ANIMAL USER'S HANDBOOK

INFORMATION ABOUT YOUR RESPONSIBILITY TO USE ANIMALS HUMANELY AND ETHICALLY

1 Introduction

The University of Adelaide adheres to the South Australian *Animal Welfare Act* (1985) and Regulations, the NHMRC *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* (7th edition, 2004), and other relevant animal welfare Codes of Practice. The guidelines in this Handbook have been developed to assist scientific investigators and teachers to achieve the goals of the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* (the Australian Code), and to promote the humane and ethical use of animals for scientific purposes.

2 When is AEC Approval Required?

Are You:

- Using live animals?
- Acquiring organs or tissues from living or dead animals?
- Breeding or acquiring animals?
- Applying to a granting body requiring ethics clearances before releasing funds?

All scientific research and teaching involving animals* requires AEC approval

definition below

The University of Adelaide is licensed under the Act to acquire and use animals only when approval has been granted by its Animal Ethics Committee (AEC).

No animal may be acquired, bred, held or used for any purpose until written approval has been obtained from the AEC.

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;
- holding, breeding or any other keeping of animals;
- fieldwork, including capture and release after marking.

2.1 Definitions based on the Australian Code

***Animal:** any live non-human vertebrate (including mammals, birds, reptiles, amphibians and fish) or cephalopods such as octopus, squid, and cuttlefish. The definition of animal includes embryos, foetuses and larval forms that have progressed beyond half the gestation or incubation period of the relevant species, or have become capable of independent feeding.

Examples of animals as defined by the Australian Code:

- Vertebrates: (animals with backbones) e.g. monotremes, marsupials, placental mammals, domestic animals, companion animals (cats, dogs), laboratory animals, wildlife, pest animals, fish, rats, mice, guinea pigs, rabbits, non-human primates.
- Cephalopods: e.g. octopus, squid, cuttlefish, nautilus.
- Fish, including bony fish and cartilaginous fish (sharks, skates and rays).
- **Not** insects, millipedes, annelids (worms), gastropods (slugs & snails) or spiders.
- **Not** shellfish (bivalves, mussels, oyster, scallop).
- **Not** humans.

Acquisition: obtaining animals for scientific research or teaching purposes. This includes animal breeding to produce animals for scientific or teaching use.

Scientific activity: is an activity to achieve the scientific purposes.

Scientific purpose: is all those purposes which aim to acquire, develop or demonstrate knowledge or techniques in any area of science including teaching, field trials, environmental studies, research, diagnosis, product testing, and the production of biological products.
The term *scientific purpose* includes:

- **acquisition**, demonstration or development of knowledge in a field of science
- **acquisition**, development, demonstration or exercise of scientific techniques
- **development,** or testing the use of substances or materials intended for use in connection with animals or humans.

Scientific procedure: An investigator or teacher is conducting a *scientific procedure* if **live** animals are primarily and purposefully killed, or biopsied, or sampled to obtain organs, tissues, or other substances derived from the body of an animal for *scientific purposes*. *Scientific procedures* also include any other action or observation or demonstration conducted for *scientific purposes*, including behavioural observations of animals. Prior approval by the AEC is a legislative requirement.

The term *scientific procedure* does **not** include:

- the practice of veterinary medicine or surgery by a veterinarian
- the conduct of animal husbandry carried out in accordance with a Code of Practice
- procedures performed in accordance with Wildlife legislation.

Scientific procedures conducted using **dead** and discarded animals, tissues and substances are discussed under *scavenging* (see below, section 2.2).

Teaching: Developing, imparting or demonstrating knowledge or techniques in any area of science.

2.2 Acquiring Organs, Tissues or Materials from Animals for Use in Scientific Research or Teaching by Scavenging

In some situations animal tissues and substances are available for collection from discarded **dead** animals**.** Another term used with reference to collection of materials from dead animals is "***scavenging***", or *collection from "**animals killed for other purposes**".* That is, the animals have not been specifically killed for the purpose of obtaining these materials for scientific research or teaching. This definition includes materials sourced from abattoirs.

"Scavenging" tissue from carcases is highly recommended[1] to be used (whenever possible) as an alternative to killing animals specifically for that purpose, because it reduces the number of animals used in research and teaching. Prior approval by the Animal Ethics Committee (AEC) is not a legislative requirement. However, the AEC should be informed when an investigator or teacher is "scavenging", especially if this is occurring on a regular basis. **Investigators are encouraged to inform the AEC promptly**, when practicable.

Subject to the conditions and considerations listed below, AEC approval may not be required prior to obtaining the material.

1. **The opportunity for scavenging must not influence the decision to kill the animal, nor the time when this occurs, if this comprises animal welfare*.***

2. Collection of organs, tissues, materials or substances from a **living** animal for scientific or teaching purposes is a **scientific procedure** and requires prior approval from the AEC.

