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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)* **Ethics Application Form for SOPs** to apply for the approval of **Standard Operating Procedures**  related to the operational care of, experimental work with, or training purposes  using animal vertebrates or higher invertebrates  ***AnimCare 02-02a, 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 SOP Identification |

**Please note!** SOP approval does not give access to the use of animals, but merely approves a certain procedure, technique, intervention as ethically acceptable. To implement an approved SOP for use in animals will require a full project application (typically the *[AnimCare 02-01a]* application form), referring to the approved SOP.   
Provide the necessary descriptions below to identify this SOP application:

* 1. Full, descriptive title of the SOP

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| Click or tap here to enter text. |

* 1. SOP reference number, SOP version (issue) no. and other SOP identification details

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| **Role** | **Name** | **NWU staff no.** |
| Responsible Person | Click here to enter name.. | Click here to enter number. |

* 1. Name of the SOP Responsible Person (ethics applicant / SOP authoriser)

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| Click or tap here to enter text. |

* 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** |
| Does this SOP related to an *established procedure* or for a *new procedure*? | Choose an item. |

* 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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| **Date of first application** *(i.e. the 1st submission)* | **Date of revised application** *(if applicable)* | **Version  no.** |
| Click or tap to enter a date. | Click or tap to enter a date. | Select no. |

* 1. Contracts & Informed Consent: Are there any contractual agreements with any person, group or institution involved in this SOP? If so, how many?

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

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| **Response** | **Number of contracts/consents** |
| Choose an item. | Select no. |

**Please note!** If “Yes, provide details in § 2.2 below.

* 1. Other Research Ethics Committees:

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

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| **Type** | **Response** |
| This SOP is currently / has been evaluated by ***another ethics committee*** (e.g. multi-institutional SOPs)? | Choose an item. |

**Please note!** If “Yes,   
provide details in § 2.3below

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| **Quick Navigation Links** *Hold in the “Ctrl” key + click with the mouse* | | | | | |
| Executive summary of the SOP | Applicant’s Instructions | Table of Contents | Ethical Point of Departure | Special considerations | Section 6: Checklist |

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**Tip!** Jump-link to appropriate sections: Ctrl + mouse-click on page number.

As you complete the application form, update page numbers with F9, then update page numbers only.

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| 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 SOPs related to research or animal care MUST be approved by a Scientific Committee (or an *ad hoc* Professional Care Committee) BEFORE submitting this application for ethics approval. Even when officially recognised international/national guidelines are followed, this must be confirmed by the Scientific Committee.    3. The Scientific Committee-approved SOP (for research or animal care) or the study/training guide (for training SOPs) forms the base 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. All applicants to complete the “General SOP Identification” above, as well as all Sections below. Also ensure that all attachments indicated below, and as applicable to this application, are attached. 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 SOP ethics application, where CV = curriculum vitae; 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. ***SOP:*** The Scientific Committee-approved SOP MUST be attached (see Section 3, par. 3.7 for requirements). Give this document a name starting with “1) ”. 3. ***Letter of approval:*** Attach a concise letter confirming approval of the SOP 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 SOP title, name of the SOP responsible person, the date of approval and names of committee members who approved the SOP. Give this document a name starting with “2) ”. 4. ***Monitoring sheets:*** All SOP-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:*** Ensure that a 2-page narrative CV is attached for each member of the SOP team *(responsible person, compiler, contributors, reviewers and others)* and professional supervisors that are involved in the SOP (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 each of these documents a name starting with “4a) “, “4b) “, etc. 6. ***Authorisation, registration & training:*** Attach the certificate of appropriate minimum Ethics training in the last 3 years of the *responsible person*. *For the purpose of the SOP application, no supporting documents are required regarding team members’ NWU Vivarium authorisation, animal handling course or South African Veterinary Council (SAVC) authorisation, or regarding facility registration at the SAVC.* Give these documents names starting with “5) ”. 7. ***Supervisor declarations:*** All applicable signed Supervisor Declaration Forms from relevant professional supervisors (e.g. SOP responsible person, veterinarian, pharmacist, radiation officer, biological safety officer, facility head) MUST be attached. *(****Please note!*** *The application MUST be discussed timeously (at least one week prior to submission) with ALL professional supervisors, any resulting corrections or amendments made and then returned to signed off in time for submission. Professional supervisors may not be unduly pressured to sign off to meet deadlines, so that applicants should plan for this.)* 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)* 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 (Section 6) 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 SOP applications will have an expiry date no later than three years after the approval date (may be sooner, as determined by the AnimCare committee), and will be indicated on the final certificate of approval. SOPs must be updated at least every three years. |

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| Section 1: SOP Team, Collaborators and Supervisors |

* 1. **Details of SOP Responsible Person**

Name and details of the SOP Responsible Person (ethics applicant / SOP authoriser). **Please note!** Attach a two page narrative curriculum vitae (CV) for all SOP team members.

