

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

<https://health-sciences.nwu.ac.za/healthethics>

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| **NWU-AnimCareREC** North-West University Animal Care, Health and Safety Research Ethics Committee *(AREC-130913-015)* **Ethics Application Form** to apply for the approval of **single** or **larger** scientific **studies**  using animal vertebrates or higher invertebratesfor research, education/training or repetitive testing purposes  ***9.1.5.1.1\_NWU-AnimCareREC\_EAF\_FEB2024, Version: 5.30*** |
| **CONFIDENTIAL!** This document contains confidential information that is intended exclusively for the applicant(s), the North-West University Animal Care, Health and Safety Research Ethics Committee (NWU-AnimCareREC) of the Faculty of Health Sciences and the designated reviewers. Should this document or parts thereof come into your possession in error, you are requested to return it to the NWU-AnimCareREC without delay or destroy it (Contact the administrative assistant at Ethics-AnimCare@nwu.ac.za). Unauthorised possession, reading, studying, copying or distribution of this material, or any other form of abuse, is illegal and subject to prosecution. |

**Please note!** Refer to ***Addendum A: Applicant’s Instructions*** and ***Addendum B: Study 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 ***Addendum D: Severity Categories***.

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| **Quick Navigation Links** *(Jump to the information by pressing the “Ctrl” key + mouse-click on the text)* | | | | | |
| Executive summary of the study | Flow diagram of the study design | Type of study | Severity category of the study | Checklist and attachments | Section 5: Harm-Benefit Analysis |

|  |  |
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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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**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 |

Provide the necessary descriptions below to identify this study application:

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

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| Click or tap here to enter text. |

* 1. **Name of the Principle Investigator (PI) / Researcher / Study Supervisor and Student**

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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 2: Study Team, Collaborators.* |

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| **Role** | **Name** *(title, first name and surname)* | | **NWU staff/student no.** |
| PI / Researcher / Study Supervisor | Click here to enter title, first name and surname. | | Click here to enter number. |
| Student  *(if applicable)* | Click here to enter title, first name and surname. | | Click here to enter number. |
| Level of the study | | Choose an item. | |

* 1. **Institutional structures and divisions under which the study 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. **Context of the study and researcher involvement**

|  |  |  |  |
| --- | --- | --- | --- |
| **Aspect** | | **Yes** | **No** |
| Scientific Research | Study scope falls inside the focus of a NWU research entity |  |  |
| Study scope falls outside the focus of a NWU research entity |  |  |
| Self-initiated research with no student involvement |  |  |
| Self-initiated research with student involvement: | | |
| * Honours study (for publication purposes) |  |  |
| * Master’s degree |  |  |
| * Doctoral degree |  |  |
| Study involves contract work |  |  |
| Education / Training | For staff of the North-West University (NWU) |  |  |
| For NWU students (undergraduate or postgraduate) |  |  |
| For other learners (not associated with the NWU) |  |  |
| Other (specify) | Click or tap here to enter text. | | |

* 1. **Type of study**

Is this an application for a *single*or a *larger study, affiliated study, educational (training) course or repetitive testing intervention in animals*? Select the option from the dropdown list below *(see “[Choose an item]” below)* that best describes this application.

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| ***More information***  ***Please note!*** *“Single” study refers to a study consisting of one or more researchers not intending to involve Master’s or doctoral students, or for the purpose of a single Master’s or doctoral study, whereas a “larger” study refers to a study planning to involve several Master’s and doctoral students and that includes the full methodology, as well as clearly identifies the objectives per student. For more elaborate definitions and explanations of “single” and “larger” studies you are referred to 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*](http://health-sciences.nwu.ac.za/healthethics/sops)*).* |

|  |
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| Choose an item. |

For a **larger study** *(not necessary for a single study)*, also provide a clear outline of the possible number of Master’s and doctoral studies envisaged *(i.e., that can be accommodated in the larger study as sub-studies)*, as well as what each student will do *(i.e., which objectives of the larger study will apply to the sub-study for that student)*. You need not know the names of the students as yet.

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| Click or tap here to enter text. |

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

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. |

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

Anticipated dates, once ethics approval has been granted.

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| ***More information***  *Here you can indicate the expected commencement and ending dates of the study, which may indicate a period of a few months to a few years. The full expected duration of the study must be filled in below. Even if the expected duration of the study is uncertain, you can still make an estimate here and report the progress with the annual monitoring report. Ensure that the commencement date is at least a few weeks after the date of the NWU-AnimCareREC meeting, at which your application is to be reviewed. The NWU-AnimCareREC will only grant ethics approval for a one-year period. Continuation of the study is granted on an annual basis for another year, after submission and review of a monitoring report. This process continues until the study comes to an end. NB: A monitoring report should also be submitted when the study is completed.*  ***Please note!***  *The NWU-AnimCareREC will only grant ethics approval for a one-year period. Continuation of the study is granted on an annual basis for another year, after submission and review of a passive monitoring report. This process continues until the study comes to an end.*  *A monitoring report should also be submitted when the study is completed.* |

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| **Envisaged Commencement Date** | **Envisaged Completion Date** |
| Click or tap to enter a date. | Click or tap to enter a date. |

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

Please indicate the appropriate severity category (compare **Addendum D: Severity Categories**) applicable to this study 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 study in full.*  ***Please note!*** *The selected category will be evaluated and may be changed by the NWU-AnimCareREC.* |

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| **Severity category for the study 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. **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 might cause documents to become corrupt, and 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. Research study proposal *(as approved)*  or study guide for training | **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 to be used in the study *(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)[[1]](#footnote-1) for each team member | **00** | Click or tap here to enter document name(s). | |
| 1. Training certificates for animal handling1  for each team member to handle animals | **00** | Click or tap here to enter document name(s). | |
| 1. Proof of recent (<3 years)1 IRIMS training for NWU staff and students | **00** | Click or tap here to enter document name(s). | |
| 1. SAVC authorisation[[2]](#footnote-2)/SACNASP registration for each team member to handle animals | **00** | Click or tap here to enter document name(s). | |
| 1. Proof of SAVC registration  of the animal facility (*when applicable)* | **00** | Click or tap here to enter document name(s). | |
| 1. Signed NWU code of conduct  for each team member | **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)1 *(copies of any  and all permits when applicable)* | **00** | Click or tap here to enter document name(s). | |
| 1. Informed consent(s)  *(when applicable)* | **00** | Click or tap here to enter document name(s). | |
| 1. Goodwill permission(s)  *(when applicable)* | **00** | Click or tap here to enter document name(s). | |
| 1. Legal authorisation(s)2  *(when applicable)* | **00** | Click or tap here to enter document name(s). | |
| 1. Approval letters from any other AREC  *(when applicable)* | **00** | Click or tap here to enter document name(s). | |
| 1. Other supporting documents not mentioned above *(when applicable – see §4.4)* | **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. 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   *(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: Study Team, Collaborators, Integrity & Legal Matters |

