

FACULTY OF SCIENCE

### APPLICATION FOR APPROVAL TO USE ANIMALS FOR RESEARCH

### OR TESTING PURPOSES

**Instructions:**

* This document must be completed electronically;
* Complete all the sections (A – F);
* Sufficient details of the study have to be provided in the application. This will assist the Committee to understand the protocol detailing the background to the research project, the design of the study and all procedures;
* If a specific question within a section is not applicable to your project, please briefly motivate why it is not applicable in the space provided;
* Should the project involve the use of previously collected samples or samples from another institution, please attach all the necessary supporting documents i.e. ethical clearance, agreement letter of sample transfer etc.
* Ensure that your final submission document includes all the required signatures;
* Please do not change the format of the form;
* Please submit the final, signed document in PDF format via email (*facultyethics@uj.ac.za*) to the Faculty Ethics Committee (FEC) before or on the scheduled agenda closing date;
* Meeting dates and agenda closing dates for the FEC are available on the “Faculty Meetings Schedule” provided annually by the Head of Faculty Administration;
* Where applicable, please refer to the following documents:
	+ **Department of Health (DoH 2015; 2nd Ed or latest version)**
	+ **South African National Standard: Care and Use of Animals for Scientific Purposes (SANS 10386:2021 Ed 2)**

**A: DETAILS OF APPLICATION**

1. **APPLICATION TYPE** (MARK THE APPROPRIATE BLOCK WITH “X”)

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| **NEW PROJECT** | **ONGOING PROJECT** | **AMENDED PROPOSAL** |
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1. **RESEARCH TYPE** (MARK THE APPROPRIATE BLOCK WITH “X”)

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| **ACADEMIC** (Research by academic staff or postdoctoral researchers, i.e. not for degree purposes) |  |
| **CONTRACT** (Research for contract purposes) |  |
| **DEGREE** (Research for degree purposes – staff or students) |  |
| **PROTOCOLS** (Research for practicals or protocol development) |  |

1. **PROJECT TITLE / STUDY FIELD**

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**B: DETAILS OF RESEARCHERS**1. **PRINCIPAL INVESTIGATOR/RESEARCHER**

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| **STUDENT / STAFF NUMBER** |  |
| **INITIALS AND SURNAME** |  |
| **CONTACT NUMBER** |  |
| **EMAIL ADDRESS** |  |
| **STREET ADDRESS** |  |
| **PREVIOUS QUALIFICATION** |  |
| **CURRENT DEGREE REGISTERED FOR (E.G. MSc ENVIRONMENTAL MANAGEMENT)** |  |
| **BRIEFLY ELABORATE ON RELEVANT PREVIOUS EXPERIENCE IN ANIMAL RESEARCH (Include number of years)** |  |

1. **SUPERVISOR**

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| --- | --- |
| **STAFF NUMBER** |  |
| **INITIALS AND SURNAME** |  |
| **CONTACT NUMBER** |  |
| **EMAIL ADDRESS** |  |
| **DEPARTMENT** |  |
| **HIGHEST QUALIFICATION** |  |
| **BRIEFLY ELABORATE ON RELEVANT PREVIOUS EXPERIENCE IN ANIMAL RESEARCH (Include number of years)** |  |

 1. **CO-SUPERVISOR (include additional tables below, if required)**

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| **STAFF NUMBER (if applicable)** |  |
| **INITIALS AND SURNAME** |  |
| **CONTACT NUMBER** |  |
| **EMAIL ADDRESS** |  |
| **DEPARTMENT/INSTITUTION** |  |
| **HIGHEST QUALIFICATION** |  |
| **BRIEFLY ELABORATE ON RELEVANT PREVIOUS EXPERIENCE IN ANIMAL RESEARCH (Include number of years)** |  |

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**C: DETAILS ON FUNDING**

(MARK THE APPROPRIATE BLOCK WITH “X”)

