REGULATION OF CERTAIN SCIENTIFIC PROCEDURES IN VICTORIA
Prevention of Cruelty to Animals Regulation 92(20), 95(16)

APPLICATION FOR MINISTERIAL APPROVAL TO CONDUCT SCIENTIFIC PROCEDURES INVOLVING DEATH AS AN ENDPOINT

Explanatory Notes

- Scientific Procedure(s) involving 'death as an endpoint' refer to procedure(s) 'where the death of the animal is a deliberate measure of the procedure and there will be no intervention to kill the animal humanely before death occurs in the course of the procedure'.

- Persons who seek approval to conduct scientific procedures, or a series of scientific procedures involving death as an endpoint must after making application to their nominated Animal Ethics Committee (AEC), apply for Ministerial approval to conduct such procedures. The proposal must be given preliminary assessment by the AEC and a copy of the application to the AEC and relevant comments from the AEC must accompany the application for Ministerial approval.

- The Department of Economic Development, Jobs, Transport & Resources (DEDJTR) will assess this application and make recommendations to the Minister as to whether the application should be approved. It is the responsibility of the investigator making this application to provide sufficient, detailed information as per the application below which will be held in confidence by the DEDJTR.

- In particular any relevant legislation, which requires lethal testing or toxicity testing involving death as an endpoint, for example registration of a product, diagnostic evaluation or lethal disease progression, should be disclosed in this application.

- A separate application must be submitted by an applicant for <u>each project</u> which involves death as an endpoint. Applications should be submitted well in advance as each application may take up to 2 months with the assessment process.

- Documents to be submitted for each application:
- A completed application form for Ministerial approval
- A completed AEC application and relevant AEC comments once submitted to the nominated AEC for preliminary assessment
- All Standard Operating Procedures (SOPs) and other supporting documents cited in the AEC application

Documents are to be submitted to:

The Minister for Agriculture,
C/ Manager Licensing and Audit
Biosecurity, DEDJTR
475 Mickleham Rd
Attwood, VICTORIA 3049

Any questions can be directed to the Manager Licensing and Audit, Biosecurity on 03 9217 4107.

INFORMATION TO BE PROVIDED

Note that dotted lines indicate where information is to be submitted. Their lengths are NOT an indication of the amount of material required. Submissions with insufficient information will be returned for elaboration.

1. The proposal

1.1 Title of proposal: ……...……...

1.2 AEC Identification Number: ……

1.3 Principal Investigator (PI) submitting the proposal and contact details (email, phone, post)
……..……..……..

1.4 Licence under which PI would conduct the procedures: ……...

1.5 Select the appropriate box and carefully explain how these scientific procedures are related to your selection:

- ☐ potentially life saving treatment for animals or human beings - ……..…….; or
- ☐ research in connection with cancer in animals or human beings - …...……; or
- ☐ development and assessment of the humaneness of vertebrate pest control agents -……
……...; or
- ☐ investigation of environmental contaminants - …….…….

2. Regulatory Requirements

2.1 Are these procedures/tests required by State or Commonwealth legislation? If so, provide details of the relevant legislation - …….

2.2 Are these procedures/tests required for export of the chemical or biological agent being tested? If so, name which countries require these tests - ……...

3. Ongoing program or series of scientific procedures – if the proposal is part of an ongoing testing/monitoring program, the following information which summarises the results of this death as an endpoint testing performed by the licensed institution over the last 12 months is required. Write 'N/A' (not applicable) as appropriate.

3.1 The actual numbers of animals used in such procedures/testing over the last 12 months. Alternatively it may be most practical to use the most recent calendar year return figures - ……
…….

3.2 How many animals died (not euthanased) as a direct result of these procedures/testing over the last 12 months? (Case Fatality and Survival rates may be provided)……...

3.3 Associated with this testing program how many animals were euthanased over the last 12 months, as an early end point? …….……..

3.4 Any improvements or progress which has been made in the course of conducting such procedures/testing should be described here, particularly towards the goals of replacement, reduction and refinement (including humane endpoints implemented): ……

4. Alternatives to animal use and death as an endpoint. By answering the following, please explain how the objective of the scientific procedure cannot be achieved by other scientific means.

4.1 What non-animal alternatives are available to replace the proposed use of animals? (For example, ELISA, other in vitro assays, computer-modelling etc). Please provide evidence of the search tools employed (including web addresses) and the dates, key words used in any web based searching. Please explain why these alternatives cannot be used by the applicant…….

4.2 What alternatives are available to reduce the numbers of animals proposed for these procedures/testing? …….

4.3 What is the specific justification for the number of animals proposed? Please note if a biological statistician has approved these numbers and experimental design……

4.4 What alternatives are available to avoid the use of death as an endpoint? (For example, use of clinical, biochemical or pathological changes/markers as an indicator of the potency or toxicity of the agent being tested. Alternatively, the use of computer modelling, videos or other media to demonstrate toxicity or disease progression……...

5. Specific information about the procedure(s) and their impact

5.1 Name of the agent to be tested/used in the procedure: …….

5.2 Description of the agent (physical, chemical), including any features that may influence animal health: …….

5.3 Route of administration: ……...

5.4 Dose or concentration:……..

5.5 Will the agent be administered more than once? If so provide details. ……...

5.6 What are the anticipated immediate and delayed effects of the agent, or complications associated with the use of the agent on the health and welfare of the animals? ……

5.7 Will analgesia, sedation or anaesthesia be used? If so provide details of the drugs, route, dose rates and indications or stage of the procedure for use. …….

5.8 Describe the monitoring and care which will be given to animals post administration of the agent and during the course of any clinical illness during the project. ……..

5.9 How many animals are expected to die with acute toxicity in the course of the project? ……...

5.10 What provisions have been made to treat or kill animals adversely affected by the procedures? ……

5.11 What is the fate of the surviving animals after the project? ……...

5.12 If animals are to be killed, state the method to be used and the personnel responsible, indicating their position (veterinarian, animal carer, investigator etc). …….

6.Declaration. I declare the information supplied to be true, complete, and correct and that the procedures if approved will be carried out in accordance with any conditions determined by the Minister.

Name of Principal Investigator: ……..

Signature of Principal Investigator: …… Date: ……..