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| ***More information***  *The “SOP Responsible Person” accepts final, overall responsibility for the management of the total SOP. The SOP Responsible Person is sometimes referred to as the SOP Authoriser. Only NWU staff, or extraordinary professors in collaboration with staff of the North-West University, may register as SOP Responsible Person. The SOP Responsible Person is a part of the SOP team.* |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| *Surname* | Click here to enter text. | | | | | |
| *Full names* | Click here to enter text. | | | | | |
| *Title* | Click here to enter text. | | *NWU staff no.* | | Click here to enter text. | |
| *Faculty* | Click here to enter text. | | | *Entity* | Click here to enter text. | |
| *Status* | Choose an item. | | *Rank / Designation* | | Click here to enter text. | |
| *Qualifications**[[1]](#footnote-1)  & Profess. Reg.**[[2]](#footnote-2)* | Click here to enter text. | | *Competency Certification**[[3]](#footnote-3)* | | Click here to enter text. | |
| *Functions & Responsibilities* | Click here to enter text. | | | | | |
| *E-mail* | Click here to enter text. | | | | | |
| *Cell* | Click here to enter no. | *Tel (w)* | Click here to enter no. | | *Tel (h)* | Click here to enter no. |
| *Office physical address* | Click here to enter text. | | | | | |
| *NWU box or postal address* | Click here to enter text. | | | | | |

* 1. **Other Members of the SOP Team   
     *(involved in the design, compilation, review and monitoring of the SOP)***
     1. Names, qualifications and associations of the SOP compiler, SOP contributors and SOP reviewers (excluding professional supervisors who may not be directly involved in the execution of the SOP – see §2.3).  **Please note!** Attach a two page narrative curriculum vitae (CV) for each SOP team member.

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

|  |  |  |  |  |  |
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| Type name  or “not applicable”. | Compiler |  | Type details of specific function here. | Type details  or “not applicable”. | Type details  or “not applicable”. |
| Contributor |  |
| Reviewer |  |
| Other |  |

*Complete one table with information per SOP team member.   
For more members, fill in the relevant details (as in the table above) in the text box below.*

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| Click or tap here to enter text. |

* 1. **Collaborations**

Declare with full details all collaboration agreements, e.g. with researchers or lecturers from another institution, national or international, who will be working on a defined section of the SOP.

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| ***More information***  *Your local team may collaborate with a team from a different institution in South Africa or internationally, thereby, for example, to incorporate and benefit from their expertise and/or facilities. Typically in such cases you take responsibility for a certain part of the SOP and the collaborator for a different part. These responsibilities and agreements must be fully described and declared here.* |

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| **Name of Collaborator** | **Full Description and Declaration** |

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

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

* 1. **Professional Supervisors** *(where and as applicable)*
     1. Name and qualifications of all supervisory professional persons (e.g. veterinary surgeon, pharmacist, veterinary nurse, qualified scientist, etc.)   
        **Please note!** The professional supervisor(s) may not be part of the SOP team!   
        **Please note!** Attach a two page narrative *curriculum vitae* (CV) for all professional supervisors of the SOP.

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

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| Section 2: Legal Matters |

* 1. **Conflict of Interest and Sponsorships**
     1. Declare with full details any conflict of interests of any one member of the SOP team or professional supervisor (see § 2.1, 2.2, 2.3 & 1.4).

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| ***More information***  *Examples of conflict of interest: financial, non-financial: intellectual, bias, overly optimistic promises of potential benefits, role of the researcher/s, desire of professional advancement, desire to make a scientific breakthrough, relationship with participants.* |

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| **Name of Team Member** | **Complete Description and Declaration** | **How will this be managed?** |

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

*Type one researcher name per row, or type “none” if there are no researchers with a conflict of interest.   
To add for more rows, click in the last (very right) cell and press the [Tab] key on your keyboard.*

* + 1. Give full details of all sponsors of the SOP (name, address, affiliation with the SOP and the nature and extent of each sponsor’s contribution).