3. In some situations, animal tissues and substances from living animals are discarded following routine animal husbandry practices, or are discarded from veterinary practices following veterinary surgery or veterinary medical procedures. **The specific details of the particular situation must be provided to the AEC in order to determine whether AEC approval is required prior to collection or use of these materials for scientific or teaching purposes.** As **living** animals are involved there may be legal, ethical or welfare issues (e.g. owner consent). This is a University requirement.

4. In some situations, animal materials and substances (including urine, faeces, feathers and hair) are found discarded by an animal in its environment. **The specific details of the particular situation must be provided to the AEC in order to determine whether AEC approval is required prior to collection or use of these materials for scientific or teaching purposes.** As **living** animals are involved there may be legal, ethical or welfare issues (e.g. tracking wildlife, entering private property).

5. **Killing** an animal specifically to collect tissues or substances for scientific or teaching purposes is also a scientific procedure, is not considered to be a case of "scavenging", and therefore requires prior approval from the AEC.

What do I have to do if scavenging?

- **Scavenging from carcases**
  AEC approval is not required prior to collecting and using the tissues or materials sourced from carcases. However, the AEC should be informed when an investigator or teacher is "scavenging", especially if this is occurring on a regular basis. Investigators are encouraged to inform the AEC promptly, when practicable.

From the NHMRC Australian code of practice for the care and use of animals for scientific purposes, 7th Edition.
[1] "3.3.21 Where practicable tissues from animals being killed should be shared among investigators and teachers in line with the principle of Reduction."

If considered desirable an Application for AEC approval of a project involving "scavenging" can be submitted.

"Scavenging" is not required to be entered in the *Annual Statistics Return and Progress Report*, however the source of the tissues/materials and the circumstances surrounding their collection must be documented and made available to the AEC upon request. Animal houses and investigators both have responsibilities for documenting the reason for the death of an animal, and the subsequent fate of the carcase.

- **Discarded tissues and substances from living animals**
  The AEC must be informed prior to collecting and using the material, as living animals are involved and there may be legal, ethical or welfare issues. The source of the tissues/materials and the circumstances surrounding their collection must be documented and made available to the AEC upon request.

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 road kills) require a wildlife permit from the Department of Environment and Heritage.
- If animal tissues are imported from overseas then additional permits may be required (AQIS, CITES).

3 Planning a new research project – how to implement the key principles of Replacement, Reduction and Refinement

The Australian Code requires research investigators, teachers, animal carers and AECs to ensure that the use of animals in scientific activities is justified, and that there are no alternatives to using animals. When animal use is justified, pain and distress must be alleviated or minimised. These key principles are encapsulated as **Replacement, Reduction and Refinement (the 3Rs).**

The 3Rs are defined as follows:

- **Replacement**: If a viable alternative method exists that would partly or wholly replace the use of animals in a project, the Code requires investigators to use that alternative. Examples of alternative methods include in vitro techniques and computer models.
- **Reduction**: A project must be designed to use no more than the minimum number of animals necessary to ensure scientific and statistical validity. However, the principle of reducing the number of animals used should not be implemented at the expense of greater pain and distress for individual animals.
- **Refinement**: Studies must be designed to avoid or minimise both pain and distress in animals, consistent with the scientific objective. Investigators must also be competent in the procedures they perform. Project design must take into account
    - the choice of animals, their housing, management and care and their acclimatisation
    - the choice of techniques and procedures
    - the appropriate use of sedatives, tranquillisers, analgesics and anaesthetics
    - the choice of appropriate measures for assessing pain and distress
    - the establishment of early intervention points and humane endpoints
    - adequate monitoring of the animals
    - appropriate use of pilot studies.

