

Faculty of Health Sciences Ethics Office for Research, Training and Support
[health-sciences.nwu.ac.za/healthethics](http://health-sciences.nwu.ac.za/healthethics)

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| 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*****Sub-Study Ethics Application Form** to apply for the approval of **sub-studies** under already approved **larger** scientific **studies** using animal vertebrates or higher invertebrates for research, education/training or repetitive testing purposes**AnimCare 03-01a, Version 5.10 (June 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!**

* You may use ***only a cover letter*** *(i.e. not this form)* for sub-study applications, particularly experienced researchers. Please ensure that you explain all aspects of the sub-study in this letter (see 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>) and attach all required supporting documents (see §1.15 Checklist and attachments below). Alternatively, you may use ***this application form*** *(optional)* to ***guide & facilitate*** your application for the ethical approval of a sub-study, so that you do not miss anything important.
* Refer to ***Addendum A: Applicant’s Instructions*** and ***Addendum B: Research Proposal 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 Ethical Point of Departure*** and ***Addendum D: Severity Categories***.

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| **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. |
| **Principle Investigator/ Researcher/ Study Supervisor** | Click here to enter text. |
| **Student** *(name & surname)* | Click here to enter text. |
| **Study Title** | Click here to enter text. |

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| Section 1: Larger and Sub-Study Identification and Information |

Provide the necessary descriptions below to identify this study application:

* 1. **Ethics number of the larger study**

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| Click or tap here to enter text. |

* 1. **Full, descriptive title of the larger study**

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| Click or tap here to enter text. |

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

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| Click or tap here to enter text. |

* 1. **Name of the Principle Investigators (PI) / researchers / study supervisors**

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| ***More information****In case of research studies this refers to the person who takes final* ***responsibility****, or in case of training courses to the Lecturer. In the case of postgraduate studies, also provide the details of the postgraduate student and select the postgraduate level of the study from the dropdown list. The extended study team is described in Section 3: Study Team, Collaborators and Professional Supervisors.* |

|  |  |  |
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| **Role** | **Name** *(title, first name and surname)* | **NWU staff/student no.** |
| PI / researcher / study supervisor of the larger study | Click here to enter title, first name and surname. | Click here to enter number. |
| PI / researcher / study supervisor of the sub-study | Click here to enter title, first name and surname. | Click here to enter number. |
| Student | Click here to enter title, first name and surname. | Click here to enter number. |
| Level of the sub-study | Choose an item. |

* 1. **Permission for the sub-study under the larger study**

Did the leader of the larger study grant permission that the sub-study may take place under the larger study, also defining exactly what will be permitted or excluded?

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| ***More information****A signed copy of such a written permission letter, with conditions agreed upon, MUST be attached.* |

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| Yes | [ ]  | No | [ ]  | The PI / researcher / study supervisor of the larger study and sub-study is the same person | [ ]  |

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

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

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

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| Yes | [ ]  | No | [ ]  | Click here to provide a brief description of any new substances. Also indicate any expected or unknown risks and potential toxicities, and how these will be managed. |

* 1. **How does the sub-study fit into the already approved larger study?**

Clearly describe how the sub-study fits into the larger study, by describing and comparing the objectives, study design, methodologies and animals of the two. The larger study should have indicated potential sub-studies, and you may then refer to how it was described in, and applied from the larger study.

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| ***More information****Explain clearly (1) which objectives of the larger study will be investigated in the sub-study, (2) which part of the study design of the larger study is included in the sub-study, (3) which methodologies of the larger study will be employed in the sub-study, and (4) which animals indicated in the larger study will be employed in the sub-study.****Please note!*** *If any new aspects specified above are added to the sub-study, the large study should first be amended to accommodate these changes or additions, whereafter the sub-study can be applied for.* |

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| Click or tap here to enter text. |

* 1. **Track record of submission dates and version numbers of the sub-study application**

Indicate the date of submission of the first application and of any subsequent revisions (based on feedback from NWU-AnimCareREC) of the sub-study 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. |

* 1. **Envisaged commencement and completion date of the sub-study**

Anticipated dates, once ethics approval has been granted.

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| ***More information******Please note!*** *Approval for a maximum of one year will be granted. Thereafter an annual monitoring report will serve as mechanism for notification of completion, or to obtain permission for continuation of the sub-study.* |

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| **EnvisagedCommencement Date** | **EnvisagedCompletion Date** |
| Click or tap to enter a date. | Click or tap to enter a date. |

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

Summarise the study in not more than **150 words**, outlining the problem statement, objectives, methods and study design (including animal numbers, treatment groups, interventions, measurements, statistical analyses, etc. as applicable), as well as expected outcome/benefit. This should be as much in **layman’s terms** as reasonably possible, so that a wider audience can understand.

