

Faculty of Health Sciences Ethics Office for Research, Training and Support

[health-sciences.ac.za/healthethics](http://www.nwu.ac.za/healthethics)

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| North-West University Animal Care, Health and Safety Research Ethics Committee**NWU-AnimCareREC***registered as Animal Research Ethics Committee (AREC) with the South African National Health Research Ethics Council (NHREC) of the National Dept. of Health,* ***Reg. no. AREC-130913-01*****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 02-01a, Version 5.10 (Jul 2019)** |
| **CONFIDENTIAL!** This document contains confidential information that is intended strictly and exclusively for the applicant and the NWU-AnimCareREC. Should this document or parts thereof erroneously come in your possession, you are requested to destroy it or to return it to Ethics-AnimCare@nwu.ac.zawithout delay. Unauthorised possession, reading, studying, copying or distribution of this material, or any other form of abuse, is illegal and prosecutable. |

**Please note!** Refer to ***Addendum A: Applicant’s Instructions*** and ***Addendum B: SOP Requirements*** for more information on how to complete this ethics application form and for requirements for the research proposal document. Also familiarise yourself with ***Addendum C: Moral Declaration*** and ***Addendum D: Severity Categories***.

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| **Quick Navigation Links** *Hold in the “Ctrl” key + click with the mouse* |
| Executive summary of the  | **Error! Reference source not found.** | Severity category of the  | Checklist and attachments | Section 5: Harm-Benefit Analysis |

|  |  |
| --- | --- |
| **Research Ethics Number** | **NWU-?????-??-??** |
| **Campus** | Click here to enter text. |
| **Faculty** | Click here to enter text. |
| **Research Entity** | Click here to enter text. |
| **Discipline** | Click here to enter text. |
| **SOP Responsible Person** | Click here to enter text. |
| **Student** *(name & surname)* | Not applicable to SOPs |
| **SOP Title** | Click here to enter text. |

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

As you are completing the application form, you have to update page numbers with the F9 keyboard function.

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| Section 1: General Study Identification & Application Process Info |

**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 ethics application for a SOP, which then will refer 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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| Click or tap here to enter text. |

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

|  |  |
| --- | --- |
| **Name** *(title, first name and surname)* | **NWU staff no.** |
| Click here to enter title, first name and surname. | Click here to enter number. |

* 1. **Institutional structures and divisions under which the SOP resides**

|  |  |
| --- | --- |
| Campus(es) | Click here to enter details. |
| Research entity(ies) | Click here to enter details. |
| Faculty(ies) | Click here to enter details. |
| Discipline(s) | Click here to enter details. |

* 1. **Type of SOP application**

Does this SOP relate to an established procedure or for the development of a new procedure?

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| Choose an item. |

* 1. **Track record of submission dates and version numbers of this application**

Indicate the date of submission of the first application and of any subsequent revisions (based on feedback from NWU-AnimCareREC) until the current version.

|  |
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| ***More information****Provide a track record of the submissions and versions of this application, from the first submission, subsequent revisions until the current version. 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.). Complete the date until the current version, and leave the dates for the remainder unselected.****Please note!*** *The latest version will always be used as the current version for the purpose of any passive or active monitoring, or audit. The dates and version no. (based on previous submissions, corrections and/or amendments) may automatically be calculated by an electronic submission platform (once implemented).* |

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| --- | --- | --- | --- | --- | --- |
|  | Select date. |  | Select date. |  | Select date. |
|  | Select date. |  | Select date. |  | Select date. |
|  | Select date. |  | Select date. |  | Select date. |

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

Anticipated dates of the various steps of approval, implementation, review and ethics approval of the SOP.

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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 NWU-AnimCareREC. Ensure that the envisaged implementation date is after the date of the NWU-AnimCareREC 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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| **InternalSOP Approval Date** | **EnvisagedSOP Implementation Date** |
| Click or tap to enter a date. | Click or tap to enter a date. |

|  |  |
| --- | --- |
| **Specified / EnvisagedSOP Review Date** | **EnvisagedEthics Approval Date** |
| Click or tap to enter a date. | Click or tap to enter a date. |

* 1. **Severity category of the SOP**

Please indicate the appropriate severity category (compare **Addendum D: Severity Categories**) applicable to this SOP as a whole. This can be completed here only when considering the cumulative severity category as indicated in **question 5.2** below, towards the end of this application form.

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| ***More information****This estimation should be done after you have described your SOP in full.****Please note!*** *The selected category will be evaluated and may be changed by NWU-AnimCareREC.* |

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| **Severity category for the SOP as a whole:** | **Choose an item.** |

**Motivation and/or any comments:**

Briefly motivate your selection of the category as indicated above, with reference to question 5.2.

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| Click or tap here to enter text. |

* 1. **Special conditions associated with implementation of this SOP in a study?**

Declare Whether any of the conditions below may potentially apply to implementation of the SOP to a study *(i.e. a separate ethics application)*, so that NWU-AnimCareREC should be aware of this potential requirement when reviewing a study referring to the current SOP in this application.

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| ***More information****When* ***transporting*** *animals or animal samples that do or may contain* ***pathogens****, a transport permit, materials transfer agreement (****MTA****), and/or permit from the Department of Agriculture, Forestry and Fisheries (****DAFF****) must be in place. Section 20 of the Animal Diseases Act, 1984 (Act No 35 of 1984) requires that any study involving pathogens, or any organism that may potentially become pathogenic or harmful to the environment, animals or humans, regardless of where performed, requires a* ***Section 20 permit****.****SACNASP:*** *This council (*[*https://www.savc.org.za/*](https://www.savc.org.za/)*) ensures and administers the mandatory registration of natural scientists as required in terms of The Natural Scientific Professions Act of 2003.****SAVC:*** *Section 23(1)(c) authorisation is required under the Veterinary and Para-Veterinary Professions Act (Act 19 of 1982) is regulated by the South African Veterinary Council (SAVC -* [*https://www.savc.org.za/*](https://www.savc.org.za/)*). This is described in the guidance document of the SAVC’s “Guidance for the categorical classification system for the authorisation of persons who perform veterinary or para-veterinary procedures on animals for scientific purposes (including for research, teaching, testing or validation)”, 2018:**“Authorisation is required for procedures defined as veterinary or para-veterinary procedures, services or functions in the Regulations or Rules for the veterinary or para-veterinary professions; or for clinical veterinary or para-veterinary procedures that are carried out on animals for scientific purposes, that may cause an animal a level of fear, pain, suffering, distress, deterioration or lasting harm, that is equivalent to, or higher than, that caused by inserting a hypodermic needle according to good veterinary practice. Killing is considered to be a procedure when an animal is killed for scientific purposes, including the killing of animals that were bred or acquired, but not used, for scientific purposes. Welfare monitoring or welfare assessment is considered to be a procedure in which clinical judgement is used to assess or diagnose the presence or degree of fear, pain, suffering, distress, deterioration in wellbeing or lasting harm. The transport of docile animals within a building; and general animal husbandry; are not considered to be procedures.**Describe the groupings of veterinary and para-veterinary procedures, functions or services, for which authorisation for scientific purposes may be applied for, as follows:** ***Category A:*** *Minor, minimally invasive, or killing procedures, that do not involve sedation, analgesia or general anaesthesia;*
* ***Category B:*** *Minor or minimally invasive procedures involving sedation, analgesia or brief (< 15 minutes duration) general anaesthesia, with no residual pain on recovery; or surgical procedures conducted under brief non-recovery general anaesthesia;*
* ***Category C:*** *Surgical procedures involving general anaesthesia; the administration and maintenance of balanced or more prolonged (≥ 15 minutes duration) general anaesthesia; or use of neuromuscular blocking agents;*
* ***Category D:*** *Other procedures or techniques that do not fall into any of the other Categories [Note: This Category should only be used in exceptional cases];*
* ***Category E:*** *Health practitioners registered with the Health Professions Council of South Africa (HPCSA) who perform Category A to C procedures, in cases where the procedures on humans are included in the health practitioner’s Scope of Practice;*
* ***Category F:*** *Persons who perform, on a professional or employment level, inter alia some of the services, functions or procedures of veterinarians, laboratory animal technologists or other para-veterinary professionals.”*

