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| These guidelines are included in the form as hidden text. To turn off the hidden text, click“**Show/Hide** ¶” on the **Standard** toolbar. When hidden text is shown, it will be red in colour, and is marked with a dotted underline. |

The Flinders University / Southern Adelaide Health Service Animal Welfare Committee

**Application for MODIFICATION**

**of an approved project**

**GUIDELINES**

Initial version 22 September 2009; revised 29 October 2009; revised 18 May 2010

**Introduction**

Under SA legislation, approval by an Animal Welfare Committee (AWC) is required **before** any changes to an approved project can commence.

This application form is to be used for **MODIFICATIONS to an approved project**.

Following approval of a number of minor amendments to a project, the AWC may request the submission of a new application.

Where the amendment will result in an adverse impact on the animals (additional to that predicted in the approved project), will change the classification of the severity of the experiments, or where the ethical implications of the modification had already been considered as part of the Application for the project. Such amendments will require the submission of a new Application. Examples include:

⦁ Change in the direction of the project, particularly with respect to the stated aims of the project as outlined in the original Application.

⦁ Significant change to the procedures to be performed. For example:

⦁ Procedures under anaesthesia where the project previously involved only the removal of tissues following euthanasia.

⦁ Surgical procedures with recovery where the project previously involved surgical procedures without recovery.

⦁ Addition of a laparotomy to a project involving only blood collection.

* A significant increase in the number of animals required. The determination of whether the increase in animal numbers is minor or significant is at the discretion of the AWC.
* Replacement of Chief Investigator.

All persons involved with the use of animals must be familiar with:

1. SA Animal Welfare Act 1985
2. Australian code of practice for the care and use of animals for scientific purposes (the Code)
3. Australian Code for the Responsible Conduct of Research
4. The policies and guidelines of the Animal Welfare Committee (AWC)

These documents may be accessed from the animal ethics website:

http://www.flinders.edu.au/research/info-for-researchers/ethics/committees/animal/animal\_home.cfm

**An understanding of the relevant legislation is the responsibility of the investigators.**

**General guidelines**

*Acknowledgement: This application form and guidelines are based on those used by the Newcastle University Animal Care and Ethics Committee, amended for use by Flinders University/SAHS Animal Welfare Committee with permission of Newcastle University Research Services.*

1. **Use PLAIN ENGLISH in your application.**

*Legislative background – Australian Code.*

*Clause 2.2.1 (viii): The AWC may “approve only those studies for which animals are essential and justified and which conform to the requirements of the Code. This should take into consideration factors including ethics, the impact on the animal or animals and the anticipated scientific or educational value”.*

*Clause 2.2.15: “Information provided in proposals must be sufficient to satisfy the AEC that the proposed use of animals is justified by weighing the predicted scientific or educational value of the proposal against the potential impact on the welfare of the animals. An essential component of this assessment by the AEC involves consideration of the steps taken by the applicant to comply with the principles of the 3Rs specified in the Code. It is important that all AEC members are provided with sufficient information to participate in the assessment of proposals. This can only be achieved by the use of* ***plain English*** *in the proposal. Applicants must ensure that where the use of scientific language is deemed unavoidable, it is supported by a suitable lay description or a glossary of terms.”*

Remember that the AWC is composed of people who are not experts in your field. The use of specialist language is not helpful to the committee and may delay processing of an application while explanations are sought. **Hints:**

* + Use language suitable for a media release.
  + Use everyday language that can be understood by an interested, intelligent person without a scientific background. Assume those assessing your application have either no medical scientific background or no knowledge of your area of research.
  + Avoid using scientific jargon or unexplained abbreviations. The need for plain English is especially important for your description of the aims of your project.
  + Where the use of scientific terminology is unavoidable, you should consider providing an explanation of these terms or a glossary. This glossary is to be used for scientific terminology where lay terms are not available but not as a substitute for lay language.
  + Do **not** include extracts from a grant application as most are not written in the manner required by the legislation.

