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### UNIVERSITY of ZULULAND RESEARCH ETHICS COMMITTEE (UZREC)

### APPLICATION FOR APPROVAL TO USE ANIMALS FOR RESEARCH OR TEACHING PURPOSES

### COMPLETING APPLICATION FORMS

1. This form must be completed by students or staff of the University of Zululand submitting a research proposal involving research on animals or using animals for teaching purposes.
2. Please refer to 'Guidelines for Applicants' for information on completing this application form.
3. The completed and signed form, together with the research proposal, must be submitted to AREC via FREC.
4. Note that applications that are incomplete, are incorrectly completed and/or are not appropriately signed will be returned to the applicant without being reviewed.
5. It is mandatory that **all sections** in this application form be completed.
6. **Please note –** It is not the role of the Research Ethics Committee to assess a proposal on scientific merit or on the experimental design, but a **flawed experimental design is unethical** and will be regarded as such.
7. The **Three R’s (Replacement, Reduction and Refinement)** guide the ethical use of animals in science:
	1. ***Replacement refers to methods which avoid or replace the use of animals in an area where animals would otherwise have been used***
	2. ***Reduction refers to any strategy that will result in fewer animals being used***
	3. ***Refinement refers to the modification of husbandry or experimental procedures to minimize pain and distress***

**COMPLETE ALL SECTIONS. MUST BE TYPED.**

**SECTION A: PROJECT DETAILS**

**1: PROJECT TITLE**

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| **2: PRINCIPAL INVESTIGATOR/RESEARCHER**  *(Corresponding author*  | *Yes* |  | *No* |  |
| **Name** | **Contact Number** | **e-mail address** | **Contact Address** |
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| **Qualifications** |  |
| **Details of appropriate experience in animal research** |  |

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| **3: SUPERVISOR/CORRESPONDING AUTHOR (if applicable)** *(Corresponding author*  | *Yes* |  | *No* |  |
| **Name** | **Contact Number** | **e-mail address** | **Contact Address** |
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| **Qualifications** |  |
| **Details of appropriate experience in animal research** |  |

**4: Co-WORKERS (involved directly with procedures on Animals**

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| **Name** | **Contact Number** | **e-mail address** | **Contact Address** |
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| **Qualifications** |  |
| **Details of appropriate experience in animal research** |  |
| **Name** | **Contact Number** | **e-mail address** | **Contact Address** |
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| **Qualifications** |  |
| **Details of appropriate experience in animal research** |  |

**5: FUNDING**

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| Is this project fully funded | **YES** | **NO** |
| Does the funding of the project depend on the project being approved by the Ethics Committee? | **YES** | **NO** |

**6: TYPE OF RESEARCH**

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| Academic |  | Contract |  | For degree purposes |  | Degree |  |

**7: RESEARCH CATEGORY**

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| **See description and examples of categories at end of document** |
| A | Studies on invertebrate animals or live isolates | □ |  | B | Studies on vertebrate animals involving field observations and routine examinations  | □ |
| C | Experiments on vertebrate species that are expected to produce little or no discomfort | □ | D | Experiments that involve minor stress or pain (short-duration pain) to vertebrate species | □ |
| E | Experiments that involve significant but unavoidable stress or pain to vertebrate species | □ | F | Procedures that involve inflicting severe pain near, at, or above the pain tolerance threshold of unanaesthetised, conscious animals | □ |

**SECTION 2: PROJECT DETAILS**

**1. COMMENCEMENT OF RESEARCH**

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| Expected Starting Date |  | Expected Completion Date |  |
| I declare that the project has not commenced without approval (signature) |  |

1. **BRIEF JUSTIFICATION**

(Provide an introductory paragraph NOT EXCEEDING 500 WORDS, *supported by relevant scientific literature,* as a motivation for conducting the study and explains what problems, questions, needs or scientific or clinical observations have led to the planning of the experiment.) *(Please type)*

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1. **AIM/S OF THE PROPOSED STUDY**

