POLICY AND PROCEDURES (2015)

1. TERMS OF REFERENCE

1.1 Mandate

The Animal Ethics Committee (AEC) is a subcommittee of the Committee for Research Ethics and Integrity of the University of Pretoria, which reports to the Senate Committee for Research. The mandate of the AEC is to ensure that the use of experimental animals is justified, that alternatives have been considered, that the number of animals used is reduced to a minimum, that unnecessary suffering of the animals is excluded and their well-being ensured and that the S.A. National Standard (the care and use of animals for scientific purposes), i.e. welfare standards for each species, is maintained (see Appendix 1).

1.2 Membership

The composition of the Animal Ethics Committee will be in accordance with the National Standard and will be as follows:

Faculty of Veterinary Science (3 members of which one will act as the Chairperson)

- Faculty of Natural and Agricultural Sciences (3 members)
- Faculty of Health Sciences (2 members)
- Faculty of Law (1 member)
- The Director of the UPBRC (Ex-officio non-voting expert consultant)
- Representative from an Animal Welfare Organization (Ex-officio) and
- A representative with scientific training, but not employed by the University of Pretoria

The composition and functioning of the Committee can be adjusted to meet the requirements of the National Standard or any other legislation that controls the functioning of the AEC or any related Ethics Committees. *Ex-officio* members are appointed for their tenure, members of the Faculties of Health Sciences, Veterinary Science and Law are appointed by the respective Deans, and members of the Faculty of Natural and Agricultural Sciences are appointed by its Faculty Board. The Chairperson is appointed by the Vice-Principal for Research on the recommendation of the Dean, Faculty of Veterinary Science and a Deputy Chair elected by the Committee.

1.3 Meetings

The AEC will set a schedule for regular meetings to review and decide on submissions. The chairperson may call ad hoc meetings as and when necessary. The schedule will be advertised on the website. Four members shall constitute a quorum.

1.4 Confidentiality

All members of the AEC will be required to sign a confidentiality

agreement in order to ensure the confidentiality of all research proposals.

1.5 **Administration**

The AEC Administrator, appointed by the Vice-principal for Research, is responsible for the coordination of AEC activities, including the receipt and distribution of submissions, compiling of agendas and minutes for the meetings and other secretarial duties. Each of the 3 Faculties involved in animal experimentation can appoint a contact person, if required, to handle internal procedures and to send submissions to the administrator.

1.6 **Standard Procedures**

- All members of staff, students, visiting academics and researchers and any other person using animals for research, teaching or demonstrations as an activity of the University of Pretoria must submit an application for ethical approval to the AEC before the activity may commence.
- Applications are approved by consensus or, if necessary, by a majority vote. The committee may require minor amendments, in which case the Chairman can be authorized to sign the approval as soon as the requirements are met, or major amendments, in which case the application must be resubmitted. In the case of urgent or non-contentious applications the Chairman is authorized to sign the approval after consultation with one or more members of the committee. Such approvals must be ratified at the next committee meeting. If an application is not approved the applicant(s) has (have) the right to appeal to the relevant Dean and eventually to the Senate Committee for Research Ethics and Integrity whose decision will be final.
- Approved submissions will be kept on record. Any deviations from the approved procedures with any ethical implications must be submitted for approval using the amendment form. All relevant forms are available on the system.
- Approvals are only valid for one year. Before its expiry researchers must apply for an extension, if required, using the annual report form on the system. The status of the project, the number of animals that have been used and whether an extension of the approval is needed must be provided.
- Researchers from other institutions involved in animal studies in collaboration with UP staff or students have to obtain ethical approval from the UP-AEC.
- The AEC may not give retrospective approval or base its approval solely on that of another institution's ethical committee. Approval by the home institution can be submitted as supporting documentation, however.
- If data obtained by a researcher at another institution is accepted by a Faculty for academic purposes, the candidate must submit a full application to the AEC with proof that all animal experiments were carried out according to the standards set by the National Code, including a copy of that institution's approval. The AEC can then express an opinion that the data was obtained under acceptable conditions, without accepting any legal responsibility.