***Please note!******Professionals registered at the SAVC*** *(i.e. veterinarians and para-veterinarians) may perform procedures within their scope of practice and therefore do not need SAVC authorisation. Simply indicate their SAVC registration from the drop box below.**If applicable to this SOP, is a* ***permit*** *required by law for the capture, collection, transport or detention of this (these) species? Will it be required to import any animals or samples?****Please note!*** *More information can be found on the NWU-AnimCareREC website, or via consultation.* |

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| **Condition** | **Yes** | **No** |
| **Scheduled substances** that will require prescription and oversight by a veterinarian and/or pharmacist (in which case a study using this SOP will have to appoint appropriate professional supervisors) |[ ] [ ]
| **Veterinary or para-veterinary** procedures that will require supervision by a SAVC-registered professional, and/or may require SAVC authorisation by a researcher |[ ] [ ]
| **Procedures associated with natural science professionals** that will require SACNASP registration by a researcher |[ ] [ ]
| **Transportation** of animals or animal samples (i.e. tissue or fluids) that may potentially contain **pathogens** (in which case a study using this SOP will require a MTA and section 20 permit from DAFF) |[ ] [ ]
| Any requirements for **permits** to perform a study that wants to implement this SOP, for example access to **national parks** or **protected areas** or import of animals or animal samples |[ ] [ ]

* 1. **Checklist and attachments**

Indicate the number of each type of attachment below, together with the document names of all the attachments. Document names, as explained below, should follow a systematic order.

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| ***More information****More information on required attachments is available at the end of this document in* ***Addendum A: Applicant’s Instructions****:** *Remember to start* ***document names*** *as per prescribed format (see “****Addendum A: Applicant’s Instructions****”), i.e. starting with the* ***designated numbering****, for example**[****1) Cover letter****], [****2) Research proposal****],etc.)*
* *Where there are two or more documents per category (i.e. line number in the table below), provide the* ***names*** *of both* ***documents****, again using the designated* ***numbering*** *before the descriptive name, for example [****5.1) SOP for waste removal****] and [****5.2) SOP for euthanasia****], etc.).*

***Please note!*** *Please keep the* ***names brief****, because long names will not save properly in the complex folder systems sometimes required for official archiving.* |

|  |  |  |
| --- | --- | --- |
| **Document(s)** | **No**  | **Name(s) of documents** |
| 1. Cover letter for the application
 | **00** | Click or tap here to enter document name(s). |
| 1. SOP *(as approved)*
 | **00** | Click or tap here to enter document name(s). |
| 1. Approval letter from the Scientific Committee
 | **00** | Click or tap here to enter document name(s). |
| 1. This completed ethics application form
 | **00** | Click or tap here to enter document name(s). |
| 1. Approved SOPs referred to in this SOP *(copies of animal intervention SOPs)*
 | **00** | Click or tap here to enter document name(s). |
| 1. Animal welfare monitoring sheets *(general and project specific)*
 | **00** | Click or tap here to enter document name(s). |
| 1. Proof of ethics training (<3 yrs) for the SOP responsible person
 | **00** | Click or tap here to enter document name(s). |
| 1. Training certificates for animal handling for each team member to handle animals
 |  | Not applicable to SOP development |
| 1. SAVC authorisation/SACNASP registrationfor each team member to handle animals
 |  | Not applicable to SOP development |
| 1. Proof of SAVC registration of the animal facility (*when applicable)*
 |  | Not applicable to SOP development |
| 1. Signed NWU code of conduct for the SOP responsible person
 | **00** | Click or tap here to enter document name(s). |
| 1. Narrative curriculum vitae of each team member
 | **00** | Click or tap here to enter document name(s). |
| 1. Contract(s) *(signed copies of any and all contracts when applicable)*
 | **00** | Click or tap here to enter document name(s). |
| 1. Permits(s) (copies of any and all permits when applicable)
 |  | Not applicable to SOP development |
| 1. Informed consent(s) (when applicable)
 |  | Not applicable to SOP development |
| 1. Goodwill permission(s) (when applicable)
 |  | Not applicable to SOP development |
| 1. Legal authorisation(s) (when applicable)
 |  | Not applicable to SOP development |
| 1. Approval letters from any other AREC (when applicable)
 | **00** | Click or tap here to enter document name(s). |
| 1. Other documents not mentioned above (when applicable)
 | **00** | Click or tap here to enter document name(s). |
| 1. **Signed declarations** as applicable by the:
	1. PI / Researcher / Study Supervisor (MUST)
	2. Director (MUST)
	3. Supervising Veterinarian (MUST)
	4. Biosafety Officer (MUST)
	5. Animal Facility Manager (MUST)
	6. Supervising Pharmacist
	7. Laboratory Animal Technician (LAT)
	8. Radiation Protection Officer
	9. Any other professional supervisor not mentioned above
 | Included **in this form** below  *(or find in the Table of Contents above)* … to be completed and signed electronically  *(only if not possible, print, complete & sign,  scan and attach the declaration page)* |

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| Section 2: SOP Team, Collaborators, Integrity & Legal Matters |

* 1. **Summary of persons included in the SOP team**

Fill in the number concerned for ALL options. Ensure that the participant numbers in this table correspond with the individuals in §2.3, 2.4, 0, 2.7 & 2.9 below.

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| ***More information****The* ***study supervisor*** *is generally viewed as the individual who takes the* ***overall responsibility*** *for all aspects of the study e.g. the principle investigator, researcher or study supervisor.**The* ***on-site assisting study supervisor*** *is generally the individual responsible for the* ***day-to-day management*** *of the study.* |

|  |  |
| --- | --- |
| **Description** | **Number** |
| **SA** | **Foreign** |
| **Only for SOPs** | NWU researchers | 0 | 0 |
| NWU supporting staff | 0 | 0 |
| External co-workers *(outside the NWU)* | 0 | 0 |
| **Only for SOPs** | Sponsors | 0 | 0 |

In the table above, NWU = North-West University

Any other members of the SOP team not mentioned above *(specify and explain)*

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| Click here to enter text. |

* 1. **Contact details of the SOP Responsible Person**

Name and details of the SOP responsible Person.

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| ***More information****The SOP Responsible Person is the member of the SOP team who assumes final, overall responsibility for all aspects of the SOP (i.e. 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 Researcher for ethics applications.****Please note!******ATTACH*** *a two-page narrative curriculum vitae (CV) for the SOP Responsible Person.* |

|  |  |
| --- | --- |
| **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. |
| **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. **Details of ALL Members of the SOP Team**

Names, qualifications and associations of ALL SOP team members *(including the SOP Responsible Person and co-workers, but excluding professional supervisors who may not be directly involved in the SOP - see §2.4)*.

