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| SOUTH AUSTRALIAN ANIMAL ETHICS APPLICATION FOR ANIMAL ETHICS COMMITTEE APPROVAL OF PROJECT INVOLVING RESEARCH ANIMALS |

(NOT Wildlife, Teaching or Breeding Colony Maintenance)

Please do not use this form if you require University of Adelaide Animal Ethics Committee approval.

The University web form is accessible at the ethics website: <http://www.adelaide.edu.au/ethics/animal/guidelines/>

**To which committees are you submitting? Email completed form to:**

|  |  |
| --- | --- |
| Flinders AWC: School of Biological Sciences | [awsc@flinders.edu.au](mailto:awsc@flinders.edu.au) |
| Flinders AWC: School of Medicine | [aersc@flinders.edu.au](mailto:aersc@flinders.edu.au) |
| PIRSA/SARDI | PIRSA.AnimalEthics@sa.gov.au |
| SAHMRI | secretary.aec@sahmri.com |
| SA Pathology/CALHN | [SAPathologyAEC@sa.gov.au](mailto:SAPathologyAEC@sa.gov.au) |
| University of South Australia | [animalethics@unisa.edu.au](mailto:animalethics@unisa.edu.au) |
| Women's and Children’s Health Network (WCHN) | [Mary.Thorne@health.sa.gov.au](mailto:Mary.Thorne@health.sa.gov.au) |
| Wildlife | [DEWNR.WildlifeEthicsCommittee@sa.gov.au](mailto:DEWNR.WildlifeEthicsCommittee@sa.gov.au) |

Instructions

* This form is NOT to be used for Teaching or Breeding Colony Maintenance applications;
* After completing this form please refer to the relevant Animal Ethics Committee for the preferred method of submission via Word or pdf.

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| Office Use  Only | **Project Number:** |  | **Date Received:** |  | **Revision Number:** |  |

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| --- | --- |
| Title of Project |  |
| Name of Primary Applicant |  |
| Species/Strain(s) |  |
| Procedure Types (Refer Q7) |  |
| Pain Classifications  (Refer Q8) |  |

|  |  |
| --- | --- |
| Expected date for animal use to begin? |  |
| Expected date for animal use to end? |  |
| Project duration? |  |
| Does this application relate to a previously approved Protocol? | Yes  No |
| If so, give previous approval number(s) |  |
| Have reports on these projects been lodged? | Yes  No |
| Does this project involve any of the following: | Honours Student  Masters Student  PhD Student |
| Funds Source  (Grant ID is applicable) |  |
| Approval to share information | By submitting this application I give approval for this application and any information relating to it to be shared by South Australian Animal Ethics Committees and the Animal Welfare Unit within the Department of Environment, Water and Natural Resources for the purposes of administration, approval and monitoring.  Yes |
| Declaration of interest | Is there any actual or potential interest, including financial interest or other relationship or affiliation by any research/team member involved in the project that may affect judgements and decision regarding the wellbeing of the animals involved? See Code [Clause 2.7.4](http://www.nhmrc.gov.au/book/australian-code-practice-care-and-use-animals-scientific-purposes/2-7-responsibilities#2.7.4) [xxi]  Yes  No  If yes, outline the potential and any steps to be taken to ensure the ethical integrity of the project. |

Primary Applicant

Reminder: All Honours/Masters and PhD studies must be approved by an AEC. The applicant must be the degree candidate supervisor. The University of Adelaide requires ethics applications to be made using its online form.

|  |  |  |
| --- | --- | --- |
| Name (include title) |  | |
| Applicant's Institution and Department |  | |
| Contact details  (including After Hours) | Email |  |
| Phone |  |
| Mobile |  |
| Correspondence to |  | |
| Co-applicant | | |
| Name (include title) |  | |
| Institution and Department |  | |
| Contact details (including After Hours) | Email |  |
| Phone |  |
| Mobile |  |

Other Applicant/s

|  |  |  |
| --- | --- | --- |
| Name (include title) |  | |
| Institution and Department |  | |
| Contact details (including After Hours) | Email |  |
| Phone |  |
| Mobile |  |
| Name (include title) |  | |
| Institution and Department |  | |
| Contact details (including After Hours) | Email |  |
| Phone |  |
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| Name (include title) |  | |
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| Contact details (including After Hours) | Email |  |
| Phone |  |
| Mobile |  |
| Name (include title) |  | |
| Institution and Department |  | |
| Contact details (including After Hours) | Email |  |
| Phone |  |
| Mobile |  |

1. Short Lay Summary (Maximum 100 words)

A lay summary is a brief summary of a research project that is used to explain complex ideas and technical and scientific terms to people who do not have prior knowledge about the subject.

