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Faculty of Health Sciences Ethics Office for Research, Training and Support
[health-sciences.nwu.ac.za/healthethics](http://health-sciences.nwu.ac.za/healthethics)

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| **AnimCare** Ethics Committee on Animal Care, Health and Safety in Research *(AREC-130913-015)***Ethics Reviewer Report Form**for **new standard full** ethics applications for **single** or **large** scientific **projects** using animal vertebrates or higher invertebrates for research or training purposes***AnimCare 02-01b, Version 4.10 (Nov 2016)*** |
| **CONFIDENTIAL!** This document contains confidential information that is intended strictly and exclusively for the applicant and AnimCare Committee. Should this document or parts thereof erroneously come in your possession, you are requested to destroy it or to return it to AnimCare without delay. Unauthorised possession, reading, studying, copying or distribution of this material, or any other form of abuse, is illegal and punishable. |
| **NWU Ethics Number: *(issued upon 1st submission)*** | Click or tap here to enter text. |

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| Review Information |

Provide the necessary review information below:

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| Reviewer code | Date of Review |

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| Type details here. | Click or tap to enter a date. |

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| General Project Identification |

Provide the necessary descriptions below to identify this project application:

* 1. Project’s ethics number

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| Type details here. |

**PS!** Did you enter it also in the header above? *(…it helps to enhance filing)*

* 1. Full, descriptive title of the project

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| Type details here. |

* 1. Name of the Project Head (principle investigator / study leader)

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| Type details here. |

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| Summary Report for Applicants |

**Applicants** will find here a summary of all comments that this reviewer made *(listed for your convenience)* for the various ethical considerations indicated further below. These various considerations can still be visited for details as necessary.

***List of the Reviewer’s Comments and Questions to the Applicant***

1. **Aims, Background and Significance:**
[Type details here.]
2. **Scientific Design:**[Type details here.]
3. **Animal model to be used:**
[Type details here.]
4. **Research Procedures:**
[Type details here.]
5. **The 3Rs:**
[Type details here.]
6. **Animal Welfare:**
[Type details here.]
7. **What Happens at the End of the Study?:**
[Type details here.]
8. **Safety Measures:**
[Type details here.]
9. **Risk-Benefit Ratio:**
[Type details here.]
10. **Competence of team members & supervisors:**
[Type details here.]
11. **Facilities:**
[Type details here.]
12. **Storage of Biological Specimens:**
[Type details here.]
13. **Data Analysis and Monitoring:**
[Type details here.]
14. **Budget:**
[Type details here.]
15. **Insurance:**
[Type details here.]
16. **Conflict of Interest:**
[Type details here.]
17. **Legal Requirements:**
[Type details here.]
18. **Additional Comments or Questions for Researchers:**
[Type details here.]

***Reviewer Recommendation: Project category & Final Recommendations***

1. **Recommended experience category:** [Choose an item.]***Motivation / Comment:*** Click or tap here to enter text.
2. **Reviewer’s Final Assessment:**[Choose an item.]***Motivation / Comment:*** Click or tap here to enter text.

**PS!** Whereas applicants are welcome to read below, the essence of comments and/or questions is summarised above.

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| Reviewer’s Instructions* 1. Always ensure that you have the latest version of the application form, downloadable from <http://health-sciences.nwu.ac.za/healthethics>. Previous versions will not be accepted.
	2. Please complete the Review Information and General Project Identification on the first page, before you type your comment/questions on each of the questions below.
	3. **Important!** Please click the appropriate box for “Yes” and “No”, and then please double-click on the word in brackets such as *[Type details here.]* below. This will highlight the word, but not the brackets. Now type your comments or questions in between the brackets, replacing the word. To create new lines within a comment box, press [Shift] + [Enter] on your keyboard. These words are linked to the paragraphs of the summary report above, which will be updated by the office, thereby to create a summary report.
	4. Where a reviewer makes a comment about a methodological issue, please indicate whether the change is required or merely recommended.
	5. Submit via e-mail the completed Ethics Application Form (with the attached documentation as discussed above) to the Faculty of Health Sciences Ethics Office for Research, Training and Support (Ethics-AnimCare@nwu.ac.za). Please type the e-mail subject as:  **Reviewer Report for NWU-???-??-S? (applicant’s initials & surname)**.
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| 1. **Aims, Background and Significance**
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Consider the following questions in your assessment, providing comments or questions, and whether these are recommendations or requirements:

* Are the study aims and objectives clearly specified?
* Is there adequate preliminary data to justify the research?
* Are adequate references provided? (Where possible, the literature review should include pertinent references to local research in the proposed field of study)
* Why is this research important to conduct? Will it add important knowledge to the field?
* Is there an executive summary and study outline provided?