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| ***More information****Team members include researchers, professionals, care takers, etc. who assisted with the development or are responsible for maintenance of the SOP.****Please note!******ATTACH*** *a two-page narrative curriculum vitae (CV) for each team member involved in the SOP.****Please note!*** *In the table below:** *“Functions and Responsibilities” relates to the role of the individual within the SOP.*
* *“Competency Certification” refers to the requirement that all team members should provide copies of valid certificates for ethics training (within the last 3 years), and that those researchers or students who will be handling animals should also have undergone training in animal handling and have obtained SAVC authorisation/SACNASP registration to do so (not applicable when NOT handling animals or if registered as a professional with the SAVC).* ***ATTACH*** *copies.*
 |

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| --- | --- | --- | --- | --- |
| **Name** *(and NWU no. if applicable)* | **Functions and Responsibilities** | **Qualifications and Prof. Registr.** | **Competency Certification** | **Affiliation** |

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

*Please note! Type the information for only one professional supervisor per row. For more professional supervisors, add more rows by clicking on the [Tab] key while the curser is in the last column.*

* 1. **Professional Supervisors (where and as applicable)**

Name and qualifications of all supervisory professional persons (e.g. veterinary surgeon, pharmacist, veterinary nurse, qualified scientist, etc.).

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| ***More information****Professional Supervisor indicates that the individual is an independent monitor involved during data gathering of the SOP and acts as an advocate for the animal subjects.****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.****Please note!*** *In the table below:** *“Functions and Responsibilities” relates to the role of the individual within the SOP, which can refer to SOP design, processing and/or archiving of data, reporting and/or writing of article, SOP guidance, training, performing certain procedure on animals, etc.*
* *“Competency Certification” refers to the requirement that all team members should provide copies of valid certificates for ethics training (within the last 3 years), and that those researchers or students who will be handling animals should also have undergone training in animal handling and have obtained SAVC authorisation/SACNASP registration to do so (not applicable when NOT handling animals or if registered as a professional with the SAVC).* ***ATTACH*** *copies.*
 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Name** | **Functions and Responsibilities** | **Qualifications and Prof. Registr.** | **Competency Certification** | **Affiliation** |

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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 details or “not applicable”. |

*Please note! Type the information for only one professional supervisor per row. For more professional supervisors, add more rows by clicking on the [Tab] key while the curser is in the last column.*

* 1. **Collaborators**

Declare with full details all collaboration agreements, e.g. with team members 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.****Please note!*** *Refer to §2.8 below if collaborations involve non-NWU parties. A copy of the contractual agreement, as approved by the NWU Legal Office,* ***MUST BE ATTACHED****.****Please note!*** *Refer to §2.6 if there is any conflict of interest, and then declare this in full in §2.6.* |

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| --- | --- | --- |
| **Name of Collaborator** | **Full Description and Declaration** | **National or International** |

|  |  |  |
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| Type name or “not applicable”. | Type details or “not applicable”. | Choose an item. |

*Please note! Type the information for only one collaborator per row. For more collaborators, add more rows by clicking on the [Tab] key while the curser is in the last column.*

* 1. **Conflict of Interest**

Declare with full details any conflict of interests of any one member of the SOP team or professional supervisor.

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| ***More information****Examples of conflict of interest: financial, non-financial: intellectual, bias, overly optimistic promises of potential benefits, potential to cause coercion or otherwise affect roles of the SOP team, desire of professional advancement, desire to make a scientific breakthrough, relationship with participants. Clearly explain the type of conflict and how this will be managed or resolved.* |

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

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

*Please note! Type the information for only one team member with a conflict of interest per row. For more team members with a conflict of interest, add more rows by clicking on the [Tab] key while the curser is in the last column.*

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of Sponsor** | **Contact Details** | **Affiliation and Contribution** | **Nature & Extent** |

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

*Please note! Type the information for only one sponsor per row. For more sponsors, add more rows by clicking on the [Tab] key while the curser is in the last column.*

* + 1. Is any SOP team 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.

|  |  |  |
| --- | --- | --- |
| **Name of Researcher** | **Association with Sponsor** | **Remuneration or Benefits** |

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

*Please note! Type the information for only one researcher per row. For more researchers, add more rows by clicking on the [Tab] key while the curser is in the last column.*

* 1. **Contractual Agreements**

Declare with full details all contractual agreements (e.g. with team members, collaborators or sponsors) on the SOP. This is particularly important for multi-institutional collaborations (i.e. bilateral of multilateral cooperation agreements), when a contractual agreement is required.

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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 use and affect intellectual property right. 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.****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* *Ethics-AnimCare@nwu.ac.za**, together with submission of this application.* |

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| --- | --- | --- |
| **Name of Contractor** | **Full Declaration and Description** | **Contract Included?** |

|  |  |  |
| --- | --- | --- |
| Type name or “not applicable”. | Type details or “not applicable”. | Choose an item. |

*Please note! Type the information for only one contractor per row. For more contractors, add more rows by clicking on the [Tab] key while the curser is in the last column.*

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| Section 3: Essential Details of the Scientific Study |

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

Summarise the SOP in not more than **150 words**, outlining the scope, objectives and methods.

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| Click or tap here to enter text. |

* 1. **Explanation of the SOP in layman’s term**

Summarise the SOP in **layman’s terms**, so that someone without expertise in animal sciences (i.e. a wider audience) will understand the essence of the SOP. Explain in simple terms why the SOP is important, what will be done, by whom and to what kind of animals.

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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. It should be aligned with the SOP and give the reader a “bird’s-eye view” of the SOP set-up and apparatus. If not applicable, clearly state that.

|  |
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| ***More information******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. **The SOP**

Standard Operating Procedure (SOP) as approved by the Scientific Committee must be attached. For more information, refer to Addendum B: SOP Requirements below.

* 1. **Evaluation and approval by a formal scientific committee**

Provide proof that this SOP has already been evaluated and approved by a formal scientific committee.

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| ***More information****The Scientific Committee is also sometimes referred to as a committee for higher degrees, research committee, etc.****Please note!*** *A letter confirming approval of the research proposal by the scientific committee* ***MUST BE ATTACHED*** *and submitted to* *Ethics-AnimCare@nwu.ac.za**, together with this application. This letter should be printed on a formal letterhead and signed by the chairperson of the scientific committee, as well as state the approved SOP title, name of the primary investigator, the date of approval, names of committee members who approved the SOP, plus suggest (estimate) and motivate the severity category 0 to 5 of the SOP.****Please note!*** *Whenever the Chairperson of the Scientific Committee is a team member for this application, he/she should step down to avoid conflict of interest and the vice-chairperson or another authorised signatory should sign.* |

|  |  |
| --- | --- |
| **Confirm** | **Details** |
| **Yes**[ ]  | Name of the NWU scientific committee | Click or tap here to enter text. |
| Members of scientific committee present | 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 scientific committee (compulsory) for all research studies **BEFORE** it will be reviewed by NWU-AnimCareREC. |
| **n/a**[ ]  | This is an education/training course |

**Any comments:**

|  |
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| Click or tap here to enter text. |

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| Section 4: Specific Ethical Implications of SOP Design |

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

Give a full description of the animals that you will use.

|  |  |  |  |
| --- | --- | --- | --- |
| **Animal species** | **Number** | **Sex** | **Age/Mass** |
| Click or tap here to enter text. | 00 | Choose | Type here. |

*Please note! Type the information for only one animal species per row. For more animal species, add more rows by clicking on the [Tab] key while the curser is in the last column.*

* 1. **Special SOP considerations**

Indicate in the table below which of the following special considerations apply to the current SOP: *(Mark ALL options as “Yes” or “No”.)*

|  |  |  |
| --- | --- | --- |
| **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 (see §0 to §4.8) below, in particular regarding the kind of stressors, risks and associated precautionary 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 NWU-AnimCareREC-approved SOPs, but still need to provide brief descriptions of the procedure.

**Motivation and/or any comments** *(****optional - only if necessary*** *to highlight or explain matters in the table above, not mentioned elsewhere in the questions below).*

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| Click or tap here to enter text. |

The questions below describe how the 4Rs have been taken into account in the planning of the SOP, and how they will be taken into account during the execution of the SOP. Although some questions may address more than one of the Rs (i.e. there may be some overlap), they have been grouped as sensibly as possible and to cover all key aspects of the respective Rs.

