Summary

|  |  |  |  |
| --- | --- | --- | --- |
| Title of Project | |  | |
| Name of Primary Applicant | |  | |
| Name of Deputy | |  | |
| Anticipated Start Date |  | Anticipated End Date |  |
| Project Duration (months) | |  | |
| Funding Source | |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| Total Number of Animals Requested | |  | |
| Overall Pain/Distress Classification | |  | |
| Project Purpose | |  | |
| Related to previously approved project? |  | | If yes, give number: |
| Have reports been lodged? | |  | |
| Do you propose to publish the results? | |  | |
| If you do not propose to publish your results, please explain why. | |  | |

GLOSSARY:Scientific terms or abbreviations should not be used in this application unless unavoidable and if so, a suitable lay explanation must be provided.

|  |  |
| --- | --- |
| Scientific Terms or Abbreviations | Lay Explanation |
|  |  |

AEC approval of a project does not guarantee that animals, space for holding them, or assistance from animal facility staff, will be automatically available. Liaison with management of the animal facility is essential.

I have liaised with the relevant animal facility and have confirmation that the required resources are available. Please list the animal facility contact below.

|  |  |
| --- | --- |
| Name | Facility |
|  |  |

**Animal Information Summary Table**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Animal Group** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** |
| Ctrl/expt/sham |  |  |  |  |  |  |  |  |  |  |
| Sex |  |  |  |  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Species |  |  |  |  |  |  |  |  |  |  |
| Strain |  |  |  |  |  |  |  |  |  |  |
| Origin |  |  |  |  |  |  |  |  |  |  |
| Number |  |  |  |  |  |  |  |  |  |  |
| Age/weight |  |  |  |  |  |  |  |  |  |  |
| Purpose of experiment |  |  |  |  |  |  |  |  |  |  |
| Number used per month |  |  |  |  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Immune Competency |  |  |  |  |  |  |  |  |  |  |
| GMO? |  |  |  |  |  |  |  |  |  |  |
| Toxicology Study? |  |  |  |  |  |  |  |  |  |  |
| Anaesthesia? |  |  |  |  |  |  |  |  |  |  |
| Pain Management? |  |  |  |  |  |  |  |  |  |  |
| Pain/Distress Classification |  |  |  |  |  |  |  |  |  |  |
| Fate of Animals |  |  |  |  |  |  |  |  |  |  |

1. Short Lay Summary
2. Provide a lay description of the project and its aims, and its hypothesis**.**

Include an explanation of the new information or understanding sought as well as relevant citations. Attach cited papers to the end of this document.

1. In what way does this proposal relate to your previous or concurrent work?

Please explain how your proposal adds in a meaningful way to an existing body of knowledge.

1. Applicants

For higher degree students, the applicant must be the degree candidate supervisor.

|  |  |  |
| --- | --- | --- |
| **Primary Applicant (Project Holder)** | | |
| Name (include title) |  | |
| Applicant’s Institution and Department |  | |
| Contact Details (including after hours) | Email |  |
| Phone |  |
| Mobile |  |
| Correspondence to |  | |
| **Deputy Project Holder** | | |
| Name (include title) |  | |
| Applicant’s Institution and Department |  | |
| Contact Details (including after hours) | Email |  |
| Phone |  |
| Mobile |  |

Other Applicant/s

|  |  |  |
| --- | --- | --- |
| **Name (include title)** |  | |
| Applicant’s Institution and Department |  | |
| Contact Details (including after hours) | Email |  |
| Phone |  |
| Mobile |  |
| **Name (include title)** |  | |
| Applicant’s Institution and Department |  | |
| Contact Details (including after hours) | Email |  |
|  | Phone |  |
|  | Mobile |  |
| **Name (include title)** |  | |
| Applicant’s Institution and Department |  | |
| Contact Details (including after hours) | Email |  |
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| **Name (include title)** |  | |
| Applicant’s Institution and Department |  | |
| Contact Details (including after hours) | Email |  |
|  | Phone |  |
|  | Mobile |  |
| **Name (include title)** |  | |
| Applicant’s Institution and Department |  | |
| Contact Details (including after hours) | Email |  |
|  | Phone |  |
|  | Mobile |  |

