

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

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| North-West University Animal Care, Health and Safety Research Ethics Committee**NWU-AnimCareREC***registered as Animal Research Ethics Committee (AREC) with the South African National Health Research Ethics Council (NHREC) of the National Dept. of Health,* ***Reg. no. AREC-130913-01*****Category 0 Application Form** for category 0 scientific studies using **animal vertebrates** or **higher invertebrates** for research, education/training or repetitive testing purposes, but without study-related animal welfare implications**AnimCare 02-03a, Version 5.21 (September 2019)**  |
| **CONFIDENTIAL!** This document contains confidential information that is intended strictly and exclusively for the applicant and the NWU-AnimCareREC. Should this document or parts thereof erroneously come in your possession, you are requested to destroy it or to return it to Ethics-AnimCare@nwu.ac.zawithout delay. Unauthorised possession, reading, studying, copying or distribution of this material, or any other form of abuse, is illegal and prosecutable. |

The majority of new scientific studies using animals in research will use this application form for ethics review and approval.

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| **Quick Navigation Links** *Hold in the “Ctrl” key + click with the mouse* |
| Executive summary of the study | Flow diagram of the study design | Severity category | Checklist and attachments |

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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.

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

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| Section 1: General Study Identification |

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 responsible researcher or study leader**

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

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

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

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

* 1. **Checklist and attachments**

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

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

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

|  |  |  |
| --- | --- | --- |
| **Document(s)** | **No**  | **Name(s) of documents** |
| 1. Cover letter for the application
 | **00** | Click or tap here to enter document name(s). |
| 1. Research study proposal, permission letter, source study proposal & ethics approval
 | **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. Any lab SOPs to be used in the study*(copies of lab SOPs)*
 | **00** | Click or tap here to enter document name(s). |
| 1. Animal welfare monitoring sheets *(general and project specific)*
 |  | Not applicable |
| 1. Proof of applicable ethics training (<3 yrs) for each team member
 | **00** | Click or tap here to enter document name(s). |
| 1. Training certificates for animal handling for each team member to handle animals
 |  | Not applicable |
| 1. SAVC authorisation/SACNASP registration for each team member to handle animals
 |  | Not applicable |
| 1. SAVC registrationof the animal facility (*when applicable)*
 |  | Not applicable |
| 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) *(copies of any and all permits as 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) *(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 documents not mentioned above *(when applicable)*
 | **00** | Click or tap here to enter document name(s). |
| 1. **Signed declarations** as applicable by the:
	1. PI / Researcher / Study Supervisor (MUST)
	2. Director (MUST)
	3. Biosafety Officer
	4. Statistician
	5. Supervising Pharmacist
	6. Radiation Protection Officer
 | Included **in this form** below,  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.* |

|  |  |
| --- | --- |
| **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 On-site Assisting Study Supervisor.* |

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

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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. |

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

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

Names, qualifications and associations of all team members and co-workers (excluding professional supervisors who may not be directly involved in the study - see §3.4).

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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 responsible researcher or study leader.****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.* |

|  |  |  |  |
| --- | --- | --- | --- |
| **Name and NWU number** *(if applicable)***.** | **Functions and Responsibilities** | **Qualifications and Profess. Registr.** | **Affiliation** |

|  |  |  |  |
| --- | --- | --- | --- |
| Type name and no., or “not applicable”. | Type details or “not applicable”. | Type details or “not applicable”. | Type details or “not applicable”. |

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

* 1. **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. pharmacist for scheduled substances)*.

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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 §4.3 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 §4.1 if there is any conflict of interest, and then declare this in full in §4.1.* |

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

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

*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.

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

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

|  |  |  |  |
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| 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.

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

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

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

* 1. **Contractual Agreements**

Declare with full details all contractual agreements (e.g. with team members, collaborators or sponsors) on the 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**, together with submission of this application.* |

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| **Name of Contractor** | **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 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. **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**, 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. **Informed Consent from Owner**

Whenever research is done on the property or involving animal tissues of private owners, informed consent **MUST** be signed.

