**The Flinders University Animal Welfare Committee**

**ANIMAL ETHICS APPLICATION**

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| **Application for Biomedical Project Involving Animals** |

Instructions

* Use this form for work undertaken using animals in the **College of Medicine and Public Health Animal Facility;**
* For work undertaken using animals in the **College of Science and Engineering Animal Facility**, please complete the Biology Application Form;
* This form is **NOT** to be used for Biology applications;
* Every question must be answered;
* Contact the [Animal Ethics Officer](mailto:animal.welfare@flinders.edu.au), Animal Welfare Committee, with any enquires relating to this form;
* If this application is urgent, contact the [Animal Ethics Officer](mailto:animal.welfare@flinders.edu.au) to discuss an expedited review;
* After completing this form, submit an electronic copy to the appropriate Sub-Committee.

**Sub-Committee: Email completed form to:**

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| --- | --- |
| Animal Ethics Review Sub-Committee (AERSC) | [aersc@flinders.edu.au](mailto:aersc@flinders.edu.au) |

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| --- | --- | --- | --- | --- | --- | --- |
| Office Use  Only | **Project Number:** |  | **Date Received:** |  | **Version Number:** |  |

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| --- | --- |
| Title of Project |  |
| Name of Primary Applicant |  |
| Species/Strain(s) |  |
| Procedure Category (Refer to Q6)  (State highest level only) |  |
| Pain/Distress Classification  (Refer to Q7)  (State highest level only) |  |

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| --- | --- |
| Application Type  *(tick primary purpose only)* | Research  Breeding  Teaching |
| Length of Approval requested? | 3 Years  Other: |
| Does this project involve any of the following: **Don’t tick any box if student/s are not known/enrolled yet.** | Honours Student  Masters Student  PhD Student  Undergraduate |
| Funds Source - Is the proposed work subject of a grant application? | Yes. Detail grant below.  Submitted  Funded  **Grant Project No.:**  **Funding Body:**  **Grant Project Title:** |
| No. Is there any other source of funding? |
| 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  No |
| 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

|  |  |  |
| --- | --- | --- |
| Name (include title) |  | |
| Department |  | |
| Contact details | Email |  |
| Phone  *(Business Hours)* |  |
| Mobile |  |
| Emergency Correspondence to if Primary Applicant unavailable |  | |
| Flinders University student/staff/affiliate  External…Employer: | | |
|  | | |
| Co-applicant | | |
| Name (include title) |  | |
| Department |  | |
| Contact details | Email |  |
| Phone  *(Business Hours)* |  |
| Mobile |  |
| Flinders University student/staff/affiliate  External…Employer: | | |

Other Applicant/s

|  |  |  |
| --- | --- | --- |
| Name (include title) |  | |
| Department |  | |
| Contact details | Email |  |
| Phone  *(Business Hours)* |  |
| Mobile |  |
| Flinders University student/staff/affiliate  External…Employer: | | |
|  | | |
| Name (include title) |  | |
| Department |  | |
| Contact details | Email |  |
| Phone  *(Business Hours)* |  |
| Mobile |  |
| Flinders University student/staff/affiliate  External…Employer: | | |
|  | | |
| Name (include title) |  | |
| Department |  | |
| Contact details | Email |  |
| Phone  *(Business Hours)* |  |
| Mobile |  |
| Flinders University student/staff/affiliate  External…Employer: | | |

1. Summary

1.1 Provide a **Short** **Lay Description** of the project and its aims.

* 1. Detail the significance.

**For Example*:*** It is the responsibility of the applicant to explain to the AEC:

**1)** Why the project needs to be conducted;

**2)** What the benefits are; and

**3)** Explain how your proposal adds in a meaningful way to an existing body of knowledge.

2. SOPs and Guidelines

2.1 Are procedures used in this study described in any AWC Approved SOPs or Guidelines?

Yes  No, Move to Q3

**2.1.1 List all AWC-approved SOPs and Guidelines referred to in this application.**

* Indicate the section/s of this application (e.g Q3.2 Detailed Experimental Plan) in which the SOPs and Guidelines are referred to.
* **Do not** attach these SOPs to this application.

3. Project Description

3.1 Animals Required

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Common Name | Scientific Name | Strain | Sex | Age or  Size | Total Number for duration of project  *(Or explanation if total number is Unknown)* |
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3.2 Provide a **Detailed Experimental Plan**. Describe what happens to the animals from the time they are obtained until the time the project is completed. For teaching applications=

1 Outline the maximum number of students/trainees to be supervised by each teacher.

2 Outline the maximum and minimum number of animals to be used by each student/trainee and justify the total number of animals used.