**Satisfactorily addressed?**

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| **Yes** | **No** |  | **If no, provide comments and/or questions for the applicant** |
| [ ]  | [ ]  |  | [Type details here.] |

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| 1. **Scientific Design**
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Consider the following questions in your assessment, providing comments or questions, and whether these are recommendations or requirements:

* Is the scientific design adequate to answer the study questions?
* Is the scientific design adequately described and justified?
	+ Does the study involve a placebo?
	+ If so, why is a placebo needed?
	+ Could the study be done without a placebo?
* Is there a persuasive justification for using a placebo?
* Are study aims and objectives achievable in the given time frame?
* Do the principal and co-investigators have appropriate academic and clinical credentials and experience to conduct this study?

**Satisfactorily addressed?**

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| **Yes** | **No** |  | **If no, provide comments and/or questions for the applicant** |
| [ ]  | [ ]  |  | [Type details here.] |

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| 1. **Animal model to be used**
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Consider the following questions in your assessment, providing comments or questions, and whether these are recommendations or requirements:

• Is the selection of the animal model appropriate for the question being asked?

• Is the rationale for the proposed number of animals reasonable?

• Is justification for the use of this specific model clearly stated and reasonable?

• Are the animals appropriately conditioned to the study environment, procedures and handlers?

• Does the study include models that require specialised care e.g. genetic knockout models, repletion/depletion models etc.?

* + -If yes, are adequate safeguards included to protect the health and wellbeing of the animals?
	+ -Can the study be done without including these models?

• What arrangements will be made to monitor the animals? Is an animal monitoring sheet provided and does the sheet address all areas of animal welfare?

• Have any of the studies been performed previously? If so, why should they be repeated e.g. toxicology studies?

• Did the applicant indicate if there is a need for permits?

• Have the SOPs to be used been approved by the AnimCare committee?

**Satisfactorily addressed?**

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| --- | --- | --- | --- |
| **Yes** | **No** |  | **If no, provide comments and/or questions for the applicant** |
| [ ]  | [ ]  |  | [Type details here.] |

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| 1. **Research Procedures**
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Consider the following questions in your assessment, providing comments or questions, and whether these are recommendations or requirements:

* Are the rationale and details of the research procedures adequately described and acceptable?
* Is there a clear description of the animal husbandry and care processes to be implemented?
* Are the proposed tests or measurements appropriate, valid and reliable to answer the scientific question?
* Are individuals who are performing procedures adequately trained and competent?
* Is the study designed so that statistically valid results can be obtained?

**Satisfactorily addressed?**

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| **Yes** | **No** |  | **If no, provide comments and/or questions for the applicant** |
| [ ]  | [ ]  |  | [Type details here.] |

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| 1. **The 3Rs**
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Consider the following questions in your assessment, providing comments or questions, and whether these are recommendations or requirements:

* Has the applicant implemented the principles of reduce, replace and refine in the setting up of this research project?
* Are there any specific risks to the researcher (e.g. safety concerns)? If so, are the appropriate precautions taken?
* If the study is not to be undertaken in the Vivarium are the appropriate facilities available at the site where the research will take place?
	+ Are animal care conditions appropriately discussed?
	+ Are the waste management systems present and effective?
	+ Are the staff appropriately trained and competent in the methodologies to be used?
	+ Are the facilities appropriate and able to undertake the project as discussed?
	+ Do the facilities have the appropriate equipment required for the study?
	+ Is there an ad hoc veterinarian available in case of emergency?

**Satisfactorily addressed?**

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| **Yes** | **No** |  | **If no, provide comments and/or questions for the applicant** |
| [ ]  | [ ]  |  | [Type details here.] |

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| 1. **Animal Welfare**
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Understanding that reasonable discomfort, pain or suffering of animals may be justified in exceptional cases, and understanding the context of the project:

* Is it demonstrated that animal welfare will take precedence over the benefit of the project?
* Are pro-active measures in place to promote animal welfare (e.g. environmental enrichment)?
* Will animal welfare be monitored (including appropriate monitoring sheets)?
* Are measures and procedures in place to intervene if animal welfare is compromised?

**Satisfactorily addressed?**

|  |  |  |  |
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| **Yes** | **No** |  | **If no, provide comments and/or questions for the applicant** |
| [ ]  | [ ]  |  | [Type details here.] |

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| 1. **What Happens at the End of the Study?**
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Consider the following questions in your assessment, providing comments or questions, and whether these are recommendations or requirements:

* Is the appropriate method of euthanasia used at the end of the study?
* How will findings be disseminated to the wider research community (e.g. peer-reviewed scientific journals, conference presentation, and internal report)?
* Has the disposal of all waste appropriately been addressed?