1. It is highly recommended that you ask a colleague and a person with a non-scientific background to read your application before it is submitted.
2. The application must be self-contained and not refer to other animal ethics or grant applications for detail.
3. The AWC corresponds directly with the Chief Investigator only. **The Chief Investigator is responsible for ensuring that all persons involved with the use of animals on the project receive or have access to a copy of the application, and any subsequent correspondence from the AWC regarding the application.**
4. Approval covers the precise details contained within this application. Any subsequent changes, including changes to personnel, must receive prior approval from the AWC.

**For guidelines on specific questions in the application form, see later in this document.**

**Notes on using the form**

1. Ensure that you are using the current version of the application form by downloading a copy from the animal ethics website each time.
2. Use the **hidden text function in this form** to access guidelines for many questions. To show the text with the hidden text effect, click“**Show/Hide** ¶” on the **Standard** toolbar. When hidden text is shown, it will be red in colour, and is marked with a dotted underline. This text will not be seen on the printed version. Guidelines are also available at: http://www.flinders.edu.au/research/info-for-researchers/ethics/committees/animal/animal\_home.cfm
3. All questions must be answered, even if your response is "Not Applicable".
4. Answers to questions must be typed.
5. Insert your responses in the boxes provided. The box will expand to accommodate the length of your response. The size of the box may be increased by adding paragraph marks. Boxes or tables may be copied by highlighting the box and using the "Edit, copy" and then "Edit, paste" commands. Do not delete sections or amend the formatting of this form unless instructed to do so.
6. Attachments for the application may be downloaded from http://www.flinders.edu.au/research/info-for-researchers/ethics/committees/animal/animal\_home.cfm

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ***AWC USE ONLY*** | | | | | | | | |  |
|  |  | |  | |  |  | | |  |
| Date Received: |  | | Version  Number: | |  |  |  | |  |
|  |  |  |  |  |  |  | |  |  |
| Project Number: |  | | Modification  Number: | |  |  | |  |  |
|  |  |  |  |  |  |  | |  |  |

**The Flinders University / Southern Adelaide Local Health Network Animal Welfare Committee**

**Application for MODIFICATION**

**of an approved project**

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| To access guidelines for questions on this form, use the **hidden text function:** Click“**Show/Hide** ¶” on the **Standard** toolbar. When hidden text is shown, it will be red in colour, and is marked with a dotted underline. |

|  |  |
| --- | --- |
| **URGENT Consideration**  *Legislative background – Australian Code. Clause 2.2.11:*  *“The AEC may establish an executive that must include at least one member from Category C or D who:*   1. *may approve minor modifications to projects for review at the next AEC meeting;* 2. *may not approve new proposals.”*   Sufficient justification must be provided for a request for urgent consideration of a minor modification application prior to the next scheduled meeting of the AWC. **Such justification is usually based on animal welfare grounds.** Lack of forward planning or failure to comply with procedures for ordering of animals is not sufficient justification for urgent consideration. Urgent consideration of a Modification Application is **not automatic**. The decision will be made by the AWC Executive on a case-by case basis.  Is urgent consideration of this application required **before** the next scheduled meeting of the AWC? | |
|  | No. **Go to Section 1.** |
|  | Yes. **Please provide JUSTIFICATION below.** |
| If YES, please provide clear reasons for the necessity for urgent consideration. | |
|  | |

***Section 1. Administration***

|  |  |  |
| --- | --- | --- |
| 1.1 | **Chief Investigator:**  (Title / first name / family name) The Chief Investigator should be the same Chief Investigator as on the Initial Application for the project. |  |
| 1.2 | **Current Email:The title of the project must be the same as on your Initial Application for animal ethics approval. A change in the title should be explained or the research should be covered by a new Application.** |  |
| 1.3 | **Project Title:** |  |
| 1.4 | **Current AWC Approval Number:** This number was allocated to this project on its most recent approval (or renewal of approval) by the AWC, and is detailed in the current Animal Research Authority issued for the project by the responsible institution. |  |
| 1.5 | **IBC Reference Number:** |  |

*An application fee may be applied to applications from researchers not associated with Flinders University or Southern Adelaide Health Service. An application fee may be applied to applications from researchers not associated with Flinders University or Southern Adelaide Health Service. An application fee may be applied to applications from researchers not associated with Flinders University or Southern Adelaide Health Service. An application fee may be applied to applications from researchers not associated with Flinders University or Southern Adelaide Health Service. An application fee may be applied to applications from researchers not associated with Flinders University or Southern Adelaide Health Service An application fee may be applied to applications from researchers not associated with Flinders University or Southern Adelaide Health Service*