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| Is the project fully funded? | **YES** |  | **NO** |  |
| Does the funding of the project depend on the project being approved by the Faculty Ethics Committee? | **YES** |  | **NO** |  |
| **Please note:** Final approval of the project by the FHDC of the Faculty of Science will depend on the project being approved by the Faculty Ethics Committee. |

**D: COMMENCEMENT OF RESEARCH**

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| Expected starting date of the study or part of the project requiring ethical clearance (e.g. 1 March 2020). Please note that this date cannot precede the FEC meeting date): |  |
| Expected completion date (e.g. 31 October 2020):  |  |
| **I DECLARE THAT THE PROJECT HAS NOT COMMENCED WITHOUT APPROVAL (print name and signature of principal investigator):** | **Name:****Signature:****Date:**  |

**E: DETAILS OF THE PROJECT**

(MARK THE APPROPRIATE BLOCK WITH “X”)

1. **EXPERIMENTAL CATEGORY**

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| **A1** | Experiments on embryonated eggs or cephalopods, decapods or lower macro-invertebrates |  | **A2** | Studies on vertebrate species during the course of routine examination, sampling, procedures and treatment |  |
| **B** | Experiments on vertebrate species that are expected to produce little or no discomfort |  | **C** | Experiments that involve minor stress or pain (of short duration) to vertebrate species |  |
| **D** | Experiments that involve significant but unavoidable stress or pain to vertebrate species |  | **E** | Procedures that involve inflicting severe pain near, at, or above the pain tolerance threshold of un-anaesthetised, conscious animals (vertebrates) |  |

*\*Definitions from: Laboratory Animal Science, Special Issue, January 1987, p. 12*

1. **BRIEF JUSTIFICATION**

(Provide a brief introductory statement NOT EXCEEDING 500 WORDS and *supported by relevant scientific literature* that explains what research problems, questions, needs or scientific or clinical observations or new ideas have led to the planning of the experiment)

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1. **AIMS OF THE PROPOSED STUDY**

(State these briefly and succinctly)

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

(These are required to aid the reviewing committee in performing a harm/benefit assessment and include benefits to the scientific community, advancement in science etc.)

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1. **HYPOTHESIS**

(State the hypothesis for the study and briefly summarize the expected results)

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1. **ANIMAL REQUIREMENTS**

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| Species | Common name: |
| Scientific name: |
| Strain  |  |
| Source of animals: |  |
| Are the animals domesticated or not? |  |
| Total number of specimens required: |  |
| Number of male specimens required: |  |
| Number of female specimens required: |  |
| What age range will be required? |  |
| If working on laboratory rodents, what is their microbial status (for definitions, see <https://www.ncbi.nlm.nih.gov/books/NBK235136/>). |  |

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

(Briefly justify the choice of species (why exactly is this species particularly suitable to address the research question), and the numbers to be used. If there is limited availability, or large numbers are to be used, provide additional rationale for their selection and numbers. State also what non-sentient model/s were considered and on what grounds they were rejected)

Sentience: “*The quality of being able to experience feelings*” (Cambridge Dictionary) - including pain.

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| Elaborate on the choice of species:Elaborate on the sample size to be used:Consideration of non-sentient models: |

1. **EXPERIMENTAL DESIGN**

(Describe the study design/experimental planning and explain why this design is considered suitable to address the research question. 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 understandable manner)

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

(Describe how the sample size was determined either by calculation (statistical design) or by specification (i.e. use of a validated testing protocol) or any other strategy)

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1. **STEPS OF THE EXPERIMENTAL ANIMAL PROCEDURES**

(Describe briefly in short annotated sentences IN SEQUENCE, all the steps that will be performed in conducting the proposed experiment. These include: duration of animal holding and animal use, the collection of samples (if body fluids give routes of collection and volumes), operative procedures, etc.)

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1. **STATISTICAL ANALYSIS**

(Briefly describe how the data obtained from the study will be analysed statistically, explain the choice of specific statistical tests, and state by whom the analyses will be performed. Do not just say which software will be used - explain the actual statistical tests and their relevance).