- Whenever owned animals are used for research or testing purposes informed consent forms signed by the owners are required.
- In order to ensure that all legal requirements are met the AEC may require the submission of copies of applications for permits issued by relevant statutory bodies such as government departments.
- In the case of "umbrella" projects, e.g. where a number of postgraduate students collaborate in a research project under the supervision of a senior researcher, the supervisor should submit a primary application but each student must also submit an application referring to the primary one but indicating his/her contribution to the study. An approval certificate can then be issued in each student's name as required for theses by some faculties

The AEC reserves the right to interview the researcher and/or the study director; to inspect the facilities where animals are housed and experimental procedures performed; prior to or during the experiment; to request that records are made available; and to seize any animal and stop an experiment if deemed necessary.

The AEC submits an annual report to the Senate Committee for Research Ethics and Integrity that sets out the number of projects that were received and approved / not approved, and any other matter in terms of the Mandate.

2. CATEGORIES OF ANIMAL USE

2.1 Experimental Animals

The use of all vertebrate and certain invertebrate animals for research or testing purposes require an ethics approval. The application form for this purpose is designed to provide the committee with all the information it needs to assess the required ethical aspects and to guide the applicant in providing the necessary details

2.2 Animals used for non-experimental purposes

2.2.1 A separate Standard Operating Procedure (SOP) application form is provided for animals used in teaching. Such animals must be housed and handled according to the S.A. National Standard (see Appendix 1) and all procedures performed on the animals must be listed. Each Faculty can develop internal procedures for the submission of the forms to the AEC Coordinator.

2.2.2 The following information must be submitted to the AEC at the end of every academic year: the number of animals involved the buying, breeding and disposal of animals and the number of contacts between animals and students in the case of teaching animals.

2.2.3 A person should be identified who will be directly responsible for overseeing the health and welfare of the animals. Procedures for providing care for the animals in case of emergency should be described.

2.2.4 The use of animals in continuing education courses must be authorized by the Animal Ethics Committee; SOP applications for approval must include all details of the planned course, animal care, procedures to be performed, aftercare, and disposal of animals.

2.3. Clinical cases

2.3.1 The Animal Ethics Committee must see to it that clinical cases be housed and cared for according to the National Standard and the Veterinary and Para-veterinary Professions Act (Act 19 of 1982).

2.3.2 Clinical cases (including donors) should be managed in accordance with the currently accepted standards. Patients should get the full benefit of the expertise and equipment available.

2.3.3 No unauthorized research may be conducted on clinical cases. This includes taking samples by invasive means or exposure of patients to irradiation for the sake of the investigation. No drugs or procedures that are either controversial or of unproven value, may be applied without prior authorization. This authorization is based on the evaluation of a comprehensive research project, which should include the details of the informed consent of the owners of the animals. The research project must clearly indicate the reasonable cause where any poisonous or injurious drug or substance is administered to any animal.

3. FEES

No fee will be charged by the AEC for the ethical approval of projects initiated and submitted by staff members or students of the University of Pretoria. For projects submitted by non-staff members or projects carried out under contract a nominal fee of R3500.00 plus VAT will apply.

4. BIOHAZARDS

4.1 The term *biohazard* refers to the use of organisms, viruses and other material of biological origin, as well as chemicals, radioactive substances and other forms of irradiation, which may have an adverse effect on man, animals, plants and the environment. The authorized use of these substances must be ascertained by the Animal Ethics Committee.

4.2 The necessary precautions and procedures followed (statutory if applicable) should be taken to ensure that there be no unacceptable risk to the researcher, staff, members of the public, animals, plants and the environment from the use of these bio-hazardous substances.

5. COMPLAINT PROCEDURES

5.1 Complaints can be reported to any member of the AEC. The person reporting the complaint can do so verbally or preferably in writing, and may insist on anonymity. All complaints lodged are to be taken seriously and the Committee should act promptly.

