

CONSTITUTION OF UNIVERSITY OF THE FREE STATE ANIMAL RESEARCH ETHICS COMMITTEE

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1. INTRODUCTION

Research is fundamental to the vision of the University of the Free State (UFS) and the UFS aims to be one of the top three research universities in South Africa. Such a vision can only be achieved by conducting ethically sound research. The University will pursue this vision through its mission of advancing excellence in the scholarship of research. Therefore, the UFS is committed to becoming a university recognised across the world for excellence in academic achievement as a result of conducting ethically sound research. The Senate Research Ethics Committee (SREC) has been established as a standing committee of the UFS, with its main goal being to promote this principle. To achieve this goal, specific Research Ethics Committees have been established to conduct objective ethical reviews of all research projects. The Animal Research Ethics Committee (AREC) reports to the SREC and function independently from the faculties of the UFS.

The University of the Free State is involved with animals used for scientific purposes in medicine, biology, agriculture, veterinary and other animal sciences, as well as teaching studies in South Africa. The University includes animal use in research, teaching, field trials, product testing, diagnosis, the production of biological substances and environmental studies.

The following documents can be read in conjunction with this constitution:

- Animal Protection Act No.71 of 1962
- Animal Diseases Act No.35 of 1984
- Veterinary and Para veterinary Professions Act No.19 of 1982
- Medicines and Related Substances Control Act No.101 of 1965
- Fertilisers, Farm feeds, Agricultural Remedies and Stock Remedies Act No.36 of 1947
- SANS 10386:2021. The care and use of animals for scientific purposes
- Ethics in Health Research. Principles, Processes and Structures. Department of Health, Republic of South Africa (2015).
- Any other relevant provincial and national legislation
- Guide to the care and use of animals in research and teaching. Animal Research Ethics Committee, University of the Free State.

These documents are amended from time to time. A central feature is that the University must have an Animal Research Ethics Committee ("the AREC"), and that no animal may be used for research or teaching without the AREC's prior approval.

2. OBLIGATIONS OF RESEARCHERS AND TEACHERS

The care and well-being of experimental animals are the ultimate responsibility of the researchers and teachers. This includes, but is not limited to, compliance with the conditions set by the AREC for a particular protocol. The UFS AREC Constitution and attachments include these and other University provisions.

The contact of research on animals is bound by the provisions of the UFS Code of Conduct for Research.

3. GUIDING PRINCIPLES

In carrying out its Terms of Reference (see Attachment 2), the AREC must satisfy the legal and ethical requirements of the University, while facilitating appropriate research and teaching activities. It aims to do so primarily by encouraging awareness of legal and ethical issues of animal welfare among researchers and teachers, while also reserving the power to enforce compliance with the University.

In pursuance of these aims, the AREC must ensure that the care of all animals on and off University properties minimises pain, distress and discomfort. Animal use in research and teaching is allowable only when:

- (i) here is not an acceptable procedure alternative to the use of animals available;
- (ii) justification is provided in terms of expected advancement in knowledge;
- (iii) facilities and techniques are available to ensure that pain, distress and discomfort to animals is minimised; and
- (iv) the researcher or teacher is competent in the appropriate procedures.

In applying these principles, applicants submitting protocols for approval must comply with the "Guide to the care and use of animals in research and teaching" of the AREC.

4. MEMBERSHIP AND FUNCTIONING

Refer to the Terms of Reference – Attachment 2, and Current Membership – Attachment 3 of this document.

5. FURTHER AREC OBLIGATION

The AREC has the following further obligations:

- (i) Develop and maintain Emergency Procedures for experimental animals (see Attachment 6)
- (ii) Develop and maintain Grievance Procedures (see Attachment 8)
- (iii) Develop and maintain Application and Reporting Procedures (see Attachment 9).

6. ATTACHMENTS

The attachments to this Constitution are policies created by the AREC and are to be read in conjunction with the Constitution. These policies may be varied from time to time without altering the constitution.

UNIVERSITY OF THE FREE STATE ANIMAL RESEARCH ETHICS COMMITTEE

GUIDELINES COVERING THE WELFARE OF ANIMALS USED FOR SCIENTIFIC RESEARCH AND TEACHING ACTIVITIES

(i) **DEFINITIONS:**

(a) Animal

Live, sentient non-human vertebrate, including eggs, fetuses and embryos, that is; fish, amphibians, reptiles, birds and mammals, and encompassing domestic animals, purposes-bred animals, farm animals, wildlife and higher invertebrates such as the advanced members from the Cephalopoda and Decapoda. The immature forms of non-human vertebrates from the following stages of development are included:

- i) mammals, birds and reptiles: from halfway through gestation or incubation periods;
- ii) fish and amphibians: from the time at which they become capable of independent feeding.

IMPORTANT NOTE FROM SANS 10386:2021 - The researchers should submit proposals to use all invertebrates for consideration by the AREC.

(b) Distress

Acute or chronic response of an animal caused by stimuli that produce biological stress which manifests as abnormal physiological or behavioural responses.

(c) Euthanasia

Act or practice of ending the life of an animal as painlessly and humanely as possible.

(d) Farm animals

Animals which are used in commercial agriculture, including cattle, sheep, pigs, poultry, goats, horses, fish and wildlife that are farmed.

(e) Institution

Entity that uses animals for scientific purposes and teaching studies.