1. Animals Source and Housing

|  |  |
| --- | --- |
| Source: |  |
| Animals held at: (including location, room number etc) |  |
| Transport requirements: |  |
| Procedures performed at: |  |
| Maximum number housed at any one time: |  |
| Maximum time held: |  |
| Special considerations: (is any special feeding, handling or isolation required?) |  |
| Have any of the animals been the subject of previous scientific or teaching activity? (ie Reuse: code ref 1.22, 1.24 and 2.3.15)  If so, explain why they are to be used again and include details of the previous use. |  |

1. Purpose of the Project (cross primary purpose only)

|  |  |
| --- | --- |
|  | The understanding of human or animal biology |
|  | The maintenance or improvement of human or animal welfare |
|  | The improvement of animal management or production |
|  | The achievement of educational objectives |
|  | Environmental study |

1. Do you propose to publish the results?

If not, please explain why. If the proposed work is not the subject of a grant application, what peer review mechanism will be applied to the scientific basis of the application?

1. Procedure Category (cross all appropriate categories)

|  |  |
| --- | --- |
|  | Observational Studies e.g. Behavioural study, feeding trial obtaining weights and body measurements. |
|  | Animal Unconscious; No Recovery: Animal killed prior to commencement of project or killed while under general anaesthetic |
|  | Minor Conscious Intervention; No Anaesthesia: e.g. injections, leg-banding, blood sampling, toe or ear clipping for identification purposes, implanting microchips without anaesthesia. |
|  | Minor Procedures with Recovery: e.g. Organ biopsies, implanting microchips under anaesthesia, micro CT. |
|  | Minor Surgery with Recovery: Implanting slow release devices, implanting abdominal transmitters, chronic cannulation of vessels. |
|  | Major Surgery with Recovery: eg: e.g. bone surgery, implanting abdominal radio-transmitters |
|  | Minor Physiological Challenge: e.g. minor infection, minor or moderate genetic deformity, early oncogenesis; residue testing. |
|  | Major Physiological Challenge: e.g. major infection, oncogenesis without pain alleviation; environmental deprivation for extended periods. |
|  | Death as an Endpoint: e.g. lethality testing, vaccine testing where death is a planned and necessary part of the study (see Code definition and clause 1.13). |

1. Pain/Distress Classifications (cross and complete where appropriate)

**No Pain or Distress**

|  |  |
| --- | --- |
| **Procedures** | **Extent and Duration** |
|  |  |
|  |  |

**Mild Pain or Distress**

|  |  |
| --- | --- |
| **Procedures** | **Extent and Duration** |
|  |  |
|  |  |

**Moderate Pain or Distress**

|  |  |
| --- | --- |
| **Procedures** | **Extent and Duration** |
|  |  |
|  |  |

**Substantial Pain or Distress**

|  |  |
| --- | --- |
| **Procedures** | **Extent and Duration** |
|  |  |
|  |  |

**Severe Pain or Distress**

|  |  |
| --- | --- |
| **Procedures** | **Extent and Duration** |
|  |  |
|  |  |

**Death as an Endpoint**

|  |  |
| --- | --- |
| **Procedures** | **Extent and Duration** |
|  |  |
|  |  |

1. Project Overview

Describe what happens to the animals from the time they are obtained until the time the project is completed. Please use language that would be understood by a general audience.

1. Experimental Plan

Please attach a flow chart either as a PDF at the end of this document (instructions on guide sheet) or insert flow chart as a JPEG or PNG file in this section of the document. Include animal numbers in each component of the flow chart.

1. Experimental Design

Please explain and justify your experimental design choices. These may include statistical calculations of required animal numbers, plans for randomisation and blinding and choice of controls.

