



Guidelines for the ethical use of animals in research and teaching

If you would like to receive this information/publication in an accessible format (such as large print or audio) please call the Customer Service Centre on 136 186, TTY 1800 122 969, or email customer.service@dpi.vic.gov.au.

Published by the Department of Primary Industries
Biosecurity Victoria, April 2011.

© The State of Victoria 2011.

This publication is copyright. No part may be reproduced by any process except in accordance with the provisions of the *Copyright Act 1968*.

Authorised by the Department of Primary Industries
1 Spring Street, Melbourne 3000.

Disclaimer

This publication may be of assistance to you but the State of Victoria and its employees do not guarantee that the publication is without flaw of any kind or is wholly appropriate for your particular purposes and therefore disclaims all liability for any error, loss or other consequence which may arise from you relying on any information in this publication.

**For more information about DPI go to www.dpi.vic.gov.au
or phone the Customer Service Centre on 136 186.**

Contents

Introduction	3
Glossary of Terms	4
Acronyms commonly encountered	7
Animal Ethics Note: 1.1 - Animal welfare for animals in research and teaching	
Animal Ethics Note: 1.2 - Animal Ethics Committees	
Animal Ethics Note: 2.1 - Responsibilities of institutions towards ensuring the welfare of animals in research and teaching	
Animal Ethics Note: 2.2 - Licensing of scientific premises	
Animal Ethics Note: 2.3 - Expression of interest proforma	
Animal Ethics Note: 3.1 - Animal Ethics Committees - General membership information	
Appendix 1 Responsibilities of institutions	
Appendix 2 Chairperson responsibilities	
Appendix 3 Category A member - Veterinarian	
Appendix 4 Category B member - Scientist	
Appendix 5 Category C member - Animal welfarist	
Appendix 6 Category D member - Lay member	
Appendix 7 Category E member - Animal care staff	
Animal Ethics Note: 3.2 - Animal Ethics Committees - Guidelines for the conduct of AECs	
Animal Ethics Note: 3.3 - Animal Ethics Committee - Project proposal assessment guide	
Animal Ethics Note: 3.4 - AEC guidelines for management of adverse incidents	
Animal Ethics Note: 3.5 - AEC guidelines for site inspections	
Animal Ethics Note: 3.6 - Applications involving multiple AECs	
Animal Ethics Note: 3.7 - Post-approval monitoring	
Animal Ethics Note: 4.1 - The Three R's	
Animal Ethics Note: 4.2 - Understanding and interpreting a research plan	
Animal Ethics Note: 4.3 - Interpreting experimental design and statistical analysis	
Animal Ethics Note: 4.4 - Guidelines for the euthanasia of animals	
Animal Ethics Note: 4.5 - Planning the use of animals for research or teaching	
Animal Ethics Note: 4.6 - Guidelines for investigator record keeping	
Animal Ethics Note: 4.7 - Contingency planning	
Animal Ethics Note: 5.1 - Effective communication skills	
Animal Ethics Note: 5.2 - Dispute resolution	
Useful resources	





Introduction

This Guide is intended to provide you with the legislative background to the ethical use of animals in research and teaching and to inform you of some of the support and resources available from the Bureau of Animal Welfare.

The Bureau of Animal Welfare is part of the Victorian Department of Primary Industries, and is responsible for ensuring that animal use in science and teaching is compliant with the relevant legislation (the Prevention of Cruelty to Animals Act 1986).

This Guide contains information and resources important to your ability to carry out your responsibilities under the legislation. You should review this manual carefully, attend training regularly (see below) and ensure you are familiar with the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes (7th edition, 2004)

In addition to this manual, the Bureau of Animal Welfare provides a number of resources to aid AEC members, researchers, teachers, animal care staff and others:

- The Animals in Research and Teaching webpages (starting at www.dpi.vic.gov.au/animalwelfare/procedures) which include guidance on ethical and welfare decision making;
- Introductory AEC, Advanced AEC, Chairperson and Institution training seminars are held by the Bureau of Animal Welfare each year (completion of Advanced and Chairpersons training at least once every three years contributes to the requirement of Licensed Institutions to provide adequate training to AEC members);
- A biannual electronic newsletter;
- An industry forum -the AEC Advisory Committee;
- Financial support for independent (category C and D) AEC members to attend the Australian and New Zealand Council for the Care of Animals used in Research and Teaching (ANZCCART) annual conference; and
- Consultation and advice to AEC members, researchers, teachers, and others active in the area.
- Annual seminar of current topics for AEC members, researchers and teachers.

To protect your privacy, any personal information collected by us (Bureau of Animal Welfare) will be stored and used by the Bureau of Animal Welfare, Department of Primary Industries for the purposes of administering the Prevention of Cruelty to Animals Act 1986 (the Act). You have the right of access to this information by contacting the Department through the Bureau. This information may be disclosed to another government organisation for the purpose of administering or enforcing the Act or another relevant Act.

Should you require any further information and/or support please do not hesitate to contact the Bureau of Animal Welfare.



Glossary of Terms

(the) Australian Code

Refers to the Code of Practice for the Care and Use of Animals for Scientific Purposes (7th Edition, 2004) published by the Australian Government Publishing Service, Canberra, October 2004.

Breeding for Scientific Procedures

The breeding of certain animals in Victoria for use in Scientific Procedures must also be licensed. These animals are termed Specified Animals and are guinea pigs; rats, mice, rabbits other than rats, mice and rabbits bred in their native habitat; and non-human primates. Breeding of these animals for supply to other institutions for scientific procedures must be authorised by a Specified Animal Breeding Licence.

Death as an end-point and other regulated high impact procedures

“Death as an end-point” (DAEP) Scientific Procedures are rare, potentially highly intrusive procedures where the death of an animal is the measure for evaluating an activity, and where the animal will not be killed humanely prior its death.

Death as an endpoint procedures may only be carried out for the achievement of prescribed, highly beneficial outcomes, and only where the objective cannot be achieved by any other scientific means.

These procedures must be approved by the Minister for Agriculture, and any modifications to a previously approved DAEP project must also be submitted to the Minister for consideration.

It is an offence liable for prosecution for a person to carry out Scientific Procedures involving the eye of an animal to determine the irritancy of a chemical or biological agent, unless those procedures are done under terminal anaesthesia.