(f) Pain

Awareness of acute or chronic discomfort that occurs in varying degrees of severity as a result of study procedures, injury, disease or confinement.

(g) Researcher

Person recognised by the AREC as competent to conduct an approved scientific study that involves animals.

(h) Scientific study

Study or a series of related studies that form a discrete piece of work, performed to acquire and develop knowledge or techniques in any scientific discipline, including studies for the purposes of research, diagnosis, product testing, field trials, environmental studies, and the production of biological substances.

(i) Teacher

Person recognised by the AREC as competent to conduct an approved teaching activity that involves animals.

(j) Teaching activity

Activity that involves animals and is performed to acquire, develop or demonstrate knowledge or techniques in any scientific discipline, including studies for the purposes of teaching and training in primary, secondary and tertiary institutions.

(k) Wellbeing

Welfare. Tendency towards a relatively stable equilibrium between interdependent elements, especially as maintained by physiological and psychological processes.

(ii) **GENERAL PROVISIONS**

- (a) The following provisions supplement, and are to be read in conjunction with, the Constitution of the Animal Research Ethics Committee.
- (b) In these Guidelines, "researchers" refers to the person named as Principal Investigator in an application (whether for research or for teaching) which has been approved by the AREC.
- (c) Unless otherwise provided, the Guidelines apply to all dealings with vertebrate animals kept on and off University properties, including observational, nutritional, metabolic, physiological, surgical or psychological activities.
- (d) Scientific and teaching activities must not commence until written approval has been obtained from the AREC.
- (e) No animals are to be procured for specific research projects until written approval has been obtained from the AREC.
- (f) All experiments involving live animals shall be carried out under the supervision of a member of staff with appropriate training and experience.
- (g) All staff involved in performing physical veterinary procedures should either be registered with or authorised by the South African Veterinary Council to perform these procedures.
- (h) Daily animal care records should be kept, in order to determine the duration of problems, should they arise, concerning the animals' wellbeing, and to monitor the efficiency of husbandry practices. A Daily Activity Log must be maintained and displayed where the animals are held. A template for the log may be obtained from the director of the Animal Research Centre. The log must be made available at any time for members of the AREC to inspect.
- (i) On completion of experiments, researchers shall ensure that animals return to grazing paddocks or animal houses are clearly identified and that the exact nature of the experiment is recorded on individual animal records. Individual animal records must be maintained for animals that are used for more than one research protocol. The records must also be available anytime should the members of the AREC require them. Researchers and teachers can make use of the Animal Welfare Score Sheet available on the RIMS system.
- (j) Any unforeseen sign of pain, suffering or distress in any animal must be reported promptly to the Emergency Contact listed on the Authority and/or the director of the Animal Research Centre or experimental facility (see Attachment 6)
- (k) Researchers in doubt as to their responsibilities should seek guidance from the AREC Chair.

- (I) The justification for continuing or repeating experiments must be on the basis of the results obtained as well as the potential effects on the welfare of the animals, and must constantly be subject to review.
- (m) Researchers should note that, apart from legal and moral considerations, activities involving the use of animals that produce undue pain, distress or discomfort may result in data that are unsatisfactory or misleading when extrapolated to normal conditions.

(iii) SPECIFIC PROVISIONS

- (a) Other than in exceptional circumstances, any large mammals may not be tethered as part of a research protocol. Any large mammals may not normally be tethered in metabolism cages. Alternatives to tethering in terms of conditioning are to be investigated, and researchers are advised to seek advice from the AREC. The maximum time that sheep may be held in metabolism cages is 28 days.
- (b) Wild animals can suffer severe stress on their first contact with humans and new surroundings. Researchers must use the most effective techniques for minimising stress during restraint, capture, marking, transport, maintenance and killing of wild animals. In appropriate instances prior permission to carry out these procedures on wild vertebrates must have been granted by the appropriate Governing Authorities. The relevant permits/licenses must be obtained from the Free State Department Economic development, Tourism and Environmental Affairs as well as the National Department of Agriculture, Land Reform and Rural Development.
- (c) Domestic farm animals should be healthy, well grown, adequately vaccinated and treated for internal and external parasites, unless this specifically affects the research proposed, before entry on to any UFS property.
- (d) Strict adherence to the SANS 10386:2021 guidelines are followed in all animal experimentation.

ANIMAL SURGERY

- (a) In these Guidelines, chronic surgical experiments are those in which a surgically manipulated animal is allowed to recover from anaesthesia, while acute experiments are those in which it is not.
- (b) Persons undertaking chronic surgical experimentation will normally be required to have satisfactorily completed appropriate training or have an equivalent amount of practical experience in undertaking surgical techniques. All persons must either be registered or authorised to perform these techniques by the SAVC, as required by South African law.
- (c) Acute surgical experiments may be carried out by persons without surgical training provided the animal is suitably anaesthetised and the operation is supervised by a suitably qualified person who is either registered or authorised by the SAVC.
- (d) Neither this section nor the AREC Constitution applies to surgical operations on University property which are considered a normal part of routine husbandry practices that should adhere to SAVC regulations.

(iv) STUDENT RESEARCHERS

- (a) Postgraduate or other students involved in animal research may not be listed as a Principle Investigator on an application submitted to AREC, but they must be mentioned in the application as students.
- (b) Before commencing their work, all such students should complete an appropriate training course in animal welfare, such as a workshop. The AREC could recommend any person named on an application attend such a workshop, unless the person can demonstrate that they have attended or completed equivalent training.

