

**Research Ethics Committee: Animal Care and Use
(REC: ACU)**



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**STANDARD OPERATING PROCEDURES
AND GUIDELINES**

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1. TERMS OF REFERENCE

- 1.1 Stellenbosch University (SU) recognises that the advancement of biological, medical, agricultural and ecological knowledge and the development of improved means for the protection of the health and well-being both of man and of animals require the use of animals of a wide variety of species in research and teaching activities. These types of activities comes with the implied responsibility to ensure that all animals, i.e. "live, sentient non-human vertebrate, 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*" (*SANS 10386:2008*) used in research and teaching are cared for and used in ways judged to be scientifically, technically, and humanely appropriate.
- 1.2 The **Research Ethics Committee: Animal Care and Use (REC: ACU)** is mandated by the **Senate Research Ethics Committee (SREC)** of the University to function as an independent research ethics committee (REC) under the auspices of the SREC for the purpose of reviewing and approving all research and teaching activities involving animals, taking into consideration ethical and welfare aspects as well as scientific or educational value in accordance with accepted and applicable national and international normative and procedural standards.
- 1.3 The REC: ACU functions in compliance with, but not limited to, the following documents and guidelines:
 - a) South African National Standard for the Care and Use of Animals for Scientific Purposes - SANS10386:2008
 - b) The Medical Research Council Guidelines on Ethics for Medical Research; Book 3: Use of Animals in Research and Training
 - c) The Guide for the Care and Use of Laboratory Animals, 8th Edition; Office of Laboratory Animal Welfare, USA
- 1.4 All staff members and students are expected to at least consult the documents mentioned in 1.3 before planning a research or teaching activity involving animals.
- 1.5 Animals shall be handled only by persons instructed and competent in methods that avoid distress and do not cause injury. It is the responsibility of the relevant department to ensure that staff and students receive the necessary training.
- 1.6 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 animal REC to outweigh the potential harm to the individual animal subject.

Therefore all research and teaching involving animals must be approved by the REC: ACU before the activity commences, so that a formal evaluation of the potential harm/benefit equation can be undertaken.

- 1.7 All research and teaching activities involving animals conducted under the auspices of this university must uphold the "Three R" principles for humane animal research, namely:
 - 1.7.1 **Replacement** refers to methods that avoid using animals. The term includes absolute replacements (i.e., replacing animals with inanimate systems such as computer programs) as well as relative replacements (i.e., replacing animals such as vertebrates with animals that are lower on the phylogenetic scale).
 - 1.7.2 **Reduction** of the numbers of animals in experiments by design strategies that facilitate use of the smallest number that will allow valid information to be obtained from the study. The principle of reduction should not be implemented at the expense of the greater suffering of individual animals. Furthermore, the production of animals for scientific purposes should be rationalised to avoid the over production of animals and the consequent euthanasia of healthy animals.
 - 1.7.3 **Refinement** of animal sourcing, animal care practices and experimental procedures to eliminate physical and psychological distress within limitations imposed by the objectives of the research.
- 1.8 The REC: ACU has a mandate and responsibility to monitor, inspect and assess the acquisition, transportation, production, housing, care, use and disposal of animals used for teaching and research purposes at, or under the auspices of, Stellenbosch University.
- 1.9 The REC: ACU will monitor that all investigators involved with the use of animals in research and teaching are competent to do so and have received adequate training in the use of animals in this context (including ethics and practical techniques)
- 1.10 The REC: ACU, or chairperson on its behalf, can suspend or terminate any study where the **committee** considers that any relevant legislation is being breached. The Chairperson/ACUC shall investigate any suspected or alleged non-compliance with the SANS 10386:2008, relevant legislature, or protocol requirements and conditions and report it to the institutional Research Integrity Officer. (SANS p.16)
- 1.11 The REC: ACU will report its activities and decisions to the Senate Research Ethics REC: ACU SOP Oct 2011. Approved by SREC: 09 March 2012

Committee on a regular basis.