* 1. **Summary of persons included in the study**

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.* |

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| --- | --- | --- | --- |
| **Description** | | **Number** | |
| **SA** | **Foreign** |
| **Only for research studies** | Study supervisor(s) *(e.g., PI/researcher/study supervisor)* | 0 | 0 |
| On-site assisting study supervisor(s) *(day to day managers)* | 0 | 0 |
| Internal co-workers *(researchers and postgraduate students of the NWU)* | 0 | 0 |
| External co-workers *(researchers outside the NWU)* | 0 | 0 |
| Assistants/field workers | 0 | 0 |
|  | Sponsors | 0 | 0 |
| **Only for education and training  (e.g., undergraduate practicals)** | Educator | 0 | 0 |
| Internal co-workers *(lecturers of the NWU)* | 0 | 0 |
| External co-workers *(lecturers outside the NWU)* | 0 | 0 |
| Undergraduate students *(of the NWU)* | 0 | 0 |
| Postgraduate students *(of the NWU)* | 0 | 0 |
| Other learners *(not associated with the NWU)* | 0 | 0 |
| Assistants/field workers | 0 | 0 |

In the table above, NWU = North-West University

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

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| Click here to enter text. |

* 1. **Summary of professional supervisory persons are involved in this study**

Fill in the number concerned for ALL options. Ensure that the participant numbers in this table correspond with the individuals in §2.6 below.

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| ***More information***  *“****Professional supervisor****” indicates that the individual is an* ***independent*** *person on a supervisory capacity, that is involved during data gathering of the study, and provides specific required expertise to protect the participants. They may in no way be directly part of the research team. (Fill in the number involved in ALL options).* |

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| --- | --- | --- | --- | --- |
| **Researcher / Supervisor** | **No.** |  | **Researcher / Supervisor** | **No.** |
| **Supervisory Veterinarian** | 0 |  | **Supervisory Pharmacist** | 0 |
| **Supervisory LAT and/or  Veterinary Nurse** | 0 |  | **Radio Protection Officer** | 0 |
| **Supervisory qualified scientist** | 0 |  | **Other *(specify below)*** | 0 |

Specify any other supervisory person, if indicated above:

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| Click here to enter text. |

* 1. **Contact details of the PI / Researcher / Study Supervisor**

Name and details of the Principle Investigator (PI) / Researcher / Study Supervisor.

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| ***More information***  *The PI / Researcher / Study Supervisor is the member of the study team who assumes final, overall responsibility for all aspects of the study (i.e., management of the total study). Only NWU staff, or extraordinary professors in collaboration with staff of the North-West University, may register as PI / Researcher / Study Supervisor for ethics applications.*  ***Please note!******ATTACH*** *a two-page narrative curriculum vitae (CV) for the PI / Researcher / Study Supervisor, including:*   * *researcher’s qualifications* * *career path/experience to date* * *specific research experience applicable to the present study (e.g., methodology or skills required)* * *supervisory experience* * *last research ethics training* * *publication list of applicable articles (for the past 4 years)* |

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| **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 the On-site Assisting Study Supervisor**
     1. Is the Study Head also the Site Supervisor?

|  |
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| ***More information***  *Where the PI / Researcher / Study Supervisor is not physically present or consistently available and where a more direct supervision of the research activities is necessary, or where the PI / Researcher / Study Supervisor is relatively inexperienced (e.g., junior researchers in the case of a research study, or lecturers in the case of education/training), a suitable researcher/lecturer may be designated as On-site Assisting Study Supervisor. The On-site Assisting Study Supervisor is therefore the individual responsible for the day-to-day onsite/direct/one-on-one management of the study when the PI / Researcher / Study Supervisor cannot fulfil this responsibility, or for overseeing the study to support an inexperienced PI / Researcher / Study Supervisor, where this is deemed necessary. The On-site Assisting Study Supervisor is part of the study team.*  ***Please note!******ATTACH*** *a two-page narrative curriculum vitae (CV) for the PI / Researcher / Study Supervisor, including:*   * *researcher’s qualifications* * *career path/experience to date* * *specific research experience applicable to the present study (e.g., methodology or skills required)* * *supervisory experience* * *last research ethics training* * *publication list of applicable articles (for the past 4 years)* |

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| **Yes** | **No** | **Number of Site Supervisors** | **00** |

* + 1. If “Yes”, this section can be left blank. If “No” (i.e., if the PI / Researcher / Study Supervisor is not the On-site Assisting Study Supervisor) details of each On-site Assisting Study Supervisor must also be supplied. However, if “Yes”, this section can be left blank.

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

*Please note! Complete one table with information per On-site Assisting Study Supervisor..*

* 1. **Details of ALL Members of the Study Team**

Provide the names, functions & responsibilities, qualifications & professional registrations, competency certification and affiliation of ALL team members *(including the PI/researcher/study supervisor, student(s), collaborators),* and who will typically be publishing as co-authors *(but excluding professional supervisors who may not be directly involved in the study - see §2.6)*.

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| ***More information***  *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 team member involved in the study, including*   * *researcher’s qualifications* * *career path/experience to date* * *specific research experience applicable to the present study (e.g., methodology or skills required)* * *supervisory experience* * *last research ethics training* * *publication list of applicable articles (for the past 4 years)*   ***Please note!*** *For larger studies involving multiple postgraduate students over multiple years,* ***you MUST apply for a sub-study under the large study for each new student when joining the research team****.*  ***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 no. if applicable)* | **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. **Professional Supervisors (where and as applicable)**

Provide the names, functions & responsibilities, qualifications & professional registrations, competency certification and affiliation of ALL supervisory professional persons *(e.g., veterinary surgeon, pharmacist, veterinary nurse, qualified scientist, etc.)*.

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| ***More information***  *Being a Professional Supervisor implies that the individual is an independent monitor involved during data gathering of the study and acts as an advocate for the animal subjects.*  ***Please note!*** *The professional supervisor(s) may NOT be part of the study team!*  ***Please note!******ATTACH*** *a two-page narrative curriculum vitae (CV) for all professional supervisors of 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** | **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 researchers or lecturers from another institution, national or international, who will be working on a defined section of the study.

