ANIMAL RESEARCH ETHICS COMMITTEE (AREC)
APPLICATION FOR ETHICAL CLEARANCE FOR THE USE OF ANIMALS IN RESEARCH OR TEACHING AND LEARNING

APPLICATION NO.

Documents required for application to UL-AREC

- UL AREC application form
- Research proposal
- Budget/funding information
- Evidence of applications/approval from any other Ethics Committees where applicable
- Proof of Faculty Higher Degrees Committee (FHDC) approval for this proposal (scientific merit)
- Proof of qualifications for personnel involved in the supervision of animal care and other procedures, particularly for high-risk studies e.g. *in-vivo* drug toxicity studies)
- CVs for the supervisor/s, researchers and students involved in the study.

Submission deadline
A completed application form and the relevant documents must be submitted three weeks prior to the scheduled UL-AREC meetings.

Submit the hard copies to:
Secretariat for the Animal Research Ethics Committee
arec@ul.ac.za

DECLARATION BY PRINCIPAL INVESTIGATOR

1. Moral Philosophy

The ethical review of proposed animal experiments is predicated upon the acceptance by the AREC that,

a) non-human vertebrates are organisms fully worthy of moral concern and
b) their interests must be protected as far as possible in their use for advancement of biological knowledge and for the promotion of the health and welfare of animals and humans and protection of the environment.

2. Animal Interests

a) In the use of animals, animal interest's obligate scientists and educators to:

b) Not allow animals to be used for research and/or to be killed for trivial, irrational, unjustified or inappropriate reasons

c) Permit animals to live, reproduce and grow under conditions that are comfortable and reasonably natural to their species

d) Keep animals free from disease, parasitism, injury and pain by prevention, rapid diagnosis and treatment

e) Allow animals to be able to express normal behaviour through providing as far as possible sufficient space, proper facilities in which to live and in the company of the animal's own kind recognising the inherently social nature and hence the necessity of a social relationship for many species

f) Protect animals from fear, deprivation, stress, distress and pain by ensuring that their living conditions, handling and treatment will be such that it will either minimise or eliminate the causation of these states upon those animals which are used for research, teaching and testing

g) Not unnecessarily repeat animal experiments the outcome of which is already known or is predictable

3. Humaneness

The principles of humane experimental technique proposed by Russell & Burch must be followed in the planning and conduct of animal experiments. These comprise:

a) **Replacement** of animals with non-sentient research systems, i.e. researchers should strive to avoid using of animals if alternative methods can yield the data they need.

b) **Reduction** of the numbers of animals which are to be used to a minimum by design in order to achieve only sufficient statistical power to allow the objects of the experiment to be achieved.

c)**Refinement** of the experimental methodology to be adopted by the implementation and if necessary by the improvisation of procedures which will have the least distressing or harmful effect to the animals and when this is not avoidable to counter those effects by the use of ataractics (tranquillisers), neuroleptics (dissociative agents), anaesthetics, analgesics and other effective strategies.

d) **Responsibility** everyone using animals, whether for experimentation, testing diagnosis, teaching or sourcing of tissues or body fluids is responsible in their personal capacity for assuring that the animals that they use are afforded the highest levels of welfare and protection from abuse, and violations of the interests accorded to them.

4. Animal Protection

Animals should be protected from research designs which involve pain, illness, isolation, mutilation (whether by surgery or otherwise) and/or premature death until such research can be demonstrated to be absolutely imperative and related to health, welfare and environmental problems which are potentially catastrophic in nature and for which alternative designs using non sentient systems are not feasible.

5. Relevance

Animal based teaching and research must address an important question relevant to the AREC's objectives in advancing knowledge, education, science and human and animal welfare through research, be based on plausible hypothesis and have a reasonable prospect of yielding good results.

6. Personal Declaration

I, (full name) ……., as Principal Investigator

in this application, hereby declare that I am familiar with the precepts, policies and responsibilities outlined under Section A and will personally undertake to see that these are upheld in the conduct of this study, should it be approved.

