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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)* **Conversion of ‘Umbrella’ to Larger Projects** to apply for the approval of previously approved  **‘Umbrella’** projects *(former term)* to **Large** **Projects**  ***AnimCare 02-05a, 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:  *(of ‘umbrella’ project)*** | Click or tap here to enter text. |

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| General Project Identification |

Provide the necessary descriptions below to identify the approved project:

* 1. Full, descriptive title of the project

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| Click or tap here to enter text. |

* 1. Name of the Project Head *(principle investigator / study leader in case of research projects, or educator in case of training projects)* 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. Application dates & version number of this application

*(Fill in below the date of the first and current submissions of this ethics application.   
Also fill in the version number of the current submission, where the 1st submission will be version no. 1, and thereafter, the 1st corrections based on comments from the Ethics Committee will be version no. 2, etc.)*

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| **Approval Date** | **Expiry Date** |
| Click or tap to enter a date. | Click or tap to enter a date. |

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| Applicant’s Instructions  1. **General instructions**    1. The sole purpose of this once-off application is to assist researchers to convert their currently approved ‘umbrella’ projects to the new large projects. Most of these AnimCare-approved projects will comply with the definition of a large study (below). However, the implementation of the latest regulations and legislation, there may be new requirements for submission of information, letters or certificates that you may not have submitted with your original application. This form will assist you to determine which additional submissions should be made for your project to comply with all new requirements.    2. **Importantly!** “Larger” projects include, but are 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, repeatedly performed for different clients from time to time. 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)*. **You should now check which of these are now outstanding and need to be submitted**.    Figure 1: Flow diagram of all documents to be submitted with the ethics application, where SAVC = South African Veterinary Council, CV = curriculum vitae; CoC = Code of Conduct; SOP = standard operating procedure. More details follow below.   1. ***This application form:*** Would have been submitted previously. 2. ***Project proposal:*** **Please verify!** The Scientific Committee-approved project proposal MUST be attached. Give this document a name starting with “1) ”.. 3. ***Letter of approval:*** **Please verify!** Attach a concise letter confirming approval of the project proposal by the Scientific Committee (see §1.a 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:*** **Please verify!** All project-specific monitoring sheets (to observe any undue pain and suffering, and to manage (alleviate) pain and suffering when humane endpoints are reached) MUST be attached. Give each of these documents a name starting with “3a) ”, “3b) “, etc. 5. ***Narrative CVs & Codes of Conduct:*** **Please verify!** Ensure that a 2-page narrative CV is attached for each member of the project team *(project head, supervisor, researchers, students, co-workers, technicians, assistants, etc.)* and professional supervisors that are involved in the project (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 each researcher *(project head, researchers, students)* a copy of their signed NWU Code of Conduct for Researchers. Give each of these documents a name starting with “4a) “, “4b) “, etc. 6. ***Authorisation, registration & training:*** **Please verify!** Attach the certificate of appropriate minimum (a) Ethics training in the last 3 years plus the (b) NWU Vivarium authorisation, or (b) proof of an appropriate animal handling course plus South African Veterinary Council (SAVC) authorisation. Lastly, (c) an SAVC registration certificate must be attached for all animal holding facilities. This is required for each student / researcher / assistant participating in the project and working with (handling) animals. Give these documents names starting with “5) ”. 7. ***Supervisor declarations:*** Please sign only the latest declaration form for Project Heads. Other declarations would have been submitted previously. 8. ***Other documents:*** Would have been submitted previously. 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 open questions and then the checklist to ensure your application contains all required documents. You are advised to convert final versions of documents to PDF (i.e. “save as PDF”) before submitting them via e-mail.   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. 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.   **Please note!**   * 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. * 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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| Section 1: Basic Project Information |

* 1. **Executive summary of the project**

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. |

* 1. **Flow diagram of the project design**

Provide a simplistic flow diagram / schema of the overall study design, typically indicating the breakdown of the various control and test groups, animal numbers, interventions, measurements. It should be aligned with the study objectives and give the reader a “bird’s-eye view” of the whole study.   
**Please note!** Develop this in JPG, PNG, Enhanced Metafile or other compatible format, click on the icon in the middle of the block, browse “From a file” and upload the picture file.

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* 1. **Estimated animal experience category**

Please indicate the appropriate category applicable to this application.

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| ***More information***  *All vertebrate or higher invertebrate animal protocols and interventions must be classified according to the probable experience of the animal (discomfort, stress & distress) as below, also adhering to national legislation, the National Code for the handling and use of animals and the North-West University’s (NWU) regulations in this regard. Ethics approval is required for use of vertebrate or higher invertebrate animals, whereas for all other animals the Ethics Committee must only be notified (see Category 0). Categories of impact on animal wellbeing (in the laboratory, wild, farm or domestic) are as below, from which you need to make your selection according to the most severe intervention in your application.* |

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| **Cate-gory** | **Description** | **Select** |
| **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. |  |
| **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). |  |
| **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. |  |
| **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. |  |
| **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. |  |
| **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. |  |