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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 study and the collaborator for a different part. These responsibilities and agreements must be fully described and declared here.*  ***Please note!*** *Refer to §2.10 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 §2.8 if there is any conflict of interest, and then declare this in full in §2.8.* |

|  |  |  |
| --- | --- | --- |
| **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 member of the study team or professional supervisor.

|  |
| --- |
| ***More information***  *Examples of conflict of interest: financial, non-financial: intellectual, bias, overly optimistic promises of potential benefits, role of the researcher(s), desire of professional advancement, desire to make a scientific breakthrough, relationship with participants. 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 study (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 participant in the study directly or indirectly involved with one or more of the sponsors? Does any member of the study 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** |

|  |  |  |  |
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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 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 study. 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 certain aspects on the availability of raw data in terms of 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*](mailto: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.*

* 1. **Confidentiality & non-disclosure agreements**

People other than the research team involved in the research and that could pose a risk to confidentiality, should sign confidentiality agreement(s). The people who need to sign these documents should be clearly indicated in your proposal.

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| ***More information***  *Please submit all indemnity forms (see indemnity forms as approved by the legal office on the web page)* |

* 1. **Indemnity**

If people are involved in the research as part of the research team, but are not North-West University (NWU) staff *(i.e., on the NWU payroll or by contract)*, they will not be covered by the insurance of the NWU and will thus have to sign an indemnity form (e.g., transport of non-NWU individuals in University vehicles).

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| ***More information***  *Please submit all indemnity forms (see indemnity forms as approved by the legal office on the web page)* |

* 1. **Animal studies done at non-NWU animal facilities**

Declare with full details of all studies done at animal facilities that are **NOT** under the jurisdiction of the North-West University (NWU).

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| ***More information***  *For all facilities not affiliated with the NWU, proof* ***MUST*** *be provided that this facility is registered with the South African Veterinary Council (SAVC) and/or another applicable statutory body, plus the NWU-AnimCareREC must have a cooperative oversight agreement with the animal research ethics committee (AREC) that oversees that facility, understanding that this AREC must be registered with the National Health Research Ethics Council (NHREC) or a body recognised as equivalent at the discretion of NWU-AnimCareREC.* ***Onsite responsibilities*** *of the overseeing AREC includes, but are not limited to, training, professional support, SAE reporting and active monitoring. More information can be found on the NWU-AnimCareREC website, or via consultation.*  ***Please note!*** *A copy of any* ***SAVC registration certificate*** *of the facility, plus a copy of the* ***cooperative oversight agreement*** *between NWU-AnimCareREC and the facility’s NHREC-registered AREC* ***MUST BOTH BE ATTACHED****.* |

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| --- | --- |
| **Name of Facility** | **Full Declaration and Description** |

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

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

* 1. **Transport of any animals, transfer of any biological materials or work with infectious or potentially infectious pathogens**

Declare with full details all animals to be transported, or the transfer of any biological materials/samples to facilities or laboratories outside of the North-West University (NWU), or work with infectious or potentially infectious pathogens, or transport of animals or biological materials which may contain infectious or potentially infectious pathogens.

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| ***More information***  *In such cases, 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.*  ***Please note!*** *A copy of any* ***transport permits****,* ***MTAs****, approved by the NWU legal office and signed by the appropriate NWU line-management, and/or* ***DAFF’s Section 20 permit******MUST BE ATTACHED*** *and submitted to* [*Ethics-AnimCare@nwu.ac.za*](mailto:Ethics-AnimCare@nwu.ac.za)*, together with submission of this application. In select instances where ethical approval is required before the permit is issued, this should be indicated, and a conditional approval can then be issued by NWU-AnimCareREC, which will only become full approval upon submission of the permit.*  ***Please note!*** *More information can be found on the NWU-AnimCareREC website, or via consultation.* |

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| **Permit or MTA** | **Full Declaration and Description** |

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

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

* 1. **Environmental studies requiring permits**

Declare with full details all environmental studies that will require a permit, not described above.

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| ***More information***  *Is a permit required by law for the capture, collection, transport or detention of this (these) species? If so, describe it here and mention the name and address of the authorising authority.*  ***Please note!*** *A copy of any* ***permits******MUST BE ATTACHED*** *and submitted to* [*Ethics-AnimCare@nwu.ac.za*](mailto:Ethics-AnimCare@nwu.ac.za)*, together with submission of this application. In select instances where ethical approval is required before the permit is issued, this should be indicated, and a conditional approval can then be issued by NWU-AnimCareREC, which will only become full approval upon submission of the permit.* |

|  |  |
| --- | --- |
| **Permit** | **Full Declaration and Description** |

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

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

* 1. **Registration/authorisation at SACNASP or SAVC**

Please indicate the appropriate registration or authorisation status or requirement of either the South African Veterinary Council (SAVC) or of the South African Council for Natural Scientific Professions (SACNASP). Indicate the status or requirement per researcher or student.

|  |
| --- |
| ***More information***  ***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.* |

|  |  |  |
| --- | --- | --- |
| **Name of the researcher / student** | **Procedure(s)** | **Status/Requirement** |
| Click to type name. | Click or tap here to enter text. | Choose an item. |

*Please note! Type the information for only team member working with animals per row. For more individuals, add more rows by clicking on the [Tab] key while the curser is in the last column.*

* 1. **Informed Consent from Owner**

Whenever research is done on the property or involving animals of private owners, informed consent **MUST** be signed before the animals are accessed.

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| ***More information***  *The informed consent form to be signed by the owner typically includes information of procedures, benefits & potential risks, liability waiver, intellectual property, etc.*  ***Please note!*** *A copy of any* ***informed consent for animal owners*** *(English copy – see example template)* ***MUST BE ATTACHED*** *and submitted to* [*Ethics-AnimCare@nwu.ac.za*](mailto:Ethics-AnimCare@nwu.ac.za)*, together with submission of this application. Translation to other languages, as indicated, is done once approved and then also submitted to the NWU-AnimCareREC.* |

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| Section 3: Essential Details of the Scientific Study |

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

Summarise the study in not more than **250 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.

