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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)* **Sub-Study Ethics Application Form** for approval of sub-studies under already approved larger projects  using animal vertebrates or higher invertebrates for research or training purposes  ***AnimCare 03-01a, 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** Click or tap here to enter text. | **Date received** Click or tap to enter a date. |

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| General Project Identification |

Provide the necessary descriptions below to identify this project application:

* 1. Full, descriptive title of the larger 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. Ethics approval no. and the current expiry of the larger project’s ethics approval

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| **Ethics approval no.** | **Expiry Date** |
| Click or tap here to enter number. | Click or tap to enter a date. |

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

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| General Information  1. **What constitutes a sub-study under a larger project?**   A larger project refers to a well-defined but compiled / complex project, which can be subdivided into several well-defined smaller sub-studies, for example a large study to train multiple postgraduate students each in a sub-study, or a well-defined large training project with several sub-compiled workshops. Therefore, a sub-study must be a well-defined section of an already approved larger project, so that it aligns with the objectives, study design and methodology that was already defined for the large study. If it is different or adds to what was defined in the larger project, it is not a sub-study any longer. Alternatively, the large study can first be amended to accommodate the changes or additions, whereafter the sub-study can be applied for.   1. **Conditions for a sub-study**   The following must apply for a study to be approved as a sub-study of a large study:   1. The sub-study can only be approved within the validity period of the approved larger project. That also implies that, when the approval of the main study expires *(i.e. without a monitoring report to extend the project)*, the approval of the sub-study will automatically expire as well. 2. The objectives, methodology and animals used in the sub-study may all involve only a sub-section of what was defined in the larger project, but they may not add/change anything to what was already defined in the larger project. Accordingly, the associated category of the impact on animal wellbeing will not be higher than that of the larger project. 3. Any new supporting documentation, such as sub-study-specific monitoring reports, and for new team members (e.g. new postgraduate student) the certificates of training in ethics and animal handling, SAVC or other authorisation, etc. must be available and attached. 4. Where the sub-study involve continuous testing of new substances, additional information MUST be provided (see question 1.4 below) 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.  Applicant’s Instructions  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 sub-study proposals/protocols MUST be approved by a Scientific Committee BEFORE submitting this application for ethics approval.    3. The Scientific Committee-approved larger project plus sub-study proposals forms the base documents that are evaluated in conjunction with this application form. This application form is very concise with minimal information, and merely guides the applicant in the process.    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. **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 SAVC = South African Veterinary Council, CV = curriculum vitae; CoC = Code of Conduct; SOP = standard operating procedure. More details follow below.   1. ***Cover letter & this application form:*** Include a short cover letter describing your intent with a sub-study and its context, as well as this completed application form, and these documents should start with “0). 2. ***Larger project proposal, ethics certificate & sub-project proposal:*** The Scientific Committee-approved larger project proposal *(as submitted to AnimCare before),* ethics approval certificate of the larger study *(as issued before)* and Scientific Committee-approved sub-study proposal MUST be attached *(similar requirements as for the large study proposal)*. Give these documents names starting with “1) ”. 3. ***Letter of approval:*** Attach a concise letter confirming approval of the sub-study proposal by the Scientific Committee (see §1.a above). This letter should be printed on a formal NWU 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:*** Only if an appropriate monitoring sheet was not included in the approved large study application, new sub-study-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:*** Ensure that a 2-page narrative CV is attached for each new member of the project team *(e.g. new portgraduate students)* and new professional supervisors that are involved in the sub-study (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 new researcher on the team a copy of their signed NWU Code of Conduct for Researcher. Give each of these documents a name starting with “4a) “, “4b) “, etc. 6. ***Authorisation, registration & training:*** Only for new team members 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. Give these documents names starting with “5) ”. 7. ***Supervisor declarations:*** The project head of the large study MUST sign the permission form that the sub-study may take place under the larger project, also defining exactly what will be permitted or excluded. This signed Supervisor Declaration Forms MUST be attached. Give each of these signed documents a name starting with “6a) ”, “6b) “, etc. 8. ***Other documents:*** Any other new applicable documents *(that was not included in the approved large study application)*, such as permission letters, permits, collaborators, sponsors, 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 this 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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| SUB-STUDY ADDITIONAL INFORMATION |

* 1. **Executive summary of the sub-study**

Summarise the sub-study in *150 words max*, describing how it fits in the large study and outlining the problem statement, objectives, methods & study design (including animal numbers), as well as expected outcome / benefit of the sub-study. This should be as much in layman’s terms as reasonably possible, so that a wider audience can understand.

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

Provide a simplistic flow diagram / schema of the overall sub-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 sub-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. **Typical requirements for the sub-study proposal**

The sub-study proposal, as approved by a NWU Research Proposal Committee (RPC), should contain the following elements:

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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),  **plus** an indication of how this study fits in the large study   + 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 research / training proposal. |

* 1. **New substances to be tested in the sub-study**

In cases where the sub-study involve continuous testing of new substances (e.g. newly synthesised drugs, new extracts, toxins or other compounds that was not defined in the larger project), more details MUST be provided on the substances to be tested. Whereas the larger project provides details about the objectives and kind of substances (e.g. chemical class) to be evaluated, the exact new substances are not known at the time of the umbrella application. When eventually synthesised, the risks that these new substances in the sub-study hold for animals may be unique.

Are any newly synthesised / isolated substances tested in live animals in the sub-study?

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| **Yes** | **No** |  | **Short description of substance(s)** |
|  |  |  | Type motivation here, or type “Not applicable”. |

Only if **“Yes”**, the properties (e.g. chemical or other), potential / expected physiological effects, side-effects and other potential risk of the new substance(s) should be explained in the proposal of the sub-project, as well as detailed precautionary and monitoring measures (including monitoring sheets) to minimise risk and to optimise animal well-being. Also provide any unique humane end-points applicable. Compare what is described for the new substance(s) with what was described in the approved larger project.

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| Checklist |

Ensure that you have all required documents for submission of your monitoring report:

**or**

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| **Submission of electronic copies via e-mail** ([Ethics-AnimCare@nwu.ac.za](mailto:Ethics-AnimCare@nwu.ac.za)) | |
| **This completed application form** |  |
| **Ethics approval certificate of the larger project**  (scanned copy) |  |
| **Larger project proposal** as approved by the Scientific Committee   (i.e. Research Proposal Committee /Education Proposal Committee) |  |
| **Sub-study proposal** as approved by the Scientific Committee   (i.e. Research Proposal Committee /Education Proposal Committee) |  |
| **Scientific Committee’s** signed **letter of approval** of the **sub-study**   (i.e. by the Research Proposal Committee /Education Proposal Committee) |  |
| **New monitoring sheets** *(only if not included in the approved larger project application)* to observe any undue pain and suffering, and to manage (alleviate) pain and suffering when humane endpoints are reached |  |
| **Narrative CVs** of **new** members only |  |
| Copy of the signed **NWU Code of Conduct for Researchers** of **new** members only |  |
| **Proof of ethics training** of **new** members only  (minimum SANS training during the last 3 years) |  |
| **Vivarium authorisation** of **new** members only  (following animal handling course and SAVC authorisation) |  |
| **Proof of SAVC authorisation** of **new** members only  (included in Vivarium authorisation) |  |
| **Proof of training in animal handling** of **new** members only  (included in Vivarium authorisation) |  |
| **Project head’s permission that the sub-study may fall under the larger project**  *(scanned copy of signed form)* |  |
| 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. |