1.6 **Contact person for this application (if not the Chief Investigator or Alternate Chief Investigator):** This is often the person who is responsible for the drafting of the application (eg. honours or PhD student or junior researcher who is directly involved with the research project). This person will receive a copy of the correspondence from the AWC regarding the outcome of this application, in addition to the Chief Investigator and Alternate Chief Investigator.

|  |  |
| --- | --- |
| **Name:** Title/first name/family name |  |
| Email address: |  |
| Telephone (Business Hours): |  |
| Telephone (After Hours): |  |

1.7 **Previous modifications.** Summarise, and provide dates for, any modifications to the project that have been approved *since approval was granted* for the initial application. Information in this section will assist the AWC to place this application in context.

|  |
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1.8 **Indicate the category that best fits the proposed amendment.**

**A. Extension of time of existing approved project**

|  |  |  |
| --- | --- | --- |
| **Approval No.:**  ***Original*** *expiry date:* | Current expiry date: | New expiry date: |
| Reason for extension: | | |

**B. Modification to previously approved protocol**

|  |  |  |  |
| --- | --- | --- | --- |
| **Approval No.:** | | **Expiry Date:** | |
| *Provide details in the boxes next to the modification sought:* | | | |
| Requested modification | Previously approved | | New request |
| (i) Modified experimental step/swith approved animals |  | |  |
| (ii) Modified experimental step/s |  | |  |
| with additional animalswith additional species |  | |  |
| (iii) Additional experimental step/swith approved animals |  | |  |
| (iv) Additional experimental step/s |  | |  |
| with additional animals |  | |  |
| with additional species |  | |  |
| (v) Additional animals only |  | |  |
| (vi) Change of species only |  | |  |
| (vii) Additional species only |  | |  |
| (viii) Additional strain only |  | |  |

**C. Change of Investigator or Other Personnel**

1. Investigator/s **leaving** project

*Repeat rows as needed*.

|  |  |  |  |
| --- | --- | --- | --- |
| **Approval No.:** | | **Expiry Date:** | |
|  | **Name** (including title) | | **Effective date/s** |
| **Investigator(s) leaving project:** |  | |  |
|  | |  |
| **Other People leaving project:** |  | |  |
|  | |  |

1. **New investigator/s** on project – contact details

*For each new person involved with the use of animals in this project outline their level of experience in the use of the proposed techniques and procedures, in handling the selected animal species and the experimental steps in which they will be involved, plus with the date on which they attended Animal Ethics Online Training. Repeat rows as needed.*

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

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

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

1. **New investigator/s** on project - qualifications & experience

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Name** | **Qualifications** | **Detail experience in experimental steps to be undertaken (and over what period) and the species being used**  (If no experience, **describe** how relevant experience will be obtained) | **In which experimental step/s is this person involved?** | **Date this person completed Flinders University’s**  **Animal Ethics Online Training (AEOT)** |
| **Investigator(s):** |  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
| **Other People Participating:** |  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

1.9 **Health and/or safety risks**

*Legislative background – Australian Code.*

*Clause 2.2.16 (xii): “Practical considerations to assist AECs and animal carers. Specify any special risks to other animals or humans arising from the project (see 3.3.50 - 3.3.54).”*

*Clause 3.3.52: “The AEC should require evidence that the Institutional Biosafety Committee (IBC) has been consulted and that appropriate measures for containment, disposal and decontamination of biohazardous material have been established.”*

(i) Will the amendments to this project involve any changes to the health and/or safety risks to other animals, people or the community, or changes to the use of genetically modified organisms?

|  |  |
| --- | --- |
|  | Yes. **Please complete part (ii).** |
|  | No. **Go to Question 1.10.** |

(ii) Indicate which of the following health and/or safety risks to other animals, people or the community are involved with this amendment.