**Satisfactorily addressed?**

|  |  |  |  |
| --- | --- | --- | --- |
| **Yes** | **No** |  | **If no, provide comments and/or questions for the applicant** |
| [ ]  | [ ]  |  | [Type details here.] |

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| 1. **Safety Measures**
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Consider the following questions in your assessment, providing comments or questions, and whether these are recommendations or requirements:

* Have all biological and environmental hazards bee identified?
* Are all measures in place to manage biological safety?

**Satisfactorily addressed?**

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| **Yes** | **No** |  | **If no, provide comments and/or questions for the applicant** |
| [ ]  | [ ]  |  | [Type details here.] |

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| 1. **Risk-Benefit Ratio**
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Consider the following questions in your assessment, providing comments or questions, and whether these are recommendations or requirements:

* Are the risks and benefits of the study discussed?
* In your opinion, will the benefits outweigh the risks (i.e. can the study be justified)?

**Satisfactorily addressed?**

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| **Yes** | **No** |  | **If no, provide comments and/or questions for the applicant** |
| [ ]  | [ ]  |  | [Type details here.] |

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| 1. **Competence of team members & supervisors**
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Consider the following questions in your assessment, providing comments or questions, and whether these are recommendations or requirements:

* Academic qualifications suitable?
* Professional registrations and/or authorisations appropriate?
* Proof of scientific, research, educational and/or technical experience and competence?
* Appropriate skills and mentoring?

**Satisfactorily addressed?**

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| **Yes** | **No** |  | **If no, provide comments and/or questions for the applicant** |
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| 1. **Facilities**
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Consider the following questions in your assessment, providing comments or questions, and whether these are recommendations or requirements:

* Are all facilities suitable and resourced?
* Are specialised facilities validated and authorised?
* Are all facilities available?

**Satisfactorily addressed?**

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| **Yes** | **No** |  | **If no, provide comments and/or questions for the applicant** |
| [ ]  | [ ]  |  | [Type details here.] |

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| 1. **Storage of Biological Specimens**
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Consider the following questions in your assessment, providing comments or questions, and whether these are recommendations or requirements:

* Will biological specimens be stored for future use?
* Will samples be stored at NWU or at an external site?

**Satisfactorily addressed?**

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| **Yes** | **No** |  | **If no, provide comments and/or questions for the applicant** |
| [ ]  | [ ]  |  | [Type details here.] |

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| 1. **Data Analysis and Monitoring**
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Consider the following questions in your assessment, providing comments or questions, and whether these are recommendations or requirements:

* Are the plans for data and statistical analysis defined and justified?
* Are there adequate plans for monitoring the animals for pain and distress, especially if not at the Vivarium e.g. humane end-points?

**Satisfactorily addressed?**

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| **Yes** | **No** |  | **If no, provide comments and/or questions for the applicant** |
| [ ]  | [ ]  |  | [Type details here.] |

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| 1. **Budget**
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Consider the following questions in your assessment, providing comments or questions, and whether these are recommendations or requirements:

* Is the budget reasonable to complete the project?
* Is the budgeted money available for the study?

**Satisfactorily addressed?**

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| **Yes** | **No** |  | **If no, provide comments and/or questions for the applicant** |
| [ ]  | [ ]  |  | [Type details here.] |

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| 1. **Insurance**
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Consider the following questions in your assessment, providing comments or questions, and whether these are recommendations or requirements:

* In the case of non-NWU study sites, is there provision for insurance for research related injuries, if applicable?

**Satisfactorily addressed?**

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| **Yes** | **No** |  | **If no, provide comments and/or questions for the applicant** |
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| 1. **Conflict of Interest**
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Consider the following questions in your assessment, providing comments or questions, and whether these are recommendations or requirements:

* Do any personnel involved in the design, conduct or analysis of the research have any proprietary interests (e.g. royalties, patents, trademarks, copyrights or licensing agreements) involving any agent, device or software being evaluated in the study?

**Satisfactorily addressed?**

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| **Yes** | **No** |  | **If no, provide comments and/or questions for the applicant** |
| [ ]  | [ ]  |  | [Type details here.] |

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| 1. **Legal Requirements**
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Consider the following questions in your assessment, providing comments or questions, and whether these are recommendations or requirements:

* Are all contracts in place and checked by NWU legal office
* Are all required permits in place?