2. Provide a lay description of the project and its aims, and its hypothesis.

3. Animals Required

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Common Name | Scientific Name | Strain | Sex | Age or  Size | Number /  Month | Total  Number for  duration  of project | Explanation if total number is  unknown |
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4. Animals Source and Housing

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 prior to submitting this form.

*I have liaised with the relevant animal facility and have confirmation that the required resources are available.*

|  |  |
| --- | --- |
| *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? (i.e. Reuse: Code ref* (see [Clauses 1.22–1.24](http://www.nhmrc.gov.au/book/australian-code-practice-care-and-use-animals-scientific-purposes/section-1-governing#1.22) and [2.3.15](http://www.nhmrc.gov.au/book/australian-code-practice-care-and-use-animals-scientific-purposes-8th-edition-2013/2-3#2.3.15))  *If so explain why they are to be used again and include details of the previous use.* |  |

5. Other authorisations required

5.1 Is the acquisition, retention or use of the animals subject to any permit, law or regulation of the State or Commonwealth?

e.g. your licence number for teaching, research or experimentation in South Australia under the *Animal Welfare Act 1985*, Scientific permit number under the *National Parks and Wildlife Act 1972*, Protected native or imported species; Australian Bird and Bat Banding Scheme (ABBBS) Banding Authority; Ministerial Exemption under Section 115 of the *Fisheries Management Act 2007*, SA Health Department Controlled Substances Licence (if required)

Yes  No

If Yes, please provide details of the permit number and permit holder.

6. 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 education objectives. |
|  | Environmental study. |

7. Procedure Category (cross all appropriate categories)

|  |  |
| --- | --- |
|  | Observational Studies: e.g. behavioural study, feeding trial, pitfall trapping, obtaining weights and body measurements. |
|  | Animal Unconscious; No Recovery: Animal killed prior to commencement of project or killed while under general anaesthetic e.g. killing animals for voucher specimens. |
|  | Minor Conscious Intervention: No Anaesthesia: e.g. injections, leg-banding, blood sampling, fitting radio-collars, attaching transmitters with glue or tape, toe or ear clipping for identification purposes, implanting microchips without anaesthesia. |
|  | Minor Procedures with Recovery: e.g. Organ biopsies, attaching radio-collars or transmitters under anaesthesia, implanting microchips under anaesthesia, removing teeth, micro CT. |
|  | Major Surgery with Recovery: 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). |

8. Pain/Distress Classifications (cross where appropriate)

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Category** | **Procedures** | **Extent and Duration Suffering** |
|  | No pain or distress |  |  |
|  | Mild pain or distress |  |  |
|  | Moderate pain or distress |  |  |
|  | Substantial pain or distress |  |  |
|  | Severe pain or distress (Animals in this category must be humanely killed) |  |  |

9. Using Lay Language describe what happens to the animals from the time they are obtained until the time the project is completed. (Background Scientific Data should be included in Q 10).

10. Experimental Plan and Flow Chart (Attach if space is insufficient)

*If required, attach flow chart at end of document.*

11. Administered substances

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Administered substance | Dose Rate  (mg/kg) | Frequency | Route  Administered& needle size | Concentration (mg/ml) & total dose (mg) to be given | Possible adverse effects of administration or withdrawal of substance? |
| Anaesthetic Agents |  |  |  |  |  |
| Post-Operative Analgesia |  |  |  |  |  |
| Tranquillisers |  |  |  |  |  |
| Antibiotics |  |  |  |  |  |
| Other Substances |  |  |  |  |  |
| Research Compounds/Test  substances/Devices/  Biologicals |  |  |  |  |  |
| Humane Killing Agents |  |  |  |  |  |

11.1 What experience do you have in using these agents?

11.2 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? E.g. perform a Pilot Study?

11.3 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.