1. Substances to Be Administered

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Administered Substance | SOP  Reference No. | Dose Rate | Frequency | Route Administered | Volume & Needle Size |
| Anaesthetic Agents | | | | | |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| Post Operative Analgesia | | | | | |
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|  |  |  |  |  |  |
| Tranquilisers | | | | | |
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|  |  |  |  |  |  |
| Antibiotics | | | | | |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| Other Substances | | | | | |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| Research Compounds/Test Substances/Devices/Biologicals | | | | | |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| Humane Killing Agents | | | | | |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

* 1. What experience do you have in using these agents?
  2. If this project involves the use of an administered substance/compound for which you do not have full knowledge of its effects, how are you going to manage this?
  3. If novel test compounds are to be used in an experiment or screening assay, what is known about the toxicity of these compounds? Please explain how this information is to be found or the lack of knowledge managed.

1. Has a mortality rate been included in the number of animals requested?

Attached a Mortality Sheet if applicable.

1. List in bullet points, possible adverse consequences to animals of the research interventions or procedures.

•

•

•

1. Animal Monitoring and Post-Operative Care – Identification of Potential Pain/Distress

Detail the monitoring that will be made of the animals during the experiment, especially if surgery is performed or illness is being induced. Attach your Clinical Record Sheet at the end of this document and identify who will complete it and at what frequency.

1. What will happen to the animal at the end of the procedure or project?

* If it is to be killed, what method is to be used?
* How will you determine the animal is dead? (Exsanguinations under anaesthesia do not ensure death. A method to ensure death must be employed.)
* How will the carcass be disposed of?
* If animals are not to be humanely killed at the end of the experiment, what is to happen to them?

1. Does the work pose health risks to other animals?  Yes  No

If yes, please provide details.

1. Ethical Issues
   1. Ethical Considerations

Please discuss the ethical issues that the AEC will need to consider when reviewing this proposed experimentation. (See Clauses 1.18-1.30 of the Code)

* Identify and justify all procedures to cause pain or distress. What steps will be taken to avoid or minimise such pain or distress?
* What is the welfare cost to the animal?
* In what way is the level of pain/discomfort justified?
* How does this mesh with the cost/benefit?
  1. Reduction
* Describe how you will reduce the number of animals used within this protocol.
* Describe the steps taken to reduce factors that are not part of the experimental design of the project and are known to contribute to variability of experimental results, including the use of animals of known genetic, biological and behavioural background.
* If both or single genders are used, you must elaborate as to how reduction was considered whilst considering your scientific merit.
  1. Refinement
* Please justify your selection of species.
* This is refinement of the procedures in order to improve the welfare of the animals.
* Please focus on the animals.
* The duration of activities must be no longer than required to meet the aim(s) of the project and must be compatible with supporting and safe guarding animal wellbeing.
* What steps will be taken to avoid or minimize such pain or distress?

* 1. Replacement

This answer should explain why animals need to be used at all. Your response should include the following:

* A list of any potential alternatives to animal use
* Whether any of these alternatives would be used
* Details of literature searches you have undertaken

1. If only using one gender, detail why both sexes cannot be used. Reference to relevant literature is required if sex-based physiology is cited as the basis of your choice.
2. If this is a disease model, include a description of how the model works. Detail the effects of progression of the disease process, identify humane end-points, and explain your previous experience with the model. If the reference is free and publicly accessible, then please just include the citation. Otherwise we would appreciate inclusion of the actual paper with the submission.
3. Safety Hazards and Regulatory Matters