Laboratory Animals Code of Practice

Refers to the Victorian Code of Practice for the Housing and Care of Laboratory Mice, Rats, Guinea Pigs and Rabbits approved by Governor in Council on 12 October 2004 and published in the Victorian Government Gazette G51 on 16 December 2004, at pages 3419-3461.

Licence Nominee

The Licence Nominee is the person nominated by a licence applicant to be legally responsible for scientific procedures and any breeding of specified animals. The Licence Nominee is the first point of contact for the Bureau of Animal Welfare as the licensing authority, and will be corresponded with on all matters relating to the licence, such as breaches of licence conditions, licence audits, reporting of animal use, and Animal Ethics Committee composition and conduct. This person must hold a position in the licensed institution such that they are familiar with the work being conducted, yet senior enough to be able to effect change where necessary.



Not-for-profit organisation

A not-for-profit organisation is one defined by the Prevention of Cruelty to Animals Regulations 2008 as an organisation that

- is not established for the purposes of profit or gain; and
- has a primary purpose or objective that is operated not for profit or gain; and
- does not distribute any part of the profit or gain in the conduct of activities by the organisation to any entity; and
- has whole charitable, benevolent, philanthropic or recreational purposes; and
- is not a school or an educational institution; and
- is not a body which promotes or is funded by horse racing or greyhound racing.

Pound Animals Code of Practice

Refers to the Victorian Code of Practice for the Use of Animals from Municipal Pounds in Scientific Procedures approved by the Governor in Council on 19 April 1988 and published in the Victorian Government Gazette G47 on 7 December 1988 at pages 3549-3660.

Scientific Premises

A Scientific Premises is a premises ordinarily used for scientific procedures (see below).

The legal occupier of premises ordinarily used for scientific procedures must apply for a licence from the Department of Primary Industries (DPI). The DPI must be notified in writing of other locations where scientific procedures are conducted (fieldwork).

Scientific Procedures

Scientific Procedures include the use of animals for:

- acquiring, demonstrating or developing scientific knowledge
- acquiring, demonstrating, developing or exercising scientific techniques
- developing or testing the use, hazards, safety, or efficiency of vaccines, substances, drugs, materials or appliances intended for use in connection with human beings or animals.

Scientific Procedures Fieldwork Licence

A scientific procedures fieldwork licence (SPFL) authorises the use of premises or locations that are not to be ordinarily used for Scientific Procedures (i.e. that are not Scientific Premises). Examples might include the use of production animals on farms, the intermittent use of Scientific Premises licensed under a Scientific Procedures Premises Licence held by another institution, or the use of animals in the wild.

No premises or locations are listed on a SPFL, and this work is termed "Fieldwork". Procedures, personnel, and location(s) must be approved by the nominated Animal Ethics Committee and standards appropriate to the level of use must be maintained. The licence holder must ensure that the Bureau of Animal Welfare is notified of the fieldwork after approval by the AEC and prior to commencement of any Scientific Procedures.

Scientific Procedures Premises Licence

A scientific procedures premises licence (SPPL) authorises the licence holder to use animals for research, teaching or testing in Victoria, at the sites nominated on their licence, under the approval of a nominated Animal Ethics Committee.



Specified Animal

Specified Animals include the following animal species:

- guinea pigs,
- rats, mice and rabbits not bred in their native habitat, and
- non-human primates.

Specified Animal Breeding Licence

A Specified Animal Breeding Licence authorises the breeding of Specified Animals for supply to other institutions for use in Scientific Procedures. Practices which may involve the medical or physical treatment of Specified Animals or the extraction or derivation of tissues, materials or substances from their bodies may be authorised by the SABL (subject to AEC approval), only if they are necessary for the breeding, sale, and delivery of the animals.

The Act

Refers to the *Prevention of Cruelty to Animals Act 1986*.

The Regulations

Refers to the *Prevention of Cruelty to Animals Regulations 2008*.



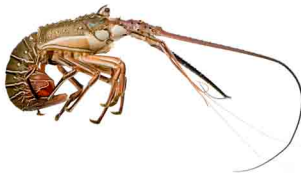
Acronyms commonly encountered

ACUC	Animal Care and Use Committee (NSW)
AEC	Animal Ethics Committee
AEEC	Animal Experimentation Ethics Committee
ANZCCART	Australia and New Zealand Council for the Care of Animals in Research and Teaching
ANZFAS	Australian and New Zealand Federation of Animal Societies
ANZLAA	Australia and New Zealand Laboratory Animal Association
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARC	Australian Research Council
ARRP	Animal Research Review Panel (NSW)
AVA	Australian Veterinary Association
AVAWE	Australian Veterinary Association Welfare Ethics (special interest group)
AWAC	Animal Welfare Advisory Committee (Vic)
AWC	Animal Welfare Committee (of NHMRC)
AWIC	Animal Welfare Information Centre (US)
AWSC	Animal Welfare Science Centre
AWWG	Animal Welfare Working Group (Australia)
BVA	British Veterinary Association
CAAT	Centre for Alternatives to Animal Testing (USA)
CCAC	Canadian Council on Animal Care
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DAFF	Department for Agriculture Fisheries and Forestry (Australian Government)
DPI	Department Primary Industries (Vic)
ECVAM	European centre for the Validation of Alternative Methods
FRAME	Fund for the Replacement of Animals in Medical Experiments
IACUC	Institutional Animal Care and Use Committee (USA, Singapore)



ICLAS	International Council for Laboratory Animal Science
NCCAW	National Consultative Committee on Animal Welfare (Australia)
NHMRC	National Health and Medical Research Council
PIMC	Primary Industries Ministerial Committee
PISC	Primary Industries Standing Committee
RSPCA	Royal Society for the Prevention of Cruelty to Animals (Australia)
UA	Universities Australia
UFAW	University Federation for Animal Welfare (UK)





Animal welfare

for animals in research and teaching

Animal Ethics Note: 1.1 September 2010

Background:

In 1989 an Australian Senate Select Committee was established to review the welfare of animals used for research or teaching purposes. The Committee reviewed the public debate across Australia about the use of animals in research and teaching. The Committee's final report concluded that, "there is no doubt that the majority of the population supports biomedical research involving the use of animals, provided that effective controls are operating to keep the number of the animals and the level of pain and distress to a minimum. Until such time as the majority of Australians are persuaded that animal experimentation should not be carried out, and that is translated into legislative form, experimenters have a right to use animals within the regulations and guidelines imposed on such use by government and the scientific community".

In addition, the Committee's final report made several recommendations about the need to strike a balance between the benefits and the costs of animal experimentation. One of those recommendations included the development of Animal Ethics Committees (AECs).