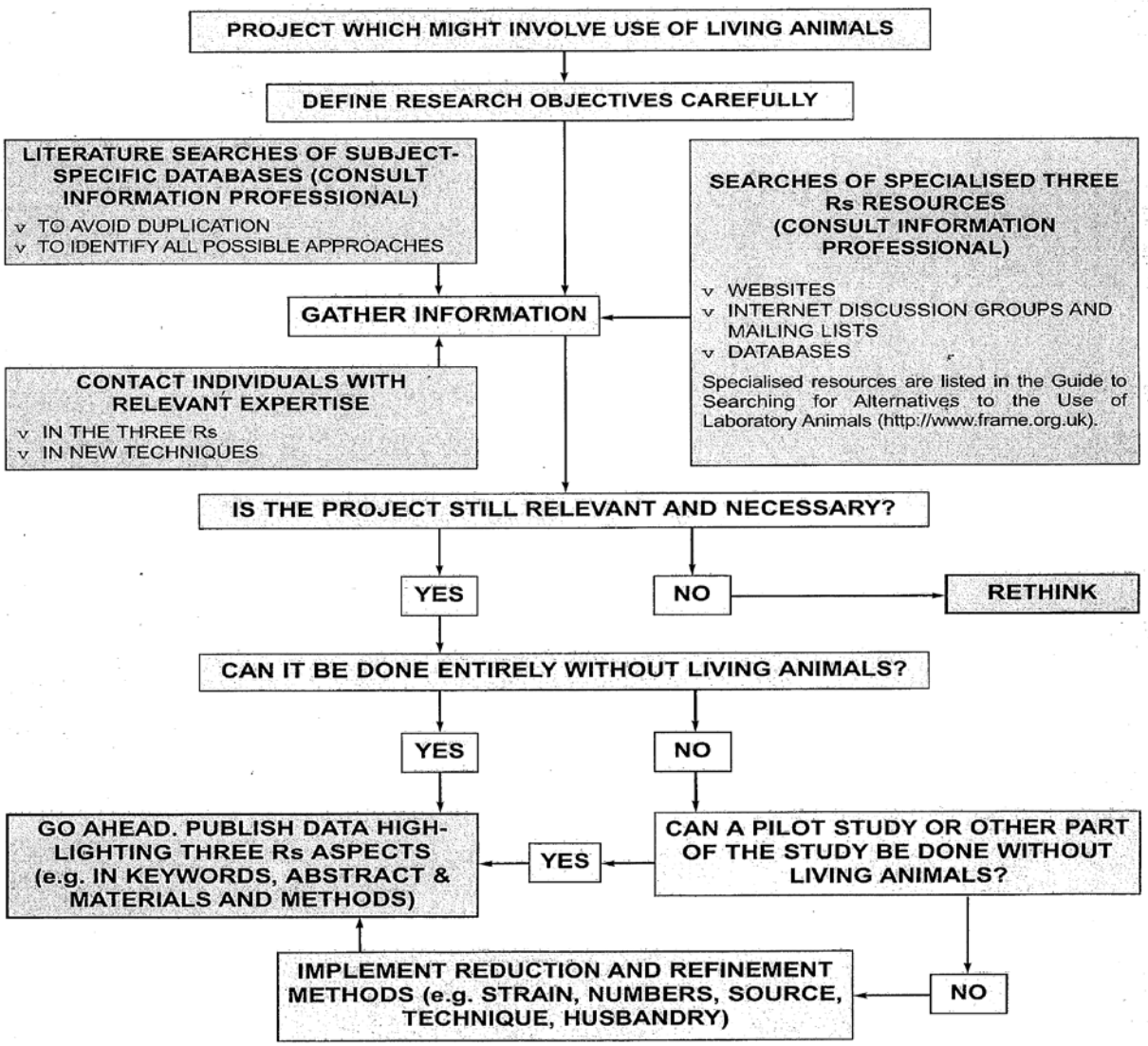
Other key principles in addition to the 3Rs include **Justification** and **Responsibility**:

- **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 take into account all aspects of the project that may have an adverse impact on the animals.
- **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.

Source: NHMRC *Guidelines to promote the wellbeing of animals used for scientific purposes: The assessment and alleviation of pain and distress in research animals. (2008)*

3.1 Implementing the Key Principle of Replacement: Planning strategy flowchart for considering non-animal alternatives when designing new research projects

Source: Focus on Alternatives (http://www.focusonalternatives.org.uk/ and NHMRC *Guidelines to promote the wellbeing of animals used for scientific purposes: The assessment and alleviation of pain and distress in research animals. (In preparation)*



3.2 Implementing the Key Principle of Reduction

Good Experimental Design
Poorly designed studies or inappropriate statistical analysis of results is a waste of animals, and this is unethical. Investigators must ensure their experimental design, objectives and hypotheses are thoroughly considered when planning any research involving animals. Good experimental design means that the experiment should be 'statistically designed', that is:

- Repeatable
- Unbiased (for example, the treated and control groups have the same environment)
- Precise (so that the chance of detecting treatment effects is as high as possible). (Festing 2000)

Your responsibility for implementing good experimental design from the outset is emphasised.