|  | Details | Have all clearances/approvals been applied for/given in writing by the relevant committees?  If no, give an explanation. | | If approved give permit no. and expiry date |
| --- | --- | --- | --- | --- |
| Committee | Tick an option |
| Unsealed isotopes |  | Radiation Safety Committee (radiation.safety@sahmri.com) | Yes  No  Pending |  |
| Ionising radiation (Sealed sources) E.g. X-Ray or Gamma |  | Radiation Safety Committee (radiation.safety@sahmri.com) | Yes  No  Pending |  |
| Carcinogen/teratogenic or highly toxic chemicals including cytotoxic drugs IARC monographs groups 1&2 carcinogens, heavy metals and chemicals with a ChemWatch chronic or acute health risk rating of 4. |  | WHS & Environmental  (biosafety.committee@sahmri.com) | Yes  No  Pending |  |
| Pathogenic Organisms |  | IBC/Other  (biosafety.committee@sahmri.com) | Yes  No  Pending |  |
| Genetically Modified Organisms |  | IBC  (biosafety.committee@sahmri.com) | Yes  No  Pending |  |
| Health risks to staff |  | WHS | Yes  No  Pending |  |
| Health risks to other animals |  | Facility Manager | Yes  No  Pending |  |
| Human subjects or cells |  | Human Ethics Committee | Yes  No  Pending |  |
| Are the animals to be administered any substance, compound or biological product which is imported, or subject to, a Dept of Agriculture Import and/or *In Vivo* Use Permit?  If Yes:   1. Have you discussed the matter in writing with the appropriate institutional Quality Manager/ Compliance Officer and supplied the permit for review (quality@sahmri.com)? 2. What is the permit number and expiry date?   If No:  Should the source of your material change, you must inform the institutional Quality Manager/ Compliance Officer/IBC and you must inform the Animal Ethics Committee(s) in writing. | | | Yes  No  Yes  No |  |

1. Credentials of all those involved in the project

|  | Name and qualification | Detail the experience each participant has in the procedures to be undertaken with the species being used If no experience, describe how relevant training and supervision will be obtained. | In which procedure(s) is this person involved? | Date this person attended an Animal Users Training Day | Has the investigator been registered for competencies relating to the procedures in this application? |
| --- | --- | --- | --- | --- | --- |
| Chief Applicant(s) |  |  |  |  |  |
| Other People Participating |  |  |  |  |  |

1. Attachments Summary Checklist

|  |  |
| --- | --- |
| Type | Attachment |
| Flow Chart | Yes  No |
| Clinical Record Sheets | Yes  No |
| Unapproved or Project-Specific SOPs | Yes  No |
| Risk Analysis Form | Yes  No |
| Publications | Yes  No |
| Other  Please detail: | Yes  No |

1. Declarations

Declaration by the Primary Applicant

I hereby declare that:

1. I am familiar with and will comply with the relevant Commonwealth and State or Territory legislation and the requirements of the Australian Code for the care and use of animals for scientific purposes, 8th Edition 2013 (The Code).
2. To the best of my knowledge this proposal conforms to the Code (8the Edition 2013) and the South Australian Animal Welfare Act 1985
3. I have read Section 2 of the Code that sets down the responsibilities of investigators. I accept responsibility for the conduct of all procedures detailed in this application and for the supervision of all personnel delegated to perform any such procedures.
4. I agree to comply with procedures described and any conditions imposed by the Animal Ethics Committee.
5. Sufficient and adequate resources will be available to undertake the proposed study.
6. I will communicate all AEC conditions and directives to all named investigators.

|  |  |  |
| --- | --- | --- |
| Primary Applicant’s Name | Primary Applicant’s Signature | Date |
|  |  |  |

Declaration by the Other Applicant’s

I hereby declare that:

1. I am familiar with and will comply with the relevant Commonwealth and State or Territory legislation and the requirements of the Australian Code for the care and use of animals for scientific purposes, 8th Edition 2013 (The Code) and the South Australian Animal Welfare Act 1985 and its regulations.
2. I have read the application and I accept responsibility for the project when the Primary Applicant is unavailable.

|  |  |  |
| --- | --- | --- |
| Other Applicant’s Name | Other Applicant’s Signature | Date |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

Declaration by the SAHMRI Chair on behalf of the SAHMRI Animal Ethics Committee

I hereby declare that:

1. I am satisfied that the Primary Applicant and his/her associated team has the appropriate qualifications and experience to perform the work with minimum distress to the animals.
2. I believe this work meets the requirements of the Australian Code for the care and use of animals for scientific purposes, 8th Edition 2013 (The Code) and the South Australian Animal Welfare Act 1985 and its regulations.
3. I have read the application and I am satisfied that this work is of sufficient scientific merit to proceed and that adequate resources will be available to undertake the proposed study.