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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** in not more than **250 words**, 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 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. **Study proposal**

Study Proposal (for research studies) as approved by the Scientific Committee must be attached. For more information, refer to Addendum B: Study Proposal Requirements below.

|  |
| --- |
| ***Please note!*** *For each study a detailed proposal has to be submitted and is used as the main document for the review of your application. The proposal should reflect the ethical aspects of the research throughout, and as a minimum contain a section reflecting on ethical considerations. Attach the proposal approved by the Scientific/Proposal Committee of your research entity.* |

* 1. **Type of scientific field(s)**

Which of the following categories best describe the type of scientific field for which the animals are used? *(mark all that are applicable)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Agricultural sciences | |  |  | Human health sciences |  |
| Conservational and wildlife sciences | |  |  | Veterinary and para-vet. sciences |  |
| Environmental sciences | |  |  | Zoological sciences |  |
| Biological sciences | |  |  | Education or training |  |
| Other (please specify) | Click or tap here to enter text. | | | | |

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

This study should have been *first reviewed and approved* by a Scientific/Proposal Committee prior to your ethical approval applications.

|  |
| --- |
| ***More information***  *The NWU-AnimCareREC has to have proof of confirmation of the approval by the Scientific/Proposal Committee. A template is available on the web page for this purpose.*  ***Please note!***  *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.*  *A letter confirming approval of the research proposal by the scientific committee* ***MUST BE ATTACHED*** *and submitted to* [*Ethics-AnimCare@nwu.ac.za*](mailto: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.*  *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 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:**

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

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| Section 4: Specific Ethical Implications of the Study |

* 1. **Species(s) category of animals**

Which of the following categories best describe the species/classification of the animals employed in this study? *(mark all that are applicable)*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Amphibians |  |  | Fish |  |  | Pigs |  |
| Birds |  |  | Guinea pigs |  |  | Rabbits |  |
| Cats *(domestic)* |  |  | Goats |  |  | Rats |  |
| Cattle |  |  | Fish |  |  | Reptiles |  |
| Cephalopods |  |  | Horses |  |  | Sheep |  |
| Decapods |  |  | Lower invertebrates |  |  | Vertebrate larvae, tadpole, etc. |  |
| Dogs *(domestic)* |  |  | Marine mammals |  |  |
| Embryonated eggs |  |  | Mice |  |  | Wildlife game *(not above, please specify below in “other”)* |  |
| Embryos (other) |  |  | Non-human primates |  |  |
| Other *(please specify)* | | Click or tap here to enter text. | | | | | |

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

Give a full/accurate description of the animals (species & strain) that you will use in this study. If more than one species is to be used, copy the table and describe each in full.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Species & strain** | Type here. | **Number** | 00 | **Sex** | Choose | **Age/ Weight** | 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. **Habitat of animals**

Which of the following categories best describe the habitat of the animals employed in this study? *(mark all that are applicable)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Domestic animals | |  |  | Laboratory animals (non-NWU) |  |
| Farm or agricultural animals | |  |  | Private owner property |  |
| Feral animals | |  |  | Rivers, dams, sea, aquaculture |  |
| Free roaming wildlife | |  |  | Zoo or captive wildlife |  |
| Laboratory animals (NWU) | |  |  | International territory |  |
| Other (please specify) | Click or tap here to enter text. | | | | |

* 1. **Vulnerability & special use of animals**

Which of the following categories describe any special vulnerability or special use of the animals employed in this study *(mark all that are applicable)*:

|  |
| --- |
| ***Please note!*** *Any aspect marked below will require not only a description at the bottom of the table, but will also have to be addressed in the harms analysis as part of the harm-benefit analysis at the end of this ethics application form.*  *In case of selection of any of these matters, additional information, authorisation, permits, etc. may be required and should be attached. This should be described in the description at the bottom of the table. Such matters may include, but is not limited to, the following:*   * *Woking with pathogens may require will involve biological safety and appropriate training, facilities, registration (e.g., Section 20 permit), etc.* * *Veterinary clinical trials[[3]](#footnote-3) or preclinical studies with health products[[4]](#footnote-4) that may eventually feed into clinical trials, will require registration of the study with SAHPRA.* * *Threatened or endangered animal species may require a permit.* * *Animals with impaired conditions or special needs may require specialised facilities, expertise and monitoring.* * *GLP studies require proof of accreditation.* * *Studies involving severe, prolonged stress or pain, require special justification, expertise and monitoring.* * *Transport of animals and/or samples may require transport permits, material transfer agreements (MTAs), permission of the state veterinarian, etc.* |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Threatened or endangered species | |  |  | Animal model of human disease |  |
| Vulnerable species or strain with special needs, behaviour, sensitivity | |  |  | Veterinary clinical trial |  |
| Animals with impaired health, behaviour or mental state | |  |  | Preclinical study on health product |  |
| Animals with anatomical, physiological or functional disabilities | |  |  | Severe, prolonged stress or pain, or other procedure-induced vulnerability or otherwise harmful interventions |  |
| Animals with pain, injury, disease, fear and/or distress | |  |  |
| Genetically modified animals | |  |  | Special type of study (e.g., efficacy, toxicology, safety, product testing) |  |
| Infecting or exposing animals to pathogens, or induction of disease | |  |  | Xenograft study |  |
| Exposing animals to toxins or substances with undesirable side-effects | |  |  | General anaesthesia, surgery, invasive procedure |  |
| Good laboratory practice (GLP) studies | |  |  | Subjecting animals to multiple invasive procedures? |  |
| Exposing animals to physical or mental stressors | |  |  | Capture, restraint and/or transport of animals |  |
| Aversive/suboptimal environment, social isolation or food/water deprivation | |  |  | Staged predator observation |  |
|  | |  |  | Other *(specify below)* |  |
| If any of the above is selected, describe[[5]](#footnote-5) | Click or tap here to enter text. | | | | |

* 1. **Environmental & biosafety risks, consequences of, or mitigations in the study**

Which of the following categories describe any environmental and/or biosafety risks of, consequences of, or applied mitigations applicable of this study *(mark all that are applicable)*:

|  |
| --- |
| ***Please note!*** *Any aspect marked below will require not only a description at the bottom of the table, but will also have to be addressed in the harms analysis as part of the harm-benefit analysis at the end of this ethics application form.* |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Pathogens associated with communicable disease | |  |  | Scheduled medicines |  |
| Injections, blood samples and similar interferences | |  |  | Previously untested compounds or effects in animals unknown |  |
| Generated biological waste | |  |  | Generated chemical waste |  |
| New genetic manipulation | |  |  | Use of radio-active substances |  |
| Potential or real environmental impact of the study interventions | |  |  | Animals reused, rehomed, re-introduced in breeding or habitat |  |
| Excess breeding expected? | |  |  | Excess biological materials stored/shared? |  |
| If any of the above is selected, describe1 | Click or tap here to enter text. | | | | |

* 1. **Animals expected to reach humane endpoint as a result of the experimental procedure**

Is there a reasonable expectation that some animals may reach humane endpoint during the study, for example certain metastatic xenograft studies or risky invasive procedures?