|  |  |  |
| --- | --- | --- |
|  | Anaesthetic gases | |
|  | Carcinogens | |
|  | Teratogens | |
|  | Chemically hazardous material or cytotoxic substances (not including anaesthetic gases) | |
|  | GMOs – the use or production of genetically modified animals or animals with a naturally occurring mutation that were not described in the original application **(Complete Attachment i)** | |
|  | GMOs other than animals | |
|  | Biologically hazardous materials (microorganisms, human tissue, fluids etc) | |
|  | Radiation hazard | |
|  | Potential zoonosis | |
|  | Other - Provide BRIEF details here: |  |
|  | Not Applicable | |

(iii) **IBC Approvals**

If you have indicated the use of GMO animals or other and/or biologically hazardous materials in the boxes above, please include here the IBC approval and expiry date or approval pending details relating to this project.

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1.10 **Funding.** Is this amendment associated with a new source of funding? Information regarding any new funding sources for this project must be provided so that AWC approval for this application can be correctly linked to the funding application. If you have any inquiries regarding the associated grant application, contact the Research Grants Officer, Research Services.Office.

|  |  |
| --- | --- |
|  | No. **Go to next section.** |
|  | Yes. **Please detail.** |

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**Sections 2 and 3**

You must use plain English in these sections. For hints regarding the use of plain English, see under “General guidelines” earlier in the document.

***Section 2: Modification details***

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| Use **PLAIN ENGLISH** in your responses to the following sections – everyday language that can be understood by an educated lay person who has no medical or scientific background. Do not use scientific jargon and avoid using abbreviations. |

**2.1 Overview of modification**

*Legislative background – Australian Code. Clause 2.2.16 (ix):*

*“Proposals must identify and justify the impact of all aspects of the project on an animal’s wellbeing from the time it is obtained until the project is completed and detail how that impact will be minimised. The assessment of potential impact should include:*

*1. A step-by-step description of what will happen to each animal including:*

1. *transportation, acclimatisation and conditions of housing and handling*
2. *experimental and other procedures, including dose and route of any substance or treatment given and method, volume and frequency of samples collected*
3. *surgical and related procedures including dose of anaesthetic, analgesic and tranquillising agents and methods of monitoring their adequacy and side-effects*
4. *the sequence and timing of events from start to finish for individual or groups of animals, and*
5. *the arrangements for the animal or animals at the completion of the project, including, if applicable, the method of humane killing.*

*AECs, investigators and teachers are required by the Code to consider the principle of Refinement to minimise the adverse impact of the intended project on animals. This can only be achieved if all activities involving animals are described in full. To assist in the understanding of the use of animals in the project. An animal-use flowchart may assist in this process.”*

2.1.1 **Provide the lay summary from the originally approved project proposal.** Include the original aim/s, benefits, experimental design and animal species to be used for the project. Information in this section serves to provide a focus on the proposed amendment to the approved protocol, and will be included on the Animal Research Authority for the project.

|  |
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2.1.2 **Brief description of the modification.** Give a one sentence/phrase description of each proposed amendment. Information in this section serves to provide a focus on the proposed amendment to the approved protocol, and will be included on the Animal Research Authority for the project.

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2.1.3 **Detailed description.** In providing details, it is important that you highlight where the proposed amendment fits within the currently approved protocol. **HINT:**

* Copy the relevant section of the approved protocol from the final approved Application.
* Insert information relevant to this amendment.
* Highlight the relevant section so that the proposed changes are clear.

(i) Provide a description of the proposed modification and indicate how it will fit within the currently approved protocol.

|  |
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(ii) Indicate whether the proposed modification involves any of the following procedures/situations. **The appropriate attachment must be appended to your application, unless it is an AWC Approved SOP/SWMS.**

Omission of essential information is a common cause of delays in the processing of an application. Attachments have been developed for specific procedures, to ensure that your application includes the required information pertaining to that procedure or situation. Section 3.3 of the Australian Code provides detailed information on requirements for specific situations (eg. anaesthesia, surgery)

Appropriate use of Standard Operating Procedures (SOPs) may facilitate the preparation of applications, and in some cases replace an attachment. *Legislative background – Australian Code. Clause 2.2.17:*

*“Where appropriately applied, Standard Operating Procedures (SOPs) may facilitate the preparation of proposals by investigators and teachers. There is a risk that the use of SOPs may reduce the rigour with which procedures are considered by the AEC and, therefore, SOPs should only be referred to in proposals under the following circumstances:*