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| ***More information***The 4Rs are described in the SANS 10386 2nd Ed, 2018 as follows:* **Replace:** Methods that avoid or replace the use of animals in an experiment where they would have otherwise been used.  *(****Please note!*** *This could include* ***absolute*** *replacement with non-animal alternatives to achieve the study objectives (absolute replacement), or* ***partial/relative*** *replacement with tissue of fluids obtained from euthanised animals, or replacement of higher order animals with less sentient animals.*
* **Reduce:** Methods that minimize the number of animals used per experiment or study, by enabling the researchers to obtain comparable levels of information from fewer animals or to obtain more information from the same number of animals, thereby avoiding further animal use. *(****Please note!*** *Reduction should NOT compromise statistical validity or increase suffering (e.g. re-use of one animal for multiple invasive procedures).*
* **Refine:** Methods that minimize the pain, suffering, distress or lasting harm which may be experienced by the animals. *(****Please note!*** *This could include latest techniques that yield results with less discomfort or suffering, or that allow animals to thrive and yield more reliable results.)*
* **Responsibility:** The knowledge and acceptance of one’s Responsibilities. *(****Please note!*** *It should be clear what the responsibility and accountability of each member of the team is, and what the communication channels for encountered problems are.)*
 |

* 1. **Replace**
		1. **Alternatives to replace animals**

Are there any ethically friendlier alternatives available to achieve the SOP objectives meaningfully (e.g. lower order/less sentient animals, or *in vitro* tissue cultures, or computer models, etc.)?

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

* + 1. **Justification of animal use**

Provide a justification for the use of vertebrates or higher invertebrates, as well as for the choice of the species for this SOP.

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| Click or tap here to enter text. |

* 1. **Reduce**

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

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

[Refer to **question 4.2** above] 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. |

Is this species readily available (e.g. from the NWU Vivarium or Aquarium)? If “No”, motivate why this species is more suitable for your research than those that are in fact available, mention where the animals are available and what the microbiological status of these subjects is.
*(Please mark with* **X** *in the appropriate box and provide a motivation if “Yes”)*

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

* + 1. **Disturbance variables**

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

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| ***More information****Which 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 SOP 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. **Humane endpoints and monitoring of animals**

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 and 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 studies 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?****Please note!*** *General and SOP-specific monitoring sheets* ***MUST BE ATTACHED****.* |

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| Click or tap here to enter text. |

* + 1. **Euthanasia** *(fate of the animals)*

Describe which method(s) of euthanasia will be applied and the rationale thereof. Also describe how animals will be disposed of.

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| ***More information****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 NWU facilities (Vivarium or Aquarium), refer to the appropriate approved SOP and provide only a brief description thereof. However, animals to be used outside the NWU Vivarium, detailed descriptions* ***MUST BE PROVIDED****.****Please note!*** *Always follow best practices, supported by relevant references (e.g. for snap freezing of exothermic animals, which should be preceded by appropriate cold anaesthesia, etc.).* |

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| Click or tap here to enter text. |

* 1. **Responsibility**
		1. **Animal handling**

Have all persons who will be handling the animals completed an appropriate course in animal handling?

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

* + 1. **Expertise, skills and legal competencies**

[Refer to **question 4.2** above] What expertise, skills and legal competencies are needed to implement the SOP? Do the Responsible Person and other team members have at their disposal the necessary background/expertise/qualifications/authorisations/professional registrations to implement the techniques/procedures concerned? Refer to §4.7.2, where you will describe how you will ensure training and competence before and throughout the course of the SOP?

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| Click or tap here to enter text. |

* + 1. **Animal holding facilities, housing conditions and care**

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 and guidelines, providing for adequate care to promote welfare, including holding conditions and regular monitoring of animals. Describe matters related to responsible practice here that have not already been described and addressed as legal requirements in §**Error! Reference source not found.**.

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| ***More information****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.)****Please note!*** *For all animal holding facilities, attach the SAVC registration certificate.* |

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

* + 1. **Detailed description of all other specialised facilities**

[Refer to **question 4.2** above] 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, SOPs and documentation for waste management, radio-active work (if applicable), etc.

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| Click or tap here to enter text. |

* + 1. **Transportation of animals**

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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| Click or tap here to enter text. |

* + 1. **Risks to the experimenter(s) and associated precautionary measures**

[Refer to **question 4.2** above]. 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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| Click or tap here to enter text. |

* + 1. **Is there any significant bearing of this SOP on any endangered or protected species or significant impact on the environment?**

Provide more details if this SOP involves work with or impact on any endangered or protected species, or with any significant impact on environmental integrity.

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| ***More information******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” (as available on the website of the Ethics Office (*[*http://health-sciences.nwu.ac.za/healthethics/animcare-application-notification-forms*](http://health-sciences.nwu.ac.za/healthethics/animcare-application-notification-forms)*).* |

|  |  |  |  |
| --- | --- | --- | --- |
| **Yes** | **No** |  | **If “yes”, provide details** |
| [ ]  | [ ]  |  | Type motivation here, or type “Not applicable”. |

* 1. **Other specific matters**
		1. **Storage and archiving of data**

Explain how, where and how long the research data will be stored.

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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 SOP the original data of published results in order to verify the accuracy and validity thereof?**Management of data/biological samples:* * *What data (electronic and hard copies) and biological samples will be stored? How it will be stored?*
* *How data in its various forms will be managed, and by whom will it be managed?*
* *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?*
* *For how long biological samples be stored? Who will instruct sample destruction and how the samples be destroyed?*

***Please note!*** *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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| Click or tap here to enter text. |

* + 1. **Overall management, quality assurance and monitoring of the SOP**

Describe **HOW** you as the researcher will manage, assure quality and monitor each of the following five aspects during the implementation and progress of the SOP.

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| ***More information****Describe in detail* ***HOW*** *you will ensure compliance with the following matters, including quality assurance measures and time-frames for the management of these aspects.*1. ***Training of team members and ensuring of competence*** *(i.e. before the SOP commences, and during initial execution of potentially harmful or difficult procedures). In terms of training of inexperienced team members, such as students, the animal handling course may not be sufficient. If, for example a student needs to perform injections, he/she may need direct professional supervision for the first number of injection sessions, until comfortable and demonstrated sustainably competent. More invasive procedures may require longer or permanent professional supervision, or in select cases may even require more regular intervals for assessment of continued competence.*
2. ***Maintenance of any specialised equipment****. Equipment should be appropriately serviced and calibrated at regular intervals. No apparatus can be assumed in good condition, but appropriate quality assurance and record keeping thereof is necessary.*
3. ***Compliance*** *with the approved proposal. Responsible Person or Study Leader and Professional Supervisors should actively monitor compliance with the approved proposal throughout the study, as it progresses.*
4. ***Management of ethics*** *throughout the research process, including the reporting of any and all unscheduled incidents or adverse events. All unscheduled adverse events or other ethical concerns, as they may arise, should be managed timeously and according to approved standard operating procedure.*
5. ***Management of amendments*** *during the execution of the study (if applicable). Any changes to any aspect of SOP design, substances, methodology, or even the smallest matter should be approved via an amendment application (expedited process).*
 |

|  |  |
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| 1. **Training and competence**
 | Click here to enter text. |
| 1. **Maintenance of equipment**
 | Click here to enter text. |
| 1. **Proposal compliance**
 | Click here to enter text. |
| 1. **Ethics management**
 | Click here to enter text. |
| 1. **Management of amendments**
 | Click here to enter text. |

* 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: Harm-Benefit Analysis |

* 1. **Interventions and associated harm**

[Refer to and consider **Addendum D: Severity Categories**, as well asError! Reference source not found.**, question 1.8**, as well as **questions 4.2, 4.6.5, 4.6.1, 0 & 5.1** above]. Identify all key interventions on live animals in the SOP (i.e. withholdings, handling, exposure, procedures, methods, procedures, tests, etc.)*.* Then consider associated animal experience, stressors, risks and justification of these interventions:
**Please note!** Whereas for human studies we estimate risk-benefit, or for projects we estimate cost-benefit, in animal studies we estimate harm-benefit. Benefit should outweigh the harm, for a SOP to be approved.