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| Click or tap here to enter text. |

* 1. **Explanation of the study in layman’s terms**

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

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| Click or tap here to enter text. |

* 1. **Flow diagram of the sub-study design**

Provide a simplistic flow diagram/schema of the overall study design, typically indicating the breakdown of the various control and test groups, animal numbers, interventions, measurements. It should be aligned with the study objectives and give the reader a “bird’s-eye view” of the whole study.

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

Provide proof that this sub-study 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. In case of education/training, the official study/training guide will suffice.****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 study title, name of the primary investigator, the date of approval, names of committee members who approved the study proposal, plus suggest (estimate) and motivate the severity category 0 to 5 of the study.****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.* |

|  |  |
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| **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 study 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. |

* 1. **Severity category of the sub-study**

Please indicate the appropriate severity category (compare **Addendum D: Severity Categories for Animal Interventions**) applicable to this sub-study as a whole.

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| ***More information****This estimation should be done after you have described your study in full, and you have considered all interventions. The severity category of the sub-study can never be higher than that of the approved larger study.****Please note!*** *The selected category will be evaluated and may be changed by NWU-AnimCareREC.* |

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| **Severity category for the larger study:** | **Choose an item.** |
| **Severity category for the sub-study:** | **Choose an item.** |

**Motivation and/or any comments:**

Briefly motivate your selection of the category of the sub-study as indicated above.

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| Click or tap here to enter text. |

* 1. **New Members of the Study Team**

Names, qualifications and associations of any new members of the team not already indicated in the larger study.

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| ***More information****New team members include researchers and postgraduate students in the case of a research study, or lecturers in the case of education/training, and assistants/field workers who form part of the study team.****Please note!******ATTACH*** *a two-page narrative curriculum vitae (CV) for each new team member involved in the study.****Please note!*** *In the table below:** *“Functions and Responsibilities” relates to the role of the individual within the study, which can refer to study design, processing and/or archiving of data, reporting and/or writing of article, study 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.*
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| **Name and NWU number** *(if applicable)***.** | **Functions and Responsibilities** | **Qualifications and Profess. Registr.** | **Competency Certification** |

|  |  |  |  |
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| Type name and no., 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 team member per row. For more team members, add more rows by clicking on the [Tab] key while the curser is in the last column.*

* 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.* |

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| **Document(s)** | **No**  | **Name(s) of documents** |
| 1. Cover letter for the application
 | **00** | Click or tap here to enter document name(s). |
| 1. Larger study proposal, ethics approval, permission letter, sub-study proposal
 | **00** | Click or tap here to enter document name(s). |
| 1. Approval letter for the sub-study from the Scientific Committee
 | **00** | Click or tap here to enter document name(s). |
| 1. This completed sub-study ethics application form
 | **00** | Click or tap here to enter document name(s). |
| 1. Any new SOPs to be used in the sub-study*(copies of animal intervention SOPs)*
 | **00** | Click or tap here to enter document name(s). |
| 1. Any new 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 each new team member
 | **00** | Click or tap here to enter document name(s). |
| 1. Training certificates for animal handling foreach new team member to handle animals
 | **00** | Click or tap here to enter document name(s). |
| 1. SAVC authorisation/SACNASP registration each new team member to handle animals
 | **00** | Click or tap here to enter document name(s). |
| 1. Proof of SAVC registration of anynew animal facility (*when applicable)*
 | **00** | Click or tap here to enter document name(s). |
| 1. Signed NWU code of conduct for each new team member
 | **00** | Click or tap here to enter document name(s). |
| 1. Narrative curriculum vitae of each new team member
 | **00** | Click or tap here to enter document name(s). |
| 1. Any new contract(s) *(signed copies of any and all contracts when applicable)*
 | **00** | Click or tap here to enter document name(s). |
| 1. Any new permits(s) *(copies of any and all permits when applicable)*
 | **00** | Click or tap here to enter document name(s). |
| 1. Any new informed consent(s) *(when applicable)*
 | **00** | Click or tap here to enter document name(s). |
| 1. Any new goodwill permission(s) *(when applicable)*
 | **00** | Click or tap here to enter document name(s). |
| 1. Any new legal authorisation(s) *(when applicable)*
 | **00** | Click or tap here to enter document name(s). |
| 1. Any new 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 new declarations** by the:
	1. Researcher / Sub-study Supervisor (MUST)
	2. Director (MUST)
	3. Supervising Veterinarian
	4. Biosafety Officer
	5. Animal Facility Manager
	6. Statistician
	7. Supervising Pharmacist
	8. Laboratory Animal Technician (LAT)
	9. Radiation Protection Officer
	10. Any other professional supervisor not mentioned above
 | Included **in this form** below,  and only when new,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: Declarations *(to complete & sign)* |

