NORTH-WEST UNIVERSITY
YUNIBESITI YA BOKONE-BOPHIRIMA
NOORDWES-UNIVERSITEIT

Faculty of Health Sciences Ethics Office for Research, Training and Support
health-sciences.nwu.ac.za/healthethics

AnimCare Ethics Committee on Animal Care, Health and Safety in Research *(AREC-130913-015)*

Guide to Ethics Application & Report Forms

related to **scientific projects** using **animal** vertebrates or higher invertebrates for **research** or **training** purposes

AnimCare 00-01a, Version 4.10 (Nov 2016)

1. Basic Applicant's Instructions

Which AnimCare form(s) should I complete? How do I apply for ethical clearance? How do I report an incident? How do I write annual monitoring reports?

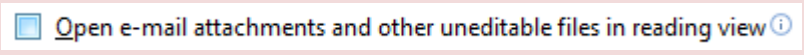
Step 1: Select the appropriate AnimCare form to be completed from the options explained on the following pages below *(see schema and descriptions of the various forms)*. Most applicants will need to request the latest version of the following documents from the Ethics Office:

- appropriate application or report form;
- declaration forms document;
- other helpful information forms as needed *(optional)*.

Step 2: Always ensure that you have the latest version of the application form, downloadable from http://health-sciences.nwu.ac.za/healthethics, select [AnimCare] from the menu, then from the drop-down select the appropriate [Application Forms], [Report Form] and [Declaration Forms] to be downloaded. Previous versions will NOT be accepted.

Step 3: Follow the form's applicant's instructions *(as described in each form)* to complete the form and to prepare all required supportive documentation.

Please note! *If you use Office2013 / Office365, the document may open in "reading mode", so that you will need to click on [View] / [Edit] to complete the form. If the document does not open, or you get an error message that MS Word "stopped working", open MSWord (empty document), select [File] / [Options], then the [General] tab, then untick the following default setting near the bottom of the frame:*



The problem should now be solved.

Step 4: Ensure that all required documents are included *(guided by the check list included at the end of the application/report form)*.

Step 5: Submit the form and attachments as per instruction *(described in each application/report form)*. Also please familiarise yourself with the submission deadlines for monthly AnimCare meetings *(i.e. when the agenda closes)* at http://health-sciences.nwu.ac.za/healthethics, and select to view the **[AnimCare Meetings Schedule]**

