

18. Annexures

Annexure 1. Rules relating to the practising of the para-veterinary profession of Laboratory Animal Technologist (Notice 1445 of 1997 *Government Gazette*, 3 October 1997)

VETERINARY AND PARA-VETERINARY PROFESSIONS ACT, 1982 (ACT NO. 19 OF 1982)

It is hereby made known for general information that –

- (a) the South African Veterinary Council has under section 30 (1) of the Veterinary and Para-Veterinary Professions Act, 1982 (Act No. 19 of 1982), made the rules relating to the practising of the para-veterinary profession of laboratory animal technologist as set out in the Schedule; and
- (b) the Minister of Agriculture has under section 30(3) of the said Act approved the rules concerned.

H Kruger
Registrar: South African Veterinary Council

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SCHEDULE

Definitions

1. Any word or expression in this Schedule to which a meaning has been assigned in the Act shall have that meaning, and –

“**animal experiment**” means any procedure whereby an animal is used in experiments for the purposes contemplated in rule 4.11;

“**experimental animal**” means non-human vertebrates and non-human vertebrate fetuses which are bred or acquired for the sole purpose of use as an animal experiment;

“**the Act**” means the Veterinary and Para-Veterinary Professions Act, 1982 (Act No. 19 of 1982); and

“**the profession**” means the para-veterinary profession of laboratory animal technologist.

**SERVICES THAT PERTAIN TO THE PROFESSION
OF LABORATORY ANIMAL TECHNOLOGIST**

General services

2. For the purposes of the Act the following services shall be deemed to be general services which pertain to the para-veterinary profession of laboratory animal technologist:
 - 2.1 care of experimental animals;
 - 2.2 oral and parenteral administration and administration by inhalation of scheduled and experimental substances;
 - 2.3 administration of scheduled substances for anaesthesia and euthanasia;
 - 2.4 collection of body fluids including blood, urine by free flow and ascites, and the collection of tissues including smears, faeces, post mortal samples and bacterial swabs for diagnostic and experimental purposes;
 - 2.5 clinical observation;
 - 2.6 preparation of animals for surgery;
 - 2.7 monitoring of animals before, during and after an operation;
 - 2.8 performance of minor surgical procedures such as lancing of abscesses and suturing of superficial wounds;
 - 2.9 assisting with experimental surgical procedures;
 - 2.10 use of tranquilliser dart gun and blowpipe;
 - 2.11 capture of wild animals for the purpose of research;
 - 2.12 transportation of experimental animals;
 - 2.13 training and examination of trainee laboratory animal technologists; and
 - 2.14 teaching of students or researchers who require training in any specific aspect of laboratory animal technology.

Execution of general services

- 3.1 The services referred to in rule 2 shall –
 - (a) be carried out under the supervision of a veterinary or medical practitioner; and
 - (b) be performed on experimental animals only.
- 3.2 Rule 2 shall not be construed in a manner so as to prohibit –
 - (a) a veterinarian or a veterinary specialist from performing the services referred to in rule 2; and
 - (b) other para-veterinarians from performing procedures as set out for their profession.

Special services

4. For purposes of the Act the following services shall be deemed to be special services which pertain to the para-veterinary profession of laboratory animal technologist:
 - 4.1 daily general care of laboratory animals;
 - 4.2 management of various breeding programmes;
 - 4.3 production of specified pathogen-free animals;
 - 4.4 use and management of specialised animal house equipment;
 - 4.5 maintaining and monitoring of animal house environment;
 - 4.6 control of sanitation of hygiene in the animal house;
 - 4.7 sterilisation and disinfection of the animal house and animal house equipment;
 - 4.8 supervision over the feeding of experimental animals including the preparation of feed for special diets;
 - 4.9 biohazard containment in the animal house including endogenous and exogenous containment;
 - 4.10 general supervision, administration and use of laboratory animal facilities; and
 - 4.11 conducting of experiments with experimental animals for any of the following purposes:
 - (a) the advancement of knowledge;
 - (b) to test a hypothesis;
 - (c) to supply a product;
 - (d) to provide organs, tissues or sera;
 - (e) to act as a host;
 - (f) to impart or demonstrate existing knowledge;
 - (g) to learn to teach surgical and other techniques;
 - (h) to comply with statutory requirements for testing or collecting data on any substance or product; and
 - (i) to make audiovisual recordings of any of the above.

