RESEARCH ETHICS COMMITTEE: ANIMAL CARE AND USE (REC: ACU)

TERMS OF REFERENCE

and

STANDARD OPERATING PROCEDURES

*Version **3***

2024

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REC: ACU SOP Version History

The latest published version of Stellenbosch University REC: ACU SOPs are available at: http://www.sun.ac.za/english/research-innovation/Research-Development/integrity-ethics/animal-ethics

SOPs must be accessed only directly through the REC: ACU website to ensure the correct version is used. NOTE:Do not "Google Search" as older, incorrect versions of the SOP document may appear in search results;

The onus is on research applicants to ensure they are working to the correct version of the SOPs.

REC: ACU SOP Version Log

Version	Effective Date	Reason for change
3	Month 2022	Approved by the Senate Research Ethics Committee (SREC) on 07 March 2024 Revised following: 1) Internal *REC: ACU SOP Task Team* review to improve clarity and depth of guidelines for research applicants; 2) National Health Research Ethics Council (NHREC) Audit (June 2021); 3) Revised SANS guideline – SANS 10386:2021 Edition 2;
2	March 2012	Approved by the Senate Research Ethics Committee (SREC) on 9 March 2012
1	October 2011	Approved by the Senate Research Ethics Committee (SREC) in October 2011

1. TERMS OF REFERENCE

1.1 Research Ethics Committee: Animal Care and Use

1.1.1 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 requires the use of animals of a wide variety of species in research and teaching activities. These types of activities come 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: 2021) used in research and teaching are cared for and used in ways judged to be scientifically, technically, and humanely appropriate.

1.1.2 The **Research Ethics Committee: Animal Care and Use (REC: ACU)** is mandated by the National Health Research Ethics Council (NHREC), National Department of Health and 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 purposes 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.

1.1.3 The REC: ACU functions in compliance with, but not limited to, the following documents and guidelines:

1.1.3.1 South African National Standard for the Care and Use of Animals for Scientific Purposes – SANS 10386:2021 (SANS 10386: 2021);

1.1.3.2 The Medical Research Council Guidelines on Ethics for Medical Research; Book 3: Use of Animals in Research and Training (South African Medical Research Council, 2004);

1.1.3.3 The South African Department of Health guidelines for the use of animals for Scientific Purposes (Department of Health, 2015);

1.1.3.4 The Guide for the Care and Use of Laboratory Animals, 8th Edition; Office of Laboratory Animal Welfare, USA (Office of Laboratory Animal Welfare, 2011);

1.1.3.5 the Animals Protection Act, 1962 (Act No. 71 of 1962) (Animals Protection Act, 1962);

1.1.3.6 the Animal Diseases Act, 1984 (Act No. 35 of 1984) (Animal Diseases Act, 1984);

1.1.3.7 the Veterinary and Para-veterinary Professions Act, 1982 (Act No. 19 of 1982) (Veterinary and Para-veterinary Professions Act, 1982);

1.1.3.8 the Animal Health Act, 2002 (Act No. 7 of 2002) (Animal Health Act, 2002);

1.1.3.9 the Medicines and Related Substances Control Act, 1965 (Act No. 101 of 1965) (Medicines and Related Substances Control Act, 1965); and

1.1.3.10 the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947) (Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947);

1.1.3.11 Other Acts that may be relevant are: the Genetically Modified Act, 1997 (Act No. 15 of 1997) (Genetically Modified Act, 1997); the Animal Identification Act, 2002 (Act No. 6 of 2002) (Animal Identification Act, 2002); the National Environmental Management: Biodiversity Act, 2004 (Act No. 10 of 2004) on Threatened Or Protected Species Regulations (National Environmental Management: Biodiversity Act, 2004).

1.1.4 It is compulsory for all staff members and students to at least consult the documents mentioned in 1.3 before planning a research or teaching activity involving animals.

1.1.5 SAVC authorization includes inter alia:

1.1.5.1 The practising of a veterinary or para-veterinary profession means the rendering of any service deemed by the rules to relate specially to the veterinary or relevant para-veterinary profession or the prescribing and supplying of any veterinary medicine, as regulated by the Veterinary and Para-Veterinary Professions Act (Veterinary and Para-veterinary Professions Act, 1982), as well as the Medicines and Related Substances Control Act (Medicines and Related Substances Control Act, 1965). Specific attention is particularly given to the performing of any act aimed at the diagnosing, treating, or preventing of any pathological or physiological condition in any animal or which constitutes a surgical procedure on any animal. As outlined in the Act such professionals must be **registered** with the South African Veterinary Council based on prescribed qualifications, formal examination, or both.

1.1.5.2 Section 23 of the Act (Veterinary and Para-veterinary Professions Act, 1982) prohibits unregistered persons from practising any of the professions referred to in the Act or performing any of the procedures referred to in the Act. Section 23(1)(c) permits the Veterinary Council to **authorise** a non-registered person in writing to render FOR GAIN a service deemed to pertain specially to a veterinary or para-veterinary profession. Gain is indirect within the scope of employment with any employer, including the State, and includes professional experience gained as a result of such employment. The authority granted is subject to such conditions as the Council may determine. **Authorisation** in terms of Section 23(1)(c) of the Act will be considered for persons in temporary or full-time employment of academic institutions, research institutions, industrial institutions, service organisations, animal welfare organisations and/or private employers. In all instances, authorisation will only be considered if the applicant has a firm offer of employment from a specific institution/organisation or private employer or is placed in an accredited academic/training/research programme.

1.1.5.3 Authorisation may be sought based on the below outlined categories: A: CATEGORIES OF ACTIVITIES IN WHICH PERSONS WITH VETERINARY

QUALIFICATIONS NOT RECOGNISED BY COUNCIL WILL BE CONSIDERED FOR AUTHORISATION 1. Industry 2. Research 3. Service-rendering (animal welfare, embryo transfer, state veterinary service, etc.) 4. Training (Educational). B: CATEGORIES OF ACTIVITIES IN WHICH PERSONS WITHOUT VETERINARY AND/OR PARAVETERINARY QUALIFICATIONS WILL BE CONSIDERED BY COUNCIL FOR AUTHORISATION 1. Service rendering (animal welfare, embryo transfer) 2. Industry 3. Research 4. Training (Educational).

1.1.5.4 Authorisation in both categories A and B will be considered in relation/with specific reference to: 1. A specific employer or institution; 2. A specific duration; 3. The scope of procedures to be performed and the proven competency of the applicant; 4. Specific requirements/limitations which may be imposed on the applicant; and 5. A suitably registered supervising professional.

1.1.5.5 GUIDELINES FOR UNIVERSITIES IN RESPECT OF APPLICANTS IN CATEGORY B4 [TRAINING] 1. Authorisation will be restricted to those activities relating to teaching, research, service-rendering and/or professional development which would normally involve the practising of a veterinary or para-veterinary profession as defined in the Act and performed on behalf of and whilst in the employ of or placed in a specific academic/research programme of the academic institution; 2. Authorisation will be valid for a maximum period of 2 years. Renewal of authorisation may be considered at Council's discretion. The possibility of long-term authorisation as a result of fixed employment with the specific employer may be considered at Council's discretion; and 3. Renewal of authorisation will only be considered for individuals in fixed employment on receipt of a satisfactory status report submitted by the institution and person under whose supervision the candidate performs his or her duties.

1.1.6 The use of animals in scientific research, teaching, and testing 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. **For this reason, all research, teaching, and testing involving animals must be approved by the REC: ACU so that a formal evaluation of the potential harm/benefit equation can be undertaken before the activity commences.**

1.1.7 All research and teaching activities involving animals conducted under the auspices of this university must uphold the "Three R" principles for humane animal research (and modified in SANS 10386:2021 to include responsibility, i.e. Four Rs), as outlined in section 6.3 under Review Criteria.

1.1.8 SANS 10386:2021 recognises the importance of responsibility and has formally included this facet in the 'Four Rs'. SANS 10386:2021 specifies the responsibilities of all stakeholders and circumstances including but not limited to institutions, Animal Ethics Committees, investigators, animal caretakers, attending veterinarians, in the application of veterinary care, in the education, training, supervision and competence of personnel, lecturers and

teachers, and animal managers in situations of research, teaching, demonstration and training. The fourth R underpins all activities and the practice of the alternative principles (SANS 10386: 2021).

1.1.9 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.

1.1.10 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).

1.1.11 The REC: ACU can suspend or terminate any study where the **committee** considers that ethical benchmarks are not being met or that any relevant legislation is being breached. The REC: ACU or its appointed subcommittee shall investigate any suspected or alleged non-compliance with the SANS10386:2021, relevant legislature, or protocol requirements and conditions, and report it to the institutional Research Integrity Officer. (SANS 10386: 2021, p. 22).

1.1.12 The REC: ACU will report its activities and decisions to the Senate Research Ethics Committee on a regular basis.

1.1.13 The REC: ACU will report on an annual basis to the National Health Research Ethics Council (NHREC) and acknowledges that the NHREC has the right to audit this report and the running of the committee.

1.2 REC: ACU Executive Committee (REC: ACU EXCO)

1.2.1 Membership, Quorum and Officers

1.2.1.1 The REC: ACU EXCO consists of the REC: ACU Chairperson, REC: ACU Vice Chairperson, Manager: REC: ACU and the Director: Office for Research Integrity and Ethics;

1.2.1.2 The Secretariat is provided by the Office for Research Integrity and Ethics;

1.2.1.3 Meetings are held no less than three times per year;

1.2.1.4 A quorum constitutes the Chairperson, Vice-Chairperson, Manager: REC: ACU and the Director: Office for Research Integrity and Ethics or his/her officially delegated representative;

1.2.1.5 Formal agendas and minutes are maintained that are distributed according to sound office practices;

1.2.1.6 Decisions are made by seeking consensus;

1.2.1.7 The Committee may extend rights of audience and debate on an ad hoc basis.

1.2.2 Purpose and scope

1.2.2.1 REC: ACU EXCO reports on the work of the Committee over time, reflects on the synergistic functioning and the meaningfulness of processes and arrangements in place;

1.2.2.2 Considers overarching matters identified or referred to the REC: ACU EXCO;

1.2.2.3 Discusses and finds solutions to pressing conceptual interpretations and concerns, if any;

1.2.2.4 Investigate any suspected or alleged ethical violations or non-compliance with the SANS10386:2021, relevant legislature, or protocol requirements and conditions, and report it to the institutional Research Integrity Officer (SANS 10386: 2021);

1.2.2.5 Provides opportunities for networking and mentorship; and

1.2.2.6 Reviews and approves documents and processes pre submission to Stellenbosch University's Senate Research Ethics Committee (SREC).

2. WRITING, REVISING AND MANAGING STANDARD OPERATING PROCEDURES

2.1 Overview

REC: ACU Standard Operating Procedures are documents containing detailed written mandatory and/or advisory instructions and guidelines that relate to important tasks and practices associated with REC: ACU functioning, the review and approval of animal care and use for scientific purposes, and requirements for conducting and monitoring research, teaching, and testing activities involving animals.

2.2 Purpose

The purpose of this Overview is to describe the preferred method for preparing, writing, revising, updating, and approving all REC: ACU SOPs.

2.3 Scope and responsibilities

2.3.1 All SU researchers and their collaborators, SU REC: ACU members and staff are responsible for working in accordance with approved SOPs;

2.3.2 All SU staff and affiliates to whom the REC: ACU SOPs apply are responsible for identifying new SOPs that need to be written, or errors and omissions in current SOPs that need to be revised;

2.3.3 Requests to write or update REC: ACU SOPs must be emailed to the REC: ACU Manager via email to wabeukes@sun.ac.za or the email address of the employed REC:ACU Manager;

2.3.4 The Research Ethics Committee (REC) Manager: Animal Care and Use in the Office for Research Integrity and Ethics is responsible for the oversight of REC: ACU SOPs, as well as plans for writing, revising and implementation of REC: ACU SOPs;

2.3.5 The REC: ACU SOPs may be written by the REC Manager: Animal Care and Use, Director: Office for Research Integrity and Ethics, the REC: ACU Chairperson or Vice Chairpersons or persons delegated to write or revise SOPs by the REC Manager: Animal Care and Use, Director: Office for Research Integrity and Ethics, and/or the REC: ACU Chairperson;

2.3.6 The REC: ACU Manager: Animal Care and Use, the REC: ACU Chairperson and the REC: ACU Vice Chairperson, in collaboration with the Director: Office for Research Integrity and Ethics, are responsible for ensuring that the SOPs remain accurate, current, and compliant with any changes to national and international research ethics guidelines and/or regulatory requirements;

2.3.7 The REC: ACU SOPs may be circulated to REC: ACU EXCO and REC: ACU committee members and other designated animal ethics technical experts for expert advice and feedback.