5.2 The member of the AEC to whom the complaint is reported should gather the necessary information to assess the extent of the problem and inform the Chairman who, after consultation with members, will decide on the

further course of action. If the problem is of a serious nature, an extra-ordinary meeting of the Committee can be called.

5.3 In order to investigate a reported complaint the Committee can do any or all of the following:

- Conduct an immediate inspection of the reported complaint.
- Inform the responsible person in writing that a complaint has been lodged against him or her, and that the problem should be remedied as soon as possible to comply with ethical requirements.
- Order the research to be suspended until the outcome of the investigation is known.

5.4 If the AEC deems it necessary the matter could be referred to the University Disciplinary Committee, in which case the AEC would be the pro forma complainant and will supply the Disciplinary Committee with a sworn factual statement regarding the incident.

6. UTILIZATION OF THE UPBRC

In 2002 the University of Pretoria approved the establishment of its Biomedical Research Centre at the Onderstepoort Campus as a centralized facility for research involving experimental animals. The mandate of the Centre includes the following:

1. The provision of facilities for experimental animals that meet the highest international standards.

2. The training of specialized professional and technical staff who can assist and supervise researchers in carrying out approved research projects involving experimental animals.

3. Assuring that all ethical and legal requirements for the care and use of experimental animals, as set out in the National Standard, are met, thus protecting both the researcher and the University against possible legal actions.

4. The improvement of the general standard of animal experimentation and ensuring that animal use is justified.

6.1 Utilization of the UPBRC facilities

Establishment of the UPBRC was preceded by extensive negotiations between the faculties involved. Agreement was reached that in order to meet the above requirements, and to justify the considerable investment by the university, it was essential that its facilities should be used whenever possible.

Consequently the Grové Animal Centre at the Faculty of Health Sciences and various other small animal housing units were closed down and all experimental procedures which involves animals and which will benefit man or other animals must be done at the UPBRC. However, the following exceptions to this rule were agreed upon:

1. Where animals are used for teaching purposes they may be housed at the relevant department, provided that adequate housing

and qualified staff are available and have been approved by the AEC.

2. When animals are studied for their own benefit, as in the case of the Zoology Department, it can be done at their own specialized facilities after inspection and approval by the AEC. The same applies to studies on farm animals at the 'proefplaas' and on wildlife by the Mammal Research Institute.

3. When facilities outside the University are used, they need to be approved by the AEC and/or the NSPCA and in some cases by DAFF.

APPENDIX 1

CODE OF ETHICS AND PROCEDURES FOR THE USE OF ANIMALS IN TEACHING AND RESEARCH

A Preamble:

(a) The University of Pretoria affirms that humans have an obligation to respect animals and to appreciate that they are sensitive to pain, respond to stress and may remember such experiences.

(b) The optimal care of experimental animals is essential and in the interests of both animals and research. There are two main reasons for this proposition. First, proper care and use promote the welfare of animals and contributes to the attainment of the high ethical and humane standards expected of a civilised society. Secondly, it is expensive to use animals in experiments. Experimental animals, which are housed in poor facilities or are suffering from disease produce poor, unreliable and unrepeatable results and are wasteful of resources.

(c) The University expects its members to make every effort to refine, reduce and replace animal experimentation.

(d) The University affirms that the use of animals in experiments should be justified fully and that discomfort, stress and distress should be kept to a minimum or, ideally, avoided.

(e) The University affirms that all aspects of the Animals Protection Act (Act 71 of 1962) shall be adhered to in its housing of animals and in its use of animals in experiments (as defined in B(b)).

B Definitions

(a) Experimental animal

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.

(b) Animal experiment, scientific purpose

An "animal experiment" is any procedure which uses animals for one or more of the following “scientific purposes”:

(i) the advancement of knowledge

(ii) to test a hypothesis

(iii) to supply a product

(iv) to provide organs or tissues or sera

(v) to act as a host

(vi) to impart or demonstrate existing knowledge

(v) to teach or learn surgical or other techniques

(vi) to make audiovisual recordings or any of the above

(vii) to fulfil statutory requirements for testing, or collecting data on, any substance or product.