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| ***Please note!***  *If “Yes”, describe in full exactly what is expected to happen and why, what are the animals likely to experience, justify why this is necessary, describe in full how the animals will be monitored, how many animals or percentage of animals are expected to reach humane endpoint and any other mitigating factors to prevent animal suffering.*   * *Provide supporting information* *(e.g., previous studies or other references, and not a wild guess) on which this expectation is based.* * *This question is about reaching humane endpoint and intervention before inhumane suffering occurs, and not about animals reaching the moribund state or dying prior to intervention (which should not be allowed).* * *If, as expected (described here) and ethically approved, animals then reach humane endpoint during the study, and the approved mitigating interventions are introduced, this must be recorded and reported in the passive monitoring report. However, this does not need to be reported as a serious adverse event (SAE). Nevertheless, if this expected number/percentage or expected severity is exceeded, or anything outside of what was ethically approved, needs to be formally reported as an SAE.* * *This will also have to be addressed in the harms analysis, as part of the harm-benefit analysis at the end of this ethics application form. This may potentially be acceptable only when unavoidable, justified and with all mitigating factors in place.* |

|  |  |
| --- | --- |
| **Answer** | **Description** |
| - select - | Click or tap here to enter text. |

|  |
| --- |
| **Consideration of the 4Rs** |
| The questions below describe how the 4Rs have been taken into account in the planning of the study, and how they will be taken into account during the execution of the study. 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:   1. **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.* 2. **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).* 3. **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.)* 4. **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 study objectives meaningfully (e.g., lower order/less sentient animals, or *in vitro* tissue cultures, or computer models, etc.)?

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

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| Click or tap here to enter text. |

* 1. **Reduce**
     1. **Motivation for study design**

Motivate the design, group sizes and conditions, as indicated in the proposal, by referring to similar published studies and/or refer to pilot studies that have already been carried out to justify the above design, number of animals, group sizes and conditions. Have you optimized (‘**Refined**’) the design to ensure minimal impact on animal well-being, optimal animal number and implementation of alternatives where possible?

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

* + 1. **Justification of animal numbers**

Provide a justification for the indicated number of animals per control and study group and in total to be used in this study. Also indicate **HOW** you determined the minimum number of animals to be used, without jeopardising the statistical validity of the data?

|  |
| --- |
| ***More information***  *The minimum number of animals (sample size) required can, for example, be determined by means of the following:*   1. *Statistical* ***power analysis*** *(generally preferred for animal studies)* 2. ***Resource equation*** *method (when a power analysis is not possible)* 3. ***Evidence-based*** *estimation (when sufficient experience exists and as published, with similar animal species, type of measurements and study design)* 4. ***Standard/accepted guidelines*** *(e.g., for specific test protocols)*   *You may also consult other useful information resources:*   1. *NC3Rs* [*https://www.nc3rs.org.uk/experimental-designstatistics*](https://www.nc3rs.org.uk/experimental-designstatistics) *(accessed online on 29 Aug 2018)* 2. *J Pharmacol Pharmacother. 2013 Oct-Dec;4(4): 303–306* 3. *Festing MFW* [*http://www.3rs-reduction.co.uk/html/6\_\_power\_and\_sample\_size.html*](http://www.3rs-reduction.co.uk/html/6__power_and_sample_size.html) *(accessed online on 29 Aug 2018)* |

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

* + 1. **Method of selection and/or randomisation**

Describe how the allocation (apportionment) of animals to control and test groups will be performed and the manner by which randomisation will be assured. If not applicable, please motivate.

|  |
| --- |
| ***More information***  *In case of field studies, it is important to indicate how you will select the animals to be included in the study/study groups. In all types of studies it is also important to indicate how you will assure that allocation of animals into control and test groups are done in a truly randomised manner, even including allocation to specific cages if applicable. Typically when all animals from a particular test group is housed in one cage, this may be considered as “pseudo-replication”, since there may also be dependence on cage as confounding factor to affect the outcome. Consider all of these matters in your comments below.* |

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

* + 1. **Drug and test substances**

Are any drugs or other test substances administered to animals in the current study?

|  |  |
| --- | --- |
| **Yes** | **No** |
|  |  |

If yes, please answer the questions below *(in addition to details provided in your study proposal document)*:

1. List the drugs and/or test substances, also indicating for each its purpose in the study, the dose(s) and route of administration to be used. Also indicate for each whether it is registered at SAHPRA for the purpose to be used, or refer to supporting information *(e.g., publications or section in your study proposal)* for its application and dose(s) to be used in the study.

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| Click or tap here to enter text. |

1. Are drugs and test substances to be used during the project suitable for administration to the experimental animals participating in the project with respect to route of administration, pH, viscosity, constituents, dose volume, temperature at the time of administration, sterility etc.? Please motivate, explain how you will ensure this, and provide supporting references where applicable.

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1. Are all ingredients of the formulation making up the test compound suitable for administration via the method of administration proposed?

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| Click or tap here to enter text. |

1. Are all test compounds, drugs or placebos mentioned above expected to cause any pain, suffering or adverse effects to the experimental subjects intended to participate in the project? If so, please explain and indicate mitigating factors, as well as applicable welfare monitoring and other measures to optimise safety, minimise suffering and optimise rapid response time.

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| Click or tap here to enter text. |

* + 1. **Statistical methodology**

Describe the means by which the statistical analyses of the data will be conducted. If not applicable, please motivate.

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| ***More information***  *Statistical methodology could include, but is not limited to, descriptive statistics, group comparisons to be made, adjustments for multiple comparisons (e.g., Dunnett, Tukey, Bonferonni, etc.), any other specific statistical tests to be performed.* |

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

* + 1. **Statistical consultation**

Has this study been approved by a statistician and/or Statistical Consultation Service of the North-West University? Approval of the design and statistical justifiability of your study before submission of the ethics application is important and certainly strongly recommended, since it may identify unnecessary shortcomings beforehand and can speed up the process of ethical approval.

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| ***More information***  *A special section is devoted to statistical justifiability of your intended study. In this regard, the soundest research problem, methodology and data processing can’t make a study succeed if the study design (experimental design) did not take into account statistical justifiability. Poor statistical planning can cause a good study to fail and may render the results useless for answering the set research problems. To involve animals in such a poorly planned study now would be unethical. It is therefore important to indicate in this section how you as PI / Researcher / Study Supervisor will ensure that your study design is statistically justifiable.*  *In addition, appropriate application of statistical analyses when processing data is critical to yield trustworthy results, and again you as PI / Researcher / Study Supervisor should ensure that this will be implemented, as indicated also in you study proposal.*  *In conclusion, assurance of good, meaningful data, appropriate statistical processing and meaningful interpretation of the data begins with thorough planning of the study design, and include also appropriate application of statistical analyses when processing data.* |

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| **Yes** | **No** |  | **Additional Comments** |
|  |  |  | Type motivation here, or type “Not applicable”. |

If “Yes”, **ATTACH** the completed and signed “Declaration Form” (separate document). If “No”, ensure that enough information is available in the application form to make it possible for evaluators to check the justifiability of the study design.