2.4 The identification or need for a new or revised SOP

2.4.1 All REC: ACU SOPs must be current and fit for purpose and must therefore undergo regular review;

2.4.2 A review of each SOP must be carried out at least once every three years, or;

2.4.3 New or revised SOPs may be necessary earlier and should be generated when:

2.4.3.1 The need has been identified by consensus amongst REC: ACU EXCO or REC: ACU committee members;

2.4.3.2 New or revised national or international research regulations, ethics guidelines orprocedures are introduced;

2.4.3.3 Recommended by the National Health Research Ethics Council (NHREC);

2.4.3.4 Clarification or additions are required to accommodate situations not well defined by the SOPs;

2.4.3.5 Gaps in procedures become apparent.

2.5 Review and approval of new or revised SOPs

2.5.1 **Minor new or revised SOPs**

2.5.1.1 Minor new or revised SOPs have no potential impact on animal safety, rights or welfare, integrity of data or regulatory compliance;

2.5.1.2 Minor new or revised SOPs are reviewed by the REC Manager: Animal Care and Use, Director: Office for Research Integrity and Ethics, and the REC: ACU Chairperson;

2.5.1.3 The REC: ACU EXCO is responsible for final approval of minor new and revised SOPs.

2.5.2 **Major new or revised SOPs**

2.5.2.1 Major new or revised SOPs have a potential impact on animal safety, rights or welfare, integrity of data or regulatory compliance;

2.5.2.2 Major new or revised SOPs are reviewed by the full REC: ACU committee and REC: ACU EXCO;

2.5.2.3 Feedback from the full REC: ACU committee and REC: ACU EXCO is incorporated into the writing or revision of SOPs;

2.5.2.4 The full REC: ACU committee and REC: ACU EXCO are responsible for provisional approval of major new and revised SOPs;

2.5.2.5 The Senate Research Ethics Committee (SREC) is responsible for final approval of major new and revised SOPs.

2.6 SOP version control

2.6.1 **Modification history** must be detailed in an *SOP Version History Log* as a prefix to the REC: ACU SOP content;

2.6.2 **Version numbers** in the format *x.x* must be assigned to every new issue of a SOP;

2.6.2.1 Minor new or revised SOPs result in an increment after the decimal point (e.g., 2.0 to 2.1);

2.6.2.2 Major new or revised SOPs result in a change before the decimal point (e.g., 2.2 to 3.0);

2.7 SOP distribution and record keeping

2.7.1 The REC: ACU will make finalized versions of all SOPs available on the Office for Research Integrity and Ethics website: http://www.sun.ac.za/english/research-innovation/Research-Development/integrity-ethics/animal-ethics;

2.7.2 The REC: ACU Manager will **notify** SU researchers, REC: ACU members and staff when a new or updated version of a SOP is published;

2.7.3 A paper copy of each finalised SOP version is stored in the 'SOP master folder' in the Office for Research Integrity and Ethics, Division for Research Development (DRD).

3. APPOINTMENT AND MEMBERSHIP

3.1 Overview

The REC: Animal Care and Use (REC: ACU) has been established for the purpose of reviewing and approving all research, teaching and testing 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.

The composition and functions of the REC: ACU must meet the minimum standards and requirements, as set out in the South African National Standard for the care and use of animals for scientific purposes (SANS 10386: 2021) and the Department of Health (2015) *Ethics in health research: Principles, structures and processes.*

3.2 Purpose

The purpose of this Overview is to outline the procedure for appointing the REC: ACU Chairpersons and committee members and to describe their roles and responsibilities. The Overview further defines REC: ACU composition and describes the management of conflict of interest, confidentiality, and continuous professional development in animal research ethics.

3.3 Chairperson: Appointment and Responsibilities

3.3.1 The Chairperson is appointed by the Senate Research Ethics Committee (SREC) of Stellenbosch University for a three-year renewable term on the recommendation of the Director: Office for Research Integrity and Ethics and Manager: Research Ethics (Animal Use and Biosafety) in cooperation with the Research Ethics Office Senior Director: Research, Innovation and Post Graduate Studies;

3.3.2 The Chairperson may serve a maximum of three consecutive terms;

3.3.3 The Chairperson of the REC: ACU performs a leadership, oversight and advisory role in the conceptualization, management and conduct of animal research ethics initiatives at the institution. To be and to do such, the Chairperson needs to be a respected academic with significant experience in animal research, teaching, and testing activities.

3.3.4 The responsibilities of the Chairperson include but are not limited to:

3.3.4.1 Play an Animal Research Ethics leadership role in the institution;

3.3.4.2 Provide courageous and respected leadership in research ethics;

3.3.4.3 Be a champion for the importance of ethics-in-context;

3.3.4.4 Cooperate and liaise with research ethicists and committees across SU campuses, the wider Western Cape and nationally, towards developing and promoting best practices in research ethics oversight;

3.3.4.5 Advise and consult, as agreed, with researchers, REC: ACU members and members of the Office for Research Integrity and Ethics on research ethics issues;

3.3.4.6 Identify and support the enactment of research integrity cases where necessary and the right thing to do;

3.3.4.7 To ensure thorough scientific review of applications based on the expertise of committee members and the Chairperson and experience of the Chairperson in international peer-review, because animal ethics approval, can only be given for scientifically sound research;

3.3.4.8 Identify conflicts of interest between reviewers and applicants;

3.3.4.9 Participate in non-compliance investigations where applicable;

3.3.4.10 Play a leadership role in the development and implementation of REC: ACU policies and procedures;

3.3.4.11 Possess a comprehensive knowledge of national and international research ethics guidelines and regulations, institutional policies and relevant legislation;

3.3.4.12 Represent the REC: ACU in the REC: ACU Executive Committee (EXCO);

3.3.4.13 Represent the REC: ACU in the Senate Research Ethics Committee (SREC);

3.3.4.14 Represent the REC: ACU at the annual National Health Research Ethics Council (NHREC) REC: ACU meetings and other meetings at national level;

3.3.4.15 Promote a culture of respect within the research community for the REC: ACU process and for research ethics more broadly;

3.3.4.16 Have an in-depth understanding of the ethical issues, REC: ACU SOPs, SU research policies, the Department of Health (2015) guidelines and the SANS 10386: 2021 that are applicable to studies that are reviewed by the REC: ACU. The REC: ACU Chair is not expected to be the only, or ultimate authority on compliance issues – the Director: Office for Research Integrity and Ethics or other members of the REC: ACU or Secretariat also take responsibility for compliance verification, but the REC: ACU Chair is expected to be an active and knowledgeable partner in this aspect of the REC: ACU system;

3.3.4.17 Represent the REC: ACU in discussing REC: ACU decisions and requirements with researchers and other stakeholders, and have the courage and confidence to uphold decisions that may not be popular with investigators, the research community, University officials and/or external stakeholders;

3.3.4.18 Provide assistance to the Manager REC: ACU, to prepare an annual report for the National Health Research Ethics Council (NHREC) on the nature and volume of the REC: ACU's activities;

3.3.4.19 Make inputs to ensure or support adequate resources (financial, human, knowledge development) to conduct health research ethics duties in line with national and international benchmarks;

3.3.4.20 Contribute to the development, review, enactment and monitoring of REC: ACU policies, procedures, guidelines and SOPs;

3.3.4.21 Perform administrative duties such as the review of electronic communication, appointments, and the preparation of directive documents;

3.3.4.22 Delegate their duties to the REC: ACU Vice Chairperson on a case-by-case basis, where necessary;

3.3.4.23 Under exceptional circumstances, jointly with the Director: Office for Research Integrity and Ethics, conduct specific reviews and/or review and provide input to specific research ethics issues.

3.3.5 Conduct and direct the proceedings of monthly REC: ACU meetings;

3.3.5.1 Chairpersons are expected to attend a minimum of 70% of the REC: ACU meetings scheduled for the year. 100% attendance is, however, preferable;

3.3.5.2 With the assistance of the secretariat, decide on review categorization, for example expedited, meeting assigned or excluded from review;

3.3.5.3 With the assistance of the secretariat, select reviewers with necessary expertise to perform initial and ongoing reviews but without a conflict of interest;

3.3.5.4 With the assistance of the secretariat, prepare the agenda before meetings and review the minutes after meetings;

3.3.5.5 Have respect for committee members from diverse backgrounds, perspectives and sources of expertise;

3.3.5.6 Facilitate sound ethical discourse, teamwork-with-integrity and the reaching of consensus at meetings;

3.3.5.7 Be a gatekeeper for animal welfare and safety –and carefully managing risk and benefit;

3.3.5.8 Where necessary, enact review decisions in line with national guidelines and with careful consideration of animal(s), researcher(s) and important scientific endeavours;

3.3.5.9 Conduct selected expedited and full committee reviews, as agreed, or delegate this task to suitably qualified individuals;

3.3.5.10 Preview all protocols presented to the full-committee and when necessary, communicate with reviewers so that important REC: ACU issues are identified ahead of the full-committee sitting;

3.3.5.11 Vote (where consensus is not reached) on protocols at the full committee meeting together with other REC: ACU members;

3.3.5.12 With the assistance of the secretariat, review letters to researchers conveying REC: ACU decisions andrequirements relating to their protocols;

3.3.5.13 Manage complaints and concerns submitted to the Office of Research Integrity and Ethics and to recommend solutions;

3.3.5.14 Delegate their duties to REC: ACU Vice Chairpersons on a case-by-case basis, where necessary.

3.4 Vice-Chairpersons: Appointment and Responsibilities

3.4.1 A Vice-Chairperson is nominated and selected by members of the REC: ACU for a three-year renewable term;

3.4.2 The Vice-Chairperson may serve a maximum of three consecutive terms, preferably overlapping with the Chairperson for the purposes of continuity;

3.4.3 The Vice-Chairpersons' responsibilities are to:

3.4.3.1 Attend a minimum of 70% of the REC: ACU meetings scheduled for the year. 100% attendance is, however, preferable;

3.4.3.2 Perform duties delegated by the Chairperson;

3.4.3.3 Act as Chairperson in the absence of the Chairperson;

3.4.3.4 Provide active in-meeting support, for example meeting management, timekeeping, and conceptual and support to the Chairperson and members;

3.4.3.5 Vote on protocols at the full committee meetings together with other REC: ACU members, where consensus is not reached;

3.4.3.6 Act as a member of the REC: ACU EXCO;

3.4.3.7 Advise and consult, as agreed, with researchers, REC: ACU members and members of the Office for Research Integrity and Ethics on research ethics issues;

3.4.3.8 Participate in non-compliance investigations where applicable;

3.4.3.9 Represent the REC: ACU in the REC: ACU Executive Committee (EXCO);

3.4.3.10 General responsibilities which accompany committee membership.

3.5 Committee members: Appointment and Responsibilities

3.5.1 Appointment to REC: ACU will be by nomination and co-option;

3.5.2 All new members to REC: ACU will undergo a formalized set of induction requirements, of which a minimum would include:

3.5.2.1 Orientation session to REC: ACU SOPs, guidelines and processes as coordinated and offered by the Office for Research Integrity and Ethics;

3.5.2.2 Receive a full set of the REC: ACU Guidelines and SOPs as well as the relevant National Guidelines and core reading material;

3.5.2.3 Training in the use of the relevant software application used (*Infonetica*) as arranged by the Office for Research Integrity and Ethics;

3.5.2.4 Attendance of at least one full REC: ACU meeting as an observer.

3.5.3 REC: ACU members are appointed, with a letter of appointment, by the Senate Research Ethics Committee (SREC);

3.5.4 REC: ACU members may serve a maximum of three consecutive terms;

3.5.5 On appointment, REC: ACU members sign a confidentiality and non-disclosure agreement;

3.5.6 REC: ACU members will serve for a renewable term of three (3) years;

3.5.7 REC: ACU members are expected to attend a minimum of 70% of the REC: ACU meetings scheduled for the year. 100% attendance is, however, preferable;

3.5.8 Stellenbosch University obtains professional liability insurance to cover both affiliated and non-affiliated members when carrying out any professional duties under the auspices of REC: ACU;

3.5.9 Committee members' responsibilities are to:

3.5.9.1 Perform reviews in a timeous fashion and meet review deadlines communicated by the REC: ACU secretariat;

3.5.9.2 Provide timeous written notice if unable to take on a particular review (within 3 working days of receiving review allocations) to the REC: ACU Chairperson and secretariat;

3.5.9.3 Attend meetings on a regular basis and not leave until meetings are adjourned;

3.5.9.4 Should the primary reviewer not be present at the meeting to present their review to the committee the Chairperson or the second reviewer may take over these review duties in order not to delay the review process;

3.5.9.5 Maintain strict confidentiality regarding protocol information, reviews and decisions, and all other matters discussed at committee meetings (see *Section 3.9 Confidentiality* for more detail);

3.5.9.6 Disclose potential conflicts of interest to the Chairperson and committee coordinator, and where a conflict does exist, not review the protocol and recuse themselves during discussion of and voting on the protocol (see *Section 3.8 Conflict of Interest* for more detail);

3.5.9.7 Remain impartial and objective when reviewing protocols;

3.5.9.8 Respect each other's views and the deliberative process;

3.5.9.9 Serve as a primary reviewer for research in their area of expertise;

3.5.9.10 Serve as a general reviewer of all research discussed at full committee meetings;

3.5.9.11 Decide independently if the design of proposed studies is scientifically sound enough to justify animal use, will protect animal's safety, rights and welfare, and comply with relevant ethics guidance and regulations;

3.5.9.12 Recommend whether to approve, require revisions, defer or reject studies following deliberation at full committee meetings;

3.5.9.13 Perform expedited reviews;

3.5.9.14 Keep up to date with national and international research ethics guidelines and regulations.

3.6 REC: ACU Composition

3.6.1 The membership and composition of the REC: ACU is reflected on the committee roster;

3.6.2 Towards its primary mandate to protect the rights and welfare of animals in research, teaching and testing, REC: ACU requires diverse membership to provide expertise in and sensitivity to a broad range of scientific and ethical considerations;

3.6.3 REC: ACU members are appointed by the Senate Research Ethics Committee (SREC) on the recommendation of the Research Ethics Office for a renewable three-year term;

3.6.4 REC: ACU composition is reported to and monitored by the REC: ACU Executive Committee (EXCO), the Senate Research Ethics Committee (SREC) and the National Health Research Ethics Council (NHREC);