In Victoria, the use of animals for research and teaching is regulated by Part 3 of the *Prevention of Cruelty to Animals Act 1986* and Part 4 of the *Prevention of Cruelty to Animals Regulations 2008*. Under the Act, the conduct of Scientific Procedures using animals in Victoria must be licensed by the Department of Primary Industries, and the Regulations prescribe the principles and guidelines set out in the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* (2004).

The Australian Code of Practice for the Care and Use of Animals for Scientific Purposes 7th Edition (2004):

The key to implementation of improved welfare of animals used for scientific research in Australia is the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* (2004) (the Australian Code).

The basic philosophy behind the Australian Code is that it is acceptable to use animals for scientific purposes provided that this use can be justified and that the principles of the Three R's are applied. The justification is decided through weighing the benefits of using the animals against the costs to the animals. It is this function of AECs that make them the key to humane animal use in research and teaching.

The Australian Code defines the functions and composition of AECs, and can be viewed or downloaded at www.dpi.vic.gov.au/animalwelfare/scientificprocedures.

What is an Animal Ethics Committee?

The mechanism used to strike the balance between benefits and costs of the use of animals for experimentation is the Animal Ethics Committee (AEC). An AEC assesses applications to use animals for scientific purposes and teaching by weighing the scientific or educational value of that use against the potential effects on the welfare of the animals.

The primary responsibility of AECs is to ensure that all care and use of animals is conducted in compliance with the Australian Code. AECs apply a set of principles that govern the ethical conduct of work involving the use of animals for scientific purposes. The role of the AEC is to:

- ensure that the use of animals is justified,
- provide for the welfare of those animals and
- incorporate the principles of Replacement, Reduction and Refinement (Three R's)



AECs fulfil their mandate by:

1. considering the ethical implications of a project,
2. assessing approved projects for compliance with the legislation and the codes of practice,
3. approving Standard Operating Procedures utilised for projects involving the use of animals,
4. monitoring animal housing and animal care, and
5. inspecting animal housing and care facilities.

In Victoria, all institutions involved in the use of animals for research and/or teaching purposes must obtain one or more licences from the Bureau of Animal Welfare, Department of Primary Industries Victoria. Both the institution that holds the licence and any project investigator are legally responsible for maintaining the welfare of animals in use or in their care.

Who is on an Animal Ethics Committee?

In accordance with the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes, an AEC must comprise at least four persons, one from each of the following categories:

Category A: Veterinary surgeon with experience relevant to the activities of the institution

Category B: Scientist or teacher with substantial recent experience in animal based research or teaching

Category C: a person with demonstrable commitment to, and established experience in, furthering the welfare of animals, who is not employed by or otherwise associated with the institution, and who is not involved in the care and use of animals for scientific purposes

Category D: Layperson who has never engaged in the use of animals for scientific purposes beyond their undergraduate education and who is independent of the institution

It is recommended, but is not mandatory, that a senior member of the animal care staff be a member of the AEC, known as a Category E member.

For more information about Animal Ethics Committees, refer to the Animal Ethics Note 2.1 “Animal Ethics Committees”.

What are the Three R’s?

The Three R’s form a framework for the assessment of the humaneness of animal use in research and teaching. Investigators are required by law to make sure that they minimise any pain or other harm they cause to the animals they use for research, teaching, and testing. The 3Rs Principle provides a framework for ensuring that animals are only used when necessary (Replacement), that no more animals are used than are required to achieve the objectives of the work (Reduction), and that if any noxiousness is caused during the work, it is kept as low as possible (Refinement).

For further information on the Three R’s, refer to Animal Ethics Note 4.1: “The Three R’s”.



Animal Ethics Committees

Animal Ethics Note: 1.2 September 2010

Background:

The Prevention of Cruelty to Animals Act 1986 (the Act) requires that institutions conducting research using animals comply with the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes/Teaching 2004 (the Code) and nominate an Animal Ethics Committee (AEC) to oversee the conduct of the institution's care and use of animals for scientific purposes.

Section 2 of the Code details the responsibilities of institutions and their AECs. This Animal Ethics Note provides basic information regarding the purpose and composition of AECs.

It is important that prospective and existing AEC members are familiar with Section 2 of the Code; specifically, the terms of reference, operating procedures, membership for AECs, assessment of proposals, and monitoring and reporting requirements.

The Role of an AEC:

The primary responsibility of AECs is to ensure that all care and use of animals is conducted in compliance with the Code. AECs apply a set of principles that govern the ethical conduct of people whose work involves the use of animals for scientific purposes. The role of the AEC is to ensure that the use of animals is justified, provides for the welfare of those animals and incorporates the principles of Replacement, Reduction and Refinement (the Three R's).

AEC Membership:

In accordance with the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes, an AEC must comprise at least four persons, one from each of the following categories:

Category A: Veterinary surgeon with experience relevant to the activities of the institution

Category B: Scientist or teacher with substantial recent experience in animal based research or teaching

Category C: a person with demonstrable commitment to, and established experience in, furthering the welfare of animals and who is independent of the institution

Category D: Layperson who has never engaged in animal experimentation beyond their under-graduate education and who is independent of the institution

It is recommended, but is not mandatory, that a senior member of the animal care staff be a member of the AEC, known as a Category E member. To further assist the AEC to function effectively, institutions may appoint as members, people with skills and background of value to the AEC. The AEC may also invite people (non-members) with specific expertise to provide advice as required.

The Code states that, if the Committee has more than four members, Categories C plus D should represent no less than one third of the members. Although few AEC decisions are made by majority decision, this stipulation protects AECs from perceptions of bias in favour of the institution or other parties. Members additional to the Categories A, B, C and D may be appointed as voting or non-voting members.



AEC members:

- consider and discuss the purpose and likely benefits of the proposed research;
- consider the need for the use of animals, the number requested, evidence of use and consideration of alternatives, and reasons for rejection of known alternatives;
- discuss the invasiveness of procedures, repetitive procedures, analgesia, anaesthesia, endpoints, euthanasia, and other matters which affect the day-to-day existence of the animals and consider refinements wherever possible;
- consider meeting procedures, executive power, decision-making procedures, dispute resolution procedures and so on, to ensure that all AEC activities are fair and reasonable;
- ensure that scientific details are presented and explained in a manner which is understandable to lay members of the AEC;
- regularly inspect the animal holding and laboratory areas, and examine and advise on caging/housing, feeding rosters, monitoring rosters and records, bedding, lighting, environmental enrichment and other aspects of animal care;
- consider annual and final research reports;
- finally, consider whether proposals are justified weighing the scientific or educational value of the study against the potential effects on the welfare of animals.