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1. **ADMINISTRATION OF ALL MEDICINES AND/OR EXPOSURE SUBSTANCES**

(List ***all*** substance administrations to the animals and give routes of administration, dosages per body mass including anaesthetics, analgesics, tranquilizers, euthanizing agents and exposure substances. State who is legally responsible for prescribing and directing the administration of the controlled Scheduled 3–6 medicinal substances and other controlled substances and provide their acceptance of this responsibility by signature)

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

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, socialisation, behavioural needs and enrichment of their immediate environment.)

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| Housing or confinement:Feeding and watering:Physical and psychological wellbeing: |

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| **NAME OF FACILITY USED:** |  |
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| **PHYSICAL ADDRESS:** |  |
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| **EMERGENCY CONTACT NUMBER:** |  |
| **FACILITY MANAGER (NAME, 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, and any in-house accreditation obtained)

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1. **RESTRAINT OF 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)

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1. **ANIMAL WELLBEING**

(Describe the specific steps that have been taken to refine the experimental procedures to make it as humane as possible, i.e. minimising the negative impacts of the proposed procedures on the animals’ wellbeing)

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1. **SEVERITY OF EFFECTS OF THE EXPERIMENTAL PROCEDURES ON THE ANIMALS**

(List the procedures that may cause deprivation, fear, distress and pain. Describe what sensations the animal may feel. **Categorise these as minimal, intermediate or high\*.** Give the likely duration in each case. Describe what specific steps will be taken to alleviate these conditions through the use of tranquilizers, dissociative agents, analgesics, anaesthetics or other methods. Estimate how effective these are likely to be)

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\**Please see Laboratory Animals 24: 97 – 130, 1990 for details. Link: https://journals.sagepub.com/doi/pdf/10.1258/002367790780890185*

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, 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)

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1. **MONITORING OF CLINICAL CHANGES IN EXPERIMENTAL ANIMALS**

(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 animals’ wellbeing)

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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. Justify these in terms of the needs of the experiment to attain its objectives)

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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 20. The veterinarian must be registered or authorised with the SAVC and is preferably independent of the research group)

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| **PERSON RESPONSIBLE FOR VETERINARY CARE OF ANIMALS:** |  |
| **REGISTRATION NUMBER:** |  |
| **EMERGENCY CONTACT DETAILS:** |  |
| **SIGNATURE & DATE:** |  |

1. **PERSONNEL ACTIVITIES**

(Describe the specific *responsibilities* and *duties* of EACH PERSON who will be involved with the procedures on animals, preferably in a tabular format)

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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)

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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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1. **PERMISSION OF RELEVANT AUTHORITY/IES, COLLABORATORS OR SUPPLIERS OF SAMPLES TO DO THE STUDY**

(Are permits or agreement documents required to do the study. Please attached copies of the permit, letters of approval. Ethical clearance can only be granted conditionally until the necessary documents are submitted)

1. **OTHER ETHICS COMMITTEES**

(Should the study require ethical clearance from other Ethics Committees, what is the status of those applications?)

1. **ANY OTHER INFORMATION, WHICH MAY BE OF VALUE TO THE COMMITTEE, SHOULD BE PROVIDED HERE.**

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**F: SIGNATURES:**

**THE APPLICANT/S CONFIRM THAT THE INFORMATION PROVIDED IN THIS APPLICATION IS CORRECT AND A TRUE REPRESENTATION OF THE PROPOSED RESEARCH**

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| **PRINCIPAL INVESTIGATOR /** **RESEARCHER:**   | **SIGNATURE & DATE:**  |
| **SUPERVISOR:** | **SIGNATURE & DATE:** |
| **CO-SUPERVISOR / COLLABORATOR****(add additional rows, if necessary):** | **SIGNATURE & DATE:** |

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| **Departmental screening by****FEC member or senior colleague prior to submission (NAME AND SURNAME):** |  |
| **SIGNATURE AND DATE:** |  |