3.6.5 REC: ACU membership composition is continuously monitored to ensure appropriate representation:

3.6.5.1 The Chairperson and the relevant coordinator monitor the ability of the Committee to review the range and specificity of protocols submitted to the Committee – both in terms of scientific discipline/ subject field(s) and research methodology/ies;

3.6.5.2 The Chairperson and the relevant coordinator identify expert needs to enable the Committee to review protocols as submitted by and within relevant animal medicine and veterinary health disciplines;

3.6.5.3 When a member resigns from the REC: ACU, the choice of a replacement takes into account the overall balance of the committee and specific expertise that is required;

3.6.6 At least annually REC: ACU will submit documentation detailing current REC: ACU membership and vacant appointments in specific expertise areas to the Deans and Vice Deans, Faculties of Medicine and Health Sciences, Science and Agricultural Sciences;

3.6.7 REC: ACU may accompany this documentation with suggestions for specific nominees to fill vacant appointments, if these persons have already been identified;

3.6.8 Potential experts will be nominated by the Deans through a consultative process with relevant departmental heads in the Faculties and/or other relevant stakeholders;

3.6.9 Such nominated experts will undergo relevant induction training and preparation as outlined in *Section 3.10*.

3.6.10 In line with the Department of Health (2015) Ethics in Health Research: Principles, Processes and Structures (2nd ed) and SANS 10386:2021 the REC: ACU membership composition must satisfy the following requirements:

3.6.10.1 Consist of members that collectively allow the committee to meet its responsibilities;

3.6.10.2 Consist of members who are persons of good standing and who have a working knowledge of research ethics codes and guidelines;

3.6.10.3 Be representative of South Africa's demographic profile;

3.6.10.4 Have a Chairperson and one Vice-Chairperson;

3.6.10.5 Have at least four (4) members serving on the committee, one from each of the following categories of membership:

3.6.10.6.1 **Category A** – A person with qualifications in veterinary science, who is registered or authorized as a veterinarian in terms of the relevant national council, and with experience relevant to the institution's activities or the ability to acquire relevant knowledge;

3.6.10.6.2 **Category B** – A suitably qualified person with substantial and recent experience in the use of animals for scientific purposes relevant to the institution and the business of the REC: ACU. This shall include possession of a higher degree in research or equivalent experience;

3.6.10.6.3 **Category C** – A person who demonstrates commitment to, and established experience in, furthering the welfare of animals, not employed by, or otherwise associated with the institution, and not currently involved in the care and use of animals for scientific purposes. Veterinarians with specific animal welfare interest and experience may meet the requirements of this category. In the cases where a veterinarian acts as category C member, there shall be an additional category A veterinarian (i.e., one veterinarian cannot act as both categories A and C members). The person should be selected on the basis of active membership of, and endorsement by an animal welfare organization. This member should bring an animal welfare perspective to the REC: ACU deliberations. While all members of the REC: ACU shall consider the welfare of the animals, the category C member brings to the committee a special awareness of current community and broader animal welfare concerns;

3.6.10.6.4 **Category D** – An independent person(s) who does not currently and has not previously conducted scientific studies or teaching activities using animals, either in their employment or beyond their undergraduate education, and who is not an employee of the institution, except under defined circumstances (for example, tenured academic staff from non-animal scientific departments). If such an employee is appointed, the individual shall be in a senior position, and shall not be supervised by other committee members or by anyone involved in the animal research at the institution. The institution shall provide clear reasons for the necessity to appoint an employee in this category.[1]

3.6.10.7 Have additional members to assist the REC: ACU to function effectively:

3.6.10.7.1 The institution should appoint to the REC: ACU person(s) responsible for the routine care of animals within the institution, ensuring that committee members have up-to-date information of all of the various facilities;

3.6.10.7.2 The institution may appoint additional members with necessary skills and background of value to the REC: ACU;

[1] The category D member should not fit any of the other categories (i.e., they should not be a veterinarian, should not have present or past research or teaching experience using animals, and should not qualify as an animal welfare member). They should be members of the wider community who can contribute different and independent perspectives to the AEC deliberations. It is envisaged that the category D member will have no other association with the institution apart from his or her membership of the AEC. The wording says "except under defined circumstances" to cater for the special situation that exists at universities where tenured academic staff from departments not including life sciences, biological sciences and health sciences can be seen as being truly independent of the departments where medical or scientific research is undertaken. Other than this given specific situation, appointments to category D member should not be made internally, therefore, secretaries or administrative staff is deemed not suitable. Persons closely associated professionally with the institutions are also deemed not suitable. The category D member should be viewed by the wider national community as bringing a completely independent view to the committee and might include people such as distinguished public figures, business people, teachers, retirees, accountants, and lawyers.

3.6.10.8 Have access to expertise in that the REC: ACU may invite people with specific expertise to provide advice, as required;

3.6.10.9 Strive to a balance of membership in that Categories C and D members shall, together, represent at least one-third of the REC: ACU membership. In the cases where category D members are associated with the institution, there shall be at least one category D member who is not associated with the institution;

3.6.10.10 Include by invite or request, where applicable, *bona fide* students, researchers and other interested parties to attend meetings as non-voting observers, subject to the signing of confidentiality undertaking and subject also to being excluded from certain agenda items as determined by the Chair;

3.6.10.11 Ensure that individuals who are responsible for business development in the REC: ACU's institution (University of Stellenbosch) are prohibited from serving as members or ex- officio members on the REC: ACU or carrying out day-to-day operations of the review process;

3.6.10.12 In special circumstances, at the discretion of the Chairperson, multiple members may be assigned to specific fields and put forward as alternative members when representing on the REC: ACU roster. Alternate members only count towards a quorum if they are present as a replacement to the main member, not in addition to the main member.

3.7 Quorum and voting requirements

3.7.1 The REC: ACU must review relevant new and continuing studies at a full committee meeting only when a quorum is present;

3.7.2 In accordance with the Department of Health (2015) Ethics in Health Research: Principles, Processes and Structures (2nd ed) and SANS 10386:2021:

3.7.2.1 at least one member from each of the membership categories A, B, C and D shall be present throughout the meeting to establish a quorum for the conduct of a meeting; and

3.7.2.2 Categories C and D members, together, shall represent at least one-third of those members present.

3.7.3 Alternate members only count towards a quorum if they are present as a replacement to the main member, not in addition to the main member;

3.7.4 The Chair and Vice-Chair count towards the quorum;

3.7.5 Observers, guests and ex-officio members do not count as part of the quorum;

3.7.6 A quorum must be maintained. If the quorum fails, further studies cannot be reviewed and must be held over until the next convened meeting;

3.7.7 In the event that a consensus decision on an application cannot be reached, members will vote in accordance with the SANS 10386:2021 guidelines.

3.7.8 The Chair may not vote, but in the cases of a tie across categories, the Chair has the deciding vote in accordance the SANS 10386:2021 guidelines.

3.7.9 Any member with a conflict of interest on an application may not vote.

3.8 Conflict of interest

3.8.1 REC: ACU members are expected to make decisions and conduct their oversight responsibilities in an independent manner, free from bias and undue influence. REC: ACU members and immediate family, i.e., spouse or dependents may not be involved in activities that could be perceived as conflicting with their REC: ACU responsibility. The integrity of the REC: ACU review process can be compromised if such conflicts of interests are not disclosed and where necessary, avoided. No REC may have a member participate in the REC's initial and continuing review of any project in which the member has a conflicting interest except to provide information requested by the REC. These policies cover each type of review conducted by the REC: ACU;

3.8.2 REC: ACU members must disclose any relationship, interest or other circumstances, which could reasonably be perceived as creating a conflict of interest –including the following:

3.8.2.1 **Personal relationship:** The REC: ACU member has a personal relationship with the principal investigator or key personnel of a research protocol under review by the REC: ACU;

3.8.2.2 **Relationship to the research study:** The REC: ACU member (his/her spouse or immediate family member) is the principal investigator or co-investigator of the research protocol under review by the REC: ACU;

3.8.2.3 **Business relationship or affiliation:** The REC: ACU member serves as a trustee, director, officer, owner or partner of a for-profit entity that could be affected by the outcome of the research protocol under review by the REC: ACU;

3.8.2.4 **Financial interest:** The REC: ACU member has a financial interest related to the research (financial interest in the sponsor, product, or service being tested) that could be affected by the outcome of the research protocol under review by the REC: ACU. Included in the definition of financial interest are equity interests e.g., stock, stock options or other ownership interests, payment or expectation of payment derived from intellectual property rights (e.g., patent royalties); and payments received from a for-profit entity forconsulting or other services;

3.8.2.5 Involvement of the REC: ACU member, consultant, or their immediate family in the design, conduct, or reporting of research.

3.8.3 REC: ACU members are required to disclose those interests that may be affected by the research,which is the subject of the research proposal and that might otherwise reasonably be perceived to affect their independent unbiased judgment with respect to the REC: ACU's review of the protocol or related matters;

3.8.4 All REC: ACU members who identify a potential conflict of interest are required to sign the conflict-of-interest declaration form (Appendix II: REC: ACU Conflict of interest declaration form) and submit to the REC: ACU coordinator prior to, or during the meeting. The Chairperson and committee shall determine whether a conflict exists, and these members recuse themselves from the discussions of, and voting on, these protocols. The determination of whether or not a conflict exists shall be reflected in the minutes;

3.8.5 The Chairperson may similarly become involved in a situation of potential conflict of interest. In this case he/she should discuss the matter with the Committee, or the Chairperson of the Senate Research Ethics Committee, whichever is seen to be most appropriate;

3.8.6 **Recusal:** REC: ACU members who have a conflict of interest related to any research protocols that the REC: ACU is about to consider will refrain from participating in any discussion of the protocol or related matters, except to the extent necessary to provide relevant factual information requested by the chair. Unless requested by the chair to provide such information to the REC: ACU, the REC: ACU member with a conflict of interest will recuse themselves from the meeting during the discussion and voting process i.e., will not be counted toward the quorum. The REC: ACU member's absence will be documented in the minutes with the indication that a conflict of interest was the reason for the absence. The outcome of the committee decision in the absence of the recused member will not be discussed upon return of the member concerned but may be conveyed after closure of the meeting;

3.8.7 All reviewers will sign a COI declaration which is part of the protocol review form. REC: ACU members assigned as a primary or secondary reviewer for a protocol or related matters, with respect to which a conflict of interest has been identified, will notify the chair so that the protocol can be reassigned;

3.8.8 In the event that the conflict of interest involves the Chairperson, he or she will appoint the Vice- Chairperson, or another member as acting Chairperson (with approval of the committee). The acting Chairperson will conduct the meeting, for the remainder of the discussion, of the item in question.

3.9 Confidentiality

3.9.1 **Confidential Information** shall mean certain proprietary, personal, veterinary or protocol-specific information, which the REC: ACU member acknowledges to be confidential. Such information includes all protocols relating to research with animal subjects and associated documentation. The Confidential Information may be conveyed in written, graphic, oral, or physical form including (but not limited to) scientific knowledge, skills, processes, inventions, techniques, formulae, products, business operations, patient requirements, biological materials, designs, sketches, photographs, drawings, specifications, reports, studies, findings, data, plans or other records, and/or software;

3.9.2 All REC: ACU members and support staff shall sign a standard confidentiality and non-disclosure agreement on appointment to REC: ACU.

3.10 Continuous professional development in research ethics

3.10.1 All members undergo an REC: ACU orientation and ongoing research ethics training;

3.10.2 To stay abreast with recent development in the broad area of research ethics and science, REC: ACU members are supported through the Office for Research Integrity and Ethics for;

3.10.2.1 Research ethics training: REC: ACU members are encouraged to attend research ethics training workshops and seminars offered at Stellenbosch University and/or by other agencies. Our REC: ACU office regularly updates members on course offerings and covers the cost of this training for interested members;

3.10.2.2 In-meeting training: REC: ACU meetings are also used as a training platform for members since discussions and debates on relevant research ethics issues are encouraged. The chairperson will in addition offer targeted discussions on pertinent ethics topics at REC: ACU meetings;

3.10.2.3 In-house research ethics training: The Office for Research Integrity and Ethics will arrange for at least one in-house research ethics training workshop by an ethics expert for committee members.

3.11 Consultants and ad hoc reviewers

3.11.1 The REC: ACU Chairperson may seek expert opinion in the interests of time or in the interests of ethical animal care and use;

3.11.2 The REC: ACU full committee may defer to another meeting or obtain consultation if there is not at least one person on the REC: ACU with appropriate scientific or scholarly expertise or other expertise or knowledge to conduct an in-depth review of the protocol. Reasons for seeking additional or special competence may include but are not limited to the need for:

3.11.2.1 Additional ethical, scientific, veterinary, statistical or scholarly expertise;

3.11.2.2 Particular knowledge about specific animal populations or specific procedures related to the care and use of animals for scientific purposes.