The ethics of using animals for research and teaching

The ethics of the use of animals for research and teaching is an area of which all AEC members need to have some knowledge, so that they can explain their own point of view, and appreciate the opinions of others.

The AEC must appraise an application with regard to the three Rs of Replacement, Reduction and Refinement (as required by the Code). It should evaluate the animal husbandry and housing, as well as the experience of the scientific and technical staff and students involved.

Any animal pain or distress that may result must be clearly stated in a proposal and the AEC must consider how this is to be monitored and alleviated if not prevented. This includes the application of humane end points, the appropriateness of the method of euthanasia (if required) and the competence of the staff to perform it humanely.

The ethical judgements required in the assessment of a project can be difficult to make. Ethicists have developed a number of techniques to resolve ethical issues. ANZCCART describes one of these techniques, the Harm-Benefit Analysis or the cost-benefit analysis. For further information please visit <http://www.adelaide.edu.au/ANZCCART>.





Responsibilities of institutions

towards ensuring the welfare of animals in research and teaching

Animal Ethics Note: 2.1 September 2010

Introduction:

Institutions that use animals for scientific purposes (research and/or teaching) must implement processes that ensure the governing body of the institution or its delegate (known as the **Institution Representative** or **Licence Nominee**) complies with the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes (2004)* and the *Prevention of Cruelty Act Victoria (1984)*.

Responsibilities under the Code:

At minimum the Institution or its representative must:

- (i) nominate an AEC, directly responsible to the governing body of the institution or its delegate, to manage project applications falling under each of their licences;
- (ii) ensure, through the AEC, that all scientific and teaching activities involving the use of animals comply with relevant legislation and the Code;
- (iii) ensure that investigators and teachers are aware of their responsibilities under the Code, by the provision of educational programs, continuing training and workshops;
- (iv) respond promptly and effectively to recommendations from the AEC to ensure that all care and use of animals for scientific purposes within the institution remains in accordance with the Code;
- (v) address concerns raised by the AEC regarding non-compliance with the Code which may include disciplinary action upon advice of the AEC. The institution and the AEC should prepare written procedures, which are agreed to by the institution to deal with non-compliance and any grievance related to the AEC process. **The written procedures must clearly define the reporting mechanisms and the responsibilities of all parties to ensure fair and effective processes;**
- (vi) seek comment from the AEC on all matters that may affect the welfare of animals used for scientific purposes by the institution, including the building or modification of animal facilities;
- (vii) ensure that the AEC approves guidelines for animal care and use within the institution and that these are implemented, including those which ensure that emergencies, such as fire and power failure, are detected promptly and dealt with effectively;
- (viii) provide the AEC with the resources required to fulfil its terms of reference and operational requirements. This includes provision of resources for orientation and education of AEC members, administrative assistance and, where appropriate, the reimbursement of out-of-pocket expenses and/or payment of an allowance to AEC members;
- (ix) conduct an annual review of the operation of the AEC, including an assessment of the AEC's Annual Report and a meeting with the AEC chairperson (see [Annual AEC Self-Audit](#), available from the Bureau of Animal Welfare);
- (x) provide all relevant personnel including AEC members with details of the institution's policy on the care and use of animals, confidentiality, Freedom of Information legislation, legal requirements, privacy policy and commercial considerations;
- (xi) establish mechanisms to respond to enquiries or complaints concerning the use of animals within the institution and ensuring that personnel and students may voice concerns without jeopardising their employment, careers or coursework;



- (xii) establish and make known procedures for the fair resolution of disagreements between AEC members, between the AEC and investigators or teachers, or between the AEC and the institution
- (xiii) provide personnel and AEC members with information on potential disease hazards and other Occupational Health and Safety (OH&S) issues associated with the care and use of animals;
- (xiv) ensure that there are adequate numbers of appropriately trained and skilled personnel to care for the animals; and
- (xv) ensure that appropriate veterinary services are available and that there is access to diagnostic services.

Licence Nominees/Institution Representatives:

To conduct research or teaching using animals the Code requires institutions to obtain one or more **licences** from the Bureau of Animal Welfare. For each licence, an Institution must nominate a senior staff member to take responsibility for that licence. As a result, the licence nominee (sometimes referred to as the Institution Representative) is legally responsible for all research carried out under their given licence on behalf of the institution.

Therefore, it is essential that the Licence Nominee is aware of the terms of reference and operating procedures of the AEC assessing projects being carried out under their licence, and that the nominee maintains frequent communication with the chairperson (and Executive Officer) of their AEC to ensure that all use of animals under their licence is conducted in accordance with the Act and the Code.

Responsibilities of Licence Nominees/Institution Representatives:

The **key responsibility** of the Licence Nominee is to **ensure that the Institution is fulfilling all its responsibilities under the Act and the Code.**

In particular, the following responsibilities should form a major part of the Licence Nominees interactions with the AEC:

- respond promptly and effectively to recommendations from the AEC to ensure that all care and use of animals for scientific purposes within the institution remains in accordance with the Code;
- address concerns raised by the AEC regarding non-compliance with the Code which may include disciplinary action upon advice of the AEC;
- seek comment from the AEC on all matters that may affect the welfare of animals used for scientific purposes by the institution, including the building or modification of animal facilities;
- ensure that the AEC approves guidelines for animal care and use within the institution and that these are implemented, including those which ensure that emergencies, such as fire and power failure, are detected promptly and dealt with effectively;
- provide the AEC with the resources required to fulfil its terms of reference and operational requirements
- **conduct an annual review of the operation of the AEC, including an assessment of the AEC's Annual Report and a meeting with the AEC chairperson (see Annual AEC Self-Audit);**



AEC Executive Officers/AEC Secretaries:

Institutions may find the need to appoint one or more AEC Executive Officers to assist the Chairperson to manage the administrative aspects of AEC functioning.

Responsibilities of Executive Officers/AEC Secretaries:

The main responsibility of an AEC Executive Officer is to ensure that all applications to the AEC are clearly expressed and contain all the main relevant information. This will assist efficiency and well-focused decision making.

