Faculty AEC (through the secretariat) must provide a copy of the protocol ***in its final approved form together with an accurate schedule of planned procedures (with dates)*** to the Senate Animal Ethics Committee (SAEC).

NOTE: the Principal Investigator is responsible for supplying the schedule of planned procedures to the Chair of Faculty AEC at the time of application for authorisation.

6. The SAEC must peruse the protocol, raise queries if necessary, and then convey any comments or queries to the SAEC Chair, who must communicate these to the Faculty AEC Chair. This means that the Faculty AEC does not communicate its decision to approve the protocol to the PI until final approval is also received from SAEC. The full committee of SAEC

is not expected to re-review the proposal at a convened meeting; the SAEC Chair may instruct full committee review of the protocol at a convened meeting in his/her discretion. If queries are raised by SAEC, these should be communicated to the Faculty AEC Chair.

7. If amendments are recommended by the SAEC during its review process, these must be discussed and agreed to or not by the Faculty AEC; the protocol must be updated or not; the minutes of the meeting must reflect the final decision.

8. If the protocol is amended, the **new** final version must be sent to the SAEC for approval. If the SAEC declines to approve a protocol, the PI may initiate an appeal according to SAEC policy and procedures. Neither use nor research involving NHPs may commence in the absence of SAEC approval.

9. Upon SAEC approval, the Faculty AEC Chair must get confirmation from the Animal Unit Director (or equivalent institutional official) that he/she is in receipt of the final approved protocol and documentation to support the release of any animals to the responsibility of the PI.

10. Oversight of protocol monitoring:

- a) Unless monitoring of the research is formally delegated to an external AEC by written agreement incorporating any specific SAEC criteria as may be specified to ensure the ethical use of animals in the research, the SAEC Inspecting Veterinarian is required to conduct an unannounced inspection of the animals used in the initiated experiment and to convey his findings in a report to the SAEC. The timing of the inspection is decided by the SAEC Inspecting Veterinarian on the basis of the schedule of planned procedures (see above).
- b) Where monitoring is formally delegated to an external AEC by written agreement incorporating any specific SAEC criteria as may be specified to ensure the ethical use of animals in the research, the policies and standards for oversight may not materially differ from those established at UCT under the authority of the Senate Animal Ethics Committee (C.I.12 below).

11. If the NHPs are held at a non-UCT site, ready access is required. This will be facilitated by facility managers and the PI.

12. Inspection of the animals either by the SAEC inspecting veterinarian or by a veterinarian to whom inspection is assigned under a cooperative agreement includes:

- a) An assessment of whether the protocol is being adhered to closely and appropriately for purposes of ensuring animal well-being
- b) An evaluation of the degree of suffering of the animal, especially whether the severity exceeds that predicted in the protocol
- c) Whether adequate analgesia is being provided
- d) Whether adequate environmental enrichment is being provided, especially for animals being used in long-term (exceeding 2 months) experiments
- e) Whether housing and husbandry measures are being implemented in accordance with applicable policies and standards

13. After the unannounced inspection conducted prior to the initiation of the research, the SAEC Inspecting Veterinarian must send his report and recommendations (initial report) to the Chair of the SAEC. Regular NHP inspections and reporting will follow during the performance of the NHP research. See Section II, Regular NHP inspections and reporting, below.

14. If protocol non-compliance or violations or deviations are noted in the initial report, consistent with the requirement for inspection and monitoring reports generally, the Chair of SAEC must call for reports from the Faculty AEC on the non-compliance or violations or deviations, and report to SAEC as soon as possible (see below).

II Regular NHP inspections and reporting

1. Unless monitoring of the research is formally delegated to an external AEC by written agreement incorporating SAEC criteria to ensure the ethical use of animals in the research, the SAEC Inspecting Veterinarian must:

- a) Inspect NHP and animal-user areas that pertain to UCT-based research and/or researchers on both a regular and an ad hoc basis in terms of this SOP. The UCT Office of Research Integrity can facilitate access and permissions.
- b) Visit NHP facilities on a pre-arranged basis at least once a year for a thorough inspection (pre-arranged annual inspection).
- c) Conduct the pre-arranged annual inspection with the Animal Unit Manager (or other appropriate person) who must accompany the SAEC Veterinarian for this purpose.
- d) Make ad hoc visits out at least quarterly at the SAEC Veterinarian's discretion and these visits may be unannounced. Note that 'unannounced' does not preclude a telephone call or other communication to the facility before the inspection for the sake of conventional politeness.
- e) Make every effort to liaise directly with the Research Animal Facility Director (or equivalent institutional official) during or after an ad hoc visit so that minor problems and queries can be resolved immediately.

III Procedure following SAEC Veterinarian reports

1. After inspections, the SAEC Inspecting Veterinarian must send his/her report and recommendations (regular NHP inspection report) to the Chair of SAEC.

2. If protocol non-compliance or violations or deviations affecting animal well-being are noted in a regular NHP inspection report, the Chair of SAEC must call for reports from the AEC on these issues and report to SAEC as soon as possible.

3. In the event of a significant deviation from protocol or animal welfare violation, an Animal Incident Report should be completed and submitted as per the applicable AEC reporting procedure (e.g. AEC Reporting of Protocol Deviations Unanticipated Problems and Welfare Violations in Animal Research SOP (available at www.health.uct.ac.za/research/animalethics)).