The Faculty of Health Sciences provides a Statistical Support Service which can be accessed at http://www.adelaide.edu.au/health/research/statsupp/

Optimising the number of animals proposed to be used
It is a requirement of the Australian Code of Practice that any experimental proposal involving animal use is scientifically justified. Australian Code Section 2.2.16:

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

Justification for the number of animals required may include:

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

Recommended reading:

Festing, MFW (2006 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, http://www.rsmpress.co.uk/bkfesting.htm

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),
http://dels.nas.edu/ilar_n/ilarjournal/43_4/v4304festing_a.shtml
http://dels.nas.edu/ilar_n/ilarjournal/43_4/v4304festing_b.shtml

Festing M (2000) *Doing better animal experiments; together with notes on genetic nomenclature of laboratory animals*, ANZCCART Facts Sheet, insert ANZCCART News, Vol.13, No 3
http://www.adelaide.edu.au/ANZCCART/publications/Better%20Animal%20Exp_11.pdf

Simon, S (2007 website update) *StATS: Steve's attempt to teach statistics,* http://www.childrens-mercy.org/stats/

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

3.3 Implementing the Key Principle of Refinement

The Australian Code requires investigators to identify "*all aspects of animal use and management, including scientific procedures, handling and housing, that may adversely impact on the animals' wellbeing and how this impact will be minimised*" (Section 2.2.16 [ix]).

3.3.1 Planning Stage

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

- **Consider the choice of animals** (ie species, 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.
- **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.
- **Minimise the severity**: substitute less invasive for more invasive procedures
- **Minimise the duration** of time an individual animal is used.
- **Training & skills** of personnel
- **Supervising** students and inexperienced personnel
- **Minimising pain & distress:** appropriate use of sedation, anaesthesia, analgesia, monitoring and other strategies.
- **Plan early and humane experimental endpoints** and euthanasia criteria
- **Appropriate use of pilot studies** to refine experimental design and methodology, determine effective dose/response etc.

3.3.2 Monitoring Strategy & Use of Clinical Record Sheets

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
- the frequency of monitoring
- the people who will conduct the monitoring, and their training
- the system for the recording of observations. Use of both Laboratory record books and Clinical Record Sheets is usually recommended.

Examples of Abnormal Clinical Signs

- Ataxia (abnormal movement/'wobbly'/lameness)
- Change in the normal individual or group behaviour/abnormal behaviour
- Decreased activity/reluctant to move
- Eating of bedding or neonates
- Excessive licking and scratching
- Hunched posture
- Loss of appetite
- Dull, ruffled hair coat/'fluffed up'
- Ungroomed appearance
- Reduced food or water intake
- Weight loss
- Diarrhoea
- Dehydration
- Pale or sunken eyes
- Unusually docile or aggressive when handled
- Vocalisation

Based on: Laboratory Animal Services Clinical Score Sheet and NHMRC Guidelines to promote the wellbeing of animals used for scientific purposes: The assessment and alleviation of pain and distress in research animals (2008). http://www.nhmrc.gov.au/health_ethics/animal/issues.htm#b

3.3.3 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.

During the acclimatisation period, researchers and animal carers should familiarise themselves with the 'normal' range of behaviours of a particular animal or group of animals. 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.

Source: NHMRC *Guidelines to promote the wellbeing of animals used for scientific purposes: The assessment and alleviation of pain and distress in research animals. (2008)*

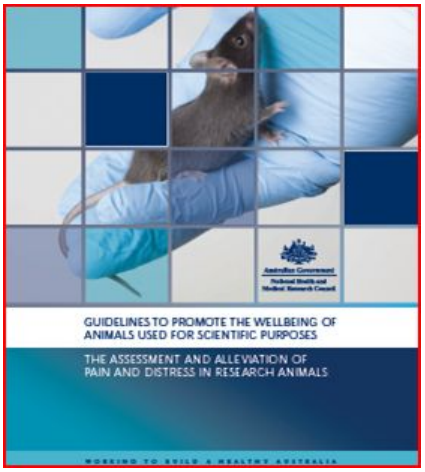
3.4 Checklist for promoting animal wellbeing

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 (eg 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	
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 or analgesia	
Provide palliative treatment for pain and distress, eg post-operative nursing, comfortable bedding, optimal environmental temperature and humidity, 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	
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 to the AEC	
Report adverse events promptly to the AEC	
Report annually on progress of the project	
Report at the completion of the project	
Report to the AEC on other occasions as required	

AEC = animal ethics committee; SOP = standard operating procedure

Source:

NHMRC Guidelines to promote the wellbeing of animals used for scientific purposes: The assessment and alleviation of pain and distress in research animals. (2008)



4 Obtaining University of Adelaide 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 Reduction, Replacement 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.

All University personnel who wish to use animals for teaching, research or experimentation must obtain ethical approval from the University of Adelaide AEC 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. All student projects must receive University of Adelaide ethical clearance.

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.

4.1 Who must apply?

- Staff employed by the University of Adelaide must apply to the University AEC for any acquisition, or scientific or teaching use of animals.
- Teaching staff of the University must apply for University of Adelaide AEC approval of University teaching classes that involve animal use.
- University affiliates supervising University of Adelaide research students must apply to the University AEC and **dual clearance** is required if work is conducted at another institution.
- Bodies or affiliates other than above proposing holding or use of animals on University premises will be considered on a case by case basis. Approval of the Deputy Vice-Chancellor & Vice-President Research (on advice from the General Counsel) may be required to access the services of the AEC.