In addition, an AEC Executive Officer may:

- liaise with the AEC Chairperson and members to determine appropriate meeting dates and corresponding project application deadlines;
- liaise with scientists and teachers submitting application regarding incomplete or incorrect applications and outcomes of project application assessments;
- timetable facilities inspections and meetings with Institution Representatives and Licence Nominees;
- recording, collating and distribution of meeting Agendas, Minutes and Reports;
- manage correspondence with the Bureau of Animal Welfare.





Licensing of scientific premises

Animal Ethics Note: 2.2 September 2010

Introduction:

The *Prevention of Cruelty Act Victoria 1984* (the Act) requires that the use of animals for Scientific Procedures be conducted under a **Scientific Procedures Licence**. This License is issued and administered by the Department of Primary Industries (DPI), Bureau of Animal Welfare as the licensing authority.

What is a Scientific Procedure?

Scientific Procedures include the use of animals for:

- acquiring, demonstrating or developing scientific knowledge
- acquiring, demonstrating, developing or exercising scientific techniques
- developing or testing the use, hazards, safety, or efficiency of vaccines, substances, drugs, materials or appliances intended for use in connection with human beings or animals.
- *Production of biological products* must be licensed if those products are for use in research or teaching, or if the techniques used are considered to be sufficiently pioneering.
- Breeding of a new strain or hybrid of a genetically modified animal is also considered to be a Scientific Procedure and must be conducted under the auspices of a Scientific Procedures licence.

What types of animals must be covered by a licence?

Use of the following animal types in Scientific Procedures must be licensed:

- all fish and amphibians
- mammals, birds and reptiles above the mid-point in gestation
- adult decapod crustaceans
- adult cephalopods.

Breeding for Scientific Procedures

The breeding of certain animals in Victoria for use in Scientific Procedures must also be licensed. These animals are termed Specified Animals and are:

- guinea pigs;
- rats, mice, and rabbits that are not bred in their native habitat; and
- non-human primates.

Breeding of these animals for supply to other institutions must be authorised by a Specified Animal Breeding Licence.

Excluded activities

Animal uses that do not require licensing for Scientific Procedures are:

- the treatment of an animal for the purpose of promoting its health or welfare by or in accordance with the instructions of a veterinary practitioner ;
- the conduct of animal husbandry carried out in accordance with a Code of Practice and;
- the collection, taking, banding and marking of wildlife. **The use of microchips, and tracking, data storage, and telemetry devices, however, must be licensed.**



What is a Scientific Procedures Licence?

There are two main types of Licences:

- a Scientific Procedures Premises Licence (SPPL)
- a Scientific Procedures Fieldwork Licence (SPFL)

The type of Licence required depends on the type and location of the research to be conducted.

All fields of science are covered by the licensing requirements, including but not limited to medical, dental, veterinary, agricultural, behavioural, ecological, pest management and biological sciences. All sectors operating in Victoria must comply, including private company, government, university, hospital, research institute, TAFE, school, volunteer organisations, and independent individuals.

Licences will only be issued to legal entities; that is, entities that can be prosecuted in Victoria. Legal entities include natural persons and bodies corporate. Bodies corporate include ASIC-registered Australian and international companies, institutions incorporated by statute of an Australian parliament, and associations incorporated under Australian State or Territory incorporation legislation, such as Consumer Affairs Victoria. An Australian Business Number alone **does not** indicate body corporate status.

Licence Requirements:

Anyone applying for a Licence must meet the following criteria:

- the applicant/s must have an agreement with a properly constituted and functioning Animal Ethics Committee (AEC).
 - o The AEC oversees all animal use for the licence.
- The nominated AEC will be listed on the licence and no other AEC may be used.
- The nominated AEC may be established by the licence holder or be an AEC run by another institution.
 - o **In either case, responsibility for the conduct of the AEC remains with the licence holder.**
 - o If the AEC does not operate in a legal manner, the licence holder must ensure that the AEC practices become compliant or cease to use that AEC.
 - o If an AEC is no longer used the use of animals under that licence must cease until a replacement AEC can be found and an application made to the Bureau to have the replacement AEC listed on the licence.
- A licence holder wishing to conduct Scientific Procedures must apply for approval for the project to the nominated AEC.
 - o An application must provide the Committee with sufficient information to assess whether the potential gain provided by the work is worth the impact on animal welfare.
 - o Information requested will include detail and context of the planned procedures, the personnel involved and their levels of training, and animal acquisition, housing and monitoring, as well as implementation of the principles of “the 3 R.s” - i.e. whether:
 - Alternatives to animal use have been considered (Replacement)
 - Only minimal numbers of animal necessary for the project outcome are planned to be used (Reduction)
 - All risks to animal wellbeing must be minimised (Refinement)
- Organisations or individuals undertaking activities not approved by an AEC, or under the approval of an improperly constituted or functioning AEC are liable to prosecution.

Licence application forms can be found at: www.dpi.vic.gov.au/animalwelfare/procedures.



The Scientific Procedures Premises Licence (SPPL):

A Scientific Procedures Premises Licence authorises the use of facilities for Scientific Procedures. Scientific Premises are listed on the licence and are regularly inspected by the Bureau of Animal Welfare as the licensing authority, as well as by the Animal Ethics Committee. All Scientific Premises must be annually audited by the AEC listed on the Licence to ensure that the facility is being properly maintained.

The audit will examine:

- general upkeep and record keeping,
- maintenance of appropriate environments, and
- establishment of emergency systems to protect animal welfare.

Any facility being used to hold or conduct research must have a Scientific Procedures Premises Licence. There must be a clear line of management of all persons conducting Scientific Procedures at that premises linking their activities to an SPPL.

For example: an institution **owns** diagnostic facilities used for Scientific Procedures by other institutions, but does not conduct any scientific procedures themselves. The facilities are only used occasionally by each institution, although cumulatively the use qualifies the facilities as a Scientific Premises. Because of the nature of use, none of the users could be held responsible for the premises and would not be required to hold a Scientific Procedures Premises Licence for those facilities (although they would be required to hold a licence to authorise this as "Fieldwork"). The premises-owner therefore would be required to hold a SPPL covering the diagnostic facilities and would be responsible for ensuring that appropriate standards are maintained, even though the owner itself does not conduct Scientific Procedures.

A licence holder may use Scientific Premises under the authority of its licence whether or not it legally occupies those premises. For risk management purposes however, it is strongly recommended that licence holders establish a formal agreement for Scientific Premises use, setting out responsibilities and liabilities of the various parties.

