ANIMAL USER'S HANDBOOK

UPDATED 2025

A Guide to Researcher Responsibilities for the Humane and Ethical Care of Animals in Research and Teaching

THE UNIVERSITY OF ADELAIDE ANIMAL ETHICS COMMITTEE
OFFICE OF RESEARCH ETHICS, COMPLIANCE AND INTEGRITY

Contents

INTRODUCTION

1. OVERVIEW/PURPOSE/BACKGROUND

This handbook provides the materials that you need to understand the requirements for the use of animals in research or teaching as outlined in the *Australian Code for the Care and Use of Animals for Scientific Purposes (*8th Edition, 2013) (the Code). These include the application for approval for animal use through the Animal Ethics Committee (AEC) and sign off for training as proof of attainment of both the knowledge of your responsibilities and technical competencies required to undertake this work.

Further clarification concerning policies, guidelines and definitions can be sought from the AEC Secretariat, Research Services Office of Research Ethics, Compliance and Integrity, The University of Adelaide. https://www.adelaide.edu.au/research-services/ethics-compliance-integrity/animal-ethics/animal-ethics-resources.

The University of Adelaide adheres to the South Australian *Animal Welfare Act 1985* (SA) and Regulations and the NHMRC *Australian Code for the Care and Use of Animals for Scientific Purposes (*8th Edition, 2013) (the Code). The guidelines in this Handbook have been developed to assist scientific investigators and teachers to comply with the Code and to promote the humane and ethical use of animals for scientific purposes.

The Governing principles underpinning the Code[1] are:

1.1 Respect for animals must underpin all decisions and actions involving the care and use of animals for scientific purposes. This respect is demonstrated by:

(i) Using animals only when it is justified
(ii) Supporting the wellbeing of the animals involved
(iii) Avoiding or minimising harm, including pain and distress, to those animals
(iv) Applying high standards of scientific integrity
(v) Applying the principles of Replacement, Reduction and Refinement (the 3Rs) at all stages of animal care and use i.e.:
    a. The *Replacement* of animals with other methods of investigation or teaching
    b. The *Reduction* in the number of animals used
    c. The *Refinement* of techniques used to minimise the adverse impact on animals and enhancement of their wellbeing by environmental enrichment
(vi) Knowing and accepting one's responsibilities

1.2 The care and use of animals for scientific purposes must be subject to ethical review.

1.3 A judgement as to whether a proposed use of animals is ethically acceptable must be based on information that demonstrates the principles in Clause 1.1 and must balance whether the negative effects on the wellbeing of the animals involved is justified by the potential benefits to humankind.

[1] National Health and Medical Research Council (2013) Australian code for the care and use of animals for scientific purposes, 8th edition. Canberra: National Health and Medical Research Council, Section 1, Paragraph 1.1 – 1.4, p.9.

1.4 The obligation to respect animals, and the responsibilities associated with this obligation, apply throughout the animal's lifetime, including acquisition, transport, breeding, housing, husbandry, use of the animal in a project, and provisions for the animal at the conclusion of their use.

Social licence to use animals

The social licence to use animals for research, teaching and experimentation refers to the 'informal' acceptance granted to researchers by the community. As societal values change, so does the social licence that permits certain activities. The ban on cosmetic testing on animals in Australia from 1 July 2020 is a good example where strong public support and the loss of the 'social licence' for cosmetic testing have led to the change in legislation.

"As the use of animals in research and teaching has become increasingly scrutinised by the public over the last few decades, it is necessary to gain consent for animal use that would pass the scrutiny of most of the public, i.e., the concept of "social licence". The Codes regulating animal use form the basis of laws in all jurisdictions. Approval to use animals in research and teaching provided by these Animal Ethics Committees (AECs) offers protection to the researcher against prosecution for cruelty to animals under the law. The framework that regulates the care and use of animals for scientific purposes includes legislation, mandatory codes of practice, AECs and institutional guidelines. Collectively, the elements of this framework assure the public that animal welfare is safeguarded to a level acceptable to the public. Some "scientific purposes" may meet the definition of animal cruelty under the law and are only acceptable after scrutiny and approval by the AEC."[2]

Further reading:

- The Ethics Centre. Ethics Explainer: Social license to operate. 23 Jan 2018; https://ethics.org.au/ethics-explainer-social-license-to-operate/
- Gordon, Lorraine. Social licence for animal ag. 10 October 2019. The Land; https://www.theland.com.au/story/6429036/social-licence-for-animal-ag/
- Hampton, J.O. and Teh-White, K. (2019), Animal welfare, social license, and wildlife use industries. Jour. Wild. Mgmt., 83: 12-21. doi:10.1002/jwmg.21571; https://wildlife.onlinelibrary.wiley.com/doi/abs/10.1002/jwmg.21571
- Hampton JO, Jones B, McGreevy PD. Social License and Animal Welfare: Developments from the Past Decade in Australia. Animals. 2020; 10(12):2237. https://www.mdpi.com/2076-2615/10/12/2237; https://doi.org/10.3390/ani10122237

2. PERIODIC REVIEW REQUIREMENT

The Animal Users Handbook should be reviewed by the Animal Ethics Committee (AEC) in accordance with changes to the Code and/or the Act and with a maximum of four years between reviews. The AEC may appoint a subcommittee to perform reviews as needed; proposed changes to the Animal Users Handbook should be submitted to the full Committee for approval.

Any recommendations arising from annual institutional review of the AEC, or the external review will be incorporated into the Animal users Handbook.

[2] Module 1, ANZCCART Training

3. USEFUL ACRONYMS

Act, the	*Animal Welfare Act 1985 (SA)*
AEC	Animal Ethics Committee
AES	Animal Ethics Secretariat
UV	University Veterinarian
CI	Chief Investigator
Code, the	*Australian Code for the Care and Use of Animals for Scientific Purposes* (8th Edition, 2013)
CRS	Clinical Record Sheet
DEW	Department of Environment and Water
LAS	Laboratory Animal Services
SOP	Standard Operating Procedures
3Rs	Replacement, Refinement and Reduction

4. KEY CONTACTS

Animal Ethics Secretariat

General AEC enquiries: aec@adelaide.edu.au

Amanda Camporeale: Senior Research Ethics Officer (Animal Ethics)

E: amanda.camporeale@adelaide.edu.au; T: 8 8313 6310

Karina Burns: Secretary, Animal Ethics Committees

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University Veterinarians

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Laboratory Animal Services

Tiffany Boehm, LAS Manager
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las.manager@adelaide.edu.au; T: 8 8313 5340

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Training Enquires

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General Enquires

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SECTION ONE: ANIMAL ETHICS PROTOCOLS

5. WHEN DO YOU NEED ANIMAL ETHICS COMMITTEE APPROVAL?

Are You:

- Using live animals for research
- Using live animals for teaching in a manner not covered by the Veterinary Surgeons Act or Clause 4.17 of the Code*
- Acquiring organs or tissues from living or dead animals
- Breeding or acquiring animals
- Applying to a granting body requiring ethics clearances before releasing funds
- Submitting results for publication that require ethical clearance

Section 2.4 (iv) of the Code states that: All activities, including projects that involve the care and use of animals for scientific purposes must*:

(a) Be subject to ethical review, approval and monitoring by an AEC
(b) Commence only after approval has been granted by an AEC
(c) Be conducted in accordance with AEC approval
(d) Cease if approval from the AEC is suspended or withdrawn

All use of animals by University personnel or holding of animals at University premises must be approved by the AEC before commencement*. In this context, use and holding includes:

- the use or involvement of animals in research projects or experiments, irrespective of the site involved, the ownership of the animal, or the source of funding*;
- the use of animals in undergraduate laboratory classes*;
- the use of animals for training staff and students;
- holding, breeding or any other keeping of animals*;
- fieldwork, including capture and release after marking*.

* Exclusions from the need for AEC approval for teaching:

All research requires AEC approval. However, the use of animals in the teaching of veterinary medicine and animal husbandry is not always covered by the Code but is covered by the Veterinary Surgeons Act. If the animal is being treated for its own benefit or having a husbandry procedure done that is routine veterinary or normal farm practice, then these activities do not need AEC approval. However, if the timing of the treatment or husbandry procedure is changed to suit a teaching schedule, rather than as routine care or normal farm seasonal practice, then this activity does need an AEC approval. If students are observing, or participating in, procedures that fall within the realm of normal veterinary or husbandry practices within a clinical or farm setting, these procedures do not need AEC approval.

If you have any queries about your specific teaching project, please contact a University Veterinarian for advice. Refer also to Section 4.17 of the Code.

When animals are to be held in the premises of another institution staff and students must apply to the AEC established by that institution. If the other Institutional AEC is not recognised by the University of Adelaide under a Deed of Reciprocal Access then dual approval is required. If the staff or students are working at a facility that does not have an AEC then they would be required to apply to the University of Adelaide AEC.

6. DEFINITIONS WITHIN THE CODE

Definitions identified as relevant to the responsibilities of investigators[3]:

Activity: any action or group of actions undertaken that involves the care and use of animals, including acquisition, transport, breeding, housing and husbandry of those animals. An activity may involve one or more procedures. Activities are described in an application to the animal ethics committee. See also 'Project'.

Animal: any live non-human vertebrate (that is, fish, amphibians, reptiles, birds and mammals encompassing domestic animals, purpose-bred animals, livestock, wildlife) and cephalopods.

Note: the Code stipulates that Institutions are responsible for determining when the use of an animal species not covered by the Code requires approval from an AEC, taking into account emerging evidence of sentience and ability to experience pain and distress ... when embryos, foetuses and larval forms have progressed beyond half the gestation or incubation period of the relevant species, or they become capable of independent feeding, the potential for them to experience pain and distress should be taken into account.[4]

Current best practice: a practice, procedure, method or process that has proven to be most effective in supporting and safeguarding animal wellbeing, and that:

- takes into consideration the relevant aspects of species-specific biology, physiology and behaviour
- is based on the best available scientific evidence (or, in the absence of scientific evidence, accepted practice), which includes the potential adverse impact of conditions and procedures on the wellbeing of the animals
- includes strategies to minimise adverse impacts.

Investigator: any person who uses animals for scientific purposes. Includes researchers, teachers, undergraduate and postgraduate students involved in research projects, and people involved in product testing, environmental testing, production of biological products and wildlife surveys.

Person with ultimate responsibility: person who is responsible for the overall management and conduct of an individual project (the Chief Investigator), and for ensuring that clear lines of responsibility, communication and accountability regarding the care and use of animals in the project are identified. This person is responsible for the daily monitoring of animals used for scientific purposes or the delegation to members of the group or apply to Laboratory Animal Services (LAS) for assistance by fee for service arrangement (applying to LAS for assistance does not guarantee LAS can provide assistance).

Procedure: a technique employed when caring for or using animals for scientific purposes. One or more procedures may be used in an activity.

Project: an activity or group of activities that form a discrete piece of work that aims to achieve a scientific purpose.

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[3] National Health and Medical Research Council (2013) Australian code for the care and use of animals for scientific purposes, 8th edition. Canberra: National Health and Medical Research, pp. 3 -6.

[4] National Health and Medical Research Council (2013) Australian code for the care and use of animals for scientific purposes, 8th edition. Canberra: National Health and Medical Research, p. 1.

Scientific purpose: all activities conducted with the aim of acquiring, developing or demonstrating knowledge or techniques in all areas of science, including teaching, field trials, environmental studies, research (including the creation and breeding of a new animal line where the impact on animal wellbeing is unknown or uncertain), diagnosis, product testing and the production of biological products.

Unexpected adverse event: an event that has a negative impact on the wellbeing of animals and was not anticipated in the approved project or activity.

An unexpected adverse event may result from different causes, including but not limited to:

- death of an animal, or group of animals, that was not expected (e.g. during surgery or anaesthesia, or after a procedure or treatment)
- adverse effects following a procedure or treatment that were not expected
- adverse effects in a larger number of animals than predicted during the planning of the project or activity, based on the number of animals actually used, not the number approved for the study
- a greater level of pain or distress than was predicted during the planning of the project or activity
- power failures, inclement weather, emergency situations or other factors external to the project or activity that have a negative impact on the welfare of the animals.

Any of these adverse outcomes require that early notification is made to LAS, a University Veterinarian by phone or email and later to the Animal Ethics Committee in writing. Please see section 6.6 reporting an adverse event.

7. APPLYING FOR AEC APPROVAL

All studies using animals must be approved and monitored by an AEC. AECs are responsible for ensuring, on behalf of institutions, that all care and use of animals complies with the Code, the use of animals is justified, and the principles of Replacement, Reduction and Refinement are followed.

Institutions are responsible for ensuring that any use of animals for scientific purposes is approved and monitored by an AEC. **Before** a project using animals can begin, any new protocols must be approved by an AEC. The exception here is in veterinary and animal husbandry teaching as defined previously in Section 2 and in accordance with Section 4.17 of the Code.

All University personnel who wish to use animals for teaching, research or experimentation must obtain ethical approval as required prior to any use or involvement with animals, irrespective of where they are located, where animals may be housed or used, or of the source of funding.

AEC approval is required before animal holding space is allocated and before animals are acquired or supplied. Ethical approval of a project does not guarantee that the animals, or space for holding them, will be available. It is for the applicant to ensure this availability.

8. WHO MUST APPLY?

Staff, titleholders and students at the University of Adelaide must apply to the University AEC if animals are to be held on University premises, with the exception of veterinary patients held in the University clinical facilities or production animals held for routine husbandry on University-associated farms. If the work involves any fieldwork, then University of Adelaide AEC approval is required irrespective of any other AEC approvals also required.

When animals are to be held in the premises of another institution staff and students must apply to the AEC established by that institution. If the other Institutional AEC is not recognised by the University of Adelaide

under a Deed of Reciprocal Access then dual approval is required. If the staff, titleholders or students are working at a facility that does not have an AEC then they are required to apply to the University of Adelaide AEC: e.g. The Queen Elizabeth Hospital or Women's and Children's Hospital.

All research requires an AEC approval.

9. WHO DOES NOT NEED TO APPLY?

The University does not accept applications from individuals external to the University if they have no University affiliation.

Teachers may not require AEC approval if their teaching activities meet the requirements of the exemption clause in the Code. Section 4.17 of the Code contains an exemption from the requirement to seek AEC approval for certain activities:

> " AEC approval is not required for the training and application of agricultural extension work practices, or the training of students in veterinary science, veterinary nursing or animal technology to achieve competency-based outcomes in routine procedures if **all** of the following apply:
>
> (i) the animals are at their home property or a premises licensed by a state or territory Veterinary Surgeons Board i.e. on a farm or in a veterinary clinic or hospital
> (ii) the procedures would normally occur as part of routine management or veterinary clinical management of the animal
> (iii) the animals are not subjected to anything additional to routine management or veterinary clinical management of the animal
> (iv) the teacher is competent to carry out the procedure
>
> If all the above criteria are met, AEC approval is not required for clinical veterinary and animal husbandry teaching/training activities."

10. MUTUAL ACCEPTANCE OF ETHICS APPROVALS IN SOUTH AUSTRALIA

The University of Adelaide has in place a *Deed for Reciprocal Access to Animal Ethics Committees* with the following South Australian AECs: Flinders University, SAHMRI, UniSA, and PIRSA. This means where teaching, research or experimentation will be undertaken by a collaboration of staff from multiple institutions, in most instances only a single AEC approval is required for the activity. The Deed enables the mutual recognition of AEC approvals for teaching, research or experimentation conducted in the premises of the other organisation. University of Adelaide staff and students are not required to obtain University of Adelaide AEC approval when their animal work is solely being conducted in the other organisation's facilities and is approved by the other AEC.

Approval must be obtained from the AEC established by the organisation that is responsible for the premises in which the animals will be housed. However, if the animals will not be held captive, approval must be obtained from the AEC established by the institution which employs or engages the Chief Investigator on an Animal Ethics Application.

If the animals are held at multiple institutions, then AEC approval from both University of Adelaide and the other institution is required, unless directed otherwise by the AES.

The Deed for Reciprocal Access to Animal Ethics Committees outlines the approval and administrative processes to be followed when researchers apply to one of the AECs.

If the investigator obtains approval from another organisation's AEC, they do not need to notify the University of Adelaide's AEC of the approval because the Animal Ethics Secretariat of the approving institution will be responsible for fully informing the non-approving organisation. Each institution will be responsible for ensuring that both organisations are fully informed of their animal-based research activities.

The investigator can still choose to obtain approval from both committees. If they obtain 'dual' approval, then they also need to obtain approval for minor amendments from both AECs and provide annual and adverse event reports to both AECs.

Existing University of Adelaide approvals that are no longer required because work is covered by the approval of the other organisation's AEC can be closed off, removing the need to seek approval for minor amendments from both committees and report to both committees.