3 Outline the maximum number of times each animal will be used.

4 What steps have you taken to minimise the number of animals required?

5 To reduce animal use, will animals or their tissues, at the conclusion of your programme, be suitable for use in another protocol? If YES, please provide brief details.

6 Describe how the ethical implications of using animals in this teaching programme will be addressed with the staff and students involved, e.g. Introductory talk, notes, seminar, etc.

7 Detail how the educational objectives will be assessed.

* Refer to AWC Approved SOPs where applicable.
* For TEACHING applications, click on the “show/hide” button ( ¶ ) for additional instructions.

3.3 Flow Chart (Attach if space is insufficient)

3.4 Justify your selection of research animal.

3.5 Is group blinding to be used?

Yes  No

If **NO**, explain why.

3.6 Is group randomisation to be used?

Yes  No

If **NO**, explain how the animals are to be assigned to each group.

3.7 Provide a detailed description and explain in detail the expected mortality rates for each stage of the project

* (i.e. capture, transport, acclimatisation, rearing, holding, experimental period, surgical period, background species/age-related mortality, etc).
* Speak to the Animal Facility Manager if you are unsure of the expected mortality for the strains you are using.
* How will this be accounted for in your blinding and randomisation protocols?

3.8 Is this project in total or in part solely for the purposes of determining numbers required for statistical validly?

NO.

YES. Detail:

3.9 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. |  |

3.10 Have you referred to a statistician?

Yes  No

Please explain:

3.11 Is this project a continuation or follow-on from previous work?

Yes  No

If **YES**, please clarify 1) what were the key findings from your previous work, and 2) how it relates to the work described in this project.

4. Animals

4.1 Animals Source and Housing

|  |  |
| --- | --- |
| *Source:* | College of Medicine and Public Health Animal Facility  Other: |
| *Will the use of animals occur outside of South Australia?* | No  Yes. If Yes, please provide details of the permit/licence number and permit holder: |
| *Is this the first time that you have brought this animal strain into the CMPH Animal Facility?* | No, it has been held in CMPHAF previously.  N/A, no animals to be held in CMPHAF.  Yes. If yes, please submit a **Phenotype Report** with this application. |
| *Animals held at:*  *Procedures performed at:* | CMPHAF  Other. Detail: |
| CMPHAF  Other. Detail: |
| *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)) | No.  Yes. If yes, explain why they are to be used again and include details of the previous use: |

4.2 Have you liaised with the relevant animal facility and have confirmation that the required resources are available?

* 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.

**YES**, *I have liaised with the relevant Animal Facility and have confirmation that the required resources are available.*

**NO**, *I haven’t yet liaised with the relevant Animal Facility.*

**N/A**

4.3 What will happen to the animal at the end of the project?

* If it is to be euthanised, 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 euthanised at the end of the experiment, what is to happen to them?

5. Purpose of the Project *(Tick primary purpose only)*

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| --- | --- |
|  | 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. |

6. Procedure Category *(Tick all appropriate categories)*

|  |  |
| --- | --- |
|  | Negligible or Low Impact Observational Studies: e.g. behavioural study, feeding trial, pitfall trapping, obtaining weights and body measurements. |
|  | Animal Unconscious; No Recovery: Animal euthanised prior to commencement of project or euthanised while under general anaesthetic e.g. euthanised 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, light sedation. |
|  | 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). |

7. Pain/Distress Classifications *(Tick where appropriate)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Category** | **List Procedures** | **Detail Extent and Duration of Suffering** | **How will Suffering be Minimised?** |
|  | 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 euthanised) |  |  |  |

8. Animal Monitoring

8.1 Detail the monitoring that will be made of the animals once allocated to a project, but prior to use in experimental procedures.

* **Attach** your Clinical Record Sheet and/or Maintenance Monitoring Sheet and/or Running Mortality Sheet at the end of this document and identify who will complete it and at what frequency.
* Include intervention/actions points.
* Refer to SOPs where applicable.

8.2 Detail the monitoring that will be made of the animals during and immediately post procedures (until recovery from the procedure) the experiment.

* **Attach** your Clinical Record Sheet and/or Maintenance Monitoring Sheet and/or Running Mortality Sheet at the end of this document and identify who will complete it and at what frequency.
* In particular, describe the care and monitoring animals will receive **post anaesthesia**, where applicable.
* Include intervention/actions points.
* Refer to SOPs where applicable.

8.3 Detail the ongoing monitoring that will be made of the animals post procedures.

* **Attach** your Clinical Record Sheet and/or Maintenance Monitoring Sheet and/or Running Mortality Sheet at the end of this document and identify who will complete it and at what frequency.
* Include intervention/actions points.
* Refer to SOPs where applicable.