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| --- | --- | --- |
| **Name of Sponsor** | **Contact Details** | **Affiliation & Contribution** |

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

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

* + 1. Is any participant in the SOP directly or indirectly involved with one or more of the sponsors? Does any member of the SOP team receive any form of remuneration or other benefits from the sponsor(s), either directly or indirectly? Give full details.

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| **Name of Researcher** | **Association with Sponsor** | **Remuneration or benefits** |

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

*Type one researcher name per row, or type “none” if there are no researchers with such an association.   
To add for more rows, click in the last (very right) cell and press the [Tab] key on your keyboard.*

* 1. **Contractual Agreements**

Declare with full details all contractual agreements (e.g. with team members, collaborators or sponsors) on the SOP.   
**Please note!** A copy of any contractual agreements, approved by the NWU legal office and signed by the appropriate NWU line-management, MUST be attached and submitted to the Office of the Health Research Ethics Committee, together with submission of this application.

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| ***More information***  *Sometimes there are e.g. contractual obligations with co-workers of organisations outside the University. These contractual obligations may e.g. place restrictions on certain aspects on the availability of raw data i.t.o. intellectual right of ownership. Particularly where foreign co-workers are involved, these contracts can get complex. Therefore you must indicate here what these contractual obligations encompass, whether the University approved and sanctioned it and declare and describe any other potential legal and ethical implications thereof.* |

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| **Name of Contractor** | **Full Description and Declaration** |

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

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

* 1. **Other Animal Research Ethics Committees**

Provide full details of all other Animal Research Ethics Committees (ARECs) evaluating the SOP.

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| **Other Research Ethics Committee** *(if applicable)* | | | |
| **Name of  AREC** | Click to type name. | | | |
| **Name of  institution** | Click to type name. | Click to type name. | Click to type name. | |
| **Approval date** | Click to enter date. | Click to enter date. | Click to enter date. | |
| **Ethics approval no.** | Click to type number. | | | |

*Type information for only one committee per table, or type “none” if there are no other committees.   
For more RECs, fill in the relevant details (as in the table above) in the text box below.*

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| Click or tap here to enter text. |

* 1. **Insurance**

The North-West University has insurance at its disposal to cover the risk of claims against the University in case of harm to animals due to professional negligence – the maximum cover is R100 million per annum *(all studies included, amount updated 2016)*. However, this is only available if SOPs are ethically approved and researchers have kept to the SOP. You should familiarise yourself with the insurance *(information available from the Ethics Office on request)*, and weigh this against potential risks to the researchers, students, assistants, animals and environment.

* + 1. Have you familiarised yourself with the NWU insurance and is this insurance adequate?

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| **Yes** | **No** |  | **Details** |
|  |  |  | Type details here. |

* + 1. Do you have any other / additional insurance for the SOP?

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| **Yes** | **No** |  | **Details** |
|  |  |  | Type details here. |

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| Section 3: General SOP Information |

* 1. **Validity of the SOP**

Confirm that this SOP has already been evaluated and approved by a formal Scientific Proposal Committee or a Professional Care Committee (PCC).   
**Please note!** A letter confirming approval of the SOP by the aforementioned committee MUST be attached and submitted to the Office of the Animal Research Ethics Committee, together with this application.

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| ***More information***  *The NWU Committee refers to a Scientific Proposal Committee (SPC) or a Professional Care Committee (PCC), also sometimes referred to as a committee for higher degrees, research committee, educational committee, etc.). Even when officially recognised international/national guidelines are followed, this must be confirmed by the SPC/PCC. In case of a training SOP, the official study/training guide will suffice.* |

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| **Confirm** |  | **Details** | |
| **Yes** |  | Body underwriting the SOP, or name of NWU committee | Click or tap here to enter text. |
| Full reference to the SOP, or members of NWU committee | Click or tap here to enter text. |
| Date of approval | Click or tap to enter a date. |
| **No** |  | **Please note** that the SOP proposal **MUST** be approved by a formal SPC/PCC (compulsory) for all SOPs **BEFORE** it will be reviewed by AnimCare. | |
| **n/a** |  | This is a training SOP and the study/training guide is attached. | |

**Any comments:**

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| Click or tap here to enter text. |

* 1. **Full, descriptive title of the SOP**

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| Click or tap here to enter text. |