If the University AEC approval is not closed, all requirements for reporting remain – i.e., investigators must still obtain approval for amendments from each AEC and report adverse events and annually to each AEC until that approval is closed.

To close an existing University of Adelaide AEC approval investigators must advise the Animal Ethics Secretariat (AES) (aec@adelaide.edu.au) with the project number, project title, Chief Investigator's name and AEC Approval Number. Upon the Chief Investigator's written advice, the AES will confirm that the University of Adelaide ethics approval has been closed. Note that the investigator will still be required to provide an annual report on the project for the annual reporting period; however, for these projects the AEC will accept the annual report that is required to be submitted to the other institution.

11. DUAL APPROVAL

Dual approval is required:

- Where animals are to be held in the premises of another institution and the other Institutional AEC is not recognised by the University of Adelaide under a Deed of Reciprocal Access.
- If the project involves animals held at multiple institutions, unless directed otherwise by the AES
    - As a guideline, animals that are not held overnight in University of Adelaide facilities, may not require dual approval (note: this does not apply to field-based projects). If the animals are not held overnight at The University of Adelaide, please discuss requirements with the AES. The AES and UV may agree that email notification of the other institutions ethics approval, including the application and approval letter as an attached file, may be sufficient and a separate University of Adelaide approval may not be required.
    - Example situations include use of Adelaide Microscopy facilities to image an animal, or animals being transported to The University of Adelaide for immediate humane killing, sample collection and tissue analysis.

12. STUDENT RESEARCH

In the case of a student research project, the supervisor is the Chief Investigator with the student named as either Co-Investigator or an Associate Investigator.

13. UNDERGRADUATE TEACHING PROJECTS

The application form is designed primarily in relation to research projects and whilst is not specifically tailored to teaching should be used as a guide to the details required for ethical consideration of the work.

Please note that all proposals for animal use in teaching in which students are to interact with, or handle, animals or carry out a procedure on an animal must clearly include details of:

- the maximum number of students to be supervised by each teacher;
- the minimum and maximum number of animals to be used by each student;
- the maximum number of times each animal will be used; and
- how the attainment of the educational objectives within the curriculum will be assessed.

In addressing the last dot point, the AEC requires a clear statement of the educational objectives for the teaching exercise accompanied by an assessment which clearly supports the request to use animals i.e. dissection skill, anatomical knowledge, etc.

The Code details responsibilities associated with the care and use of animals for the achievement of educational outcomes in science in Section 4, paragraph 4.1 – 4.17.

In addition, applications involving use of animals for undergraduate teaching:

- must include references to any alternatives available. Approval for use of animals in undergraduate teaching cannot be expected where practicable alternatives to animals could be used effectively.
- should demonstrate how teachers have trialled alternative teaching methods, which do not involve the use of animals, or demonstrate why the use of animals is sufficiently superior to warrant exemption from this requirement

14. OVERSEAS PROPOSALS

Before submitting an application to the AEC, University staff should contact the University AEC Secretariat if any staff or student research or teaching involving animals is proposed in other countries and obtain advice on a case-by-case basis in line with the requirements of 2.6.9 – 2.6.14 of the Code.

Investigators responsible for a project conducted in another country should, as a minimum, ensure that:

- the project complies with the governing principles of the Code, provided that such compliance does not breach relevant local legislation
- the project is not conducted in another country as a mechanism of avoiding compliance with the Code *[the Code 2.6.13].*

Investigators who plan to use animals in another country must obtain approval from the AEC for such use. Investigators must provide the AEC with advice on how the proposed project can meet the principles of the Code, taking into account compliance with local requirements [*the Code 2.6.14*].

15. HOW DO YOU APPLY?

Applications should be submitted to the AEC using the current online application form available through Research Master. The form should contain sufficient information to satisfy the AEC that the proposed use of animals is justified and complies with the principles of Replacement, Reduction and Refinement. The justification process includes weighing the predicted scientific or educational value of the proposal against potential impact on the welfare of the animals, and justification given for the number of animals requested.

This guide to compiling ethics applications (Appendix 1) has been developed by the University Veterinarians to assist researchers with the style of answers that the AEC requires and thus help them to compile an application that is more likely to be favourably considered, and more rapidly approved, by the AEC. Please also refer to section 4.2 for further tips on writing good ethics applications.

Applications should be written in plain language that can be understood by all members of the AEC. The AEC represents a cross section of the community and has lay members who are non-scientists, so the language should be similar to that in a press release where terms are defined, and acronym use minimised. The predicted impact to animals must be identified in all sections of the application, and how this impact will be minimised must be clearly described. Advice on these matters can be obtained from a University Veterinarian. Sufficient detail is required in the body of the application to allow the reader to gain a clear understanding of what an animal's day will entail including drugs administered, anaesthetic and analgesic agents used, doses and routes of administration and post-procedural monitoring details. A timeline illustrating the procedures that each animal will experience throughout the project including drugs used, procedural details and analgesia and endpoints to help the AEC fully comprehend the experimental plan is encouraged.

The online application form seeks information from applicants in order to meet the requirements of the Code. All sections of the application form must be completed to comply with the Code. Applications need to be complete and be of a satisfactory standard and level of detail before the AEC can consider them.

Applicants should be familiar with the Code and first read the 'Animal ethics introduction' and 'Guidelines for seeking ethics approval and clearance requirements' and 'Laboratory Animal Services Policies and Procedures' which can be found on the Research Services webpage under Animal Ethics Applications (https://www.adelaide.edu.au/research-services/ethics-compliance-integrity/animal-ethics/animal-ethics-applications).

Upon submission, applications are reviewed/ pre-screened by the University Veterinarians and the comments of the UVs returned to the applicants to be addressed where the application requires modification. A good edit prior to submission to eliminate typographical errors and incomplete sentences is appreciated. The use of 'N/A' in any section is not acceptable.[5] Failure to have the application pre-screened by the UVs results more frequently in the failure to gain approval at the first AEC meeting and the need to resubmit and present to the subsequent AEC meeting in person. Missing information or pre-screen comments not addressed will result in delayed decision-making. There are also real time benefits in seeking UV comment on your application prior to initial submission to smooth the approval process.

Following pre-screen, the resubmitted application must be received by the AES prior to the deadline date (as listed on the Research Ethics, Compliance and Integrity website: https://www.adelaide.edu.au/research-services/ethics-compliance-integrity/animal-ethics/animal-ethics-applications#deadlines) in order to be included on the Agenda for the subsequent AEC meeting.

Information, helpful writing tips and links concerning the use of the application form can be found on the University website at: http://www.adelaide.edu.au/ethics/animal/guidelines/applications/ as well as in the Animal Ethics and Welfare Induction Course.

To access the AEC Online form:

- open a browser and go to ResearchMaster (https://rme.adelaide.edu.au/)
- Login using your standard University username and password.
- For further support or questions, visit the Research Services Website (Research Master Enterprise (RME) | Research Services | University of Adelaide) or contact researchsystems@adelaide.edu.au.

[5] Animal Ethics and Welfare Induction Course: Writing an application to the AEC

SECTION TWO: TRAINING

There are several AEC training requirements that must be met prior to approval for animal use. This guide for researcher responsibilities for training and AEC expectations (Appendix 2) has been developed by the University Veterinarians to assist researchers identify their responsibilities for training, demonstration of competency and also provides an overview of training processes. The AEC requires this information so if it is included in the application, it will assist the application to be more rapidly approved by the AEC.

16. KNOWLEDGE

Firstly, investigators must be familiar with their responsibilities under the Code. At a minimum, investigators should read and comply with:

- Section 1: Governing Principles
- Section 2.4: Responsibilities of investigators
- For investigators that also care for animals: Section 2.5: Responsibilities of animal carers
- Section 2.6 Other responsibilities of institutions, investigators and animal ethics committees
- Section 3: Animal wellbeing (including Sections 3.1, 3.2, 3.3 and 3.4)
- For teachers: Section 4: The care and use of animals for the achievement of educational outcomes in science

Investigators should also be familiar with all relevant safety information relating to their work and have completed all local inductions.

New staff and students requiring access to LAS must also complete compulsory induction training.

Additional opportunities for increasing knowledge and understanding in relation to animal ethics and animal welfare are encouraged and include:

- NHMRC guides and resources (https://www.nhmrc.gov.au/research-policy/ethics/animal-ethics):
    - The 3Rs
    - Ensuring quality in animal studies
    - Use of animals in NHMRC funded research
    - Use of Australian Native mammals
    - Non-human primates
    - Genetically modified and cloned animals for scientific purposes
    - Use of animals for testing of cosmetics
    - Guidelines to promote the wellbeing of animals used for scientific purposes
- The ARRIVE (Animal Research: Reporting of In Vivo Experiments) guidelines (https://www.nc3rs.org.uk/arrive-guidelines) have been developed to improve standards of *reporting* the results of animal experiments.
- The PREPARE guidelines for planning animal research and testing (https://norecopa.no/prepare) provide guidelines for *planning* animal research from day one.
- The Canadian Council on Animal Care (CCAC) Three Rs (https://3rs.ccac.ca/), provides those involved with the use of animals in science with easily accessible, useful, and relevant information and resources on the Three Rs - replacement, reduction and refinement alternatives

17. INSTRUCTION AND COMPETENCY

Animal Ethics and Welfare Course

It is expected that all new University of Adelaide animal users will undertake training in animal ethics and welfare if they are to obtain clearance to work with animals. The Animal Ethics Committee requires:

- all University staff, students, titleholders and other applicants that have not completed an AEC approved training course within the last 5 years to complete the currently approved training (ComPass). (Animal Ethics Training | Research Services | University of Adelaide) and supply the completion certificate to the AEC.

- refresher training in animal ethics and welfare be completed by all animal users at least every three years, in accord with requirements for continuing professional development (CPD) in the Australian Code;

- all animal users renew their animal ethics and welfare training when the Code or relevant regulations change, as may be determined necessary by the AEC;

- all applicants completing the currently approved training (ComPass) also successfully complete the online assessment before commencing work with animals.

  Effective 1 March 2021, the AEC has approved the Australian & New Zealand Council for the Care of Animals in Research and Teaching online training course, ComPass (ANZCCART Competency Passport) as the required training for all animal users applying to the AEC. ComPass is a free online course covering the Australian Code and the NZ Guide and welfare issues relating to animal use in research and teaching, and is suitable for researchers, teachers and animal ethics committee members. The course is the product of input of Animal Welfare Officers from across Australia and New Zealand. ComPass includes an online quiz to demonstrate your competency. The course currently includes 7 core learning modules:

- Module 01 – Ethics, animal use and the legislation

- Module 02 – The Animal Ethics Committee and what they want

- Module 03 – Research project and teaching activity planning

- Module 04 – Animal wellbeing and the 3Rs

- Module 05 – Unexpected Adverse Events and what to do

- Module 06 – Are my animals well?

- Module 07 – The end of life – humane methods of killing

- Module 08 – Final quiz for modules 01-07

The course, and instructions for registering, is available at: https://anzccart.adelaide.edu.au/compass . To enrol and register for the course click on the button 'ComPass Animal Welfare Training – Phase One' which is below the course instructions. Once enrolled you can login at your convenience as the training is self-paced.

Phase 2 has stand-alone modules, each with an individual certificate of completion so you can choose those topics relevant to your needs. Three modules are available now with another five still to come:

Aseptic technique

Minimally invasive techniques without anaesthesia, including wildlife trapping

Anaesthesia for minor procedures

Modules to come soon:

Anaesthesia for major procedures

Surgical principles and materials

Performing a post-mortem examination

Managing a breeding colony

Behavioural testing in rodents

Certificates demonstrating successful completion of the online quiz should be forwarded to aec@adelaide.edu.au for recording in the AEC Training Register. If the training does not appear for an individual on the Expertise Report generated from within an online Animal Ethics application, the certificate of course completion will need to be uploaded to the page '11.5 Attached Documents' of the application.

Further information Animal Welfare | University of Adelaide

18. TECHNICAL COMPETENCE

Investigators must also prove technical competence in the procedures listed in the application. Ensuring personnel are trained and competent is the responsibility of the Chief Investigator.

For all procedures performed by investigators in their protocols, demonstration of the methods used should be documented via the appropriate Standard Operating Procedure (SOP). There is a comprehensive list of existing AEC approved SOPs available on the LAS website including restraint techniques, injection methods, anaesthesia and analgesia use and methods for humane killing.

An animal training suite laboratory has been established at the Helen Mayo South (HMS) LAS facility on level 6. In the training suite, there are multiple stations where investigators can come to practice their technical skills on inanimate models.

- Models can be used to practice injection methods in mice and rats – subcutaneous, intramuscular, intraperitoneal, and intravenous models are available.
- For those performing surgery, there are models to help achieve technical skills in suturing, knot tying, sterile preparation of the skin, opening kits and preparing the skin of both the animal and the surgeon using aseptic technique including scrubbing methods.
- To assist in analgesia and anaesthesia training, there are stations to practice assembling the anaesthetic machine, and performing a linear local anaesthetic block.
- There are several stations designed to assist in gaining proficiency in instrument use and dissection methods.

Booking the training suite is essential with minimum 2 business days' notice via las_training@adeladie.edu.au

For mice and rats, basic practical animal training sessions and competency assessment are available via LAS and the University Veterinarians. For more information, please contact LAS via las_training@adelaide.edu.au

Competency assessment can be used as proof of competence for AEC applications.

For all species, the University Veterinarians are available to discuss training needs with investigators and will assist them to identify appropriate training if the University Veterinarian is not able to provide the training.

More project-specific skills should be signed off by the supervisor, or other skilled person in the laboratory group e.g., mouse pancreatectomies. If needed, some cadaveric training animals for these complex procedures can be obtained from the LAS culls by prior arrangement. Advice on surgical methods, analgesia, and anaesthesia methods is available from the UVs.

Further opportunities for practical handling training are outlined on the University Veterinarian web page (https://www.adelaide.edu.au/animalwelfare/user-training).

19. ADDITIONAL TRAINING

Investigators working in particular areas will also need to have completed required competency or qualifications or licence requirements to undertake particular activities with animals, for example, use of radioactive substances/apparatus, working with GMOs, operation of firearms, boating, diving safety, use of drones, field work requirements, etc.

All investigators should refer to the following University information for other relevant requirements in relation to information, training and competency:

- HSW Policy and Handbook: https://www.adelaide.edu.au/hr/hsw/hsw-policy-handbook#hsw-handbook-chapters-faqs
- Drones: https://www.adelaide.edu.au/environment/uraf/
- Gene Technology /GMOs: https://www.adelaide.edu.au/research-services/ethics-compliance-integrity/gene-technology
- Legal Compliance Framework Legislation Directory: https://www.adelaide.edu.au/legalandrisk/compliance/legislation-directory

SECTION THREE: PLANNING A NEW RESEARCH PROJECT

Investigators need to address the Planning Research and Experimental Procedures on Animals: Recommendations for Excellence (PREPARE) and Animal Research: Reporting of In Vivo Experiments (ARRIVE) guidelines in order to minimise animal wastage. Journals are increasingly using these guidelines as part of their editorial/ review processes so knowledge of them is becoming increasingly vital to publication success.

The PREPARE guidelines include a two-page checklist (Appendix 3), which summarises the 15 topics in PREPARE.
The ARRIVE guidelines (Appendix 4) are a checklist of recommendations to improve the reporting of research involving animals – maximising the quality and reliability of published research, and enabling others to better scrutinise, evaluate and reproduce it.

20. THE KEY PRINCIPLES OF REPLACEMENT, REDUCTION AND REFINEMENT

The Code requires research investigators, teachers, animal facility staff and AECs to ensure that:

- the use of animals in scientific activities is justified;
- animal wellbeing is supported;
- harm, including pain and distress is minimised for those animals used;
- high standards of scientific integrity are applied;
- individuals are aware and accept their responsibilities; and
- the key principles of Replacement, Reduction and Refinement (the 3Rs)[6] are applied**.**

There are various accepted definitions of the 3Rs, the table below provides the definitions provided in a recent Information Paper[7] on the 3Rs by the NHMRC as well as the definitions provided on the 3Rs Microsite developed by the Canadian Council for Animal Care (CCAC).

	NHMRC	CCAC
Replacement	Methods that permit a given purpose of an activity or project to be achieved without the use of animals	Replacement refers to methods which avoid or replace the use of animals in an area where animals would otherwise have been used
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	Reduction refers to any strategy that will result in fewer animals being used
Refinement	Methods that alleviate or minimise potential pain and distress and enhance animal wellbeing	Refinement refers to the modification of husbandry or experimental procedures to minimize pain and distress

6 Russell, W., & Burch, R. (1959). The principles of humane experimental technique.
7 Information paper: The implementation of the 3Rs in Australia, Canberra: National Health and Medical Research Council (2019), p. 4.