3.11.3 Consultants and ad hoc reviewers:

3.11.3.1 Must have access to all documents submitted to the REC: ACU relevant to the specific study under review;

3.11.3.2 May take part in deliberations and may make recommendations concerning the study;

3.11.3.3 May not vote unless required by a particular protocol and such voting status is confirmed by the REC: ACU in advance on a case-by-case basis;

3.11.3.4 Must affirm that they have no conflict of interest with respect to the specific studies that they are invited to review;

3.11.3.5 Must maintain strict confidentiality with respect to the specific protocol and the meeting's proceedings;

3.11.3.6 May provide information about a specific study by written reports and/or by attending the meeting.

3.12 Evaluation of REC: ACU Members and Chairpersons

3.12.1 The REC: ACU Chairperson, Vice-Chairpersons and members will be evaluated annually. This will be done by means of both an objective and subjective assessment;

3.12.2 **Objective assessment:** At the end of each academic year, the REC: ACU secretariat will provide the following metrics for each REC: ACU member:

3.12.2.1 Number of meetings attended and chaired out of the total number of meetings;

3.12.2.2 Number of exempt determinations made;

3.12.2.3 Number of minimal risk protocols reviewed;

3.12.2.4 Number of protocols reviewed that went to the convened REC: ACU meeting;

3.12.2.5 Number of reviews completed as the primary reviewer;

3.12.2.6 Number of reviews completed as the secondary reviewer.

3.12.3 **Subjective assessment:** At the end of each academic year, each REC: ACU member will complete a self-evaluation form;

3.12.4 The results of the REC: ACU member assessments are shared with REC: ACU Chairpersons and are used to make determinations regarding training, development and the composition of the REC: ACU itself;

3.12.5 The results of the REC: ACU member assessments and REC: ACU Chairperson and Vice-Chairperson assessments are presented at the REC: ACU Executive Committee (EXCO) meeting and are used to make determinations regarding training development, the composition of the REC: ACU itself, and overall improvement of the Office for Research Integrity and Ethics.

3.13 Institutional recognition of REC: ACU membership

3.13.1 The Office for Research Integrity and Ethics will inform the Senate Research Ethics Committee (SREC) and the Director: Office for Research Integrity and Ethics, SU, of the titles, names and affiliation of all REC: ACU members on an annual basis or earlier as necessary. This information will also be available on the relevant SU website;

3.13.2 REC: ACU members may indicate such committee membership (and portfolio if any, within the Committee) in their Curriculum Vitae and profile such membership when applying for, for example, promotion or a new position;

3.13.3 Heads of Departments and affiliated units will consider the workload of REC: ACU members in the organisation and work distribution of departmental members where possible;

3.13.4 SU will recognize the membership and work of an REC: ACU member in the institutional annual performance review as a positive and worthy endeavour;

3.13.5 SU will strive to put mechanisms in place to recognize and support REC: ACU members for the work they do. Such could include funding research ethics networking and training opportunities and appreciative events;

3.13.6 The workload and responsibilities of REC: ACU Chairpersons will be specifically considered – equitable financial and other resources as agreed to be put in place by the institution to support the needs, time, and effort of Chairpersons.

5. REC: ACU APPLICATION REQUIREMENTS AND REVIEW PROCESS: NEW RESEARCH

5.1 Overview

All animal care and use for scientific purposes, including research conducted under the auspices of Stellenbosch must be submitted to the REC: ACU for approval, *prior to the commencement of any project related activities*. Research protocols are reviewed both from an ethics perspective and from the scientific and methodological perspective to ensure that animal research is justified. This Overview covers all new applications and prescribes investigator responsibilities for submittingdocuments to the REC: ACU.

5.2 Purpose

The purpose of this Overview is to define and describe the application requirements and review process for new research reviewed by the REC: ACU.

5.3 REC: ACU application and review process: New research

5.3.1 **To submit a REC: ACU application for new research:**

5.3.1.1 As far as possible before a submission deadline, submit an electronic copy of the REC: ACU application package via the REC: ACU online application portal, *Infonetica©* at: https://applyethics.sun.ac.za.

5.3.2 Guidelines for submissions are available from the Office for Research Integrity and Ethics website at http://www.sun.ac.za/english/research-innovation/Research-Development/integrity-ethics/animal-ethics;

5.3.3 REC: ACU applications can be submitted on a rolling basis, but must be received by the published REC: ACU submission deadline in order to be considered for the agenda of that meeting;

5.3.4 The dates for REC: ACU meetings and submission deadlines are available from the Office for Research Integrity and Ethics website at http://www.sun.ac.za/english/research-innovation/Research-Development/integrity-ethics/animal-ethics;

5.3.5 **Submission of a research application by the REC: ACU submission deadline does not guarantee that application will be incorporated into a specific meeting agenda and/or review cycle.** If the number of research applications submitted by a particular submission deadline is too large for one committee meeting to accommodate, the research application will appear at the next available meeting.

5.4 Expedited review

5.4.1 In order to expedite the ethical review process, and avoid unnecessary delays in certain instances, the REC: ACU can, with good reason and at the discretion of the Chairperson and the Manager: Research Ethics (Animal Care and Use), mandate a subcommittee

comprising the Chairperson and one external member from Category C or D to review certain study related documentation such as study amendments, progress reports, adverse event reports and emergencies;

5.4.2 Once a decision is made, an REC official notification will be sent to the investigator;

5.4.3 **This subcommittee does not have the authority to approve new applications** (SANS 10386: 2021, p. 18);

5.4.4 All documentation pertaining to expedited review procedures will be submitted to the next convened REC: ACU meeting for consideration for ratification of approvals and other decisions;

5.4.5 The convened REC: ACU 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.

5.5 Full committee review (convened REC: ACU meeting)

5.5.1 A new application for the care and use of animals for scientific purposes requires review at a convened (full) REC:ACU meeting[2];

5.5.2 For studies where lower order invertebrates or dead animals (that died naturally or were killed for another purpose) or their tissues 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 Office for Research Integrity and Ethics website at http://www.sun.ac.za/english/research-innovation/Research-Development/integrity-ethics/animal-ethics. These notifications will be approved in an expedited process as described in Section 5.4;

5.5.3 The application forms and guidelines for submission of a new research protocol or teaching programme to the REC: ACU can be downloaded from the Office for Research Integrity and Ethics (ORIE) website at http://www.sun.ac.za/english/research-innovation/Research-Development/integrity-ethics/animal-ethics. Application procedures must be followed as outlined on the ORIE website;

5.5.4 The REC: ACU convenes at least every two months to review and consider:

5.5.4.1 Continuing Review Reports: *Progress Reports* for active projects and *Final Reports* for closing/finalised research;

5.5.4.2 New applications for the care and use of animals for scientific purposes;

5.5.4.3 Major protocol amendments;

5.5.4.4 Adverse events reported in previously approved studies;

5.5.4.5 General and Overview matters; and/or

5.5.4.6 Allegations of misconduct in research or other complaints.

[2] SANS10386: 2021 does not allow expedited or subcommittee review of new applications for the care and use of animals for scientific purposes (SANS 10386: 2021, p. 18)

5.5.5 **Pre-meeting process**

5.5.5.1 New research applications must be received by the REC office by the published agenda due dates (usually 2 weeks prior to the upcoming REC meeting) in order to be considered for the agenda of that meeting;

5.5.5.2 Agenda closure dates are published in conjunction with meeting dates but do not guarantee that applications will be incorporated into a specific agenda. If the number of research applications submitted by the agenda due date is too large for one committee meeting to accommodate, the research application will appear at the next meeting;

5.5.5.3 The applicant submits the application via https://applyethics.sun.ac.za;

5.5.5.4 The REC Secretariat allocates each research application to two members of the committee, at least two weeks prior to the meeting for evaluation and review;

5.5.5.5 The Chairperson reviews all review assignments prior to review allocations to committee members and may, at her/his discretion, co-opt an expert for a particular review, if s/he feels the committee does not have the necessary expertise to adequately evaluate all aspects of a particular research application;

5.5.5.6 In order to facilitate the review process, the primary reviewer may contact the applicant prior to the REC: ACU meeting to request additional information or clarification, if deemed necessary;

5.5.5.7 Subject to signing a non-disclosure agreement, the external reviewer may be requested to make a written report available to the Chairperson prior to the meeting;

5.5.5.8 Committee members submit their completed reviews prior to the meeting;

5.5.5.9 Reviewers make written comments available to the Chairperson, prior to each meeting.

5.5.5.10 Apologies for non-attendance need to be made to the secretary by email.

5.5.6 **Convened REC: ACU meeting:**

5.5.6.1 Each member of the committee receives an electronic copy of the agenda outlining any announcements and all reviews to be discussion;

5.5.6.2 The agenda is displayed electronically on the MS Teams channel or projected onto a screen, if the meeting is held in person;

5.5.6.3 The Chairperson opens the meeting;

5.5.6.4 A quorum must be present for all decision making (see detailed quorum requirements in Section 3.7);

5.5.6.5 The secretary records those present and also notes apologies. Attendance of members is verified through online verification;

5.5.6.6 The minutes of the previous REC: ACU meeting are corrected and accepted;

5.5.6.7 New agenda items are generally discussed in the following order, but this may be subject to change depending on volume and type of items received at each meeting:

- 5.5.6.7.1 Matters arising from the previous meeting;
- 5.5.6.7.2 General items;
- 5.5.6.7.3 New Applications, amendments, deviations, adverse events, progress reports/final reports and animal notifications;
- 5.5.6.7.4 Ratification of applications provisionally approved via expedited subcommittee review;
- 5.5.6.7.5 Other documents/submissions for noting/approval.

5.5.6.8 New applications are introduced by the Chairperson. The primary reviewer presents a summary and review of the study to the committee. The second reviewer adds additional comments. The NSPCA member then comments on the application from that body's perspective. Discussion is then opened to the full committee. Throughout the discussion the application documents pertaining to the study are projected by the secretary onto a screen for review by the convened committee;

5.5.6.9 If the applicant is a member of the committee s/he may answer any specific queries that members wish to address and will be recuse her/himself prior to discussion and decision-making. This recusal is recorded in the minutes;

5.5.6.10 Applicants will not attend the meeting routinely, unless requested to do so by the Chairperson. Applicants may request to present information to the committee that will assist with decision making and attendance at the meeting is at the discretion of the Chairperson;

5.5.6.11 The Chairperson facilitates discussion and summarises the perceived viewpoint(s) of the committee;

5.5.6.12 Decision making will generally be by consensus. If consensus is not reached, the REC: ACU will note the non-consensus, and this will be recorded in the minutes;

5.5.6.13 In the event that a clear decision cannot be established by the committee, the Chairperson will have the final deciding vote, or decision on an alternate way forward.

5.5.6.14 One of the following decisions must be made:

5.5.6.14.1 **Approved**: The proposed project is approved in its current form, with no changes required. The date of approval is considered the date that all conditions were determined to be met and the date on which the applicant can start the project;

5.5.6.14.2 **Approved with stipulations**: The proposed project is approved with minor administrative alterations required and/or specific conditions that must be met. The onus is on the applicant to meet these stipulations prior to the start of any project related activities;

5.5.6.14.3 **Modifications required**: The proposed application has no major ethical concerns, but a number of clarifications or methodological changes are required. The applicant must resubmit the revised application. The review can be finalised by an expedited review process i.e. without having to serve before the full committee again. Revisions will be reviewed by the primary reviewer and Chairperson and if accepted, a letter of approval will be issued;

5.5.6.14.4 **Deferred**: The application has major methodological and/or ethical concerns and requires considerable revision. The applicant must resubmit the revised application. The revised application will be reconsidered at a convened (full) committee meeting; or

5.5.6.14.5 **Rejected:** The proposed project may not be resubmitted.

5.5.6.15 Once a decision is made, a REC official notification will be sent to the applicant;

5.5.6.16 The REC will defer the proposed research to another meeting, or obtain consultation if there is not at least one person on the REC with appropriate scientific or scholarly expertise or other expertise or knowledge to conduct an in-depth review of the protocol;

5.5.6.17 The secretariat records all decisions, and the method by which they were made, in the minutes. All discussion points, issues of controversy and reasons for decisions are documented in the minutes. The secretariat also documents any member leaving or entering the room during the meeting, in order to record recusals and ensure that a quorum is always present;

5.5.6.18 The committee will hold meetings electronically (e.g., via MS Teams), but will aim to hold an annual physical meeting at which members can also meet informally after the meeting. As committee members are, however, spread over two campuses which are 30 km apart, electronic meetings will be preferred in light of global sustainability considerations;

5.5.6.19 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 will a formal letter of approval be issued;

5.5.6.20 It is the responsibility of the applicant to comply with all requests and return the requested documentation quoting the reference number to the REC: ACU;

5.5.6.21 The applicant may not start the project until a final REC approval letter has been issued;

5.5.6.22 One copy of the approved full application as well as a copy of the REC: ACU approval letter, filed at the front of the application, will be sent to the applicable animal research facility.

5.6 Documents required for REC: ACU application: New research

5.6.1 **Completed electronic REC: ACU Application Form** submitted via the REC: ACU online application portal, *Infonetica©* at: https://applyethics.sun.ac.za;

5.6.2 **PI-generated protocol synopsis (as requested and submitted on the electronic application form).** The synopsis must:

5.6.2.1 Be less than 250 words per section;

5.6.2.2 State the goals of the study;

5.6.2.3 Describe and justify why and how animals are used, preferably with reference to *Section 6.3: Review Criteria*;

5.6.2.4 Provide a summary of the research protocol and experimental design;

5.6.2.5 Be readily understood by committee members who include non-scientists and community members. Write in simple, non-technical language and spell out acronyms on first use;

5.6.2.6 Contain sufficient information for committee members to evaluate the proposal independently of any other protocol documentation. Aside from the primary reviewers, all other committee members rely heavily on only the synopsis and supporting documentation to review, discuss and vote on a proposal in the meeting.