(v) FURTHER INFORMATION

The following guideline documents are available:

- SANS 10386:2021 The care and use of animals for scientific purposes
- American Veterinary Association Guidelines
- Canadian Council Care and Use Committee (Guidelines on the use of Farm Animals)
- NSPCA Humane endpoints Score Sheet
- NSPCA Animal Welfare Score Sheet

(vi) STANDARD OPERATING PROCEDURES:

The AREC has developed a number of Standard Operating Procedures in consultation with UFS Researchers. The Standard Operating Procedures are available from the administration office of the AREC. All SOP's comply with the guidelines as set out in the SANS 10386:2021 document. However, it remains the responsibility of each facility and researcher to develop and maintain their own SOP's. The AREC may be requested to provide input on these SOP's. These SOP's may be submitted together with an application for ease of reference.

UNIVERSITY OF THE FREE STATE ANIMAL RESEARCH ETHICS COMMITTEE

TERMS OF REFERENCE

The AREC is obliged to consider all ethical and welfare aspects, as well as the scientific or educational value of the use of animals for research and reaching purposes, in accordance with the UFS AREC Constitution. These terms of reference should be read in conjunction with the AREC Constitution. In particular, the AREC must:

- (i) approve guidelines and SOP's (when requested by the institution as stated in the SANS 10386:2021) for the care of animals that are bred, held, and used for scientific purposes on behalf of the institution;
- (ii) examine all applications for the use of animals, and approve, modify or reject them in accordance with the guiding documents;
- (iii) approve only those studies for which animals are essential and justified and which conform to the requirements of the SANS 10386:2021, taking into consideration factors including ethics, the impact on the animals and the anticipated scientific or educational value.
- (iv) withdraw approval for any project which no longer complies with the constitution or has been seen to be misleading to the AREC;
- (v) maintain a record of proposals and projects;
- (vi) comply with the reporting requirements of the University;
- (vii) monitor the acquisition, transport, production, housing, care of, use, and fate of animals;
- (viii) ensure that any unexpectedly suffering animal is treated or humanely euthanized and that the matter is reported to the AREC in a timely manner;
- (ix) examine and comment on all plans and policies of the University which may affect the welfare of animals used for scientific purposes;
- (x) Determine any measures, develop appropriate policies, make any recommendations or take any proper action needed to ensure that the standards imposed by the University are maintained.
- (xi) require that all members declare any conflict of interest and deal with situations in which a conflict of interest arises;
- (xii) perform all other duties imposed on the University for the care and use of animals for scientific purposes; and
- (xiii) consider and report on any matter referred to it by the Vice-Chancellor, Deputy Vice-Chancellor or the SREC of the UFS.

UNIVERSITY OF THE FREE STATE ANIMAL RESEARCH ETHICS COMMITTEE

CURRENT MEMBERSHIP

Chair

Appointed by the Vice-Rector: Research and Internationalisation (or chairperson of the SREC), following a nomination process within the AREC from the AREC members. The Chair is subsequently elected by the AREC members in addition to the membership, for a three year, once renewable term.

- a. The Chair of the AREC is elected from the members of the AREC.
- b. The Chair must be a permanent staff member of the UFS.
- c. The Chair should preferably hold a senior position in the institution.
- d. As recommended by the NHREC, the Chair should have experience serving on an AREC. Therefore, the Chair should preferably have served on the AREC for at least one year, in order to be familiar with the processes and functioning of the AREC.
- e. The Chair should have a background in Biological sciences.
- f. The following member portfolios cannot be elected as Chair: Category A member, Category C member, Category D member, and Representative from the Animal facilities of the UFS.
- **NOTE:** Category A member and the Representative from the Animal facilities of the UFS cannot be elected as Chair due the high incidence of conflict of interest that will be occur in the execution of the duties as Chair.

Category C member cannot be elected as Chair because they are not employed by the UFS.

Category D member cannot be elected as Chair because they are most likely not employed by the UFS, or may not have a background in Biological sciences.

- g. The Chair may not serve in the portfolio as Chair for a continuous period of more than six years.
- h. The Chair is elected at the first AREC meeting after the portfolio of Chair became vacant.
- i. The co-chair will chair the meetings during the period when the portfolio of Chair is vacant and during the meeting when a new Chair is elected.
- j. Nominations for the portfolio of Chair:
 - i. All members of the AREC may nominate a member for the portfolio of Chair.
 - ii. Only nominees nominated by one member and second by one other member will be included in the election of the portfolio of Chair.
 - iii. All members of the AREC has one (1) vote for the election of the Chair.

k. <u>Election process for the portfolio of Chair:</u>

- i. Election can be by the showing of hands or by closed ballot.
- ii. Nominated members also has one vote.
- iii. If election occur by the showing of hands, the nominated member are excused from the meeting during the election process.
- iv. The nominated member with the highest number of votes are the elected Chair.
- v. If more than one member have an equal number of highest votes, a second round of voting will occur.
- vi. During the second round of voting, each member will have one vote.
- vii. During the second round of voting, the vote will only be between the members with equal numbers of highest votes from the first round of voting.
- viii. An election process similar to the first round of voting will be followed.
- ix. The nominated member with the highest number of votes are the elected Chair.
- x. If a tie exist after the second round of voting, the matter will be referred to the SREC for selecting a Chair from the nominated members with an equal highest number of votes following the second round of voting.
- xi. The Vice-Rector: Research and Internationalisation (chairperson of the SREC) must formally and in writing appoint the Chair, following the election process above.
- I. <u>Term of service of the Chair:</u>
 - i. The Chair is elected in the position of Chair for a period of three (3) years.
 - ii. If the remaining part of the term of appointment as member (term of membership with the AREC) of the newly elected Chair is less than three (3) years, the AREC will request the SREC/ Vice-Rector: Research and Internationalisation to extend the duration of that term to end three (3) years from the date of election as Chair.
 - iii. The Chair may be re-elected once.
 - iv. The Chair may not serve in the portfolio as Chair for a continuous period of more than six years.