**Satisfactorily addressed?**

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| **Yes** | **No** |  | **If no, provide comments and/or questions for the applicant** |
| [ ]  | [ ]  |  | [Type details here.] |

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| 1. **Additional Comments or Questions for Researchers**
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Any additional comments or questions not raised above.
*(Also, in rare cases where the applicant indicated any significant bearing of this study on any endangered or protected species or significant impact on the environment, was the form on “Estimated Environmental Impact Category” (form no. NS Ethics 01-01a) completed and approved by the ethics committee of Environmental Sciences?)*

**Satisfactorily addressed?**

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| **Yes** | **No** |  | **If no, provide comments and/or questions for the applicant** |
| [ ]  | [ ]  |  | [Type details here.] |

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| 1. **Recommended experience category**
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In your opinion, what is the category of the most severe experience the animals will experience during the execution of the study? Please select from the drop-down below:

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| Please indicate the appropriate category **→** applicable to this application *(descriptions below)*: | **[Click here to choose an item from the list.]** |

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| **Category 0**  **- None**, e.g. use of dead vertebrate or higher invertebrate animals (already euthanized legally and ethically for another purpose and not for this project) or tissue or biological fluids thereof, or using any live lower invertebrate. Also archived animal specimens from the laboratory, museum, private or any other collections. Non-invasive behavioural studies, e.g. observation of wild animals *in situ* (natural environment) without interference, including minimal disturbance to other biota. Domestic or farm animals on their home property, where procedures are occurring as normally part of the routine management or professional (e.g. veterinary) care. |
| **Category 1**  **- Mild**, e.g. keeping of animals in captive conditions (including all animals housed in registered animal holding facilities), or animals collected domestically, from the farm, in the field or other environment, confined and/or transported for subsequent observation. Handling animals or applying minimally invasive examinations, depriving animals of food/water for a few hours (no longer than experienced in nature) or anaesthetising animals that will not regain consciousness (non-recovery). |
| **Category 2**  **- Medium**, defined as induced stress of short duration, not requiring anaesthesia or tranquilisation, e.g. parenteral administrations, small subcutaneous implants, exercise or low-stress behavioural testing. Collection of tissue from animals after non-anaesthetic euthanasia for research purposes. Open field testing. Depriving animals of food or water for periods longer than experienced in nature, but without becoming distressful or causing permanent harm. |
| **Category 3**  **- Severe**, defined as induced stress of short duration, requiring anaesthesia or tranquilisation, e.g. surgical procedures (including larger implants), multiple injection sites or high-stress fluid/tissue sampling, e.g. cardiac puncture. Procedures that include known disease or severe stress-inducing agents/interventions (e.g. known genetic manipulations, pathogens, toxicity studies or toxic agents, nutrition and trauma, such as perceived unescapable predator exposure), provided the study is terminated (i.e. endpoint) at the onset of relevant symptoms (e.g. lowest observed effect concentration). Restriction of movement over a prolonged periods of time, e.g. metabolic cages or keeping large animals in bomas. |
| **Category 4**  **- Very severe**, defined as induced stress of long duration, e.g. prolonged stress (>30 minutes) without anaesthesia or tranquilisation, anaesthesia of long duration (>30 minutes), procedures producing defects or long-term feeding (> 2 days) of deficient or special diets. Forced swim or exercise tests with exhaustion as the end-point. Cancer models and new genetic manipulation. |
| **Category 5**  **- Excessively stressful**, where exceptional motivations & justification are needed for approval, e.g. application of noxious stimuli to conscious animals from which the animal cannot escape or any experiments in which total distress is the likely outcome. Toxicity / virulent studies where the endpoint is the moribund state or death. Extended social isolation of sociable animals (e.g. social isolation rearing of rats). Real, staged predator exposure which may lead to attack with harm or kill. |

**Motivation and/or any comments** *(optional)*

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| Click or tap here to enter text. |

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| 1. **Reviewer’s Final Assessment**
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In your opinion, what is the recommendation for the approval level of the project? Please select from the drop-down below:

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| Please indicate the appropriate category **→** applicable to this application *(descriptions below)*: | **[Click here to choose an item from the list.]** |

**Motivation and/or any comments** *(optional)*

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| **Approved** No changes required. All ethical considerations have been appropriately addressed. |
| **Approval with minor changes** Minor changes needed regarding specific aspect(s) of study or additional information requested from PI. Chair or designee will approve revisions. |
| **Approval with several changes** Major changes needed as protocol is poorly written, lacking information relating to scientific and/ or ethical aspects, needs to be rewritten and resubmitted. |
| **Deferred** There are significant ethical concerns or questions that requires fundamental redesign, resubmission and comprehensive review of the whole application. |
| **Disapproved** There are significant ethical concerns or questions that make the study unacceptable. |

***- End of Report –***