2. MEMBERSHIP AND APPOINTMENT

- 2.1 The REC: ACU is appointed biennially by the SREC for a two year term, to review all new and on-going research studies and all teaching programmes that involve the use of animals, and that occur under the auspices of Stellenbosch University.
- 2.2 Membership number will be a minimum of seven.
- 2.3 Members will be persons of good standing who have a working knowledge of the ethical codes and guidelines mentioned previously and must collectively have the ethical and scientific background and expertise to competently review, approve and monitor all protocols submitted to it, in order to ensure the on-going protection of animal subjects.
- 2.4 The membership shall include at least one member of each of the following categories as prescribed by the SANS guideline:
 - 2.4.1 Category A: A veterinarian who is familiar with the use of animals in research and teaching.
 - 2.4.2 Category B: An animal research scientist (minimum of 3 members).
 - 2.4.3 Category C: A person who has no affiliations to the university and represents an animal welfare society, e.g. NSPCA.
 - 2.4.4 Category D: An independent, non-affiliated person who is not (and never has been) involved in animal experimentation.
 - 2.4.5 Ex Officio: A person responsible for the daily care of research animals within the university.
- 2.5 In addition to this, the REC: ACU will also include representatives from CapeNature and the National Department of Agriculture.
- 2.6 Category C and D members should represent no less than one third of total members (SANS p.14)

- 2.7 Category B members will be nominated by the faculties of Science, Agrisciences and Health Sciences. Each faculty will nominate at least two members and these members cannot be from the same academic department.
- 2.8 The Chairperson of the REC: ACU will be a senior person staff member of the institution and be elected by the members after a formal nomination process which shall occur prior to the convened meeting where said election takes place.
- 2.9 The REC: ACU chairperson shall have the authority to immediately terminate or suspend any experiment on behalf of the committee if the chairperson considers that any relevant legislation is being breached.
- 2.10 New members will be orientated and receive on-the-job training in the review of ethics applications. All members will also be encouraged to attend workshops and other relevant training opportunities when available.
- 2.11 No member of the REC: ACU 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 or her REC duties.
- 2.12 The Chairperson may co-opt new members when necessary. The CV of the prospective new member will be forwarded to the SREC who will officially appoint the member.
- 2.13 The REC: ACU may consult external experts to assist them with the review of a particular protocol, when and if necessary.
- 2.14 Each member of the committee will sign a non-disclosure agreement on appointment to the committee.
- 2.15 External experts will also be required to sign a non-disclosure agreement when approached to assist in the review of protocols.

3. FUNCTIONING OF THE COMMITTEE FOR ANIMAL CARE AND USE

- 3.1 The REC: ACU will convene at least on a bi-monthly basis, and more frequently if necessary to review and consider:
 - 3.1.1 New proposals for the use of animals in both research and teaching.
 - 3.1.2 Amendments to approved projects or teaching programmes.
 - 3.1.3 Annual progress reports and applications for renewal.

- 3.1.4 Final reports and project closures.
- 3.1.5 Reports on discontinued trials.
- 3.1.6 Adverse event or incident reports
- 3.1.7 General administrative and policy matters.
- 3.2 In addition the REC: ACU will:
 - 3.2.1 Monitor, inspect and assess the acquisition, transport, housing, care, use and disposal of animals.
 - 3.2.2 Facilitate the training of technical staff and researchers involved in any aspect of animal research.
- 3.3 The presence of 50% plus one member will constitute a quorum. In addition at least one member from each of categories A-D must be present to constitute a quorum (SANS10386:2008 p. 18)

4. ADMINISTRATIVE SUPPORT STRUCTURE

- 4.1 The **REC: ACU** administrative office is situated within the Division for Research Development at Stellenbosch University main campus. The following staff members are appointed by the University to assist with the efficient running of this Committee:
 - 4.1.1 Manager: Research Support
 - 4.1.2 Administrative Officer: Animal Ethics, Environmental Ethics and Biorisks
- 4.2 Collective Responsibilities of the secretary to the REC: ACU is to ensure that all processes, documented hereunder, occur efficiently and timeously, in particular to:
 - 4.2.1 Ensure that the application process as described in Section 8, proceeds efficiently.
 - 4.2.2 Compile agenda for each meeting and distribute it timeously.
 - 4.2.3 Attend every meeting and record the minutes.
 - 4.2.4 Liaise with researchers in writing with respect to all decisions taken in the meeting.