Please note! *No late submissions can unfortunately be accommodated.*

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2. AnimCare Principles

2.1 Ethical Point of Departure

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

2.2 Categorisation of animal wellbeing

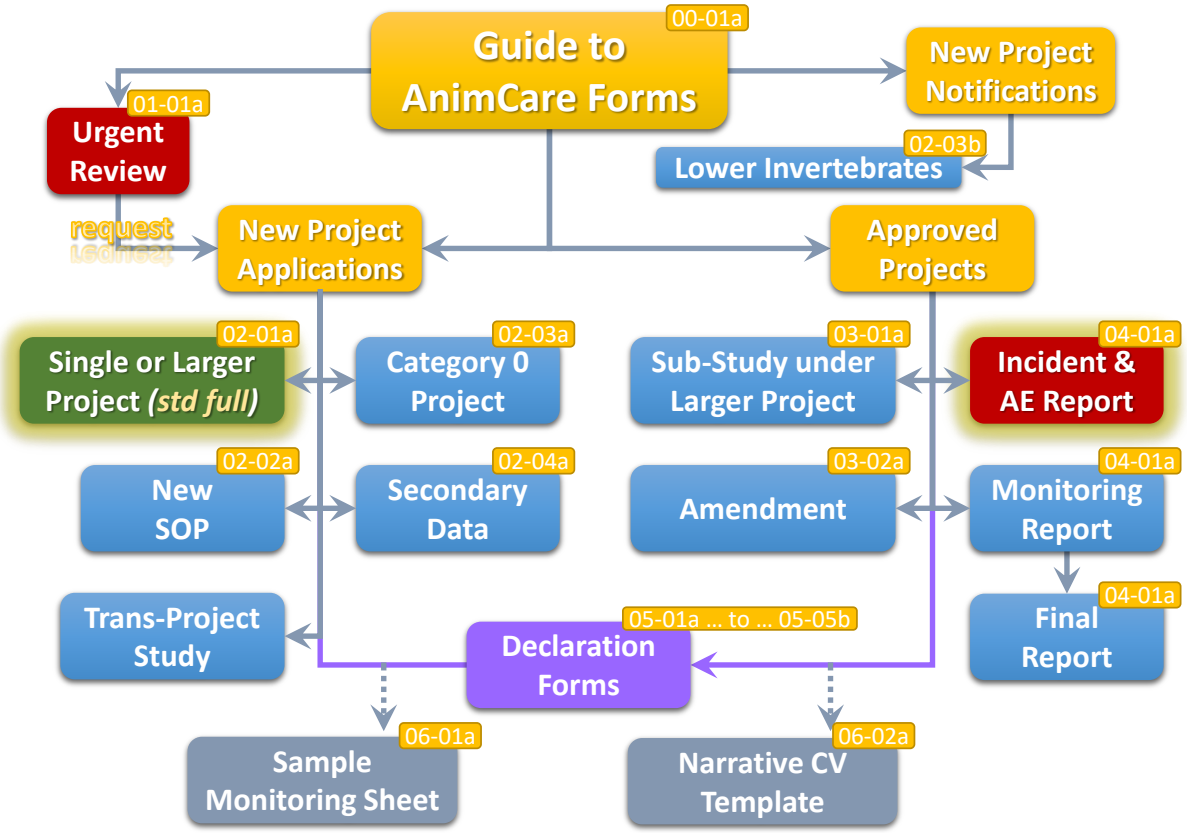
All vertebrate or higher invertebrate animal protocols and interventions must be classified according to the probable experience of the animal (discomfort, stress & distress) as below, also adhering to national legislation, the National Code for the handling and use of animals and the North-West University's (NWU) regulations in this regard. Ethics approval is required for use of vertebrate or higher invertebrate animals, whereas for all other animals the Ethics Committee must only be notified (see Category 0). Categories of impact on animal wellbeing (in the laboratory, wild, farm or domestic) are as below, from which you need to make your selection according to the most severe intervention in your application.

Cate-gory	Description
0	**None**, e.g. use of dead vertebrate or higher invertebrate animals (already euthanized legally and ethically for another purpose and not for this project) or tissue or biological fluids thereof, or using any live lower invertebrate. Also archived animal specimens from the laboratory, museum, private or any other collections. Non-invasive behavioural studies, e.g. observation of wild animals *in situ* (natural environment) without interference, including minimal disturbance to other biota. Domestic or farm animals on their home property, where procedures are occurring as normally part of the routine management or professional (e.g. veterinary) care.
1	**Mild**, e.g. keeping of animals in captive conditions (including all animals housed in registered animal holding facilities), or animals collected domestically, from the farm, in the field or other environment, confined and/or transported for subsequent observation. Handling animals or applying minimally invasive examinations, depriving animals of food/water for a few hours (no longer than experienced in nature) or anaesthetising animals that will not regain consciousness (non-recovery).
2	**Medium**, defined as induced stress of short duration, not requiring anaesthesia or tranquilisation, e.g. parenteral administrations, small subcutaneous implants, exercise or low-stress behavioural testing. Collection of tissue from animals after non-anaesthetic euthanasia for research purposes. Open field testing. Depriving animals of food or water for periods longer than experienced in nature, but without becoming distressful or causing permanent harm.
3	**Severe**, defined as induced stress of short duration, requiring anaesthesia or tranquilisation, e.g. surgical procedures (including larger implants), multiple injection sites or high-stress fluid/tissue sampling, e.g. cardiac puncture. Procedures that include known disease or severe stress-inducing agents/interventions (e.g. known genetic manipulations, pathogens, toxicity studies or toxic agents, nutrition and trauma, such as perceived unescapable predator exposure), provided the study is terminated (i.e. endpoint) at the onset of relevant symptoms (e.g. lowest observed effect concentration). Restriction of movement over a prolonged periods of time, e.g. metabolic cages or keeping large animals in bomas.
4	**Very severe**, defined as induced stress of long duration, e.g. prolonged stress (>30 minutes) without anaesthesia or tranquilisation, anaesthesia of long duration (>30 minutes), procedures producing defects or long-term feeding (> 2 days) of deficient or special diets. Forced swim or exercise tests with exhaustion as the end-point. Cancer models and new genetic manipulation.
5	**Excessively stressful**, where exceptional motivations 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.

3. Types of AnimCare Application & Report Forms

3.1 Schema of forms

Below is a schema showing all the different AnimCare forms available to project managers who wish to apply for ethical clearance or report on incidents or progress. Below the schema you will find a concise description of each type of AnimCare form, which you may use to select and obtain the appropriate form that you need to complete.