(c) Principal Investigator

A full-time employee of the University of Pretoria and the applicant who submits applications for the use of animals for research, testing and teaching.

The provisions of the South African National Standard 10386 "The Care and Use of Animals for Scientific Purposes" apply. The information provided under points C to F below is a summary and the Standard is considered the reference document.

C Use and Care of Experimental Animals

(a) Prior authorisation must be obtained from the Animal Ethics Committee before any animals may be used for scientific purposes. All experimental animals shall be identifiable and their records shall be available for inspection.

(b) The principal object of the use of animals shall be to obtain useful results and scientific information of high quality to the benefit of animals and humankind.

(c) The experimentation shall not be purposeless or unnecessary. Experiments accompanied by pain will be allowed only if they are shown to be purposeful in producing results that can benefit humans or animals, and where the benefits are clearly commensurate with the pain caused.

(d) The use of animals shall be thoroughly and scientifically planned and based on knowledge of the problem under study and so designed that the expected results will justify the execution of the experiment.

(e) All efforts shall be made to reduce the use of animals to a minimum. Animals may not be used if a reasonable and valid alternative exists. When animals are used, all efforts shall be made to minimise the impact the experiment may cause on the welfare of the animals concerned.

(f) Wildlife conservation ethics shall be applied to all wild animals as regards the removal of endangered species from a population, the translocation of species and over-exploitation. Note: Members of species captured in one place and brought into the laboratory should, upon release, be reintroduced to the same place to help conserve the gene pool of that species.

(g) The husbandry and care of animals must comply with the most recent, internationally recognised minimum standards and recommendations. Special attention shall be given to aspects such as appropriate feeding, adequate and clean water, good environmental hygiene, adequate ventilation and elimination of excessive heat, cold and noise from the environment of the animal. Precautionary measures shall be taken to prevent diseases, injuries, over crowding and stress factors and to protect the animals from endo- and ectoparasites.

Social and behavioural requirements must be considered. Social animals should always be housed in groups where possible and the specific needs for their psychological well being should be considered.

(h) Animals collected in the field for further study as preserved specimens should be appropriately killed and preserved as soon after collection as possible to avoid unnecessary stress.

(i) Animals shall be kept for no longer than the minimum period necessary, and shall be disposed of immediately after cessation of experimental work.

D Use and Care of Experimental Vertebrate Animals

(a) Ensure that this code of ethics and procedures are adhered to.

(b) Experiments that cause protracted intense pain from which the animal cannot escape shall not be performed. Where the experiment inflicts more than negligible pain or more pain than the use of anaesthetics would cause, the use of painkillers or the administration of anaesthesia according to accepted laboratory animal practice or recognised veterinary practice, whichever is the more stringent, is obligatory until the procedure is completed. Subject to C(c) above, the only exception to this principle shall be cases where the administration of anaesthesia would nullify the aims of the experiment and the results could not be obtained by any other more humane method. Such experiments must be considered and approved by the Animal Ethics Committee at a formal meeting.

(c) The clinical care of animals before, during and after application of experimental procedures shall be of a high standard, according to accepted veterinary and laboratory animal practice, and shall aim to avoid, minimise or end discomfort, pain, or any other harmful effects which may arise from the procedure.

(d) The scientist in charge of any animal experiment must be prepared to terminate it if it becomes clear that the continuation thereof will cause unnecessary pain and suffering. If the procedure causes serious injury the animal must be killed before recovery from anaesthesia. If it becomes clear that an animal will suffer unnecessary pain or discomfort after an experimental procedure, it must be killed in a humane manner and according to accepted veterinary principles, which ensure immediate death. No experimental animal may be disposed of before certainty exists that death has occurred.

(e) No animal shall be subjected to more than one procedure that causes significant pain. Any exception to this must be considered and approved by the Animal Ethics Committee at a formal meeting.

(f) Confinement facilities:

(i) The cages in which animals are held and the premises in which the cages are housed shall comply with the latest acceptable local or international standards for the species where these exist.