21. GUIDES FOR IMPLEMENTING THE 3RS

The 3Rs Microsite offers a step-by-step search guide for Canadian researchers to assist in implementing the 3Rs, this resource also provides a useful guide for Australian researchers.

There are a number of centres worldwide promoting the 3Rs and involved in the development and validation of alternative non-animal models for research. Within Australia, the Medical Advances Without Animals Trust (MAWA) is currently developing The Australian Centre for Alternatives to Animal Research (ACAAR) in partnership with the Australian National University (ANU) in Canberra, the first of its kind in Australia. The MAWA website states: The Trust provides research and equipment grants, fellowships, scholarships, bursaries and sponsorships to scientists and scholars throughout Australia in a competitive award process, and funds a range of other initiatives to further MAWA's goals.

The organisation Australia and New Zealand Council for the Care of Animals in Research and Teaching (ANZCCART) is a useful resource for general information and publications around responsible use of animals in research. There is also information and resources on the 3Rs provided in the University's Animal Ethics and Welfare Induction Course.

In the UK, The National Centre for the Replacement Refinement & Reduction of Animals in Research (NC3Rs) offer an updated definition of the 3Rs on their webpage, the table below is a reproduction of this.

	Standard	Contemporary
Replacement	Methods which avoid or replace the use of animals	Accelerating the development and use of models and tools, based on the latest science and technologies, to address important scientific questions without the use of animals
Reduction	Methods which minimise the number of animals used per experiment	Appropriately designed and analysed animal experiments that are robust and reproducible, and truly add to the knowledge base
Refinement	Methods which minimise animal suffering and improve welfare	Advancing research into animal welfare by exploiting the latest in vivo technologies and by improving understanding of the impact of welfare on scientific outcomes

A recent publication: Information Paper: Implementation of the 3Rs in Australia (2019) based upon a survey conducted by the NHMRC, provided useful insights on attitudes held by investigators, AEC members and institutions around barriers and enablers to implementing the 3Rs within Australia. The table below highlights respondents' views on key enablers to implementation of the 3Rs. Perceived barriers were also discussed:

"All participant groups identified the lack of appropriate scientific or technological innovation as the primary barrier to implementation of the 3Rs. Other key barriers included comparability of data (identified by investigators) and insufficient funding available (identified by institutional representatives)"[8].

22. KEY ENABLERS TO IMPLEMENTATION OF THE 3RS

Replacement	Reduction	Refinement
• Greater availability of human tissues • Increased funding to develop replacement options • Technical advances in tissue engineering • Help to identify replacement techniques • More predictive computer models	• Statistical evidence that fewer animals would provide the required research results • Increased sharing of data or collaboration between research groups • Increased sharing of data or collaboration between institutions	• Help to identify refinement methods • Increased sharing of information between research groups • Increased sharing of information sharing between institutions • Greater willingness among investigators to change their methods

Other key enablers to implementation of the 3Rs are:

- for **Refinement**, understanding that improved welfare by enhanced enrichment will decrease research result variability[9], and
- for **Replacement** and **Reduction**, the increased use of inanimate models for technical skills training (available on level 6 of Helen Mayo South Building on the North Terrace Campus).

Other key principles in addition to the 3Rs include Justification and Responsibility.

23. JUSTIFICATION

The Code requires projects using animals 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 consider all aspects of the project that may have an adverse impact on the animals *[the Code 1.5 – 1.7].*

The Code Section 1, Paragraph 1.7 states: An animal ethics committee (AEC) must be satisfied that there is sufficient evidence to support a case that the proposed use of animals is justified.

[8] Information paper: The implementation of the 3Rs in Australia, Canberra: National Health and Medical Research Council (2019), p.18.
[9] Bailoo JD, Murphy E, Boada-Saña M, Varholick JA, Hintze S, Baussière C, Hahn KC, Göpfert C, Palme R, Voelkl B and Würbel H (2018) Effects of Cage Enrichment on Behavior, Welfare and Outcome Variability in Female Mice. Frontiers in Behavioral Neuroscience. 12:232. doi: 10.3389/fnbeh.2018.00232.

During a project if it becomes apparent animals are not suitable for their proposed use, researchers are to contact the UVs and/or Facility Managers for recommended actions. Consideration will be given to if it constitutes an adverse event, if so, researchers to follow adverse event procedure and include these scenarios in the annual report.

24. RESPONSIBILITY

The Code states that 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 [the Code 2.4].

The Code Section 2, Paragraph 2.4.1 states: Investigators have personal responsibility for all matters that relate to the wellbeing of animals that they use, including their housing, husbandry and care. This responsibility extends throughout the period of use approved by the AEC until provisions are made for the animal at the conclusion of their use.

25. IMPLEMENTING THE KEY PRINCIPLE OF REPLACEMENT

Replacement is defined within the Code[10] as:

- Methods that replace or partially replace the use of animals must be investigated, considered and, where applicable, implemented. This investigation should be reported in your application.
- Before the use of animals is considered, all existing information relevant to the proposed aim(s), including existing databases, must be examined. Replacement techniques that must be considered include the use of epidemiological data; physical and chemical analysis; computer, mathematical and inanimate synthetic models; simulations; in vitro systems; non-sentient organisms; cadavers; and clinical cases.
- Opportunities to replace the use of animals must be kept under review during the lifetime of a project. Where relevant and applicable, the outcome of this review must be implemented in current projects and taken into account in planning future projects.

The use of inanimate models for skills training is encouraged to reduce animal use. Low fidelity models have been proven to be an excellent and useful entry to skills training in both medical and veterinary training.

The CCACs 3Rs Microsite provides resources relevant to the implementation of replacement in animal-based research, including extensive information on Alternative Test Methods which details various types of research replacements currently available. The Microsite also has an Animal Index which collates resources by species. As mentioned above, there is also a step-by-step search guide which provides detailed information for researchers on how to conduct a 3Rs information search, this guide includes a page on Replacement Alternatives. The National Centre for the Replacement Refinement and Reduction of Animals in Research provide a comprehensive collection of 3Rs Resources to assist investigators and animal technicians implement the 3Rs. The publication From Guinea Pig to Computer Mouse: Alternative Methods for a

[10] National Health and Medical Research Council (2013) Australian code for the care and use of animals for scientific purposes, 8th edition. Canberra: National Health and Medical Research Council, Section 1, Paragraph 1.18 - 1.20, p.11.

humane Education (2nd ed.) is available for free download and provides details of over 500 alternatives to animal use.

26. IMPLEMENTING THE KEY PRINCIPLE OF REDUCTION

Reduction is outlined within the Code[11] as:

- The number of animals used in a project must be the minimum necessary to achieve the proposed aim(s) and to satisfy good statistical design[12]. The use of too few animals may invalidate the experimental result and result in wastage of animals.
- The number of animals used may be reduced by the appropriate reuse of individual animals. The benefits of reusing animals must be balanced against any adverse effects on their wellbeing, taking into account the lifetime experience of the individual animal. Reuse of animals requires particular justification and specific AEC approval.
- Activities involving the use of animals must not be repeated within a project or between projects unless such repetition is essential for the purpose or design of the project (e.g. sound experimental design, statistical analysis, corroboration by the same or another investigator).
- Reducing the number of animals used should not result in greater harm, including pain and distress, to the animals used.
- All possible steps must be 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. Reduction of experimental variables may result in reduced animal use.
- Where practicable, tissue and other biological material from animals being killed must be shared among investigators or deposited in a tissue bank (e.g., Adelaide Biobank) for subsequent distribution.
- Breeding of animals must be managed to avoid or minimise the production of excess animals. A new line of animal should not be generated if a similar suitable animal line is available to the investigator. When a new animal line is generated, the colony should be made available as a source for other investigators, as appropriate.
- Animals of both genders should be used equally with the obvious exception of reproductive studies. The use of one gender exclusively needs rigorous justification in order to be passed as this almost inevitably increases wastage by 100% of the opposite gender.
- The CCACs 3Rs Microsite provides information on Reduction Alternatives as part of its step-by-step search guide. Michael Festing has launched a site 3Rs – Reduction.co.uk which is still under development but can be accessed in its developing stages. The site provides a short course on experimental design for research with laboratory animals.

Optimising the number of animals proposed to be used

It is a requirement of the Code that any experimental proposal involving animal use is scientifically justified *[the Code 1.1, 1.5 – 1.7].* The AEC application form asks for justification for the number of animals used.

Justification for the number of animals required may include:

- Teacher: student, and student: animal ratios in teaching activities. Accounting for both student and animal safety and welfare.
- Statistical Consideration: investigators are asked to provide the AEC with evidence that there has been statistical consultation during experimental design, and that appropriate sample sizes or group sizes have been selected based on a power analysis, resource equation, pilot study or another

[11] National Health and Medical Research Council (2013) Australian code for the care and use of animals for scientific purposes, 8th edition. Canberra: National Health and Medical Research Council, Section 1, Paragraph 1.21 - 1.27, p.11.
[12] See the ARRIVE and PREPARE guidelines.

scientifically valid basis.

- Substitution of methodology enabling 'repeat measures' or 'crossover studies' on a single animal for methods requiring an individual animal for each time point and treatment group, where appropriate.
- Implementation of "Scavenging" of tissues when appropriate (See Section 9.2 for further information on scavenging)

Recommended Reading

Das, R.E., Fry, D., Preziosi, R.F., & Hudson, M. (2009). Planning for Reduction. Alternatives to Laboratory Animals, 37, 27 - 32.

Festing, MFW (2020 website) http://isogenic.info/index.html

Festing MFW, Overend P, Gaines Das R., Cortina Borja M and Berdoy M (2002) The Design of Animal Experiments: Reducing the use of animals in research through better experimental design. Laboratory Animal Handbook Series, 14, RSM Press.

Festing MFW (2002) Introduction: The design and statistical analysis of animal experiments.

Festing MFW and Altman, DG (2002) Guidelines for the design and statistical analysis of experiments using laboratory animal in Experimental Design and Statistics in Biomedical Research, ILAR Journal V43(4), https://www.ncbi.nlm.nih.gov/pubmed/12391400

Kilkenny C, Browne WJ, Cuthill IC, Emerson M, Altman DG (2010) Improving Bioscience Research Reporting: The ARRIVE Guidelines for Reporting Animal Research. PLoS Biol 8(6): e1000412. https://doi.org/10.1371/journal.pbio.1000412

Parker, R.M., & Browne, W.J. (2014). The place of experimental design and statistics in the 3Rs. ILAR journal, 55 3, 477-85.

Smith, A. J., Clutton, R. E., Lilley, E., Hansen, K. E. A., & Brattelid, T. (2018). PREPARE: guidelines for planning animal research and testing. *Laboratory animals*, *52*(2), 135-141.

Van Belle, G (2002) Statistical Rules of Thumb, Wiley-Interscience, http://www.vanbelle.org/toc.htm

27. IMPLEMENTING THE KEY PRINCIPLE OF REFINEMENT

Refinement is outlined within the Code[13] as:

- Steps must be taken at all times to support and safeguard animal wellbeing. The effectiveness of strategies for supporting and safeguarding animal wellbeing must be kept under review during the lifetime of activities, including projects. Where relevant and applicable, the outcome of this review must be implemented in current activities and taken into account in planning future activities, including projects.
- People who care for and use animals must ensure that procedures are performed competently, and

[13] National Health and Medical Research Council (2013) Australian code for the care and use of animals for scientific purposes, 8th edition. Canberra: National Health and Medical Research Council, Section 1, Paragraph 1.28 – 1.30, p.12.

(a) be competent for the procedure they perform, or
(b) be 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. Animals must not be held for prolonged periods as part of an approved project before their use, without AEC approval.

There is a need for technical training and its assessment, with confirmation given to the AEC. There are links to online training on practical techniques available on the University Veterinarian website under User Training. There is also a technical skills lab available to staff and students located on level 6 of Helen Mayo South Building on the North Terrace Campus. Introductory training sessions and assessment can be booked with the LAS staff or the UVs.

The CCACs 3Rs Microsite provides information on Refinement Alternatives as part of its step-by-step search guide. This page has specific information on Species and Model Selection, Imaging Technologies and Microdosing.

28. WRITING THE APPLICATION

It is essential to complete the online ANZCCART Competency Passport training prior to writing your application to gain useful information about many aspects of the process. The course provides a module on the topic of completing an AEC application.
Please also refer to the guide for compiling aec applications which will guide researchers with the style of answers that the AEC requires to questions posed by RM and thus help them to compile an application that is more likely to be favourably considered, and more rapidly approved, by the AEC.

Breeding applications must be clearly distinguishable from experimental applications. This is because the ethical considerations for each application type differ:

Breeding applications need to request the number of breeding animals required to establish and maintain the colony, including stock animals for allocation to projects, and address the ethics and welfare issues related to breeding.

Experimental applications need to request the number of animals required to address specific research questions that are predicated on power calculations, or other evidence, and address the ethics and welfare issues related to the experimental procedures. Where possible, a new breeding application and experimental application for the same project should be submitted together to be considered by the AEC simultaneously. Please refer to the Laboratory Rodent Breeding Application Guidelines.

The key to writing a good application is to provide all the information the AEC needs to make a decision within the body of the application. Attach separate images, if necessary, of equipment or trapping or monitoring gear. Missing information results in delays in decision-making. Attaching research papers is not helpful as the volume of material already within each meeting's application is such that extra material is likely not to be reviewed in detail.

Proposals must provide the Animal Ethics Committee sufficient information to satisfy the Committee that the use of animals is justified and complies with the principles of replacement, reduction and refinement. From information provided in the body of the application, AEC members should be able to understand exactly what will happen to the animals over time including drug dosing, frequency and routes of administration, analgesia, anaesthesia, all other interventions including changes to housing and husbandry, as well as endpoint times or triggers.

Proposals should allow the Committee to easily assess information provided. Applications should not include text directly lifted from grant applications as the AEC is made up of lay and non-scientific readers. They should be written in a manner that can be understood by all members of the Committee and must identify the impact of all sections of the proposal on animals used and means by which the impact will be minimised.

The information sought from applicants is required to meet the requirements of the Code [the Code 2.7.1 – 2.7.6]. Applicants should be familiar with the contents of the Code before completing the application form.

Please read the Code carefully before submitting an application for ethical approval to the Animal Ethics Committee. A University Veterinarian will be pleased to provide veterinary advice and technical assistance. Applicants are encouraged to contact the UVs in the planning stages prior to submission to the AEC on matters regarding animal wellbeing.

Applications need to be complete and be of a satisfactory standard and level of detail before the AEC can consider them. Applicants will receive written advice if an application requires amendment to achieve the required standard. Please read the 'Application Information' before submitting an application for ethical approval to the AEC.

When writing a new scientific or teaching project, it is essential that the matters listed below are adequately addressed.

- Consider the choice of animals (i.e., species, strain, sex, age, physiological, microbiological and health status), their housing, management and care and their acclimatisation following transport to the facility or to the experimental setting.
- Use of randomisation
- Blinding of observer as to the group during assessment of results
- Bias amelioration strategies
- Use of environment enrichment strategies
- Perform a risk assessment on the scientific plan and identify both likely and unlikely causes of pain and distress
- List the clinical signs and other appropriate measures for assessing pain and distress and develop a strategy to monitor for these[14].
- Minimise the severity: substitute less invasive for more invasive procedures
- Minimise the duration of time an individual animal is used
- Training & skills of personnel[15]
- Supervising students and inexperienced personnel
- Minimising pain & distress: appropriate use of sedation, anaesthesia, analgesia, monitoring, and other strategies, see SOPs for opioid, NSAID and local anaesthetic use as well as Rodent Procedures and Pain guidelines.
- Plan for early and humane experimental endpoints and euthanasia criteria, refer to SOPs for euthanasia. See LAS for Clinical Record Sheets to be used.
- Appropriate use of pilot studies to refine experimental design and methodology, determine effective dose/response etc. For novel models, these are encouraged.

[14] The NC3Rs has useful resources on Grimace Scales in pain assessment for rodents and other species.
[15] See SOPs (standard operating procedures; found on the Laboratory Animal Services website under Policies and Procedures, University login required), Local Anaesthetic, Opioid, NSAID SOPS and Rodent Procedures and Pain Classifications Guidelines, available on the Laboratory Animal Services website and University Veterinarian website.

Language and style:

The most important thing to remember, when writing the application, is that the AEC is comprised of members of the public (lay members), as well as those with associations to the University. The background of the individuals in the AEC varies enormously, with many members having no scientific training or experience. It is important that all members, including lay members, can easily read, understand, and assess an application. If any member finds an application difficult to read or understand, resubmission may be requested.