12. Animal Number Justification

12.1 Please refer to POWER calculations to explain how the animal numbers are derived.

* Multiple power calculations are required in applications featuring more than one experiment, i.e. where completely separate groups of animals are used to produce different outcome measures.
* Refer to [\*GPower](http://www.softpedia.com/get/Science-CAD/G-Power.shtml) calculation tool for assistance.
* There are a minority of instances where Power calculations are not possible. In such instances, applicants need to fully justify to the AEC how the proposed animal use meets, but does not exceed, the experimental goals.

|  |  |
| --- | --- |
| For each power calculation, the following information is required: | |
| 1. What is the key outcome measure of interest? |  |
| 1. What is the effect size of minimum biological significance? (i.e. the smallest difference between groups that is of biological interest) |  |
| 1. What is the estimated standard deviation (SD) of this outcome measure?   (**Note:** An estimate of the SD can be derived from personal experience, from previously published work by others, from pilot data, or from the results of related experiments) |  |
| 1. What power level (1-beta) and statistical significance (alpha) will be employed?   (**Note:** a combination of high power and stringent significance greatly increases sample size. Where appropriate, please justify) |  |
| 1. What statistical test will be employed for data analysis? And, will data be analysed using a one- or two-sided test?   **Note:** If applicants plan to use sequential sampling and testing (e.g. the variable-criteria Sequential-Stopping Rule) to ensure that no more than the minimal number of animals will be used, please indicate here and in question 16.2 |  |

12.2 Have you referred to a statistician?

Yes  No

If no, please explain:

13. Animal Monitoring - Identification of Potential Pain/Distress

13.1 Identify and justify all procedures with potential to cause pain or distress. What steps will be taken to avoid or minimise such pain or distress?

13.2 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.

14. Post-Operative Care - Surgical Projects

15. 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?

16. Please discuss the ethical issues that the AEC will need to consider when reviewing this proposed experimentation. Your answer should address the 3Rs, Replacement, Reduction & Refinement. (See Clauses 1.18–1.30 of [the Code](http://www.nhmrc.gov.au/book/australian-code-practice-care-and-use-animals-scientific-purposes/section-1-governing)).

“Not applicable” is not acceptable.

|  |  |
| --- | --- |
| 1. Ethical Issues  e.g.:   * 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 |  |
| 2. Reduction: |  |
| 3. Refinement: |  |
| 4. Replacement  Consideration of Alternatives  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   This answer should explain why animals need to be used at all. |  |

17. New Information or Understanding Sought

* It is the responsibility of the applicant to explain to the AEC why the project needs to be conducted and what the benefits are.
* Unnecessary duplication is unacceptable.
* Please explain how your proposal adds in a meaningful way to an existing body of knowledge.

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

* It is useful for the AEC to understand how this proposal fits into the broad research strategy/interest of your group.

19. Please justify your selection of research animal.

20. 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.

21. Published Articles

22. Do you propose to publish the results? If not, please explain why.

23. 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?

24. Health risks posed to other animals

25. Does this project involve the use of unsealed radioisotopes?

Yes  No

If yes, please indicate:

a) the radioisotope

b) the amount to be used at any one time

c) what precautions will be taken

d) whether other staff involved with the experiment have been notified

e) the name of the licensed operator who will oversee the use of the radioactive material.

26. Other Safety Hazards and Regulatory Matters

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | | Have all clearances/approvals been applied for/given by the relevant committees and Safety Officers? If No, give an explanation. | | If approved give permit no. and expiry date |
|  |  | Committee | Tick an option |  |
| Ionising radiation?  (Sealed sources)  Eg. X-Ray or Gamma | Chemical or administered substance: | Radiation Safety Officer | Not Applicable  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? | Chemical or administered substance: | OH&S (OHS and environmental) | Not Applicable  Yes  No  Pending |  |
| Pathogenic organisms? | Agent: | IBC/Other | Not Applicable  Yes  No  Pending |  |
| Genetically Modified Organisms |  | IBC | Not Applicable  Yes  No  Pending |  |
| Health risks to staff? | How affected? | OHS | Not Applicable  Yes  No  Pending |  |
| Health risks to other animals? | How affected? | ACF policy | Not Applicable  Yes  No  Pending |  |
| Human subjects or cells |  | Human Ethics Committee | Not Applicable  Yes  No  Pending |  |
| Are the animals administered any administered substance, compound or biological product which was imported under an AQIS “Permit to import quarantine material”?  If Yes:   1. Have you discussed the matter with the appropriate institutional AQIS Licence Compliance Officer?   2) What is the Permit Number?  If NO: should the source of your material change, you must inform the institutional AQIS Compliance Officer/IBC and you must inform the approving Animal Ethics Committee in writing. | | | Yes  No |  |

27. 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? | Animal Users Permit (if applicable) |
| Chief Applicant(s): |  |  |  |  |  |
| Other People Participating |  |  |  |  |  |

28. Dual/multiple AEC approval

Is approval by more than one AEC required?

