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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)* **Secondary Data Ethics Application Form** for using secondary data of previously performed projects  using animal vertebrates or higher invertebrates for research or training purposes  ***AnimCare 02-04a, 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 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 application:

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

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| **Type** | **Response** |
| Is this an application for a *research project* or for an *education/training project*? | Choose an item. |
| Is this an application for a *single*or a *larger project*(where *“larger****”*** refers to, for example (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) | Choose an item. |

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| Applicant’s Instructions In some cases the secondary data of previously performed studies using animals can be used for a different study. The original study may be from the same or a different researcher, and from the same or a different institution. The basic steps outlined below 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 research project proposals/protocols MUST be approved by a Scientific Committee BEFORE submitting this application for ethics approval.    3. The Scientific Committee-approved project proposal (for research projects) or the 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.    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 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 Scientific Committee-approved new project using the secondary data proposal MUST be attached. Give this document a name starting with “1) ”. 3. ***Letter of approval:*** Attach a concise letter confirming approval of the new project proposal by the Scientific Committee (see 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:*** 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. **New Project** |

The new project refers to the project that will use secondary data from a different study using animals

* 1. **Executive Summary of the New 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. **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. |

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| 1. **Previous Project** |

The previous project refers to the original project that used the animals, from which the secondary data will be derived and used.

* 1. **Executive Summary of the Previous 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. **Details of animals involved in the previous project**

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| Click or tap here to enter text. |

* 1. **Ethical clearance**

Provide details about the ethical clearance of the previous project *(by which ethics committee and from which institution and country, copy of the ethics clearance certificate and number, any specific conditions of the ethics clearance, approval and expiry date of such clearance, any incident or other reports of that project which may affect ethics clearance, etc.)*.

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| Click or tap here to enter text. |

**Please note!** A copy of the ethics clearance certificate of the previous project must be attached to this application.

* 1. **Status of Previous Project**

Provide details about the current status of the previous project *(i.e. approved and in process, discontinued, completed)*.

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| Click or tap here to enter text. |

* 1. **Details of the provider *(source)* of the secondary data from the previous project**

Describe the provider of the secondary data to be used.

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| Click or tap here to enter text. |

* 1. **Data collection**

Explain how the data from the previous project was collected. Details must be sufficient to allow the Ethics Committee to ascertain that the data collection was indeed ethically sound and also of high scientific quality, collected by appropriately competent and authorised individuals

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| Click or tap here to enter text. |

* 1. **Data Integrity**

Explain how the raw and/or worked-up data from the previous project that you will utilise for the new study was stored to ensure data integrity. Can it be ascertained that the data was collected by competent individuals?

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| Click or tap here to enter text. |

* 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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| 1. **Other Important Information** |

* 1. **Contractual agreement / permission**

Provide details about the contractual agreement and/or permission to use the secondary data, with specific reference to intellectual property and any allowed and disallowed use of the data.

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| Click or tap here to enter text. |

**Please note!** A copy of any contractual agreement of permission in writing must be attached to this application.

* 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 ethics application form** |  |
| **Scientific Research/Education Committee’s signed letter of approval of the new project that will utilise the secondary data** |  |
| **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, agreements, contracts and/or permits** |  |
| **Project head’s declarations for secondary data applications**  *(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. |