Dual clearance
University personnel whose animals are to be located within other institutions must apply to the University's AEC as well as to the ethics committee of the other institution(s).

University degree candidates located within other institutions require ethical clearance by the University's AEC as well as the institutional committee at the place where research is conducted.

The University of Adelaide AEC online form is to be used for all applications.

Student research
In the case of a student project, the supervisor is to be the applicant with the student named as also involved. University degree candidates located at another institution require dual clearance (see above).

Undergraduate teaching projects

The application form is designed primarily in relation to research projects. It may not be entirely appropriate for a teaching submission but should be used as a guide to the details required for ethical consideration of the work. Additional procedures apply to applications involving use of animals for undergraduate teaching - refer to Use of animals in undergraduate teaching.

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** 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 time each animal will be used; and
-how the attainment of the educational objectives will be assessed.

In addressing (4) 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. disection skill, anatomical knowledge, etc.

4.1.1 Overseas proposals

University staff must notify the University AEC 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 2.2.45 and 2.2.46 of the Australian Code.

4.2 How do you apply?

All applications are to be submitted electronically using The University of Adelaide AEC online form. Information, helpful writing tips and links concerning the use of this form can be found on the University website at: http://www.adelaide.edu.au/ethics/animal/guidelines/applications/

Applicants should first read the 'Animal ethics introduction' and 'Guidelines for seeking ethics approval and clearance requirements' and Laboratory Animal Services Policies and Procedures'

Access to the AEC Online form is controlled using the same username and password as your University email account. If you do not have a current password please follow the advice given at the website (**extract below).

5 The Application Process

5.1 Writing the Application

5.1.1 Writing the Application Proposal information

Written proposals should place before the AEC sufficient information to satisfy the AEC that the proposed use of animals is justified and complies with the principles of Replacement, Reduction and Refinement.

Written proposals should be presented in a form that allows the AEC to easily assess information provided. They should be written in a **PLAIN ENGLISH** manner that can be understood by all members of the AEC and must identify the impact of all sections of the proposal on animals used and means by which the impact will be minimised.

The Application form seeks information from applicants in order to meet the requirements of the Australian code of practice for the care and use of animals for scientific purposes 7th Edition 2004 (refer to Proposals-general (2.2.15-2.2.16)). Applicants should be familiar with the contents of the Code before completing the application form.

The Animal Welfare Officer (AWO), Dr Denise Noonan (830 34107), will be pleased to provide veterinary advice and technical assistance. Applicants for ethical approval may find it useful to contact the AWO in the planning stages prior to submission to the AEC.

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.

5.1.2 Provision of information on genetically modified animals

The Investigator will provide information to the AEC on the phenotype of genetically modified animals which are proposed to be used in a research or teaching project. The information is to be provided by submitting a completed "*Phenotype Report for Genetically Modified Animals*" when applying to the AEC for approval to import, breed, hold or use genetically modified animals.

5.1.3 Completing and Submitting the Application

Before you begin *(**extracts from the University website)*

Applicants should first read the Animal ethics introduction, Guidelines for seeking ethics approval and clearance requirements, The AEC Animal User's Handbook and Laboratory animal services policies and procedures.

All applications are to be submitted electronically using the online form at the animal ethics website. Access to the online form is controlled using the same username and password as your University email account. University staff are automatically provided with an entry in the University directory (known as LDAP). For security and privacy reasons it will be necessary for external applicants, 'visitors', to apply to Information Technology Services (ITS) for a user name and password to the University directory. Further information is at the IT Services website: Accounts and passwords.

Steps to completing the online form

The form consists of a series of pages each containing one or more questions. Each page is validated as you progress through the form. You can cut and paste text and move easily throughout, and guideline/help information is included at each step.

As primary investigator you must commence the application. You may nominate a first co-researcher to have equal access to the application. Both of you will require entries in the University directory. You produce a print out of the application - this will not resemble the entry pages, it is designed to provide clear and concise, species specific detail for AEC members. You lodge electronically noting electronic lodgement does not constitute a formal ethics application.

Declaration and endorsement - All persons named as involved in the project are to sign the printed version of the application form. The Head of School/Department is to countersign the printed version before submission, and to assume responsibility for ensuring that the procedures are carried out in accordance with final ethical approval.

You must submit a fully signed copy of the printed application, as submitted electronically, and 14 photocopies to the AEC Secretary, Research Branch, Level 7, 115 Grenfell Street, The University of Adelaide, SA 5005.

The University's Animal Ethics Committee is formed into two faculty-based Committees, Science and Medical - each meet 8 times a year to consider all applications for ethical approval including variation to existing clearances. There are **separate submission deadlines** for the two AECs. Applications must be received by the Secretary by 12 noon on the deadline date if they are to be included on the Agenda for the subsequent AEC meeting.