Lay language means minimising scientific jargon where possible, using plain language where possible and avoiding excessive numbers or acronyms. While it may not always be possible to avoid using scientific terminology, where it is used a plain English definition / explanation should be provided when it is first used. Acronyms that are fundamental to an application are okay but should be defined in full the first time they are used.

The animal ethics application is not a peer-reviewed scientific review or grant funding application. Do not copy and paste from grant funding applications. While you must convince the AEC of the scientific merit, avoid using large numbers of references in text or detailed explanations of laboratory techniques not relevant to the application. Clear, concise, well-structured answers that give a broad understanding to all members of the AEC are more important than detailed scientific answers that only a fellow scientist would understand.

Length:

Length does not matter, and a long application should not be interpreted as a good application. A short application with clear explanations is much better than a long, confusing application. While it is good writing technique to try and keep an answer as short as possible, the application should be as long as is necessary to clearly and simply answer the questions.

Experience and training requirements:

Please make it clear what the experience or training requirements are for all the investigators. It is important to demonstrate that investigators are either competent and experienced in proposed procedures or will be given adequate training, support, and supervision to become competent.

Project title:

Should succinctly explain the principal aim of the project and what aspect of a given disease the proposed research is attempting to understand and/or improve (e.g., pathogenesis, therapy).

Short lay summary:

It is very important that this project summary is written in lay language, so it is intelligible to lay members of the AEC. It should succinctly explain what the project hopes to achieve and, if successful, what the significance of these positive research results will be to improving an understanding of this disease. Keep in mind that this summary is what will be provided by the University to an external organisation (e.g., newspaper) seeking to understand what this research is all about.

Scientific justification:

This section provides the researcher with an opportunity to explain to the reader what the project aims to achieve and how it will hopefully lead to a better understanding of disease development mechanisms/treatment modalities. A good answer to this question will help the reader understand why the

use of animals is justified in achieving these aims. Again, it is very important to write this section in lay (non-scientific) language.

Animal number justification:

A good answer here will provide the reasoning behind how animal numbers were derived and how the size of experimental cohorts was arrived at. This section is closely scrutinised and frequently debated by the AEC.

The AEC will generally require a power calculation to justify the number of animals sought (or explain why this cannot be performed) and researchers are encouraged to consult (and cite) a biostatistician, unless they are very experienced with statistical methods.

Typically, members of the AEC will look for consistency of numbers throughout an application and compare numbers here with those provided in sections 5.1 Animals required, 6.1 Procedure description, any attached flowchart / experimental plan etc. It is important, before submitting an application to review the numbers in various sections and ensure they are all consistent.

The 3 R'S (replacement, reduction, refinement):

The 3 Rs are now a major focus of improving animal welfare standards and, accordingly, your answers to these questions should be carefully considered and well argued.

- **Replacement:** There will be many projects for which an animal model is clearly required. However, you should explain why an *in vivo* system is obligatory to achieve the aims of your research and why other alternatives (e.g*., in vitro*) are unsuitable.

- **Reduction:** In addition to showing that the minimum number of animals will be used (and justify this with a statistical power calculation) to achieve the aims of this research, you are encouraged to consider using surplus animals from this (and other) universities/research institutions and making any unused animals from your project available to other researchers.

Gender is becoming an issue in scientific research, and you should explain why only one sex is being used (if this is the case). There may be instances in which proof-of-principle is initially desired to be demonstrated in one sex and, if proved, will then be extended to the opposite sex, but this should be carefully explained.

- **Refinement:** This is arguably the most scrutinised of the 3R's by the AEC and your answer should reflect a well-considered inclusion of improvements to the experimental paradigm from the animal's perspective. For example, what will be done to alleviate/minimise pain/distress (analgesia, anaesthesia, sedation), what training will investigators undergo and what is their experience, what environmental enrichment (e.g., hides or aspen block) will be provided to create better conditions for the animals and allow normal behaviours to be performed, and how will you make it easier for animals to eat and maintain body weight (e.g., soaked food)? Please note that nesting material is a basic minimum requirement for all rodents and not considered environmental enrichment.

A carefully constructed CRS will be an important element of the "Refinement" process and it should be specific to the project under consideration (see later comments on CRS).

If the experimental procedure is invasive and/or painful, the level of pain/distress induced should be quantified and justified in terms of the importance/relevance of the expected experimental outcomes.

Animals required:

Very important: Ensure that the total number of animals requested here matches the animal numbers stated in other parts of the application.

Animal housing:

Please check with the facility manager, in advance, that there will be accommodation available when you need it. Also, if assistance is required for animal monitoring, this should be arranged in advance and agreement stated in the application.

Some species of animal are more social than others and the isolation of such animals causes stress. On that basis the AEC's expectation is that sheep, rats, mice and rabbits (for example) will not be housed in individual pens/cages. The AEC recognises that there are circumstances in which individual housing is acceptable or preferable, and applicants need to provide justification for individual housing in responding to the question in the form. Applicants proposing use of confinement or restriction of animal movement must provide the AEC with detailed scientific justification.

Animal fate:

Be consistent with any method of humane killing throughout the application. Use correct terminology.

Procedure description:

When writing details of procedures, keep in mind what the AEC member will need to know. This should be in language intelligible to lay members of the AEC (scientific terms, unless in common usage, should be explained in lay terms, use common name of animal species as well as the scientific name).

You should state precisely:
- what happens to the animals from the time they are obtained until the time the project is completed.
- what is the impact of the procedures and treatments upon the animals (degree of pain or distress) and how will this be managed
- state which tissues will be collected and, if blood is to be collected, the volume and frequency of its collection
- where applicable, state how many people will be assisting with procedures (e.g. for anaesthesia, typically two people are present, one to perform the procedure and one to assist and monitor the animals. This needs to be clearly stated).
- give a brief explanation of how outcomes will be evaluated / results will be analysed and precisely what techniques will be used to evaluate the results.
- all surgical procedures require analgesia
- all surgical procedures require the use of aseptic technique – see online course elective content and relevant SOP

There will be separate sections for teaching applications or wildlife projects etc. which will drill into the details around staff to student numbers, maximum time of restraint, maximum number of students per animal, environmental conditions etc. It does not hurt, where applicable, to reinforce those details in procedure description or any other relevant section to ensure the AEC appreciate the point.
Ensure you discuss any transportation, acclimatisation, humane killing etc.

Please include references to relevant SOPs in the procedure description, such that is understood you are aware of relevant SOP's and will refer to them.

Animal monitoring:

The frequency of monitoring should be clearly stated, and justified, together with the persons who will perform the monitoring and their experience. A CRS will form a critical part of the monitoring process and it should be specific to the project under consideration (if a generic CRS is used, this should be justified). The CRS should:

- Provide an area to list 2 contact persons and their contact phone numbers
- List all the clinical parameters likely be expressed by animals in this project (including dyspnoea if tumour metastasis is anticipated)
- Starting weight and weight loss columns should be included and the time at which they were taken recorded
- Assign a score to all the clinical parameters listed
- Show cut-off scores when action (e.g., seek veterinary advice, euthanasia) is required
- For tumour studies, any assessment of weight loss due to tumour-induced cachexia should take account of any counterbalancing increase in body weight to due enlargement of the tumour mass. As a guide, a tumour volume of 1000 mm^3 is equivalent to ~ I gram of normal body tissue.

Substances administered:

- You should include all drugs/other agents/cell lines to be administered to animals, together with their dose rate, and frequency and route of administration.

Transport of animals:

Please remember to include the relevant transport SOP in your application.

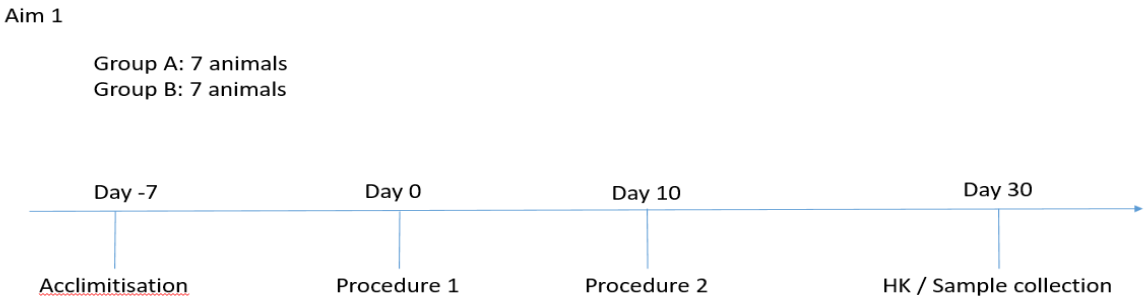
Funding:

Please include the name of the funding body and the application number. In addition to evaluation of a research project on animal welfare grounds, external, peer-reviewed funding is an important part of the AEC assessment of the scientific validity of the proposed study.

Attached documents (these must be PDF):

- **A flowchart or experimental plan** complements the application, especially the procedure description, and is very useful to the AEC. It does not need to be flashy / can be very plain. It will be closely examined. A good flowchart can make a big difference in the AEC's understanding and subsequently how they view an application. It is very worthwhile investing time in developing a good flow diagram. A good flowchart is often constructed in Microsoft Powerpoint and allows a quick and easy understanding of the overall experimental design, including a timeline of when procedures will be performed, and the number of animals required at each time-point. It is essential if there are multiple aims/arms of the project. A good flowchart will enable the reader to more readily appreciate the overall aims and conduct of the research, with the allocation of animal numbers to each phase of the project being clearly shown. A very basic example is below (example only, you can present your flowchart however you would like/suits the project). Text explanations can accompany,

the key feature is to make it easy to understand what is happening in the planned experiment.



- **Sometimes a detailed experimental plan is attached** that may have been prepared for a funding application or publication. This is okay and can be useful for those members who would like to dig into things a little more, but it is not essential.
- **Pictures / diagrams** of equipment or facilities are always encouraged and in certain circumstances will be requested if not attached – the classic a picture is worth a thousand words. e.g., picture of a bird with a tracking device attached.

29. STANDARD OPERATING PROCEDURES (SOPs)

Typically, the AEC like to see SOP's or documents attached that explain major procedures or demonstrate they are standard techniques in the field. Any bespoke SOP's need to be attached and should be referenced in Procedure Description. Please make sure any SOP is up-to-date and relevant. SOPs are available on the Laboratory Animal Services website under Policies and Procedures (University login required).

30. ENVIRONMENTAL ENRICHMENT

The housing environment of laboratory animals is designed around principles of standardisation, space conservation, practicality and cost effectiveness[16]. These principles result in sterile, uniform, housing environments that do not allow for species-specific behaviours and are associated with reduced welfare outcomes such as repetitive, compulsive behaviours related to stress and boredom[17].

Bailoo et al. (2018) considered the various health outcomes of environmental enrichment in female mice. The key findings of this study were that the greatest outcomes were found from the greatest degree of environmental enrichment, and that environmental enrichment did not increase variability in experimental outcomes.

The NC3Rs website provides details on minimum Housing and Husbandry standards for a number of species. These provide species-appropriate enrichment strategies, such as nesting material, like paper or soft wood, for rodent species. These strategies are simple to implement and will be associated with better health outcomes without introducing variability into experimental outcomes.

[16] Bailoo JD, Murphy E, Boada-Saña M, Varholick JA, Hintze S, Baussière C, Hahn KC, Göpfert C, Palme R, Voelkl B and Würbel H (2018) Effects of Cage Enrichment on Behavior, Welfare and Outcome Variability in Female Mice. Frontiers in Behavioral Neuroscience 12:232. doi: 10.3389/fnbeh.2018.00232;
[17] Würbel, H., & Garner, J. P. (2007). Refinement of rodent research through environmental enrichment and systematic randomization. *NC3Rs*, *9*, 1-9.

31. PROVISION OF INFORMATION ON GENETICALLY MODIFIED ANIMALS

If you propose to use any animals that are genetically modified organisms (GMOs) or introduce any genetically modified cells or microorganisms into animals, you must also obtain authorisation from the Institutional Biosafety Committee (IBC). The IBC application form is available at *https://www.adelaide.edu.au/research-services/ethics-compliance-integrity/gene-technology/gmo-dealings#applications*. Contact the IBC Secretary if you have any questions *ibc@adelaide.edu.au*

Investigators are required to provide information to the AEC on the phenotype of genetically modified animals as part of their application. The Jackson Laboratory (JAX) has a Mouse Phenome Database which may be useful to some investigators.

Additional changes must be reported using the Phenotype Report for Genetically Modified Animals. This document can be found under Animal Ethics Reporting Requirements on the University of Adelaide Research Services website.

The Code provides guidance for the creation and breeding of a new animal line, including genetically modified and cloned animals, where the impact on animal wellbeing is unknown or uncertain". It is recommended that: "[u]sers should refer to relevant international literature and information resources for technical and scientific information on specific topics, and current best practice for specific methods and techniques. Information is also available from the Office of the Gene Technology Regulator". The Mouse Phenome Database may be useful to some investigators (JAX labs as above).

Relevant information for investigators on use and reporting of genetically modified animals can be found in the Code in Section 2, Paragraph 2.4.30 - 2.4.33, and Section 3, Paragraph 3.3.24.

There is also a presentation on maintaining breeding colonies on the UVs site as lab animal elective material for the Animal Welfare Induction course.

32. MONITORING STRATEGY AND USE OF CLINICAL RECORD SHEETS

There are generic CRS forms available for general health monitoring as well as for monitoring tumour models on the LAS web site. These include many of the considerations below but in some circumstances, you may need to customise one of these CRS forms for your work.

For each research protocol, the development of a strategy to assess, minimise and monitor pain and distress requires decisions to be made regarding:

- the clinical signs or observations that will be used to assess an animal's wellbeing or clinical condition as the project progresses. These need to be relevant to the species, and to the anticipated impact of the scientific procedures and experimental conditions identified by the risk assessment.
- the clinical sign or combination of clinical signs that will indicate that intervention (including euthanasia) is necessary
- the actions that will be taken if a problem is detected - when will UVs input be needed
- the frequency of monitoring needed over and above the mandatory daily monitoring
- the people who will conduct the monitoring, and their training and weekend/holiday rostering
- the system for the recording of observations is the Clinical Record Sheet that forms part of the approval process and should reflect the anticipated clinical changes and appropriate endpoints

Examples of Abnormal Observations or Clinical Signs[18]

- Abnormal movement /'wobbly'/ataxia
- Lameness / abnormal gait/ poor limb use
- Change in the normal individual or group behaviour
- Decreased activity/reluctant to move
- Eating of bedding or neonates: stress response
- Excessive licking and scratching of self: stress response
- Hunched posture / arched back: pain response
- Loss of appetite
- Dull, ruffled hair coat/ 'fluffed up' or ungroomed appearance
- Reduced food or water intake (only measurable for singly housed animals)
- Weight loss
- Diarrhoea
- Dehydration – skin tenting
- Pale or sunken eyes
- Unusually docile or aggressive when handled: pain or stress response
- Vocalisation
- Porphyria - red tear staining around the eyes in rats: stress response
- Pain face scale: see NC3Rs resources on Grimace Scales
- Hyperactive: drug reaction
- Hair loss: over-grooming, stress response 'barbering'
- Fighting: overcrowding or introduction of an inappropriate new cage mate, stress response
- Abdominal distention
- Rectal prolapse / bleeding
- Blood staining in cage: urination/fighting

Monitoring the animal for pain and distress

So that adverse effects on the animal can be predicted and assessed, it is imperative that the observer be familiar with the normal and abnormal characteristics of each of the species used in a study.

The definition of 'normal' for a particular animal species may vary according to the housing or environmental conditions for the animal, the presence or absence of humans and other external stimuli, and whether the animal has been specifically bred as a research animal. It may also vary between strains or breeds within the same species, and even among individuals within a strain or breed[19].

During the acclimatisation period, researchers and animal facility staff should familiarise themselves with the 'normal' range of behaviours of a particular animal or group of animals[20]. Measurements of physiological, biochemical and neuroendocrinological markers may also be made during this period to establish baseline levels. Establishment of normal circadian patterns is a sensitive indicator of physiological adaptation to a new environment and validates a stable baseline for physiological responses.

The Code Section 3, Paragraph 3.3.8 – 3.3.15 deals with anaesthesia, analgesia and sedation, and management of pain and distress. See also the Local Anaesthetic, Opioid and NSAID use and Rodent

[18] Source: Laboratory Animal Services Clinical Score Sheet;
In the Animal Ethics and Welfare Induction Course under elective topic 2 is a useful talk called 'Are my animals well';
NC3Rs provides a video on Training on the 3Rs
[19] The NC3Rs has useful resources on Grimace Scales in pain assessment
[20] The Animal Ethics and Welfare Induction Course has a talk on assessment of pain under elective topic 3

Procedures and Pain Classifications Guidelines, available on request by the University Veterinarians. These guides give specific pain classifications and appropriate dose requirements for anaesthesia and analgesia. They also include the dilution recipes of drugs used for our smaller rodent species to enhance their safe use.