* + 1. **Repetition of previous work**

Will the current study entail any repetition of previously done work? If “Yes”, provide full motivation why this is necessary.   
*(Please mark with* **X** *in the appropriate box and provide details if “Yes”)*

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

* + 1. **Breeding/sourcing of the animals**

Describe how you will arrange for the breeding or sourcing of the animals (e.g., to enable timely production and/or avoid overproduction).   
**Please note!** For animals to be used in the PCDDP 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.

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* 1. **Refine**
     1. **Details of products to be introduced or administered to animals**

[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. |

In case of drugs or other substances to be administered, describe in full:

* the pharmacology (mechanism of action, therapeutic or other wanted effects, indications, expected side effects or toxicity in the animals of the study, contraindications, etc.);
* whether it has been used in the animal species of this study before and how well it was tolerated;
* the proposed route of administration and suitability thereof;
* what the dose/dosage and duration of administration will be, and what this is based on.

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In case of drugs or other substances to be administered that have not been formulated and registered as such with SAHPRA, give a full description of the route of administration and suitability thereof. Also describe the proposed pH and viscosity of the vehicle for the drug administration. Describe the stability of the drug formulation, whether it will be freshly prepared or stock solutions will be stored, and how quality control will be assured?

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| Click or tap here to enter text. |

* + 1. **Details of animal models**

Is this species readily available (e.g., from the PCDDP Vivarium or NABF 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”)*

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

* + 1. **Disturbance variables**

Describe the foreseeable disturbance (background) variables of the study 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 study, e.g., different researchers carrying out the study/experiment; more than one laboratory being used; different days during which the study/experiment 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 study 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 study-specific monitoring sheets* ***MUST BE ATTACHED****.* |

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* + 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 (PCDDP Vivarium or NABF Aquarium), refer to the appropriate approved SOP and provide only a brief description thereof. However, animals to be used outside the PCDDP 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 study? Do the PI / Researcher / Study Supervisor, research supervisor, researcher(s)/assistants, field workers etc. have at their disposal the necessary background/expertise/qualifications/authorisations/professional registrations to implement the techniques/procedures concerned? Refer to §4.7.4, where you will describe how you will ensure training and competence before and throughout the course of the study?

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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 study 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 §2.11.

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| ***More information***  *For animals to be used in the PCDDP 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 PCDDP Vivarium, brief descriptions will suffice. Also, where the study 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 study 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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* + 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 study on any endangered or protected species or significant impact on the environment?**

Provide more details if this study 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)*).* |

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

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| **Other ethico-legal matters and project management** |

* 1. **Other specific matters**
     1. **Process of obtaining informed consent from animal owners**

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

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| ***More information***  *If applicable to your study, explain the process you will follow to obtain consent from animal owners before you gain access to their animals. Also refer to and explain the informed consent form you will use, and in which languages you plan to translate this.*  ***Please note!***   * *A copy of the* ***English*** *version of any* ***informed consent form MUST BE ATTACHED*** *and submitted to* [*Ethics-AnimCare@nwu.ac.za*](mailto:Ethics-AnimCare@nwu.ac.za)*, together with submission of this application. Once the English version has been approved, you should have it translated to the other indicated languages and submit a copy of the translated versions to the NWU-AnimCareREC.* * *You may find an* ***example template*** *of the informed consent form for animal owners (to guide you in setting up such your study-specific informed consent form) on the website of the Ethics Office (*[*http://health-sciences.nwu.ac.za/healthethics/about-us*](http://health-sciences.nwu.ac.za/healthethics/about-us)*).* |

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* + 1. **Goodwill Permission**

There are sometimes also other interest group representatives/stakeholders (e.g., property managers, community leaders, tribal chiefs or other). They will usually have their own forms of provide a letter of permission. Please describe any such permissions required below.

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| **Name of stakeholder** | **Full Description of Permission** |

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

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

* + 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 study. Furthermore, does any person have the right to request to see and study the original data of published results in order to verify the accuracy and validity thereof?*  *Management of data/biological samples:*   * *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 study**

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 study *(research or training)*.

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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 study 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. PI / Researcher / Study Supervisor 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 study design, substances, methodology, or even the smallest matter should be approved via an amendment application (expedited process).* 6. ***Management of researcher/student safety*** *during the execution of the study (if applicable). In particular, when students will be working in desolate areas or after hours in animal facilities, or when there are specific risk of infectious disease or physical harm in the area, you need to describe how safety will be ensured (for example by having a second person always present, by having inoculations or prophylactic medications, a first aid kit, safety training, etc. Mention the risk and discuss your preventative safety measures. When available, also refer to the applicable SOP (e.g., the PCDDP Vivarium SOP, or other SOP) describing the procedures for the management of such situations.* |

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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. **Management of researcher / student safety** | Click here to enter text. |

* + 1. **Time-frame of the whole study**

Describe the time-frame (i.e., study progress outline or schedule) with projected dates until completion.

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| Click or tap here to enter text. |

* + 1. **Time-schedule for animal facilities** *(if applicable)*

If research is to be performed at an **animal facility**, explain how you discussed the feasibility of the study with the facility manager, and also provide your time schedule plan and the facility’s procedures for ordering the animals.

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| ***More information***  *The following should be kept in mind, or be explained here:*   1. *Animals are not simply available, but need to be bred on request.* ***Breeding programmes*** *usually take a minimum of 9 weeks to deliver the requested number of animals from breeding pairs, but may take longer depending on the kind of animals and number of animals required, or on time for* ***import*** *if necessary. You should have planned for this and describe your planning below.* 2. *Also explain your* ***time schedule*** *for performing the experiments with the animals at the facility, demonstrating that it is feasible and that the capacity (including staff and rooms) at the animal facility is indeed sufficient at that time of the planned study.* 3. *If necessary, you may refer to* ***attachments*** *with more details on time schedules and planning.* |

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* + 1. **Budget**

Will sufficient funding to cover the budget of the study, and as outlined in the study proposal, be available and sufficient to complete the study, in particular before initiating any breeding or use of animals?

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

* + 1. **Dissemination of information**

Describe how you plan to disseminate the research findings to the scientific community (how and quantity), and also how you will ensure that any significant finding is explicitly disseminated to the appropriate authority and/or to the public.