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| ***More information****The informed consent form to be signed by the owner typically includes information of potential risks, insurance and/or liability waiver, intellectual property, etc.****Please note!*** *A copy of any* ***informed consent****, approved by the NWU legal office and signed by the appropriate NWU line-management,* ***MUST BE ATTACHED*** *and submitted to* *Ethics-AnimCare@nwu.ac.za**, together with submission of this application.* |

|  |  |
| --- | --- |
| **Name of the Owner** | **Full Description of Agreement** |

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

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

* 1. **Goodwill Permission**

Whenever informed consent if provided by an owner, there are sometimes also other interest group representatives/stakeholders (e.g. property managers, community leaders, tribal chiefs or other) who provide goodwill permission under the informed consent of the owner. This **MUST** also be signed where applicable.

|  |
| --- |
| ***More information******Please note!*** *A copy of any* ***goodwill permission****, approved by the NWU legal office and signed by the appropriate NWU line-management,* ***MUST BE ATTACHED*** *and submitted to* *Ethics-AnimCare@nwu.ac.za**, together with submission of this application.* |

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

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

|  |
| --- |
| Section 3: Essential Details of the Scientific Study |

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

Summarise the study in not more than **150 words**, outlining the problem statement, objectives, methods and study design (including animal numbers, treatment groups, interventions, measurements, statistical analyses, etc. as applicable), as well as expected outcome/benefit.

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

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

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

|  |
| --- |
| 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.

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

|  |
| --- |
|  |

* 1. **Study proposal**

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

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

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

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

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

|  |
| --- |
| Section 4: Additional Information |

* 1. **Animals and/or biological samples to be used**

|  |  |
| --- | --- |
| **Animal species & tissue** | **Number of animals or samples** |
| Click here to type species. | **00** |

*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. **Motivation why Category 0 applies**

Motivate clearly why Category 0 (i.e. no impact on animal welfare – see Addendum D: Severity Categories below) should apply for this study.

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

* 1. **Special study considerations**

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

|  |  |  |
| --- | --- | --- |
| **Description** | **Yes** | **No** |
| 1. Genetic material, genetic modification/manipulation, or genetically modified/manipulated
 | [ ]  | [ ]  |
| 1. Pathogens associated with communicable disease
 | [ ]  | [ ]  |
| 1. Endangered and protected species or sensitive ecological systems
 | [ ]  | [ ]  |
| 1. Use of radio-active substances
 | [ ]  | [ ]  |
| 1. Generated chemical or biological waste
 | [ ]  | [ ]  |
| 1. Any other aspect of potentially ethically sensitive nature
 | [ ]  | [ ]  |

**Please note!** If any of the above is “Yes”, you will have to ensure that appropriately detailed information on this matter is provided in the questions below, in particular regarding the kind of stressors, risks and associated precautionary measures regarding animal wellbeing, justification, risks and associated safety measures regarding the researcher and/or environment, expertise, skills and legal competencies and the facilities. You may refer to NWU-AnimCareREC-approved SOPs, but still need to provide brief descriptions of the procedure.

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

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

* 1. **Details of the owner of the animals, or provider (source) of the biological samples for this project, including the ethics approval numbers of projects from which the samples originated** *(attach permission letter)*

|  |
| --- |
| Click or tap here to enter text. |
| Ethics approval number(s) | Click or tap here to enter ethics approval numbers. |

* 1. **When biological samples of animals are to be used in this study, describe why and how the samples from live animals would have been obtained ethically anyway, or how the animals would have originally been euthanized ethically anyway *(i.e. unrelated to this project)*.**

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

* 1. **Details of the method(s) to obtain the biological samples from dead animals for the purpose of this project**

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

* 1. **Details of the suitability of the biological samples for use in this project** *(e.g. previous treatments will not adversely affect intended analyses)***, of measures for ensuring sample integrity** *(e.g. appropriate storage conditions & security)***, of record keeping** *(e.g. with information for identification and history)***.**

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

* 1. **Details of sound disposal of the biological samples after use in this study**

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

* 1. **Describe any health and safety risks to researchers, student or other staff members** *(e.g. any biological hazard)***, as well as appropriate safety measures**

|  |
| --- |
| 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?**

|  |  |
| --- | --- |
| Select | If yes, click or tap here to provide details. |

**Please note!** If yes, please provide details on the risk level, identify risk factors and associated precautionary/mitigating measures, AND complete the form on “Estimated Environmental Impact Category” (form no. NS Ethics 01-01a).

