Year:	

University of Venda

RESEARCH ETHICS ANIMAL PROTOCOL APPLICATION

It must be signed by the Principal Investigator (the applicant) and other persons who are vouching for specialised aspects of the experimental

INSTRUCTIONS

- The application must be typed
- The following documents must be attached:
  - Proof of Registration (If applicable)
  - Registration of the Project
  - Approved Project Proposal
  - Abstract
  - Tools(e.g. Questionnaire, Consent Form)
  - Recommendations (With all relevant signatures)

INITIATING DEPARTMENT:

<table>
<tr><td rowspan="4">DEPARTMENT</td><td rowspan="2">Submitted</td><td>Day</td><td>Month</td><td>Year</td></tr>
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Recommended</td></tr>
<tr><td colspan="4">Authorized by: Head of Department</td></tr>
<tr><td rowspan="4">SCHOOL</td><td rowspan="2">Submitted</td><td>Day</td><td>Month</td><td>Year</td></tr>
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Approved</td></tr>
<tr><td colspan="4">Authorized by: (School Dean)</td></tr>
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A. PERSONAL DETAILS

1.1 Title:_____ Staff / Student Number:_____
1.2 Name of Applicant (Project Leader): _____
1.3 Academic Qualifications: _____
1.4 Department: _____ School: _____
1.5 Position: _____
1.6 Email: _____ Telephone: _____
Registration

*****(Please indicate if applicant is registered with the Health Professions Council of South Africa (HPCSA) or the South African Veterinary Council (SAVC) and provide registration number(s))

B. TITLE OF RESEARCH:

_____

_____

_____

_____

C. CO-WORKERS

Name	Institution and Department	Role

D. PROTOCOL

1. Project Information (mark applicable answer with **X**)					
New Study		**Extension of Approved Project**			
Fundamental Research		**Development of Products for Animal medicine**		**Education and Training**	
If education and training, for which course			**No. of course participants**		
Nature of training:					
Demonstration		**and/or Hands on Exercise**		**and/or Field trip**	
Source of funding for study					
Expected starting date		**Expected completion date**			
2. Background information					

3. Repetition of experimental procedures

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

4. Scientific Aim(s) of the proposed study/teaching activity

(state these briefly and succinctly)

5. Potential benefits of the research findings/teaching activity

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

6. Hypothesis/ Research Question

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.

7. Animals required for protocol:

- Please list the animals required in the table below. Add as many rows as required.
- Where applicable, provide proof of the owner's consent.
- In the case where animals that were subjects in a previous study or teaching activity are going to be used, identify these clearly, provide a justification for their re-use and include details of the previous experience.)

Species	Strain	Gender	Age/Body Mass	Number required	Microbial Status	Source

Animal re-use:

8. Justification for the use of sentient animals

Briefly justify:

- the use of animals,
- the choice of species,
- the 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 model(s) were considered and on what grounds they were rejected.

9. Reduction of number of animals to a minimum to achieve scientific objective

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.

10. Refinement

Describe the specific steps that have been taken to refine the experimental procedures to make them as humane as possible i.e. reducing numbers of animals and the severity of the experimental treatments on the animals.

11. Experimental design

Describe:

- how the animals will be allocated to experimental and control groups,
- how the experimental treatments will be assigned to each group,
- data to be collected

12. Experimental procedure(s)

(Describe briefly in short annotated sentences and in sequence all the steps that will be performed in conducting the proposed experiment

13. Animal caging, care and monitoring

- Briefly describe how the animals will be caged and what provisions have been made for the physical and psychological wellbeing

14. Animal transport

Should it be necessary to transport any animals during the duration of the study, please indicate

- how the animals will be transported,

15. Severity of effects of the experimental procedure on the animals

- List the procedures that may cause deprivation, fear, distress and pain and describe what sensations the animal may feel in the table below. (Add additional rows if necessary.)

Procedure	Anticipated sensation	Category	Duration	Steps to be taken	Anticipated effectiveness

Justification:

16. Humane endpoints

- Describe how humane endpoints will be implemented.

17. Ultimate Fate of the animals.

- If this information has not been given earlier in this application, briefly state
- What the fate (rehabilitation and release, return to stock, euthanasia) of the group of experimental animals is to be at the end of the study.

18. Administration of medicinal substances

- List **all** substances to be administered to the animals. (Please note that only registered vets can prescribe schedule 4-7 substances)

Substance	Route	Dosage/body mass	Frequency	Monitoring	Responsible person

Responsible person		**Qualification(s)**	
Acceptance Signature		**Date**	
Responsible person		**Qualification(s**	
Acceptance Signature		**Date**	

19. Occupational Health and Safety

- Does the project pose any hazards to other animals and/or staff, including allergic reactions?
- If it does, state the specific safety procedures to be adopted to contain these hazards and measures in place to treat affected persons or animals.

20. Monitoring during fieldwork

Describe how animals will be monitored and which records will be kept as proof of monitoring.

E. SCIENTIFIC REVIEW STATEMENT

Every application has to be supported by a declaration that it has undergone prior scientific review outside of the applicant's respective Unit or Group.

I declare that this research protocol has been peer reviewed by the (tick answers)☑

Schools Research Ethics Committee ☐

Other ☐ (specify which……

…… …… ……..

Name and Surname Signature Date

Chairman of Reviewing Committee (print name)

F. DECLARATION

7. Moral philosophy

The ethical review of proposed animal experiments is predicated upon the acceptance by the University that, non-human animals are organisms fully worthy of moral concern and as such, 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.

8. Animal interests

In the use of animals for research, teaching and testing, animal interests obligate scientists and educators to:

- Not allow animals to be used for research and/or to be killed for trivial, irrational, unjustified or inappropriate reasons.
- Permit animals to live, reproduce and grow under conditions that are comfortable and reasonably natural to their species.
- Keep animals free from disease, parasitism, injury and pain by prevention, rapid diagnosis and treatment.
- 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.
- 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.
- Not unnecessarily repeat animal experiments the outcome of which are already known or are predictable.

9. Humaneness

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

These comprise:

- **Replacement** of animals with non-sentient research models or systems, i.e. researchers should strive to avoid the use of animals if alternative methods can yield the data they need.
- **Reduction** of the numbers of animals in experiments by design strategies that facilitate the use of the smallest number that will allow valid information to be obtained from the study and that will not be implemented at the expense of greater suffering of individual animals.
- **Refinement** of animal sourcing, animal care practices and experimental procedures are to be adopted to minimise or remove physical and psychological distress 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.

10. 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.

11. Relevance

Animal based teaching and research must address an important question relevant to the University'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.

12. 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 which they use are afforded the highest levels of welfare and protection from abuse, and violations of the interests accorded to them.

13. Personal Declaration

7.1 I, (full name) ……..……., as Principal Investigator in this application, hereby declare that I am familiar with the precepts, policies and responsibilities outlined above, that I am familiar with the minimum standards for the care and use of animals for scientific purposes

……..…… ……..……..

Signature of applicant **Date**

G. Signature of Project Leader

_____ _____ _____

Name and Surname Signature Date

Signatures of other Researchers involved in this Project:

_____ _____ _____

Name and Surname Signature Date

_____ _____ _____

Name and Surname Signature Date

_____	_____	_____
Name and Surname	Signature	Date

Signature of Project Supervisor *(Applicable for Student Projects)*

_____	_____	_____
Name and Surname	Signature	Date

Research Ethics Committee resolution:

Approved	
Not Approved	

_____	_____	_____
Name and Surname Chairperson, REC	Signature	Date