- **I agree not to deviate from the approved protocol without obtaining clearance for any desirable or** necessary changes that may need to be made in the methods used which may affect the welfare of the animal subjects
- At the conclusion of the study I undertake to report on its outcome to **the AREC** and if it has not been completed within six months of it being cleared by the Committee, to submit progress reports at six monthly intervals until the study has been completed
- In my opinion, all persons named and working under my supervision have **the training** and skills needed to carry out their responsibilities for experimental procedures, care and handling of the species being used

Ethical approval is compulsory

Ethical approval is not optional, but compulsory, and no project may be initiated before this approval has been received. Approval must comply with the requirements of all authorities under which the project team falls (e.g. the country's laws, employer, professional councils, etc.) and, where requirements differ, the strictest requirement applies. All relevant approval must already have been obtained (inter alia, an allocated ethics number) before any project may commence. Ethically responsible use (according to international convention) and ethical approval is also a prerequisite for most grant applications and for publication in all good, accredited international scientific journals. Furthermore, any person has the right to request to see and study the original data of published results in order to verify the accuracy and validity thereof.

The project leader is personally responsible

The ethical justifiability of any project remains the responsibility of the project leader, who must himself/herself with the ethical implications of any project and must manage it responsibly. The AREC offers the researcher/s a service in order to facilitate the obtaining of the necessary ethical approval from the University of Limpopo (and in line with international guidelines), and does not simply lay down unnecessary aggravating rules. The responsibility remains with the researcher to ensure that the necessary ethical approval is obtained and that the panel is provided with the necessary

information for assessment in a friendly, understandable and accessible way. The application form is designed to make it as clear and easy as possible for both the applicants and evaluators to act ethically justifiably and to meet the requirements.

Title of research study

DECLARATION BY APPLICANT

NB: Undergraduate and honours students may not sign this declaration.

a) I am suitably qualified to perform or supervise the procedure/s proposed in this research project.
b) This research project is likely to advance knowledge in the field of study.
c) The work does not to my knowledge unnecessarily repeat other studies.
d) The study has been designed not to use more animals than necessary.
e) The study has been designed to minimise discomfort, stress and distress of the animals.
f) Having carefully considered all possible alternatives, I am satisfied that it is absolutely necessary to use animals to attain the objectives of this project.
g) I shall comply with any restrictions or modifications required by the AREC.
h) I agree to provide AREC with progress report about the work at 6 months intervals or when requested to do so.

Name (in capitals)		
Qualifications		
University Department		
Date		
Authorised under the Veterinary and Para-veterinary Professions Act 1982	YES	NO
Experience in animal research (Type of studies and years of experience)		
Signature		

SECTION A

1. **Application category** Answer YES or NO

(a) Fundamental research (E.g. postgraduate research)					
(b) Development of products for human/ animal medicine					
(c) Education and Training		**Graduate**		**Undergraduate Course code**	
Demonstration		**Laboratory Exercise**		**Students be handling animals**	
Supervised by					

2. Relevant Research Committee

Has the specific research proposal been reviewed for scientific merit by the relevant research committee?

YES, name of committee	
NO, explain why not	

3. Other ethical review/s

Has this application been submitted or will it be submitted for ethical review by any other ethics committee(s)?

4. Projected time period of the study. (Maximum project time allowable, is three years' subject to acceptable annual progress reports.)

From	To

5. Details

5a. Applicant

Name		**Qualifications**	
Univ. Dept.		**Tel.**	
e-mail		**Staff/ Student No.**	

5b. Principal investigator (if not applicant)

Name		**Qualifications**	
Univ. Dept.		**Organisation**	
E-mail		**Tel no.**	

5c. Co-workers

List names, qualifications and duties of co-workers involved in this project. Clearly indicate the person responsible for performing animal care, handling and other applicable procedures.