**Please note!** Title must be the same as the one provided op the 1st page.

* 1. **Envisaged SOP approval, implementation and review dates and the envisaged ethics approval date**

Anticipated dates, once ethics approval has been granted

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| ***More information***  *Here you can indicate the envisaged SOP approval, implementation and review dates and the envisaged ethics approval date. As a general norm, the review date is within two years of the approval date. The SOP approval, implementation and review dates are determined by the SOP development processes, whereas the ethics approval date is determined by AnimCare. Ensure that the envisaged implementation date is after the date of the AnimCare meeting at which your application is to be reviewed. There may be cases of existing implementation of a SOP within an approved SOP, where it has been reviewed (which is a different scenario).* |

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| **Envisaged SOP Approval Date** | **Envisaged SOP Implementation Date** |
| Click or tap to enter a date. | Click or tap to enter a date. |

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| **Envisaged SOP Review Date** | **Envisaged Ethics Approval Date** |
| Click or tap to enter a date. | Click or tap to enter a date. |

* 1. **Executive summary of the SOP**

Summarise the SOP in *150 words max* of the SOP, outlining the scope, objectives & methods. 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. **Specs**

Sketches/images & specifications of the procedure set-up and all apparatus. If these are included in the SOP, simply refer to the relevant section of the SOP. If not applicable, clearly state that.   
**Please note!** Develop a sketch or image 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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| Click or tap here to enter text descriptions to supplement the sketch/image below. |
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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. |  |
| **N/A** | **Not applicable**, for procedures that does not involve direct interaction with animals, although its implementation may eventually affect wellbeing. This may include, for example, the cleaning and setting up of animal cages, provision of environmental enrichment, food preparation, climate control, etc. |  |

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

**Motivation and/or any comments:**

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| Click or tap here to enter text. |

* 1. **Required SOP-related attachments**

Please ensure that then following SOP-related documents are attached:

* 1. ***SOP***   
     Attach the SOP as approved by the Scientific Committee.
  2. ***SOP-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).
  3. ***Letter confirming approval of SOP***Attach a concise letter confirming approval of the SOP 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 SOP title, name of the SOP responsible person, the date of approval and names of committee members who approved the SOP proposal.   
     **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 4: Specific Ethical Implications of SOP |

The information contained in this part is additional to what is contained in the SOP.

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| **Ethical Point of Departure**   1. AnimCare recognises the **moral dilemma** of using sentient animals with sensations and emotions for experimentation. At the same time, we accept that experimentation with animals is **essential** to advance biomedical sciences, ultimately reducing suffering and enhancing life and wellbeing:    1. In all instances sound **motivation** and **justification** for the use of animals and procedures must be provided.    2. The **repetition** of previously performed research experiments with animals will not be considered, unless it can be motivated to be necessary and shown to contribute to new knowledge. 2. The principle of the **3Rs** will be applied:    1. ***Replace:*** to replace animals with alternatives where possible    2. ***Reduce:*** to reduce the number of animals used to the minimal that will still provide scientifically verifiable answers    3. ***Refine:*** to refine experimental design and procedures (to replace animals where possible, select the optimal animal model, minimise stress to animals, reduce the number of animals used, and optimise the data obtained from experiments). 3. Ethical reflection will consider human / experimenter safety, animal wellbeing and environmental integrity. In this regard, the **wellbeing of animals will remain of utmost importance**, firstly by ensuring humane treatment of animals at all times, and by recognising undue stress, pain or discomfort and making relief thereof a priority above the interest of scientific / experimental interest. 4. All keeping, handling, and experimentation with animals must be done according to well-designed experimental protocols and with appropriate safety measures in place, in appropriate, approved, maintained and monitored **facilities** and by appropriately qualified, trained and competent **researchers** and **technicians**, under supervision of appropriately qualified and registered **professionals** (see §1.5). 5. All projects utilising animals for research or training purposes at the North-West University will stand the test of scientific integrity and **must be approved by AnimCare** or another appropriate Animal Research Ethics Committee (AREC) of the NWU.   **These ethical issues should be addressed by the applicant in Section 4.** |

* 1. **Animal(s) description**

Give a full description of the animals that is used in the SOP. *[Reduce]*   
**Please note!** The “Number” of animals in the table below refer to a typical number (or range) where this SOP is applied in an experimental design.