* 1. **Describe how you will ensure that any significant finding is explicitly disseminated to the appropriate authority** *(e.g. notifying the Medical Research Council regarding any manifested toxicity or finding that may bear on safety of a drug in humans, or the Department of Agriculture, Forestry and Fisheries regarding any finding that may bear on environmental safety)* **and/or to the public** *[Responsibility]*

|  |
| --- |
| Click or tap here to provide details. |

* 1. **Statistical justification**
		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 and the number of replicates.

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

* + 1. **Justification of sample sizes/numbers per control and test groups**

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

|  |
| --- |
| ***More information****The sample size required can, for example, be determined by means of the following:** *Statistical* ***power analysis*** *(generally preferred)*
* ***Resource equation*** *method (when a power analysis is not possible)*
* ***Evidence-based*** *estimation (when sufficient experience exists and as published, with a similar analyses and study design)*
* ***Standard/accepted guidelines*** *(e.g. for specific test protocols)*

*You may also consult other useful information resources:** *NC3Rs* [*https://www.nc3rs.org.uk/experimental-designstatistics*](https://www.nc3rs.org.uk/experimental-designstatistics) *(accessed online on 29 Aug 2018)*
* *J Pharmacol Pharmacother. 2013 Oct-Dec;4(4): 303–306*
* *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)*
 |

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

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

Describe how the allocation of samples 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 animal or biological samples 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 samples into control and test groups are done in a truly randomised manner. Typically, when all animals or samples from a particular test group is grouped or pooled, this may be considered as “pseudo-replication”, since there may also be dependence on grouping or pooling confounding factor to affect the outcome. Consider all of these matters in your comments below.* |

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

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

|  |
| --- |
| **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.

|  |
| --- |
| ***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 Responsible Researcher or Study Leader 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 Responsible Researcher or Study Leader 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.* |

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

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

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

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

* + 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.

|  |
| --- |
| ***More information****The following explain what you should describe here:** *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).*
* *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.*
* *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.*
 |

|  |
| --- |
| 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.

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

* 1. **Any additional comments from the Project Head**

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

|  |
| --- |
| Section 5: 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. |

|  |
| --- |
| Section 6: 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. 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 all required and appropriate safety measures are in place and that appropriate monitoring and response measures are in place,
4. 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.
5. 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.
6. 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.
7. 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. |

|  |
| --- |
| * 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. |

|  |
| --- |
| * 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. |

|  |
| --- |
| * 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. |

|  |
| --- |
| * 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. |

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

This section is to be completed by the Radiation Officer who verified the study design and animal numbers.

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

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

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

1. Details of the radio-active nuclide authorisation

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

1. Risks & competence

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

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

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| 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** and of the **SOP for the he expedited review process, SOP-Ethics\_1.5**, as available on the website of the Ethics Office (<http://health-sciences.nwu.ac.za/healthethics/sops>).

For descriptions and examples of studies that will qualify for **Category 0** applications, see **Addendum D: Severity Categories** below.