Name	Organisation	Qualification	Experience	Specific Duties

Name	After hours Tel No. for emergencies	Email address	Registration[1] or authorisation[2]

6. Permits

Should any permits be required for this project, please list.

Relevant authority	Study site location, address	Application date	Status (pending or approved: attach certificate)

SECTION B

DETAILS OF THE STUDY

1. Background

Describe the project and explain why your study is important. (What do you want to do and why do you want to do it?) Write it in such a way that people who are not familiar with your field of study can understand it (use lay terms). Provide a brief background to your study and place it in context. (What has been done?) Cite the most relevant and significant articles published in your field of study and place these articles in a reference list. What will your study add to the current knowledge in this field?

2. Rationale for use of non-human vertebrates

Justify the use of animals, the choice of species, numbers to be used and if there is limited availability or large numbers are to be used, provide additional rationale for their selection and numbers. State also which non-animal models were considered and on what grounds they were rejected.

3. Statement of specific objective/s of the study

State the major specific objective briefly, but clearly, e.g. "For teaching basic mammalian anatomy", or “To determine the effect of supplementing *Moringa oleifera* on growth performance in sheep".

4. Potential benefits of the study

This will enable the reviewing committee to perform a harm/ benefit assessment.

SECTION C

1. Animals

1a. Animals required

Species	Strain (if applicable)	Sex	Age/Body Mass	Number of animals required

1b. Animal confinement

Briefly describe how the animals will be captured? What provisions have been made for their physical and psychological wellbeing, i.e. comfort, socialisation, behavioural needs and enrichment of their environment?

1c. Procedures and inspections

Can standard husbandry procedures be followed, including at least once daily welfare monitoring?