- 4.2.5 Ensure that the post-meeting processing of new applications, as described in section 7, proceeds efficiently.
 - 4.2.6 Accept all interim correspondence for protocol amendments and liaise with Chairperson if appropriate.
 - 4.2.7 Receive and process all progress reports.
 - 4.2.8 Assist the Chairperson in addressing queries or complaints.
 - 4.2.9 Facilitate the REC: ACU monitoring role, as discussed in section 12.
 - 4.2.10 Forward queries or complaints to the Chair, when appropriate.
 - 4.2.11 Keep SOP's updated.
- 4.3 Responsibilities of the Manager: Research Support
- 4.3.1 Ensure that the REC: ACU processes comply with national and international guidelines and regulations and stay abreast of international practice including the SANS standard.
 - 4.3.2 Liaise on a regular basis with staff in the Animal Research Facility and address any queries, concerns or complaints.

5. APPLICATION PROCEDURE AND REVIEW PROCESS PRIOR TO MEETING

- 5.1 All animal research conducted under the auspices of Stellenbosch must be submitted to the REC: ACU for approval, *prior to commencement*. Research protocols are reviewed primarily from an ethical perspective although the scientific and methodological aspects are also taken into account.
- 5.2 The application forms and guidelines for submission of a research protocol or teaching programme to the REC: ACU can be downloaded from the Division of Research Development (DRD) website at www.sun.ac.za/research. Application procedures must be followed as outlined on the DRD website.
- 5.3 The following documents must be submitted:
 - 5.3.1 Application Form
 - 5.3.2 Research protocol
 - 5.3.3 Permits (where relevant)

- 5.4 Please note:
- 5.4.1 Applications must be submitted prior to the agenda closure date.
 - 5.4.2 These dates and dates of meetings are available from the secretary of the REC: ACU and is also available on the DRD website.
 - 5.4.3 The application and supporting documentation will be checked for completeness by secretary of the REC: ACU.
 - 5.4.4 The Chairperson or delegated member will allocate the application to a primary and a secondary reviewer. In order to facilitate the review process, the primary reviewer may contact the applicant prior to the SU-ACUC meeting to request additional information or clarification, if deemed necessary.
 - 5.4.5 The Chairperson may, at his/her discretion, consult an external reviewer for a particular protocol, 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.
- 5.5 For studies where lower order invertebrates or dead animals (that died naturally or were killed for another purpose) will be used, the committee must be notified, but a full application is not required. The necessary format for this notice is available on the DRD website. These notifications will be approved in an expedited process as described in section 8.

6. MEETING PROCEDURE AND APPLICATION OUTCOME

- 6.1 The REC: ACU will convene at least every two months to discuss and review the progress of ongoing animal research projects and teaching programmes from an ethical perspective and to consider new applications for research and teaching activities that involve animals.
- 6.2 **Please note:**
- 6.2.1 Members will be requested to sign an attendance register
 - 6.2.2 And make apologies at least two weeks in advance, if unable to attend.

- 6.2.3 The meeting will proceed according to a formal Agenda which will be distributed to all members, along with copies of all relevant material, prior to the meeting. The agenda may include any matters pertaining to the ethical oversight of research and teaching at Stellenbosch University including matters arising from the previous meeting, new applications, review of study amendments and progress reports, ratification of projects approved by an expedited review process, monitoring and evaluation reports etc.
- 6.2.4 Minutes documenting main decisional points, will be recorded.
- 6.2.5 An applicant who is member of the REC: ACU may answer any specific queries that other members wish to address, but should voluntarily recuse him/herself prior to discussion and decision-making.
- 6.2.6 Applicants will not attend the meeting routinely, unless requested to do so by the Chairperson or unless they request to appeal against a previous application refusal and this request is granted by the Chairperson.
- 6.2.7 Decision making will generally be by consensus. If consensus is not reached, then the REC: ACU will vote on a proposal, and this will be recorded in the minutes.
- 6.2.8 An application will be given one of the following statuses.
- 6.2.8.1 **Approved**- The researcher can start the project
 - 6.2.8.2 **Modifications required**- The researcher must make and resubmit certain changes to the protocol. These changes will be reviewed by the primary reviewer and Chairperson and if accepted, a letter of approval will be issued.
 - 6.2.8.3 **Deferred**- The project requires major changes or the committee has major concerns. Changes to the protocol must be reviewed at a convened meeting.
 - 6.2.8.4 **Rejected** The project cannot be resubmitted in its current form.
- 6.3 The committee, will as far as practically possible, hold physical meetings, but if necessary meetings can also be conducted electronically (e.g. via Skype).