Vice-Chair

Appointed from the membership and selected by the AREC. The person must be UFS employee. The Vice-Chair will hold office for the term of their appointment to the AREC.

- a. The Vice-Chair of the AREC is elected from the members of the AREC.
- b. The Vice-Chair must be a staff member of the UFS.
- c. The elected Chair cannot simultaneously serve as Chair and Vice-Chair
- d. The Vice-Chair is elected at the first AREC meeting after the portfolio of Vice-Chair became vacant.
- e. Nominations for the portfolio of Vice-Chair:
 - i. All members of the AREC may nominate a member for the portfolio of Vice-Chair.

- ii. Only nominees nominated by one member and second by one other member will be included in the election for the portfolio of Vice-Chair.
- iii. All members of the AREC has one (1) vote for the election of the Vice-Chair.
- f. <u>Election process and appointment for the portfolio of Vice-Chair:</u>
 - i. Election can be by the showing of hands or by closed ballot.
 - ii. Nominated members also has one vote.
 - iii. If election occur by the showing of hands, the nominated member are excused from the meeting during the election process.
 - iv. The nominated member with the highest number of votes are the elected Vice-Chair.
 - v. If more than one member have an equal number of highest votes, a second round of voting will occur.
 - vi. During the second round of voting, each member will have one vote.
 - vii. During the second round of voting, the vote will only be between the members with equal numbers of highest votes from the first round of voting.
 - viii. An election process similar to the first round of voting will be followed.
 - ix. The nominated member with the highest number of votes are the elected Vice-Chair.
 - x. If a tie exist after the second round of voting, the chair of the AREC will have an additional vote to determine the member elected to the portfolio of Vice-Chair.
 - xi. The Vice-Rector: Research and Internationalisation (chairperson of the SREC) must formally and in writing appoint the Vice-Chair, following the election process above.
- g. <u>Term of service of the chair:</u>
 - i. The Vice-Chair is elected in the position of Vice-Chair for the full duration of the term of appointment on the AREC as a member.

Membership

A. MEMBERSHIP TO THE AREC (SEE also A-2 Nomination and appointment of AREC members)

Member = member of the AREC with full voting rights.

The number of members may vary and may be changed by the AREC if necessary. Additional members may be co-opted for a limited time as needed.

Total number of members:

At least four (4) members, one from each category (A, B, C, and D discussed below).

A-1 Breakdown of membership:

Members are appointed according to the SANS 10386:2021 / NHREC categories.

I. Category A (Veterinarian):

A person with qualifications in veterinary science, with experience relevant to the studies of the institution or, in special circumstances, a person with qualifications and experience to provide comparable expertise.

a. At least 1 member

- b. A second member if possible.
- c. Appointed from UFS staff if possible.

(SEE ALSO: QUORUM REQUIREMENTS FOR AREC MEETINGS)

II. Category B (Experienced animal researcher):

A person with substantial recent experience in the use of animals in scientific studies or teaching activities.

NOTE: The AREC has the prerogative to determine if a member/nominated member qualifies as a Category B member, applying the guidelines provided in the SANS 10386:2021.

a. At least four (4) members

- b. Appointed from the Faculties of Health Sciences and Natural and Agricultural Sciences.
- c. Must comply with the requirements for a Category B member as described in the SANS 10386:2021.
- d. More may be appointed if deemed necessary by the AREC.
- e. As far as possible, there should be <u>equal representation from the Faculties of Health</u> <u>Sciences and Natural and Agricultural Sciences</u> **NOTE:** If the recommended number of Category B members from a specific Faculty cannot be reached, those vacant positions may be filled with Category B members from any other faculty.
- **NOTE:** Deans of Faculties, members of the AREC and members of the SREC may nominate members. The names of the nominees will be sent to the AREC. The AREC will recommend members for approval to the SREC. Both the AREC and SREC must take effort to ensure equal representation by the Faculties of Health Sciences and Natural and Agricultural Sciences.

III. Category C (Animal welfare organisation):

A person with demonstrable commitment to and established experience in furthering the welfare of animals, who is not employed by or otherwise associated with the institution, and who is not 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 organisation. This member should bring an animal welfare perspective to the AREC deliberations. While all members of the ARECs 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

a. At least one (1) member

- b. A second member if possible.
- c. Appointed from Animal Welfare Organization or a Veterinarian as described in the SANS 10386:2021.

IV. Category D (Lay member):

An independent person who does not currently and has not previously conducted scientific studies or teaching activities using animals, and who is not an employee of the institution, except under defined circumstances. A lay member may be appointed from the Faculties of Economic and Management Sciences, Education, The Humanities, Law, or Theology and Religion. If such an employee is appointed, the individual shall be in a senior position and shall not be supervised by other members of the committee or by anyone involved in animal research at the institution. The institution shall provide clear reasons for the necessity to appoint an employee in this category.