Breeding

The Scientific Procedures Premises Licence may be used to authorise the breeding of Specified Animals **for use by the licence-holder only**, and under AEC approval of procedures, personnel, and premises. The licence does not authorise breeding of Specified Animals for supply to other institutions. If breeding for supply is undertaken, a Specified Animals Breeding Licence is required. In line with the principle of Reduction however, if the number of Specified Animals approved for use in a project under a SPPL are subsequently found to be in excess of project requirements, these animals may be passed on to other licence holders without the need for a Specified Animals Breeding Licence.

Breeding of a new strain or hybrid of a genetically modified animal is considered to be a Scientific Procedure, and must be authorised by a Scientific Procedures Premises Licence.

Other licence conditions

All practices carried-out under the licence must be in compliance with the Code of Practice for the Care and Use of Animals for Scientific Purposes, the Victorian Code of Practice for the Housing and Care of Laboratory Mice, Rats, Guinea Pigs and Rabbits and the Code of Practice for the Use of Animals from Municipal Pounds in Scientific Procedures.



Use of locations other than Scientific Premises – Fieldwork:

A Scientific Procedures Premises Licence may also be used to authorise conduct of Scientific Procedures at locations not used as Scientific Premises and that are not listed on the licence. This use of unlisted locations is termed “Fieldwork” and the procedures, personnel, and location(s) must be agreed to by the nominated Animal Ethics Committee as with the use of Scientific Premises. Standards appropriate to the level of use must be maintained. The licence holder must ensure that the Bureau of Animal Welfare is [notified of Fieldwork](#) after approval by the AEC and prior to commencement of any Scientific Procedures. A Fieldwork Notification form can be found at www.dpi.vic.gov.au/animalwelfare/procedures.

The Scientific Procedures Fieldwork Licence (SPFL):

A Scientific Procedures Fieldwork Licence authorises the conduct of scientific procedures outside of a Scientific Premises ** (i.e. premises that are not ordinarily used for Scientific Premises). Examples might include the use of production animals on farms or the use of non-captive animals in the wild.

No premises or locations are listed on a SPFL, and this work is termed “Fieldwork”. Procedures, personnel, and location(s) must be agreed to by the nominated Animal Ethics Committee and standards appropriate to the level of use must be maintained. The **licence holder must ensure** that the Bureau of Animal Welfare is notified of Fieldwork after approval by the AEC and prior to commencement of any Scientific Procedures.

Breeding

Breeding of Specified Animals may not be not authorised by a Scientific Procedures Fieldwork Licence.

The Licence Nominee:

An individual must be nominated to be responsible for procedures under a Scientific Procedures Premises Licence - the “Licence Nominee”. The Licence Nominee is the first point of contact for the Bureau of Animal Welfare as the licensing authority. It is the License Nominee that the Bureau will contact about any matters relating to the license that may arise. For example, breaches of licence conditions, licence audits, reporting of animal use, and Animal Ethics Committee composition and conduct. The License Nominee must hold sufficient position in the Institution to be able to effect change where necessary and they must be familiar with ALL the work being conducted under their licence.

Wildlife, fish, and quarantine issues - additional permits and requirements:

The use and keeping of animals in Victoria is overseen by a number of government agencies, with concerns covering the conservation of wildlife and fish, and quarantine issues. If animals are used for Scientific Procedures or bred as Specified Animals, there may be additional requirements to those that are covered in this document that relate specifically to animal welfare and the Prevention of Cruelty to Animals Act. Information should be sought from the following agencies:

- Wildlife Research Permits (Department of Sustainability and the Environment) are required for the use wildlife for research or teaching. Contact environmental.research@dse.vic.gov.au, or the Customer Service Centre on 136 186.
- A permit and or other authorisation under the Fisheries Act 1995 is required to translocate and stock fish in Victoria for the purpose of research (Department of Primary Industries Fisheries Division). Contact the Customer Service Centre on 136 186.



- Pest Animal Research/Education Permits are required for the keeping of a number of species. Department of Primary Industries (DPI) administers the Pest Animal Permit System on behalf of DSE and are applicable to universities and other appropriate institutions for research and educational purposes which are registered under the Prevention of Cruelty to Animals Act 1986. This type of permit applies to all categories of pest animals. Category 1 - Prohibited Pest Animals can only be held by VPC Approved Scientific Institutions. Contact the Pest and Exotic Animal Permit Officer on (03) 57611611 or the Customer Service Centre on 136 186.
- The Office of the Gene Technology Regulator supports the Gene Technology Regulator in the performance of his functions under the *Gene Technology Act 2000*, introducing a national scheme for the regulation of genetically modified organisms and managing risks.
- The Australian Quarantine Inspection Service (AQIS) provides import and export inspection and certification for the use of imported animals for scientific purposes.





Expression of interest proforma

Animal Ethics Note: 2.3 December 2010

This proforma Expression of Interest is provided by the Victorian Bureau of Animal Welfare (BAW) to assist Institutions' in the recruitment of independent members to their Animal Ethics Committees.

Is it recommended that information provided when advertising or using other methods of recruitment should include at least the following:

- An explanation of the work performed by the institution, the benefit to the community or to animals and the role of the AEC in promoting animal welfare and good science;
- A realistic estimate of the time commitment required;
- An outline of the types of support provided by the institution for AEC members, including training opportunities, access to library and other resources. Honoraria, reimbursement of out-of-pocket expenses etc.

If a decision is made to advertise then the following outlets or organisations may be suitable:

- Local newspapers
- Seek
- GoVolunteer
- Probus
- Rotary
- University of the Third Age

Recommended reading for prospective members includes the Bureau of Animal Welfare Animal Ethics Note 3.1: Animal Ethics Committee Membership which is available from the Bureau on request.



Call for Expression of Interest

(Insert Institution Name) Animal Ethics Committee

Category C Welfare Members

Category D Lay Members

Background

Insert Brief introductory statement about the Institution

The Prevention of Cruelty to Animals Act 1986 requires that institutions conducting research and teaching using animals comply with the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes 2004 and designate an Animal Ethics Committee (AEC) to oversee the conduct of the institution's care and use of animals for scientific purposes.

An AEC comprises at least 4 persons, one from each of the following categories:

Category A: Veterinary surgeon

Category B: Scientist or teacher

Category C: Animal Welfare person

Category D: Lay person

The AEC is responsible for assessing applications to use animals for scientific purposes and teaching by weighing the scientific or educational value of that use against the potential effects on the welfare of the animals.