3.2 Types & Descriptions of AnimCare Application & Report Forms

The form numbers below correspond to the numbers in the schema above.

3.2.1 AnimCare 00-01a: AnimCare Forms to Complete

This current guide provides applicants with information on which AnimCare application or report form to complete, as well as instructions on how to obtain the latest version of the appropriate form.

3.2.2 AnimCare 01-01a: Urgent Review

In special cases where urgent attention is necessary to approve applications related to projects of strategic importance *(for example the outbreak of an epidemic requiring urgent research or investigation)*, it may be possible to fast-track the review and obtain ethical approval in a shorter period of time. One may then apply for an application to be fast-tracked, whereafter the normal application must still be done, but with the process in a substantially shorter space of time. For fast-tracking a review, complete the **Urgent Review Form**, plus the appropriate application form for project approval *(e.g. **Application Form for Single or Larger Projects** – see below)*. The fast-tracked review of your application will be initiated once approval has been granted for the urgent review.

3.2.3 AnimCare 02-01a: Single or Larger Projects *(standard application form)*

This **Application Form for Single or Larger Projects** should be used to apply for the use of animals for purposes of research *(e.g. laboratory or field investigations)*, education/training *(e.g. undergraduate practicals)* or repetitive testing or monitoring interventions *(e.g. standard toxicology tests or monitoring of animal phenotype)*. Most new projects will use this standard form for full review and ethical approval.

In this context "single" project refers to a:

- simple, stand-alone study with pre-identified *(usually few)* researchers / students and roles

In this context "larger" project refers to, for example *(but not limited to),* a:

- well-defined but compiled / complex study, which can be subdivided into several well-defined smaller sub-studies for multiple postgraduate students, or
- well-defined larger training project, which can be subdivided into several sub-compiled workshops or repetitions, or
- standard test or monitoring intervention, repeatedly performed for different clients from time to time.

See associated declaration forms below: AnimCare 05-01a-j

3.2.4 AnimCare 02-02a: New SOP

All Standard Operating Procedures (SOPs) related to the operational care of, experimental work with, or training purposes using animal vertebrates or higher invertebrates, must obtain ethical approval via completion of the **Application Form for SOPs**. Such approval will not give access to the use of animals, but can be used to corroborate certain interventions or procedures in project applications.

See associated declaration forms below: AnimCare 05-02a; 05-01c

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

3.2.5 AnimCare 02-03a: Category 0 Projects

All scientific projects involving animal vertebrates or higher invertebrates, but without ethical implications, must obtain ethical approval via completion of the **Application form for category 0 projects**. This applies, for example, when using tissue of animals that have already been euthanized for a different purpose *(***Please note!** *This form does NOT apply when live animals must be euthanized to obtain the tissue, in which case the* ***Application Form for Single or Larger Projects*** *must be completed.).* Also non-invasive behavioural studies observing wild animals in situ (natural environment) without interference, including minimal disturbance to other biota. Also 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.

See associated declaration forms below: AnimCare 05-02b

3.2.6 AnimCare 02-03b: Projects Using Lower Invertebrates

All scientific projects involving lower vertebrate animals *(e.g. insects, arachnids like spiders and scorpions, worms, molluscs like snails, corals, water creatures such as star fish, jelly fish and sponges, etc.)*, does not need ethical clearance. However, AnimCare must be notified of such projects and may interfere if there is any doubt regarding safety, legal, ethical or other important matters. Notification to AnimCare is done via completion of the **Notification form for projects using lower invertebrates**.

See associated declaration forms below: AnimCare 05-02d

3.2.7 AnimCare 02-04a: Secondary Data

All projects using secondary data of previous scientific projects that used animal vertebrates or higher invertebrates, must obtain ethical approval via completion of the **Application form for Secondary Data**. This applies, for example, to collaborative projects, where the previous study that used animal vertebrates or higher invertebrates now makes data from measurements or observations available, and these data are now used in the new project using secondary data.

See associated declaration forms below: AnimCare 05-02c

3.2.8 AnimCare 02-06a: Withdraw application in process

If your submitted an application, and it is still in process (i.e. not yet approved), you may retract the application by completing this form.