- a. At least one (1) member
- b. A second member if possible.
- c. Appointed according to the SANS 10386:2021 requirements for a Lay-member.

V. Representative from Animal Facility:

a. One (1)member

b. Representatives from other Animal facilities of the UFS may be co-opted if deemed necessary by the AREC.

NOTE: Current animal facilities of the UFS:

- i. Animal Research Center of the UFS (Faculty of Health Sciences)
- ii. Animal facility on QwaQwa campus (Faculty of Natural and Agricultural Sciences).
- iii. Metabolic unit (Faculty of Natural and Agricultural Sciences)
- iv. Zebra fish unit (Faculty of Natural and Agricultural Sciences)
- v. Paradys Experimental Farm (Faculty of Natural and Agricultural Sciences)
- **NOTE**: When a study is performed at the animal facility on the Qwa-Qwa campus, the person in charge of the unit will be co-opted on the committee.

VI. Additional members

- a. Not compulsory
- b. May be appointed or co-opted if deemed necessary by the AREC.

NOTE: It will typically include members with the following specialities:

- i. Any member with expertise that will benefit the functioning of the committee.
- ii. Bioethicists
- iii. Biometricians
- iv. Statisticians
- v. Behavioural biologists
- vi. Ethologists
- vii. Co-opted people from time to time to provide expertise on specific issues, or to seek written advice.

VII. ETHICS OFFICER

Currently no Ethics officer from the Central Ethics Office at the DRD will serve on this committee.

VIII. EX OFFICIO MEMBERS (Administrative officer)

a. One (1) member

A-2 Nomination and appointment of AREC members:

- a. Nominations for proposed members for the AREC occur only when a vacancy exists in the membership of the AREC.
- b. The chair of the AREC or chair of the SREC will request nominations for a vacant position in the AREC.
- c. Nominations must comply with the requirements for the vacant position (see A-1 Breakdown of membership).
- d. Members of the AREC, members of the SREC and Deans of Faculty (UFS) can nominate members for the AREC.
- e. Nominations must be in writing.
- f. Nominations must accept the nomination in writing.
- g. Serving on the AREC is a voluntary service provided by members, as such, no members may be forced to serve on the AREC.
- h. Nomination process:
 - i. Proposed members for the AREC must be nominated by at least one person (from above mentioned group), and second by one other person (from above mentioned group).
 - ii. The names of the nominees will be sent to the AREC. The AREC will recommend members for approval to the SREC.

- **NOTE:** For Category B members, both the AREC and SREC must take effort to ensure equal representation by the Faculties of Health Sciences and Natural and Agricultural Sciences. If the recommended number of Category B members from a specific Faculty cannot be reached, those vacant positions may be filled with Category B members from any other faculty.
 - i. Appointment of AREC members:
 - i. The SREC/ Vice-Rector: Research and Internationalisation will appoint members of the AREC from the nominees recommended by the AREC.

j. <u>Term of service of AREC members:</u>

- i. Members are appointed for a period of three (3) years.
- ii. Members may be re-elected for additional terms of three years.
- iii. Members may only serve a maximum period of three (3) terms.
- iv. A member may be re-elected for an additional term, at the end of term, above the three (3) term limit, if proof can be provided that no alternative person can be recruited for that specific portfolio.

QUORUM REQUIREMENTS FOR AREC MEETINGS

The AREC decided to deviate from the requirements set in the SANS 10386:2021 to enable the continuous functioning of the committee.

The AREC will consider a meeting as quorate when 1/3 of members are present.

The proposed requirements for a quorum, and the accompanying motivation, will be presented to the NHREC for their input and approval.

SANS 10386:2021 par. 5.3.3.5.6 addresses Meeting procedures and 5.3.3.5.6.1 states: "At least one member from each of the membership categories A, B, C and D shall be present throughout the meetings to establish a quorum for the conduct of a meeting. Categories C and D members, together, shall represent at least one-third of those members present."

- Failure to reach a quorum, according to the requirements of SANS 10386:2021 par 5.3.3.5.6.1 is highly likely, considering only having one Category A member, one Category C member, and one Category D member.
- b. It is unlikely that the AREC (UFS) will ever have more than one member in Categories A and C, due to difficulty to attract, appoint and retain members in these categories.
- c. The AREC (UFS) will implement operational procedures to ensure proper input and contributions from Category A, C and D members, even when they are absent during meetings. The operational procedures will include the following:

I. Category A member (Veterinarian):

- i. All Animal Ethics applications will be reviewed/evaluated by the veterinarian before the AREC meeting, with special emphasis regarding veterinary procedures, animal welfare and aspects of the application that will be the responsibility of a veterinarian. The veterinarian needs to APPROVE the application. The application can be send back repeatedly to the applicant to clarify and/or improve the application to the satisfaction of the veterinarian, before the official meeting.
- ii. If the category A member is absent during a meeting, only applications APPROVED by the veterinarian before the meeting, will be considered by the meeting for final ethics approval.
- iii. The Chair of the AREC takes responsibility to ensure compliance with the above during meetings.

OR

iv. The Category A member will be allowed to transfer his powers and responsibilities to a registered Para veterinary professional to act as a secundes during meetings where she/he cannot be present. The secundes must be approved by the AREC before the meeting commence.