Further information about the use of animals in research and teaching, including the role of Animal Ethics Committees, is available at the Victorian Bureau of Animal Welfare website (www.dpi.vic.gov.au/animalwelfare).

Key Criteria

Category C members

- demonstrable commitment to, and established experience in, furthering the welfare of animals
- not employed by or otherwise associated with the institution
- not involved in the care and use of animals for scientific purposes

Veterinarians with specific animal welfare interest and experience may be suitable Category C members.

Category D members

- have not engaged in the use of animals for scientific purposes either in your employment or beyond your undergraduate education
- not employed by or otherwise associated with the institution



Time Commitment

The AEC conducts (insert frequency) meetings of approximately (insert number) hours during business hours. Reading of material prior to the meeting requires approximately (insert number) hours. Occasional membership of an Executive Committee may also be necessary and would require approximately (insert number) hours. Attendance at one inspection of animal holding facilities per year will be necessary.

Support & Resources

- Access to library resources is available. Attendance at relevant conferences and seminars is encouraged and supported.
- Morning tea/afternoon tea/lunch is provided during meetings.
- Out-of-pocket expenses e.g. travel and parking, printing will be reimbursed.
- A sitting fee is available. (Optional)

How to Apply

Insert Information about application process







Animal Ethics Committees

General membership information

Animal Ethics Note: 3.1 September 2010

Introduction:

Under Australian State and Territory law we have a duty to provide for animals' physical and behavioural needs. In Victoria, the relevant legislation regulating the use of animals in science is contained in the *Prevention of Cruelty to Animals Act (1986)*. The needs of animals used in science and how they can be met are outlined in the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes 2004*.

The *Prevention of Cruelty to Animals Act 1986* (the Act) requires that institutions conducting research using animals comply with the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes 2004* (the Code) and establish an Animal Ethics Committee (AEC) to oversee the conduct of the institution's care and use of animals for scientific purposes.

Section 2 of the Code details the responsibilities of institutions and their AECs. This Animal Ethics Note provides basic information regarding the purpose and composition of AECs.

It is important that prospective and existing AEC members are familiar with Section 2 of the Code; specifically, the terms of reference, operating procedures, membership for AECs, assessment of proposals, and monitoring and reporting requirements.

The primary responsibility of AECs is to ensure that all care and use of animals for a scientific procedure is conducted in compliance with the Code. AECs apply a set of principles that govern the ethical conduct of people whose work involves the use of animals for scientific purposes. The role of the AEC is to ensure that the use of animals is justified, provides for the welfare of those animals and incorporates the principles of Replacement, Reduction and Refinement (the Three R's).

What are the Three R's?

The Three R's form a framework for the assessment of the humaneness of animal use in research and teaching. Investigators are required by law to make sure that they minimise any pain or other harm they cause to the animals they use for research, teaching, and testing. The *3Rs Principle* provides a framework for ensuring that animals are only used when necessary (Replacement), that no more animals are used than are required to achieve the objectives of the work (Reduction), and that if any noxiousness is caused during the work, it is kept as low as possible (Refinement).

For further information on the Three R's, refer to Animal Ethics Note 4.1: "The Three R's".

AEC Membership:

In accordance with the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes, an AEC must comprise at least four persons, one from each of the following categories:

Category A: Veterinary surgeon with experience relevant to the activities of the institution

Category B: Scientist or teacher with substantial recent experience in animal based research or teaching

Category C: a person with demonstrable commitment to, and established experience in, furthering the welfare of animals and who is independent of the institution

Category D: Layperson who has never engaged in animal experimentation beyond their under-graduate education and who is independent of the institution



It is recommended, but is not mandatory, that a senior member of the animal house staff be a member of the AEC, known as a Category E member. To further assist the AEC to function effectively, institutions may appoint as members, people with skills and background of value to the AEC. The AEC may also invite people (non-members) with specific expertise to provide advice as required.

When appointing additional voting members to the AEC, consideration should be given to maintenance of a quorum in accordance with the Code's requirements. The Code states that, if the Committee has more than four members, Categories C plus D should represent no less than one third of the members. Although few AEC decisions are made by majority decision, this stipulation protects AECs from perceptions of bias in favour of the institution or other parties. Members additional to the Categories A, B, C and D may be appointed as voting or non-voting members. The final membership of voting members should comply with the Code's requirements for 1/3 independent membership.

All categories of members are equally valuable and valued. The knowledge, expertise and personal opinions of individual members vary considerably, but certain overlapping characteristics and abilities are desirable if the AEC is to function well as a group and the members are to find the work rewarding. These include:

- (i) an acceptance that ethical experiments on animals can be carried out as long as there is no alternative;
- (ii) courtesy and patience in dealing with other committee members and with investigators;
- (iii) willingness to listen as well as to speak; and
- (iv) clarity and succinctness in oral and written communication.

AEC members must also in particular:

- consider and discuss the purpose and likely benefits of the proposed research;
- consider meeting procedures, executive power, decision-making procedures, dispute resolution procedures and so on, to ensure that all AEC activities are fair and reasonable;
- ensure that scientific details are presented and explained in a manner which is understandable to lay members of the AEC;
- consider the need for the use of animals, the number requested, evidence of use and consideration of alternatives, and reasons for rejection of known alternatives;
- review Standard Operating Procedures (SOPs);
- visit the animal holding area, and inspect caging/housing, feeding rosters, monitoring rosters and records, bedding, lighting, environmental enrichment and other aspects of animal care.
- discuss the invasiveness of procedures, repetitive procedures, analgesia, anaesthesia, arrangements for humane death, and other matters which affect the day-to-day existence of the animals and consider refinements wherever possible;
- consider annual and final research reports.

The Code also allows the AEC to appoint an Executive to approve minor modifications to approved projects and deal with emergencies between full AEC meetings. One of either the Category C or the Category D members must be on the Executive. The Executive may not approve new proposals. Any decisions made by the Executive must be reviewed by the AEC at its next meeting and be recorded in the minutes.

It is a condition of all Scientific Procedures licenses that the institution notify the Bureau of Animal Welfare of any change in membership of an Animal Ethics Committee within 14 days of that appointment. The Bureau of Animal Welfare requests sufficient information about the nominee to assess their suitability for the proposed membership Category in accordance with the Code.