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 *(or InfoEd online once launched)* 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 CoC = code of conduct; 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 sub-study, title and ethics approval number of the larger study, principal investigator and student *(if applicable)*, type of application *(i.e. category 0)*, animal species involved *(e.g. for samples, in situ animal observation, within normal care, etc. – see definitions below under Addendum D: Severity Categories)* and other information that will provide context. Give this document a name starting with [1) Cover letter].
2. ***Research study proposal, and only if applicable also the permission letter, the source study proposal and/or its ethics approval letter:*** The study proposal for the category 0 study MUST be attached (see Addendum B: Research Proposal Requirements below), which must be Scientific Committee-approved for all research studies. If and as applicable, also attach the permission letter from the owner of the animals or animal tissue (e.g. abattoir, Principle Investigator / Researcher or Study Leader of the study from which samples are obtained, farmer, etc.), indicating that the category 0 may have access to, and/or use of the samples or animals, also defining exactly what will be permitted or excluded. If applicable, also add the ethics approval letter of the source study from which samples are obtained, and if this is not a NWU-approved study, also add the study proposal or a descriptive executive summary thereof. Give each of these documents a name starting with [2.1) ###]; [2.2) ###], etc.
3. ***Letter of approval:*** Attach the letter of approval of the 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:*** Not applicable to Category 0 studies.
7. ***Proof of ethics training:*** Proof of applicable 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:*** Not applicable to Category 0 studies.
9. ***SAVC authorisation:*** Not applicable to Category 0 studies.
10. ***Facility registration:*** Not applicable to Category 0 studies.
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 the Responsible Researcher or Study Leader *(not necessary for other team members in the case of Category 0 studies)* and any professional supervisors *(e.g. pharmacist, radiation officer if and as applicable)* 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 or permission letters:*** If applicable, attach a copy of all permits as required, or the letter of the study leader of a previous animal study from which the animal tissue is obtained, granting permission to use the tissue, and what it may be used for. 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. **Where applicable, this should include the permission from the owner of the animal tissue to use the tissue and specifications of what it may be used for, and when tissue is collected from an abattoir or similar facility, also its permit of registration**. 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 documents:*** Any other supporting documents not mentioned above. Give each of these documents a name starting with [19.1) ###]; [19.2) ###], etc.
20. ***Signed declarations:*** *Included in this ethics application form above, to be completed and signed electronically only if new. However, if a hard copy is signed, attach.*

***Please note!*** *The application MUST be discussed timeously with ALL professional supervisors, any resulting corrections or amendments made and then returned to be signed off in time for submission. Professional supervisors may not be unduly pressured to sign off to meet deadlines, so that applicants should plan for this.*

* 1. ***Signed declaration by the Responsible Researcher or Study Leader:*** The Responsible Researcher or Study Leader MUST sign the declaration.
	2. ***Signed declaration by the director of the research entity:*** The director of the research entity MUST complete and sign the declaration form.
	3. ***Signed declaration by the biosafety officer:*** If applicable, the biosafety officer MUST complete and sign the applicable declaration.
	4. ***Signed declaration by the statistician:*** The consulted statistician should complete and sign the declaration form. 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.
	5. ***Signed declaration by the supervising pharmacist:*** If applicable, scheduled substances must be stored and dispensed by the supervising veterinarian or a supervising pharmacist. In the latter case, the consulted supervising pharmacist should complete and sign the declaration form only if new *(i.e. not included in the larger study application)*.
	6. ***Signed declaration by the supervising radio protection officer (RPO):*** When the study involves the use of radio nuclides, the consulted radio protection officer (RPO) should complete and sign the declaration form only if new *(i.e. not included in the larger study application)*.
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).

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| Addendum B: Research Proposal Requirements |

The research proposal (or training study guide) forms the pivotal document of any ethics application, and must discuss the scientific/educational validity or the study, as well as address ethical considerations and implications, and scientific integrity of the application. Consult also the latest version of the SOP for the research ethics approval application process, SOP-Ethics\_1.4), as available on the website of the Ethics Office (<http://health-sciences.nwu.ac.za/healthethics/sops>).