II. Category C member (Animal Welfare Organization representative)

- i. The category C member typically know in advance, at which meetings she/he will be absent.
- ii. Effort will be made to plan/reschedule meetings for dates when the Category C member can be present.
- iii. The Category C member will be allowed to send a secundes to meetings where she/he can not be present. The secundes must be approved by the AREC before the meeting commence.
- iv. All Animal Ethics applications will be reviewed/evaluated by the Category C member before the AREC meeting, with special emphasis regarding animal welfare.
- v. If the category C member is absent during a meeting, only applications with written feedback from this member will be discussed.

III. Category D member (Lay-member)

- i. Effort will be made by the AREC to appoint more than one Category D members to limit the possibility of meetings with no Category D member present.
- The Category D member will be allowed to transfer his powers and responsibilities to a secundes during meetings where she/he cannot be present. The secundes must comply with all the requirements for a Category D member. The secundes must be approved by the AREC before the meeting commence. The secundes must be knowledgeable on Animal ethics.

Obligations of members

Committee members are obliged to treat AREC business as confidential and to declare any conflict of interest to the committee. Members are required to complete a confidentiality acknowledgement and conflict of interest undertaking prior to their appointment. If members have any questions or concerns about an application they may seek clarification from the researcher, prior to the meeting, after consulting the Chair.

The AREC will deal with situations in which a conflict of interest arises by:

- Requiring members to disclose the nature of their interest and conflict as soon as possible after they become aware of anything that may be reasonably considered to be a conflict of interest.
- Requiring a member whose objectivity may be influenced by an interest to leave the meeting at an appropriate time.
- Considering and responding to any concern raised by a researcher or teacher that an AREC member has an interest that may have influenced the objectivity of an AREC decision. In this instance, the Chair must advise the complainant, in writing, of the AREC's response. If the complainant is not satisfied with the AREC's response, a grievance may be lodged, in accordance with the UFS AREC Grievance Procedures.

Executive

The AREC delegates certain powers to its Executive Committee which consists of the Chair, the Secretary, the Category A member and one other member. The Secretary serves on the Executive Committee, as on the Committee, in a non-voting capacity.

The Executive Committee may not approve new proposals, but it may approve minor modifications to existing projects for review at the next AREC meeting.

Frequency of meetings

The committee will meet at least once every 4 months. Dates for the following academic year are finalised at the end of the previous year. Emergency meetings are arranged *ad hoc*.

UNIVERSITY OF THE FREE STATE ANIMAL RESEARCH ETHICS COMMITTEE

CONFIDENTIALITY ACKNOWLEDGEMENT To be signed by each committee member and kept on record.

Statement and undertaking by members of the Animal Research Ethics Committee

I, the undersigned,

_____ (full names)

hereby declare that I shall keep confidential all information that may come to my knowledge through the proceedings of the Animal Research Ethics Committee of the UFS.

I understand that breach of confidentiality may cause damage to trial subjects, researchers and research projects that may result in legal liability of the University and of myself.

Conflict of Interest declaration:

I further undertake to declare to the Animal Research Ethics Committee of the UFS any interest I may have in any research project discussed by the Committee and to excuse myself from the meeting for the duration of the discussion of such project.

SIGNED at ______ on the ______202___

SIGNATURE

Attachment 5

UNIVERSITY OF THE FREE STATE

ANIMAL RESEARCH ETHICS COMMITTEE

MONITORING AND INSPECTION

INSPECTIONS

Members of the AREC must inspect all animal housing and laboratory areas regularly. Inspections are to be organised and outcomes recorded by the Secretary. Records of inspections include the names of those who attended, observations, any identified problems, follow-up and outcomes. Inspections of fieldwork conducted at extremely remote sites or where access is difficult, may be inspected by an agent or delegate and can be facilitated or corroborated with photographic or video imaging. Any new facilities must be inspected prior to the animals being housed in the facilities.

Inspections are designed to ensure all housing and research facilities are of a high standard and animals are being cared for in accordance with the SANS 10386:2021. These inspections also enable the members to fully appreciate the facilities and the research being undertaken. A Report to the SREC on inspection tours must be submitted in writing.

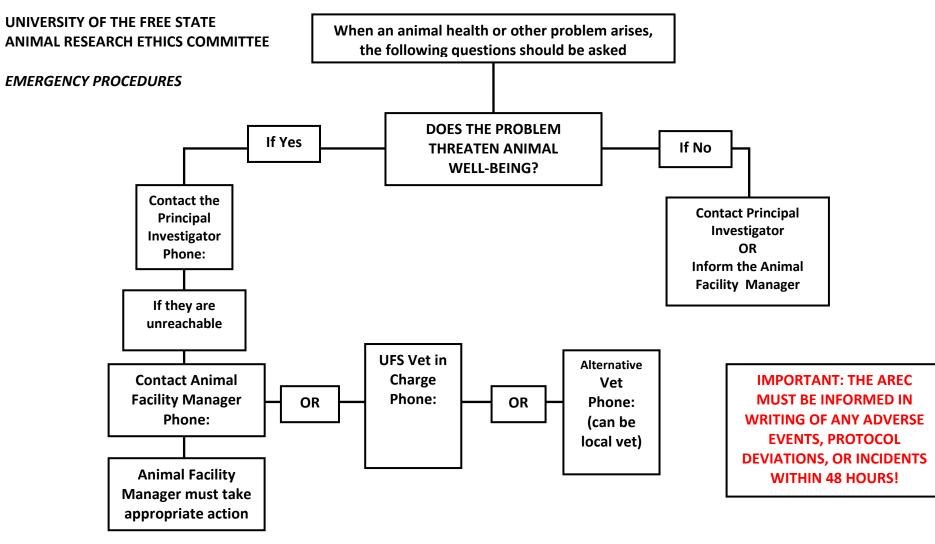
At least two members of the AREC are expected to visit the animal holding areas on campus and the outlaying farms at least once annually.

