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GESONDHEIDSWETENSKAPPE

INTERFACULTY ANIMAL ETHICS COMMITTEE

STANDARD OPERATING PROCEDURE

SOP NUMBER: AEC-001

TITLE: EVALUATION OF PROTOCOLS

VERSION NUMBER: 2

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

Changes from the previous version	
Entire SOP	The entire SOP has been updated and reformatted to reflect the current documentation and submission systems available

1. Documentation

- Constitution of the Interfaculty Animal Ethics Committee
- Guide to the Care and Use of Animals in Research and Teaching (The Guide)
- 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 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.

3.3 An Admin Check is performed by the RIMS administration and the Chairperson of the AEC is informed by e-mail that an application has been submitted.

3.4 The Chairperson logs in to RIMS performs an initial screen of the protocol. The Chairperson selects a number of suitable reviewers depending on the degree of invasiveness of the protocol and submits tom RIMS. RIMS informs the AEC Administrator which reviewers should perform the evaluation.

3.5 The RIMS administrator informs each reviewer that a protocol has been allocated to them.

3.6 Reviewers log in to RIMS and download the reviewer's checklist (Appendix A) by clicking on the link provided in the review window. Responses are filled in on the checklist and the checklist is uploaded after completion. The reviewers also complete the fields in the online form and choose appropriate responses from drop down lists. The response is submitted to RIMS. The reviewer can give:

- 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.

3.7 Committee members are allowed five working days to evaluate the application. After the five working days, a reminder is sent to non-responders. If no response is received, the RIMS administrator will inform the chairperson and a decision will be made if an alternative reviewer should be approached.

3.8 The RIMS administrator forwards all comments received from the reviewers to the applicant/principal investigator for a response.

3.9 The applicant submits all responses online.

3.10 The responses of the applicant/investigator are then forwarded to all the reviewers for consideration.

3.11 If the response is accepted by reviewers and there is consensus that all comments and queries have been addressed to the satisfaction of the Committee reviewers, the application can be approved.

3.12 All applications with the reviewer responses are tabled at the monthly meetings of the AEC for approval or referral to the next meeting.

3.13 The agenda of an Ethics Committee meeting includes summaries of all applications, the comments of reviewers and responses by the applicant if applicable. The agenda is distributed to all committee members.

3.14 The application is discussed by the Committee. All members have the opportunity to participate in the discussion.

3.15 Member(s) with a conflict of interest do not participate in the decision making process and are not included as reviewers. Such members are requested to leave the meeting venue before the application is discussed if it is refereed to the quarterly Committee meeting.

3.16 The decision of the Committee is by consensus. If consensus is not possible a majority of one vote is decisive.

3.17 If the committee approves the protocol, a letter is signed by the Chairman or a designated deputy and sent to the applicant within five working days after the meeting.

3.18 A complaint procedure is available for applicants who are not satisfied with the decision of the Committee. If the problem could not be resolved with the above mentioned procedure, the Faculty of Health Sciences could appoint an Appeal Committee for a final resolution.

APPENDIX A

INTERFACULTY ANIMAL ETHICS COMMITTEE OF THE UFS

RESEARCH ETHICS REVIEWER'S CHECKLIST AND COMMENTS

1. Is there sufficient justification for the proposed research?	☐ Yes ☐ Unsure ☐ No ☒ N/A
2. Are the specific aims, hypotheses and research questions clearly identified?	☐ Yes ☐ Unsure ☐ No ☒ N/A
3. Is the experimental design of the project in keeping with the aims of the proposals?	☐ Yes ☐ Unsure ☐ No ☒ N/A
4. Does the protocol adequately justify the use of live animals?	☐ Yes ☐ Unsure ☐ No ☒ N/A
5. Does the proposed animal model make sense for the research project?	☐ Yes ☐ Unsure ☐ No ☒ N/A
6. Is there adequate statistical or technical justification for the number of animals requested?	☐ Yes ☐ Unsure ☐ No ☒ N/A
7. Have the "Three Rs" (replacement, reduction and refinement) been adequately addressed?	☐ Yes ☐ Unsure ☐ No ☒ N/A
8. Have all surgical and non-surgical procedures been clearly and completely described, consistent with the experimental design outline?	☐ Yes ☐ Unsure ☐ No ☒ N/A
9. Has pain, discomfort and distress to the animal(s) been minimized or avoided to the fullest extent possible?	☐ Yes ☐ Unsure ☐ No ☒ N/A
10. Will medical care be provided when needed? Is a veterinarian available when needed?	☐ Yes ☐ Unsure ☐ No ☒ N/A
11. Is there any appropriate plan for monitoring animals for pain, discomfort and distress, including criteria for determining early euthanasia (humane endpoint)?	☐ Yes ☐ Unsure ☐ No ☒ N/A
12. Are the members of the research team qualified and experienced in the procedures to be performed?	☐ Yes ☐ Unsure ☐ No ☒ N/A
13. Is the harm to animal interest reasonable in relation to potential benefits of the proposal?	☐ Yes ☐ Unsure ☐ No ☒ N/A
14. Is the method of euthanasia (when applicable) clearly stated and appropriate?	☐ Yes ☐ Unsure ☐ No ☒ N/A
15. Is the housing for the animals suitable and is appropriate care available for animals?	☐ Yes ☐ Unsure ☐ No ☒ N/A