1. ***Research Proposal***
Attach the Research Proposal *(for research studies)* as approved by the Scientific Committee, or the study guide *(for training courses)*. Research proposals MUST contain at least the following elements:
	* Title *(concise, clear, descriptive)*
	* Responsible Researcher or Study Leader *(name and designation)*
	* Literature review *(outlining current knowledge and questions, previous research/training, specific research problem and justification for the study, or training need, references)*
	* Study aim and objectives *(may include a hypothesis where applicable)*
	* Research methodology *(study/experimental design/layout, animal type, number, housing, handling, and applicable techniques, procedures and assays, humane endpoints – with sufficient detail to allow thorough ethics evaluation)*.

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

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

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

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

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| Addendum C: Moral Declaration |

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

1. It is recognised that non-human animals are valuable beings, **worthy of dignity and respect that** should be protected. In this regard it also recognises the **moral dilemma** of using sentient animals with sensations and emotions for experimentation. At the same time, it is accepted that experimentation with animals is **essential** to advance biomedical sciences, ultimately reducing suffering and enhancing life and wellbeing:
	1. In all instances sound **motivation** and **justification** for the use of animals and procedures must be provided.
	2. The **repetition** of previously performed research experiments with animals will not be considered, unless it can be motivated to be necessary and shown to contribute to new knowledge.
	3. Animal should be **protected from exploitation** via their use in research for trivial, irrational, unjustified or inappropriate reasons.
	4. Animals should **receive optimal care** to promote thriving, manage any disease and avoid unnecessary suffering.
2. The principle of the **4Rs** will be applied to promote humaneness:
	1. ***Replace:*** to replace animals (in absolute, relative or partial terms), where possible, with non-animal alternatives, tissue and fluids of already euthanised animals or less sentient animals
	2. ***Reduce:*** to reduce the number of animals used to the minimal to answer the research question(s), without compromising statistical validity or increasing animal suffering
	3. ***Refine:*** to refine experimental design, animal interventions/procedures and/or the animal model(s) employed to promote thriving of animals *(welfare)*, minimise discomfort and/or suffering *(harm)* and to optimise scientific value *(benefit)*.
	4. ***Responsibility:*** to promote responsible care and use of animals by ensuring competence of all who work with animals, to fostering a culture of compassion and care, to establish clear communication channels for unscheduled adverse events, and to establish clear responsibilities and accountability.
3. Ethical reflection will consider human / experimenter safety, animal wellbeing and environmental integrity. In this regard, the **wellbeing of animals will remain of utmost importance**, firstly by ensuring humane treatment of animals at all times, and by recognising undue stress, pain or discomfort and making relief thereof a priority above the interest of scientific / experimental interest.
4. All keeping, handling, and experimentation with animals must be done according to well-designed experimental protocols and with appropriate safety measures in place, in appropriate, approved, maintained and monitored **facilities** and by appropriately qualified, trained and competent **researchers** and **technicians**, under supervision of appropriately qualified and registered **professionals**.
5. All projects utilising animals for research or training purposes at the North-West University will stand the test of **scientific integrity** and **must be approved by AnimCare** or another appropriate Animal Research Ethics Committee (AREC) of the NWU. In all studies sound scientific integrity shall be evaluated to ensure trustworthy, repeatable results and to provide maximum benefit from the study. In particular, when health-of health-related studies are performed in animals, there is an additional responsibility to ensure that studies are truly translatable and able to advise follow-up animal studies and clinical studies in humans as accurately and comprehensively as possible.

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| Addendum D: Severity Categories |

The following severity categories for animal interventions (i.e. classification of pain, discomfort or stress) have been adopted by the NWU-AnimCareREC. These categories are applicable to selections under **General Study Identification, question (m)** and to **question 2.2** above.

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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 10386:2018, 2nd ed.* |

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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. Cancer models and new genetic manipulation. |
| **5** | **Excessively stressful**, where exceptional motivations and justification are needed for approval, e.g. application of noxious stimuli to conscious animals from which the animal cannot escape or any experiments in which total distress is the likely outcome. Toxicity/virulent studies where the endpoint is the moribund state or death. Extended social isolation of sociable animals (e.g. social isolation rearing of rats). Real, staged predator exposure which may lead to attack with harm or kill. |