

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

[health-sciences.ac.za/healthethics](http://www.nwu.ac.za/healthethics)

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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. C member** (animal welfarist) for the review of **single** or **larger** scientific **studies** using animal vertebrates or higher invertebrates for research, education/training or repetitive testing purposes  **AnimCare 02-01b3, 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 |

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| Ethically Acceptable Standard of the Science |

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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? If ALL of these conditions have been met satisfactorily (in your opinion), 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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| 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.? If ALL of these conditions have been met satisfactorily (in your opinion), 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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| Animal Welfare, Safety |

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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, sever and prolonged physiological and/or psychological suffering, etc.) been fully described, and is there sufficient competence to monitor and manage these? If ALL of these conditions have been met satisfactorily (in your opinion), 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 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)? If ALL of these conditions have been met satisfactorily (in your opinion), 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 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? If ALL of these conditions have been met satisfactorily (in your opinion), 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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| Have the humane endpoints been well described and will this be adequately monitored, recorded on appropriate monitoring sheets and managed? If ALL of these conditions have been met satisfactorily (in your opinion), 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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| 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? If ALL of these conditions have been met satisfactorily (in your opinion), 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 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?? If ALL of these conditions have been met satisfactorily (in your opinion), 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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| 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? If ALL of these conditions have been met satisfactorily (in your opinion), 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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| 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)? If ALL of these conditions have been met satisfactorily (in your opinion), 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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| 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? If ALL of the questions related to this principle have been met satisfactorily addressed (in your opinion), indicate “Yes”, otherwise indicate “No” and provide comments, questions and/or recommendations below. |  | **Yes** | **No** |
| **N/A** | |
| Please provide your assessment and any comments and/or questions for the applicant here, even if it is appropriately addressed. | | | |
| 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? If ALL of the questions related to this principle have been met satisfactorily addressed (in your opinion), 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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| 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? If ALL of the questions related to this principle have been met satisfactorily addressed (in your opinion), 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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| 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? If ALL of the questions related to this principle have been met satisfactorily addressed (in your opinion), 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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| 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? If ALL of these have been met satisfactorily addressed (in your opinion), 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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| 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 –***