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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)* **Cat. 0 Ethics Application Form** for category 0 projects using animal vertebrates or higher invertebrates  for research or training purposes, but without ethical implications  ***AnimCare 02-03a, 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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| General Project Identification |

Provide the necessary descriptions below to identify this project application:

* 1. Full, descriptive title of the project

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| Click here to enter text. |

* 1. Name & university no. of the Project Head *(principle investigator / study leader / responsible educator)* and Postgraduate Student *(if applicable)*

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| **Role** | **Name** | **NWU staff/student no.** |
| Project head | Click here to enter name.. | Click here to enter number. |
| Student | Click here to enter name.. | Click here to enter number. |

* 1. Discipline(s), Name of the NWU Research Entity(ies), Faculty(ies) and NWU Campus(es)

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| Click here to enter text. |

* 1. Type of application:

*(Select the appropriate option from each dropdown list below)*

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| **Type** | | **Response** | | |
| Is this an application for a *research project,* *education/training project or repetitive testing/monitoring intervention*? | | Choose an item. |
| Is this an application for a *single*or a *larger project*? | | Choose an item. |

**Please note!** “Single” refers to a simple, stand-alone study with pre-identified *(usually few)* researchers / students and roles, whereas a “larger” refers to, for example *(but not limited to)*, a well-defined but compiled / complex study, which can be subdivided into several well-defined smaller sub-studies for multiple postgraduate students, or a well-defined large training project, which can be subdivided into several sub-compiled workshops or repetitions, or a standard test or monitoring intervention, repeatedly performed for different clients from time to time).

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| Applicant’s Instructions Projects using biological samples of animals that are already dead (excluding where the vertebrate or lower invertebrate animal, regardless the developmental stage, is to be euthanized for the purpose of the study) for further *in vitro* experimentation may qualify for exemption of ethical clearance and be considered **Category 0** projects.   1. **General instructions**    1. **Important!** 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. All research project proposals/protocols MUST be approved by a Scientific Committee BEFORE submitting this application for ethics approval.    3. All applications and supporting documentation must be in English only, and only electronic versions submitted via e-mail will be accepted.    4. Complete this application form and attach all supporting documentation (e.g. certificates, authorisation documents to verify sound sources of animal tissue/fluids and disposal).    5. You are advised to convert final versions of documents to PDF (i.e. “save as PDF”) before submitting them via e-mail.    6. You will be requested to submit printed hard copies of all final documents for required record keeping, but only following ethics review, corrections and final approval. 2. **Documents & attachments to be submitted**   The following schema and descriptions below explain all documents to be submitted *(compare with the check list at the end of this document)*:    Figure 1: Flow diagram of all documents to be submitted with the ethics application, where CV = curriculum vitae; CoC = Code of Conduct; SOP = standard operating procedure. More details follow below.   1. ***This application form:*** Give this document a name starting with “0) ”, for example  “0) Application Form.docx”. Any cover letter (optional) or rebuttal/response letter in case of amendments/corrections, should also start with “0) “. 2. ***Project proposal:*** The project proposal MUST be attached, which must be Scientific Committee-approved for all research projects. For training projects, however, the study guide should be attached here, and for SOPs, the SOP document should be attached. Give this document a name starting with “1) ”. 3. ***Letter of approval:*** Attach a concise letter confirming approval of the project proposal by the Scientific Committee (see above). This letter should be printed on a formal letterhead and signed by the chair of the Scientific Committee, as well as state the approved project title, name of the principle investigator, the date of approval and names of committee members who approved the project proposal. Give this document a name starting with “2) ”. 4. ***Monitoring sheets:*** Not applicable 5. ***Narrative CVs & Codes of Conduct:*** Ensure that a 2-page narrative CV of the applicant (project manager) is attached (demonstrating qualifications, professional registrations, publications over the last 4 years, other publications related to the project, research expertise and other relevant competencies). Also attach for a copy of the applicant’s signed NWU Code of Conduct for Researchers. Give each of these documents a name starting with “4a) “, “4b) “, etc. 6. ***Authorisation, registration & training:*** Not applicable 7. ***Supervisor declarations:*** The signed Declaration Form for the Project Manager and Director of Research MUST be attached. Give each of these signed documents a name starting with “6a) ”, “6b) “, etc. 8. ***Other documents:*** All applicable permission letters, permits and contracts received from relevant governing bodies, collaborators, sponsors or others, informed consent from owners *(if applicable)*, as well as any AnimCare-approved SOPs MUST be attached. Give each of these documents a name starting with “7a) ”, “7b) “, etc. 9. **Final submission steps for this application**   The following process must be followed to submit ethics applications *(until the implementation of Info-Ed, whereafter online submissions will apply)*:   * 1. Complete the checklist (end of document) to ensure your application contains all required documents.   2. 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](mailto:Ethics-AnimCare@nwu.ac.za)).   3. Submit the original hard copies of the signed pages of declaration forms to the Faculty of Health Sciences Ethics Office for Research, Training and Support, Box 500, North-West University, Potchefstroom, 2520 *(tel 018 299 1208)*.   **Please note!**   1. All applicants must ensure that all required finalised documents as indicated above are included with the submission of your ethics application. NO additional attachments or version correction(s) will be accepted after submission.  If this does occur and the application was incomplete, the application will be withdrawn (additional administrative fees may be incurred) and the whole application will have to be resubmitted with all of the documents attached, which could mean that the application may not be considered for the originally intended meeting date and postponed to a later date. 2. All approved applications will have an expiry date no later than one years after the approval date (may be sooner, as determined by the AnimCare committee), and will be indicated on the final certificate of approval. Submission of the annual monitoring reports two months prior to the expiry date may serve as extension of approval for another year as required. |