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| * 1. **Declaration by the Sub-Study’s PI / Researcher / Supervisor**
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I, the undersigned, hereby apply for approval of this sub-study using vertebrate or higher invertebrate animals, as described in the scientific study proposal, 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. I have permission to perform this sub-study under the larger study by one of the following means:
	1. I have obtained written permission from the Principle investigator (PI) / Researcher / Study Supervisor of the larger study that this sub-study may take place under the larger study, also defining exactly what will be permitted or excluded, and I undertake to strictly abide by the terms of this agreement, OR
	2. I am the leader of both the larger study and of this sub-study.
3. The current study and its experimental design is scientifically justifiable and affordable (i.e. it can be finished once the use of animals will have commenced). Accordingly I:
	1. will ensure sound scientific integrity and research ethics in the planning, execution, data handling and work-up and scientific reporting of the current study,
	2. will ensure that all raw data is stored safely and remains in the possession of the North-West University,
	3. undertake to respect intellectual property rights throughout and to avoid any form of plagiarism.
4. The use of animals can be justified for the current sub-study, no unnecessary repetition of previously done work is included and due consideration has been given to implementation of the 3Rs (replace, reduce and refine, which I am familiar with) and the principle of due responsibility. I therefore also confirm that:
	1. the sub-study objectives cannot be achieved meaningfully through replacement of animal subjects (e.g. lower order animals without consciousness/feeling or tissue or other models),
	2. the experimental design is such that the minimum number of animal subjects is used, no animals are wasted unnecessarily and the optimal quantity of data is obtained from the studies with the number of animals used,
	3. any discomfort/suffering for animal subjects is kept to the minimum and no unnecessary suffering is caused,
	4. the potential predominant benefit arising from the study exceeds the harm to the animal subjects.
5. I will always value the wellbeing of the animal subjects above the interest to continue with or complete an experiment or the study, and the humane handling and treatment of animals and immediate relief of any undue discomfort, pain or distress will remain the highest priority of all team members,
6. I will ensure that the sub-study is managed ethically justifiably from start to finish. This imply that I will:
	1. oversee the sub-study, in agreed cooperation with the PI / researcher / study supervisor of the larger study,
	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 implement the approved studies/procedures/interventions,
	3. where applicable and necessary, always ensure that I have the necessary permits at my disposal before the relevant actions are carried out,
	4. confirm that the facilities where animals are housed and procedures performed is appropriately maintained and registered, and that all instruments and apparatus are appropriate for the animals, well maintained and calibrated as required,
	5. confirm that all required and appropriate safety measures are in place and that appropriate monitoring and response measures are in place,
7. I have familiarised myself with the processes and form for unscheduled incidents and adverse events, and will ensure that all team members (including students) working with the animals will be properly informed and trained in emergency procedures as well as provided with the report guidelines and forms.
8. The information provided in this application is, to the best of my knowledge, correct and that no ethical codes will be violated by the study.
9. I will not deviate from the approved proposal, or if required I will formally apply for approval of any amendments, and I understand that the study may be suspended or terminated if I deviate from the proposal without the approval of the Ethics Committee, which may also lead to disciplinary action.
10. I will report to NWU-AnimCareREC:
	1. without delay, as prescribed by the unscheduled incident and adverse event report, any such unscheduled incidents or adverse events experienced during the course of the study,
	2. annually to the Ethics Committee (or as determined by the Ethics Committee) on the prescribed monitoring report form concerning any and all progress and ethical aspects of the study,
	3. concerning any and all progress and ethical aspects of the study once the study is completed.

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| **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**
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This section is to be completed by the Director of Research (research projects) or Director of School/Institute (training projects).

I, the undersigned, hereby declare that the project may proceed 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 project.

