

Faculty of Health Sciences Ethics Office for Research, Training and Support

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| North-West University Animal Care, Health and Safety Research Ethics Committee **NWU-AnimCareREC**  *registered as Animal Research Ethics Committee (AREC) with the South African National Health Research Ethics Council (NHREC) of the National Dept. of Health,* ***reg. no. AREC-130913-01*****Research Ethics Reviewer Report**  by a **cat. B member** (scientist) for the review of **single** or **larger** scientific **studies** using animal vertebrates or higher invertebrates for research, education/training or repetitive testing purposes  **AnimCare 02-01b2, Version 5.10 (July 2019)** |
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| General Review Identification |

Provide the necessary review information below:

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| Reviewer code | Date of Review |

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| **Click or tap here to enter code.** | Click or tap to enter a date. |

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| General Study Identification |

Provide the necessary descriptions below to identify this project application:

* 1. **Ethics number *(issued upon 1st submission)***

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| **Click or tap here to enter number.** |

* 1. **Full, descriptive title of the study**

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| Click or tap here to enter text. |

* 1. **Name of the responsible researcher/study leader**

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| Click or tap here to enter text. |

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| General Matters of Ethical Concern |

**Please note!**

For each questions in Sections 1 & 2 below mark the appropriate tick box as follows:

* “**Yes**” only if **ALL** of the applicable have been met satisfactorily addressed *(in your opinion)*, otherwise, whereafter you may (i.e. optional) point out commendable aspects. In **Section 2**, however, you then **SHOULD ALWAYS** also motivate your selection.
* “**No**” *(even if most are addressed and only one matter not)*, and then **ALWAYS** provide comments, questions and/or recommendations in the text box below the question *(including i) what do you observed that is of concern, ii) why is this a problem and iii) what should be done to address the concern)*, or
* “**N/A**” if the question is not relevant to this study.

For each question in **Sections 2 & 3**, you **SHOULD ALWAYS** motivate your selection and/or comment in the text box below the question.

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| Ethically Acceptable Standard of the Science |

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| Has the study proposal been evaluated and approved by a scientific committee, and is the attached approval letter appropriate (i.e. signed by an authorised person without conflict of interest and including a recommendation of the severity category of the potential harm to the animals)? |  | **Yes** | **No** |
| **N/A** | |
| Click or tap here to provide comments, questions and/or recommendations. | | | |

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| Is the study title appropriate to the content of the research, also always reflecting the animals to be used where and as applicable? |  | **Yes** | **No** |
| **N/A** | |
| Click or tap here to provide comments, questions and/or recommendations. | | | |

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| It the executive summary clear, truly reflective of the number and type(s) of animals to be used, study aims, study design and methodology, etc., and written in laymen’s terms? |  | **Yes** | **No** |
| **N/A** | |
| Click or tap here to provide comments, questions and/or recommendations. | | | |

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| Is the study layout schema clear, truly reflective of the study design, treatment groups, the number and type(s) of animals to be used, interventions, measurements, time-lines, etc.? |  | **Yes** | **No** |
| **N/A** | |
| Click or tap here to provide comments, questions and/or recommendations. | | | |

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| Does the study show scientific integrity in terms of aspects including:sound knowledge of literature,clear problem statement and relevance, aims and objectives,appropriate and rational study design, methodology and statistical analyses,responsiveness to peer review and scrutiny andconsideration of ethical implications? |  | **Yes** | **No** |
| **N/A** | |
| Click or tap here to provide comments, questions and/or recommendations. | | | |

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| Are the aims and/or objectives of the study achievable and is the study likely to produce the expected outcomes? |  | **Yes** | **No** |
| **N/A** | |
| Click or tap here to provide comments, questions and/or recommendations. | | | |

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| In the case of health- and health-related research, is there good reason to believe (sound evidence) that the animal models employed will have good translatability to the human condition and/or treatment, and that the results obtained will be able to appropriately and responsibly inform any prospective clinical studies (e.g. in terms of safety and efficacy)? |  | **Yes** | **No** |
| **N/A** | |
| Click or tap here to provide comments, questions and/or recommendations. | | | |

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| Is appropriate statistical expertise or consultation evident *(if applicable)*, and is the animal numbers justified (e.g. by a power analysis, or from literature or as prescribed by a standardised protocol)? |  | **Yes** | **No** |
| **N/A** | |
| Click or tap here to provide comments, questions and/or recommendations. | | | |