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| 1. **Project Description** |

*Executive Summary:* Summarise the project in *150 words max*, outlining the problem statement, objectives, methods & study design (including animal numbers), as well as expected outcome / benefit. This should be as much in layman’s terms as reasonably possible, so that a wider audience can understand.

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| Click or tap here to enter text. |

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| 1. **Motivation why Category 0 applies** |

Motivate clearly why Category 0 (i.e. no ethical implications) should apply for this project.

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| Click or tap here to enter text. |

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| 1. **Additional Information** |

* 1. **Details of animals involved and biological samples to be used in this project**

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| Click or tap here to enter text. |

* 1. **Details of the provider (source) of the biological samples for this project, including the ethics approval numbers of projects from which the samples originated**

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| Click or tap here to enter text. | |
| Ethics approval number(s) | Click or tap here to enter ethics approval numbers. |

* 1. **Description of why and how the animals would have been euthanized originally, anyway *(i.e. unrelated to this project)***

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| Click or tap here to enter text. |

* 1. **Details of the method(s) to obtain the biological samples from dead animals for the purpose of this project**

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| Click or tap here to enter text. |

* 1. **Details of the suitability of the biological samples for use in this project** *(e.g. previous treatments will not adversely affect intended analyses)***, of measures for ensuring sample integrity** *(e.g. appropriate storage conditions & security)***, of record keeping** *(e.g. with information for identification and history)***.**

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| Click or tap here to enter text. |

* 1. **Details of sound disposal of the biological samples after use in this study**

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| Click or tap here to enter text. |

* 1. **Describe any health and safety risks to researchers, student or other staff members** *(e.g. any biological hazard)***, as well as appropriate safety measures**

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| Click or tap here to enter text. |

* 1. **Is there any significant bearing of this study on any endangered or protected species or significant impact on the environment?**

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| Select | If yes, click or tap here to provide details. |

**Please note!** If yes, please provide details on the risk level, identify risk factors and associated precautionary/mitigating measures, AND complete the form on “Estimated Environmental Impact Category” (form no. NS Ethics 01-01a).

* 1. **Envisaged commencement and completion date of the project, once ethics approval has been granted**

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| **Envisaged  Commencement Date** | **Envisaged  Completion Date** |
| Click or tap to enter a date. | Click or tap to enter a date. |

* 1. **Describe how you will ensure that any significant finding is explicitly disseminated to the appropriate authority** *(e.g. notifying the Medical Research Council regarding any manifested toxicity or finding that may bear on safety of a drug in humans, or the Department of Agriculture, Forestry and Fisheries regarding any finding that may bear on environmental safety)* **and/or to the public** *[Responsibility]*

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| Click or tap here to provide details. |

* 1. **Any additional comments from the Project Head**

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| Click or tap here to enter text. |

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| Checklist |

Ensure that you have all required documents for submission of your ethics application:

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| **Submission of electronic copies via e-mail** ([Ethics-AnimCare@nwu.ac.za](mailto:Ethics-AnimCare@nwu.ac.za)) | |
| **This completed category 0 ethics application form** |  |
| **Research proposal, study guide or SOP**   *(i.e. for research, education/training or repetitive testing/monitoring)* |  |
| **Scientific Committee’s** signed **letter of approval** for the research project |  |
| **Narrative CV of the applicant** *(project manager)* |  |
| Copy of the signed **NWU Code of Conduct for Researchers**  for each researcher in the project team *(project head, researchers, students)* |  |
| **Relevant certificates, authorisations, contracts and/or import/export permits** |  |
| **Project head’s declarations for category 0 applications declarations**  *(scanned copy of signed form)* |  |

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| **List of Attachments** Including the signed declaration forms, please list each document attached to this application |
| 1. Click or tap here to enter text. |