3.2.9 AnimCare 03-01a: Sub-Study under a Larger Project

All sub-studies under larger projects, or trans-project studies, using animal vertebrates or higher invertebrates, must obtain ethical approval via completion of the **Application form for sub-studies under larger projects**. Sub-studies under umbrella projects applies, for example, when a new postgraduate student joins the larger project, and performs a well-defined sub-section of the larger project for a Masters or doctoral study. Trans-project studies apply, for example, when a new postgraduate student joins several larger projects, and performs a well-defined sub-section under each. **Please note!** Each new postgraduate student joining a larger project, MUST apply for approval of a sub-study under the larger project, or a trans-project study. Also, the sub-study may not add any objectives, study design or methodology that were not defined in the larger study – in which case the larger study must first be amended *(see AnimCare 03-02a)* before the sub-study can be applied for.
See associated declaration forms below: AnimCare 05-03a

3.2.10 AnimCare 03-02a: Amendments

Projects using animal vertebrates or higher invertebrates may require amendments *(minor adjustments or additions)* as the project progresses, for example when new discoveries are made. In such cases an application must be submitted to apply for the amendment, using this form.
See associated declaration forms below: AnimCare 05-03b and AnimCare 05-03c

3.2.11 AnimCare 04-01a: Adverse Event Reporting

Any and all animal-related adverse events *(untoward occurrence related to the project procedure)* that threatened or affected human safety *(i.e. of the researcher, student or NWU Vivarium staff)*, animal wellbeing, and/or the integrity or safety of the environment *(e.g. animal holding facility or university premises)* MUST be reported to AnimCare without delay. This form is to be used and also provides clear guidelines and instructions on the immediate interventions required, urgent interventions (within 24 hours) and timely interventions to contain the situation, and reporting of the adverse event, followed by the eventual resolving of the matter. **Please note!** Researchers working with animals should be familiar with these instructions should always have an electronic or printed copy available.
See associated declaration forms below: AnimCare 05-04a

3.2.12 AnimCare 04-02a: Monitoring Report

Every approved project using animal vertebrates or higher invertebrates for research & training purposes MUST submit regular monitoring reports, including progress reports *(requesting continuation of the project for another year)* and a final reports *(when the project is completed)*. Both (a) annual progress reports and (b) final reports are submitted on the same monitoring report form. Monitoring reports are submitted no less than annually, and AnimCare may also determine more regular reporting for higher category projects. Monitoring reports, using this form, are due even when no work has been done during the reporting period and must be submitted on time. AnimCare may suspend or terminate any project when reports are not submitted timeously. Once a project using animal vertebrates or higher invertebrates for research / training purposes is completed or terminated, even when no work has been done, the project head MUST submit a final report.
See associated declaration forms below: AnimCare 05-05a or 05-05b

3.2.13 AnimCare 05-###: Declaration Forms *(to be signed)*

These documents contain declaration and permission forms to be signed where and as appropriate by the project manager / responsible person, director (of research, school or unit), professional supervisors (e.g. veterinary surgeon, animal technician(s) and pharmacist), biosafety officer, facility manager and biostatistician and others. Applicants should select the appropriate forms as applicable to their application. Typically an appropriate selection from declaration forms [AnimCare 05-01a] to [AnimCare 05-01j] accompany the standard application form [AnimCare 02-01a], whereas declaration forms [AnimCare 05-02a] to [AnimCare 05-05b] accompany the appropriate application or report form as implicated.

The following declaration forms are available:

Declarations for Standard Single or Larger Projects

- [AnimCare 05-01a v4.10] Declaration by Head for Single & Larger Projects (v4.10)
- [AnimCare 05-01b v4.10] Declaration by Director (v4.10)
- [AnimCare 05-01c v4.10] Declaration by Veterinary Surgeon (v4.10)
- [AnimCare 05-01d v4.10] Declaration by Pharmacist (v4.10)
- [AnimCare 05-01e v4.10] Declaration by LAT (v4.10)
- [AnimCare 05-01f v4.10] Declaration by Other Professional Supervisor (v4.10)
- [AnimCare 05-01g v4.10] Declaration by Biosafety Officer (v4.10)
- [AnimCare 05-01h v4.10] Declaration by Facility Manager (v4.10)
- [AnimCare 05-01i v4.10] Declaration by Biostatistician (v4.10)
- [AnimCare 05-01j v4.10] Declaration by Radiation Officer (v4.10)