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| ***More information***  *The following explain what you should describe here:*   1. *The* ***scientific community*** *is typically informed via publication in scientific journals, a dissertation or thesis, a scientific report, or podium/poster presentations at conferences. Indicate what and how many you envisage (an estimate).* 2. *The* ***authorities*** *could typically be informed, for example, via notification of the South African Health Products Regulatory Authority (SAPHRA) regarding any manifested toxicity or finding that may bear on safety of a drug in humans, or the Department of Agriculture, Forestry and Fisheries (DAFF) regarding any finding that may bear on environmental safety.* 3. *The* ***public*** *is typically informed via public engagement or an appropriate posting/article in layman’s media (social media, local newspaper or magazine) may in some cases inform the public and uphold public responsibility.* |

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| Click or tap here to provide details. |

* 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 as **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 study (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 study 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[[6]](#footnote-6) 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:*   1. *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 study layout) are involved in this specific intervention.*  1. *Indicate and describe the specific harm**[[7]](#footnote-7) 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.)* |

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| **Inter-vention  #1** | **Description of intervention** | Type details here. | | | | | | | | | | | | | | | | |
| **Which species, test group?** | Type details here. | | | | | | | | | | | | | | | | |
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| **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. | | | | | | | | | | | | | | | | |

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| **Inter-vention  #2** | **Description of intervention** | Type details here. | | | | | | | | | | | | | | | | |
| **Which species, test group?** | Type details here. | | | | | | | | | | | | | | | | |
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| **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. **Benefit, scientific integrity and translatability of the study**

Reflect on the likely **benefit** from this study *(by referring to and considering your* ***Research Proposal*** *(i.a. the problem statement, hypotheses & expected outcomes)*, the matters related to **research integrity** *(discussed in* ***Section 4: Specific Ethical Implications of the Study****)*, as well as the **translatability** of the study results and findings to real-life practice *(for example the human condition or treatment in the case of preclinical 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 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.* |

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

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

[Refer to and consider **question 5.1** above]. This question describes the overall outcome of the respective harm analyses of all individual particular interventions in the previous question, as compared to the overall benefit analysis.

**Please note!** Benefit should outweigh harm for any study to be approved.

|  |
| --- |
| ***More information***  ***Harm-benefit analysis:***   1. ***Indicate and describe the overall harm****2 associated with this study:*  * *Indicate the cumulative severity category plus degree of overall harm2 associated with this study, considering all of the specific harm in the previous question. The cumulative severity category refers to the overall experience of the animal resulting from all interventions. This should be estimated/deduced/projected, either from the most severe intervention, or when multiple consecutive (combination of) interventions per animal would cumulatively aggravate the experience of the animal, it may be higher than the category for the most sever single interventions.* * *Indicate the degree of overall harm2 associated with this study on a scale from 0 to 5.*  1. ***Indicate and describe the overall benefit****2 associated with this study:*  * *Give a brief description the specific benefit (theoretical or practical value) associated with this particular intervention* * *Indicate the domain of the benefit (i.e., who or what will benefit), e.g., social benefits (including human health from a better understanding of a particular phenomenon or treatment, animals directly when the animals in the experiment will benefit from, for example, a treatment, animals indirectly when the representative species will benefit, but not the animals being used themselves, or the environment) socio-economic benefits, scientific benefits, educational benefits or enhancement of safety and efficacy.* * *Indicate the degree of overall benefit2 associated with this study on a scale from 0 to 5.*  1. ***Indicate the final outcome of your analysis****, as applicable to this study:*  * *Consider from the cumulative severity factor, overall harm2 and overall benefit2 of the study, whether overall the benefit2 of the study outweighs the overall harm2 of the study. Add a brief motivation and comments to support your final analysis.*   ***Please note!*** *It is particularly important to clearly motivate your analysis outcome. As an example, in a case of “extreme harm = 5”, with “very high” benefit, it may still be that the benefit outweighs harm when benefit is in multiple domains and/or of extreme/critical significance and/or with critically important impact. Even more so in such cases a clear motivation becomes of paramount importance for ethical approval of the study.*  ***Please note!*** *Keep the motivation concise and to the point.* |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | | | | | | | | | | | | |
| **Overall Harm** | **Cumulative severity category (overall degree of harm)** | **0**  **Negli-gible** |  | **1**  **Low** |  | **2**  **Mild** |  | | **3**  **Mode-rate** |  | **4**  **High** |  | **5**  **Ex-treme** |  |
|  |  |  | | | | | | | | | | | | |
| **Overall Benefit** | **Description  of the benefit (what?)** | Type details here. | | | | | | | | | | | | |
| **Domain  (who/what  will benefit?) … choose one or more options** | **Humans  (e.g., health)** | |  | **Animals  (direct)** | |  | **Animals  (indirect)** | | |  | **Environ-ment** | |  |
| **Socio-economic** | |  | **Scientific** | |  | **Educational** | | |  | **Safety and efficacy** | |  |
| **Overall degree of benefit** | **Negli-gible** |  | **Low** |  | **Mild** |  | | **Mode-rate** |  | **High** |  | **Very high** |  |
|  |  |  | | | | | | | | | | | | |
| **Analysis outcome** | **Benefit outweighing the harm?** | **Yes** | |  | **Equal** | |  | | **Unclear** | |  | **No** | |  |
| **Motivation  and comments** | Type details here. | | | | | | | | | | | | |

|  |
| --- |
| 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 study 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 study.

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

|  |
| --- |
| 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)* |

|  |
| --- |
| * 1. **Declaration by the PI / Researcher / Study Supervisor** |

I, the undersigned, hereby apply for approval of this 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. 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.
3. The use of animals can be justified for the current 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 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.
4. 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,
5. I will ensure that the study is managed ethically justifiably from start to finish. This imply that I will:
   1. oversee the 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,
6. 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.
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 study.
8. 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.
9. 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.

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

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

|  |
| --- |
| ***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?

|  |
| --- |
| 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?

|  |
| --- |
| 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?

|  |  |  |  |
| --- | --- | --- | --- |
| **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?

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

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

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

|  |
| --- |
| ***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 facility/site for housing or experimental purposes.

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

1. Did a **consultation** take place between the animal facility/site manager (or authorised individual) and the principal investigator (PI) to discuss and agree on specifics of the planned study, regarding the availability of resources *(including about funding, personnel, that the physical infrastructure of the facility is suitable, and that appropriate equipment are available)*.

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

1. Is the animal facility(ies)’/site(s)’ infrastructure, operations and equipment **suitable** to carry out the project and to care for the animal species and perform the indicated procedures, as described in this application?

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

1. Is the animal facility(ies)/site(s) **available** to carry out the project, as described in this application?

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

1. Are the animal facility(ies)’/site(s)’ **staff** authorised, competent and available to supervise and support the researchers and care for the animals, as described in this application?