Execution of special services

- 5.1 The services referred to in rule 4 shall be performed on experimental animals only.
- 5.2 Rule 4 shall not be construed in a manner so as to prohibit –
 - (a) a veterinarian or veterinarian specialist from performing the services referred to in rule 4; and
 - (b) other para-veterinarians from performing procedures as set out for their profession.

Code of conduct for persons practising the profession

- 6.1 A person who practises the para-veterinary profession of laboratory animal technologist shall base his or her personal and professional conduct thereon that –
 - (a) he or she is a member of a learned and honourable profession

who is required to act at all times in a manner that shall maintain and promote the prestige, honour, dignity and interests of the profession and of the persons by whom it is practised;

- (b) he or she is morally obliged to serve the public to the best of his or her ability by maintaining at all times the highest standards of humane care of laboratory animals and professional conduct;
- (c) he or she shall not seek any personal advantage at the expense of any colleague in the profession; and
- (d) he or she shall not permit himself or herself to be exploited in a manner which may be detrimental to an animal, a researcher, the public or the profession.

6.2 A laboratory animal technologist shall –

- (a) execute the instructions of a veterinarian discerningly and faithfully;
- (b) refuse to take part in any unethical behaviour or procedure;
- (c) keep himself or herself informed of all the statutes and statutory provisions which affect him or her in the practising of the profession;
- (d) be familiar with the ethical rules pertaining to the profession of laboratory animal technology and shall promote these rules at all times;
- (e) treat any information acquired during the course of his or her employment as strictly confidential and shall not divulge such information to any person except his or her employer;
- (f) refrain from expressing any criticism in public through which the reputation, status or practice of a colleague in the profession is or could be undermined or injured, or through which a reflection is or could be cast on the probity, skill, methods or conduct of such a colleague; and
- (g) at all times keep detailed and accurate records of all information and experiments and which shall be kept on file for at least five years.

6.3 All persons practising as laboratory animal technologists work for the same good cause and they shall therefore co-operate with each other and the authorities concerned to promote that cause.

6.4 The place at or from which a person practices as a laboratory animal technologist shall comply with the applicable minimum standards for experimental animals as determined by the Council from time to time.

6.5 When advertising of any nature is undertaken, a laboratory animal technologist must be aware of public opinion and of any possible implications which may prove detrimental to the profession of laboratory animal technology.

6.6 The fundamental responsibility of a laboratory animal technologist is to provide optimal and exemplary standards of humane animal care to experimental animals at all times.

Annexure 2. Application for ethical review of a proposal to use sentient animals (including their embryos and fetuses) for either research, teaching or testing

MEDICAL RESEARCH COUNCIL

ETHICS COMMITTEE FOR RESEARCH ON ANIMALS (ECRA)

APPLICATION FOR ETHICAL REVIEW OF A PROPOSAL TO USE SENTIENT ANIMALS (INCLUDING THEIR EMBRYOS AND FETUSES) FOR EITHER RESEARCH, TEACHING OR TESTING.

- This application must be typed.
- It must be signed by the Principal Investigator (the applicant) and other persons who are vouching for specialised aspects of the experimental design (i.e. statistician, safety officer, and persons responsible for supervising the use of scheduled medicinal substances.
- The application needs to be written simply, briefly and *is not to exceed* the framework of the spaces provided.
- The application should be mailed to the Secretary of ECRA, PO Box 19070, Tygerberg, 7505, or faxed to (021) 938-0200, to arrive before the MRC's quarterly deadline dates for submissions
- Telephone enquiries on any ECRA-related matters may be directed to either the Chairman or Secretary of the ECRA c/o MRC, at (021) 938-0911.

Application No.
To be allocated by ECRA

A. APPLICANT

Name:		Applicant's Title:	
Department:			
Tel. Nos: (w)		Fax:	Cell:
e-mail address:			
Qualifications		Appropriate Experience in Animal Research (Type of studies and years of experience)	

B. CO-WORKERS

(involved directly with procedures on animals)

Name:			
Department:			
Telephone Number:			
E-Mail address:			
Qualifications and/or SAVC Registration No.			
Appropriate experience in animal research			

C. OTHER CO-WORKERS

(Collaborators)

Name	Department/Institution	Qualifications	Nature of involvement

D. ACCREDITATION COMPLIANCE

List the names (and accreditation numbers) of all the above persons who have successfully completed the institutional course of accreditation to use the institution's laboratory animal facilities and perform animal experiments.