5.6.3 **Full Project Proposal and/or research protocol (as requested and submitted on the electronic application form)**

The full proposal should at a minimum:

5.6.3.1 Specify a project title;

5.6.3.2 State whether if the researcher is applying in the capacity of the Project Investigator / Project Leader, as well as co-applicants and students and whether the study is for post graduate degree purposes, the duration of the

study (expected start and end dates), and if sufficient funding is available to complete the study;

5.6.3.3 Provide a Scientific Introductory Statement, no more than 500 words which should describe the rationale of the experiment and the potential significance. In particular, this section should clarify how this work builds on previously published studies. Key references should be cited and then listed;

5.6.3.4 Provide a detailed description of the experimental design, including:

5.6.3.4.1 Research Question and or Hypothesis;

5.6.3.4.2 Research Aims;

5.6.3.4.3 Research Objectives;

5.6.3.4.4 Experimental Design: Study type;

5.6.3.4.5 Justify the use of animals: Indicate why this research is being conducted on animals and, if appropriate, why it cannot be conducted on humans, cell cultures or other in vitro systems, or using computer or other physical models. State also which non-animal model(s) were considered and what grounds they were rejected (include at the end of this page the recent references to support your statement);

5.6.3.4.6 Describe how the animals will be allocated to experimental and control groups, the number of animals in each group, how this group size was determined to give statistical validity to the trial, and how the experimental treatments will be assigned to each group. A flow diagram may be attached but should be easily understood;

5.6.3.4.7 Number of animals to be used. Justify of the number of animals to be used, citing the relevant literature and which method was used to determine numbers e.g. power analysis or consultation with X statistician.;

5.6.3.4.8 Describe the measures that will be used to ensure that the animal's welfare needs are met or enhanced, i.e. The specific steps that have been taken to refine the protocol procedures to make them as humane as possible, such as reducing the severity of the experimental treatments on the animals, the precise housing and care, reducing stress, providing enrichment for caged animals.

5.6.3.5 Indicate the relevant pain and distress category;

5.6.3.6 Indicate if animals will be infected with a controlled veterinary pathogen or human pathogen and if organisms are genetically modified;

5.6.3.7 Indicate the type of animals (Laboratory, Farm or Wild);

5.6.3.8 Indicate the Type of Project (New or Pilot study or Teaching);

5.6.3.9 Applicant and Co-Investigators Information;

5.6.3.10 Details of the Primary Investigator / Co-Investigators;

5.6.3.11 Specific animal duties;

5.6.3.12 Animal detail: Species, Strain / Breed, sex, quantity, body mass, age and source;

5.6.3.13 Housing and care, including housing details and who the responsible person is for daily care of the animals;

5.6.3.14 Maximum length of time animals will be held;

5.6.3.15 List all procedures over and above the routine care with specific attention to procedures that may cause deprivation, fear, distress and pain;

5.6.3.16 List all drugs to be used including anaesthesia and where and how these drugs are to be stored and who will administer them as prescribed in Section 23 (2) of the Veterinary and Paraveterinary Professions Act, Act 19 of 1982 and in Section 22A (1) of the Medicines and Related Substances Act, Act 101 of 1965 (see addendum on Overview for responsible research conduct);

5.6.3.17 Describe euthanasia, including route of administration, how death will be confirmed and steps to be taken in case of emergency;

5.6.3.18 List and briefly describe other procedures including:

- 5.6.3.18.1 The purpose of the procedures,
- 5.6.3.18.2 Severity scale,
- 5.6.3.18.3 Duration,
- 5.6.3.18.4 Frequency and justification for repetition, and
- 5.6.3.18.5 Steps to be taken in case of emergency.

5.6.3.19 Describe in detail the restraint procedure;

5.6.3.20 Welfare monitoring - sheet needs to be uploaded:

- 5.6.3.20.1 Briefly state what clinical and behavioural criteria will be specifically monitored to assess the animal's overall well-being, how often this will be done by whom and how records will be kept as proof of monitoring;
- 5.6.3.20.2 Indicate if animals require special housing or dietary conditions.

5.6.3.21 Indicate if and how animals will be transported before, during or after this study and the required permits if relevant;

5.6.3.22 Identify potential ill effects on the animals that may result in premature termination of the experiment (Humane Endpoints);

5.6.3.23 Indicate the ultimate fate of the animals and state how the animals and/or animal carcasses are to be disposed of in a responsible and ecologically sound manner. Provide details of service providers;

5.6.3.24 Detail the potential benefits of the study. These are required to aid the committee in performing a harm/ benefit assessment. Also state how you will determine whether these benefits were obtained;

5.6.3.25 Identify and justify any aspects of the study that could reasonably be considered ethically controversial. Detail how these ethical issues will be addressed and any extra protections that will be implemented;

5.6.3.26 Provide a list of references.

5.6.4 Provide a **Scientific Review Statement:** a template is provided and should be uploaded. Every Application has to be supported by a declaration that it has undergone prior scientific review outside of the applicants respective Unit or Group;

5.6.5 Provide information on **Related Ethics Review:** Indicate whether the application has been sent for a related ethics review, if yes, provide the relevant Ethics number, Title of the Project, Name and Surname of the PI, and briefly state the relevance of this to the current application;

5.6.6 List and provide any **Permits** required for the project and the relevant Issuing Authority;

5.6.7 List and provide **Other letters of authorisation from institutions and/or landowners;**

5.6.8 Include: Supervising Veterinarian Registration, South African Veterinary Council (SAVC) certification for all SAVC authorized participants, completed drug prescription and veterinary confirmation form;

5.6.9 For studies that intend to send or receive data or samples to or from another location or institution, a **Material Transfer Agreement (MTA)**

5.6.10 **Signed investigator declaration and conflict of interest forms** for each investigator and research supervisor. Complete and sign an "investigator declaration" and declare any conflict of interest for each principal investigator, co-investigator, sub-investigator and research supervisor;

5.6.11 **Describe Occupational Health and Safety measures in place,** to manage and prevent any hazards associated with the care and use of animals in your project. Note: Approval for meeting occupational health and safety standards is not the mandate of the REC: ACU and should be separately reviewed and approved by the relevant institutional body according to your Departmental/Faculty/Institutional Occupational Health and Safety procedures;

5.6.12 Other relevant documentation;

5.6.13 Additional documents:

5.6.13.1 **Drug Prescription and Veterinary Confirmation form**

5.6.13.2 **Scientific Review Statement**

5.6.13.3 **Permission for use of private animals in research and teaching**

6. REVIEW CRITERIA

6.1 Overview

The essential Overview of REC: ACU is to protect the dignity, rights, safety, and well-being of all animals in health-related and teaching research. REC: ACU will do this through independent, prospective, and ongoing ethics review of all projects involving the care and use of animals for scientific purposes undertaken by members of staff, registered students and affiliates of the University.

6.2 Purpose

The purpose of this Overview is to outline the considerations and factors that may influence the scientific validity and ethical acceptability of the research.

6.3 Review criteria

Please see Appendix I: REC: ACU review guide for the detailed REC: ACU review framework. REC: ACU uses the following internationally accepted criteria for review: **Scientific value:** The care and use of animals for scientific purposes shall be subject to scientific review.

6.3.1.1 REC: ACU shall be satisfied that there is sufficient evidence to support a case that the proposed use of animals are justified;

6.3.1.2 A judgement as to whether a proposed use of animals is ethically acceptable shall be based on information that demonstrates the governing principles. This judgement shall balance whether the potential negative effects on the well-being of the animals involved is justified by the potential benefits;

6.3.1.3 The obligation to respect and preserve the dignity of animals shall always prevail. The responsibilities associated with this obligation, apply throughout the animal's lifetime, including acquisition, transport, breeding, housing, husbandry, use of the animal in a project, and provisions for the animal at the conclusion of their use.

6.3.2 Respect for animals shall underpin all decisions and actions of all people involved in the care and use of animals for scientific purposes. This is demonstrated by:

6.3.2.1 using animals only when it is justified,

6.3.2.2 supporting the well-being of the animals involved,

6.3.2.3 avoiding or minimizing harm, including pain, suffering, distress, and lasting harm, to those animals, and

6.3.2.4 applying high standards of scientific integrity;

6.3.2.5 applying the four Rs at all stages of animal care and use:

6.3.2.5.1 the *Replacement* of animals with alternatives;

6.3.2.5.2 the *Reduction* in the number of animals used;

6.3.2.5.3 the *Refinement* of techniques used to minimize the adverse impact on animals; and

6.3.2.5.4 the knowledge and acceptance of one's *Responsibilities*.

6.3.3 **Justification of the use of animals**

Evidence to support a case to use animals shall demonstrate that:

6.3.3.1 a project has scientific or educational merit, and has the potential benefit for humans, animals, or the environment,

6.3.3.2 the use of animals is essential to achieve the stated aims, and suitable alternatives to replace the use of animals to achieve the stated aims are not available,

6.3.3.3 the project involves the minimum number of animals required to obtain valid data, and

6.3.3.4 the project involves the minimum adverse impact on the well-being of the animals involved.

6.3.4 Projects shall only be undertaken to:

6.3.4.1 obtain and establish significant information relevant to the understanding of humans or animals (or both);

6.3.4.2 maintain and improve human or animal (or both) health and welfare;

6.3.4.3 improve animal management or production;

6.3.4.4 obtain and establish significant information relevant to the understanding, maintenance or improvement of the natural environment;

6.3.4.5 to achieve educational outcomes in science, as specified in the relevant curriculum or competency requirements.

6.3.5 **Support the well-being of animals**

6.3.5.1 The well-being of animals used for scientific purposes shall be considered in terms of the cumulative effects of an animal's lifetime experience. At all stages of the care and use of an animal, measures should be taken to ensure that the animal's environment and management are appropriate for the species and the individual animal and support the animal's well-being;

6.3.5.2 Practices and procedures used for the care and management of animals shall be based on current best practice that takes into consideration the relevant aspects of species-specific biology, physiology, and behaviour;

6.3.5.3 Is based on the best available scientific evidence (or, in the absence of scientific evidence, accepted practice), which includes the potential

adverse impact of conditions and procedures on the well-being of the animals; or

6.3.5.4 Includes strategies to minimize adverse impacts;

6.3.5.5 Special ethical consideration and ACU approval are required where the conditions specified in Section 6.3.4.2 are precluded by the requirements of a project or activity.

6.3.6 **Scientific validity:** The proposed research must be:

6.3.6.1 Scientifically valid; **and**

6.3.6.2 Research must be well designed and conducted (e.g., clear aims, rigorous design, adequate sample, adherence to GCP, sound data analysis). Even a valuable research question can be poorly researched, resulting in unreliable data. Poorly designed research that is not scientifically sound is unethical because it wastes resources and exposes animals to risks and inconvenience for no purpose if the research yields inaccurate conclusions/ misleading answers.

6.3.7 The proposed investigators/researchers/study coordinators must be:

6.3.7.1 *Suitably qualified to undertake the research*. Studies that have a substantial clinical component, where the principal Investigator is not a clinician, s/he should appoint an HPCSA-registered clinician as a co-Investigator to the study;**and**

6.3.7.2 *Registered with the South African Veterinary Council (SAVC)* to perform any procedures included in the application, or other South African statutory body, as appropriate. If not registered with SAVC or other statutory body, the committee shall, based on the applicant's CV and other documentary submissions, satisfy itself that the applicant is competent to undertake the roles described in the protocol, subject to legal requirements;

6.3.7.3 For non-South African citizens, proof of registration with an equivalent body in their home country *and* in South Africa will be necessary. Where this is not available, then a motivation and/or other supporting documents from a locally registered person or appropriate authority should accompany the application as evidence of competence;

6.3.7.4 All the relevant documents, including Proof of SAVC certification, should be included in the review of the application.

6.3.8 The proposed research has the following resources:

6.3.8.1 Adequate number of qualified staff;

6.3.8.2 Adequate animal facilities;

6.3.8.3 Access to animals for the desired research;

6.3.8.4 Access to approved funding.

6.3.9 Reasonable risk-benefit ratio: The so-called Harm to Benefit Ratio, i.e., the use of animals in scientific research, teaching, and testing 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. **For this reason, all research, teaching, and testing involving animals must be approved by the REC: ACU so that a formal evaluation of the potential harm/benefit equation can be undertaken before the activity commences;**

6.3.10 All research and teaching activities involving animals conducted under the auspices of this university must uphold the “Four R" principles for humane animal research (SANS 10386: 2021), namely:

6.3.10.1 **Replacement** refers to methods that avoid using animals. The term includes absolute replacements (i.e., replacing animals with inanimate systems such as computer programs or non-living models) as well as relative replacements (i.e., replacing animals such as vertebrates with animals that are lower on the phylogenetic scale).

6.3.10.2 **Reduction** of the numbers of animals in experiments by design strategies that facilitate use of the smallest number that will allow statistically valid information to be obtained from the study. On the other hand, the numbers of animals should not be reduced below the numbers that would allow statistically significant results to be generated, the argument being that if reduced below statistical validity, then the use of animals is also not justified. 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.

6.3.10.3 **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.

6.3.10.4 **Responsibility** towards the experimental animals that will be used as stipulated in SANS 10386:2021.

6.3.11 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;

6.3.12 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);

6.3.13 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/ACU shall investigate any suspected or alleged non-compliance with the SANS 10386:2021 relevant legislature, or protocol requirements and conditions and report it to the institutional Research Integrity Officer (SANS 10386: 2021, p. 16);

6.3.14 The REC: ACU will report its activities to the Senate Research Ethics Committee on a regular basis;

6.3.15 The REC: ACU will report on an annual basis to the National Health Research Ethics Council (NHREC) and acknowledges that the NHREC has the right to audit this report and the running of the committee;

6.3.16 **Fair selection of animals for the research/teaching – Justification of the use of animals**.

The use of animals in scientific research, teaching and testing 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. For this reason, all research, teaching, and testing involving animals must be approved by the REC: ACU so that a formal evaluation of the potential harm/benefit equation can be undertaken before the activity commences. The selection of animals for the proposed research must be fair and just;

6.3.17 In making this assessment REC: ACU shall take into account the purpose of the research and the setting in which the research will be conducted;

6.3.18 Animals must be selected according to the scientific goals of the study, such as sex, species, age, breed/strain, geographic area:, and other relevant criteria.