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| Animal Welfare and Safety Matters |

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| Have all invasive procedures in animals (e.g. genetic manipulations, disease models, invasive procedures, implants, drug administrations, dietary manipulations, toxicology, restraint, severe and prolonged physiological and/or psychological suffering, etc.) been fully described, and is there sufficient competence to monitor and manage these? |  | **Yes** | **No** |
| **N/A** | |
| Click or tap here to provide comments, questions and/or recommendations. | | | |

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| Are other precautionary safety measures and monitoring to protect human experimenters, animals and the environment in place, clear and appropriate (including, as applicable to the study, any and all risk to experimenters, measures for animal procedures, animal handling, transport of animals, endangered or protected species, environmental impact, infections and genetic manipulation)? |  | **Yes** | **No** |
| **N/A** | |
| Click or tap here to provide comments, questions and/or recommendations. | | | |

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| Are any animal housing facilities *(when applicable)* registered with the SAVC (and when involving infectious procedures with DAFF), have they been inspected by NWU-AnimCareREC and the NSPCA in the last year, are all housing conditions, general care and handling of animals appropriate, and are expertise and competence of care at these facilities appropriate? |  | **Yes** | **No** |
| **N/A** | |
| Click or tap here to provide comments, questions and/or recommendations. | | | |

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| Have the humane endpoints been well described and will this be adequately monitored, recorded on appropriate monitoring sheets and managed? |  | **Yes** | **No** |
| **N/A** | |
| Click or tap here to provide comments, questions and/or recommendations. | | | |

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| Has the end of study for animals been well described, and are matters such as reintroduction or euthanasia *(if applicable)* justified, permitted and legal, compatible with study objectives and according to acceptable methods to minimise suffering? |  | **Yes** | **No** |
| **N/A** | |
| Click or tap here to provide comments, questions and/or recommendations. | | | |

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| Are there any endangered or protected animal species involved in this study, and if so, are all measures in place to comply with responsible use and legal requirements of these animals? |  | **Yes** | **No** |
| **N/A** | |
| Click or tap here to provide comments, questions and/or recommendations. | | | |

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| Study Management & Social Responsibility |
| Click or tap here to provide comments, questions and/or recommendations. |

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| Is the overall project management clearly explained (including management of team member competence & training, equipment maintenance/calibration schedules, waste management, logistics and storage of data)? |  | **Yes** | **No** |
| **N/A** | |
| Click or tap here to provide comments, questions and/or recommendations. | | | |

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| Is the timeframe for the study clearly indicated and realistic? |  | **Yes** | **No** |
| **N/A** | |
| Click or tap here to provide comments, questions and/or recommendations. | | | |

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| Is the budget for the study clearly indicated and sufficient to complete the study once started? |  | **Yes** | **No** |
| **N/A** | |
| Click or tap here to provide comments, questions and/or recommendations. | | | |

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| Is it clearly described how the researchers intent to disseminate information (including to the scientific community, any statutory body as applicable and to the public), and do these all seem appropriate? |  | **Yes** | **No** |
| **N/A** | |
| Click or tap here to provide comments, questions and/or recommendations. | | | |

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| Competence, Legal Matters and Conflict of Interest |

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| Are the team members appropriately *(i.e. where and as applicable for their role in this study)* competent, trained to handle the animals, qualified, SAVC authorised or SACNASP registered, and did they all provide proof of ethics training (<3 yrs), a narrative CV and a signed copy of the NWU code of conduct? |  | **Yes** | **No** |
| **N/A** | |
| Click or tap here to provide comments, questions and/or recommendations. | | | |

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| Have copies of all required legal documents, as approved by the NWU legal office and duly signed, been attached (including any and all applicable contracts, material transfer agreements (MTAs) and/or other agreements)? Have all required permits been attached? |  | **Yes** | **No** |
| **N/A** | |
| Click or tap here to provide comments, questions and/or recommendations. | | | |

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| Are the information in required informed consents and goodwill permissions and/or legal authorisations (if and when applicable) appropriate and clear, with all necessary and required information included? If it requires any translation, was this clearly indicated how this will be managed? |  | **Yes** | **No** |
| **N/A** | |
| Click or tap here to provide comments, questions and/or recommendations. | | | |