33. CHECKLIST FOR PROMOTING ANIMAL WELLBEING

Planning the study	
• Determine whether alternative, non-animal techniques could be used	
• Anticipate the extent of pain and distress and work out the ways in which it can be controlled	
• Choose the most humane methods possible	
• Balance the anticipated pain and distress to individual animals against the possibility of lesser pain to a greater number	
• Design the research protocol to last for the shortest possible time (e.g. choosing the earliest practicable endpoint)	
• Learn the normal behaviour of the species and the signs of pain and distress	
• Consider whether the proposed techniques are the best possible ones that could be used	
• Perform a pilot study to refine protocol	
Conducting the study	
• Monitor animals for changes in behaviour and signs of pain and distress throughout the study	
• Provide animals with adequate pain management, including anaesthesia and analgesia	
• Use analgesia pre-emptively	
• Provide palliative treatment for pain and distress, e.g. post-operative nursing, comfortable bedding, optimal environmental temperature and humidity, wet food minimal noise, etc.	
• Kill humanely and without delay any animal that appears to be suffering unforeseen pain and distress that cannot be promptly alleviated	
• Evaluate unforeseen complications and determine adequacy of criteria for intervention and humane endpoint	
• Report adverse events immediately so early intervention can be made to reduce ongoing problems	
• Reviewing techniques and promoting strategy	
• Continue to review techniques and refine them whenever possible	
• Review SOPs for scientific and teaching procedures	
• Review husbandry SOPs	
• Continue to review procedures for the care and management of animals in holding facilities	
• Continue to review procedures to ensure good practice	
Reporting	
• Report adverse events promptly to the AEC	
• Report annually on progress of the project	
• Report at the completion of the project	

• Report completion of pilot studies before initiating the full study	
• Report to the AEC on other occasions as required	

34. TRANSPARENCY

The NHMRC guidelines Best Practice Methodology in the use of Animals for Scientific Purposes[21] states:

Effective and transparent reporting of animal-based studies is essential to inform future scientific studies and policy. Poor reporting makes it difficult for other investigators to reproduce results and to derive the maximum scientific knowledge from studies involving animals and risks the unnecessary use of additional animals by inappropriate repeat studies.

Effective and transparent reporting requires the reporting of key information on how studies are designed, conducted, and analysed in publications. It also encompasses:

- provision of access to data on which findings or conclusions are based
- reporting of negative impacts on animal wellbeing during the conduct of the study
- reporting to the AEC of the outcomes of previous or related work — including adverse outcomes — that are used to justify new and continuing work, particularly when projects continue for many years.

On way investigators can engage with transparency is by providing sufficient detail on animal use conditions in publications to enable accurate reproduction of methodology. The ARRIVE guidelines are a useful resource on reporting animal use for investigators.

SECTION FOUR: THE APPLICATION PROCESS

35. COMPLETING AND SUBMITTING THE APPLICATION

Overview of submission process

There are two faculty-based Animal Ethics Committees, Science and Medical, which meet to consider all applications for ethical approval including amendments or variations to existing approvals.

Applications must be submitted in accordance with the submission deadline schedule on the Research Services website. There are separate deadlines for the two committees for submission of applications. Applications submitted after deadlines will be held until the next meeting cycle unless otherwise negotiated with the Animal Ethics Secretary.

To create a new application login to the ResearchMaster system To amend an existing approved login to the ResearchMaster system and create a new minor amendment application.

The form consists of a series of pages each containing one or more questions, each page is validated as the user progresses through the form. Guidelines and help information are included within the form.

[21] National Health and Medical Research Council (NHMRC) 2017 (Updated July 2018), Best practice methodology in the use of animals for scientific purposes, p.8.

Once the online form sections are completed submit online. Submit applications prior to advised deadlines.

An online preview (Pre-Screen) takes place before a final version of the application is submitted. Pre-screen preview will take place during a 2-week period. This pre-screen is done by both the Research Secretariat and then by the UVs and provides an opportunity to ensure that you have provided the information needed for AEC submission. Please respond to the comments/ requests of the pre-screeners as failure to do so will likely result in the application failing to be approved at the meeting. Resubmission to the next meeting means that you will be invited to attend in person to explain and defend your application resulting in unnecessary time delays in gaining approval to start your work.

System generated emails will be sent regarding acknowledgements, instructions and requests for further information and revision or subsequent actions. It is important to note that all correspondence is online within the application. You may be required to provide additional information and revise your application online.

Due to the volume of material to review, applications are sent to AEC members 1 week prior to each meeting.

After the AEC has considered your application, you may be required to respond to queries. Ensure that all information is provided, attachments included and that you resubmit your application online, following review of the resubmitted application.

All subsequent project documentation will be available to you within the record online.

To access an application previously approved by the AEC for a project completed before 31 December 2008 please contact the AES.

36. CONSIDERATION OF APPLICATIONS AND OUTCOME NOTIFICATION

The consideration of an application by the AEC will normally result in one of the following outcomes:

- The application is approved outright at a meeting and no conditions are imposed by the committee as it is compliant with the Code
- The application receives approval with conditions
- A pilot study is approved
- Deferred decision – a decision on the project is deferred pending further information in relation to the activity
- The application is not approved, and the applicant is asked to revise and resubmit the application

Decisions by the AEC with regard to approval, modification or rejection of a proposal, or withdrawal of approval for a project are made in accord with Section 2, Paragraph 2.3.1– 2.3.16 of the Code and are usually made after consensus is reached by the AEC members.

Scientific or teaching activities involving the use of animals must not start before receiving written approval and an animal ethics approval number from the AES. AEC approval is required before animal holding space is allocated and before animals are supplied. Ethical approval of a project does not guarantee that the animals, or space for holding them, will be available. It is for the Investigator's responsibility to ensure this availability.

Investigators have direct and ultimate responsibility for all matters related to the welfare of their animals and must act in accord with all the requirements of the Code. This includes daily monitoring of animals including weekends and holidays.

The application for approval covers the whole project and, while it is not necessary to make a separate application for each experiment within the project, the detailed description of the proposed experiments and the answers to particular questions should adequately cover all experiments within the project.

No new application can be approved other than at a meeting of the AEC.

37. MAKING AMENDMENTS TO AN APPROVED PROTOCOL

All applications for amendment are considered at scheduled AEC meetings unless the AEC has deemed it appropriate that the Executive can review. Please see the guide under each amendment criteria on the animal ethics website for what can be reviewed by the Executive. The website also has information on what is and is not considered a minor amendment request.

SECTION FIVE: CONDUCTING THE PROJECT

38. SUPERVISING STUDENTS AND INEXPERIENCED PERSONNEL[22]

Students and inexperienced personnel working with animals must have:

- close, competent supervision *[the Code 4.13]*.
- been instructed in the appropriate methods of handling and caring for animals *[the Code 2.1.8 (ii)]*;
- demonstrated that they are capable of performing the necessary tasks with care and competence.
- adequate resources available *[the Code 2.1.5 (ii)].*

The attainment of competence in a particular technique should be initially demonstrated and subsequently assessed by a member of the LAS team or the UV prior to sign off. Please see the training section. The skills laboratory in the Helen Mayo South building has been established to assist in developing technical skills in new students and researchers by providing access to inanimate models for practice of technical skills.

The Code Section 4, Paragraph 4.12 states: Teachers must ensure that students have the opportunity to discuss the ethical and social issues, and legal responsibilities, involved in the care and use of animals for scientific purposes, at a level appropriate to their learning ability and comprehension, and before the use of animals commences.

Institutions need to ensure that research trainees are aware of, and comply with, government and institutional guidelines for ethical requirements for research using animals *[the Code 2.1.2 (v)].*

Information on training for University of Adelaide Staff and Students can be found at the University Veterinarian website or by contacting LAS (8313 1746) or the UVs (8313 4107).

39. INVESTIGATOR'S RESPONSIBILITIES FOR DAILY MONITORING OF THEIR ANIMALS

It is an expectation of the University of Adelaide AEC and the Code (Section 2.2.26) that animals will be monitored by the Principal Research Investigator or their delegate on a daily basis, except as agreed with LAS as a technical assistance request.

The Code Section 2 Paragraph 2.4.5 states: A person must be identified who has ultimate responsibility for the care and use of animals in a project. The person with ultimate responsibility is the principal investigator. This person must:

a) Ensure that all people involved in the project understand and accept their roles and responsibilities

[22] Source: NHMRC Guidelines to promote the wellbeing of animals used for scientific purposes: The assessment and alleviation of pain and distress in research animals.

b) (ii) Ensure that procedures and resources are in place so that all people involved in the care and use of animals in the project can meet their responsibilities, including their education, training and supervision as appropriate

c) (iii) Be competent with respect to the wellbeing of animals used in the project

Animal monitoring responsibilities of the Principal Research Investigator[23]:

- The daily monitoring of a Research's animal(s) begins the day the animal(s) arrive at the Facility. Daily monitoring is the responsibility of the CI or their delegate

Technical Assistance Request for Monitoring

- If, under special circumstances, the Principal Investigator or anyone in their research group, cannot come in on a particular day to monitor their animals, you can apply for assistance via the Laboratory Animal Services website.

- If adding to your AEC application that LAS will be assisting with monitoring, this must be pre-arranged with the LAS Team Leader prior to submitting the application.

- Please fill in and submit a Technical Assistance form providing minimum 2 business days' notice. Any Technical Assistance forms submitted do not guarantee LAS assistance as priority applies to the LAS Animal Technician's daily tasks. An email will be sent by the Team Leader to the Principal Investigator confirming whether or not LAS can assist. Please note: A Technical Assistance fee will be added to your monthly invoice for time taken to provide Technical Assistance. Technical Assistance hourly rates can be found via the Laboratory Animal Services Website.

The Code Section 3, Paragraph 3.2.1 states: Procedures for ensuring that a health status of the animals is maintained that safeguards animal wellbeing and meets the requirements of their proposed use (see Clause 3.1.8) must include:

- monitoring and assessment of animals by a competent person with sufficient frequency to ensure that sick or injured animals are promptly detected and identified, and that appropriate action is taken

- Monitoring frequency is part of the approval process for a specific procedure. It is an absolute require that this monitoring is done daily but the approval of some more invasive procedures require monitoring much more frequently especially around the time of the procedure. This must be outlined as part of the approval application

- provision of veterinary clinical care and advice. Again, this is a requirement often mandated as part of the CRS approval process

[23] Source: Standard Operating Procedures (Rats & Mice) #38 Animal Monitoring Guidelines for Researchers and Animal Technicians (Laboratory Animal Services)

40. LAS RESPONSIBILITIES WITH RESPECT TO FACILITY MONITORING

Prompt detection and effective management of disease outbreaks and emergencies such as fire, power failure, temperature regulation and biosafety issues

Preventive protocols under LAS and veterinary direction or supervision, as appropriate, including animal biosecurity; quarantine; and the surveillance, diagnosis, treatment and control of diseases.

41. ROLE OF ANIMAL FACILITY STAFF IN THE MONITORING PROCESS OF RESEARCH ANIMALS

Animal facility staff are required to support animal wellbeing and minimise pain and suffering *[the Code 2.5.4 – 2.5.13].*

The Code Section 3, Paragraph 3.1.31 - 3.2.32 states: The person responsible for the wellbeing of animals at any given time must be clearly identified (see Clauses 2.1.7 [i], 2.4.20 [ii] and 2.5.1).

When developing strategies for supporting and safeguarding animal wellbeing, investigators and animal carers should:

(i) consult with all relevant people and/or groups responsible for the wellbeing of the animals

(ii) clearly identify the person responsible for monitoring the animals

(iii) ensure good communication and cooperation between all parties involved.

42. ANIMAL MONITORING RESPONSIBILITIES OF ANIMAL TECHNICIANS[24]:

Laboratory Animal Services staff check that all cages have food and water on a daily basis.

If food or water levels are found to be below half full, LAS staff will top up the food or change the water bottle.

Mouse IVCs are cleaned, as a minimum, once per fortnight and rat cages are cleaned weekly.

During cage changing and checking, LAS staff pick up each animal and inspect for signs of ill health. If any animals appear ill, LAS will check the cage card holder for a “Clinical Record Sheet in Use” sign indicating animals are on a Clinical Record Sheet (CRS). If the animals in the cage are monitored via a CRS, LAS staff will make a note if its current condition on the CRS. If the animals are not monitored via a CRS, LAS will place an orange card on the cage and follow SOP LAS #35 Animal Health Reporting. LAS will report their findings to researcher the day of cage change, but this does not constitute daily monitoring for that project. This report is copied to the UVs.

Laboratory Animal Services do not monitor research animals daily unless previously and specifically arranged with the Investigator. This process is called a technical assistance request and is on a fee for service basis.

[24] Standard Operating Procedures (Rats & Mice): #38Animal Monitoring Guidelines for Researchers and Animal Technicians (Laboratory Animal Services)

43. CONSULTING THE FACILITY MANAGER

Regardless of whether animal house staff are formally involved in monitoring of animals under experimentation they should be consulted or informed of the following:

- Housing arrangements for the animals. Animals must be cared for and managed so that species-specific or strain-specific physiological and behavioural needs are met *[the Code 3.1.5, 3.1.12]*
- The experimental procedures to be used; expected effects and signs to be monitored
- Safety aspects which may be pertinent to Animal Facility Staff e.g., injections of human tissue or carcinogens, use of infectious agents.
- Procedures, husbandry and care must be performed competently, by people who are competent or by people under the direct supervision of a competent person *[the Code 3.1.16]*
- Investigator telephone numbers for both normal working hours and after hours, and also other responsible persons and numbers (to cover illness and holidays) in the event of emergencies *[the Code 3.1.31- 3.2.32].* These numbers must be on the CRS and clearly posted in the rooms where animals are housed.
- When animal house staff call regarding animals in pain or distress a prompt response is required. If none is taken the animal facility manager or LAS member will take action including notifying the UVs. Alleviation of such pain and distress must take precedence over finishing a study *[the Code 3.1.27]*
- If personnel named on the animal ethics application (including amendments) are not contactable then the animal house staff must have instructions of what to do i.e., pain relief, biological sampling and endpoint. The Animal facility manager and the UV have the authority to kill animals in pain and distress when investigators on the project are not contactable.
- Adverse events and emergencies, including those that require welfare interventions such as the emergency treatment or humane killing of any animal, must be rapidly dealt with to minimise adverse impacts on animal wellbeing *[the Code 2.1.5 (v; d). 3.1.24*]. AES must be reported to the UV as soon as possible to allow response before there are further AES*.*

44. ANIMALS HELD OUTSIDE OF DESIGNATED ANIMAL HOLDING AREAS

It is University policy that all animal holding, breeding, and animal use for scientific and teaching purposes comply with the *SA Animal Welfare Act 1985* and Regulations, and the *Australian Code for the Care and Use of Animals for Scientific Purposes 2013.*

45. ANIMAL ETHICS COMMITTEE (AEC) APPROVAL AND MONITORING OF ANIMAL FACILITIES & LABORATORIES

AEC approval is required for all areas where animal use occurs, and for all animal holding areas, regardless of the duration of use or holding. Investigators who hold animals in laboratories (outside of designated animal holding areas) need permission and approval for this holding area by the AEC.

The AEC has responsibility for monitoring all animal facilities (including laboratories) associated with animal projects that it approves. Laboratories (outside of designated animal holding areas) holding animals will be inspected by the AEC at least annually. Laboratories may be inspected more frequently if the area is used for

holding animals for periods of longer than 12 hours. Frequency of inspection is to be determined by the AEC and to be related to the length of time animals are held in the laboratory.

46. LABORATORIES (OUTSIDE OF DESIGNATED ANIMAL HOLDING AREAS) WHERE ANIMALS ARE HELD BETWEEN 1 TO 12 HOURS)

If animals are to be housed outside centralised facilities overnight and/or beyond normal working hours this must be justified in the ethics application. For laboratories where animals are held between 1 to 12 hours there is a requirement to monitor the animals' environment. These laboratories must have dedicated temperature and humidity monitoring equipment. Records of daily maximum and minimum temperature and humidity are to be kept by the investigator when there are animals in the area. The investigator is to ensure that temperature and humidity are maintained within limits compatible with the health and well-being of the species of animal being held. *(Refer to Table 1 below)*

Table 1. MINIMUM STANDARDS FOR HOUSING OF LABORATORY MICE, RATS, GUINEA PIGS AND RABBITS.

Recommendations are in brackets and italics. Figures in this appendix are based on various international guidelines and codes, and current acceptable minimal standards of practice in Victoria.