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| ***More information****Discuss all key interventions on animals one by one, each in a separate table indicating animals/harm/benefit/outcome #1, #2, etc. Keep in mind that we want to honour the Five Freedoms[[1]](#footnote-1) for animals, namely (1) freedom from hunger and thirst, (2) freedom from discomfort, (3) freedom from pain, injury and disease, (4) freedom to express normal behaviour and (5) freedom from fear and distress. For each table (intervention), provide the following as indicated in the table:** *Indicate and describe the particular intervention to be analysed:*
* *Give a brief description of which intervention you are referring to. This may include, but is not limited to, animal handling, drug administration (e.g. injections or oral gavage), device implantation, surgery or other invasive procedures, infliction of pain or discomfort, exposure to stress or fear, social isolation, withholding of food, water and/or normal husbandry, behavioural testing, euthanasia, etc.*
* *Indicate which animal species, number of animals and experimental test group(s) (as reflected in the SOP specs) are involved in this specific intervention.*
* *Indicate and describe the specific harm**[[2]](#footnote-2) associated with this particular intervention:*
* *Give a brief description of what the specific harm (from the withholding/intervention/procedure) you are referring to.*
* *Indicate the context of the harm, i.e. whether is physical (including sensory, physiological) or psychosocial (including anxiety), and whether it is repetitive or of long duration (typically >30 minutes).*
* *Describe what the probable experience of the animal will be?*
* *Indicate the severity category of the harm (i.e. impact on animal wellbeing, considering the degree of discomfort or suffering, as specified by the categories officially adopted by NWU-AnimCareREC – see descriptions of these categories in* ***Addendum D: Severity Categories*** *below).*
* *How can this intervention be justified (i.e. why is it necessary)?*
* *What are the aggravating factors (i.e. cause and nature of the harm, or factors making it worse)?*
* *What are the mitigating factors (i.e. precautionary measures in place to minimise this, and to optimise wellbeing? This could include the use of painkillers, anaesthetic, intra-operative and post-operative care and/or euthanasia at the end of the experiment, proper training, and even how you implemented the 3Rs.)*
 |

|  |  |  |
| --- | --- | --- |
| **Inter-vention #1** | **Description of intervention** | Type details here. |
| **Which species, test group?** | Type details here. |
|  |  |  |
| **Harm #1** | **Description of harm (what?)** | Type details here. |
| **Context (i.e. nature of the harm) … choose one or more options** | **Number of animals** | **00** | **Physical** | [ ]  | **Psycho-social** | [ ]  | **Environ-mental** | [ ]  |
| **Acute** | [ ]  | **Chronic (lasting)** | [ ]  | **Repetitive** | [ ]  | **Long duration** | [ ]  |
| **Animal experience** | Type details here. |
| **Severity category** | **0** | [ ]  | **1** | [ ]  | **2** | [ ]  | **3** | [ ]  | **4** | [ ]  | **5** | [ ]  |
| **Justification (necessity?)** | Type details here. |
| **Aggravating factors** | Type details here. |
| **Mitigating factors** | Type details here. |

|  |  |  |
| --- | --- | --- |
| **Inter-vention #2** | **Description of intervention** | Type details here. |
| **Which species, test group?** | Type details here. |
|  |  |  |
| **Harm #2** | **Description of harm (what?)** | Type details here. |
| **Context (i.e. nature of the harm) … choose one or more options** | **Number of animals** | **00** | **Physical** | [ ]  | **Psycho-social** | [ ]  | **Environ-mental** | [ ]  |
| **Acute** | [ ]  | **Chronic (lasting)** | [ ]  | **Repetitive** | [ ]  | **Long duration** | [ ]  |
| **Animal experience** | Type details here. |
| **Severity category** | **0** | [ ]  | **1** | [ ]  | **2** | [ ]  | **3** | [ ]  | **4** | [ ]  | **5** | [ ]  |
| **Justification (necessity?)** | Type details here. |
| **Aggravating factors** | Type details here. |
| **Mitigating factors** | Type details here. |

Paragraph mark 🡺

*Copy the table #2 + paragraph mark above, click at the beginning of this line (before the word “Copy”) and paste consecutive tables*

*Please note! Type one intervention plus associated harm per table. To add for more tables, copy the whole table #2 plus its paragraph mark below (to view, unhide non-printing symbols), and paste a third, fourth, etc. table beneath, indicated with #3, #4, etc.*

* 1. **Potential benefit, scientific integrity and translatability of the SOP**

Reflect on the likely **benefit** from this SOP *(by referring to and considering* ***potential applications*** *(i.a. types of answers it may provide)*, the matters related to **research integrity** *(discussed in* ***Section 4: Specific Ethical Implications of SOP Design****)*, as well as the **translatability** of the SOP results and findings to real-life practice *(for example the human condition or treatment in the case of pre-clinical studies, or environmental sustainability in the case of environmental studies, or food production in the case of agricultural studies)*:
**Please note!** Benefit (and the robustness thereof), should withstand the “So what?” question on relevance, and will be used to ensure that benefit outweigh the harm, for a study using this SOP to be approved.

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| ***More information****The SANS 10386 discusses “governing principles in the care and use of animals for scientific purposes”, and then explains what can be seen as the “justification of the use of animals” for this purpose. It then states that (in brief summarised here) there should be evidence to support a case to use animals by demonstrating scientific merit, with the potential to benefit humans, animals or the environment. It also explains that projects using animals may be undertaken only when it is essential to obtain and establish such information, maintain and improve human and/or animal health and welfare, improve animal management or production, understand, maintain or improve the natural environment, achieve educational outcomes.* |

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| Click or tap here to enter text. |

* 1. **Overall harm-benefit analysis**

Overall harm-benefit analysis is not applicable to a SOP, but rather to a study in which the SOP is used. It is therefore not applicable to this application.

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| Section 6: Other Ethics Committees & Insurance |

* 1. **Reviews by other Animal Research Ethics Committees (ARECs)**

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

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

If so, provide full details of all other Animal Research Ethics Committees (ARECs) evaluating the SOP.

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

*Please note! Type the information for only one AREC per table, or type “none” if there are no other committees. For more ARECs, 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 as in 2016 – verify the latest****)*. However, this is only available if studies are ethically approved and researchers have kept to the approved proposal. You should familiarise yourself with the insurance *(information available from the Ethics Office on request)*, and weigh this against potential risks to the researchers, professional supervisors, students and/or assistants.