Your online application(s) can be subsequently viewed and selected, by yourself or the first co-researcher, and used as the basis for further applications.

All applications are to be submitted on the University of Adelaide AEC online form, including when dual clearance is required.

5.1.4 Tips for Writing a Good Application

Please write in a **PLAIN ENGLISH** manner that can be understood by all members of the AEC especially non-scientists – use language that avoids scientific and clinical terminology – provide definition of terms if necessary. This point cannot be over emphasised! If members of the AEC can't understand what you have written your application cannot be approved.

- **Missing information results in delays in decision-making**. Please ensure that full information is provided in the application. Attach separate pages if necessary.

- The key to writing a Good Application is to **provide all the information the AEC needs to make a decision**. The AEC is required to ask, and consider, all the points raised in Section 2.2.16 of the Australian Code, and the Application form reflects this.

- **Lay Description and Lay Summary questions** - What is the difference?
    - Lay Description of the scientific or education aims of the project and the expected benefits – use of plain English language that avoids scientific and clinical terminology is required.
    - Short Lay Summary of the project suitable for publication – limited text to give brief overview of what is required.

- Please give **common name** of animal species as well as the **scientific name**.

- When writing details of Procedures, keep in mind what the AEC members will need to know:
    - What happens to the animals?
    - What is the impact of the procedures, treatments etc upon the animals?

- It is necessary to list all drugs to be administered including the volume, dose rate and route:
    - use generic names at all times; brand names may also be included
    - doses may be specified giving an expected range (eg. 2-8 mg/kg daily)
    - special diets, and dietary additives must be specified and quantified.

- The AEC members find Flow Charts to be helpful in understanding what happens to each individual animal, or group of animals, step-by-step from beginning to end.

- AEC members expect that Clinical Record Sheets and Scientific Observation Sheets will be **tailored** to the particulars of the Project. If they are not and amendment is required, then this will result in delay. Example Clinical Records Sheets are available from the animal ethics, Animal Welfare Officer and Laboratory Animal Services websites.

- Some species of animal are more social than others and the AEC is advised that isolation of such animals causes stress. On that basis the AEC's expectation is that sheep and rats (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.

5.1.5 Submission deadlines

Applications are made online and copies must reach the AEC Secretary by **12 noon on the Friday** deadline date if they are to be included on the Agenda for the subsequent AEC meeting. Late applications will be held till the next round of business.

5.2 Consideration of Applications and Notification

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

- The application is approved, or
- The AEC approves the application subject to consideration of a satisfactory response from the investigators to queries or concerns raised by the AEC members, or
- The AEC asks for resubmission of the application, or
- The application is rejected for ethical reasons.

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 Sections 2.2.20 – 2.2.23 of the Australian Code of Practice and are usually made on the basis of consensus.

- Decisions must be made as promptly as possible
- Applicants are informed of decisions in writing

Scientific or teaching activities involving the use of animals must not start before receiving written approval and an animal ethics approval number from the AEC Secretary. When the animal use project commences, the AEC Secretary is to be advised.

- 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.
- 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. The AEC's Executive may only approve minor modification to a project when the case is urgent.

If an Applicant disagrees with a decision

If a member of the AEC or a researcher has any grievance about the operation of the Committee, they should discuss this, in confidence, with the Convenor of that AEC. If the grievance cannot be resolved they may then take their concerns to one of the representatives of the Animal Ethics Policy Committee (AEC Secretary or Animal Welfare Officer), or the Deputy Vice-Chancellor Research.

The Australian Code states

> *2.2.14 Irreconcilable differences between the AEC and an investigator or teacher must be referred to the governing body of the institution* for review of the due process. The ultimate decision of the AEC after such review must not be overridden.* * the Animal Ethics Policy Committee performs this role on behalf of the University

5.3 Requesting Amendments to Approved Projects

Guidelines regarding application for minor amendment to an approved project involving animals

It is necessary to apply to the AEC for extension of approval if the project is to continue for a longer period of **time**, if **additional animals** are required or if any change to the **procedure** is proposed. All applications for amendment are considered at scheduled AEC meetings.

The Executive of the AEC may consider and approve a minor modification to a project out of session for review at the next AEC meeting. It has been agreed that this will not be normal practice and will only happen when there is a strong argument for urgency or it has a direct animal welfare impact. *The case for urgency must be provided in writing to support the request.*

The Application for a Minor Amendment Form is found at www.adelaide.edu.au/ethics/animal/guidelines/amendments. It should be submitted by (1) email to aec@adelaide.edu.au and (2) posting with 14 copies to the AEC Secretary, Research Branch, The University of Adelaide, 115 Grenfell St, Adelaide, SA 5005.
Use of this form is limited to changes that fit within the following criteria:

Time extension: The maximum period for time extension is 12 months**.** *Do not allow the approval period to expire if work is to continue. If work has not begun and expiry is within 6 months, a time extension may be considered, effective from the original expiry date.*

Increase in animal numbers: The increase in animal numbers is no more than 30% of the original approval. *If more than 30% of the original number of animals is required, a new application must be completed.*

Change in species: If the impact on the proposed new species is consistent with the species identified in the original application.

