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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)***Amendment Ethics Application Form**to make amendments to approved projects using animal vertebrates or higher invertebrates for research or training purposes***AnimCare 03-02a, Version 4.10 (Sep 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 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. Discipline(s), Name of the NWU Research Entity(ies), Faculty(ies) and NWU Campus(es)

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| Click or tap here to enter text. |

* 1. Type of project for amendment

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

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| **Type** | **Response** |
| Is this a *research* or *education/training project*? | Choose an item. |
| Is this a *single*or a *larger project* | Choose an item. |

**Please note!** To amend a subproject under a larger project, you need to apply for approval of amendment of the large project, and then indicate how this specifically applies to the sub-project.

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| General applicant instructionsAmendments to approved protocols may be necessary as new information becomes available. The following basic steps apply: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 amendments to research project proposal MUST be approved by a Scientific Committee BEFORE submitting this application for ethics approval.
	3. The Scientific Committee-approved amended project proposal (for research projects) or the amended study/training guide (for training projects) forms the principle document that is evaluated in conjunction with this application form. This application form gives the researcher the opportunity to expand on specific ethical issues required for approval.
	4. All applications and supporting documentation must be in English only, and only electronic versions submitted via e-mail will be accepted.
	5. Complete this application form and attach all supporting documentation (e.g. certificates, authorisation documents to verify sound sources of animal tissue/fluids and disposal).
	6. You are advised to convert final versions of documents to PDF (i.e. “save as PDF”) before submitting them via e-mail.
	7. 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. **Attachments (mandatory)**

The descriptions below explain all documents to be submitted *(compare with the check list at the end of this document)*:* 1. ***This application form:*** Give this document a name starting with “0) ”.
	2. ***Amended project proposal/protocol:*** The amended Scientific Committee-approved project proposal/protocol MUST be attached (see Section 3, par. 3.4 for requirements). Mark all changes to this form with red text, OR follow MSWord top menu [Review] / [Restrict Editing], untick *“Highlight the region I can edit”* and then use the highlighter. Give this document a name starting with “1) ”.
	3. ***Monitoring sheets:*** Any new/amended 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 “4a) ”, “4b) “, etc.
	4. ***Letter of approval:*** Attach a concise letter confirming approval of the amendment by the Scientific Committee (see §2.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 “5) ”.
	5. ***Narrative CVs:*** Ensure that a 2-page narrative CV of any new members of the project team (not included in the original application) is attached (demonstrating qualifications, professional registrations, publications over the last 4 years, other publications related to the SOP, professional & research expertise, experience and other relevant competencies). Give these documents a name starting with “6a) “, “6b) “, etc.) ”.
	6. ***Vivarium authorisation:*** For all new members of the project (or for project extensions where updated Vivarium authorisations may be necessary), attach the certificate of the NWU Vivarium authorisation (based on successful completion of an appropriate animal handling course, South African Veterinary Council authorisation, etc.) for each student / researcher / assistant participating in the project and working with animals. Give this document a name starting with “7) ”.
	7. ***Other documents:*** Declaration form signed by the Project Head, plus any relevant new certificates, authorisations or contracts MUST be attached. Give each of these documents a name starting with “8a) ”, “8b) “, etc.
1. **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).
	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 of amendments concurs with the existing expiry date of the approved project. Submission of the annual monitoring report for the large project two months prior to the expiry date may serve as extension of approval for another year as required.
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| 1. **Project details**
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* 1. **Executive Summary of the Currently Approved Project**

Summarise the currently approved 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. (**Please note!** *The details of where and how these changes were made in the amended proposal document will follow in §3.5 below*).

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| Click or tap here to enter text. |

* 1. **Envisaged commencement and completion dates of the project, as approved**

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

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| 1. **Amendment Details**
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* 1. **Motivation for amendment**

Describe broadly why changes to the currently approved proposal is necessary (i.e. provide a sound motivation), and then describe in broad terms what changes should be made to address the concerns.
**Please note!** *The details of where and how these changes were made in the amended proposal document will follow in §2.4 below*)

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| Click or tap here to enter text. |

* 1. **Description of any additional animal(s) for the amendment**

Give a full description of all additional animals that you will use in the amendment *(i.e. not accounted for in the currently approved project)*.

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| **Animal species** | **Number** | **Gender** | **Age/Mass** |

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| Click or tap here to enter text. | 00 | Choose | Type here. |

*Type only one animal species per row, or type “none” if there are no animals.
To add for more rows, click in the last (very right) cell and press the [Tab] key on your keyboard.*

* 1. **Ethics category and 3Rs**

Explain how the changes to the protocol will affect the project’s ethics category, how it affects the 3Rs (specific reference to impact on animal well-being, probable animal experience, animal number, replacements & refinements).