|  |  |  |
| --- | --- | --- |
| SAHMRI Chair  For and on behalf of the SAHMRI AEC | Chair Signature | Date |
|  |  |  |

**Attachment: Flow Chart (Question 11)**

Attach as PDF or if text or an image file, copy & paste into the field below

**Attachment: Relevant Clinical Record Sheets (Question 16)**

Attach as PDF or if text or an image file, copy & paste into the field below

**Attachment: Unapproved or Project-Specific SOPs**

Attach as PDF or if text or an image file, copy & paste into the field below

**Attachment: Risk Analysis Form**

Attach as PDF or if text or an image file, copy & paste into the field below

**Attachment: Relevant Publications**

Attach as PDF or if text or an image file, copy & paste into the field below

**Attachment: Other**

Attach as PDF or if text or an image file, copy & paste into the field below

***Delete these pages from your submission***

# **Guidelines when completing Applications**

**1. Lay Language**

A "layperson" is someone who is not qualified in a given profession or does not have a specialised or professional knowledge of a certain subject. All Animal Ethics Committees in Australia include lay members who do not have specialised biomedical knowledge or expertise. Therefore, they cannot be expected to understand scientific terms, expressions or jargon.

Lay language sections of applications should be written at a level that the general community could be expected to understand. Scientific terms should not be included unless they are in common, popular use. This means that lay language sections will often be less ‘scientific’ than an abstract for a scientific paper would be, but they need to convey adequate information to enable all Committee members to understand the aims of the project and an overview of the procedures.

**2. Animal Numbers**

* The justification of animal numbers in all elements of a project is usually derived from a power calculation. However, in a small proportion of cases, a power calculation is not appropriate, and other methods of achieving statistical validity need to be described and justified.
* Please use figures and flow charts where possible to detail what happens to the animals.

* Each power calculation should include:
* The key outcome measure of interest; if you're measuring more than one outcome, base the power calculation on the one outcome that will require the highest number of animals
* A reasonable power level; the convention is for power of 0.8, so use of any other power needs to be justified
* The formula or programme used to calculate the group size; including a screenshot or printout of the calculation is very helpful

**3. 3Rs**

The Animal Ethics Committee has the responsibility of assessing each application in isolation to balance the expected welfare cost of the research against its potential benefit. Although the application as a whole is designed to aid in any assessment, the response to the 3Rs question has a significant effect on the Committee's decision.

**The following tips should help with answering the 3Rs question to the satisfaction of the Committee:**

**• Ethical Issues** - start with the welfare cost to the animal, and then the research benefit (i.e. follow the question order). This is your chance to articulate the cost-benefit of the research.

The welfare cost may include:

* + producing distress/sickness
  + animal isolation
  + duration and intensity of pain
  + in a benign study, recognise the ethical cost in using animals for human or society needs

Then discuss the benefits of your research and describe the cost to the animals. It is useful to quantify the benefits, e.g. the number of sufferers of a condition.

List the adverse effects on welfare of your research so that it may be possible to distinguish an unexpected adverse event from an expected adverse event.

* **Reduction**- focus on the experimental design and statistics.

This should include:

* + how the power calculation relates to the numbers of animals requested
  + sharing of controls
  + randomisation and blinding
  + re-use of animals (carefully justified!)
  + other designs - washout phase, crossover if they reduce animal numbers
  + both genders used?
* **Refinement** - This is meant to cover refinement of the procedures in order to improve the welfare of, or reduce harm to, the animals. It is not a question to be answered in terms of how sophisticated the experimental plan or equipment used may be, but they should be presented in terms of how they directly affect your ability to look after the interests of the animals.