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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. **Alternatives for animals** *[Replace]*

Are there any ethically friendlier alternatives available to achieve the SOP objectives meaningfully (e.g. lower order animals without consciousness / feeling, tissue cultures, computer models, etc.)?   
*(Please mark with* **X** *in the appropriate box and provide details if “Yes”)*

|  |  |  |  |
| --- | --- | --- | --- |
| **Yes** | **No** |  | **Details** |
|  |  |  | Type motivation here, or type “Not applicable”. |

* 1. **Justification of animal use** *[Justify]*

Provide a justification for the use of vertebrates and the choice of the species for this SOP. Explain briefly too what theoretical or practical value (interest/benefits) this SOP may have (e.g. benefit in terms of human and/or animal wellbeing, the environment, science, education/training, and/or the society/economy). The evaluators use this information to carry out a cost / benefit calculation.

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| Click or tap here to enter text. |

* 1. **Alternative SOPs** *[Refine]*

Are there any alternative or better SOPs or approaches to achieve what is intended with the current SOP? If “Yes”, provide full motivation why this SOP is necessary.   
*(Please mark with* **X** *in the appropriate box and provide details if “Yes”)*

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| **Yes** | **No** |  | **Motivation & Details** |
|  |  |  | Type motivation here, or type “Not applicable”. |

* 1. **Animal availability** *[Justify]*

Is this species readily available (e.g. from the NWU Vivarium)? Mention where the animals are available. *(Please mark with* **X** *in the appropriate box and provide a motivation if “Yes”)*

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| **Yes** | **No** | **n/a** |  | **Details** |
|  |  |  |  | Type details here”. |

* 1. **Permits**

Is a permit required by law for the capture, collection, transport or detention of this (these) species? If “Yes”, mention the name and address of the authorising authority.  
*(Please mark with* **X** *in the appropriate box and provide details if “Yes”. If the permits already exist, also mention the permit number, terms and conditions and expiry date)*

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| **Yes** | **No** |  | **Motivation & Details** |
|  |  |  | Type motivation here, or type “Not applicable”. |

* 1. **Special ethical considerations**

This SOP encompasses experimentation with use, administration or restraint of, or other intervention with:   
*(Mark ALL options as “Yes” or “No” with X in the appropriate box – more than one option may be “Yes”.)*

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| **Description** | **Yes** | **No** |
| 1. Genetic material, genetic manipulation, or genetically manipulated |  |  |
| 1. Pathogens associated with communicable disease |  |  |
| 1. Specialised animal models |  |  |
| 1. General anaesthesia, surgical or other severely invasive procedures |  |  |
| 1. Injections, blood samples and similar interferences |  |  |
| 1. Use / administration / deprivation of any experimental / test substances |  |  |
| 1. Toxicological studies |  |  |
| 1. Severe and/or prolonged (>30 min) physical or psychological stress, pain or suffering |  |  |
| 1. Restraint (restricting movement, e.g. leash or cage) |  |  |
| 1. Endangered and protected species or sensitive ecological systems |  |  |
| 1. Staged predator observation |  |  |
| 1. Use of radio-active substances |  |  |
| 1. Generated chemical or biological waste |  |  |
| 1. Any other aspect of potentially ethically sensitive nature |  |  |

**Please note!** If any of the above is “Yes”, you will have to ensure that appropriately detailed information on this matter is provided in the questions below, in particular regarding the kind of stressors, risks and associated safety measures regarding animal wellbeing, justification, risks and associated safety measures regarding the researcher and/or environment, expertise, skills and legal competencies and the facilities. You may refer to other AnimCare-approved SOPs, but still need to provide brief descriptions of the procedure. More information and details are provided in the blocked yellow section (***Table 1***) on the next page.

**Motivation and/or any comments** *(optional)***:**

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| Click or tap here to enter text. |