1. *new SOPs must be approved by the AEC before implementation;*
2. *SOPs must include in the title the date on which they were last approved or reviewed and be reviewed regularly by the AEC at least every three years;*
3. *AEC members must have ready access to copies of all current SOPs;*
4. *investigators or teachers named on a proposal must have the necessary skills to implement a SOP; and*
5. *variations to a SOP must be detailed in the proposal.”*

For guidelines on the use of SOPs, and SOP templates, see: <http://www.newcastle.edu.au/research/animal/sop.html>

| **Indicate if Attachment or SOP is used:** | | | **Procedure** |
| --- | --- | --- | --- |
| **Attachment** | | **SOP** |
| **C** |  |  | Non-survival surgery |
| **D** |  |  | Survival surgery |
| **E** |  |  | Use of anaesthesia not associated with surgery (survival or non-survival) |
| **F** |  |  | Blood collection (other than terminal collection) |
| **G** |  |  | Polyclonal antibody production |
| **H** |  |  | Administration of substances |
| **I** |  |  | Animals with altered genetic make-up *(manipulated, modified, naturally-occurring mutation)* |
| **J** |  |  | Capture or survey of either native wildlife, free-living exotic or feral animals |
| **K** |  |  | Transport of live animals at any time during the project |
| **L** |  |  | Death as an end-point or LD50 tests *(This does not refer to the planned euthanasia of an animal at the conclusion of a study.)* |
| **M** |  |  | Mandatory studies required for registration of a product or by an external body (eg. TGA, NRA, FDA, Human Ethics Committee) |
| **N** |  |  | Re-use of animals that have been the subject of a previous scientific or teaching activity |

**2.2. Additional Animals – Details and Reduction**

*Legislative background – Australian Code. Clause 2.2.16 (vii):*

*“Reduction. A clear description of:*

* *the number, species and strain of animals required, by treatment groups, where appropriate*
* *the reasons why this number is necessary, including whether the proposal is for a repeat of an earlier project and if so, why repetition is necessary, and*
* *whether there is an opportunity for the sharing of tissues or animals.*

*AECs and animal users are required by the Code to consider the principle of Reduction to minimise the number of animals used for scientific purposes. Excessive use of animals can result from users overstating the number of animals required to achieve a statistically valid result or requesting too few animals which may lead to needless repetition or a failure to achieve outcomes. Justification for the number of animals required may include:*

* *teacher:student and student:animal ratios in teaching activities, and*
* *statistical consideration in experimental design with regard to prior experience, and/or advice from a biometrician.”*

**ANIMAL SPECIES LISTING**

*This information is required by the State Animal Welfare Committee for statistical purposes.*

**DOMESTIC SPECIES**

010 Cattle 030 Sheep 050 Horses 070 Cats 020 Pigs 040 Goats 060 Domestic Poultry 080 Dogs 090 Other - Please specify

**LABORATORY ANIMALS**

Rats (Rattus norvegicus)

100 Outbred (indicate strain - Sprague Dawley, Wistar) 120 Inbred (indicate strain)

140 Mutant (indicate strain)

Mice (Mus musculus)

200 Outbred (indicate strain - ARC, Swiss, etc.) 240 Congenic (indicate strain)

220 Inbred (indicate strain) 260 Mutant (indicate strain)

280 Recombinant (indicate strain)

Guinea Pig (Cavea porcellus)

300 Outbred (indicate strain - Hartley, albino, etc.) 320 Inbred (indicate strain)

Rabbit (Oryctolagus cuniculus)