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

1. Have the **financial aspects** as it pertains to the use of the animal facility/site (e.g., the cost of the animals, staff supervision and support, facility breeding, care and housing of animals, space and any other matter related to cost) been agreed upon between the PI and facility management, and as reflected in the **budget** provided in the research proposal?

|  |  |  |  |
| --- | --- | --- | --- |
| **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 Statistician** |

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

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

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

|  |
| --- |
| ***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 if this application involves any work with radio-nuclides.

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

|  |
| --- |
| * 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.

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

|  |
| --- |
| 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**
   * **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.
   * All research study proposals MUST be approved by an appropriate Scientific Committee BEFORE submitting this application for ethics approval.
   * All applications and supporting documentation must be in English only, and only electronic versions submitted via e-mail will be accepted.
   * Complete this application form and attach all supporting documentation (e.g., certificates, authorisation documents to verify sound sources of animal tissue/fluids and disposal).
   * 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 §1.9 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; SACNASP = South African Council for Natural Scientific Professions; CV = curriculum vitae. 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 study, principal investigator and student *(if applicable)*, type of application *(e.g., single/larger study)*, animal species to be used and location *(e.g., in the PCDDP Vivarium, NABF Aquarium, nature reserve, etc.)* and other information that will provide context. Give this document a name starting with [1) Cover Letter].
2. ***Research study proposal:*** The study proposal MUST be attached (see Addendum B: Study Proposal Requirements below), which must be Scientific Committee-approved for all research studies. Give this document a name starting with [2) Study Proposal
3. ***Letter of approval:*** Attach the letter of approval of the 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) Scientific Committee Approval].
4. ***This ethics application form:*** The application form MUST be completed in full. Give this document the name [4) Ethics Application Form.docx].
5. ***SOPs:*** Attach a copy of all SOPs that you refer to in the 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. ***Monitoring sheets:*** All study-specific monitoring sheets to observe any undue pain and suffering, and to manage (alleviate) pain and suffering when humane endpoints are reached) MUST be attached. Give each of these documents a name starting with [6.1) ###]; [6.2) ###], etc.
7. ***Proof of ethics training:*** Proof of ethics training (preferably followed by assessment) in the last 3 years for each member of the team. Give each of these documents a name starting with [7.1) ###]; [7.2) ###], etc.
8. ***Training on animal handling:*** Provide proof of an appropriate animal handling course for each member of the team that will handle animals. Give each of these documents a name starting with [8.1) ###]; [8.2) ###], etc.
9. ***SAVC authorisation or SACNASP registration:*** Provide applicable proof of authorisation by the South African Veterinary Council (SAVC) or the South African Council for Natural Scientific Professions (SACNASP) for each member of the team that will handle animals. 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. ***Animal facility’s SAVC registration:*** If applicable, attach the appropriate SAVC registration certificate for all animal holding facilities. Give this document a name starting with [10) ###]
11. ***Codes of Conduct:*** Ensure that a signed NWU Code of Conduct for Researchers is attached for each member of the study team *(study head, supervisor, researchers, students, co-workers, technicians, assistants, etc.).*  Give each of these documents a name starting with [11.1) ###]; [11.2) ###], etc.
12. ***Narrative CVs:*** Ensure that a 2-page narrative CV is attached for each member of the study team *(study head, supervisor, researchers, students, co-workers, technicians, assistants, etc.)* and professional supervisors 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. ***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:*** If applicable attach a copy of all permits as required. 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. ***Informed consent:*** If applicable attach the copy of the informed consent form 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. ***Goodwill permission:*** If applicable, attach the copy of the goodwill permission 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. ***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 study. Give each of these documents a name starting with [18.1) ###]; [18.2) ###], etc.
19. ***Other supporting 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 as applicable. 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 PI / Researcher / Study Supervisor:*** The PI / Researcher / Study Supervisor MUST sign the declaration.
  2. ***Signed declaration by the director of the research entity:*** The director of the research entity MUST 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:*** 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:*** The consulted statistician MUST complete and sign the applicable declaration. 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:*** When applicable, scheduled substances must be stored and dispensed by the supervising veterinarian or a supervising pharmacist. In the latter case, the consulted supervising pharmacist MUST complete and sign the applicable declaration.
  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) MUST complete and sign the applicable declaration.
  10. ***Signed declarations by other supervisors:*** Any other professional supervisor not mentioned above should complete and sign the applicable declaration.

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)*:

* + Submit via e-mail the completed Ethics Application Form (with the attached documentation as discussed above) to the Faculty of Health Sciences Ethics Office for Research, Training and Support ([Ethics-AnimCare@nwu.ac.za](mailto:Ethics-AnimCare@nwu.ac.za)).

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| Addendum B: Study Proposal Requirements |

The study 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. ***Study Proposal***   
   Attach the Study Proposal *(for research studies)* as approved by the Scientific Committee, or the study guide *(for training courses)*. Study Proposals MUST contain at least the following elements:
   * Title *(concise, clear, descriptive)*
   * PI / Researcher / Study Supervisor *(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 Study 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 Study 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 Study 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 the Study 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 Error! Reference source not found.**, question 1.8** and to **question 5.2** above.

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| ***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 10386:2020, 2nd ed.* * *The examples are not exhaustive, and that they should be viewed as illustrative to guide researchers and the AREC. They should be contextualised for each study in terms of probable animal experience, based on well-informed advice.* |

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| **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. 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). Xenograft studies. Real, staged predator exposure which may lead to attack with harm or kill. |

1. If training expires while the study has not yet been completed, the researcher is responsible to update training and provide the NWU-AnimCareREC with proof of training. [↑](#footnote-ref-1)
2. If a permit or authorisation is dependent on ethics approval, proof of application must be included and final proof of the authorisation will become an in-process requirement for final approval. [↑](#footnote-ref-2)
3. See the SAHPRA Guideline on Completion of the Veterinary Medicines Clinical Trial Application Form [[html](https://www.sahpra.org.za/document/guideline-on-completion-of-the-veterinary-medicines-clinical-trial-application-form/)]. [↑](#footnote-ref-3)
4. See SAHPRA Product Registration Process [[html](https://www.sahpra.org.za/orthodox-medicines/)]. [↑](#footnote-ref-4)
5. Describe 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. [↑](#footnote-ref-5)
6. 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>, with a 1st press release at <http://webarchive.nationalarchives.gov.uk/20121010012428/http://www.fawc.org.uk/pdf/fivefreedoms1979.pdf>. [↑](#footnote-ref-6)
7. 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-7)