MONITORING

In accordance with the SANS 10386:2021, once an animal is allocated to a project, the Principal Investigator or associate researcher is responsible for the day-to-day monitoring of its wellbeing. Prior to this allocation, day-to-day monitoring is the responsibility of the animal facility managers. The AREC monitors these activities during inspections and in the review of reports, unless otherwise determined by the AREC. Mortality and morbidity reports must be submitted to the AREC on a monthly basis by all facilities.

The frequency and timing of inspections will be determined by factors such as the number and accessibility of sites, the amount, type and variety of scientific and teaching activities, and whether inspections can be combined with scheduled AREC meetings. The AREC routinely inspects animal holding areas annually. In addition, certain projects may necessitate more frequent inspections of animals and animal use.

Monitoring of protocols performed either off-campus or at remote locations will be considered after photographic evidence of the animal housing facilities has been provided to the AREC. Monitoring of protocols performed on or within the property boundaries of the University will be subject to inspection when the AREC deems it appropriate with or without notice. The AREC also may require that an AREC representative be present during certain procedures being undertaken as part of an AREC approved research protocol.



UNIVERSITY OF THE FREE STATE ANIMAL RESEARCH ETHICS COMMITTEE

GRIEVANCE PROCEDURES

1. Definition of grievance

This mechanism is set up to handle the following situations:

- (a) a formal complaint from a person not satisfied with the outcome or process following an enquiry or concern properly expressed
- (b) complaints from independent people who are not associated with the University with respect to the use of animals in research or teaching
- (c) disputes between researchers or teachers and the AREC with respect to the use of animals in research or teaching
- (d) disputed between members of the AREC

2. Making a complaint

- 2.1 A complaint must be in writing and signed
- 2.2 The complaint must be lodged with the AREC Secretary, or the AREC Chair
- 2.3 Receipt of a complaint must be acknowledged immediately in writing.
- 2.4 Complaints must be passed promptly to the AREC Chair if lodged with the AREC Secretary.

3. Investigation of complaints/Grievances

- 3.1 The responsibility for investigating a complaint lies with the AREC Chair
- 3.2 The AREC Chair must decide whether there is immediate danger of animal pain or distress. Where necessary, the powers given to the AREC by the UFS Executive to halt or suspend a project will also apply.
- 3.3 The AREC Chair shall investigate complaints in the manner provided below.
- 3.3.1 The AREC Chair may delegate the investigation, in whole or in part, to other appropriate persons, including members of the UFS AREC, or other University staff. The AREC Chair remains responsible for the investigation.
- 3.3.2 If the complaint is made against the AREC Chair, or involves potential conflict of interest for the Chair, the AREC Chair must immediately inform the Vice-Rector: Research and Internationalisation or the chairperson of SREC, who will appoint someone else to conduct the investigation. This person will have the same powers as the AREC Chair.
- 3.4 Any person acting under this section is called an "Investigator."
- 3.5 The Investigator may at all times where possible try to resolve the complaint informally.
- 3.6 Where formal processes apply, the Investigator must notify in writing all those judged to be affected by the complaint.
- 3.7 The AREC and the Vice-Rector: Research and Internationalisation or chairperson of the SREC must be notified of the complaint as soon as practical.

- 3.8 The Investigator may investigate by making all enquiries deemed relevant, including, but not limited to, unannounced inspection of facilities, examination of records, discussion with appropriate individuals, inviting any person with an interest in the proceedings to attend a meeting of the AREC for discussions and seeking any further relevant expert advice.
- 3.9 The Investigator shall keep an adequate record of the progress of the investigation.

4. Outcome of the Investigation

- 4.1 The investigator shall prepare a written report for presentation to the AREC as soon as practical.
- 4.2 If a complaint has been resolved informally, the report may simply state that fact.
- 4.3 In other cases, the report shall set out the enquiries undertaken, and contain the Investigator's recommendations on all the issues raised. These may include whether any project or procedure should be modified, whether any person was at fault and any further action that might be suggested.
- 4.4 The AREC shall consider the report and may accept, modify or reject any of the recommendations.
- 4.5 The AREC shall provide a report to the complainant and all interested parties.
- 4.6 Upon receipt of relevant comments from all interested parties the AREC will proceed to reach and implement its decisions on the report as it finds appropriate.

5. Appeals against AREC Decisions

- 5.1 Any person objecting to an AREC decision may request the Vice-Rector: Research and Internationalisation or the chairperson of the SREC to review the decision. Such a request must be made in writing, be made as soon as practical after the decision is brought down and must set out in detail the reasons for dissatisfaction.
- 5.2 All available documentation on the investigation and the AREC deliberations will be available to the Vice-Rector: Research and Internationalisation and the chairperson of the SREC. The ultimate decision of an AREC after such review must not be overridden.