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| Click or tap here to enter text. |

* 1. **Any newly introduced procedures, risks and safety measures**

Describe any newly introduced procedure(s) and/or risks, and the corresponding safety measures, as applicable to this amendment request.

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| Click or tap here to enter text. |

* 1. **Detailed identification of ALL requested 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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| Click or tap here to enter text. |

* 1. **Estimated animal experience category of the amended project**

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. 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** |
| **Current Project** | **Amended Project** |
| **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 category for the current project should be marked as already approved under the existing ethics approval number. The selected category of the amended project should be estimated by the applicant, which may be changed by AnimCare.

**Motivation and/or any comments:**

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| Click or tap here to enter text. |

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| 1. **Team Member Changes**
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* 1. **New members of the Project Team, who were not already mentioned and approved in the original project application**

Names, qualifications and associations of all other new members of the project team. **Please note!** Attach a two-page narrative *curriculum vitae* (CV) for each new team member involved in the project.
***NB!*** *When a new team member (e.g. students) will be working with (handling) animals, the name and copies of supporting documentation (e.g. certificate of animal handling course) MUST be provided to to AnimCare.*

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| **Name** | **Functions & Responsibilities** | **Qualifications***[[1]](#footnote-1)* **& Profess. Registr.***[[2]](#footnote-2)* | **Competency Certification3** |

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| Type name or “not applicable”. | Type details or “not applicable”. | Type details or “not applicable”. | Type details or “not applicable”. |

*Type one new team member’s name per row, or type “none” if there are no new members.
To add for more rows, click in the last (very right) cell and press the [Tab] key on your keyboard.*

* 1. **Resigning *(i.e. previous)* members of the Project Team (as currently approved), who were not be involved in the project any longer**

Names, qualifications and associations of all resigning members (i.e. previous members, not continuing to be part of the project team.

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| **Name** | **Functions & Responsibilities** | **Qualifications1 & Profess. Registr.2**  | **Competency Certification3** |

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| Type name or “not applicable”. | Type details or “not applicable”. | Type details or “not applicable”. | Type details or “not applicable”. |

*Type one resigning team member’s name per row, or type “none” if there are no resigning members.
To add for more rows, click in the last (very right) cell and press the [Tab] key on your keyboard.*

* 1. **Is there any significant, newly introduced 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. **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) |
| **This completed ethics application form**  | [ ]  |
| **Amended project proposal (as approved by the Scientific Committee** *(i.e. Research Proposal Committee / Education Proposal Committee)***, and with changes highlighted Note!** Remember to also amend the executive summary and flow diagram of the study design | [ ]  |
| **Scientific Committee’s signed letter of approval of the project** *(i.e. by the Research Proposal Committee / Education Proposal Committee)***, and with changes highlighted** | [ ]  |
| **Scientific Research/Education Committee’s signed letter of approval of the project amendment** | [ ]  |
| **Any new/amended monitoring sheets** *(to observe any undue pain and suffering, and to manage (alleviate) pain and suffering when humane endpoints are reached)* | [ ]  |
| **Narrative CVs of all new members of the project team** *(not included in the original application)* | [ ]  |
| **Proof of ethics training** **for all new members** *(minimum SANS training during the last 3 years)* | [ ]  |
| **Vivarium authorisation for all new members** (following animal handling course and SAVC authorisation) | [ ]  |
| **Proof of SAVC authorisation** **for all new members** (included in Vivarium authorisation)**or** | [ ]  |
| **Proof of training in animal handling** **for all new members** (included in Vivarium authorisation) | [ ]  |
| **Animal holding facility’s certificate of SAVC registration for any new facilities**  *(not included in the original application)* | [ ]  |
| **Project head’s and professional supervisor declarations forms** *(scanned copies of signed forms, as applicable to the amendment)* | [ ]  |
| **Other new permission letters, informed consent, permits and contracts**  *(as received from relevant governing bodies, collaborators, sponsors or owners)* | [ ]  |

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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.
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1. Fill in all qualifications relevant to the project, e.g. Ph.D., M.Sc., M.B.Ch.B., B.Pharm., B. Cur., M.Psig., etc. [↑](#footnote-ref-1)
2. Fill in the professional body name and your category of professional registrations with councils that are applicable to the project, e.g. HPCSA if medical doctor, SAPC if pharmacist, SANC if nurse, HPCSA if clinical psychologist, SACNASP if scientist of SA Council of Natural Science Professions, etc. [↑](#footnote-ref-2)