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

- 7.1 Decisions taken at the REC: ACU meeting will be communicated in writing to the applicant. It is not unusual for the REC: ACU to request changes to a project, or clarification of certain issues. Only once these requirements are fulfilled can a formal letter of approval be issued. The applicant may not start the project until a final letter of approval has been issued.
- 7.2 It is the responsibility of the investigator to comply with all requests and return the requested documentation quoting the reference number to the REC: ACU.
- 7.3 One copy of the approved full application as well as a copy of the approval letter, filed at the front of the application, will be sent to the applicable animal research facility.
- 7.4 Record Keeping:
- 7.4.1 A REC: ACU reference number is allocated to all new applications. This number is recorded on all correspondence and additional attachments/amendments. Copies of all trial related documents and correspondence will be filed according to this reference number and retained for a minimum of 5 years after completion of the project.
- 7.4.2 An up-to-date list of REC: ACU members identified by name, earned degrees, representative capacity; indication of experience sufficient to describe each member's chief anticipated contributions to REC: ACU deliberations; and any employment or other relationship between each member and the institution, will be retained at the REC: ACU office and be publicly available. All REC: ACU members are requested to supply the REC: ACU office with a brief updated CV summary every two years.
- 7.4.3 Minutes. The secretary of the REC: ACU shall keep an accurate record meeting attendance, apologies, recusals and whether or not a quorum was maintained throughout each meeting; main discussion points and decisions taken.

8. GUIDELINES FOR EXPEDITED REVIEW

- 8.1 In order to expedite the ethical review process, and avoid unnecessary delays in certain instances, the REC: ACU can mandate a subcommittee comprising the

Chairperson and one external member from Category C or D and the animal facilities manager to approve certain study related documentation such as study amendments, progress reports, adverse event reports and emergencies.

- 8.2 All documentation pertaining to expedited review procedures will be submitted to the committee for consideration for ratification of approvals and other decisions, at the next meeting.
- 8.3 The committee has the right to suspend approval and request additional information or changes to the project. All research activities must be suspended until the committee is satisfied that the research can proceed. **NB: This subcommittee does not have the authority to approve new applications. (SANS 5.2.5.3 Pg 18)**

9. GUIDELINES FOR ROUTINE CONTINUING REVIEW

- 9.1 International and national guidelines and regulations require that ethics committees conduct continuing review of animal research studies, at least yearly and more frequently if the level of risk warrants this.
- 9.2 **All ethics approvals expire after one year unless renewed.**
- 9.3 An application for renewal of approval is made by submitting a progress report to the REC: ACU at least six weeks before the approval expires. It is the responsibility of the investigator to submit this report in good time to ensure that the approval of an active research project or teaching programme does not lapse.
- 9.4 Acceptance of a standard progress report by the REC: ACU will constitute re-approval for the study for a further year.
- 9.5 Renewals will be granted for a maximum of two times, after which a new application must be submitted.
- 9.6 Access to the Progress Report Template will be available through the DRD-website.
- 9.7 **The REC: ACU has the authority to place restrictions on, suspend, or terminate any study in which the investigator fails to comply with the review process OR where such actions are deemed appropriate and justified by a fully convened REC: ACU meeting.**

10. GUIDELINES FOR REPORTING SERIOUS ADVERSE EVENTS/INCIDENTS.

- 10.1 It is the responsibility of the researcher or lecturer to report any animal or person related adverse events or incidents that occur during the course of a research study or teaching activity (including unexpected deaths) to the SU-ACUC, and to the animal facilities manager.
- 10.2 An incident report form, available on the DRD website, must be completed and submitted within one week of the incident and will be tabled at the next meeting for discussion. The manager of the animal research facility must co-sign the incident report or submit an independent incident report to the REC: ACU.
- 10.3 The Chairperson has the authority to take immediate appropriate action e.g. to suspend all further study related activities, if circumstances indicate that such action is warranted.