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| **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. |
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| **Date** |
| Click or tap to enter a date. | **Signature** |
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| **Any comments (optional)**Click or tap here to enter text. |

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

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| Click or tap here to enter text. |

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

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| Click or tap here to enter text. |

1. Will you be available to advise, provide necessary specialised training and/or supervise with any specialised procedures or administration of scheduled substances when requiring the direct or indirect supervision of a veterinary surgeon?

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

1. Will you be available to advise on, assist or intervene with any emergency matter *(i.e. serious incident or adverse event)* relating to animal wellbeing throughout the project, even if such an emergency is after hours?

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

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| **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. |
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| **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**
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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?

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| **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?

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| **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**
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This section is to be completed by the Manager of the animal holding / experimentation facility.

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

1. Is the facilities suitable to carry out the project, as described in this application?

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

1. Is the facilities available to carry out the project, as described in this application?

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

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| **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. |
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| **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 Statistician**
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This section is to be completed by the Statistician/Biostatistician who verified the study design and animal numbers.

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

1. Have you ascertained the experimental design of the study, and is it in your professional opinion appropriate from a statistical perspective to answer the research questions?

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

1. Can the animal numbers to be used in the study be justified as the minimum number of animals required for statistical validity?

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

1. Are the planned statistical analyses (to be performed on data to be obtained) appropriately described and are they appropriate for the study?

|  |  |  |  |
| --- | --- | --- | --- |
| **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 study 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 study 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 for this project, 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 who verified the study design and animal numbers.

|  |
| --- |
| ***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 study? | [ ]  | [ ]  |
| 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 study? | [ ]  | [ ]  |

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 study 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 study.

|  |
| --- |
| 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. **Background information**
	1. **What constitutes a sub-study under a larger project?**

A larger project refers to a well-defined but compiled / complex project, which can be subdivided into several well-defined smaller sub-studies, for example a large study to train multiple postgraduate students each in a sub-study, or a well-defined large training project with several sub-compiled workshops. Therefore, a sub-study must be a well-defined section of an already approved larger project, so that it aligns with the objectives, study design and methodology that was already defined for the large study. If it is different or adds to what was defined in the larger project, it is not a sub-study any longer. Alternatively, the large study can first be amended to accommodate the changes or additions, whereafter the sub-study can be applied for.

* 1. **Conditions for a sub-study**

The following must apply for a study to be approved as a sub-study of a large study:

* The sub-study can only be approved within the validity period of the approved larger project. That also implies that, when the approval of the main study expires *(i.e. without a monitoring report to extend the project)*, the approval of the sub-study will automatically expire as well.
* The objectives, methodology and animals used in the sub-study may all involve only a sub-section of what was defined in the larger project, but they may not add/change anything to what was already defined in the larger project. Accordingly, the associated category of the impact on animal wellbeing will not be higher than that of the larger project.
* Any new supporting documentation, such as sub-study-specific monitoring reports, and for new team members (e.g. new postgraduate student) the certificates of training in ethics and animal handling, SAVC or other authorisation, etc. must be available and attached.
* Where the sub-study involve continuous testing of new substances, additional information MUST be provided (see question 1.4 below)
* You are advised to convert final versions of documents to PDF (i.e. “save as PDF”) before submitting them via e-mail.
* You will be requested to submit printed hard copies of all final documents for required record keeping, but only following ethics review, corrections and final approval.
1. **General instructions**
	1. **Important!** Always ensure that you have the latest version of the application form, downloadable from <http://health-sciences.nwu.ac.za/healthethics>. Previous versions will not be accepted.
	2. All sub-study proposals MUST be approved by an appropriate Scientific Committee BEFORE submitting this application for ethics approval.
	3. The Scientific Committee-approved larger project plus sub-study proposals forms the base documents that are evaluated in conjunction with this application form. This application form is very concise with minimal information, and merely guides the applicant in the process.
	4. All applications and supporting documentation must be in English only, and only electronic versions submitted via e-mail will be accepted.
	5. Complete this application form and attach all supporting documentation (e.g. certificates, authorisation documents to verify sound sources of animal tissue/fluids and disposal).
	6. You are advised to convert final versions of documents to PDF (i.e. “save as PDF”) before submitting them via e-mail.
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 General Study Identification §(o) 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; CoC = Code of Conduct; SOP = standard operating procedure. More details follow below.