**Table 1:** Explanation of matters for special consideration

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| **More Information about Special Considerations**  If applicable to the SOP, comment on the following aspects in more detail in questions 4.9 and further below:   1. **Genetics***, including genetic material or manipulation, genetically modified organisms / tissue / cells.* Description of interventions & procedures, product information (approved names, suppliers / origin, methods of storage, maintenance & retention, description of materials, normal use / application, dangers & risks, standard precautionary measures, literature references), expertise & competencies, training of new team members, facilities, institution responsible for analyses. 2. **Pathogens associated with communicable disease***, including any micro-organisms or hazardous disease-forming agents.* Description of the pathogen or other disease-inducing agent, pathogen information (approved names, suppliers / origin, methods of storage, maintenance & retention, description, dangers & risks, standard precautionary measures, literature references), expertise & competencies, training of new team members and facilities. 3. **Specialised animal models***, including translational models, xenographs.* Description of the clinical and/or pathological features of the model, general model information (approved name, source / origin / supplier, housing conditions, normal uses or applications, impact on animal wellbeing, special care and monitoring requirements, literature), expertise, facilities, safety measures. 4. **General anaesthesia, surgery or severely invasive procedures**, *including intracardiac puncture, microdialysis, implants.* Description of procedures, AnimCare-approved SOPs (if available), discomfort, risks, precautionary measures, professional supervision, authorisation, competencies, training of new team members, facilities. 5. **Injections, blood samples and similar interferences***, including swabs, biological fluids, biopsies.* Description of procedures, discomfort and risks, expertise, facilities, biological waste management, precautionary measures. 6. **Use / administration / deprivation of any experimental / test substances***, including drugs or medicines (including scheduled substances), experimental foods, fluids, supplements or nutrients, dietary or nutritional deficiencies, deprivation of food or water, toxic or dangerous substances*. Approved names and description of substances, professional supervision (including of scheduled substances), safety measures, product information (name and classification, brand names, MCC registration (if applicable), indications, known or expected effects, risks and toxicity in experimental animals (pharmacological, therapeutic, nutritional, deficiency and/or toxicological), precautionary measures, literature, accepted or expected dosages and administration routes, any experimental formulation testing prior to administration. 7. **Toxicological studies***, including TD50 & LD50 studies.* Description of procedures, discomfort, risks, precautionary measures and monitoring, professional supervision, authorisation, competencies, training of new team members, facilities. 8. **Severe and/or prolonged (>30 min) stress, pain or suffering***, including physical or emotional.* Description of procedures, discomfort, risks, precautionary measures and monitoring, professional supervision, authorisation, competencies, training of new team members, facilities. 9. **Restraint***, including restricting movement with a leash or cage.* Description of procedures, discomfort, risks, precautionary measures and monitoring, competencies, training of new team members, facilities. 10. **Endangered and protected species or sensitive ecological systems**. Description of procedures, risks, precautionary measures and monitoring, competencies and licences, informed consent from any owners and training of new team members. 11. **Staged predator observation**. Description of procedures, discomfort, risks, precautionary measures and monitoring, professional supervision, authorisation, competencies and licences, informed consent from any owners, training of new team members, facilities. 12. **Radio-active substances**. Approved names and description of substances, competencies, licensing and approved facilities *(attach certificate & permission letter from radiation officer)*, precautionary measures. 13. **Chemical and/or toxic waste**. Description of waste products, competencies, facilities, precautionary measures. |

* 1. **Probable experience of the animal** *[Refine]*

[Refer to **Table 1**, p. 20.] What will the probable experience *(including severity or degree of discomfort or suffering)* of the animal be and what measures are in place to minimise this, and to optimise wellbeing?

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| ***More information***  *List the procedures that may cause restraint, discomfort, anxiety and pain. While you emphasise the probable experience of the subjects, refer inter alia to the following aspects, as applicable to your SOP:*   1. *Provide in particular details on any step that may cause any form of discomfort or even suffering. Describe clearly e.g. the use or withholding of any painkillers, anaesthetic, surgical techniques, intra-operative and post-operative care and/or euthanasia at the end of the SOP/experiment.* 2. *Describe furthermore all specific procedures and sample collections (e.g. number, frequency, routes of administration and measurements, etc.).* 3. *Categorise the procedures as minimal, intermediary or high, with reference to the categories provided in § 3.6 above). Give the probable duration of the suffering. Also describe the steps that will be taken to minimise/alleviate the suffering, e.g. the use of analgesics or anaesthetic, and estimate how effective it is likely to be.)* 4. *Describe all the steps fully and in order, so that the evaluator can form an image of the probable experience of the subject.* |

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| Click or tap here to enter text. |

* 1. **Details of products and animal models** *[Refine]*

[Refer to **Table 1**, p. 20.] Provide details of all products (e.g. genetic materials, pathogens, specialised animal models, drugs or medicines, experimental foods, fluids, supplements or nutrients, dietary or nutritional deficiencies, deprivation of food or water, toxic or dangerous substances, toxic waste).