	Name	Accreditation No.		Name	Accreditation No.
1.			5.		
2.			6.		
3.			7.		
4.			8.		

E. DECLARATION

1. Moral philosophy

The ethical review of proposed animal experiments is predicated upon the acceptance by the MRC 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 the protection of the environment.

2. Animal interests

In the use of laboratory animals, 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 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 their 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; and
- not unnecessarily repeat animal experiments the outcome of which are already known or are 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:

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

- **Refinement** of the experimental methodology to be adopted by the implementation and if necessary 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.

4. Animal protection

Animals should be protected from research designs which may cause 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 MRC's objectives in advancing knowledge, education, science and human and animal welfare through research, be based on a plausible hypothesis and have a reasonable prospect of yielding good results.

6. 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.

7. 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 under Section E and will personally undertake to see that these are upheld in the conduct of this study, should it be approved.
- 7.2** I agree not to deviate from the approved protocol without obtaining ECRA 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.
- 7.3** 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, and the care and handling of the species being used.
- 7.4** I undertake to see that accurate and up-to-date clinical records are maintained on all experimental procedures performed on animals, and that daily records relating to their treatment, health and welfare are kept over the experimental period described in this study.
- 7.5** At the conclusion of the study I undertake to report on its outcome to the Animal Ethics Committee, 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.

.....
Signature of Applicant

.....
Date

F. PEER REVIEW STATEMENT SUPPORTING THIS RESEARCH PROPOSAL

(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)

(tick answers)

I declare that this research protocol has been peer-reviewed by the

Scientific Committee

Faculty Committee

External Review Committee

Other (specify which).....

of the (Institute/Unit)

on (date).....and has been judged to be relevant, designed in accordance with accepted scientific practices and norms, and is in the opinion of the reviewers likely to be successful in achieving its objective.

(Print name)

.....

Signature, Chairman of reviewing body **Date**

G. PROTOCOL

1. Title of experiment or procedure:
(Use key words that specifically describe the animal experiment, and detail the animal species to be used)

2. NATURE OF PROJECT (tick applicable answers)

New study

Extension of approved project

Amendment/s to approved project

Research

Training

Production of biologicals for research/diagnosis/testing or other purposes (specify)

If training, for which course

No. of course participants

Source of funding for study

Expected starting date

Expected completion date

3. Background information

(Provide a brief introductory statement (a non-scientist's summary) that explains what problems, questions, needs or scientific or clinical observations or new ideas have led to the planning of the experiment. Include a few key journal references to substantiate viewpoints.)

4. Aim/s of the proposed study

(State these briefly and succinctly)

5. Potential benefits of the research findings

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

6. Hypothesis

(If an 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. Animal requirements

Animal species:

Strain:

Gender / Bodymass / Age: ////

Number required to achieve the purpose of this study:

Microbial status:

Source of animals:

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 what non-sentient model/s were considered and on what grounds they were rejected. Provide a brief narrative description of the methods and sources used to consider alternatives to the use of animals in this study.)

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. Animal caging and care

(Briefly describe how the animals will be caged and what provisions have been made for their physical and psychological well-being, i.e. comfort, socialisation, behavioural needs and enrichment of their cage environment. Also state what provisions have been made to monitor the animals after they have been treated or undergone surgery, the frequency of observations, the behavioural and other signs being looked for which suggest illness, distress or pain, and state how they will be responded to.)

11. Statement of animal care competence, expertise and experience

(Provide a short statement of the scientific knowledge, competence and experience of the person appointed to ensure the comfort, health and humane treatment of the animal subjects in this study. If procedures specific to the practising of the Veterinary or Para-Veterinary Profession are to be performed in this study, authorisation by the South African Veterinary Council may need to be obtained as a prerequisite for this application. If this has already been done, name the authorised person and provide the authorisation number.)