Declarations for Other Applications

- [AnimCare 05-02a v4.10] Declaration by SOP Responsible Person (v4.10)
- [AnimCare 05-02b v4.10] Declaration for Category 0 Projects (v4.10)
- [AnimCare 05-02c v4.10] Declaration for Secondary Data Projects (v4.10)
- [AnimCare 05-02d v4.10] Declaration for Lower Invertebrate Projects (v4.10)
- [AnimCare 05-03a v4.10] Permission by the Project Head for Sub-Studies (v4.10)
- [AnimCare 05-03b v4.10] Declaration by the Project Head for Amendments (v4.10)
- [AnimCare 05-03c v4.10] Declaration by the Veterinarian for Amendments (v4.10)

Declarations for Reports

- [AnimCare 05-04a v4.10] Declarations for Adverse Event Report (v4.10)
- [AnimCare 05-05a v4.10] Declaration for Progress Monitoring Report (v4.10)
- [AnimCare 05-05b v4.10] Declaration for Final Monitoring Report (v4.10)

Applications and reports cannot be accepted without these signatures. Declarations may be filled out and signed electronically, after which PDF versions are submitted via e-mail together with the application. Alternatively hard copies may be signed, scanned and submitted as electronic attachments with applications, according to instructions.

4. Applicant Instructions

All applicant instructions are indicated within in the respective application and report forms. These include general instructions about how to obtain the latest form, contact information, how to complete the form, what to attach, how to submit and other general guidelines and rules.

5. Matters for Special Ethical Consideration

Whenever any of the matters below are included in a study, appropriately detailed information on this matter must be provided in the application form, in particular regarding the kind of stressors, risks and associated safety measures regarding animal wellbeing, justification, risks and associated safety measures regarding the researcher and/or environment, expertise, skills and legal competencies and the facilities. You may refer to AnimCare-approved SOPs, but still need to provide brief descriptions of the procedure.

5.1 Genetics

(…including genetic material or manipulation, genetically modified organisms / tissue / cells.) Description of interventions & procedures, product information (approved names, suppliers / origin, methods of storage, maintenance & retention, description of materials, normal use / application, dangers & risks, standard precautionary measures, literature references), expertise & competencies, training of new team members, facilities, institution responsible for analyses.

5.2 Pathogens associated with communicable disease

(…including any micro-organisms or hazardous disease-forming agents.) Description of the pathogen or other disease-inducing agent, pathogen information (approved names, suppliers / origin, methods of storage, maintenance & retention, description, dangers & risks, standard precautionary measures, literature references), expertise & competencies, training of new team members and facilities.

5.3 Specialised animal models

(…including translational models, xenographs.) Description of the clinical and/or pathological features of the model, general model information (approved name, source / origin / supplier, housing conditions, normal uses or applications, impact on animal wellbeing, special care and monitoring requirements, literature), expertise, facilities, safety measures.

5.4 General anaesthesia, surgery or severely invasive procedures

(…including intracardiac puncture, microdialysis, implants.) Description of procedures, AnimCare-approved SOPs (if available), discomfort, risks, precautionary measures, professional supervision, authorisation, competencies, training of new team members, facilities.

5.5 Injections, blood samples and similar interferences

(…including swabs, biological fluids, biopsies.) Description of procedures, discomfort and risks, expertise, facilities, biological waste management, precautionary measures.

5.6 Use / administration / deprivation of any experimental / test substances

(…including drugs or medicines (including scheduled substances), experimental foods, fluids, supplements or nutrients, dietary or nutritional deficiencies, deprivation of food or water, toxic or dangerous substances.) Approved names and description of substances, professional supervision (including of scheduled & controlled substances), safety measures, product information (name and classification, brand names, MCC registration (if applicable), indications, known or expected effects, risks and toxicity in experimental animals (pharmacological, therapeutic, nutritional, deficiency and/or toxicological), precautionary measures, literature, accepted or expected dosages and administration routes, any experimental formulation testing prior to administration.

5.7 Toxicological studies

(… including TD_{50} & LD_{50} studie.) Description of procedures, discomfort, risks, precautionary measures and monitoring, professional supervision, authorisation, competencies, training of new team members, facilities.

5.8 Severe and/or prolonged (>30 min) stress, pain or suffering

(…including physical or emotional.) Description of procedures, discomfort, risks, precautionary measures and monitoring, professional supervision, authorisation, competencies, training of new team members, facilities.

5.9 Restraint

(…including restricting movement with a leash or cage.) Description of procedures, discomfort, risks, precautionary measures and monitoring, competencies, training of new team members, facilities.