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| Click or tap here to enter text. |

* 1. **Stressors, risks and justification of animal procedures** *[Refine]*

[Refer to **Table 1**, p. 20.] Briefly identify all physical and/or psychosocial stressors to be induced to animals, and then provide a justification for the selection of the procedures (methods, protocols, tests and other interventions) involving live animals. Explain briefly too what theoretical or practical value this SOP may have. The evaluators use this information to carry out a cost / benefit calculation.

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* 1. **Risks to the experimenter(s) and/or environment,   
     and associated precautionary measures**

[Refer to **Table 1**, p. 20.] Describe all risks to the experimenter(s) in handling the animals and performing the described animal procedures (for example infections, injuries, etc.). Also refer to any potential biological hazard or environmental risk. Which precautionary measures are in place to minimise risk and to report and handle any incidents.

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* 1. **Disturbance variables** *[Refine]*

Describe the foreseeable disturbance variables (background variables) of the SOP and how you will manage them.

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| ***More information***  *What background variables (disturbance variables) are inherent that cannot be kept constant in executing the SOP, e.g. different researchers carrying out the SOP; more than one laboratory being used; different days during which the procedure runs, etc. What measures are in place to control / manage / monitor these variables?* |

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| Click or tap here to enter text. |

* 1. **Who may use the SOP?** *[Refine]*

[Refer to **Table 1**, p. 20.] What expertise, skills and legal competencies *(including in handling animals and to perform specialised procedures)* are needed to implement the SOP?

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| Click or tap here to enter text. |

* 1. **Proper training and implementation of the SOP** *[Refine]*

[Refer to **Table 1**, p. 20.] How will you ensure competence throughout the course of the SOP implementation *(i.e. proper training, execution and monitoring of the SOP)*? In particular, explain how the necessary training will be provided before the SOP implementation commences.   
**Please note!** No person may use the SOP without proof of competency. How will you keep record of the abovementioned criteria?

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| Click or tap here to enter text. |

* 1. **Where may the SOP be implemented? Animal holding facilities, housing conditions and care.** *[Refine]*

Are all animal holding facilities where the SOP source animals and/or perform experiments registered with the South African Veterinary Council? Also describe in detail housing conditions (including environmental enrichment) and appropriateness of the facilities for holding animals according to national regulations & guidelines, providing for adequate care to promote welfare, including holding conditions and regular monitoring of animals. Which precautionary measures are in place to minimise risk and to report and handle any incidents?   
**Please note!** For animals to be used in the NWU Vivarium (or other approved, SAVC-registered NWU animal holding facility), only a brief description will suffice. However, animals to be used outside such a NWU facility, detailed descriptions MUST be provided. *(For work done at the NWU Vivarium, brief descriptions will suffice. Also, where the SOP holds more than minimal risk, all emergency care situations must be carried out within an emergency care space approved by the supervisory doctor.)*

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| **Yes** | **No** |  | **Details about appropriateness** |
|  |  |  | Type registration number and details here, or type “Not applicable”. |

**Please note!** For all animal holding facilities, attach the registration certificate.

* 1. **Detailed description of all other specialised facilities** *[Refine]*

[Refer to **Table 1**, p. 20.] Describe in detail all place(s) and facilities where the SOP will be implemented, in particular referring to aspects such as appropriateness for holding animals, safe and legal performance of procedures, other SOPs and documentation for waste management, radio-active work (if applicable), etc.

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* 1. **Transportation of animals** *[Refine]*

Where live animals will be transported, provide detailed descriptions of thereof, including details about precautionary measures in line with national regulations.

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* 1. **Humane endpoints and monitoring of animals** *[Refine, Welfare]*

List clinical signs peculiar to the procedures and provide criteria for humane endpoints, as outlined in attached monitoring sheets, explain monitoring procedures and frequencies, when, how and by whom will enactment of humane endpoints be ensured, explain responsibilities, describe discomfort and potential risks (for researcher, animal & environment), precautionary measures and post-mortem procedures.

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| ***More information***  *The endpoint(s) involve the stage when euthanasia is to be introduced, which can be either the experimental endpoint (e.g. when no more data will be collected or when animal tissue is to be collected for ex vivo analyses) or a humane endpoint to alleviate or end undue pain or suffering prior to the end of the experiment. In the latter case, enactment of humane endpoints, when reached, SHALL take precedence over continuation and/or completion of the SOP via anaesthesia or euthanasia.*  *All SOPs involving animals should have monitoring sheets to evaluate animal well-being. Besides this, animals should be monitored to observe any undue pain or suffering, or the deterioration of general wellbeing, and in this regard criteria for human endpoints must be set. Importantly, death or moribund (near-death) state SHALL NOT be acceptable as humane endpoints, unless exceptional motivation can be provided (e.g. certain toxicological studies). Where the experimental interference may have specific impact on the welfare of the animals, list criteria to monitor the welfare of the animals during the experiment?* |

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**Please note!** General and SOP-specific monitoring sheets MUST be attached.