9. Substances

9.1 Substance to be administered

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Substances | Dose Rate  (mg/kg) | Frequency | Route  Administered & needle size | Concentration (mg/ml) & total dose (mg) to be given |
| Anaesthetic Agents |  |  |  |  |
| Post-Operative Analgesia |  |  |  |  |
| Tranquillisers |  |  |  |  |
| Antibiotics |  |  |  |  |
| Other Substances |  |  |  |  |
| Research Compounds/Test  substances/  Biologicals |  |  |  |  |
| Humane Euthanasia Agents |  |  |  |  |

Please Note: If you intend to use a Schedule 8 drug (e.g. Ketamine, Buprenorphine, etc) the Primary Applicant is required to have a valid Controlled Substances Permit and all personnel intending to handle the drug must be listed.

9.2 What experience do **you** (and your team) have in using these agents?

9.3 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. what information is publically available for this substance/ compound? Is a pilot study required?

10. Ethics Issues

10.1 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)).

* For further explanation of what is required in this section, please read the “3R’s Example” document on the AWC website.

|  |  |
| --- | --- |
| 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:   * Methods for obtaining comparable levels of information from the use of fewer animals in scientific procedures or for obtaining more information from the same number of animals. |  |
| 3. Refinement:   * Methods that alleviate or minimise potential pain and distress, and enhance animal wellbeing.   Consideration of Refinement, should include:   * People who care for and use animals must ensure that procedures are performed competently, and be competent (or under the direct supervision of a person who is competent) to perform the procedure. * 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 safeguarding animal wellbeing. * What steps will be taken to avoid or minimise such pain or distress? |  |
| 4. Replacement:   * Methods that permit a given purpose of an activity or project to be achieved without the use of animals.   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. |  |

11. Credentials

11.1 Credentials of all those involved in the project.

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| --- | --- | --- | --- | --- | --- |
|  | **Name** | **Qualifications** | **In which**  **procedure(s) is this person involved?** | **Date this**  **person**  **completed Flinders University’s**  **Animal Ethics Online Training (AEOT)** | **Date last attended Animal Researcher Information Session**  **(ARIS)** |
| **Primary Applicant** |  |  |  |  |  |
| **Co-Applicant** |  |  |  |  |  |
| **Other Applicant/s** |  |  |  |  |  |
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11.2 For all procedures identified in section 11.1, state who have been certified as competent in the procedures in this project.

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| --- | --- | --- |
| **Procedure(s)**  *(Please use procedures as listed in the Contents of SWMSs & SOPs, where possible)* | **Detail who will be performing the procedure(s)?**  *(List everyone to be performing each procedure)* | **Have you obtained competency** *(or are on the Competency Skills Register)***for these procedure(s) at this institution or another institution?**  **If YES, provide details** *(including who certified competency)***.**  **If NO, how will competency be gained** *(i.e. through relevant training and supervision)***?** |
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12. Other authorisations required

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

* In addition to regulations governing the treatment of animals in South Australia in accordance with the Animal Welfare Act 1985 and the Animal Welfare Regulations 2012 (e.g. protected native or imported species)

Yes  No

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

13. Dual/multiple AEC approval

13.1 Is approval by more than one AEC required?

Yes  No

If Yes, which AEC(s)? Provide details.

14. Attachments Summary Checklist

|  |  |
| --- | --- |
| Type | Attachment |
| 1. Flow Chart  (Relates to Q3.3) | Yes  No |
| 2. Phenotype Report  (Relates to Q4.1) | Yes  No |
| 3. Clinical Record Sheets  (Relates to Q8.1 - Q8.3) | Yes  No |
| 4. Maintenance Monitoring Sheet  (Relates to Q8.1 – Q8.3) | Yes  No |
| 5. Running Mortality Sheet  (Relates to Q8.1 – Q8.3) | Yes  No |
| 6. Other  Please detail: | Yes  No |

15. 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 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.

(vi) I certify that I believe that this work is ethically justified and compliant with the requirements of the Code.

(vii) I agree to comply with the Flinders University Work Health and Safety Policy, and obtain any approvals as required before commencement of this project.

(viii) I agree to obtain appropriate approvals from, and comply with all the requirements of, the Flinders University Institutional Biosafety Committee (IBC) before commencement of this project.

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| --- | --- | --- |
| 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 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.

(iii) I certify that I believe that this work is ethically justified and compliant with the requirements of the Code.

(iv) I agree to comply with the Flinders University Work Health and Safety Policy, and obtain any approvals as required before commencement of this project.

(v) I agree to obtain appropriate approvals from, and comply with all the requirements of, the Flinders University Institutional Biosafety Committee (IBC) before commencement of this project.

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