7. REC: ACU APPLICATION REQUIREMENTS AND REVIEW PROCESS: CONTINUING REVIEW

7.1 Routine continued review (Annual progress reports)

7.1.1 Overview

Regulations require that animal ethics committees conduct substantive and meaningful continuing review of all approved research at least yearly and more frequently if the level of risk warrants this. The REC: ACU will determine whether the protocol needs verification from sources other than the researchers that no material changes have occurred since the previous REC: ACU review and that the research is still in compliance with the original review criteria.

7.1.2 Purpose

The purpose of this Overview is to provide guidance on the continuing review process for active research protocols.

7.1.3 Application and review process: Annual progress reports (routine continued review)

7.1.3.1 **Ethics approval is valid for one year only;**

7.1.3.2 A progress report is an application for renewal of ethics approval and must be submitted annually, unless the REC: ACU deems the project to be of particularly high risk and requests more frequent progress reports;

7.1.3.3 A progress report must be submitted to REC: ACU one year post approval followed by a final report at the end of year three;

7.1.3.4 No research may continue without this process and re-approval;

7.1.3.5 Progress reports must be submitted around 2 months before the ethics approval expiry date, so that the submission can be reviewed, and the project re-approved **prior** to the expiry date;

7.1.3.5.1 REC: ACU recognizes the logistical advantages of keeping the expiration date of the REC: ACU approval period constant from year to year throughout the life of a research project;

7.1.3.5.2 Therefore, when the REC: ACU performs continuing review and reapproves (with or without conditions) the research within 30 days *before* the current REC: ACU approval period expires, the REC: ACU may retain the anniversary of the expiration date of the initial REC: ACU approval as the expiration date of each subsequent one-year approval period;

7.1.3.6 Submit an electronic copy of the REC: ACU annual progress report application via the REC: ACU online application portal, *Infonetica©* at: https://applyethics.sun.ac.za;

7.1.3.7 REC: ACU front office administration reviews the application for completeness and may request additional information from the applicant;

7.1.3.8 If the researcher does not provide continuing review information to the REC: ACU or the REC: ACU has not approved a protocol by the expiration date, approval will lapse and

further research will be suspended (temporary halt in REC: ACU approval of some or all research activities) OR terminated (permanent halt in REC: ACU approval of ALL research activities). The suspension or termination of a trial as determined by the convened REC: ACU will result in a letter sent from REC: ACU office to the principal investigator with notice of the REC: ACU decision.

7.1.3.9 The progress report should contain sufficient information to allow the reviewer to conduct a substantive and meaningful review of the progress of the project, including any challenges or problems to animals encountered;

7.2 Protocol Amendment

7.2.1 Overview

Amendments to an approved protocol may become necessary as a study proceeds. The REC: ACU must review and approve all proposed protocol amendments before the amendment is implemented in the study.

7.2.2 Purpose

The purpose of this Overview is to outline the procedures involved in applying for an amendment to an approved protocol.

7.2.3 Definitions

Amendments are planned changes to an approved study protocol, made in advance. Amendments would include the following but are not limited to:

7.2.3.1 Additional Investigators or study sites;

7.2.3.2 Administrative changes;

7.2.3.3 Change in study aims, objectives or design;

7.2.3.4 Changes in drug usage;

7.2.3.5 Amended and/or additional animal study procedures

7.2.4 REC: ACU application and review process: Amendment application

7.2.4.1 **To submit an REC: ACU application for review of an amendment:** submit an electronic copy of the REC: ACU amendment application via the REC: ACU online application portal, *Infonetica©* at: https://applyethics.sun.ac.za;

7.2.4.2 REC: ACU amendment applications can be submitted on a rolling basis, but must be received by the published REC: ACU submission deadline in order to be considered for the agenda of that meeting;

7.3 Protocol Deviations

7.3.1 Overview

Any deviations to eliminate an immediate hazard or harm to an animal must be managed by the applicant in consultation with the supervising veterinarian and be reported to the REC: ACU **within 7 calendar days**.

7.3.2 Purpose

The purpose of this Overview is to outline the reporting of protocol deviations to the REC: ACU Definitions

7.3.2.1 A deviation is a "once off" instance when, for some reason, the protocol is not followed.

7.3.2.2 Affecting the scientific integrity and/or validity of the study

7.3.2.3 Posing a significant risk of harm to the animal

7.3.2.4 Involving a serious and/or continuing non-compliance with institutional, ethical, and/or regulatory policies

7.3.3 Procedure for submission of protocol deviations

7.3.3.1 **To submit an REC: ACU application for review of a protocol deviation:** submit an electronic copy of the REC: ACU protocol deviation application via the REC: ACU online applicationportal, *Infonetica©* at: https://applyethics.sun.ac.za;

7.4 Adverse events

7.4.1 Overview

The REC: ACU has written procedures to ensure timely reporting of adverse events which might place an animal at a greater risk of physical and psychological harm.

7.4.2 Purpose

The purpose of this Overview is to outline the procedures and timelines for reacting to and reporting of adverse events.

7.4.3 DefinitionsAdverse events: An adverse event is an unexpected incident, experience or outcome, which is not consistent with the information currently provided to the REC: ACU:

7.4.4 Procedure for reporting and reacting to adverse events

7.4.4.1 Unless otherwise specified, the investigator should report the adverse event to REC: ACU within **7 calendar days** after first becoming aware thereof;

7.4.4.2 Submit an electronic copy of the REC: ACU adverse event application via the REC: ACU online application portal, *Infonetica©* at: https://applyethics.sun.ac.za.;

7.4.4.3 Report adverse events to REC: ACU in the annual progress report;

7.4.4.4 Adverse events may be investigated further and if deemed necessary by the Chairperson, will be reported to the Research Integrity Office and/or the REC: ACU EXCO. Appropriate remedial action will be taken, if deemed necessary. Such action may include, but is not limited to:

7.4.4.4.1 Protocol revision/amendment, including possible modification in order to mitigate the newly identified risks;

7.4.4.4.2 Suspension and/or termination of the research;

7.4.4.4.3 Reporting to the appropriate regulatory agencies if deemed necessary.

8 COMMUNICATION OF REVIEW DECISIONS

8.1 Overview

To ensure that investigators are appropriately informed about REC: ACU review decisions.

8.2 Purpose

The purpose of this Overview is to outline the procedure for the communication of REC: ACU decisions to investigators.

8.3 REC: ACU decisions

For each review conducted by REC: ACU, one of the following decisions must be made:

8.3.1 **Approved:** The proposed research is approved in its current form, with no changes required. The date of approval is considered the date that all conditions were determined to be met;

8.3.2 **Approved with stipulations:** The proposed research is approved with minor alterations required.The onus is left on the research applicant to meet these stipulations prior to the start of any research related activities;

8.3.3 **Modifications required:** The proposed research has no major ethical concerns, but a number of clarifications or methodological changes are required. The research applicant must resubmit the revised research application. The review can be finalised by an expedited review process, i.e., without having to serve before the full committee again;

8.3.4 **Deferred:** The proposed research has major methodological and/or ethical concerns and requires considerable revision. The research applicant may resubmit the revised research application. The revised research application will be reconsidered at a convened (full) committee meeting;

8.3.5 **Rejected:** The proposed research may not be resubmitted;

8.4 Procedure for the communication of REC: ACU decisions

8.4.1 Decisions taken at an REC: ACU meeting, are communicated in writing to the applicant;

8.4.2 Investigators can address any queries to the REC: ACU office, which will attempt to resolve problems and liaise with the Chairperson when necessary;

8.4.3 The average **turnaround times** for notifying research applicants of the review outcome are **5-6 weeks** after the REC: ACU submission deadline

8.4.4 These expected turnaround times apply to research applications that are scientifically and ethically sound. It may take considerably longer to finalise review decisions for research applications that are scientifically and/or ethically problematic or flawed. Review time is also subject to REC: ACU capacity, and the timing of the application;

8.4.5 Research applicants should follow up with the REC: ACU office if they have not received an REC: ACU letter within the time frames specified above;

8.4.6 REC: ACU letters are issued electronically via *Infonetica©.* Please check your SU email address,including the junk folder;

8.4.7 It is not unusual for the committee to request some changes to the project, information or clarification of certain issues. Only once these requirements are satisfactorily fulfilled, will a formal letter of approval be issued;

8.4.8 The research applicant may start the project only once an **REC: ACU approval letter** has been received. If modifications are required, then all requested changes must be made before a final letter of approval is issued;

8.4.9 It is the responsibility of the research applicant to comply with all requests and return the requested documentation with a covering letter responding to the points raised, to the REC: ACU as soon as possible but not later than 3 months from the date of issue. **The application will be suspended if no feedback is received from the research applicant within 3 months;**

8.4.10 For urgent research applications, review will be considered, and if approved will be ratified by the REC: ACU at the next available meeting.;

8.4.11 REC: ACU has the authority to suspend the approval of any approved project and request further changes or additional information. All research activities must cease until this process is concluded;

9 Permission for private animal use in research and teaching

9.1 Overview

9.1.1 No investigator may involve a privately owned animal in research covered by this Overview unless the investigator has obtained permission from the animal owner;

9.1.2 Written permission must be submitted to the REC: ACU as part of the application package;

9.1.3 For projects conducted by South African investigators they must conform to the minimum standards set out by SANS 10386:2021;

9.1.4 An investigator shall ensure that all people involved in the care and use of such animals are aware of and accept their responsibilities relating to the animals, ensure that people responsible for the daily management of the animals during the project are familiar with and understand the necessary standards and legislation and are competent.

9.1.5 Permission for private animal use in research and teaching requirements in this SOP is not intended to pre-empt any applicable governmental or local laws which pertain to diseases that are controlled and notifiable under The Animal Diseases Act, Act 35 of 1984 and The Animal Diseases Regulations, R.2026 of 1986 (Animal Diseases Act, 1984; Animal Diseases Regulations, 1986);

9.1.6 Nothing in this Overview is intended to limit the authority of a registered veterinary or para-veterinary professional to provide emergency veterinary care, to the extent the registered veterinary or para-veterinary professional is permitted, under applicable governmental or local law;

10 MATERIAL TRANSFER AGREEMENTS (MTAS)

10.1 Overview

A material transfer agreement (MTA) or data transfer agreement (DTA) lays out the terms under which research resources can be shared between scientific institutions and is required to move research materials and/or data between institutions and/or countries. This Overview refers to the processes and requirements for the review of MTA terms by the REC: ACU. REC: ACU encourages the sharing of specimens and data from research involving animals in the promotion, in the cryopreservation of gametes and embryos for long term colony management of laboratory animals, and in the prospective registration of animal trials. Transfer of such materials related to research involving animas may be guided by the MTA/DTA process outlined below.

10.2 Purpose

The purpose of this Overview is to define and describe the REC: ACU application requirements and review process for Material Transfer Agreements (MTAs).

10.3 REC: ACU and SU institutional processes and requirements for MTAs

A material transfer agreement (MTA) or data transfer agreement (DTA) is required to move research materials and/or data between institutions and/or countries;

10.3.1 If material or data transfer is anticipated in a project, the research applicant completes the REC: ACU MTA Term Sheet (Available at http://www.sun.ac.za/english/faculty/healthsciences/rdsd/Pages/Ethics/Forms-Instructions.aspx) and submits this completed term sheet along with their REC: ACU application;

10.3.2 The specific terms of the MTA term sheet are reviewed by the REC: ACU to ensure that they match the commitments in the protocol and the promises made to animal owner/managers in the informed consent document, if applicable;

10.3.3 Once the project, including the MTA/DTA term sheet, is approved by REC: ACU the research applicant sends the MTA term sheet to the University's contracts office;

10.3.4 The contracts office uses the MTA term sheet to prepare an MTA which is appropriate for transferring materials as part of and in accordance with the protocol;

10.3.5 The REC: ACU should not sign the MTA nor should they be responsible for the final review and approval of the full MTA contract;

10.3.6 The approval of MTA'S lies with SU's Research Contracts Office at the Division for Research Development. In the case of FMHS the final signatory is the Vice Dean: Research.

11 DECLARING A POTENTIAL CONFLICT OF INTEREST FOR INVESTIGATORS

11.1 Overview

A conflict of interest may involve any number or combination of conditions in which a researchers' judgement concerning a primary interest (e.g., animal welfare, scientific integrity) could be biased by a secondary interest (e.g., personal or financial gain). Any potential conflict of interest should be disclosed to the REC: ACU for their review and consideration.

11.2 Purpose

The purpose of this Overview is to describe and define conflict of interest and delineate the procedure for thereporting of potential conflict of interest.