**Please note!** The selected category will be evaluated and may be changed by AnimCare.

**Motivation and/or any comments:**

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The research proposal document forms the centre of any ethics application, and must explain the scientific / educational validity or the project, as well as address ethical considerations and other matters needed to support ethical validity of the application. Please ensure that then following proposal/protocol-related documents are attached:

* 1. ***Training / Research Proposal***   
     Attach the Project Proposal as approved by the NWU Scientific Committee (i.e. Research Proposal Committee or an Education Proposal Committee). Research proposals MUST contain at least the following elements, whereas for most training proposals these may be already by captured in the study guide or training guide:

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| * + Title *(concise, clear, descriptive)*   + Project head *(name & designation)*   + Literature review *(outlining current knowledge and questions, previous research / training, specific research problem and justification for the study, or training need, references)*   + Study goal and objectives (may include a hypothesis where applicable)   + Research / training methodology (study/experimental design/layout, animal type, number, housing, & handling, and applicable techniques, protocols & assays, humane endpoints – with sufficient detail to allow thorough ethics evaluation).   **NB!** *In this section you may refer to attached standard SOPs, but then you will have to also provide here, within your proposal document, concise descriptions thereof (e.g. assays and methods). Also be specific on how an SOP will be applied to your project, particularly when the SOP is generalised for a range of applications, or motivate and specify if you need to make a modification to the SOP. Make it easy for the reviewer to follow the story-line and essential details. The reviewer should find sufficient basic information within the proposal document, so that the attached SOP is to be consulted only when the reviewers needs to see more details.*   * + Data analysis *(mathematical and statistical)*   + Expected results and impact *(either research or training)*   + Broad outline of the time schedule   + Budget *(in particular demonstrating that the study can be completed once you start using animals)*   + **Important!** **General ethical considerations** and appropriate benefit/risk ratio analyses MUST be included in your training / research proposal, so that the application form is then used to expand and ask details on specific matters. |

* 1. ***Project-specific monitoring sheets***Provide copies of the designed motoring sheets (describing at least animal identification, monitoring dates, observations when undisturbed, observations during handling, specific clinical signs and other relevant information to determine wellbeing and when humane endpoint has been reached).
  2. ***Letter confirming approval of proposal***Attach a concise letter confirming approval of the project proposal by the Scientific Committee. This letter should be printed on a formal letterhead and signed by the chair of the committee, as well as state the approved project title, name of the primary investigator, the date of approval, names of committee members who approved the project proposal and a suggested estimated animal experience category 0 to 5.   
     **Please note!** In case of a conflict of interest by the chair, he/she may not approve and another designated member should sign.

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| Section 2: Additional matters |

* 1. **Monitoring of the project**

Describe how you as the researcher will monitor the following aspects during the implementation and progress of the project *(research or training)*:

* Training of team members and ensuring of competence
* Maintenance of any specialised equipment
* Compliance with the approved protocol
* Management of ethics throughout the research process
* Management of amendments during the execution of the project *(if applicable)*
* Reporting of any and all incidents or adverse events *(if applicable)*

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* 1. **Detailed indication of all changes to the protocol**

Describe in detail any and all changes to the protocol, animal number, etc. Also indicate exactly where *(pages, paragraphs, line numbers, etc.)* and how these changes are reflected in the new amended protocol attached. Describe changes in such a way that it will be easy for reviewers to find them.

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* 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. **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. |

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| Section 3: Checklist |

Please verify which of the required applications had already been submitted before, and now include those which had not been submitted before. Check the boxes of the

**or**

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| **Submission of electronic copies via e-mail** ([Ethics-AnimCare@nwu.ac.za](mailto:Ethics-AnimCare@nwu.ac.za)) | **Included:** | |
| **before** | **now** |
| **This completed application form for conversion of the ‘umbrella’ project to a large project** |  |  |
| **Ethics approval certificate of the ‘umbrella’ project**  (scanned copy) |  |  |
| **Project proposal** as approved by the Scientific Committee   *(i.e. Research Proposal Committee /Education Proposal Committee)* |  |  |
| **Scientific Committee’s** signed **letter of approval** of the project   *(i.e. by the Research Proposal Committee /Education Proposal Committee)* |  |  |
| **Monitoring sheets** to observe any undue pain and suffering,   and to manage (alleviate) pain and suffering when humane endpoints are reached |  |  |
| **Narrative CVs** for each member of the project team *(project head, supervisor, researchers, students, co-workers, assistants, etc.)* and professional supervisors |  |  |
| Copy of the signed **NWU Code of Conduct for Researchers** for each researcher in the project team *(project head, researchers, students)* |  |  |
| **Proof of ethics training** for each member of the project team  *(minimum SANS training during the last 3 years)* |  |  |
| **Vivarium authorisation** for each member of the project team handling animals  (following animal handling course and SAVC authorisation) |  |  |
| **Proof of SAVC authorisation**   *(included in Vivarium authorisation)* |  |  |
| **Proof of training in animal handling**   *(included in Vivarium authorisation)* |  |  |
| **Animal holding facility’s certificate of SAVC registration** |  |  |
| **Project head declaration**  *(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. |