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| Is any researcher and stake holder conflict of interest appropriately addressed and managed (including transparency & IP protection, and any conflict of interest of team members, collaborators and/or sponsors)? |  | **Yes** | **No** |
| **N/A** | |
| Click or tap here to provide comments, questions and/or recommendations. | | | |

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| Did the responsible researcher or study leader sign the declaration? |  | **Yes** | **No** |
| **N/A** | |
| Click or tap here to provide comments, questions and/or recommendations. | | | |

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| Were all applicable declarations signed when and as required (e.g. supervising veterinarian, LAT, pharmacist, biosafety officer, radiation officer and/or statistician, as well as by the director of research entity and other applicable signatories)? |  | **Yes** | **No** |
| **N/A** | |
| Click or tap here to provide comments, questions and/or recommendations. | | | |

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| Specific Matters of Ethical Concern |

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| Is the ethical principle of “Replacement” (i.e. alternatives) appropriately addressed (i.e. clearly and fully identified and explained in context of the study), and is it satisfactorily motivated how it has been implemented in the planning of the study, and how it will eventual be monitored in the execution of the study? |  | **Yes** | **No** |
| **N/A** | |
| Click or tap here to provide comments, questions and/or recommendations. | | | |

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| Is the ethical principle of “Reduction” (i.e. minimum number of animals, without compromising scientific validity) appropriately addressed (i.e. clearly and fully identified and explained in context of the study), and is it satisfactorily motivated how it has been implemented in the planning of the study, and how it will eventual be monitored in the execution of the study? |  | **Yes** | **No** |
| **N/A** | |
| Click or tap here to provide comments, questions and/or recommendations. | | | |

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| Is the ethical principle of “Refinement” (i.e. methods, techniques & experimental design for optimal results and minimal suffering) appropriately addressed (i.e. clearly and fully identified and explained in context of the study), and is it satisfactorily motivated how it has been implemented in the planning of the study, and how it will eventual be monitored in the execution of the study? |  | **Yes** | **No** |
| **N/A** | |
| Click or tap here to provide comments, questions and/or recommendations. | | | |

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| Is the ethical principle of “Responsibility” (to enhance the quality of life of animals in human care, including to monitor and manage, with clear indications who is responsible for what, as well as not to violate community values) appropriately addressed (i.e. clearly and fully identified and explained in context of the study), and is it satisfactorily motivated how it has been implemented in the planning of the study, and how it will eventual be monitored in the execution of the study? |  | **Yes** | **No** |
| **N/A** | |
| Click or tap here to provide comments, questions and/or recommendations. | | | |

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| Have all harmful interventions in animals been satisfactorily justified by the applicant, in your opinion, and were all associated aggravating and mitigating factors clearly described, and were the indicated precautionary measures optimal and sufficient? |  | **Yes** | **No** |
| **N/A** | |
| Click or tap here to provide comments, questions and/or recommendations. | | | |

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| According to the harm-benefit analysis by the applicant, and in your opinion, does the benefit clearly outweigh the harm? If IN EVERY REASONABLE RESPECT (in your opinion) this have been satisfactorily addressed, indicate “Yes”, otherwise indicate “No” and provide comments, questions and/or recommendations below. |  | **Yes** | **No** |
| **N/A** | |
| Click or tap here to provide comments, questions and/or recommendations. | | | |

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| Are there any general comments not mentioned elsewhere, or any other matters of ethical concern that needs clarification or correction? |  | **Yes** | **No** |
| **N/A** | |
| Click or tap here to provide comments, questions and/or recommendations. | | | |

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| Final Review Recommendations |

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| Conditions of approval *(if applicable)* |

Indicate any conditions of approval that should apply:

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| Click or tap here to enter text. |

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| Recommended severity category |

In your opinion, what is the category of the most severe experience of the animals, or cumulative severity of experiences of the animals during the execution of the study? Please select your choice from the drop-down list below:

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| Please indicate the appropriate **category** here **→**  as applicable to this application: | Choose an item from the list. |

Motivation and/or any comments or questions

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| Click or tap here to enter text. |

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| Reviewer’s final recommendation |

In your opinion, what is your final recommendation for the approval level of the project? Please select your choice from the drop-down list below:

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| Please indicate the **approval level** here **→**  as applicable to this application: | Choose an item. |

Motivation and/or any comments or questions

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| Click or tap here to enter text. |

***- End of Report –***