Species	Room temp (°C)	Relative humidity (%)	Room vent (ACH)*	Max light** (lux)
MICE	18-24	40-70	(10-20)	350
RATS	18-24	40-70	(10-20)	350
GUINEA PIGS	18-24	40-70	(10-20)	350
RABBITS	<30 (15-24)	40-70	(15-20)	350

*Air changes per hour **Maximum light intensity recommended for albino animals is100 lux for 16 hours continuously. Extracted From: Code of Practice for the Housing & Care of Laboratory Mice, Rats, Guinea Pigs and Rabbits (2004), Department of Primary Industries, Victoria

47. LABORATORIES (OUTSIDE OF DESIGNATED ANIMAL HOLDING AREAS) WHERE ANIMALS ARE HELD FOR PERIODS OF 12 HOURS OR LONGER

All animal facilities, including laboratories, where animal holding or use occurs for periods of 12 hours or longer must meet or exceed the minimum standards listed in the Code (Section 3, Paragraph 3.2) and the 2004 Victorian Bureau of Animal Welfare *Code of Practice for the Housing and Care of Laboratory Mice, Rats, Guinea Pigs and Rabbits*, which has been adopted by The University of Adelaide.

In summary;

- The holding area must be in good repair
- The holding area must be clean and tidy
- Vermin should be controlled
- There should be contingency plans for emergencies
- There should be adequate security to prevent unauthorised access
- Air exchange, temperature, humidity, light and noise should be maintained within limits compatible with the health and well-being of the species of animal being held. *(refer Table 1 above)*
- Environmental monitoring equipment and record keeping requirements apply as for 6.4.2 above.
- Animals must receive appropriate food and clean water
- Staff caring for the animals must be trained in animal care and in how to recognise at an early stage changes in animal behaviour, wellbeing and appearance.

48. RECORD KEEPING REQUIREMENTS

- Investigators and Teachers must have a system for the recording of scientific and animal welfare observations. Use of both Laboratory record books, and Clinical Record Sheets is usually recommended. Breeding information must be recorded and stored.
- Clinical record Sheets are considered equivalent to research data.
- During the experiment, the CRS is to be stored in the animal room.
- At the end of the experiment, the CRS is stored with other laboratory records, and retained for the same period required for research data.
- The CRS and other project and breeding records are to be made available upon request to the AEC for audit and review.

49. RECORD KEEPING REQUIREMENTS ENDORSED BY THE STATE GOVERNMENT REGULATOR (DEW)

Guidelines for record keeping by investigators. This data will be required for the annual report, so it is wise to keep it up to date as the project progresses.

The Code Section 2, Paragraph 2.4.30 – 2.4.33 states:

- Investigators must maintain records of the care and use of animals, and make such records available to the institution, the AEC and authorised external reviewers.
- Investigators must ensure that records of monitoring and assessment of animals are in accordance with Clauses 3.1.21–3.1.22.
- Investigators must ensure that records include:
    (i) the origin/source of the animals and provisions for the animals at the conclusion of their use
    (ii) the number of animals used
    (iii) details of procedures, including dates, substances administered, analgesia and anaesthesia, and any unexpected outcomes
    (iv) the condition of the animal, any adverse impact on animal wellbeing and actions taken as a result
    (v) any additional information requested by the AEC
    (vi) names of people performing the procedures and entering the records
    (vii) names and contact details of people responsible for monitoring and emergency incidents.
- When activities involve genetically modified animals, records must include:
    (i) the number of animals used for the creation and maintenance of genetically modified animals
    (ii) the lineage and health status of the animals.

In general, the recording of information in a workbook should allow use of an animal to be traced from acquisition to the conclusion of the approved protocol. The following represents guidelines and is not an exhaustive list. The principles outlined in the Code (above) represent the minimum standards.

Records should be maintained by individual researchers on administrative procedures necessary for the project:

- Animal Ethics Committee approval number, date and duration of approval.
- Records relating to adherence to specific conditions which AEC may include in project approval.
- Running tally of animal use against numbers approved.
- Reports of any adverse outcomes

Monitoring of individual animals' passage through the protocol must be demonstrated, so each animal must be identified and have the following records attributable to it:

- Full ID (species, strain, sex, age, ID)
- Date of acquisition and source
- Place of housing
- Monitoring of health and welfare of the animal over the duration of the experiment and personnel involved (e.g., records of daily monitoring, completed checklists).
- Place and date of procedure
- Identification of part of approved project conducted on each date (e.g., weighing, administration of agents, surgery, killing)
- Details of procedure being conducted (e.g., dose rates, volumes of agents administered, surgical technique) and personnel involved.
- Details of anaesthesia if used: dose, administration, analgesia and monitoring and personnel involved.
- Records of recovery post-procedure +/- post-anaesthesia, including record of response to adverse events, predicted or not. Name(s) of personnel monitoring.
- Culling/ euthanasia records including reason, method and nomination of personnel involved.

The Code Section 3, Paragraph 3.1.9 states: Investigators and teachers must ensure that records of the use and monitoring of animals used for scientific purposes are maintained. Under a particular AEC approval, records should include the origin and fate of issued animals, how animal welfare was assessed, any unexpected negative impact on animal wellbeing and notation of procedures. The AEC should advise investigators and teachers of any additional information to be recorded. These records should be available for audit by the institution and authorized external reviewers.

Evidence of preparation for adverse events and adherence to Standard Operating Procedures (SOPs):

- Reference to any specific SOP.
- Specification of adverse events and procedures put in place to manage these events.

SECTION SIX: REPORTING

50. ADVERSE EVENT REPORTING

What is an expected adverse event?

An expected adverse event is disease and health issues that the University Veterinarians consider normal for a colony or species, in that a low prevalence or incidence of certain diseases or health issues are likely to occur and as such are implicit in any approved application. The difference between an unexpected and expected adverse event is at the discretion of the University Veterinarian.

Examples include sporadic: skin disease, birthing issues, congenital defects, fighting wounds, dental malocclusion, anaesthetic death, or issue (with good anaesthetic technique), neoplasia, lameness etc. All adverse events must be reported to the University Veterinarian (or, if relevant, an LAS animal technician who will inform the University Veterinarian).

What is an unexpected adverse event?

An unexpected adverse event is any event that has a negative impact on the morbidity or causes mortality of an animal that was not specified as a possible outcome in the approved animal ethics application or exceeds the frequency or severity of impacts forewarned in the approved animal ethics application or is not considered expected by the University Veterinarians.

An unexpected adverse event is not just unanticipated illness or death of an animal, it is anything that disrupts or prevents an experiment being conducted, e.g., equipment failure, breakdown of relationships between those involved in a study, severe weather, investigator illness etc.

Reporting an unexpected adverse event

All unexpected adverse events must be reported by the researcher to a University Veterinarian immediately, but no later than 24 hours of the event. In the event that this is not possible, the Manager of the relevant Animal Facility must be contacted. A post-mortem examination must be performed following any unexpected adverse event that results in mortality. Due to autolysis, this must be done as soon as possible.

The University Veterinarian will work with the investigators to try and understand the cause of the unanticipated event and what could be done to try and prevent it occurring again.

A written report for an unexpected adverse event must be submitted to the Animal Ethics Committee, using the adverse event report form, as soon as possible. Unless directed otherwise by the University Veterinarian, it must be within 14 days of the event. The report should include, or be supplemented by, supporting documentation (e.g., necropsy report, laboratory results, Clinical Record Sheets).

The Unexpected Adverse Event report should be sent to the University Veterinarian for review and addition of any relevant clinical information, before it is submitted to the Animal Ethics Committee.

Post-mortem examination: Any animal that is euthanised or found dead must have a post-mortem examination unless it is autolysed. Where practical, a veterinarian (including the UV, should perform the examination, however if the body is likely to start decomposing before a veterinarian will be available, an investigator or animal technician can perform a post-mortem examination. The investigator must take photos and appropriate samples for review by a veterinarian. Post-mortem examination is not just important for understanding the cause of the event being investigated, but also for maintaining colony health (e.g., infectious disease etc.)

51. ANNUAL REPORTING

Annual Statistics & Progress Report

It is a condition of every approved protocol, that it be reviewed annually by the applicant and reported to the AEC *[the Code 2.4.34]* using the appropriate form which can be found on the AEC website. The University will accept annual reports submitted on other institutions forms. The continuation of all projects is subject to receipt of the annual report.

State legislation requires that statistical details on the University's use of animals must be provided annually to the Minister responsible for animal welfare on a calendar year basis, by a specified date.

The Annual Statistics & Progress Report template and notes on completion are available at the AEC website.

The AES will issue a reminder to all researchers individually by email approximately two months in advance of the due date (31st January).

These reports need to detail:

- the number of animals used in the reporting period as well as the total number of animals used since the project commenced
- your initial approval and any subsequent approved variation correspondence to report total numbers of animals approved to be used
- If more than one species or animal impact procedure has been involved, you need to make separate entries (i.e., separate rows in the table) so these can be differentiated
- If no animals have been used in the reporting period, make sure to indicate 0 in total number of animals used
- Although eggs, foetuses larvae, fish fingerlings, tadpoles, animals observed in their normal environment with no interference are not included in the statistics report to Government, please report them for AEC records
- Provide details if scavenged tissue has been used or any initiatives that reduce, refine or replace animal usage. This assists the University to demonstrate its compliance with the Code
- Report the place where animals were held. This information is critical in ensuring that there is no duplication of reporting to State Government by multiple organisations, as reporting is based on the place where animals were held. Please also indicate if the animals were not used in South Australia.
- If animals are held on University premises and at another institution you will still be required to submit a report

Completion Report

For projects that have been completed or discontinued, a report should be submitted to the AEC as soon as practicable *[the Code 3.4.34].*

This report should advise on:

- whether the stated aims were achieved

- whether the number of animals used varied from the number approved and if so, why any major discrepancies occurred
- whether the wellbeing of the animals was consistent with that anticipated in the proposal
- conclusions as to how procedures in future projects could be modified to reduce any impact on animal welfare
- details of publications and presentations that have resulted from the project

52. PHENOTYPE REPORTING

The Investigator will report in their application on the phenotype* of any new genetically modified animal strain that has been developed as part of a scientific project. Following consideration of the information, the AEC may approve further use of the strain or may request a revision of the proposal.

*Phenotype: the sum of the physical, behavioural and physiological characteristics of an animal

In addition to the Phenotype Report, the requirement to promptly report unexpected occurrences of animal morbidity or mortality to the AEC applies to these projects.

53. ACQUIRING ORGANS, TISSUES, OR MATERIALS FROM ANIMALS BY SCAVENGING

Scavenging is when tissues are harvested from animals where the sample was collected after death for another reason or from a partial sample collected for another purpose e.g., an unused part of a blood sample taken for clinical purposes. The animal has not been killed for the purpose of obtaining these materials. This includes materials gathered from roadkill, abattoirs, butchers or supermarkets, partial pathology specimens or tissues from animals killed for another project or from the Biobank.

Approval to scavenge by the AEC is not a legislative requirement, however, the AEC must be informed when an investigator or teacher is scavenging, especially if this is occurring on a regular basis. Investigators are required to inform the AEC promptly.

1) To report scavenge tissue use please email aec@adelaide.edu.au with the information regarding:

- period of time for the duration of the study;
- name of animals required;
- number of animals required;
- the circumstances of the animal death and, if relating to another approved protocol, to include that information;
- the source of the tissue;
- the use of the tissue;
- the place where the tissue will be used;
- how the tissue will be disposed of; and
- activities involving the use of the animal.

54. NOTIFICATION OF USE OF SCAVENGED TISSUE

The Code[25] encourages the sharing between researchers of tissues from deceased animals for in vitro work, training or method development; such use is not regulated by the Code or the Act. Nevertheless, it is an Institutional requirement that such use be documented and reported to the AEC by way of the "Notification of Use of Tissue Scavenged" report.
Dissection of cadavers or organs is required for some tertiary teaching courses. Such use is not regulated by the Code or the Act. Nevertheless, it is an Institutional requirement that such use be documented and reported to the AEC by way of the "Notification of Use of Tissue Scavenged" report.

The use of scavenged tissue is subject to the following provisos:

- The opportunity for collecting scavenged tissue must not influence the breeding of animals nor the time or manner of humane killing of animals.
- The collection of organs, tissues, materials or substances from living animals involved in research, teaching and experimentation is a scientific procedure requiring a full application to the AEC. If a partial sample gained for another purpose is used without being specifically collected, then this is considered scavenging.
- Scavenging does not cover animals being bred nor killed specifically to obtain carcasses, organs, tissues, materials or substances; this is a scientific procedure requiring a full application to the AEC.

Notification of the use of scavenged tissue must be submitted to the AEC prior to such use, or on the day of such use should tissues become unexpectedly available, in order to allow the AES to obtain recommendation from the UV to determine if the collection and use requires AEC or other approval.

Tissues that have been processed for commercial use (e.g., obtained from a butcher, supermarket or abattoir) do not require AEC Notification.

Scavenged tissue notifications can be acknowledged by the Executive.

Additional considerations to scavenging

- When researchers are scavenging tissue from privately owned animals or Veterinary Clinics, written consent of the owner of the animal must be obtained.
- Researchers obtaining tissues (including eggs, hair and feathers) collected from living or dead native wildlife (including roadkill) require a wildlife permit from the DEW.
- If animal or human tissues, including cell lines, are imported from overseas then additional permits are very likely to be required prior to importation and may be subject to quarantine regulations.

[25] National Health and Medical Research Council (2013) Australian code for the care and use of animals for scientific purposes, 8th edition. Canberra: National Health and Medical Research, Section 1, Paragraph 1.26, p. 11.

SECTION SEVEN: UNIVERSITY POLICIES AND GUIDELINES

55. CONSCIENTIOUS OBJECTION TO USE OF ANIMALS IN UNDERGRADUATE TEACHING AND ASSESSMENT

The General Principles for the Care and Use of Animals for Scientific Purposes set out in Section 1 of the *Australian Code for the Care and Use of Animals for Scientific Purposes* should be prominently displayed and ethical guidelines such as the ANZCCART publication Australian Ethical Guidelines for Students in Laboratory Classes Using Animals or Animal Tissues is to be provided to students.

Students should be given the opportunity to discuss the ethical social and scientific issues involved in the use of animals for scientific purposes including teaching. Students should be made aware of the *Australian Code for the Care and Use of animals for Scientific Purposes* and relevant Commonwealth and State or Territory legislation.

It is recognised that some students may have a conscientious belief concerning the use of animals (whether living or dead) in teaching and/or assessment in courses in which they are enrolled.

A conscientious belief is:

(i) An individual's inward conviction of what is ethically right or wrong.

(ii) Is held genuinely, after careful consideration of the subject.

(iii) Is uninfluenced by any consideration of personal advantage or disadvantage either to oneself or others and when put to the test should be ordinarily combined with a willingness to act according to the particular conviction even though this may lead to personal suffering or material loss (e.g. receiving no mark for the practical).

- The belief does not have to have a religious basis and a Head of School does not have to accept its underlying reasoning. The student does not have to accept a disadvantage or personal cost in order to prove a conscientious belief. This is merely a tool in determining the legitimacy and strength of the belief.

- It is the responsibility of the student to identify a conscientious objection to a teaching or assessment practice and to draw this to the attention of the Head of School before undertaking the practice. An appeal cannot be made after the practice has been undertaken. The University of Melbourne Animal Protection Society provides resources on conscientious objection which may be useful to students feeling conflicted about using animals in their studies.

- It is the responsibility of the Head of School to ascertain whether the claim constitutes a conscientious objection and what arrangements can be made to accommodate it.

- The Head of School may need to request more information from the student and if appropriate from the relevant religious, cultural or other bodies to establish whether the student has a legitimate conscientious belief based on these.

- The Head of School will then discuss the matter further with other relevant personnel, such as the course coordinator, as seen fit.

- In all situations there will be group resolution of issues with the student involved at all stages in the process.

- The Head of School will be responsible for recording the student's objection and maintaining records of the discussions that have taken place.

- The student must consult with the Head of School on an annual basis to confirm that their objection continues and to allow teaching staff to make arrangements for alternative practicals.

- A student has a right to request a suitable alternative but has no right to demand that an alternative is provided or that the alternative take a particular form. Other factors that may need to be taken into consideration include:

  (i) Professional requirements of registration bodies such as the Australasian Veterinary Boards Council (AVBC) to ensure that graduates have the basic professional competencies. Thus, careful consideration of the teaching or assessment method is necessary to determine whether it is essential for veterinary practitioners.

  (ii) Whether it is a required or elective unit of study.

  (iii) Whether there is time to put in place alternative arrangements.

  (iv) Whether students would be disadvantaged in the quality of education.

  (v) Cost

  (vi) Whether it would result in the University breaching its equal opportunity obligations.

    - Students with a conscientious objection will not simply be excused from the activity - an alternative that is equally difficult may be given.