11. PROCESS OF APPEAL

Researchers who have complaints or grievances regarding the decisions of the REC: ACU must follow the Generic Standard Operating Procedure for Appeals and Complaints of the SREC (see Addendum 1).

12. POST APPROVAL MONITORING

- 12.1 The REC: ACU has the authority and responsibility to initially approve and subsequently monitor animal activities to confirm on-going compliance with and adherence to the approved protocol in terms of section 5.2.7 of the SANS 10386:2008.
- 12.2 The goal of post-approval monitoring is to work with, and in support of, research staff members and to confirm accurate and consistent protocol adherence in a collegial and unobtrusive manner.

12.3 The REC: ACU reserves the right to visit sites where approved protocols will be conducted and any animal housing facility under the auspices of SU as often as it deem necessary either announced or unannounced.

12.3.1 Announced visits will be communicated to the PI in writing at least five days prior to the visit.

12.4 If noncompliance is suspected during a visit section 1.9 of this document may be imposed.

13. OVERSIGHT AND MONITORING OF ANIMAL RESEARCH FACILITIES BY THE REC: ACU

13.1 International and national practices and guidelines emphasise the active monitoring role the Animal REC must play in ensuring that all animal research and teaching activities that is conducted under its jurisdiction, does in fact comply with recognised guidelines for humane animal use. This monitoring role includes acting as overseer of the entire animal research and teaching programme at the University of Stellenbosch.

13.2 Animal Unit Inspections

13.2.1 Representatives of the REC: ACU will conduct regular inspections of the animal research facility and other sites, at least twice a year in order to monitor and inspect the acquisition, transport, production, housing, care, use and disposal of animals:

13.2.1.1 A minimum of 2, but preferably 3, members will inspect the unit at each visit

13.2.1.2 These visits will occur at unspecified times, usually at short notice

13.2.1.3 The manager of the animal facility will be requested to accompany the REC members and respond to questions.

13.2.1.4 A written report will be compiled and tabled at the next REC: ACU meeting.

14 RECORD KEEPING IN THE ANIMAL UNIT

14.1 A complete research protocol and approval letter will be sent to the animal unit as soon as a protocol is approved.

14.2 The following (minimum data set) information should also be entered into a database for each active research project or teaching programme:

14.2.1 Principal Investigator/Applicant

14.2.2 Supervisor

14.2.3 Sub investigators.

14.2.4 Other staff involved in study.

14.2.5 Ethics reference number.

14.2.6 Department.

14.2.7 Project title.

14.2.8 Date of approval.

14.2.9 Start date.

14.2.10 Predicted end date.

14.2.11 Animals approved:

14.2.12 Species.

14.2.13 Number of animals approved.

14.2.14 Number of animals issued.

14.2.15 Date of Issue.

14.2.16 Anticipated endpoint.

14.2.17 Actual end point.

14.2.18 Number alive.

14.2.19 Number dead.

14.2.20 Date of re-approval.

14.3 In addition records relating to the acquisition, breeding, health, care, housing, use and disposal of animals should also be kept by the manager of the research facility and be made available to the REC: ACU for monitoring purposes, as requested.

15 REFERENCES

1. South African National Standard. **SANS 10386:2008** Edition 1. *The Care and Use of Experimental Animals*. 2008
2. Guide for the Care and Use of Laboratory Animals. National Research Council. National Academy Press 2011.
3. Guidelines on Ethics for Medical Research. Book 3: Use of Animals in Research and Training. 2005.