11.3 Definition and important considerations

11.3.1 A conflict of interest (COI) occurs when professional judgement regarding an interest e.g., research, or patient care, is unduly influenced by another interest (e.g., financial gain or gain in personal status);

11.3.2 Admitting to a conflict of interest is not an indication of moral failure but an honest appraisal of the potential influence of secondary interests on one's judgement and actions;

11.3.3 Conflicts of interests are an inherent and unavoidable part of the academic research environment and can be effectively managed by disclosure and transparency;

11.3.4 Investigator conflicts of interests are of particular importance when an unacknowledged or undisclosed interest, financial or otherwise, may negatively affect the welfare of animals in research, teaching, and testing. It is this aspect of COI's that is of concern and relevance to the REC: ACU;

11.3.5 Investigators must consider the potential effects that a financial relationship of any kind may have on the research or on interactions with research participants;

11.4 Procedure for the reporting of potential conflict of interest

11.4.1 All investigators are obligated to sign the Conflict of Interest Declaration that is part of the Investigator declaration;

11.4.2 In particular, investigators should disclose the following **potential** conflict of interests to the REC: ACU:

11.4.2.1 Equity or stock holding in a sponsor company;

11.4.2.2 Proprietary interests in product-patent holding, intellectual property rights, trademark, and licensing agreements;

11.4.2.3 Grants paid speaking arrangements, retainers for ongoing consultations, sitting on"Pharmaceutical Advisory Boards", etc.;

11.4.2.4 Travel/conference sponsorship;

11.4.2.5 Recruitment fees or other personal payments that are linked to study outcome, in anyway;

11.4.2.6 Co-authorship of articles, where the co-author's input has been minimal;

11.4.2.7 Funding for additional staff and facilities, especially if not directly linked to the research project;

11.4.2.8 Equipment for use in a study that will then belong to the department;

11.4.2.9 Donation of equipment unrelated to study;

11.4.2.10 Contributions to a departmental budget not directly related to project expenses.

11.4.3 Please note that all of the above may well be potential or perceived but not actual COI'S and after due discussion by the REC: ACU, may be deemed to be acceptable or appropriate, in a particular set of circumstances;

11.4.4 Procedures for declaration of interests and management of perceived, potential, or actual conflicts of interest involving the ACU members, and experts whose advice is sought by the ACU, shall require people with a conflict of interest to remove themselves from the ACU's decision making on matters that relate to the conflict of interest;

11.4.5 For decision making on applications, members with a conflict of interest shall withdraw from the meeting. Once such members have withdrawn, the remaining members shall constitute a quorum as defined in Section 3.8, i.e., one member from each of the membership categories A, B, C and D, with categories C and D together representing at least one-third of members present;

11.4.6 In the event where an investigator attempts to unduly influence a REC: ACU member it is the responsibility of that REC: ACU member to immediately report the event to the Chairperson for further management. According to the nature and the severity of the event, the matter will be referred to the Research Integrity Office or the Executive Committee as deemed appropriate.

12 RECORD KEEPING

12.1 Overview

Legal and ethical requirements regarding research, testing, and teaching involving animals require that records be kept, maintained and retained in an orderly and easily accessible manner for future reference and for audit purposes by the relevant councils, committees, and departments. The REC: ACU retains all information of research study records on an online research ethics database. The purpose of this Overview is to describe and delineate the REC: ACU procedures for record keeping.

12.2 Research projects

12.2.1 Record Keeping:

12.2.1.1 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 project 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;

12.2.1.2 An up-to-date list of REC: ACU members will be retained at the REC: ACU office and be publicly available. Members will be 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. All REC: ACU members are requested to supply the REC: ACU office with a brief updated CV every two years;

12.2.1.3 REC: ACU meeting minutes: The secretary of the REC: ACU shall keep an accurate record of meeting attendance, apologies, recusals and whether or not a quorum was maintained throughout each meeting, main discussion points and decisions taken.

12.3 REC: ACU meeting minutes

12.3.1 A REC: ACU reference number is allocated to all new applications. This number is recorded on all correspondence and additional attachments/amendments;

12.3.2 A research ethics database is used to capture the following information (minimum database) for all research project and teaching programme applications:

12.3.2.1 REC: ACU reference number;

12.3.2.2 Project title;

12.3.2.3 Research protocol;

12.3.2.4 Primary investigator/applicant details;

12.3.2.5 Supervisor;

12.3.2.6 Sub-investigators;

12.3.2.7 All other individuals involved in the study;

12.3.2.8 Department;

12.3.2.9 Species;

12.3.2.10 Number of animals approved;

12.3.2.11 Number and date of animals issued;

12.3.2.12 Date of approval;

12.3.2.13 Calendar (start date and end date);
12.3.2.14 Permits required, e.g., (Section 20), Cape Nature, National Parks Board, etc.;
12.3.2.15 Registration or authorisation by statutory body (e.g., SAVC/HSPCA);
12.3.2.16 Veterinary Supervision agreement;
12.3.2.17 Schedule drug agreement if required;
12.3.2.18 Welfare, anaesthetic, or other monitoring sheets;
12.3.2.19 Progress reports;
12.3.2.20 Modifications to previously approved research;
12.3.2.21 Incident or serious adverse effects reports;
12.3.2.22 Records of non–compliance;
12.3.2.23 All correspondence between the REC: ACU and the researchers.

12.3.3 Complete records will be sent to the animal unit after the protocol is approved and prior to commencement of project. This information should include the research protocol, ethics approval letter, contact details of primary investigator, supervisor, sub-investigators and all other individuals approved to be involved in the project and the amount of animals approved for the study;

12.3.4 Additionally, the REC: ACU Secretariat will also keep copies of records for expedited/exempt review procedures including the following:
12.3.4.1 The justification for using the expedited/exempt review procedure;
12.3.4.2 Actions taken by the reviewer.

12.4 Record of REC: ACU membership

The minutes of each REC: ACU meeting will be available for review by REC: ACU members one week prior to the next meeting for an approval vote at the subsequent REC: ACU meeting;

12.4.1 Written minutes of REC: ACU meetings will document the following:
12.4.1.1 Separate deliberations, actions or votes for each protocol review;
12.4.1.2 The basis for deferring or rejecting research;
12.4.1.3 The basis for requiring deletions or substantive changes to research;
12.4.1.4 The basis for approving research;
12.4.1.5 The determination of the level of risk category;
12.4.1.6 A written summary of the discussion of controversial issues and their resolution;
12.4.1.7 The detailed revisions required to secure approval;
12.4.1.8 The approval of exempt reviews by the Chair or designee;
12.4.1.9 The approval of required protocol modifications must be documented in the minutes of the first REC: ACU meeting that takes place after the date of the approval.

12.4.2 The meeting minutes must also document committee members' attendance with respect to the following:
12.4.2.1 Attendance at the meeting;
12.4.2.2 Member's absence from discussion, deliberation, and vote on specific protocols because of conflict of interest;

12.4.2.3 The presence of a quorum at the meeting including the presence of one non-scientific member;

12.4.3 REC: ACU meeting minutes must also document the voting results for each REC: ACU committee action as follows:

12.4.3.1 Number of votes including:

12.4.3.1.1 Total votes in favour (For);

12.4.3.1.2 Total votes opposed (Against);

12.4.3.1.3 Abstained;

12.4.3.1.4 Recused (due to conflict of interest);

12.4.3.2 The name of REC: ACU members who recused themselves due to conflict of interest.

12.5 Record of REC: ACU membership

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.

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

13.1 Overview

International and national practices and guidelines emphasise the active monitoring role that the REC: ACU 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. The objectives of animal research facilities are to protect rights and the welfare of animals used in research, teaching, and testing; and ensure compliance with currently approved guidelines, standards, and applicable regulatory requirements (where applicable). The REC: ACU has the authority to conduct inspections on any active research activities involving animals.

13.2 Purpose

The purpose of this SOP is to describe how the REC: ACU in the Division of Research Development at the Stellenbosch University shall conduct inspections of animal research facilities that are used for animal research, teaching, and testing, approved by the REC: ACU.

13.3 Animal Unit Inspection Procedures

13.3.1 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;

13.3.2 The main focus of the inspection is to ensure that the research is being conducted in an ethical manner and that animal welfare's interests is fully recognised, represented, and protected;

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

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

13.3.5 REC: ACU will conduct both routine (announced) inspections and for cause (unannounced) inspections;

13.3.5.1 Routine/Announced inspections:

13.3.5.1.1 Notification letters of intended routine inspections will be sent to the facility manager of the selected animal research facility and the facility will be given at least 2 weeks to prepare for the inspections and ensure their active participation and to protect their right to due process.

13.3.5.2 Unannounced inspections: These visits will occur at unspecified times, usually at short notice:

13.3.5.2.1 Unannounced inspections will be selected on an ad-hoc basis as necessary, either after discussion by the REC: ACU, or on specific instructions from the Senate Research Ethics Committee or the EXCO and/or at the request of Deputy Dean of Research in the Faculty of Medicine and Health Sciences;

13.3.5.2.2 An independent and suitably qualified inspector may be appointed to act on behalf of the REC: ACU, on a per project contract basis to conduct the site inspection;

13.3.5.2.3 The research facility staff will not be notified of the intended for cause (unannounced) inspection;

13.3.5.2.4 During each inspection, the inspection team/inspector will examine the structure of the facility and their standard operating procedures (SOP) to determine whether they comply with the ethical standards and regulatory requirements governing research involving animals as detailed in the specific areas of focus during site inspections below;

13.3.5.2.5 In the case of cause/unannounced inspections, the inspection team/inspector will be supplied with an Inspection Brief, which may outline the complaint/concern and indicate specific focus areas for the inspection.

13.4 Special areas of focus during site inspections

Some or all of the following areas and documents may be examined by the inspection team during the inspection process, depending on the nature of the inspection and the nature of the facility:

13.4.1 **Review of facility documents /essential documents:**

13.4.1.1 Facility registration (SAVC/DALLRD).

13.4.2 **Staff**

13.4.2.1 SAVC authorisation / registration up to date;

13.4.2.2 Continuous training records.

13.4.3 **Review of scheduled drug records (if applicable)**

13.4.3.1 Drug name, dispensing date, amount used, responsible person, and amount left recorded;

13.4.3.2 Drug logs are neat, legible, and complete;

13.4.3.3 Drugs are safely and securely locked and stored away as per regulations.

13.4.4 **Daily monitoring sheets**

13.4.4.1 Sheets should be completed neat, legible, and complete;

13.4.4.2 Sheets should be completed for every animal/cage/room whichever appropriate, every day;

13.4.4.3 Macrosheets to record daily temperature, humidity, Db, and lux;

13.4.4.4 Animals are checked daily by authorised or registered competent staff;

13.4.4.5 Veterinarian check animals once per week as per SAVC rules for research animal facility.

13.4.5 **Animals**

13.4.5.1 All animals have food, water, environmental enrichment, clean cage;

13.4.5.2 Correct stocking density according to SANS (SANS 10386: 2021);

13.4.5.3 Animals active, displaying normal behaviour, good condition, absence of injury, and distress.

13.5 Facility

13.5.1 Absent of smells, clean, neat, tidy;

13.5.2 Equipment in good working order and maintenance up to date.

13.6 Record Keeping

13.6.1 Records stored safely and securely.

13.7 Inspection report and follow up

After conducting the inspection, the following will be done:

13.7.1 The inspection team will compile a draft inspection report, which will be submitted to the Chairperson of the REC: ACU and to the facility;

13.7.2 The facility will be requested to respond formally in writing to the inspection report and address each point/query. The facility report should also include a corrective action plan, if appropriate;

13.7.3 The inspection team or the REC: ACU will then review the report, identifying irregularities in the statements and/or documents, summarising the issues that justify or refute the reasons for the initial complaint, where applicable and proposing a plan or corrective action, if appropriate;

13.7.4 The inspector/team may arrange a formal meeting with the facility, inspection team, representatives from the REC: ACU or SREC, where appropriate, to discuss any findings of the inspection including any findings of non-compliance. This meeting is formal and should be minuted in detail;

13.7.5 The Inspection Report, facility's written response and minutes of the follow up meeting are confidential and will usually be tabled at a forthcoming REC: ACU meeting;

13.7.6 The REC: ACU Chairperson and Deputy Dean of Research may jointly, in certain circumstances, decide not to table the full inspection report. However, this decision should not compromise the institutional independence of the REC: ACU;

13.7.7 Major audit findings may be reported to the SREC on a regular basis;

13.7.8 The summary report of the findings may be reported to the National Health Research Ethics Council (NHREC: ACU).

13.8 REC: ACU deliberation and decisions on the inspection report

13.8.1 The full REC: ACU will review the inspection team's summary report, the facility's written response and the minutes of the follow up meeting report, where applicable;

13.8.2 The REC: ACU will decide either by consensus or by vote to:

13.8.2.1 Accept the inspection findings and facility's written response as acceptable with no cause for further action. A final letter will be sent to the facility, briefly summarising the outcome and declaring the matter satisfactorily resolved;

13.8.2.2 Request the facility to provide additional information, or take some other form of corrective action, which may even involve a suspension of approval of the research study involved until proof of corrective action has been provided;

13.8.2.3 Withdraw study approval; and/or

13.8.2.4 Refer the matter to line management, the Deputy Dean of Research and/or the Research Integrity Office (RIO) or the SREC for further investigation and action where appropriate.

All correspondence between the REC: ACU, inspector/inspection team and facility will remain confidential except in cases of serious research non-compliance in which instance the report may be forwarded to

external regulatory bodies or funders as deemed appropriate by the EXCO after discussion with the Chairperson of the REC: ACU and other relevant stakeholders.

14 REC: ACU POST APPROVAL MONITORING

14.1 Overview

The REC: ACU has the responsibility to ensure that the conduct of all research approved by the ethics committee is monitored on an ongoing basis. The frequency and type of monitoring should reflect the degree and extent of risk of harm to animals in the research project. Monitoring routinely involves the regular review of study progress reports, but sometimes more in-depth monitoring of a project may be necessary. The objectives of post approval monitoring are to protect the welfare of animals used in research, teaching, and testing; assist researchers in strengthening their research studies; ensure quality of data; and ensure compliance with currently approved protocol/amendment(s); applicable regulatory requirements and standards (where applicable). The REC: ACU has the authority to conduct inspections on any active research activities involving animals.