Change in procedure*:* Minor modifications to procedures/methodology, including changes in drug treatments. A new application must be submitted when the scientific question is different to the original approved application. *An amendment application does not involve change in the main aims of the project or the asking of a new scientific question.*

Notification: Please apply to the AEC using the Application for Minor Amendment Form when any of the following changes are proposed so that they may be approved on behalf of the AEC.

- adding new staff and students – providing credentials, Empl ID number and contact details
- change of location of research
- change of source of animals
- refinement in techniques that are beneficial to animal welfare having a lesser impact than the original protocol
- refinement in husbandry and animal housing that is beneficial to the animal

6 Conducting the Project

6.1 Supervising students and inexperienced personnel

Students and inexperienced personnel working with animals must have:

- close, competent supervision;
- been instructed in the appropriate methods of handling and caring for animals;
- demonstrated that they are capable of performing the necessary tasks with care and competence;
- adequate resources available.

Supervisors must ensure that before using animals, students receive instruction in the ethical and legal responsibilities as well as in the appropriate methods for animal care and use.

Institutions need to ensure that research trainees are aware of, and comply with, government and institutional guidelines for ethical requirements for research using animals.

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

6.2 Investigator's Responsibilities for Routine Monitoring of their animals - Minimum of Daily Monitoring of all Animals

It is an expectation of the University of Adelaide AEC and the Australian Code (Section 2.2.26) that animals will be monitored by the chief investigator on a daily basis, except in those circumstances which makes it impossible to do so and is agreed to by the AEC.

The AEC expects that all animals are monitored on a daily basis to ensure that their basic requirements of water and food are provided and that they are in good health.

6.3 Role of Animal House Staff in the Monitoring Process of Animals Under Experimentation

Role of the LAS Animal Care Staff in animal monitoring to be negotiated may include

- Daily attendance to animals
    - clean caging and environment
    - provide food and water
    - health check
- Weekly monitoring of food and water intake
- Immediately notify unwell animals to investigator
- Seek veterinary treatment as requested or required
- Act on requests from research investigators
- Consider requests for technical support

Australian Code of Practice

4.5.3 The person-in-charge should be knowledgeable about signs of pain, distress and illness specific to each species kept and ensure that the wellbeing of all animals is regularly assessed. ***After animals are allocated to a project, investigators and teachers have primary responsibility for ensuring adequate monitoring of animal wellbeing****.*

- The direct and ultimate responsibility for monitoring animals under experimentation lies with the Chief Investigator. *[Code 1.4, 2.2.26, 3.1.1]*

- When constructing a research proposal thought must be given to who will be monitoring the animals under experimentation and that this is being performed adequately. *[Code 3.2.1 (vi), (xiii), 3.1.2, 3.3.35, 3.3.5]*
  This person must know the signs they are supposed to be monitoring. *[Code 3.3.1, 3.3.2, 3.3.3]*

- If animal house staff are asked to take any special responsibilities for monitoring animals in addition to routine husbandry, this must become part of the research proposal.

- The LAS Facility Manager and the Investigator should have a formal arrangement for animals under experimentation as the Facility Manager is not automatically part of the Research Group and relinquishes primary responsibility for animal wellbeing once the animals are allocated to a Research Project.

Consulting the Animal House 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. There needs to be room available that is suitable for the species. *[Code 1.15, 1.16, 3.2.1 (v), (ix)*

- The experimental procedures to the animals, expected effects and signs to be monitored

- Safety aspects which may be pertinent to Animal House staff eg injections of human tissue or carcinogens. *[3.3.5, 3.3.50]*

- 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. *[Code 3.1.7, 3.3.36]*

- If the animal house staff call regarding animals in pain or distress a prompt response is required. If none is taken the animal house manger will take action. Alleviation of such pain and distress must take precedence over finishing a study. *[Code 1.18, 3.3.2 (iv), 3.3.7, 3.3.36]*

- If personnel named on the animals ethics application (including amendments) are not contactable then the animal house staff must be have instructions of what to do ie pain relief, biological sampling and endpoint. The Animal House manager has the authority to kill animals in pain and distress when investigators on the project are not contactable.

- Notify animal house manager at end of project if animals need to be killed or returned to normal husbandry conditions (as per AEC approval). *[Code 3.2.1 (xvi), 3.3.17]*

6.4 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 of Practice for the Care and Use of Animals for Scientific Purposes 2004*.