(ii) Where wild animals are trapped in their natural habitat for research purposes, the cages shall comply with the standards prescribed by nature conservation authorities, with consideration of the Animal Protection Act (Act 71 of 1962) and provincial ordinances regarding nature conservation. The cages shall be visited at least daily, to prevent the animals being left for long periods without food and water and to prevent suffering or unnecessary discomfort.

(g) Transportation:

(i) Experimental animals shall be transported in accordance with recognised standards and regulations.

(ii) On arrival at an airport, seaport, railway station or other destination, the experimental animals shall immediately be unloaded and transported to suitable permanent housing.

(iii) Appropriate veterinary care shall be given to experimental animals found to be in a diseased, injured or other poor state during travel or on arrival.

E Use and Care of Experimental Invertebrate Animals

(a) The principals as set out in C(a-i) apply to all animals including the specified invertebrate animals as defined under paragraph B(c) of this code.

F Control and Inspection

(a) The immediate control of the use of experimental animals for purpose referred to in paragraph B shall rest with the Animal Ethics Committee, which shall

(i) be constituted and carry out the responsibilities as set out below;

(ii) review the code and the procedures on a continuing basis, at least annually, against internationally accepted minimum norms and standards;

(iii) make proposals as and when considered necessary for amendments to the code and/or the procedures.

(b) The Animal Ethics Committee reports to the Senate Committee for Research Ethics and Integrity. The constitution and terms of reference of the Senate Committee for Research Ethics and Integrity are as set out elsewhere.

(c) The Animal Ethics Committee shall ensure that in respect of

- faculty programmes, the Dean
- departmental programmes, the head of department
- programmes specific to a research centre, group, or unit, the head of the centre, group, or unit

accepts responsibility for the application of this code of ethics and these procedures, and shall ensure that this responsibility is exercised.

(d) The Animal Ethics Committee, or a duly designated subcommittee, shall have the right, and be required, to inspect all animals' user areas within the University, or where University resources are utilised, or where University staff or students are involved, on a regular and an ad hoc basis without warning.

(e) The Committee must satisfy itself that all persons involved in animal experiments are competent to perform the specified procedures, and ensure that adequate training is provided.

G Animal Welfare Monitoring Sheet

It is recommended that the following monitoring sheet is adapted for use in all animal experiments

Animal Welfare Monitoring Sheet

ANIMAL IDENTIFICATION:.....	**Score**	Date Time	Date Time	Date Time	Date Time	Date Time	Date Time	Date Time	Date Time	Date Time	Date Time	Date Time	Date Time	Date Time	Date Time
APPEARANCE															
Normal	0														
General lack of grooming	1														
Coat staring, ocular and nasal discharges	2														
Piloerection, hunched up	3														
FOOD AND WATER INTAKE															
Normal	0														
Uncertain: body weight ↓ <5%	1														
↓ intake: body weight ↓ 10-15%	2														
No food or water intake	3														
NATURAL BEHAVIOUR															
Normal	0														
Minor changes	1														
Less mobile and alert, isolated	2														
Vocalization, self-mutilation, restless or very still	3														
PROVOKED BEHAVIOUR															
Normal	0														
Minor depression or exaggerated response	1														
Moderate change in expected behaviour	2														
Reacts violently, or very weak and precomatose	3														
CLINICAL SIGNS															
Normal cardiac and respiratory rates, hydration	0														
Slight changes, slight dehydration	1														
C/R rates ↕ 30%, 10-20% dehydrated	2														
C/R rates ↕ 50% or very ↓, >20% dehydrated	3														
SCORE ADJUSTMENT															
If you have scored a 3 more than once, add an extra point for each 3	2 - 5														
TOTAL	**0 - 20**														
Signature (initials)															

JUDGEMENT

0 - 4 Normal
5 - 9 Monitor carefully, consider analgesics
10 - 14 Suffering; provide relief, observe regularly. Seek second opinion from day-to-day care person and/or veterinary surgeon. Consider termination.
15 - 20 Severe pain. Does your experimental protocol need rethinking?