400 Dutch Belted 420 NZ White

440 Other - Please specify

**AUSTRALIAN NATIVE ANIMALS**

**MARSUPIALS**

Macropods

500 Tammar (Macropus eugenii) 503 Eastern Grey Kangaroo (M. giganteus)

501 Quokka (M. brachyuris) 504 Western Grey Kangaroo (M. fuliginosus)

502 Bennetts Wallaby (M. rufogriseus) 505 Other - Please indicate species

Marsupial Mice

510 Kowari (Dasyuroides byrnei) 512 Other - Please indicate species

511 Dunnart (Sminthopsis - indicate species)

Native Cats

520 Eastern Native Cat (Dasyrurus viverrinus) 522 Other - Please indicate species

521 Western Native Cat (D. Geoffroii)

Bandicoots

630 Long nosed (perameles nasuta) 632 Other - Please indicate species

631 Short nosed (Isoodon macrourus)

Koala

640 Phascolarctos cinereus

Possums

650 Brush tailed (Trichosurus vulpecula) 652 Other - Please indicate species

651 Ringtailed (Pseudocheirus spp.)

**NATIVE PLACENTAL MAMMALS**

660 Dingo (Canis familiaris) 662 Other - Please indicate species

661 Native hopping mice (indicate species - Notomys alexis, etc.)

**MONOTREMES**

670 Platypus (Ornithorhynchus anatinus) 671 Echidna (tachyglossus aculeatus)

**NATIVE BIRDS**

900 Indicate species

**PRIMATES**

Macaques

700 Macaca fascicularis 702 M. mulatta

701 M. nemestrina 703 Other - Please indicate species

Baboon

705 Papio mhamadryas

Marmosets and Tamarina

710 Callithrix spp; Saguinus spp. (indicate which)

## Other primates

720 Indicate species

**OTHER SPECIES**

800 Fish (specify) 830 Birds - non-native, non-domestic (specify)

810 Amphibia (specify) 840 Invertebrates (specify)

820 Reptiles

2.2.1 Does this modification involve any change to the total number, strain or species of animals in this project?

|  |  |
| --- | --- |
|  | Yes. **Complete the remainder of Section 2.2.** |
|  | No. **Go to Section 2.3** |

**Additional Animals Required: Details**

* + 1. Please provide the species code (from list provided in guidelines, above), common and scientific name and detail additional numbers requested for each strain or type of target animal, plus total of all animals required under this modification.

|  |  |  |  |
| --- | --- | --- | --- |
| Animal by Strain/Type: | | | Number |
| Common Name | Scientific Name | Strain/Type |  |
|  |  |  |  |
|  |  |  |  |
| Total animals | | |  |

2.2.3 Does the modification involve the use or production of genetically modified animals or animals with a naturally occurring mutation, NOT covered in the original application?

*Legislative background – the Code. Clauses 3.3.56 to 3.3.63 outline specific requirements for this situation.*

|  |  |
| --- | --- |
|  | YES. **You must complete Attachment I.** |
|  | NO. |

2.2.4 Justify the choice of any new species/strain of animal required.

*Legislative background – Australian Code. Clause 3.1.8:*

*“In choosing animals, investigators and teachers must ensure that the choice of species is appropriate for the scientific purpose. Requirements for known genetic constitution, freedom from specific diseases, documented health, nutritional and environmental histories and other relevant factors should be taken into account.”*

The choice of species and strain of animal, and even the individual animal, can have significant implications for the impact of a research protocol on that animal. The AWC must be satisfied that you are using the appropriate species/strain/individual animal, and that their biological characteristics, behaviour, genetic constitution, nutritional, microbiological and general health status, and level of sentience have been appropriately considered.

|  |
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2.2.5 Provide justification for the number of additional animals requested, on the basis of experimental design and statistical consideration. For teaching protocols, justify any change to the animal/student ratio.

Justification must be provided for the total number of additional animals required for the duration of the project. Give a breakdown in tabular form of numbers of animals in each experimental or treatment group, including controls. Provide advice on the statistical analysis to be performed including analysis employed and the power function. Outline the advice you have received from a biometrician regarding the experimental design.

For projects involving tissue collection, justification for animals number may be provided in terms of the amount of tissue needed based upon the number of experiments you will conduct, the amount of tissue required for each experiment, and the amount of tissue you expect to obtain from each animal.

|  |
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2.2.6 What steps have you taken to minimise the number of additional animals required?

Examples of possible methods include:

* Choice of appropriate species/strain.
* Use of quantitative rather than qualitative endpoints.
* Proper consideration of research strategies ie. pilot studies, improvement of experimental design with particular attention to statistical methods.
* Use of statistics in the planning stages to determine the minimal number of animals per group required to obtain a significant result.