(State these briefly and succinctly.) *(Please type)*

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1. **POTENTIAL BENEFITS OF THE RESEARCH FINDINGS**

(These are required to aid the reviewing committee in performing a harm/benefit assessment.)*(Please type)*

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1. **HYPOTHESIS**

(If a hypothesis is being tested give the postulate/s (null hypothesis and alternates) to aid the reviewers in following the rationale of the proposed study.) *(Please type)*

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**SECTION 3: EXPERIMENTAL WORK ON ANIMALS**

1. **ANIMAL REQUIREMENTS**

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| Animal Species*(Please state whether domesticated or not)* |  |
| Strain |  | Total Number Required |  |

1. **JUSTIFICATION FOR THE USE OF SENTIENT ANIMALS**

(Justify the use of animals, the choice of species and the numbers to be used. If there is limited availability or the animals to be used have conservation importance, or large numbers are to be used, provide additional rationale for their selection and numbers. **State also what non-sentient methods or models were considered (with reference to appropriate scientific literature)** and on what grounds they were rejected.) *(Please type)*

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1. **EXPERIMENTAL DESIGN**

(Explain the rationale behind the study design. Give a detailed outline of the experimental design to show how many animals are required per treatment and per experimental set-up, with particular reference to determination of sample size and statistical analysis. Describe how the animals will be allocated to experimental and control groups and where applicable, how the experimental treatments will be assigned to each group. The use of flow charts is recommended. The information should be presented in an easily accessible manner.) *(Please type)*

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1. **STATISTICAL ANALYSIS**

(Describe briefly how the data obtained from the study will be analysed statistically, i.e. what statistical methods are appropriate, based on the study design. Also state by whom the analyses will be performed.) *(Please type)*

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1. **REDUCTION OF THE NUMBER OF ANIMALS TO A MINIMUM TO ACHIEVE SCIENTIFIC OBJECTIVES**

(Describe how this was determined either by calculation (statistical design) or by specification (i.e. use of a validated testing protocol) or any other strategy.) *(Please type)*

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1. **ANIMAL HOUSING AND CARE**

(Briefly describe how the animals will be housed (penned, stabled, caged or confined in any other way, kept in metabolic crates or cages, etc.), their nutrition (feeding and watering) and what provisions have been made for the physical and psychological wellbeing i.e. comfort) *(Please type)*

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| **NAME OF FACILITY USED:** |  |
| **RESPONSIBLE PERSON:** |  |
| **CONTACT NUMBER:** |  |
| **AUTHORISED SIGNATURE & DATE:** |  |

1. **STATEMENT OF ANIMAL CARE COMPETENCE, EXPERTISE AND EXPERIENCE**

(Provide a short statement of the scientific knowledge competence and experience of the person(s) appointed to ensure the comfort, health and humane treatment of the animal subjects in this study) and provide their registration credentials either with the South African Veterinary Council, the Health Professions Council of South Africa or the South African Council for Natural Sciences Professions, or any in-house accreditation obtained.) *(Please type)*

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1. **RESTRAINT OF THE ANIMALS**

(Describe the methods of physical (manual procedures and use of special restraint equipment) or chemical restraint to be used on the animals and state who the animal handler/s will be.) *(Please type)*

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1. **EXPERIMENTAL ANIMAL PROCEDURES**

(Describe in detail, in bullet form or short annotated sentences, IN SEQUENCE and for each treatment or experiment, all the steps that will be performed in conducting the proposed experiment/s. These include: duration of animal holding and animal use, the collection of samples (if body fluids give routes of collection and volumes), sampling procedure, parameters to be measured, data to be collected, administering chemicals, operative procedures, etc.) *(Please type)*

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1. **END POINTS FOR EXPERIMENTS THAT INDUCE ILLNESS OR PAIN IN ANIMALS**

(Give the endpoints of data collection in experiments or procedures that may cause animals to become ill, lose weight, become distressed and experience pain. Also state clearly whether the experimental animals will be sacrificed and for what reason. Justify these in terms of the needs of the experiment to attain its objectives.) *(Please type)*