* + 1. Describe the potential risks *(e.g. due to personal exposure, injury, health risks, harm to animals of non-NWU owners, etc.)* to which the researchers, professional supervisors, students and/or assistants are going to be subject to in so far as complications may lead to summonses.

|  |  |
| --- | --- |
| **Group** | **Potential risk of harm** |
| **Researchers** | Type details here. |
| **Professional Supervisors** | Type details here. |
| **Students** | Type details here. |
| **Assistants** | Type details here. |
| **Others** | Type details here. |

* + 1. These potential risks of harm are covered by:

|  |  |
| --- | --- |
| **North-West University** | [ ]  |
| **Sponsor(s)** | [ ]  |
| **Others *(specify)*** | [ ]  | Type details here. |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Yes** | **No** |  | **Details** |
| [ ]  | [ ]  |  | Type details here. |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Yes** | **No** |  | **Details** |
| [ ]  | [ ]  |  | Type details here. |

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| Section 7: Declarations *(to complete & sign)* |

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| --- |
| * 1. **Declaration by the SOP Responsible Person**
 |

I, the undersigned, hereby apply for approval of this SOP using vertebrate or higher invertebrate animals, as described in the SOP document, and hereby declare that:

1. I have familiarised myself thoroughly as to the content of NWU-AnimCareREC’s rules and procedures, and the latest South African National Standards and regulations for the use of animals in research and training, and I will keep to these guidelines and the details described in the scientific proposal as and when ethically approved.
2. SOP objective, scope & measures: I understand that approval of a SOP does not grant any approval for the use of animals *per se*, but rather that it approves a procedure or protocol as appropriate for implementation within an approved project, where justification can be provided. Approval of a SOP therefore strives to ascertain that the procedure is humane, that necessary safety and animal welfare measures as well as incident and adverse event reporting have been considered for the SOP, the SOP is in line with the latest and best international and/or national practices, that facilities and equipment is appropriate for the SOP, that professional supervision and training needs have been identified, etc. I declare that I have ascertained that this SOP complies with these objectives.
3. The current SOP is professionally and scientifically justifiable and will promote sound professional and scientific conduct. Although the SOP in itself cannot ensure compliance with all elements of the 4Rs (rather, that should be considered by any project that implements the SOP), I declare this this SOP contributes to principle of refinement and that replacement and reduction have been considered in its design. Furthermore, the SOP design and monitoring strives to keep any discomfort/suffering for animal subjects to the minimum.
4. I will report to NWU-AnimCareREC without delay:
	1. would it become evident (from reports or other information sources) that the SOP seems to lead to any unforeseen adverse events,
	2. whenever new, improved practices become available, so that the SOP needs update, replacement or termination.
5. I will ensure that the SOP is managed ethically justifiably from start to finish. This imply that I will:
	1. oversee the SOP,
	2. ensure that all team members (e.g. myself, co-workers/assistants/technicians) are appropriately trained, experienced, qualified, authorised, registered and otherwise legally competent to develop and refine the approved SOP,
6. I will formally apply for approval of any amendments upon revision of the SOP or change of team members, or formally notify NWU-AnimCareREC is the SOP is withdrawn, and I understand that ethical approval of the SOP may be suspended or terminated if I deviate from the SOP without the approval of NWU-AnimCareREC, which may also lead to disciplinary action.
7. The information provided in this application is, to the best of my knowledge, correct and that no ethical codes will be violated by the SOP.

|  |  |
| --- | --- |
| **Name** *(title, full names and surname)* |  |
| Click or tap here to enter text. |
|  |
| **Date** |
| Click or tap to enter a date. | **Signature** |
|  |  |
| **Any comments (optional)**Click or tap here to enter text. |

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| * 1. **Declaration by the Director**
 |

This section is to be completed by the Director of the Unit in which the SOP will be performed.

I, the undersigned, hereby declare that the SOP may implemented if it is approved by NWU-AnimCareREC and that the Study Supervisor, employed within my Unit, has appropriate and sufficient authorisation, physical facilities, equipment and funding at disposal to implement and complete this SOP.

|  |  |
| --- | --- |
| **Unit’s Name** | **Position** |
| Click or tap here to enter text. | Click or tap here to enter text. |
| **Name** *(title, full names and surname)* |  |
| Click or tap here to enter text. |
|  |
| **Date** |
| Click or tap to enter a date. | **Signature** |
|  |  |
| **Any comments (optional)**Click or tap here to enter text. |

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| * 1. **Declaration by the Supervising Veterinarian**
 |

This section is to be completed by the supervising Veterinary Surgeon, as indicated in the Ethics Application Form.

|  |
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| ***More information******Please note!*** *The professional supervisor(s) may not be part of the SOP team, and should attach a two-page narrative curriculum vitae. This section should be filled in and signed electronically.* |

1. In your opinion, what is the degree of risk to the animals involved in this SOP?

|  |
| --- |
| Click or tap here to enter text. |

1. In your opinion, what should the nature and extent of supervision during the SOP be? Is what is currently proposed in the application sufficient?

|  |
| --- |
| Click or tap here to enter text. |

1. Will you be available to advise, provide necessary specialised training and/or supervise regarding the implementation of this SOP?

|  |  |  |  |
| --- | --- | --- | --- |
| **Yes** | [ ]  |  | Click or tap here to enter text. |
| **No** | [ ]  |  |
| **N/A** | [ ]  |  |

|  |  |
| --- | --- |
| **Professional Registration & Body** | **Qualifications** |
| Click or tap here to enter text. | Click or tap here to enter text. |
| **Name** *(title, full names and surname)* |  |
| Click or tap here to enter text. |
|  |
| **Date** |
| Click or tap to enter a date. | **Signature** |
|  |  |
| **Any comments (optional)**Click or tap here to enter text. |

|  |
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| * 1. **Declaration by the Biosafety Officer**
 |

This section is to be completed by the Biological Safety Officer.

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| ***More information******Please note!*** *This section should be filled in and signed electronically.* |

1. Are the safety risks for man and environment, as described in this application, correct according to your professional judgement?

|  |  |  |  |
| --- | --- | --- | --- |
| **Yes** | [ ]  |  | Click or tap here to enter text. |
| **No** | [ ]  |  |
| **N/A** | [ ]  |  |

1. According to your professional judgement, are there adequate precautions and expertise in place to manage these risks responsibly?

|  |  |  |  |
| --- | --- | --- | --- |
| **Yes** | [ ]  |  | Click or tap here to enter text. |
| **No** | [ ]  |  |
| **N/A** | [ ]  |  |

|  |  |
| --- | --- |
| **Professional Registration & Body** | **Qualifications** |
| Click or tap here to enter text. | Click or tap here to enter text. |
| **Name** *(title, full names and surname)* |  |
| Click or tap here to enter text. |
|  |
| **Date** |
| Click or tap to enter a date. | **Signature** |
|  |  |
| **Any comments (optional)**Click or tap here to enter text. |

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| * 1. **Declaration by the Animal Facility Manager**
 |

This section is to be completed by the Manager of the animal housing facility.

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| ***More information******Please note!*** *This section should be filled in and signed electronically.* |

1. Is the facilities suitable to implement the SOP, as described in this application?

|  |  |  |  |
| --- | --- | --- | --- |
| **Yes** | [ ]  |  | Click or tap here to enter text. |
| **No** | [ ]  |  |
| **N/A** | [ ]  |  |

|  |  |
| --- | --- |
| **Professional Registration & Body** | **Qualifications** |
| Click or tap here to enter text. | Click or tap here to enter text. |
| **Name** *(title, full names and surname)* |  |
| Click or tap here to enter text. |
|  |
| **Date** |
| Click or tap to enter a date. | **Signature** |
|  |  |
| **Any comments (optional)**Click or tap here to enter text. |

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| * 1. **Declaration by the Supervising Pharmacist**
 |

This section is to be completed by the supervising Pharmacist, as indicated in the Ethics Application Form.