12. Experimental design

(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)

13. Experimental procedure/s

(Describe briefly in short annotated sentences and in sequence all the steps that will be performed in conducting the proposed experiment. These include: the arrangement of animals into groups, assignment of treatments to groups, selection of samples (if body fluids, give routes of collection and volumes), operative procedure, sampling procedure, parameters to be measured, data to be collected, outline of analysis to be performed, statistical tests, and probability level of confidence to be adopted (a non-scientist's summary is required).

14. Restraint of the animals

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

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. Categorise these as minimal, intermediate or high (with reference to the abridged scale in the MRC's *Guidelines on Ethics for Medical Research* book 3: Use of Animals in Research and Training (point 9.3.18), for assessment of the severity of scientific procedures on animals derived from the report produced by the Working Party of the Laboratory Animal Science Association, *Laboratory Animals* 1990; **24**: 97-130). Give their likely duration in time. Describe what specific steps will be taken to alleviate these conditions through the use of ataractics, dissociative agents, analgesics, anaesthetics or other methods, and state how effective these are likely to be.)

16. Fate of animals and their disposal at the end of the study

(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, 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.)

17. Administration of scheduled medicinal substances (Medicines Control Act)

(List all substance administration 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 Schedule 3 - 6 medicinal substances and other substances and provide their acceptance of this responsibility by signature.)

SUBSTANCE	ROUTE/SITE OF ADMINISTRATION	DOSE	FREQUENCY	TO BE ADMINISTERED BY

Responsible person (print name)

Qualification:

Acceptance signature:

Date:

18. Statistical analysis

(Describe briefly how the data obtained from the study will be analysed statistically and by whom the analyses will be performed)

19. 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)

20. Technical support and assurance of competence

(Describe who will be responsible for the pre, intra- and postoperative (or experimental period) care of the animals and give an indication of their experience and competence in monitoring clinical changes in the animals. Briefly state what clinical and behavioural criteria will be specifically monitored to assess the animals' well-being.)

21. End-points for experiments that induce illness in animals

(Give the end-points of data collection in experiments or procedures that may be expected to 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.)

22. Identify the person/s who will be empowered to decide that a humane end-point has been reached in this study.

Name/s

Signature/s (denoting acceptance of this responsibility)

.....

23. Staff activities

(Describe (name and duties) the specific activity of each staff member who will be involved with the procedures)

24. Biohazard statement

(Does the project pose any hazards to other animals and staff from the use of either infective agents, toxic substances, carcinogenic agents or ionising radiation? If it does, state the specific safety procedures to be adopted to contain these hazards. Provide a brief approval statement below from the Institutional Safety Officer to provide assurance of safety for this project with this person's signature of ratification. If available, also append the laboratory's occupational safety protocol and/or standard operating procedures to promote safe practices and a safe working environment.)

Safety officer name (print):

Signature:

Date:

25. Repetition of experimental procedures

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

Annexure 3. A decisional system for the ethical evaluation of animal experiments by Animal Research Ethics Committees (after Stafleu *et al.*¹⁴)

FUNCTIONS OF THE SYSTEM

- **Checklist function:** The system provides a checklist of the normally relevant factors that should be considered and assessed.
 - **A heuristic function (how to solve it):** The system focuses on the decision points. It demands an explicit justification of choices and shows the consequences of each choice.
 - **A normative function (how to work it out):** The system enables a moral stance to be taken through assigning numerical weights to relevant issues as factors, and then using these values to compare the potential benefits to humans to the potential harm to animals in the proposed animal study.
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THE PROCESS

The process comprises eight steps, as follows:

- 1. STATE THE GOAL AND POTENTIAL BENEFITS OF THE EXPERIMENT** (ECRA Ref. No.).

Note: This is a statement of comprehension of the aims and rationale of the animal study by the ECRA. It is to be brief and succinct and made in non-scientific language, beginning with words: "This study or procedure is intended to". State what is being attempted, what outcome is being hoped for, and how this may impact scientifically in terms of either providing new information or information that may alleviate either human or animal suffering, mortality, or environmental harm, or how it may promote human or animal interests.