* 1. **Euthanasia** *(fate of the animals)**[Refine, Welfare]*

Describe which method(s) of euthanasia will be applied and the rationale thereof. Also describe how animals will be disposed of. Provide information on professional supervision, authorisation, competencies, training, facilities and responsibilities of all team members to implement, observe and record humane euthanasia, including measures to ensure actual death. For animals to be used in the NWU Vivarium, only a brief description will suffice if standard procedures are followed. However, animals to be used outside the NWU Vivarium, detailed descriptions MUST be provided.

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* 1. **Storage and archiving of data**

Explain how, where and how long the research data will be stored. **N.B!** All raw data remains the property of the North-West University. Only copies may leave the storage area, and then only by authorised persons. Where an outside party, e.g. a sponsor, lays claim to the original data, certified copies must be stored on the Campus and the same rules apply as above.

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| ***More information***  *Some legislation, rules and regulations for certain professions stipulate that data must be stored for a specified minimum period. Most government departments however store data for a minimum of 7 years and it is recommended as a general rule that data is not stored for less than 7 years. You must therefore indicate here what the requirements are that apply to your SOP. Furthermore, does any person have the right to request to see and study the original data of published results in order to verify the accuracy and validity thereof?*  *Management of data/biological samples:*   1. *What data (electronic & hard copies) and biological samples will be stored? How it will be stored?* 2. *How data in its various forms will be managed, and by whom will it be managed?* 3. *Who will have access to the stored data/biological samples, how will data be regained from other research team members and, if data sharing is to occur, how will this be managed?* 4. *For how long biological samples be stored? Who will instruct sample destruction and how the samples be destroyed?* |

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| Click or tap here to enter text. |

* 1. **Monitoring of the SOP** *[Refine, Welfare]*

Where and as applicable, describe how the following aspects should be monitored by whoever implements the SOP:

1. Training of team members and ensuring of competence
2. Maintenance of any specialised equipment
3. Compliance with the approved procedure
4. Monitoring of any reported adverse events relating to the SOP, so that necessary action can be taken to reconsider the use of, or to correct any insufficiencies related to the SOP

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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?** *[Refine]*

|  |  |
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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 other aspect of potentially ethically sensitive nature**

Please describe in full any other aspect that may potentially be of an ethically sensitive nature not mentioned elsewhere and which must be brought to the attention of the Ethics Committee. Explain the measures, as applicable, that will be in place to protect the workers, subjects and the environment against the potential detrimental effects of the above-mentioned interference.

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| Section 5: Statistical Justifiability |

Not applicable to the ethics applications for approval of SOPs. Rather, statistical justifiability will be applicable to project applications implementing the SOP.

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| Section 6: 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**  (“General SOP Identification”, and all other Sections 1 to 4.) |  |
| **SOP** as approved by the Scientific Committee (i.e. Professional Care Committee, Research Proposal Committee or Education Proposal Committee) |  |
| **Scientific Committee’s** signed **letter of approval** of the SOP |  |
| **Monitoring sheets** to observe any undue pain and suffering,   and to manage (alleviate) pain and suffering when humane endpoints are reached |  |
| **Narrative CVs** of each member of the SOP team (responsible person, compiler, contributors, reviewers, etc.) and professional supervisors |  |
| **Proof of ethics training** of the SOP responsible person |  |
| **Animal holding facility’s certificate of SAVC registration** |  |
| **Supervisor declarations**  (scanned copies of signed forms – see separate document) |  |
| Other **permission letters**, **informed consent**, **permits** and **contracts**   as received from relevant governing bodies, collaborators, sponsors or owners |  |

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| **List of Attachments** Please list each document attached to this application, with the name of the document  *(including those indicated in the checklist above, as well as any other document you attached)* |
| 1. Click or tap here to enter text. |

1. Fill in all qualifications relevant to the SOP, 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 SOP, 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)
3. For all members of the SOP team, the minimum competency certification is a valid certificates for Ethics Training. Please ensure copies are attached. [↑](#footnote-ref-3)