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| ***More information******Please note!*** *This section applies only when scheduled medicines to be stored and dispensed is included in the study, and should be filled in and signed electronically. The professional supervisor(s) may not be part of the SOP team, and should attach a two-page narrative curriculum vitae. This section should be filled in and signed electronically.* |

1. Will you be available to supervise the ordering, licencing (when required), safekeeping, and dispensing of scheduled or other controlled substances for this project, when and as required by legislation?

|  |  |  |  |
| --- | --- | --- | --- |
| **Yes** | [ ]  |  | Click or tap here to enter text. |
| **No** | [ ]  |  |
| **N/A** | [ ]  |  |

|  |  |
| --- | --- |
| **Professional Registration & Body** | **Qualifications** |
| Click or tap here to enter text. | Click or tap here to enter text. |
| **Name** *(title, full names and surname)* |  |
| Click or tap here to enter text. |
|  |
| **Date** |
| Click or tap to enter a date. | **Signature** |
|  |  |
| **Any comments (optional)**Click or tap here to enter text. |

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| * 1. **Declaration by the Laboratory Animal Technician (LAT)**
 |

This section is to be completed by the supervising Laboratory Animal Technician (LAT), as indicated in the Ethics Application Form.

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| ***More information******Please note!*** *The professional supervisor(s) may not be part of the SOP team, and should attach a two-page narrative curriculum vitae. This section should be filled in and signed electronically.* |

1. Will you be available to advise on and oversee the breeding, care and monitoring of animals, and to provide necessary advice, training, supervision and/or assist with the animal procedures as applicable to this SOP, when and as required?

|  |  |  |  |
| --- | --- | --- | --- |
| **Yes** | [ ]  |  | Click or tap here to enter text. |
| **No** | [ ]  |  |
| **N/A** | [ ]  |  |

|  |  |
| --- | --- |
| **Professional Registration & Body** | **Qualifications** |
| Click or tap here to enter text. | Click or tap here to enter text. |
| **Name** *(title, full names and surname)* |  |
| Click or tap here to enter text. |
|  |
| **Date** |
| Click or tap to enter a date. | **Signature** |
|  |  |
| **Any comments (optional)**Click or tap here to enter text. |

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| * 1. **Declaration by the Radiation Protection Officer (RPO)**
 |

This section is to be completed by the Radiation Officer if this application involves any work with radio-nuclides.

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| ***More information******Please note!*** *This section applies only when radio-active substances are included in the study, and should be filled in and signed electronically. Please attach the current radio-activity authority certificate.* |

1. Details of the radio-active facility to be used for this study

|  |  |  |
| --- | --- | --- |
| **NWU name of the radio-active facility** | **Authority number** *(as issued by Radiation Control of the Department of Health* | **Type of facility** |
| Click here to enter text. | Click here to enter no. | Choose an item. |

1. Details of the radio-active nuclide authorisation

|  |  |  |
| --- | --- | --- |
| **Question** | **Yes** | **No** |
| Does your authorisation by Radiation Control of the Department of Health, as reflected in your nuclide register, include all of the radioactive nuclides and applications *(i.e. to convey, possess, use)* as relevant to this SOP? | [ ]  | [ ]  |
| Are you appropriately trained, and registered as Radiation Protection Officer for this radioactive facility by Radiation Control of the Department of Health? | [ ]  | [ ]  |
| Is your radio-active facility appropriate and accessible / your services available to the researchers for the executing the radioactive work of this SOP? | [ ]  | [ ]  |

1. Risks & competence

|  |  |  |
| --- | --- | --- |
| **Question** | **Yes** | **No** |
| In your professional opinion, are the associated risks for animal, man and environment related to the administration/use of radio-active substances, correctly described in this application, and is corresponding precautionary measures (including use and disposal) appropriate and sufficient? | [ ]  | [ ]  |
| Are the researchers/students who will be working with the radionuclides appropriately trained and experienced, or will you ensure that they receive such training before they work with the substances? | [ ]  | [ ]  |

|  |  |
| --- | --- |
| **Professional Registration & Body** | **Qualifications** |
| Click or tap here to enter text. | Click or tap here to enter text. |
| **Name** *(title, full names and surname)* |  |
| Click or tap here to enter text. |
|  |
| **Date** |
| Click or tap to enter a date. | **Signature** |
|  |  |
| **Any comments (optional)**Click or tap here to enter text. |

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| * 1. **Declaration by the a Professional Supervisor other than above**
 |

This section is to be completed by the supervising Professional (not mentioned above), as indicated in the Ethics Application Form.

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| --- |
| ***More information******Please note!*** *The professional supervisor(s) may not be part of the SOP team, and should attach a two-page narrative curriculum vitae. This section should be filled in and signed electronically.* |

1. Please describe the nature of your professional supervision in the SOP.

|  |
| --- |
| Click or tap here to enter text. |

|  |  |
| --- | --- |
| **Professional Registration & Body** | **Qualifications** |
| Click or tap here to enter text. | Click or tap here to enter text. |
| **Name** *(title, full names and surname)* |  |
| Click or tap here to enter text. |
|  |
| **Date** |
| Click or tap to enter a date. | **Signature** |
|  |  |
| **Any comments (optional)**Click or tap here to enter text. |

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| Addendum A: Applicant’s Instructions |

More detailed information are available in the latest version of the **SOP for the research ethics approval application process, SOP-Ethics\_1.4**, as available on the website of the Ethics Office (<http://health-sciences.nwu.ac.za/healthethics/sops>).

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 SOPs MUST be approved by an appropriate Scientific Committee BEFORE submitting this application for ethics approval.
	3. All applications and supporting documentation must be in English only, and only electronic versions submitted via e-mail *(or InfoEd online once launched)* will be accepted.
	4. Complete this application form and attach all supporting documentation (e.g. certificates, authorisation documents to verify sound sources of animal tissue/fluids and disposal).
	5. You are advised to convert final versions of documents to PDF (i.e. “save as PDF”) before submitting them via e-mail.
2. **Documents and attachments to be submitted**

The following schema and descriptions below explain all documents to be submitted
*(compare with the check list under §1.10 above)*:



Figure 1: Flow diagram of all documents to be submitted with the ethics application, where SOP = standard operating procedure; SAVC = South African Veterinary Council; CV = curriculum vitae. More details follow below.

1. ***Cover letter:*** Prepare a brief cover letter indicating the title of the SOP, SOP responsible person, animal species *(if and as applicable),* typical location where the SOP will be applied *(e.g. in Vivarium, Aquarium, nature reserve, etc.)* and other information that will provide context. Give this document a name starting with [1) ###].
2. ***SOP document:*** The SOP document MUST be attached, which must be Scientific Committee-approved. Give this document a name starting with [2) ###].
3. ***Letter of approval:*** Attach the letter of approval of the SOP by the Scientific Committee. This letter should be printed on a formal letterhead and signed by the chair of the Scientific Committee *(or other authorised signatory if there is a conflict of interest)*, as well as state the approved SOP title, name of the SOP responsible person, the date of approval, names of committee members who approved the study proposal and recommendation for the severity category. Give this document a name starting with [3) ###].
4. ***This ethics application form:*** The application form MUST be completed in full. Give this document the name [4) Ethics Application Form.docx].
5. ***Other related SOPs:*** Attach a copy of all other SOPs that you refer to in this SOP and/or ethics application form. Please remember that, when you refer to another SOP in the SOP document and/or ethics application form, you need to indicate which section of that SOP is applicable, and also provide a brief description of the procedure as applicable in the SOP and/or ethics application form. Give each of these documents a name starting with [5.1) ###]; [5.2) ###], etc.
6. ***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 [6.1) ###]; [6.2) ###], etc.
7. ***Proof of ethics training*** Proof of applicable ethics training (preferably followed by assessment) in the last 3 years for the SOP Responsible Person. Give each of these documents a name starting with [7.1) ###]; [7.2) ###], etc.
8. ***Training on animal handling:*** Not applicable to SOPs.
9. ***SAVC authorisation:*** Not applicable to SOPs.
10. ***Facility registration:*** Not applicable to SOPs.
11. ***Code of Conduct:*** Ensure that a signed NWU Code of Conduct for Researchers is attached for the SOP Responsible Person*.*  Give this document a name starting with [11) ###].
12. ***Narrative CVs:*** Ensure that a 2-page narrative CV is attached for each member of the SOP teamand professional supervisors that are involved in the SOP development and maintenance (demonstrating qualifications, professional registrations, publications over the last 4 years, other publications related to the study, research expertise and other relevant competencies). Give each of these documents a name starting with [12.1) ###]; [12.2) ###], etc.
13. ***Contracts:*** If applicable attach a copy of all signed contracts or other agreements, as approved by the NWU legal office. Give each of these documents a name starting with [13.1) ###]; [13.2) ###], etc.
14. ***Permits or permission letters:*** Not applicable to SOPs.
15. ***Informed consent:*** Not applicable to SOPs.
16. ***Goodwill permission:*** Not applicable to SOPs.
17. ***Legal authorisation:*** If applicable, attach the copy of the legal authorisations obtained. Give each of these documents a name starting with [17.1) ###]; [17.2) ###], etc.
18. ***Approval letters from other ARECs:*** If applicable, attach the ethical approval letters of any other animal research ethics committee (AREC) that reviewed the SOP. Give each of these documents a name starting with [18.1) ###]; [18.2) ###], etc.
19. ***Other documents:*** Any other supporting documents not mentioned above. Give each of these documents a name starting with [24.1) ###]; [24.2) ###], etc.
20. ***Signed declarations:*** *Included in this ethics application form above, to be completed and signed electronically only if new. However, if a hard copy is signed, attach.*