2. ASSESS AND SCORE HUMAN INTEREST INVOLVED IN THE ULTIMATE GOAL IN TERMS OF WELFARE, KNOWLEDGE AND ECONOMIC INTERESTS.

a) Score the human interest in terms of benefits to human and animal health and welfare and/or preservation and protection of the environment on a scale of 0 - 10.

(Can the findings of the study significantly contribute towards the prevention or alleviation of human or animal suffering, morbidity, or death, or halt or reverse ecological or environmental harm?)

HUMAN INTEREST (designated H) Score: H = _____ (0 - 10)

0 1 2 3 4 5 6 7 8 9 10 (possible scores)

Criteria for operationalising the above scale:

- 0 = no conceivable gains (e.g. Replication of existing research with no theoretical or methodological innovation. Minor educational value only)
- 5 = moderate gains likely (e.g. Some improvements in understanding, treatment, prevention of illness)
- 10 = highly important benefits likely (e.g. Prevention or treatment of a major health condition such as tuberculosis, diabetes, etc.)

b) Score the human interest in terms of potential gain of new scientific knowledge and its value to science on a scale of 0 - 5

(Can the findings of the study either lead to new hypotheses, or help to resolve or overcome problems worth solving?)

KNOWLEDGE INTEREST (designated K) Score: K = _____ (0 - 5)

0 1 2 3 4 5 (possible scores)

Criteria for operationalising the above scale:

- 0 = no scientific gains likely (e.g. Well researched and understood area of minor educational value only)
- 3 = moderate scientific gains (e.g. Refinement of existing knowledge or hypotheses)
- 5 = highly significant scientific gains (e.g. Potentially a major qualitative advance in theoretical sophistication)

c) Score the human interest in terms of the potential social and or economic benefits to humans and or animals on a scale of 0 - 5

(Can the findings of the study lead to benefits to either/or the national economy, industry, producers and consumers or impact positively on animal/environmental interests?)

ECONOMIC INTEREST (designated E) Score: E = _____ (0 - 5)

0 1 2 3 4 5

Criteria for operationalising the above scale:

- 0 = no conceivable benefits (e.g. Illustrative, academic or minor educational value only)
- 3 = some benefits likely (e.g. Some alleviation of economic hardship, especially for vulnerable or disadvantaged human populations. Economic improvement to non-human animals, such as especially vulnerable, exploited or endangered species may be evident as improvements in health, nutritional status, etc.)
- 5 = major benefits likely (e.g. Significant and sustained improvements to human and non-human populations with regard to the above considerations)

3. CALCULATE THE TOTAL INTEREST OF THE ULTIMATE GOAL (DESIGNATED IUG)

Use the formula that produces the **highest IUG score** (0 - 10) from one of the four following propositions:

- (i) _____ (H) = _____ (IUG)
- (ii) $\frac{\text{_____ (H)} + (\text{either } \text{_____ (K)} \text{ or } \text{_____ (E)}) \times 2}{2} = \text{_____ (IUG)}$
- (iii) _____ (K) + _____ (E) = _____ (IUG)
- (iv) $\frac{\text{_____ (H)} + (\text{_____ (K)} + \text{_____ (E)})}{2} = \text{_____ (IUG)}$

4. ASSESS AND SCORE THE HUMANENESS AND RELEVANCE OF THE PROPOSED EXPERIMENT IN SIX STEPS (i - vi), AS FOLLOWS:

Score

(i) Is replacement with non-sentient animals possible? (0 or 10)	If Yes score 0 If No score 10 (i) _____
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(ii) Rate the general methodological soundness of the study (0 - 10)	If score <7 score 0 (ii) _____
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0 1 2 3 4 5 6 7 8 9 10 (possible scores)

Criteria for operationalising the above scale:

- 0** = Unsound methodology (e.g. *Ad hoc* experimentation, casual clinical observations, poor or unreliable measures, etc.)
- 6** = Reasonable methodology, flaws apparent (e.g. lacking proper statistical controls, poor prospects for making inferences, inappropriate statistical model; *N* too low to achieve significance, etc.)
- 7** = Sound methodology, appropriate statistical model and controls, some improvements possible
- 10** = Rugged methodology, innovative design, well-considered statistical model (e.g. Original research design, likely to make a contribution to knowledge)

Note: Scores of 6 and 7 are effectively critical score thresholds.