YES, list the responsible person(s)	
NO, explain briefly	

2. Pilot study

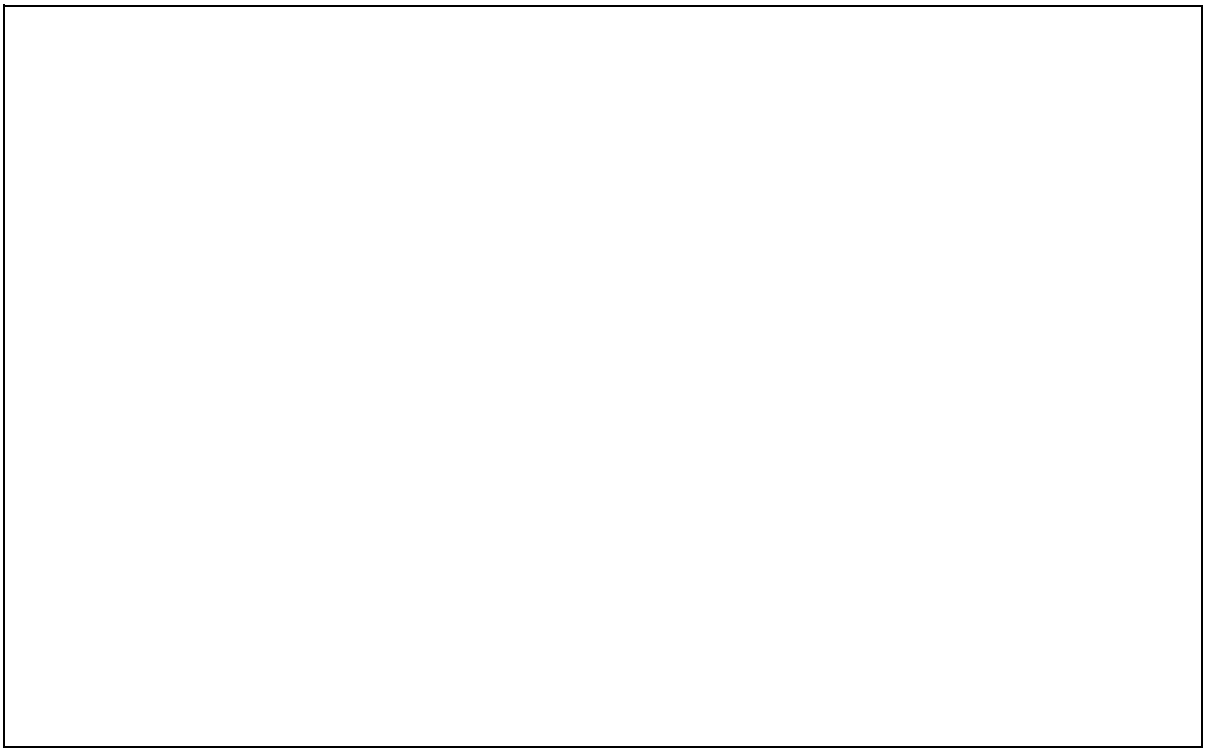
Tick (✓) YES or NO

NO	YES

3. Study design

Describe the manner in which the animals will be assigned to control and the different treatment groups, where applicable.

A. Flow diagram
B. Text (timing of procedures and interventions, duration of study, when animals will be euthanased.



4. Procedures, treatments and handling of the animals

Tick (✓) YES or NO. If YES, provide full details in the space provided. Where procedures are combined, describe the sequence of events.

	NO	YES							
A			**CAPTURE AND RESTRAINT** (chemical or physical method and duration)						
B			**NON-INVASIVE PROCEDURES, e.g faecal and blood sample collection** (method, duration, frequency, time interval between procedures, expected clinical effects)						
C			**INVASIVE PROCEDURES, e.g Broncho alveolar lavage and tissue biopsy** (method, duration, frequency, time interval between procedures, expected clinical effects)						
D			**DEPRIVATION**, **e.g. feed or water withdrawal** (type, duration, frequency)						
E			**ADMINISTRATION OF CHEMICALS/BIOLOGICALS** (agents, dose ranges, routes, schedule, expected clinical effects)						
F			**ANESTHESIA**						
			Inhalation		Halothane		Isoflurane		Other
			Injection		Dose/ route				
					Dose/ route				
			Local/regional		Dose/ site				
			Fluid therapy		Dose/ route				
			Administered by (name)						
G			**NEUROMUSCULAR BLOCKING AGENTS** (purpose, type)						
H			**SPECIAL MANAGEMENT** (diet, sedation, antibiotics, special nursing, analgesics, tranquillisers, etc.)						
			Administered by (name)						
I			EUTHENASIA (justify and provide brief description of and reference for procedure)						

J			OTHER (additional information not included above)
Details of answers above (A flow diagram may be used but should not replace important details)			

5. Pain and/ or distress expected

When										
During restraint/handling	Nil		Low		Mild		High		N/A	
During procedure	Nil		Low		Mild		High		N/A	
Immediately post procedure	Nil		Low		Mild		High		N/A	
During convalescence	Nil		Low		Mild		High		N/A	
Over long term	Nil		Low		Mild		High		N/A	
Other	Nil		Low		Mild		High		N/A	
Description of "other"										
Justify any distress or pain anticipated (Specify animal welfare monitoring and by whom. Specify different stages of the experiment and the duration and who will perform the procedures.)										

6. Relieve pain and/ or distress

NONE		If selecting this option you **MUST** provide a detailed scientific justification			
YES, analgesics; as follows		**Agent**	**Route**	**Dosage**	**Time span**

Before procedure					
During procedure					
Immediately after procedure					
Long-term					
As necessary					
Agents to be administered by					
YES, other measures (i.e. management, etc.)					

7. Justify the number of animals

Reduce the number of animals to a minimum to achieve your scientific objective. Describe how the data from the study will be analysed statistically and justify the number of animals which have been requested. Show which and how power analysis was performed (P value, power, meaning full effect size and variance.) Supply the name of the statistician consulted.