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

1. ***Cover letter:*** Prepare a brief cover letter indicating the title of the sub-study, title and ethics approval number of the larger study, principal investigator and student *(if applicable)*, type of application *(i.e. sub-study)*, animal species to be used and location *(e.g. in Vivarium, Aquarium, nature reserve, etc.)* and other information that will provide context. Give this document a name starting with [1) Cover letter].
2. ***Larger project study proposal, its ethics approval letter, permission letter & sub-project study proposal:*** The study proposal plus ethics approval letter of the larger study, as well as the study proposal of the sub-study MUST be attached (see Addendum B: Research Proposal Requirements below). Also attach the permission letter from the Responsible Researcher or Study Leader of the larger study, indicating that the sub-study may take place under the larger study, also defining exactly what will be permitted or excluded. The sub-study proposal must now also be Scientific Committee-approved. Give each of these documents a name starting with [2.1) ###]; [2.2) ###], etc.
3. ***Letter of approval:*** Attach the letter of approval of the sub-study proposal by the Scientific Committee if this application relates to a research study. 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 study title, name of the principle investigator, 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 – sub-study.docx].
5. ***New SOPs:*** Attach a copy of all new SOPs *(i.e. not already included in the larger study)* that you refer to in the sub-study proposal and/or ethics application form. Please remember that, when you refer to a SOP in the study proposal and/or ethics application form, you need to indicate which section of the SOP is applicable, and also provide a brief description of the procedure as applicable in the study proposal and/or ethics application form. Give each of these documents a name starting with [5.1) ###]; [5.2) ###], etc.
6. ***New welfare monitoring sheets:*** All new sub-study-specific welfare monitoring sheets *(i.e. not already included in the larger study)* 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. ***New proof of ethics training:*** Proof of ethics training (preferably followed by assessment) in the last 3 years for each new member of the team *(i.e. not already included in the larger study)*. Give each of these documents a name starting with [7.1) ###]; [7.2) ###], etc.
8. ***New training on animal handling:*** Provide proof of an appropriate animal handling course for each new member of the team that will handle animals *(i.e. not already included in the larger study)*. Give each of these documents a name starting with [8.1) ###]; [8.2) ###], etc.
9. ***New SAVC authorisation:*** Provide applicable proof of authorisation by the South African Veterinary Council (SAVC) or the South African Council for Natural Scientific Professions (SACNASP) for each new member of the team that will handle animals *(i.e. not already included in the larger study)*. SAVC authorisation is typically required for any veterinary of para-veterinary intervention, usually in animal holding facilities, whereas SACNASP authorisation is typically required for zoological/environmental studies, usually during field work. If you need ethics approval before council authorisation will be granted, conditional ethics approval will be issued, whereafter will to need to provide the proof of authorisation before final ethic approval will be issued. Give each of these documents a name starting with [9.1) ###]; [9.2) ###], etc.
10. ***New facility registration:*** If applicable, attach the appropriate SAVC registration certificate for all new animal holding facilities *(i.e. not already included in the larger study)*. Give this document a name starting with [10) ###]
11. ***New Codes of Conduct:*** Ensure that a signed NWU Code of Conduct for Researchers is attached for each new member of the study team *(i.e. for those not already included in the larger study).*  Give each of these documents a name starting with [11.1) ###]; [11.2) ###], etc.
12. ***New narrative CVs:*** Ensure that a 2-page narrative CV is attached for each new member of the study teamand professional supervisors *(i.e. not already included in the larger study)* that are involved in the study (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. ***New contracts:*** If applicable attach a copy of all newly signed contracts or other agreements *(i.e. not already included in the larger study)*, as approved by the NWU legal office. Give each of these documents a name starting with [13.1) ###]; [13.2) ###], etc.
14. ***New permits:*** If applicable attach a copy of all new permits as required *(i.e. not already included in the larger study)*. If you need ethics approval before the permit will be issued, conditional ethics approval will be issued, whereafter will to need to provide the permit before final ethic approval will be issued. Give each of these documents a name starting with [14.1) ###]; [14.2) ###], etc.
15. ***New informed consent:*** If applicable attach the copy of any new informed consent form *(i.e. not already included in the larger study)* to be used in English plus translated in all other languages as necessary. Take note of the NWU template to guide you in formulating the informed consent. Give each of these documents a name starting with [15.1) ###]; [15.2) ###], etc.
16. ***New goodwill permission:*** If applicable, attach the copy of any new goodwill permission *(i.e. not already included in the larger study)* form to be used in English plus translated in all other languages as necessary. Give each of these documents a name starting with [16.1) ###]; [16.2) ###], etc.
17. ***New legal authorisation:*** If applicable, attach the copy of any new legal authorisations obtained *(i.e. not already included in the larger study)*. Give each of these documents a name starting with [17.1) ###]; [17.2) ###], etc.
18. ***New approval letters from other ARECs:*** If applicable, attach any new ethical approval letters of any other animal research ethics committee (AREC) that reviewed the study *(i.e. not already included in the larger study)*. 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 [19.1) ###]; [19.2) ###], 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. ***Signed declaration by the Responsible Researcher or Study Leader:*** The Responsible Researcher or Study Leader MUST sign the declaration.
	2. ***Signed declaration by the director of the research entity:*** The director of the research entity should complete and sign the declaration form only if new *(i.e. not included in the larger study application)*.
	3. ***Signed professional supervisor letter by the veterinarian:*** The supervising veterinarian should complete and sign the declaration form only if new *(i.e. not included in the larger study application)*.
	4. ***Signed declaration by the biosafety officer:*** 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 should complete and sign the declaration form only if new *(i.e. not included in the larger study application)*.
	6. ***Signed declaration by the statistician:*** The consulted statistician should complete and sign the declaration form only if new *(i.e. not included in the larger study application)*. If an individual with appropriate statistical expertise (but not being a qualified statistician) verified statistical validity, explain this in the application form, but do not sign this declaration.
	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) should complete and sign the declaration form only if new *(i.e. not included in the larger study application)*.
	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:*** Any other professional supervisor not mentioned above should complete and sign the declaration form only if new *(i.e. not included in the larger study application)*.
1. **Final submission steps for this application**