(iii) Rate the application of humane experimental principles (application of the 3 Rs) (0 - 10)	If score <7 score 0 (iii) _____
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0 1 2 3 4 5 6 7 8 9 10 (possible scores)

Criteria for operationalising the above scale:

- 0** = research subjects could be replaced by non-sentient systems, **OR** proposed study involves excessively large sample (when effect sizes are known, or may be estimated) **OR** procedures involve the infliction of physical and/or psychological

discomfort, restraints or loss of autonomy which is preventable

- 6** = some optimisation necessary for 3 R criteria to be met (e.g. It is clear that changes can be made in one or more areas to produce more satisfactory compliance)
- 7** = a reasonable balance is seen with regard to humaneness (3 Rs) and other considerations
- 10** = scrupulous attention has been given to the criteria and the proposed study is entirely convincing in terms of compliance with 3 R principles

(iv) Rate the necessity/relevance of the study to advance science and provide new knowledge (0 - 10)

If score <5 score 0 (iv) _____

0 1 2 3 4 5 6 7 8 9 10 (possible scores)

Criteria for operationalising the above scale.

- 0** = study is redundant, or irrelevant and no advances are likely to be realised
- 4** = research replicates previous studies without refinement, or the research rationale is unconvincing in terms of the potential for producing new knowledge
- 5** = research has a reasonable prospect of generating scientific advances
- 10** = research has clear potential to generate valuable scientific advances

(v) Rate the probability of a successful outcome (0 - 10)

Score 0 to 10 (v) _____

0 1 2 3 4 5 6 7 8 9 10 (possible scores)

Criteria for operationalising the above scale:

- 0** = no likely prospect of research succeeding
- 4** = prospects are somewhat doubtful
- 5** = reasonable prospect of success
- 10** = virtual certainty of success

(vi) Rate the quality of the research group proposing the study (0 - 10)

If score <5 score 0 (vi) _____

0 1 2 3 4 5 6 7 8 9 10 (possible scores)

Criteria for operationalising the above scale:

- 0** = unqualified, non-accredited or unsuitable personnel
- 4** = problems are known to exist with group: e.g. known problems with track record, reputation, capacity, objectivity, or ability to conduct acceptable research
- 5** = no reservations about group's capacity to conduct scientific research
- 10** = experienced, highly rated group with excellent scientific and moral credibility

Then calculate the relevance and humaneness score (designated R)

Total score sum of $\frac{(i) \text{ to } (vi)}{60} = \text{_____ (R)}$

50

Note: If R is less than 0.65 the proposal will be deemed to be inadmissible.

5. CALCULATE THE HUMAN INTEREST (DESIGNATED HI) COMPONENT INVOLVED IN THE EXPERIMENTS

Interest of ultimate goal (IUG) value x relevance (R) value = HI

_____ (IUG) x _____ (R) = _____ HI

(Possible score 0 - 10)

6. ASSESS AND SCORE THE HARM TO ANIMALS' INTERESTS IN THE PROPOSED STUDY

(i) **Actual discomfort to single animal subjects (designated A, range 0 - 4)**

None = 0
Slight = 1
Moderate = 2
Severe = 3
Very severe = 4 A = _____

(ii) **Duration of discomfort to single animal subjects (designated D, range 0 - 2)**

Short or none = 0
Medium and/or frequently = 1
Long-lasting and/or
Very frequently = 2 D = _____

(iii) **Number of animals to be killed in study (designated N, range 0-2)**

<10 animals = 0
10 - 100 animals = 1
>100 animals = 2 N = _____

(iv) **Calculate total discomfort (designated T, range 0 - 6) using the following formula:**

$$A + \frac{D + N}{2} = T \text{ (possible score 0 - 6)}$$
$$\underline{\quad} + \frac{\underline{\quad}}{2} = \underline{\quad} \text{ (T)}$$

(v) **An intrinsic value of 2 (designated IV) is accorded as an additional weighting value for the animal interest.**

(vi) **Psychological complexity of the animals (designated P).**

P = Species Considerations (SC) + Sociability of Species (SS)

Species Considerations Scores	Sociability Scores
Non-human primates = 1	Highly gregarious = 1
Other vertebrates = 0.5	Moderately gregarious = 0.5
Cold-blooded animals = -2	Solitary species = 0