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1. **ADMINISTRATION OF ALL MEDICINES/SUBSTANCES**

(List ***all*** substance administrations to the animals and give routes of administration, dosages per body mass including anaesthetics, analgesics and euthanasing agents. State who is legally responsible for prescribing and directing the administration of the controlled Scheduled 3 – 6 medicinal substances and other controlled substances, if not the veterinarian listed under 12, and provide their acceptance of this responsibility by signature.) *(Please type)*

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| **RESPONSIBLE PERSON (PRINT NAME)** |  |
| **QUALIFICATION** |  |
| **ACCEPTANCE OF RESPONSIBILITY: SIGNATURE & DATE:** |  |

1. **GENERAL VETERINARY CARE**

(Provide details, including emergency contact details, of the veterinarian who will be responsible to provide the general veterinary care and who will have the authority to enforce the endpoints stipulated under Point 10. The veterinarian must be registered or authorised with the SAVC and is preferably independent of the research group.) *(Please type)*

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| **PERSON RESPONSIBLE FOR VETERINARY CARE OF ANIMALS** |  |
| **EMERGENCY Contact details** |  |
| Signature & Date |  |

1. **FATE OF ANIMALS AND THEIR DISPOSAL AT THE END OF THE STUDY**

(Briefly state the *fate* (e.g. rehabilitation and release, return to stock or euthanasia) of the experimental animals at the end of the study, what method of euthanasia is to be used, what humane rationale supports this choice and how the animals or animal carcasses are to be disposed of in a responsible and ecologically sound manner.) *(Please type)*

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1. **REFINEMENT**

(Describe the specific steps that have been taken to refine the experimental procedures to make them as humane as possible i.e. minimising the impact of the proposed procedures on the animals’ wellbeing.) *(Please type)*

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1. **CARE OF EXPERIMENTAL ANIMALS AND MONITORING OF CLINICAL CHANGES**

(Describe who will be responsible for the pre, intra- and post operative (or experimental period) care of the animals and give an indication of their experience and competence. Briefly state what clinical and behavioural criteria will be specifically monitored to assess the animal’s wellbeing.) *(Please type)*

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1. **BIOHAZARD STATEMENT**

(Does the project pose any hazards to other animals and staff from the use of infective agents, toxic substances, carcinogenic agents or ionising radiation? If it does, state the specific safety procedures to be followed to contain these hazards and provide an approval statement in the space below from the Institutional Safety Officer. If available, you may append the laboratory’s relevant SOPs and policies.) *(Please type)*

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| **FACULTY:** |  |
| **NAME of OFFICER** |  |
| **SIGNATURE & DATE:** |  |

1. **REPETITION OF EXPERIMENTAL PROCEDURES**

Is this experiment a repetition of previous work performed by the applicant or other? If so, please give details and explain why the experiment is being repeated.

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## DECLARATIONS and SIGNATURES

## I declare that the project information provided in this application is accurate and that in applying for ethics review and approval I agree to conduct the research in accordance with the *University of Zululand Policy Statement: Ethical Conduct for Research Involving Animals*, the *University of Zululand Policies and Procedures for the Ethical Conduct of Research* and the conditions of approval established by the University of Zululand Research Ethics Committee. I also acknowledge that failure to conduct research in accordance with these policies and procedures may result in permission for conducting the research being withdrawn immediately. I also acknowledge that failure on my part to adhere to appropriate South African laws regulating research with animals, and which consequently leads to litigation, will result in the immediate termination of this research and may also result in my prosecution for such offences.

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Signature of Principle Investigator Date

I am satisfied that the applicant has the technical competence required to carry out the work with minimum distress to the animals. I believe this work meets the requirements of the South African Prevention of Cruelty to Animals Act, 1985. I am satisfied that this work is of sufficient scientific merit for my Department to be involved in it, and I believe that the lay language used, where requested, makes the proposal understandable to all Animal Ethics Committee members. I also undertake to regularly monitor conditions under which animals are being maintained in the laboratory, to ensure that these are in accordance with appropriate techniques for this purpose.