The following process must be followed to submit ethics applications:

* + 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).

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| Addendum B: Research Proposal Requirements |

The research proposal (or training study guide) forms the pivotal document of any ethics application, and must discuss the scientific/educational validity or the study, as well as address ethical considerations and implications, and scientific integrity of the application. Consult also 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. ***Research Proposal***
Attach the Research Proposal *(for research studies)* as approved by the Scientific Committee, or the study guide *(for training courses)*. Research proposals MUST contain at least the following elements:
	* Title *(concise, clear, descriptive)*
	* Responsible Researcher or Study Leader *(name and designation)*
	* Literature review *(outlining current knowledge and questions, previous research/training, specific research problem and justification for the study, or training need, references)*
	* Study aim and objectives *(may include a hypothesis where applicable)*
	* Research methodology *(study/experimental design/layout, animal type, number, housing, handling, and applicable techniques, procedures and assays, humane endpoints – with sufficient detail to allow thorough ethics evaluation)*.

**Please note!** *In this section you may refer to attached standard SOPs, but then you will have to also provide here, within your proposal document, concise descriptions thereof (e.g. assays and methods). Also be specific on how an SOP will be applied to your study, particularly when the SOP is generalised for a range of applications, or motivate and specify if you need to make a modification to the SOP. Make it easy for the reviewer to follow the story-line and essential details. The reviewer should find sufficient basic information within the proposal document, so that the attached SOP is to be consulted only when the reviewers needs to see more details.*

* + Data analysis *(mathematical and statistical)*
	+ Expected results and impact *(as from the study hypothesis)*
	+ Broad outline of the time schedule *(from planning until final reporting)*
	+ Ethical considerations *(recommended as a separate section, but may be incorporated in other sections or your Study Proposal)*

**Important!** **General ethical considerations** and appropriate harm-benefit estimation MUST be included in your research proposal, typically but not necessarily under a dedicated heading. This consideration should briefly explain how you applied the 3Rs *(i.e. replace, reduce and refine)* in your study planning, as well as the 4th R *(i.e. responsibility)*, why the described harmful interventions are necessary and how benefit outweighs harm. The application form is then used to expand on these and ask details on specific matters of ethical concern.

* + Budget *(in particular demonstrating that the study can be completed once you start using animals)*
1. ***Letter confirming approval of proposal***Attach a concise letter confirming approval of the study proposal by the Scientific Committee. This letter should be printed on a formal letterhead and signed by the chair of the committee, as well as state the approved study title, name of the primary investigator, the date of approval, names of committee members who approved the study proposal, plus a suggested (estimated and motivated) severity category 0 to 5 of the study.
**Please note!** *Whenever the Chairperson of the Scientific Committee is a team member for this application, he/she should step down and the vice-chairperson or another authorised signatory should sign.*

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| 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 AnimCare** 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. These categories are applicable to selections under **General Study Identification, question (m)** and to **question 2.2** above.

|  |
| --- |
| ***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. |