This could include:

* + analgesics/anaesthetics employed
  + provision of innate behavioural needs/social housing
  + smaller needle sizes/fluid volumes
  + catheterisation versus multiple venepuncture blood sampling
  + use of non-invasive imaging or other tests (breath test)
  + osmotic mini-pumps or telemetry devices
* reduced severity from published protocols e.g. less fasting, fewer challenges
  + humane endpoints/clinical record sheets
  + pilot studies to refine animal care
  + training/competence (leave until the end of this section)
* **Replacement**

This could include:

* + videos for teaching
  + cell culture
  + use of less sentient animals
  + patient surveys
  + mannequin/models

It's important to address the question of your literature search strategy

Useful Resources:

<http://www.nc3rs.org.uk/>  
<http://alttox.org/>  
<http://www.mawa-trust.org.au/>

<http://altweb.jhsph.edu/resources/searchalt/index.html>

* Other key principles to the 3Rs include Justification and Responsibility:
* **Justification:** The Code requires that projects using animals are to be performed only after they are justified, weighing the predicted scientific or educational value of the project against the potential effects on the wellbeing of the animals. Thus, the justification must take into account all aspects of the project that may have an adverse impact on the animals.
* **Responsibility:** The Code and the Animal Welfare Act 1985 state that the investigators who use animals for scientific purposes have personal responsibility for all matters relating to the wellbeing of the animals. They have an obligation to treat the animals with respect and to consider their wellbeing as an essential factor when planning or conducting projects. To meet these responsibilities, it is essential that investigators are knowledgeable about all factors associated with the project that may affect the wellbeing of the animals they use, mechanisms to minimise these effects, the monitoring and assessment of adverse effects on animal wellbeing, and appropriate actions to take if adverse effects are observed.

**4. Clinical Record Sheets and Mortality Sheets**

If you are performing any procedures on animals, even non-invasive ones (e.g. behavioural testing), you must monitor the wellbeing of each animal (unless it's a non-recovery procedure), and this monitoring must be documented by way of a Clinical Record Sheet (CRS).

Each CRS should be designed with specific attention to what the animal will be experiencing and its potential responses to that experience - you may start with a generic/standard CRS, but it should be suitably customised for each study.

Things to include in and clearly state on the CRS are:

* Date and time of the observations
* A scoring system for clinical criteria based on objective indices which indicate suffering or negative welfare impact
* Valid intervention points (i.e. based on clinical scores)
* Clear and well described interventions (e.g. an increase in monitoring frequency; provision of supportive therapies and nursing care; provision of additional analgesia; seeking and following veterinary advice)
* Humane end-points**\***
* A column for "other observations"

***\*****If body weight loss is one of the measures generally a loss of greater or equal to 15% may require euthanasia unless veterinary advice is obtained. In some other projects a justification for a 20% weight loss may be acceptable where the weight loss is acute and rapidly reversed if everything goes to plan. If tumour size (for subcutaneous tumours) is one of the measures, a volume of greater or equal to 1500 mm3 may require euthanasia, but this depends upon having good knowledge of the systemic effects of the tumour. Some tumours become large but have limited cachexia associated with them. The point being is that body weight is only one criteria which needs consideration and things like body condition scoring are often more important.*

Be careful to ensure that the intervention and end-points shown on the CRS match those described in the monitoring section of the application form!

**5**. **Disease Models**:

There are many animal models of disease described, and often researchers wish to introduce new models to their work. In order to help the AEC make an informed decision about the new model, we would appreciate the inclusion of literature references describing in detail the technique that the investigator is proposing to use. Ideally, the experimental protocol will be outlined in some depth in the reference. If the reference is free and publicly accessible, please just include the citation. Otherwise, we would appreciate inclusion of the actual paper with the submission.

**6. Drugs**:

The administration of drugs to an animal is a procedure. Details of dose and route of administration should be provided, where possible references to studies that have used the drugs in similar types of experiments should be included to provide support for the dose and choice of agent. If a drug is new or being used for a previously undescribed purpose, then a solid justification for the experiment must be provided, based on what is known about the agent. This could include *in vitro* data, or studies with compounds of similar activity or structure. For information regarding the use and dose rates for drugs consult the relevant SOP or one of the SAHMRI veterinarians.