(SC) _____ + (SS) _____ = _____ (P) (possible scores = -2 to +2)

7. CALCULATE THE HARMED EXPERIMENTAL ANIMAL'S INTERESTS, DESIGNATED AI, USING THE FORMULA:

Total discomfort (T) + (IV = 2) + Psychological complexity (P)
= Animal Interest (AI)

(T) _____ + 2 + (P) _____ = _____ AI
(Possible score = 0 - 10)

8. ASSESS THE ETHICAL ACCEPTABILITY OF THE EXPERIMENT BY COMPARING HUMAN INTEREST (HI) (BENEFIT) VERSUS THE ANIMAL INTEREST (AI).

If the Human Interest (HI) _____ ≥ _____ the Animal Interest (AI)
the experiment **is admissible**.

If the Human Interest (HI) _____ < _____ the Animal Interest (AI)
the experiment **is inadmissible**.

Signed: Chairperson of Animal Ethics Committee

Print name:

Date:

Note: The Decisional system can be abbreviated and be scored and assessed on a single A4 page. In this booklet we have condensed it into 2 pages, overleaf. A single-page template can be obtained on the MRC's website, <http://www.sahealthinfo.org/ethics/index.htm>

**ETHICAL ANALYSIS OF A PROPOSAL FOR USE OF ANIMALS
FOR RESEARCH, TESTING AND TEACHING**

APPLICATION NO: _____ **PRINCIPAL INVESTIGATOR:** _____

TITLE: _____

1. Goal and potential benefits of the experiment or procedure.

2. Human, Knowledge and Economic Interests.

$$H = \boxed{} \quad K = \boxed{} \quad E = \boxed{}$$

(0 - 10) (0 - 5) (0 - 5)

3. Total Interest of Ultimate Goal (IUG)

(i) $H = \boxed{}$ IUG

(ii) $\frac{H + (\text{either } K \text{ or } E)}{2} \times 2 = \boxed{}$ IUG

(iii) $\frac{K + E}{2} = \boxed{}$ IUG

(iv) $\frac{H + K + E}{2} = \boxed{}$ IUG

Highest IUG Score $\boxed{}$ (0 - 10)

4. Humaneness and Relevance (R)

- | | | |
|---------------------------------------|---------------|-------|
| (i) Non-sentient replacement | (0 or 10) | _____ |
| (ii) Methodological soundness | (0 - 10) | _____ |
| (iii) Application of 3 Rs | (0 - 10) | _____ |
| (iv) Necessity/Relevance of study | (0 - 10) | _____ |
| (v) Probability of successful outcome | (0 - 10) | _____ |
| (vi) Quality of research group | (0 - 10) | _____ |
| | TOTAL: | _____ |

Calculate $\frac{\sum i \text{ to } vi}{60} = \boxed{}$ (R)

Is $R > 0,65$? If not, the study is inadmissible, if $> 0,65$ continue with the analysis.

5. Calculate Human Interest.

IUG ____ x ____ R = HI

6. Assess and score the Harm to Animal Interest.

Deprivation, discomfort, fear, distress, pain to a single animal (A)		Duration of discomfort (D)		No. of animals in study to be killed (N)	
None	0	Short or None	0	< 10	0
Slight	1	Medium & frequently	1	10 - 100	1
Moderate	2	Long lasting & }	2	> 100	2
Severe	3	Very frequently }			
Very severe	4				
A = _____		D = _____		N = _____	

Calculate total discomfort (T) $\frac{A + D + N}{2} = \text{input} \quad T (0 - 6)$

Psychological complexity (P)		Sociability Scores (SS)	
Species (SP): Non-human primates	1	Highly gregarious	1
Other vertebrates	0.5	Moderately gregarious	0.5
Cold-blooded animals	-2	Solitary species	0
SP = <input type="text"/>		SS = <input type="text"/>	

SP _____ + SS _____ = P

7. Calculate the Harmed Animal Interest (AI).

T _____ + 2 (IV) + _____ P = AI (0 - 10)

8. Ethical Judgement.

HI ≥ AI = Admissible (tick)

HI < AI = Inadmissible (tick)

Signature Chairperson of ECRA

Date:



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