14.2 Purpose

The purpose of this SOP is to describe how the REC: ACU in the Division of Research Development and Support in the Faculty of Medicine and Health Sciences at the Stellenbosch University shall conduct site inspections of research studies that are approved by the REC: ACU.

14.3 Definitions

Welfare monitoring sheet: A printed, optical, or electronic document designed to record all theprotocol required information to be **recorded for each animal.**

Inspection: The act by a regulatory authority(ies) of conducting an official review of documents, facilities, records, procedures, and any other resources that are deemed by the authority(ies) to be related to the research, training, and testing involving animals.

14.4 Scope

Senate Research Ethics Committee (SREC), Executive Committee (EXCO) of REC: ACUs, REC: ACU members and Secretariat, Investigators, and Research teams.

14.5 Responsibility

14.5.1 The REC: ACU Chairperson or a person appointed by the REC: ACU assumes responsibility for the conduct of an inspection, directs the process, and acts as a facilitator for the inspection;

14.5.2 Parties generally involved in the process include the investigator/researcher, the research team, the REC: ACU Secretariat, the REC: ACU Chairperson and the inspector/inspection team.

14.6 Allowable exceptions

This SOP is meant to be followed without deviation.

14.7 Procedures

14.7.1 REC: ACU will conduct both **routine (announced) inspections** and **for cause (unannounced) inspections**;

14.7.2 **Routine (announced) inspections** will be conducted on the following types of projects and studies:

14.7.2.1 Projects using large amounts of animals;

14.7.2.2 Projects at higher risk of having a negative impact on animal welfare, or causing pain and distress;

14.7.2.3 Investigator-driven studies;

14.7.2.4 Research that is classified are high-risk; and

14.7.2.5 Sites that are reporting many serious adverse events and incidents resulting in deaths.

14.7.3 Projects requiring post approval monitoring inspections will be decided on and discussed at next REC: ACU meeting;

14.7.4 Notification letters of intended routine inspections will be sent to Principal Investigators (PIs) of the selected projects and will be given at least 2 weeks to prepare for the inspections and ensure their active participation and to protect their right to due process;

14.7.5 **For cause or unannounced inspections** will be conducted on the following types of studies and sites:

14.7.5.1 Projects from which complaints have been received (whether by a researcher, animal facility staff member or other);

14.7.6 Projects, at which it is suspected that the procedures approved by the REC: ACU are not being followed, based on evidence provided in progress reports;

14.7.7 Sites **for unannounced inspections** will be selected on an ad-hoc basis as necessary, either after discussion by the REC: ACU, or on specific instructions from the Senate Research Ethics Committee or the EXCO and/or at the request of Deputy Dean of Research in the Faculty of Medicine and Health Sciences;

14.7.8 An independent and suitably qualified inspector may be appointed to act on behalf of the REC: ACU, on a per project contract basis to conduct the site inspection**;**

14.7.9 Principal Investigators of the selected sites will not be notified of the intended for cause (unannounced) inspection;

14.7.10 **During each inspection,** the inspection team/inspector will examine the structure of the PI's research organization and their standard operating procedures (SOP) to determine whether he/she complies with the ethical standards and regulatory requirements governing research involving animals as detailed in the specific areas of focus during site inspections below;

14.7.11 In the case of **for cause/unannounced inspections**, the inspection team/inspector will be supplied with an Inspection Brief, which may outline the complaint/concern and indicate specific focus areas for the inspection;

14.7.12 The main focus of the inspection team is to ensure that the research is being conducted in an ethical manner and that animal welfare is fully recognised, represented and protected.

14.8 Inspection report and follow up

After conducting the inspection, the following will be done:

14.8.1 The inspection team will compile a draft inspection report, which will be submitted to the Chairperson of the REC: ACU and to the PI;

14.8.2 The PI will be requested to respond formally in writing to the inspection report and address each point/query. The PI's report should also include a corrective action plan, if appropriate;

14.8.3 The inspection team or the REC: ACU will then review the report, identifying irregularities in the statements and/or documents, summarising the issues that justify or refute the reasons for the initial complaint, where applicable and proposing a plan or corrective action if appropriate;

14.8.4 The inspector/team may arrange a formal meeting with the PI, inspection team, representatives from the REC: ACU or SREC, where appropriate, to discuss any findings of the inspection including any findings of non-compliance. This meeting is formal and should be minuted in detail;

14.8.5 The Inspection Report, PI's written response and minutes of the follow up meeting are confidential and will usually be tabled at a forthcoming REC: ACU meeting;

14.8.6 The REC: ACU Chairperson and Deputy Dean of Research may jointly, in certain circumstances, decide not to table the full inspection report. However, this decision should not compromise the institutional independence of the REC: ACU;

14.8.7 Major audit findings may be reported to the SREC on a regular basis;

14.8.8 The summary report of the findings may be reported to the National Health Research Ethics Council (NHREC).

14.9 REC: ACU deliberation and decisions on the inspection report

14.9.1 The full REC: ACU will review the inspection team's summary report, the PI's written response and the minutes of the follow up meeting report, where applicable;

14.9.2 The REC: ACU will decide either by consensus or by vote to:

14.9.2.1 Accept the inspection findings and PI's written response as acceptable with no cause for further action. A final letter will be sent to the PI, briefly summarising the outcome and declaring the matter satisfactorily resolved;

14.9.2.2 Request the PI to provide additional information, or take some other form of corrective action, which may even, involve a suspension of approval of the research study involved until proof of corrective action has been provided;

14.9.2.3 Withdraw study approval; and/or

14.9.2.4 Refer the matter to line management, the Deputy Dean of Research and/or the Research Integrity Office (RIO) or the SREC for further investigation and action where appropriate.

14.9.3 All correspondence between the REC: ACU, inspector/inspection team and PI will remain confidential except in cases of serious research non-compliance in which instance the report may be forwarded to external regulatory bodies or funders as deemed appropriate by the EXCO after discussion with the Chairperson of the REC: ACU and other relevant stakeholders.

15 APPEALS AND COMPLAINTS

15.1 Purpose

The purpose of this Overview is to define, describe and outline the process for directing an appeal or complaint to the REC: ACU.

15.2 Definitions

15.2.1 Appeals arise because the REC: ACU has either rejected a research proposal, judges a protocol deviation or violation to be sufficiently serious to merit pausing or calling a halt to the research, or requires additional protections or conditions before approving a protocol and the Principal Investigator (PI) objects to the decision of the REC and wishes to appeal;

15.2.2 Complaints arise because of alleged REC procedural irregularities, breach of researcher confidentiality, unacceptable delays or conflict of interest.

15.3 Where to direct appeals or complaints

15.3.1 Appeals must be directed to the Chairperson of the REC: ACU. A researcher may not appeal directly to the Senate Research Ethics Committee (SREC);

15.3.2 Complaints should be directed, in the first instance, to the Chairperson of the REC: ACU. However, if the researcher deems the matter extremely serious and urgent, the complaint can be submitted directly, in writing, to the Chairperson of the SREC.

15.4 Appeal process

The process described below may be a two-stage process involving first the REC against which the appeal has been lodged. If the REC: ACU agrees or prefers, the matter can be referred to the SREC to be finalised. However, in order to retain the decisional integrity and independence of the REC: ACU within its own institution, PI's may not appeal directly to the SREC. The researcher retains the right to appeal or complain to the National Health Research Ethics Council, if the research falls under the jurisdiction of this council.

15.4.1 **Appeal process (REC: ACU level)**

15.4.1.1 Where a PI is dissatisfied with an REC: ACU decision, he or she has the right to obtain from the REC: ACU written reasons for its decision and should exercise this right before launching an appeal;

15.4.1.2 An appeal must be directed to the Chairperson of the REC: ACU. A researcher may not appeal directly to the Senate Research Ethics Committee (SREC);

15.4.1.3 The Chairperson of the REC: ACU must appoint a subcommittee to revisit the substance of the application together with any additional information put forward by the PI. The subcommittee must obtain at least one independent, external, expert review of the research project and the substance of the appeal. Additional reviews should be obtained if deemed appropriate. The subcommittee may have the same powers as the REC: ACU, if constituted by the REC: ACU;

15.4.1.4 The appeal is usually considered on the grounds of written submission only. However, the Chairperson of the appeal subcommittee may invite the PI to provide an additional oral submission to the subcommittee and answer questions;

15.4.1.5 After deliberation of all the information placed before it, the subcommittee must either:

15.4.1.5.1 Uphold the appeal;

15.4.1.5.2 Reject the appeal; or

15.4.1.5.3 Refer the matter to the SREC.

15.4.1.6 In the event of upholding or rejecting the appeal, the decision of the REC: ACU (or REC: ACU – subcommittee) is final;

15.4.1.7 If the REC: ACU or REC: ACU – subcommittee refers the matter to the SREC it undertakes to adhere to any decision taken by the SREC, regarding the matter;

15.4.1.8 Researchers retain the right to complain or appeal to the National Health Research Ethics Council in the event that they remain dissatisfied with the outcome of the appeal.

15.4.2 **Appeal process (Senate Research Ethics Committee Level)**

15.4.2.1 Notice in writing of the intention to refer the matter must be given by the Chairperson of the REC: ACU to the Chairperson of SREC. The PI must also be notified of this decision. The chair of the SREC must notify the Vice-Rector: Research, Innovation and Postgraduate Studies of the receipt of the appeal;

15.4.2.2 The basis of the appeal and all the relevant documentation must be submitted in writing to the Chairperson of the SREC within seven (7) days of the notice in 17.4.2.1 above;

15.4.2.3 The matter is usually heard on the basis of written submissions only, that is, no oral evidence is led. It is therefore important that the Chairperson of the REC: ACU ensure that all the information that is relevant is before the Appeal Panel of the SREC. The PI, the REC: ACU and other interested parties may make submissions to augment the existing record, in accordance with the timelines set out by the Chair of SREC (see below under Appointment of Appeal Panel).

15.4.2.4 Composition of Appeal Panel

15.4.2.4.1 The appeal will be heard by an independent panel made up of 3 to 5 members, who will ordinarily be members of the SREC, but may be other persons if deemed necessary by the Chairperson of the SREC;

15.4.2.4.2 The members of the panel must include one member from the Faculty concerned. The members of the panel must not be members of the REC: ACU;

15.4.2.4.3 In the case where special expertise might be needed to deal with technical aspects of the substance of the appeal, then such expertise should be sought without compromising the independence of the panel.

15.4.2.5 Appointment of Appeal Panel

The panel must be appointed by the Chairperson of the SREC who must draw up timelines for the submission of documentation, for the hearing of the appeal and for delivery of the panel's decision.

15.4.2.6 Powers of Appeal Panel

The appeal panel is empowered:

15.4.2.6.1 to request further information if needed;

15.4.2.6.2 to interview the parties; but if it does so, it must be in the presence of both parties, failing which, it must report to the other party the substance of the submissions or answers given and allow an opportunity to rebut;

15.4.2.6.3 to require the parties to seek to resolve the matter through mediation or seek some other route as to a possible resolution of the dispute; and

15.4.2.6.4 to recommend to the REC: ACU that the appeal be upheld; or

15.4.2.6.5 to recommend to the REC: ACU that the appeal be dismissed;

15.4.2.7 Researchers retain the right to complain or appeal to the National Health Research Ethics Council if they remain dissatisfied with the outcome of the appeal.

15.5 Complaints process

15.5.1 All complaints against the REC: ACU, for matters as described above, should be submitted directly to the REC: ACU Chairperson, who should make every effort to investigate the complaint thoroughly, resolve the issue and communicate the outcome of the investigation to the complainant;

15.5.2 Only complaints that cannot be resolved effectively by the REC: ACU Chairperson, or that are deemed to be irresolvable by either the researcher or REC: ACU Chairperson, should be submitted to the SREC;

15.5.3 The Chairperson of the SREC shall notify the Chairperson of the REC: ACU that a complaint has been made against the REC: ACU, inform him/her of the nature and substance of the complaint and request that he/she responds in writing to the complaint, providing sufficient detail;

15.5.4 The Chairperson of the SREC shall appoint an ad hoc subcommittee to investigate the complaint and report back to the full SREC at a forthcoming meeting. Where necessary the subcommittee may need to interview the complainant, the Chairperson and/or other persons;

15.5.5 The SREC shall compile a report of its findings and recommended action. The report shall be submitted to the Vice Rector: Research, the Chairperson of the REC and other parties if deemed necessary by the SREC;

15.5.6 The Chairperson of the SREC shall notify the PI of the outcome of the SREC investigation.

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APPENDICES

Appendix I: REC: ACU Disclosure of conflict of interest

I, _____

Surname and initials

hereby declare that there is a real, perceived, or potential risk to my scholarly/scientific, and/or ethical and/or professional judgment in the review of one or more of the research studies serving at the REC: Animal Care and Use (REC: ACU) meeting today.

No ☐ Yes ☐

If **Yes,** please provide

- The REC: ACU protocol number(s) [ ]
- A brief synopsis of the nature of the conflict of interest(s)

I hereby declare that the disclosed information is correct and that no other situation of real, potential, or apparent conflict of interest is known to me. I will inform the Research Ethics Office of any change inthese circumstances, including if an issue arises during the course of the meeting or during the progression of the research study itself.

_____ _____

Member signature Date

REC: ACU CHAIRPERSON REVIEW WHEN CONFLICT OF INTEREST IS DECLARED

In consultation with the Committee, I have reviewed the above declaration and consider the conflict of interest to be such that the member is

Recused ☐ Not recused ☐

from the meeting during the discussion of the particular project(s).

_____	_____	_____
Chairperson's Signature	Chairperson's Printed Name	Date