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Signature of Supervisor (if applicable) Date

**Research Categories using animals (modified from SPCA and MRC guidelines)**

The following list of categories provides possible examples of experimental procedures which are considered to be representative of each category:

1. **Experiments on most invertebrates or on live isolates**

**Possible examples**: The use of tissue culture and tissues obtained at necropsy or from the slaughterhouse; the use of eggs, protozoa or other single-celled organisms; experiments involving containment, incision or other invasive procedures on invertebrates.

1. **Studies on vertebrate animals involving field and routine observations.**

**Possible examples:** Field based observations on wild and domesticated animals, observations on animals in behavioral studies.

1. **Experiments which cause little or no discomfort or stress**

**Possible examples**: domestic flocks or herds being maintained in simulated or actual commercial production management systems; the short-term and skilful restraint of animals for purposes of observation or physical examination; blood sampling; injection of material in amounts that will not cause adverse reactions by the following routes: intravenous, subcutaneous, intramuscular, intraperitoneal, or oral, but not intrathoracic or intracardiac (Category C); acute non-survival studies in which the animals are completely anesthetized and do not regain consciousness; approved methods of euthanasia following rapid unconsciousness, such as anesthetic overdose, or decapitation preceded by sedation or light anesthesia; short periods of food and/or water deprivation equivalent to periods of abstinence in nature.

1. **Experiments which cause minor stress or pain of short duration**

**Possible examples**: cannulation or catheterization of blood vessels or body cavities under anesthesia; minor surgical procedures under anesthesia, such as biopsies, laparoscopy; short periods of restraint beyond that for simple observation or examination, but consistent with minimal distress; short periods of food and/or water deprivation which exceed periods of abstinence in nature; behavioral experiments on conscious animals that involve short-term, stressful restraint; exposure to non-lethal levels of drugs or chemicals. Such procedures should not cause significant changes in the animal's appearance, in physiological parameters such as respiratory or cardiac rate, or fecal or urinary output, or in social responses.

***Note****: During or after Category C studies, animals must not show self-mutilation, anorexia, dehydration, hyperactivity, increased recumbency or dormancy, increased vocalization, aggressive-defensive behavior or demonstrate social withdrawal and self-isolation.*

1. **Experiments which cause moderate to severe distress or discomfort**

**Possible examples**: major surgical procedures conducted under general anesthesia, with subsequent recovery; prolonged (several hours or more) periods of physical restraint; induction of behavioral stresses such as maternal deprivation, aggression, predator-prey interactions; procedures which cause severe, persistent or irreversible disruption of sensorimotor organization; the use of Freund's Complete Adjuvant. Other examples include induction of anatomical and physiological abnormalities that will result in pain or distress; the exposure of an animal to noxious stimuli from which escape is impossible; the production of radiation sickness; exposure to drugs or chemicals at levels that impair physiological systems.

***Note****: Procedures used in Category D studies should not cause prolonged or severe clinical distress as may be exhibited by a wide range of clinical signs, such as marked abnormalities in behavioral patterns or attitudes, the absence of grooming, dehydration, abnormal vocalization, prolonged anorexia, circulatory collapse, extreme lethargy or disinclination to move, and clinical signs of severe or advanced local or systemic infection, etc.*

1. **Procedures which cause severe pain near, at, or above the pain tolerance threshold of unanesthetized conscious animals**

**Possible examples**: This Category of Invasiveness is not necessarily confined to surgical procedures, but may include exposure to noxious stimuli or agents whose effects are unknown; exposure to drugs or chemicals at levels that (may) markedly impair physiological systems and which cause death, severe pain, or extreme distress; completely new biomedical experiments which have a high degree of invasiveness; behavioral studies about which the effects of the degree of distress are not known; use of muscle relaxants or paralytic drugs without anesthetics; burn or trauma infliction on unanesthetized animals; a euthanasia method not approved by the SPCA; any procedures (e.g., the injection of noxious agents or the induction of severe stress or shock) that will result in pain which approaches the pain tolerance threshold and cannot be relieved by analgesia (e.g., when toxicity testing and experimentally-induced infectious disease studies have death as the endpoint).