6.4.1. Animal Ethics Committee (AEC) Approval and Monitoring of Animal Facilities & Laboratories

6.4.1.1 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.

6.4.1.2 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.

6.4.2 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 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

*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

6.4.3 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 Australian Code of Practice (Section 4) 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 adequate 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, performance and appearance.

6.5 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.

6.5.1 Record Keeping requirements endorsed by the State Government regulator (DEH)

Guidelines for record keeping by investigators

- Section 2.2.27 of the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes (the Code) indicates that the records maintained by investigators and animal facility managers “will enable the AEC to verify that the welfare of animals has been monitored as agreed. Such records also enable a critical investigation of the cause(s) of unexpected adverse events as a basis for future prevention strategies”.

- Section 3.1.9 of the Code stipulates that "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 well being 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".

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. See the Code for more detail.

1. 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

2. 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 (eg, records of daily monitoring, completed checklists).
   - Place and date of procedure
   - Identification of part of approved project conducted on each date (eg weighing, administration of agents, surgery, killing)
   - Details of procedure being conducted (eg, 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.

3. 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.

7 Reporting progress and problems

7.1 Annual Report

Annual reporting is necessary on **all** projects approved by the University of Adelaide AEC. All approvals are conditional on provision of a statistics report and an annual progress report to the AEC in accordance with the Code. Both reports must be provided by 31 January each year

Statistics
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 (a "Word" document) and notes on completion are available at the AEC website.

Progress report
The continuation of all projects is subject to submission of **annual** reports to the AEC *(ref Code 2.2.37)* that advise on:

1. what progress has been achieved
2. any problems that may have interfered with progress of the project
3. how many animals have been used
4. whether the wellbeing of the animals is consistent with that anticipated in the proposal
5. whether any changes are envisaged
6. whether the project is meeting its aims

7.2 Phenotype Report

The Investigator will report in a timely manner to the Animal Ethics Committee (AEC) 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.

7.3 Adverse Event Reporting

All unexpected animal deaths or any adverse or unforeseen circumstances that may impact on animal wellbeing must be reported promptly to the AEC *(ref Code 2.2.28)* for necessary action and to assist in development of institutional prevention strategies.

Please contact the Animal Welfare Officer (phone 8303 4107) and provide a written report to the AEC Secretary giving:

- a brief summary of the project and description of animal use/procedures
- details of the adverse event including date(s)
- species and numbers involved
- action taken
- cause.

8 Reporting outcomes

Completion report

For projects that have been **completed or discontinued**, a report should be submitted to the AEC *(ref Code 2.2.39)* as soon as practicable. This report should advise on:

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

9 University Policies and Guidelines

9.1 Conscientious objection to use of animals in undergraduate teaching and assessment

1. The General Principles for the Care and Use of Animals for Scientific Purposes set out in Section 1 of the *Australian Code of Practice for the Care and Use of animals for Scientific Purposes* should be prominently displayed and ethical guidelines information such as the ANZCCART publication *Guidelines for students using animals or animal tissues for educational purposes* is to be provided to students.

2. 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 of Practice for the Care and Use of animals for Scientific Purposes* and relevant Commonwealth and State or Territory legislation.

3. 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.

4. A conscientious belief is:
   - An individual's inward conviction of what is ethically right or wrong.
   - Is held genuinely, after careful consideration of the subject.
   - 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 (eg 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.

5. It is the responsibility of the student to identify a conscientious difficulty with 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.

6. 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.

7. 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.

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

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

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

11. 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.

12. 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:

    - 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.
    - Whether it is a required or elective unit of study.
    - Whether there is time to put in place alternative arrangements.
    - Whether students would be disadvantaged in the quality of education.
    - Cost
    - Whether it would result in the University breaching its equal opportunity obligations.

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

14. 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.

15. 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.

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

17. 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.

9.2 Policies and guidelines available at the AEC website:

Animal Procedure Related

- Policy on metabolic crate use for sheep (pdf 82kB)
- Policy on the use of post-operative analgesia in experimental animals (pdf 137kB)

Ethics Related

- Use of animals in undergraduate teaching (pdf 115kB)

Animal Husbandry Related

- Laboratory Animal Services Policies and Procedures
- Rodent breeding and weaning policy (pdf 189kB)
- Methods of Mouse Identification

This Handbook provides essential information for all who are involved in University research and teaching involving animals. The University expects new applicants in particular to consult this Handbook as well as the animal ethics website prior to submitting proposals for ethical clearance. Further clarification concerning policies, guidelines and definitions can be sought from the AEC Secretary, Research Ethics and Compliance Unit, Research Branch,The University of Adelaide. http://www.adelaide.edu.au/ethics/