***Please note!*** *The application MUST be discussed timeously with ALL professional supervisors, any resulting corrections or amendments made and then returned to be 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.*

* 1. ***Declaration signed by the SOP Responsible Person (in this document):*** The SOP Responsible Person MUST sign the declaration included in this ethics application form (above). This should preferably be signed electronically. However, if a hard copy is signed, attach
	2. ***Signed declaration by the director of the entity:*** The director of the entity MUST complete and sign the declaration form.
	3. ***Signed professional supervisor letter by the veterinarian:*** The supervising veterinarian MUST complete and sign the applicable declaration.
	4. ***Signed declaration by the biosafety officer:*** If applicable, the biosafety officer MUST complete and sign the applicable declaration.
	5. ***Signed declaration by the animal facility manager:*** When studies are to be performed in an animal facility, the animal facility manager MUST complete and sign the applicable declaration.
	6. ***Signed declaration by the statistician:*** Not applicable to SOPs.
	7. ***Signed declaration by the supervising pharmacist:*** If applicable, scheduled substances must be stored and dispensed by the supervising veterinarian or a supervising pharmacist. In the latter case, the consulted supervising pharmacist should complete and sign the declaration form only if new *(i.e. not included in the larger study application)*.
	8. ***Signed declaration by the supervising laboratory animal technician (LAT):*** When applicable, the consulted laboratory animal technician (LAT) MUST complete and sign the applicable declaration.
	9. ***Signed declaration by the supervising radio protection officer (RPO):*** When the study involves the use of radio nuclides, the consulted radio protection officer (RPO) should complete and sign the declaration form only if new *(i.e. not included in the larger study application)*.
	10. ***Signed declarations by other supervisors:*** All other applicable signed Supervisor Declaration Forms from relevant professional supervisors (e.g. pharmacist, radiation officer, biological safety officer, facility head) MUST be attached if applicable to this SOP. *(****Please note!*** *The application MUST be discussed timeously with ALL professional supervisors, any resulting corrections or amendments made and then returned to be 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 documents a name starting with [23.1) ###]; [23.2) ###], etc.

**Please note!** Keep document names brief, because long names will not save properly in the complex folder systems sometimes required for archiving.

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. 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).

|  |
| --- |
| Addendum B: SOP Requirements |

Follow a standard SOP format, which typically includes:

* Title
* SOP number & version
* Responsible person and signatories
* Dates of approval and revision *(typically every 2 years)*
* Revision history
* Purpose
* Scope
* Responsibilities
* Procedures
* … etc.

|  |
| --- |
| Addendum C: Moral Declaration |

NWU-AnimCareREC adopted the following moral values as ethical point of departure regarding the care and use of animals in research:

1. It is recognised that non-human animals are valuable beings, **worthy of dignity and respect that** should be protected. In this regard it also recognises the **moral dilemma** of using sentient animals with sensations and emotions for experimentation. At the same time, it is accepted 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.
	3. Animal should be **protected from exploitation** via their use in research for trivial, irrational, unjustified or inappropriate reasons.
	4. Animals should **receive optimal care** to promote thriving, manage any disease and avoid unnecessary suffering.
2. The principle of the **4Rs** will be applied to promote humaneness:
	1. ***Replace:*** to replace animals (in absolute, relative or partial terms), where possible, with non-animal alternatives, tissue and fluids of already euthanised animals or less sentient animals
	2. ***Reduce:*** to reduce the number of animals used to the minimal to answer the research question(s), without compromising statistical validity or increasing animal suffering
	3. ***Refine:*** to refine experimental design, animal interventions/procedures and/or the animal model(s) employed to promote thriving of animals *(welfare)*, minimise discomfort and/or suffering *(harm)* and to optimise scientific value *(benefit)*.
	4. ***Responsibility:*** to promote responsible care and use of animals by ensuring competence of all who work with animals, to fostering a culture of compassion and care, to establish clear communication channels for unscheduled adverse events, and to establish clear responsibilities and accountability.
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**.
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 NWU-AnimCareREC** or another appropriate Animal Research Ethics Committee (AREC) of the NWU. In all studies sound scientific integrity shall be evaluated to ensure trustworthy, repeatable results and to provide maximum benefit from the study. In particular, when health-of health-related studies are performed in animals, there is an additional responsibility to ensure that studies are truly translatable and able to advise follow-up animal studies and clinical studies in humans as accurately and comprehensively as possible.

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| Addendum D: Severity Categories |

The following severity categories for animal interventions (i.e. classification of pain, discomfort or stress) have been adopted by the NWU-AnimCareREC.

|  |
| --- |
| ***More information****All vertebrate or higher invertebrate animal procedures and interventions must be classified according to the estimated experience of the animal (discomfort, stress and 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.****Please note!*** *The six severity categories here (0, 1, 2, 3, 4 & 5) are comparable with the corresponding “informative” six category examples (A1, A2, B, C, D & E) in the SANS 10386:2018, 2nd ed.* |

|  |  |
| --- | --- |
| **Category** | **Description of Severity & Examples** |
| **0** | **None**, e.g. use of dead vertebrate or higher invertebrate animals (already euthanized legally and ethically for another purpose and not for this study) 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 and 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. |

1. More information on the origins of the universal Five Freedoms can be accessed at the National Archived of the Farm Animal Welfare Council, [http://webarchive.nationalarchives.gov.uk/20121010012427/http://www.fawc.org.uk/freedoms.htm](http://webarchive.nationalarchives.gov.uk/20121010012427/http%3A//www.fawc.org.uk/freedoms.htm), with a 1st press release at [http://webarchive.nationalarchives.gov.uk/20121010012428/http://www.fawc.org.uk/pdf/fivefreedoms1979.pdf](http://webarchive.nationalarchives.gov.uk/20121010012428/http%3A//www.fawc.org.uk/pdf/fivefreedoms1979.pdf). [↑](#footnote-ref-1)
2. More information on harm-benefit analysis can be found in Laber et al. (2016) Recommendations for Addressing harm-benefit analysis and implementation in ethical evaluation – report from the AALAS-FELASA working group in Harm-benefit analysis – Part 2. Laboratory animals, 50(1S):21-42. DOI 10.1177/0023677216642397. [↑](#footnote-ref-2)