UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA

UFS·UV
HEALTH SCIENCES
GESONDHEIDSWETENSKAPPE

INTERFACULTY ANIMAL ETHICS COMMITTEE

STANDARD OPERATING PROCEDURE

SOP NUMBER: AEC-007

TITLE: SUBMISSION OF PROTOCOLS, MODIFICATIONS, AMENDMENTS, REPORTS AND REPORTING OF ADVERSE EVENTS

VERSION NUMBER: 1

WRITTEN BY	**Prof. D Litthauer**
DATE	**May 2016**
AEC APPROVAL DATE	**09 June 2016**
APPROVAL DATE	
EFFECTIVE DATE	

Changes from the previous version	
New SOP	

1. Documentation

- Constitution of the Interfaculty Animal Ethics Committee
- Guide to the Care and Use of Animals in Research and Teaching
- South African National Standard: The Care and Use of Animals for Scientific Purposes. (SANS10386:2008)
- Ethics in Health Research. Principles, Processes and Structures. Department of Health, Republic Of South Africa (2015)

2. Introduction

The care and well-being of experimental animals are the ultimate responsibility of the researchers and teachers using animals for research or teaching. This includes, but is not limited to, compliance with the conditions set by the AEC for a particular protocol.

In carrying out its Terms of Reference, the AEC 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 AEC must ensure that the care of all animals on and of University properties minimizes pain, distress and discomfort. Animal use in research and teaching is allowable only when:

(i) there is not available an acceptable procedure alternative to the use of animals;
(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 in minimized; 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" (Guide) of the Interfaculty Animal Ethics Committee.

3. Procedure:

Note: The entire process of protocol submission, review and communication by e-mail is performed by the RIMS online system.

3.1 Applications are submitted online by logging in to the RIMS online submission system using the guidelines provided in the Guide. An application number is automatically generated. Applications are submitted by the supervisor or Principal Investigator.

3.2 In this SOP, "researchers" refers to the person named as Principal Investigator in an application (whether for research or for teaching) which has been approved by the AEC.

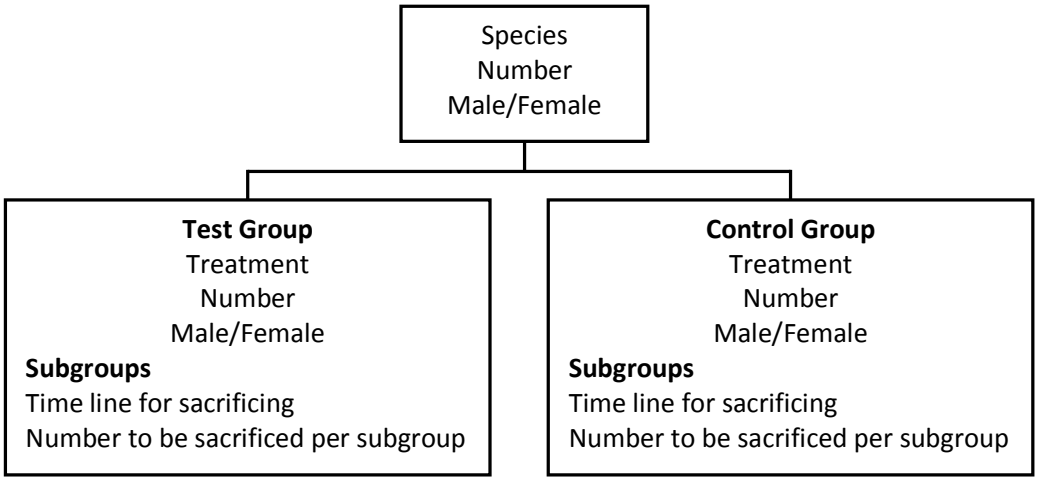
3.3 Postgraduate or other students involved in animal research may not be listed as a Principal Investigator on an application submitted to AEC, but they must be mentioned in the application as students.

3.4 Students may fill in the fields in the e-form but the application must be submitted by the supervisor.

3.5 If a project involves collaboration with another institution, the UFS investigator must apply as the principal investigator. Proof of ethical clearance for the project or a letter delegating ethical clearance to the UFS, from the collaborating institution is required.

3.6 All the fields in the e-form must be completed or, if not applicable, the researcher must enter N/A in the field. Supporting documentation should be uploaded where necessary.

3.7 Special attention should be given to the statistical motivation for the design of an experiment. Upload a tree diagram as a supporting document showing the allocation of animals to different groups. The example below is for illustration only, your experimental design will determine the structure of the tree.



3.8 A lay summary must be included in the e-form. The summary should include:

- A summary of the objectives and potential benefits i.e. why the project is important.
- Outline the sequence of the work, indicating how the different procedures will contribute towards answering the questions.
- Explain why a specific type of animal (species, strain, stage of development) is to be used.
- Indicate why alternative methods cannot be used.
- Motivate why the number of animals are to be used.
- Provide a summary of the main adverse effects likely to be caused to the animal.
- State the level of suffering that the animal will endure and its duration.
- Outline efforts to minimise adverse effects and suffering, for example improvement of techniques and special arrangements for caring for the animals
- Briefly explain how it is judged that the benefits outweigh the harms and why the research is justified.

3.9 After submission of the protocol by the researcher, the Head of Department/Departmental Chairperson is informed by e-mail that an application has been submitted. The HOD/Chair approves submission of the protocol by following the link in the e-mail. The researcher will receive a copy of the e-mail. It is up to the researcher to ensure that the HOD/Chair approves the protocol submission as soon as possible.

3.10 Meetings for the approval of protocols are held monthly. Protocols should be submitted at least ten work days before a Committee meeting for consideration at the next meeting.

3.11 After review, the researcher will be informed of the Committee decision. The decision can be:

- unconditional approval
- conditional approval – the protocol is approved but additional documents such as permits from Provincial Authorities are required
- modifications required – the applicant must respond to comments or questions by the reviewer
- rejected – the project may not proceed and a new protocol may be submitted.

3.12 The researcher will be informed in writing of the Committee Decision

3.13 The researcher responds to any modifications required by logging in to RIMS and selecting the appropriate option from the drop down list on the "Submissions" screen of the protocol. The responses of the researcher are then forwarded to all the reviewers for consideration at the next meeting.

3.14 Protocol amendments or extension/continuations must be submitted to the AEC for approval. These are submitted by logging in to RIMS and selecting the appropriate option from the drop down list on the "Submissions" screen of the protocol. The amendments or extension/continuations are considered at the next meeting of the AEC.

3.15 Annual progress reports are to be submitted at the end of each year. Researchers will be informed by e-mail when progress reports are due. These are submitted by logging in to RIMS, selecting the appropriate option from the drop down list on the "Submissions" screen of the protocol and filling in the fields on the report screen. The reports are considered at the next meeting of the AEC. The researcher will be informed if the report is not satisfactory.

3.16 Final reports are to be submitted at the completion of the project. These are submitted by logging in to RIMS, selecting the appropriate option from the drop down list on the "Submissions" screen of the protocol and filling in the required fields on the report screen. The reports are considered at the next meeting of the AEC. The researcher will be informed if the report is not satisfactory.

3.17 Any adverse event must immediately be reported to the chair of the AEC and the Head of the Animal Unit. Adverse Event reports must be submitted by logging in to RIMS, selecting the "Adverse Event" option from the drop down list on the "Submissions" screen of the protocol and filling in the required fields on the report screen. The reports will be considered at the next meeting of the AEC. The researcher will be informed if the report is not satisfactory.