5.10 Endangered and protected species or sensitive ecological systems

Description of procedures, risks, precautionary measures and monitoring, competencies and licences, informed consent from any owners and training of new team members.

5.11 Staged predator observation

Description of procedures, discomfort, risks, precautionary measures and monitoring, professional supervision, authorisation, competencies and licences, informed consent from any owners, training of new team members, facilities.

5.12 Radio-active substances

Approved names and description of substances, competencies, licensing and approved facilities (attach certificate & permission letter from radiation officer), precautionary measures.

5.13 Chemical and/or toxic waste

Description of waste products, competencies, facilities, precautionary measures.

6. Other Useful Resources

6.1 Samples & Templates

6.1.1 AnimCare 06-01a: Sample Monitoring Sheet

This document provides an editable sample template that you may use to design your own project- or procedure-specific monitoring sheet for animal welfare and to determine humane endpoints. It is not required to use this template for applications to AnimCare, but this may be helpful to ensure that all important elements are included.

6.1.2 AnimCare 06-02a: Sample Narrative CV Template

This document provides an editable sample template that team members may use to write their own narrative curriculum vitae (CV). It is not required to use this template, but this may be helpful to ensure that all important elements are included. The 2-page narrative CV should be to-the-point, without excessive details, and clearly demonstrate that the team member is indeed competent, qualified, authorised and experienced to take on the responsibilities of his/her role in the project.

6.1.3 AnimCare 06-03a: Sample Manuscript Referencing

This document provides suggested wording that may be considered for referencing ethics approval and housing of animals at the North-West University in manuscripts (e.g. articles, reports, dissertations, theses).

6.1.4 AnimCare 07-01a: Vivarium Authorisation Template

If you completed the PCDDP Vivarium Introductory Course for New Researchers and applied for authorisation at the South African Veterinary Council (SAVC), you may complete this form and request the Vivarium Head to sign it. Either Vivarium authorisation, or proper training + SAVC authorisation will be required for each member of the project team working/handling with animals.

6.2 Information, Instruction & Policy Documents

6.2.1 AnimCare 07-02a: Instructions for the Reporting of Adverse Events

These instructions relate to project procedure-related adverse events that threatened or affected human safety (i.e. of the researcher, student or NWU Vivarium staff), animal wellbeing, and/or the integrity or safety of the environment (e.g. animal holding facility or university premises). Each member of the project team working/handling with animals and each animal handling facility should have electronic or printed / posted copies freely available or accessible.

6.2.2 AnimCare 07-02b: Project Categorisation of Impact on Animal Wellbeing

AnimCare classifies all protocols and interventions using vertebrate or higher invertebrate animals according to the probable experience of the animal (discomfort, stress & distress) from Category 0 (i.e. no ethical implication) to Category 5 (i.e. excessively stressful). This document defines these categories and provides the applicant with guidelines and examples of how to categorise a particular project.

6.2.3 AnimCare 07-02c: Ethical Point of Departure

AnimCare subscribes to clear ethical principles regarding the use of animals in research, as explained in this document.

6.2.4 [AnimCare 07-02d: Instructions for Making Corrections to Reviewed Applications

AnimCare provides guidelines as to how to make changes to a reviewed and approved application, with minor or several changes requested.

6.2.5 GW Ethics Office 02: Ethics Office Application Processes

This document describes in detail the processes of the Ethics Office for ethics applications.

6.2.6 GW Ethics Office 03: Ethics Office Complaints Procedure

This document describes in detail the standard operating procedure of the Ethics Office for handling of complaints, including complaints from:

- researchers about a member of the HREC/AnimCare or the HREC/Animcare itself
- a member of the HREC/AnimCare or the HREC/AnimCare itself about a researcher
- a research participant, co-researcher, research assistant, or interested community member about research conduct and/or the researcher

6.2.7 GW Ethics Office 04: Adherence to Ethics Regulations

This important letter from the Dean of Health Sciences applies to all staff members and students of the Faculty of Health Sciences, and everyone applying under AnimCare.

6.2.8 GW Ethics Office 05: NWU Confidentiality Agreement Template

This document should be signed by any person having access to ethics application documents, in order to confirm confidentiality agreement, including to protect intellectual property.

6.2.9 GW Ethics Office 06: NWU Transport Indemnity

This document should be signed by any person who is not a NWU staff member or student, being transported by a NWU vehicle.