8. Protocol end points

Will the experimental treatment cause the animals to become ill, lose weight, become distressed and experience pain? Explain. If the animals were to become distressed, what will the criteria be to stop the treatment? Justify these in terms of the objectives of the study. What will the criteria be to stop the treatment to avoid death?

A. Experimental (when do you plan to end this study)

B. Intervention end point (what level of suffering will lead to intervention such as pain killers) C. Humane end point (when will animal be euthanased)

9. Hazardous materials and organisms

9a. Specify hazardous materials and organisms

If any of the following materials are to be used in living animals, mark with an 'X'

Radioactive isotopes		**Infectious organisms**	
Carcinogens		**Tumour Cells**	
Teratogens		**Tissue, serum or other biological material**	
Mutagens		**Transgenics**	
Toxins		**Other, specify**	
Pesticides		**None**	

9b. Biohazards and safety procedures

What are the safety protocols to handle and contain biohazard materials such as infective agents, toxic or carcinogenic substances and ionizing radiation? What precautions will be taken with these hazardous materials, live/dead animals, their tissues, and body fluids?

The signature below testifies that the PI takes full responsibility for all above and that every reasonable measure has been taken to contain hazards.

Signature	
Name (in capitals)	
University Department/ Independent Institution	
Date	

9c. Infrastructure

Are appropriate infrastructure and facilities for the study available? Describe.

10. Medicines and related substances

10a. Drug handling/administration

List the name/s and qualification/s of the person/s responsible for drug handling/administration of the drugs listed in Section 4 and 6.

Name	Registration or authorization number	Telephone No.

10b. Scheduled substances

If any substances Scheduled 3 - 6 in terms of the **Medicines and Related Substances Control Act, Act 101 of 1965** as well as **the Veterinary and Para veterinary Act (Act 19 of 1982)** e.g. analgesics, tranquilizers, anaesthetics, antibiotics, etc., will be required, list the name and qualification(s) of the person

who is legally registered or authorised to store and maintain drug register the use of these substances.

Name (print and signature)	Qualification(s)	Registration or authorization number

10c. Prescriptions

Provide details of person prescribing the drugs.

Name (print and signature)	Qualification(s)	Registration or authorization number

10d. Side-Effects

State all adverse effects for the drugs listed in 4 and 6.

11. Surgery and post-operative care

Will the animals be subjected to operations in this study? Who will perform the surgery? Can appropriate veterinary care be given to animals in this study? List the responsible person(s).

YES, provide details	
NO, explain briefly	

12. Ultimate fate of the animals

Tick **X**, appropriate box and include justification for the action

Euthanasia		**Justify**	
Return to stock		**Justify**	
Return to source		**Justify**	

13. Additional information

Provide any information not mentioned in this form that should be considered in the ethical clearance of this project

SECTION D

Declaration by Head of Department/Programme or designated person

This application is submitted with my approval and I am satisfied that the investigator is competent to undertake or supervise this research or teaching project.

Signature : _____

Date: _____

For official use

AREC REVIEW DATE	
AREC PROTOCOL REFERENCE NUMBER	
APPLICATION APPROVED (DATE)	

APPLICATION REFERRED BACK (DATE) REASONS:	
(a) Minor editorial changes, to be verified by the Chair	**YES/NO**
(b) Major revision, protocol to be re-submitted to AREC	**YES/NO**
Name and Signature of Chairperson of AREC	**Date**

APPENDIX 1

UNIVERSITY OF LIMPOPO CONSENT FORM

Project Title:

Consent statement concerning participation in a Research Project.

I have been fully informed on the aim and objectives of the proposed Research Project, and was provided the opportunity to ask questions. The aim and objectives of the Research Project are sufficiently clear to me, and I have not been pressurized to participate in any way.

I acknowledge that this Research Project has been approved by the Animal Research Ethics Committee of the University of Limpopo.

I hereby give consent to participate in this Research Project.

Signed at..... on the..... of..... 20.....

Name of Consenter	Signature
Name of Witness	**Signature**