    - Where students are to use animals as part of their training, they should be advised of this prior to the commencement of these classes and, preferably prior to enrolment.

    - In order to inform students about the extent and nature of animal use in teaching it is recommended that an introductory session be conducted in the first semester of the first year.

    - Specific website guidance will be made available including at the MyUni site for all courses where animals (or tissues) are used in teaching.

    - Teaching staff are to inform students about the role of the Animal Ethics Committee in all matters relating to use of animals. The Animal Ethics website includes the AEC requirements regarding use of animals in undergraduate teaching.

56. POLICIES AND GUIDELINES AVAILABLE AT THE AEC WEBSITE

Animal Procedure Related

- Policy on metabolic crate use for sheep (pdf 82kB)

- Procedures on Rodents – pain assessment guidelines and analgesic use recommendations (2020).

Animal Husbandry Related

- Laboratory Animal Services Policies and Procedures

- Rodent breeding and weaning policy (pdf 189kB)

SECTION EIGHT: GRIEVANCES AND DISPUTE RESOLUTION CONCERNING AEC OPERATIONS OR RULINGS

Grievances by applicants concerning AEC operation or rulings should initially be discussed, in confidence, with the Convenor. If the complainant considers that this is not appropriate (e.g., the complaint is about the Convenor) the complaint should be lodged with the Research Secretariat or the DVCR as appropriate

If the grievance cannot be resolved by such discussion, the Convenor will decide whether the matter is best referred back to the AEC or referred to the DVCR. If the issue is a breach of legislation (e.g., ill-treatment of animals) the complainant has a right, but not an obligation, to raise it with the Animal Welfare Unit DEW or the RSPCA.

Irreconcilable differences between the AEC and an applicant must be referred by the Convenor to the DVCR.

If any matter is referred to the DVCR, the AEC should be informed that this course of action has been initiated.

In some cases, other University policies and procedures will also apply (e.g., Guidelines and rules for responsible practice in research).

The DVCR will be the person responsible for resolving grievances, disputes or concerns relating to AEC operation. And for determining if any action, beyond suspension or revocation of approval of a project is warranted

Any ruling of the AEC may be appealed through the South Australian Civil and Administrative Tribunal.

The Code Section 5, Paragraph 5.6 states: Where complaints concerning the AEC process of review of an application or report cannot be resolved by communication between the complainant and the AEC that is the subject of the complaint, the institution should ensure that the complainant has access to a person or agency external to the AEC for review of the process followed by the AEC. This person or agency may be within the institution. Following this review, the AEC may need to review its process in reaching its decision regarding the application or report and re-evaluate its decision in light of the reviewed process. The ultimate decision regarding the ethical acceptability of an activity lies with the AEC and must not be overridden*.

*Note: This statement is technically incorrect, South Australian Civil and Administrative Tribunal (SACAT) can override any decision.

Appendix 1

QUICK GUIDE TO COMPILING RESEARCH APPLICATIONS FOR CONSIDERATION BY THE UNIVERSITY OF ADELAIDE ANIMAL ETHICS COMMITTEE

Drs Adam O'Connell and John Finnie

University Veterinarians

The purpose of this guide is to acquaint researchers with the style of answers that the AEC requires to questions posed by RM6 and thus help them to compile an application that is more likely to be favourably considered, and more rapidly approved, by the AEC.

Language and style:

The most important thing to remember, when writing the application, is that the AEC is comprised of members of the public (lay members), as well as those with associations to the University. The background of the individuals in the AEC varies enormously, with many members having no scientific training or experience. It is important that all members, including lay members, can easily read, understand and assess an application. If any member finds an application difficult to read or understand, resubmission may be requested.

Lay language means minimising scientific jargon where possible, using plain language where possible and avoiding excessive numbers or acronyms. While it may not always be possible to avoid using scientific terminology, where it is used a plain English definition / explanation should be provided when it is first used. Acronyms that are fundamental to an application are okay, but should be defined in full the first time they are used.

The animal ethics application is not a peer-reviewed scientific review or grant funding application. Do not copy and paste from grant funding applications. While you have to convince the AEC of the scientific merit, avoid using large numbers of references in text or detailed explanations of laboratory techniques not relevant to the application. Clear, concise, well-structured answers that give a broad understanding to all members of the AEC are more important than detailed scientific answers that only a fellow scientist would understand.

Length:

Length does not matter and a long application should not be interpreted as a good application. A short application with clear explanations is much better than a long, confusing application. While it is good writing technique to try and keep an answer as short as possible, the application should be as long as is necessary to clearly and simply answer the questions.

Experience and training requirements:

It is important to demonstrate that investigators are either competent and experienced in proposed procedures or will be given adequate training, support and supervision to become competent.

Please make it clear what the experience or training requirements are for all the investigators. The application must clearly detail which investigators are competent to perform the proposed procedures, why they are competent, which investigators need training, how they will be trained, who will provide the training and why they are competent to train.

If additional animals are needed for training, these animals must be included in the application. This is not required if LAS or UV's are training investigators using LAS animals.

Project title:

Should succinctly explain the principal aim of the project and what aspect of a given disease the proposed research is attempting to understand and/or improve (e.g. pathogenesis, therapy).

Short lay summary:

It is very important that this project summary is written in lay language so it is intelligible to lay members of the AEC. It should succinctly explain what the project hopes to achieve and, if successful, what the significance of these positive research results will be to improving an understanding of this particular disease.

Keep in mind that this summary is what will be provided by the University to an external organisation (e.g. newspaper) seeking to understand what this research is all about.

Scientific justification:

This section provides the researcher with an opportunity to explain to the reader what the project aims to achieve and how it will hopefully lead to a better understanding of disease development mechanisms/treatment modalities. A good answer to this question will help the reader understand why the use of animals is justified in achieving these aims. Again, it is very important to write this section in lay (non-scientific) language.

Animal number justification:

A good answer here will provide the reasoning behind how animal numbers were derived and how the size of experimental cohorts was arrived at. This section is closely scrutinised and frequently debated by the AEC.

The AEC will generally require a power calculation to justify the number of animals sought (or explain why this cannot be performed) and researchers are encouraged to consult (and cite) a biostatistician, unless they are very experienced with statistical methods.

Typically, members of the AEC will look for consistency of numbers throughout an application and compare numbers here with those provided in sections 5.1 Animals required, 6.1 Procedure description, any attached flowchart / experimental plan etc. It is really important, before submitting an application to review the numbers in various sections and ensure they are all consistent.

Ensure you consider additional animals for potential / likely problems and training as necessary. If you ask for the absolute minimum animals based on a power calculation, and one becomes unwell or dies, then your study will be underpowered.

The 3 R'S (replacement, reduction, refinement):

The 3 R's are now a major focus of improving animal welfare standards and, accordingly, your answers to these questions should be carefully considered and well argued.

- **Replacement:**

There will be many projects for which an animal model is clearly required. However, you should explain why an *in vivo* system is obligatory to achieve the aims of your research and why other alternatives (e.g. *in vitro*) are unsuitable.

- **Reduction:**

In addition to showing that the minimum number of animals will be used (and justify this with a statistical power calculation) to achieve the aims of this research, you are encouraged to consider using surplus animals from this (and other) universities/research institutions and making any unused animals from your project available to other researchers.

Gender is becoming an issue in scientific research, and you should explain why only one sex is being used (if this is the case). There may be instances in which proof-of-principle is initially desired to be demonstrated in one sex and, if proved, will then be extended to the opposite sex, but this should be carefully explained.

- **Refinement:**

This is arguably the most scrutinised of the 3R's by the AEC and your answer should reflect a well-considered inclusion of improvements to the experimental paradigm from the animal's perspective. For example, what will be done to alleviate/minimise pain/distress (analgesia, anaesthesia, sedation), what training will investigators undergo and what is their experience, what environmental enrichment (e.g., toys) will be provided to create better conditions for the animals and allow normal behaviours to be performed, and how will you make it easier for animals to eat and maintain body weight (e.g. soaked food)?

A carefully constructed CRS will be an important element of the "Refinement" process and it should be specific to the project under consideration (see later comments on CRS).

If the experimental procedure is invasive and/or painful, the level of pain/distress induced should be quantified and justified in terms of the importance/relevance of the expected experimental outcomes.

Animals required:

Very important: Ensure that the total number of animals requested here matches the animal numbers stated in other parts of the application. Where suitable, request additional animals to cover for animals that become unwell or die unexpectedly, so that studies do not become underpowered.

Animal housing:

Please check with the facility manager, in advance, that there will be accommodation available when you need it. Also, if assistance is required for animal monitoring, this should be arranged in advance and agreement stated in the application.

Animal fate:

Be consistent with any method of humane killing throughout the application. Use correct terminology.

Procedure description:

- You should state precisely what procedures the animals will be subjected to and their temporal sequence. This should be in language intelligible to lay members of the AEC (scientific terms, unless in common usage, should be explained in lay terms).

- State what drugs/other agents will be administered and their dose rate/frequency and route of administration.
- State which tissues will be collected and, if blood is to be collected, the volume and frequency of its collection.
- Where applicable, state how many people will be assisting with procedures (e.g. for anaesthesia, typically two people are present, one to perform the procedure and one to assist and monitor the animals. This needs to be clearly stated).
- Give a brief explanation of how outcomes will be evaluated / results will be analysed and precisely what techniques will be used to evaluate the results.
- There will be separate sections for teaching applications or wildlife projects etc. which will drill into the details around staff to student numbers, maximum time of restraint, maximum number of students per animal, environmental conditions etc. It doesn't hurt, where applicable, to reinforce those details in procedure description or any other relevant section to ensure the AEC appreciate the point.

Ensure you discuss any transportation, acclimatisation, humane killing etc. Please include references to relevant SOP's in the procedure description, such that is understood you are aware of relevant SOP's and will refer to them. Common lab animal SOP's are available on the Laboratory Animal Services (LAS) website under 'Information for staff and clients > Policies and procedures' while there are also common Roseworthy SOP's available via staff members.

Either in this section, or another relevant section, common health issues for the colony or species and likely adverse events should be recorded. For example a breeding colony is likely to have sporadic birthing issues, still born animals and congenital abnormalities in offspring. Other examples include cancer in certain mice strains, occasional lameness in livestock etc.

For higher impact studies and studies which include anaesthesia, unexpected death or illness may occur (for example death during anaesthesia). An appropriate 'expected' percentage should be included here. Ensure additional animals are requested as appropriate.

Animal monitoring:

The frequency of monitoring should be clearly stated, and justified, together with the persons who will perform the monitoring and their experience.

A CRS will form a critical part of the monitoring process and it should be specific to the project under consideration (if a generic CRS is used, this should be justified). The CRS should:

- List 2 contact persons and their contact phone numbers
- List all the clinical parameters likely be expressed by animals in this project (including dyspnoea if tumour metastasis is anticipated)
- Starting weight and weight loss columns should be included and the time at which they were taken recorded
- Assign a score to all of the clinical parameters listed
- Show cut-off scores when action (e.g., seek veterinary advice, euthanasia) is required
- For tumour studies, any assessment of weight loss due to tumour-induced cachexia should take account of any counterbalancing increase in body weight to due enlargement of the tumour mass. As a guide, a tumour volume of 1000 mm^3 is equivalent to ~ I gram of normal body tissue.

Substances administered:

You should include all drugs/other agents/cell lines to be administered to animals, together with their dose rate, and frequency and route of administration.

Transport of animals:

Please remember to include the relevant transport SOP in your application.

Training:

The CI is ultimately responsible for ensuring all investigators are competent, or that there is a training plan developed to ensure they will become competent. The application must clearly establish who is competent to perform procedures and why they are competent, who needs training, how they will be trained and assessed competent, by whom and the competency of the trainer.

Funding:

Please include the name of the funding body and the application number.

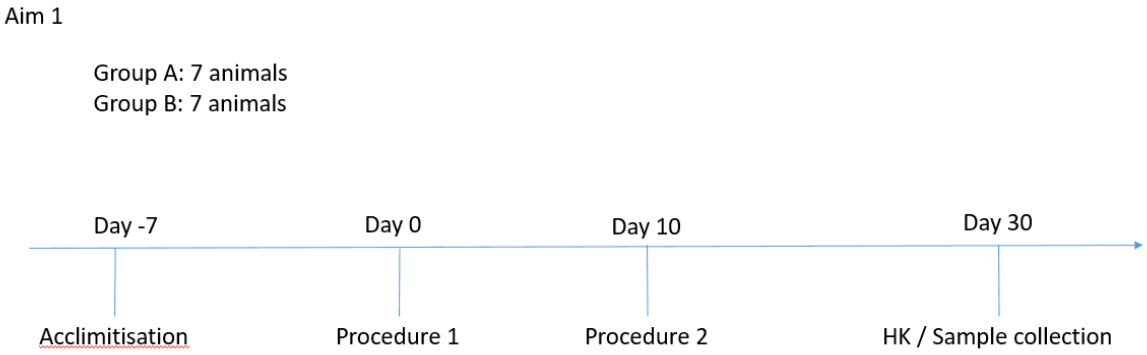
In addition to evaluation of a research project on animal welfare grounds, external, peer-reviewed funding is an important part of the AEC assessment of the scientific validity of the proposed study.

Attached documents:

These must be in PDF form.

- **A flowchart or experimental plan** complements the application, especially the procedure description, and is very useful to the AEC. It does not need to be flashy / can be very plain. It will be closely examined. A good flowchart can make a big difference in the AEC's understanding and subsequently how they view an application. It is very worthwhile investing time in developing a good flow diagram. A good flowchart is often constructed in Microsoft Powerpoint and allows a quick and easy understanding of the overall experimental design, including a timeline of when procedures will be performed and the number of animals required at each time-point. It is essential if there are multiple aims/arms of the project. A good flowchart will enable the reader to more readily appreciate the overall aims and conduct of the research, with the allocation of animal numbers to each phase of the project being clearly shown. A very basic example is below (example only, you can present your flowchart however you would like to / however suits the project). Text explanations can accompany, the key feature is to make it easy to understand what is happening in the planned

experiment.



- **Sometimes a detailed experimental plan is attached** that may have been prepared for a funding application or publication. This is okay and can be useful for those members who would like to dig into things a little more, but it is not essential.
- **SOP's / Description of procedures:** Typically, the AEC like to see SOP's or documents attached that explain major procedures or demonstrate they are standard techniques in the field. Any bespoke SOP's need to be attached and should be referenced in Procedure Description. Please make sure any SOP is up-to-date and relevant.
- **Pictures / diagrams** of equipment or facilities are always encouraged and in certain circumstances will be requested if not attached – the classic a picture is worth a thousand words. e.g., picture of a bird with a tracking device attached.

Appendix 2

Training framework

Chief Investigator responsibilities

In line with *The NHMRC Australian code for the care and use of animals for scientific purposes (8th Edition 2013)*, it is ultimately the responsibility of the Chief Investigator (CI) to ensure that individuals involved in an approved research or teaching activity involving animals are competent when performing procedures, including the care and assessment of those animals.

Prior to submitting an animal ethics application, the CI must identify the competency level and training needs of any animal users and develop a suitable training plan as necessary. Any additional animals and procedures required for training need to be included in the application. If the CI does not deliver the training, they must provide oversight and ensure any training plan provides the skills required, is completed and that the trainee has achieved competency. The CI must ensure suitable resources and time are available for training.

The CI is free to demonstrate competency of individuals in any way they deem appropriate, but must unequivocally establish, through either training or prior experience, that a person can perform a procedure in a manner that is in accordance with accepted practice, is timely, maximises opportunity for the procedure to be successful and minimises the welfare impact.

- The CI is ultimately responsible for ensuring animal users involved in an approved animal research or teaching activity are trained and competent.
- The CI can demonstrate competency in a manner they deem to be appropriate, including prior experience, but competency must be unequivocal.
- The CI must ensure that there are suitable resources and time available for training and that any training animals and procedures are part of an approved animal ethics application.

Animal user responsibilities

It is the responsibility of the animal user to ensure that their knowledge is up-to-date, that they are aware of current SOP's and best practice and that they are performing any procedures in accordance with what is approved in the animal ethics application.

It is the responsibility of all animal users to inform the CI and seek further education, training, supervision or assistance if they feel they are not competent to perform a procedure, or if it is identified as such.

It is the responsibility of any animal user who is undergoing training to actively participate in the training process and to complete any non-animal training (i.e. online training, SOP familiarisation, practicing skills on non-animal models etc.) in a timely manner before live animal training occurs.

Who can provide training?

Anyone with an appropriate level of skill, knowledge and experience can train another animal user in a procedure. The CI must be able to unequivocally demonstrate the competency and appropriateness of the

trainer. The trainer must be someone named on the animal ethics application and using animals in accordance with the ethics approval or acting under a separate valid animal ethics training approval.