Yes  No

If so, which AEC(s)?

29. Attachments Summary Checklist

|  |  |
| --- | --- |
| Type | Attachment |
| 1. Flow Chart (Question 10) | Yes  No |
| 2. Clinical Record Sheets (Question 13) | Yes  No |
| 3. Relevant SOPs | Yes  No |
| 4. Publications (Question 21) | Yes  No |
| 5. Other  Please detail: | Yes  No |

30. Declaration

|  |  |
| --- | --- |
| Project Title: |  |

Section 1: Declaration by the Primary Applicant

I hereby declare that:

(i) I and all others involved in this project are familiar with and will comply with the relevant Commonwealth and State or Territory legislation and the requirements of the [Australian Code of Practice for the care and use of animals for scientific purposes, 8th Edition 2013](http://www.nhmrc.gov.au/book/australian-code-practice-care-and-use-animals-scientific-purposes) (The Code)

(ii) To the best of my knowledge this proposal conforms to the Code (8th Edition 2013) and the South Australian *Animal Welfare Act 1985.*

(iii) I have read [Section 2 of the Code](http://www.nhmrc.gov.au/book/australian-code-practice-care-and-use-animals-scientific-purposes/section-2-responsibilities) which 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.

(iv) I agree to comply with procedures described and any conditions imposed by the Animal Ethics Committee.

(v) Sufficient and adequate resources will be available to undertake the proposed study.

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

Section 2: Other Applicant's Declaration

I hereby declare that:

(i) I am familiar with and will comply with the relevant Commonwealth and State or Territory legislation and the requirements of the [Australian Code of Practice for the care and use of animals for scientific purposes, 8th Edition 2013](http://www.nhmrc.gov.au/book/australian-code-practice-care-and-use-animals-scientific-purposes) (The Code) and the South Australian *Animal Welfare Act 1985* and its regulations.

(ii) I have read the application and I accept the responsibilities detailed therein to the extent of my involvement in this project.

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| --- | --- | --- |
| Other Applicant's Name | Other Applicant's Signature | Date |
|  |  |  |
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Section 3: Declaration by the Institutions Nominated Authority (not the Primary Applicant) i.e. Supervisor/Head of Division/Department /Institute

I hereby declare that:

(i) I am satisfied that the Primary Applicant has the appropriate qualifications and experience to carry out the work with minimum distress to the animals.

(ii) I believe this work meets the requirements of the [Australian Code of Practice for the care and use of animals for scientific purposes, 8th Edition 2013](http://www.nhmrc.gov.au/book/australian-code-practice-care-and-use-animals-scientific-purposes) (The Code) and the South Australian *Animal Welfare Act 1985* and its regulations.

(iii) I have read the application and I am satisfied that this work is of sufficient scientific merit for my Department to be involved in it and sufficient and adequate resources will be available to undertake the proposed study.

|  |  |  |
| --- | --- | --- |
| Nominated Authority | Signature | Date |
|  |  |  |

Section 4: Declaration by the Hospital General Manager (if applicable)

Does this project require access to equipment that is also used for Hospital patients?

Yes  No

If YES, approval by the CEO of the health unit is required before submitting this AEC form.

NOTE: Please attach the letter of approval to use Hospital equipment.

Approval for access is only provided for 12 months from the date of AEC approval.

|  |  |  |
| --- | --- | --- |
| General Manager | General Manager's Signature | Date |
|  |  |  |

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| --- | --- | --- |
| **AEC Use Only** | | |
| Date Received: | Action Taken:  Date of AEC meeting for consideration: | Signature of Chair, AEC |

Attachment: Flow Chart (Question 10)

Attach flow chart as pdf page or if text by copy-paste into field below

Clinical Record Sheets (Question 13)

Attach sheets as pdf pages or if text by copy-paste into field below

Attachment: Relevant SOPs

Attach as pdf pages or if text by copy-paste into field below

Attachment: Relevant Publications (Question 21)

Attach as pdf pages or if text by copy-paste into field below

Attachment: Other

Attach as pdf pages or if text by copy-paste into field below