Ordering “Either sex” or “Any” if the sex/strain of the animal is not crucial to the experiment. This practice may reduce animal use by minimising animal wastage during animal production in the animal supply unit.

* Sharing of tissues from one animal amongst other researchers in approved projects.
* Use of videos or models in part of project (particularly for teaching protocols).
* Use of *in vitro* techniques to obtain preliminary data, or to replace some *in vivo* techniques.
* Use of abattoir tissue as a source of tissue.

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2.2.7 If this modification requests a change in the current use of the Animal Facility, have you liaised with the relevant Animal Facility and confirmed that the required resources are available?

|  |  |  |
| --- | --- | --- |
|  | Yes. |  |
|  | No. **Please explain why.** |  |
|  | N/A. *(No change requested)*. |  |

***2.3 Refinement***

*Legislative background – Australian Code. Clause 2.2.16 (ix):*

*“Proposals must identify and justify the impact of all aspects of the project on an animal’s wellbeing from the time it is obtained until the project is completed and detail how that impact will be minimised.*

*The assessment of potential impact should include:*

*2. Identification of all aspects of animal use and management, including handling and housing, that may adversely impact on the animals’ wellbeing, and how this impact will be minimised. The information provided should include details of:*

1. *the Refinement of procedures that reduce the adverse impact on animals*
2. *how any impact will be monitored, assessed and managed, and*
3. *procedures to identify and quickly respond to unforeseen complications.”*

2.3.1 **Potential Impact on the animals.** Detail how the proposed amendments will impact on the well-being of the animals. Anticipate and describe any potential adverse effects, and the steps you will take to avoid, minimise or manage these effects.

The checklist for potential impacts of animal research protocols on animal welfare will assist you in completing this section - see: <http://www.newcastle.edu.au/research/animal/approval.html#forms> under "Download Forms and Guidelines". Methods by which adverse effects can be avoided or minimised include:

* choice of suitable animals
* appropriate design and management of animal accommodation
* care of animals in a manner that meets species-specific needs
* acclimatisation of the animals to the research environment, the researchers, and the research procedures
* ensuring competence or adequate training/supervision of researchers
* use of the most humane methods
* use of appropriate anaesthetic and analgesic agents
* monitoring for early detection of adverse effects
* prompt alleviation of pain or distress
* early intervention points and humane endpoints

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2.3.2 **Monitoring.** Will animals be monitored as outlined in the currently approved protocol? If NO, provide details of the new monitoring requirements and attach an amended or additional monitoring checklist if appropriate.

*Legislative background – Australian Code.*

*Clause 2.2.16 (x): “Monitoring of animals. Details of how the wellbeing of animals will be assessed throughout the project, including:*

* *method and frequency of routine monitoring of animals*
* *method and frequency of monitoring animals during and after procedures*
* *what will be done if a problem is identified including criteria for intervention, treatment, or*
* *withdrawal of the animals from the project, and*
* *names and contact details of personnel responsible for day-to-day monitoring and for dealing with any emergencies.*

*To inform AECs of the extent to which the monitoring of animals and their care has been considered in the project design.”*

*Clauses 3.1.9, and 3.3.1 to 3.3.10: Specify the legislative requirements regarding monitoring of animals with respect to researcher responsibilities, actions that must be taken, monitoring records etc.*

If this application describes new procedures or amendments that will have additional potential impact on the animals that was not described in the initial application, you must:

* provide details of the additional monitoring to be performed.
* attach an amended or additional monitoring checklist.

Refer to [http://www.newcastle.edu.au/research/animal/AWCpol.html#monitoring](http://www.newcastle.edu.au/research/animal/acecpol.html#monitoring) which includes the expectations of the AWC regarding monitoring of animals, and templates for monitoring checklists.