Where possible, training should be provided by a senior researcher, experienced research assistant, experienced animal technician, veterinarian or other person with a wide set of appropriate skills and experiences in animal procedures and care. Competent post-graduate students cannot train another individual without adequate oversight by a senior researcher.

Animal based training can occur in conjunction with experimental procedures where appropriate. An animal user named in an ethics application, who is not yet considered competent in a procedure, can perform an approved experimental procedure if they are adequately supervised as part of training to gain competency in the procedure (i.e., as an assistant).

The responsibility of the trainer

The trainer must ensure they are teaching to accepted practice and that their knowledge is up-to-date. The techniques being taught must be consistent with the procedures approved in the animal ethics application and relevant institutional SOP's. The trainer must continue to provide assistance and supervision to an animal user until they are competent.

What needs to be covered when training an animal user?

When providing procedural training to an animal user, there is a wide base of knowledge that must be taught, including (but not limited to):

- Relevant theory including any mandated or appropriate online training
- Development of skills on non-animal models
- Equipment familiarisation
- Relevant local and institutional SOP's
- Personal safety
- Biosecurity and cleanliness
- Reporting lines for animal welfare concerns and equipment issues
- Set-up and provision of equipment and consumables
- Tidying and replacing consumables after activities
- Record keeping
- Basic animal husbandry and care
- Animal monitoring and assessment for disease and compromise
- Creation of a low stress environment
- Specific procedural skills

Non-animal training should be completed before live animal training occurs. It is the responsibility of the trainee to ensure this occurs.

Overview of the training process

To minimise the welfare impact of training on animals and help ensure personal safety, non-animal training should be undertaken before live animal training. In order to monitor and care for animals unsupervised or perform advanced procedures, an animal user must first be able to perform basic or core procedures, including assessing an animal and its environment, handling and restraint, moving an animal between two locations and animal euthanasia. Therefore training in these procedures should occur first.

Recommended timeline:

CI and animal users work together to identify competencies and training needs

↓

Procedures and animals used for training approved by the AEC

↓

Compulsory online ANZCCART Compass core animal user training

↓

Recommended online ANZCCART Compass modules for specific areas of knowledge and other appropriate training and educational materials

↓

Familiarisation with appropriate SOP's and processes

↓

Non-animal training using inanimate models and equipment familiarisation (e.g. training suite)

↓

Procedural training using animals in core procedures (e.g. animal handling and restraint, animal assessment and daily care, animal euthanasia etc.)

↓

Procedural training using animals in advanced procedures e.g. injection technique, surgery, anaesthesia etc.

↓

Complete any training or competency records as appropriate

What about experienced animal users / researchers transferring to The University of Adelaide?

It is the responsibility of the CI to be able to demonstrate that they are competent in any animal procedures they will perform. The experienced animal user will need to complete any mandated (ANZCCART Compass core online animal ethics training, etc.) and institution specific training (SOP's, reporting lines etc.) at a minimum.

One method for demonstrating that an experienced animal user is competent in a procedure is to ask LAS (in LAS facilities) or the University Veterinarians to meet with, and view, the experienced animal user when they are performing a procedure and provide a signed competency assessment certificate.

Refresher training

There is no mandated period of time during which refresher training must occur (apart from the ANZCCART Compass core online animal ethics training). Refresher training is recommended if there has been a substantial period of time since a procedure was last performed by an animal user or if there is a realistic expectation that best practice or SOP's have changed since the procedure was last performed.

Resources for support of CI's and investigators in training and demonstration of competency

LAS Competency training

LAS offer competency assessment-based structured training in core skills for laboratory animal users. Core skills include handling, humane killing, injection, blood collection and anaesthetic techniques. LAS training has high demand and limited places available. LAS are not responsible for ensuring that the training they offer is available or completed before the start of an experiment. It is recommended that the CI and animal user discuss training needs as early as practicable with LAS and seek alternative options if LAS training cannot be delivered in a timely manner for experimental or teaching needs.

Due to the high demand for training by LAS, and limited resources, animal users are typically trained to a stage where they can reasonably and safely (for the animal and person) perform a procedure. In some cases, the animal user may need further practice to become truly adept, and as such ongoing support and supervision by the CI and other members of the research team is recommended until the animal user and CI are satisfied they are competent and ready for unsupervised procedural work.

As part of LAS structured training, LAS can provide training animals for out-of-session practice to animal users once they have completed initial training to the satisfaction of LAS. In this situation, it is the responsibility of the trainee to arrange access to the animals with LAS.

University Veterinarian training and competency assessment

Training needs can be discussed with the University Veterinarians who may be able to provide direct training and support for a procedure. They will also work with the CI or animal user to help identify training assistance or develop a suitable training plan.

The University Veterinarians are available and very willing to view animal users perform procedures to assist in technique refinement and competency demonstration. Where animal users are taught advanced procedures (for example surgery) by non-veterinarians, it is recommended that the CI and trainee ask the University Veterinarians to view the trainee performing the procedure, once they have learnt the technique.

Online ANZCCART Compass training

ANZCCART provide compulsory online animal ethics training for all animal users in **Phase 1: Core mandated training for AEC members and animal users**. This training consists of seven core modules on various topics and an eighth core module which is an assessment and generates a certificate of completion.

ANZCCART also provide optional stand-alone online training modules on a variety of procedural topics in **Phase 2: Competency training and knowledge base**. These modules include a certificate of completion which can be used to help demonstrate competency. Animal users should complete the modules relevant to their activities, prior to undergoing practical animal training. Topics include:

Aseptic technique.
Minimally invasive techniques without anaesthesia, including wildlife trapping.
Anaesthesia for minor procedures.
Anaesthesia for major procedures.
Surgical principals, methods and materials.
Performing a systematic post-mortem examination.
Establishing and managing a rodent breeding colony.
Maximising welfare and behavioural assessment in research animals.

Training suite

Basic practical skills should initially be learnt using non-animal models before developing those skills on animals. Basic practical skills include handling concepts, needle and syringe handling, injection techniques, suture skills, instrument dexterity, aseptic technique, anaesthetic machine set-up and any other practical skill that can be practised without using an animal.

Laboratory Animal Services Training Suite is available for unsupervised training however bookings are essential via las_training@adelaide.edu.au. The training suite consists of a range of non-animal models and stations with accompanying information and QRS scannable videos to guide trainees in skills development.

Competency Assessment Certificates and Skills Logs.

The competency assessment certificate at the end of the document provides a general guide for the scope of training required for a skill or procedure. While the training requirements for any particular procedure and animal user will vary, it is important to consider not only the procedural steps required, but the wider body of knowledge including pre-requisites, safety and biosecurity, animal welfare, professionalism and application of the 3R's (replacement, reduction and refinement).

One method for demonstrating competency is to provide a signed competency assessment certificate for each procedure an animal user develops competency in.

Another method is to maintain a skills log, which is signed and dated by the animal user, trainer and where appropriate the CI, recording procedures the animal user has been trained in and any non-animal training that has been performed.

All Species Procedural Competency Assessment and Certificate.

Candidate name: Species: Assessed by:

Assessment date:

Procedure(s):

Note for assessors: Only complete and sign this assessment form once trainee is competent in all aspects listed below, and can safely and correctly perform procedure without supervision or assistance.

Prerequisites:
• The trainee has completed appropriate online training, including;
  ○ ComPass Phase 1 'Core Mandated Training' (modules 1-7 plus module 8 'assessment')
  ○ ComPass Phase 2 modules as relevant
• The trainee has spent time developing skills on non-animal models and familiarising themselves with equipment
• The trainee can perform basic handling skills competently before they undertake other procedural training
• The trainee has been procedurally trained, using animals, for an appropriate length of time by an experienced researcher or technician

Safety and Biosecurity: • Correct use of PPE and aware of potential hazards including zoonosis, allergies and the animals defence mechanisms • Understands what biosecurity is and basic biosecurity principles • Correct and safe use of equipment, including equipment for handling animals and antisepsis
Animal welfare: • Empathetic, safe handling

• All procedures performed confidently and in a timely manner • A low stress environment is created • Attention to signs of distress, including breathing and mucosal colour during procedure / when restrained • Trainee can correctly describe major symptoms that indicate an animal is possibly distressed or unwell   ○ E.g. coat condition, movement and posture, body condition, pain signs, etc. • Knows who to report animal health and welfare concerns to and how to get assistance when concerned

Procedural
 	
• Trainee is aware to plan procedural work for an appropriate time of the day where possible, for example:
  ○ Surgery performed in the morning so recovery can be monitored easily throughout day
  ○ Stock not left in uncovered yards during middle of hot day
• Set-up is completed before any animal interaction (equipment, materials, records etc.)
• Equipment, including restraint devices, syringes and needles etc. assembled, checked and operated correctly
• A free run / distance examination is performed before the animal is handled
• Where appropriate, the trainee can competently enter animal housing and transfer animals between two locations
  ○ Co-housed and herd animals: trainee is aware of group dynamics and flight zones
• Trainee can competently restrain animals as needed
  ○ Without excessive force
  ○ The restraint time is the minimum required for a procedure
• Trainee aware of and can use any additional methods that facilitate handling and procedural work
• Trainee performs procedure in a competent and confident manner without hesitation
• Trainee monitors animals for an appropriate length of time after procedural work is completed

Professionalism: • Workspace left clean and tidy • Knows and communicates own limits • Completes records as necessary
3Rs: • Demonstrates understanding to actively seek to minimise welfare impact of procedural work

I assess the candidate to be competent and able to perform the above named procedure(s):
Assessor signature and position:

Appendix 3

PREPARE

norecopa

The PREPARE Guidelines Checklist

Planning Research and Experimental Procedures on Animals: Recommendations for Excellence

Adrian J. Smith[a], R. Eddie Clutton[b], Elliot Lilley[c], Kristine E. Aa. Hansen[d] & Trond Brattelid[e]

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PREPARE[1] consists of planning guidelines which are complementary to reporting guidelines such as ARRIVE[2].
PREPARE covers the three broad areas which determine the quality of the preparation for animal studies:

1. **Formulation of the study**
2. **Dialogue between scientists and the animal facility**
3. **Quality control of the components in the study**

The topics will not always be addressed in the order in which they are presented here, and some topics overlap. The PREPARE checklist can be adapted to meet special needs, such as field studies. PREPARE includes guidance on the management of animal facilities, since in-house experiments are dependent upon their quality. The full version of the guidelines is available on the Norecopa website, with links to global resources, at **https://norecopa.no/PREPARE**.
The PREPARE guidelines are a dynamic set which will evolve as more species- and situation-specific guidelines are produced, and as best practice within Laboratory Animal Science progresses.

Topic	Recommendation
(A) Formulation of the study	
1. Literature searches	☐ Form a clear hypothesis, with primary and secondary outcomes. ☐ Consider the use of systematic reviews. ☐ Decide upon databases and information specialists to be consulted, and construct search terms. ☐ Assess the relevance of the species to be used, its biology and suitability to answer the experimental questions with the least suffering, and its welfare needs. ☐ Assess the reproducibility and translatability of the project.
2. Legal issues	☐ Consider how the research is affected by relevant legislation for animal research and other areas, e.g. animal transport, occupational health and safety. ☐ Locate relevant guidance documents (e.g. EU guidance on project evaluation).
3. Ethical issues, Harm-Benefit Assessment and humane endpoints	☐ Construct a lay summary. ☐ In dialogue with ethics committees, consider whether statements about this type of research have already been produced. ☐ Address the 3Rs (Replacement, Reduction, Refinement) and the 3Ss (Good Science, Good Sense, Good Sensibilities). ☐ Consider pre-registration and the publication of negative results. ☐ Perform a Harm-Benefit Assessment and justify any likely animal harm. ☐ Discuss the learning objectives, if the animal use is for educational or training purposes. ☐ Allocate a severity classification to the project. ☐ Define objective, easily measurable and unequivocal humane endpoints. ☐ Discuss the justification, if any, for death as an end-point.
4. Experimental design and statistical analysis	☐ Consider pilot studies, statistical power and significance levels. ☐ Define the experimental unit and decide upon animal numbers. ☐ Choose methods of randomisation, prevent observer bias, and decide upon inclusion and exclusion criteria.

Appendix 4

	ITEM	RECOMMENDATION
Title	1	Provide as accurate and concise a description of the content of the article as possible.
Abstract	2	Provide an accurate summary of the background, research objectives, including details of the species or strain of animal used, key methods, principal findings and conclusions of the study.
INTRODUCTION		
Background	3	a. Include sufficient scientific background (including relevant references to previous work) to understand the motivation and context for the study, and explain the experimental approach and rationale. b. Explain how and why the animal species and model being used can address the scientific objectives and, where appropriate, the study's relevance to human biology.
Objectives	4	Clearly describe the primary and any secondary objectives of the study, or specific hypotheses being tested.
METHODS		
Ethical statement	5	Indicate the nature of the ethical review permissions, relevant licences (e.g. Animal [Scientific Procedures] Act 1986), and national or institutional guidelines for the care and use of animals, that cover the research.
Study design	6	For each experiment, give brief details of the study design including: a. The number of experimental and control groups. b. Any steps taken to minimise the effects of subjective bias when allocating animals to treatment (e.g. randomisation procedure) and when assessing results (e.g. if done, describe who was blinded and when). c. The experimental unit (e.g. a single animal, group or cage of animals). A time-line diagram or flow chart can be useful to illustrate how complex study designs were carried out.
Experimental procedures	7	For each experiment and each experimental group, including controls, provide precise details of all procedures carried out. For example: a. How (e.g. drug formulation and dose, site and route of administration, anaesthesia and analgesia used [including monitoring], surgical procedure, method of euthanasia). Provide details of any specialist equipment used, including supplier(s). b. When (e.g. time of day). c. Where (e.g. home cage, laboratory, water maze). d. Why (e.g. rationale for choice of specific anaesthetic, route of administration, drug dose used).
Experimental animals	8	a. Provide details of the animals used, including species, strain, sex, developmental stage (e.g. mean or median age plus age range) and weight (e.g. mean or median weight plus weight range). b. Provide further relevant information such as the source of animals, international strain nomenclature, genetic modification status (e.g. knock-out or transgenic), genotype, health/immune status, drug or test naïve, previous procedures, etc.
Housing and husbandry	9	Provide details of: a. Housing (type of facility e.g. specific pathogen free [SPF]; type of cage or housing; bedding material; number of cage companions; tank shape and material etc. for fish). b. Husbandry conditions (e.g. breeding programme, light/dark cycle, temperature, quality of water etc for fish, type of food, access to food and water, environmental enrichment). c. Welfare-related assessments and interventions that were carried out prior to, during, or after the experiment.
Sample size	10	a. Specify the total number of animals used in each experiment, and the number of animals in each experimental group. b. Explain how the number of animals was arrived at. Provide details of any sample size calculation used. c. Indicate the number of independent replications of each experiment, if relevant.
Allocating animals to experimental groups	11	a. Give full details of how animals were allocated to experimental groups, including randomisation or matching if done. b. Describe the order in which the animals in the different experimental groups were treated and assessed.
Experimental outcomes	12	Clearly define the primary and secondary experimental outcomes assessed (e.g. cell death, molecular markers, behavioural changes).
Statistical methods	13	a. Provide details of the statistical methods used for each analysis. b. Specify the unit of analysis for each dataset (e.g. single animal, group of animals, single neuron). c. Describe any methods used to assess whether the data met the assumptions of the statistical approach.
RESULTS		
Baseline data	14	For each experimental group, report relevant characteristics and health status of animals (e.g. weight, microbiological status, and drug or test naïve) prior to treatment or testing (this information can often be tabulated).
Numbers analysed	15	a. Report the number of animals in each group included in each analysis. Report absolute numbers (e.g. 10/20, not 50%[2]). b. If any animals or data were not included in the analysis, explain why.
Outcomes and estimation	16	Report the results for each analysis carried out, with a measure of precision (e.g. standard error or confidence interval).
Adverse events	17	a. Give details of all important adverse events in each experimental group. b. Describe any modifications to the experimental protocols made to reduce adverse events.
DISCUSSION		
Interpretation/ scientific implications	18	a. Interpret the results, taking into account the study objectives and hypotheses, current theory and other relevant studies in the literature. b. Comment on the study limitations including any potential sources of bias, any limitations of the animal model, and the imprecision associated with the results[2]. c. Describe any implications of your experimental methods or findings for the replacement, refinement or reduction (the 3Rs) of the use of animals in research.
Generalisability/ translation	19	Comment on whether, and how, the findings of this study are likely to translate to other species or systems, including any relevance to human biology.
Funding	20	List all funding sources (including grant number) and the role of the funder(s) in the study.

ARRIVE The ARRIVE Guidelines: Animal Research: Reporting of *In Vivo* Experiments. Originally published in *PLOS Biology*, June 2010[1]