6 Governance structures and powers of the AREC

- 6.1 The AREC Chair is authorised to immediately suspend the ethics approval of a project, pending the outcome of an investigation.
- 6.2 Upon completion of an investigation and perusal of the outcomes and corrective actions taken, the AREC can either lift the suspension, terminate the project's approval, or extend the suspension pending further review or implementation of corrective action.
- 6.3 The AREC does not have executive powers at the UFS to implement disciplinary or corrective action. However, it remains one of the core functions of the AREC to inform the correct governance structures within facilities, departments, faculties, and the university, of any wrongdoing and to make recommendations regarding corrective action.

- 6.4 All disciplinary or corrective action must take place according to the staff and student policies of the UFS, within the correct governance structures.
- 6.5 The AREC and its members are indemnified from any action (intra- and/or extrainstitutional) resulting from failure to correct certain unethical practices.
- 6.6 The authority to issue ethics approval remains with the AREC, regardless of the outcome of disciplinary action. No study is allowed to commence until a formal letter has been issued by the AREC informing the PI of the lifting of the suspension. Any study that commences without such communication, will be seen as a contravention of ethical standards, and may result in legal action.

UNIVERSITY OF THE FREE STATE ANIMAL RESEARCH ETHICS COMMITTEE

APPLICATION AND REPORTING PROCEDURES

1. Meetings and Dates

Meetings are held, the dates thereof predetermined the previous year.

2. Procedures at Meetings

All meetings are formalised and an agenda is followed and minutes taken. All new and pending studies will be discussed and approval granted only with an anonymous vote.

3. Applications

Applications must be submitted on the UFS RIMS Online submission form and uploaded at least 14 days prior to the meeting.

4. Outside Applications

All applications are managed equally.

5. Closing dates and late applications

(Applications for each agenda close 14 days prior to the meeting. Late applications will stand over to the next meeting)

6. The approval process

Approval is signified by the AREC providing an approval number stated on a "FINAL APPROVAL" letter.

Applications may be dealt with in the following ways:

- 6.1 Unconditional approval
- 6.2 Conditional approval ending the provision of further information to the satisfaction, in most cases of the committee. Conditional approval mostly involves the submission of material transfer agreements or contracts, regulatory body permits, registration certificates of research facilities or abattoirs, authorisation certificates of researchers, or permission letters of landowners. In such cases, the researcher MAY NOT proceed until the final approval has been granted.
- 6.3 Modifications required the application can be resubmitted to the committee in the light of its previous comments. If any changes are required to the RIMS application form, this will constitute modifications required. The PI must upload a single pdf file with their response to each of the modifications.
- 6.4 Rejected the project may not proceed and a new protocol must be submitted.

7. Duration and completion of approvals

A final report must be submitted on completion of each project. A time limit of one calendar year is applicable to studies unless special permission is granted. A yearly report must be submitted in all studies for annual renewal. A study may only be renewed twice (maximum three years).

UNIVERSITY OF THE FREE STATE ANIMAL RESEARCH ETHICS COMMITTEE

POWERS OF THE EXECUTIVE COMMITTEE OF THE AREC

The AREC may delegate certain powers to its Executive Committee: The executive has the Authority to:

- Discuss with researchers issues related to the outcome of their application;
- Approve minor modifications to projects for review at the next AREC meeting;
- Approve, in advance, the immediate use of animals should that be required for the diagnosis of unexplained and severe outbreaks, or morbidity/mortality, in animals or people;
- Draft and recommend changes to forms/policies/procedures of the AREC
- Halt or suspend a project; and
- Formally withdraw approval for any project or authorise the treatment or humane killing of any animal.

The Executive Committee does not have the authority to approve new proposals.

All action taken by the Executive Committee is to be ratified at the next meeting of the AREC.

UNIVERSITY OF THE FREE STATE ANIMAL RESEARCH ETHICS COMMITTEE

CONDITIONS FOR ANIMAL EXPERIMENTATION

- (i) Animal experimentation must conform to the SANS 10386:2021 and all other relevant legislation and guidelines as stipulated in the constitution.
- (ii) All research involving experimental animals must have received prior approval by the AREC and the final approval letter must be available at the study location/site.
- (iii) The person responsible must strictly adhere to the experimental procedures approved by the AREC. If during the course of an experiment the procedures are changed; the person responsible must immediately notify the Chair in writing. Changes must be classified as either major or minor changes. Minor changes would include any change that does not directly influence the welfare of the animal. Minor changes may be directly approved by the Executive Committee of the AREC. Major changes include any procedure that may directly influence the physical welfare of the animal, including, but not limited to, changes in housing conditions, the physical experimental procedures, extension of timelines, change of endpoints, or the change of agents administered. If any major changes are necessary, the study must immediately be halted, until reviewed by the Executive Committee of the AREC, and if deemed necessary, reviewed by the full AREC. No study may continue without written approval from the Chair of the AREC. Members of the AREC may request to view daily activity logs during any site inspection. Where possible approval must be obtained prior to continuation of the experiment.
- (iv) All researchers and animal facility managers must promptly (within 48 hours) notify the AREC of any unexpected adverse events that may impact on the well-being of an animal in their care. Notification is to include details of the steps taken to address the problem. In serious cases, no further experimentation is to be undertaken until the protocol has been reviewed by the AREC.
- (v) All researchers must make reports to the AREC as requested, including prompt notification of any adverse events that impact on animal wellbeing, advice when a project is completed or discontinued and the information required for the annual report of any on-going project.
- (vi) A final report must be submitted on completion of all projects.