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***Section 3. Justification***

*Legislative background – Australian Code. Clause 2.2.16 (xi):*

*“Investigators and teachers must provide justification for the use of animals in the project weighing the predicted scientific or educational value against the potential impact on the animals. In addition, particular justification must be given for potentially severe or ethically contentious procedures. For example:*

* *unrelieved pain and distress including where the planned end-points will allow severe adverse effects to occur (see 3.3.10);*
* *death as the end point (see 1.27 and 3.3.5(vi));*
* *reuse of animals (see 3.3.11);*
* *prolonged restraint or confinement (see 3.3.16);*
* *production of monoclonal antibodies by the ascites method (see 3.3.69 and 3.3.71) and*
* *the use of non-human primates (see 3.3.79).*

*This is the opportunity for the investigator or teacher to present their case for the justification of the project on the basis of the proposed benefits, sound experimental design, and the potential adverse impacts on the animals described in the proposal. The AWC is then able to decide whether it agrees that the project is justified.”*

Any amendment to an approved protocol is subject to the same scrutiny with respect to justification as applied to an Initial application. The Committee must be satisfied that the proposed amendment is appropriate and justified.

3.1Explain why the proposed amendments are necessary to meet the project aims, taking into account the ethical considerations, the impact on the welfare of the animals and the anticipated scientific or educational value.

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***Section 4: Investigator Declaration of Responsibilities***

You must do more than check “Yes” or “No” in the first part of this section. Refer back to the original Application for this project and check carefully that the information or features continue as originally stated.

You should note all of the requirements under this declaration.

Applications to the AWC are legal documents under the SA Animal Welfare Act. Accordingly, an application must have the appropriate signature. Failure to submit the fully signed original of the application to the Research Services Office will result in delays in processing of the application. If the fully signed application has not been received by the time of its consideration by the AWC, advice cannot be provided of the outcome of this deliberation.

• I have reviewed the particulars set out on the *original* Application to the AWC for this project and certify:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| (i) | That the Aims of the project are unchanged. | Yes |  | No |  |
| (ii) | That any licences that are required have been obtained and are current. | Yes |  | No |  |
| (iii) | That the "purpose" classification of the project is unchanged. | Yes |  | No |  |
| (iv) | That the "procedure" classification of the project is unchanged | Yes |  | No |  |

*(Note:* ***Where the answer is NO****, please review your application. The submission of a new Application may be required.)*

1. 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)
2. To the best of my knowledge this proposal conforms to the Code (8th Edition 2013) and the South Australian Animal Welfare Act 1985.
3. 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.
4. I agree to comply with procedures described and any conditions imposed by the Animal Ethics Committee.
5. I accept responsibility for the conduct of the project as outlined in this application in accordance with the legislation, and the requirements of the Flinders University / Southern Adelaide Health Service Animal Welfare Committee.
6. I certify that I believe that this work is ethically justified and compliant with the requirements of the Code.
7. I declare that I have the appropriate qualifications and experience to perform the procedures described in this application or to ensure that they are done correctly.
8. I accept responsibility for ensuring that each person involved with this project has the necessary experience to perform the procedures they are to carry out. If they are not already skilled in the procedures, I accept responsibility for ensuring that they obtain the necessary training in advance, and appropriate supervision, so that each procedure on an animal will be carried out in the most appropriate manner.
9. I confirm that sufficient and adequate resources will be available to undertake the proposed study.
10. I confirm that all other persons involved with this project are familiar with the SA Animal Welfare Act and Regulations, and the Australian code of practice for the care and use of animals for scientific purposes, and accept the responsibilities detailed therein to extent of their involvement in this project.
11. I confirm that all other persons involved with this project have read this application and have agreed to conduct the project as outlined in this application in accordance with the legislation, and the requirements of the Flinders University / Southern Adelaide Health Service Animal Welfare Committee.
12. I confirm that all other persons involved with this project have received or have access to a copy of this application, and will receive a copy of any associated correspondence or documentation from the AWC.

**All Investigators must sign. If an Investigator is absent** at the time of submission of an application and unable to sign the application, other Investigators may sign on their behalf and the signature of that Investigator be provided at a later date

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| --- | --- | --- | --- |
|  | *Name* | *Signature* | *Date* |
| Chief Investigator: |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | *Name* | *Signature* | *Date* |
| Co-Investigator: |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | *Name* | *Signature* | *Date* |
| Other Investigators: |  |  |  |

*Please replicate as many times as necessary.*



*You have reached the end of this form. Please ensure that you have responded to every question (even if your response is "Not applicable").*

***If you have been requested to do so, you must now complete all relevant attachments and attach them to this document.***