Joining a Committee

Before accepting an invitation to join a committee, a prospective member should ask her/himself the following questions:

- (i) Am I sure that I have enough time and interest to read lengthy applications and do any necessary background reading?
- (ii) Am I prepared to ask straightforward questions of highly qualified veterinarians and scientists, and persevere until a complete and satisfactory answer is given?
- (iii) Am I prepared to speak my mind in meetings?
- (iv) Do I feel confident that I can work with that particular committee?
- (v) Am I accepting this invitation for a negative reason? Usually this would be a plea that they cannot find anyone else or perhaps that the gender balance on the AEC is unsatisfactory. No one has a moral obligation to join a committee for such reasons.

Prospective members are advised to discuss the Terms of Reference of the Committee with the Chairperson and have a clear understanding of the type of work undertaken at the institution prior to accepting an offer of membership of the Committee.

Where appropriate, new AEC members should:

- be provided with a list of the other AEC members and brief details of their background/role on the AEC;
- meet with the Chairperson to discuss meeting procedures and other AEC activities;
- tour the animal facilities and meet staff;
- be provided with or advised of any institutional requirements for research involving animals, confidentiality, occupational health and safety and any other requirements;
- be provided with a copy of the Act and the Code and any other relevant AEC guidelines;
- be provided with access to the register of approved projects to familiarise members with current and ongoing research;
- be provided with written protocols and other material to be considered at any meeting;
- be provided with access to a library of approved SOPs, if it exists;
- be made aware of their entitlements in terms of sitting fees, remuneration of travelling expenses, office expenses and the like;
- be advised of any training opportunities provided by the institution to enhance their skills relevant to their AEC duties.

AEC Functions:

Assessing a Project

There is no standard Australia-wide proposal form, though the Code defines the information required from an applicant by an AEC. To help decide whether the use of animals is justified, based on whether the scientific or educational value of the work outweighs the potential impact on the animals, the committee must know:

- why the work is proposed
- why animals are needed
- what will be done to each animal
- what impact the work will have on the welfare of the animals



The project justification should clearly state:

- the broad context of the work
- the aim/s of the work
- the significance of the work
- why animals are needed
- what will be done to the animals in broad terms

The project description should provide:

- details of what will be done to the animals
- what impacts the interventions may have on animal welfare
- how the animals will be monitored and cared for
- a description of the endpoint of each experiment
- the phenotypes of any genetically modified animals and any special requirements they may have

The AEC should be satisfied that it knows what is happening to individual animals within a project from the time of issue for use until the endpoint of the experiment.

The numbers of animals requested for use must be clearly justified. The application should include, as appropriate, power analysis or an explanation of numbers based on requirements for tissue sampling, logistics/equipment etc. In some cases it may be better to use more animals to minimise the pain and distress caused to an individual animal. If animals are used for a number of different research projects, the impact on the animal needs to be carefully assessed and should decrease with each successive project.

The AEC must know who is responsible for the work with animals. For each person named in a proposal there must be **details** about:

- what they will do to the animals
- what experience they have with the procedure(s) they will carry out on live animals
- what training they will need, and how such training will be provided (i.e. who will provide the training)

Finally, the AEC must be provided with a comprehensive consideration of the steps taken by the applicant to comply with the principles of the Three Rs. [For further information on the Three R's, refer to Animal Ethics Note 4.1 "*The Three R's*".]

The information provided in proposals must be sufficient to satisfy the AEC that the proposed use of animals is justified by weighing the predicted scientific or educational value of the proposal against the potential impact on the welfare of the animals.

Investigators may be invited to address the AEC and answer questions. This is helpful to both parties and often results in improvements to the experimental design, to better animal welfare and a greater understanding between the AEC and investigators.

A generic proposal form developed by the AEC advisory Committee can be viewed at www.dpi.vic.gov.au/animalwelfare/procedures.



Site Inspections and Monitoring

As part of the self-regulatory system required by the Code, AECs must make regular formal inspections of animal facilities. The Code advises that *where possible, a member of the AEC who is external to the institution should participate in inspections*. In addition, in some institutions, arrangements are made from time to time for the committee to be given talks and demonstrations by investigators in the laboratories.

Site inspections may be announced in advance, so that relevant members of staff can be present; or unannounced, so that the AEC can see the facility in action on an ordinary day.

There should be at least one formal, announced site visit to each site every year and it can be useful to invite other members of the institution or the community to attend. Example Site Audit forms can be viewed at www.dpi.vic.gov.au/animalwelfare/procedures.

In addition, AECs are required to carefully monitor the progress of projects via spot-checks of experimental sites, reviews of progress and final reports, and reviews of laboratory manuals and notes. Any projects likely to cause pain and distress, particularly: study of pain, responses to stressors, certain animal models of human diseases or attempts to change behaviour by physical or chemical means, should be subject to early inspection by the AEC as a condition of approval.

Dealing with Non-compliance

It is the AEC's role to assess and manage non-compliance of investigators and their institution with respect to the Code. The AEC must set in place procedures and processes that ensure that non-compliance is dealt with swiftly and reporting to the relevant institution is prompt, clear and concise.

When an inspection detects activities that are non-compliant with the Code, the AEC must ensure that all activities cease immediately and remedial action is initiated.

Confidentiality

Some institutions may request that members of an AEC sign a 'Confidentiality Agreement' prior to or soon after appointment. The Code leaves this up to the institutions. Such agreements are usually designed to protect material that may be commercial in nature (for example, related to intellectual property, patents).

Any agreement should not prevent AEC members from seeking expert advice, or the valued views of others, on experimentation applications or other aspects of AEC activities, providing such advice is sought on a confidential basis and does not divulge any sensitive aspects of the matter. It is possible to discuss the general merits (or otherwise) of applications or issues without breaching confidentiality. The only exception may be those applications marked 'Commercial-in-Confidence'. A Confidentiality Agreement should acknowledge the need of AEC members to discuss aspects of their work with others.

Potential concerns held by independent members of AECs include the possibility of having to defend themselves in court against allegations of breach of confidentiality. Statutory protection may be provided to certain volunteers by Part IX of the *Wrongs Act 1958* (Victorian) and by the *Commonwealth Volunteers Protection Act 2003* (Federal). Careful note should be made of the definitions and legal advice should be sought on the interpretation of these Acts. In addition, governing legislation of some organisations (eg, *The XX University Act 1967*) may include provision for indemnity of formally appointed institutional Committee members, subject to any exceptions stated in the indemnity provision.



Independent AEC members make an extraordinary contribution to Victorian institutions. Institutions must comply with the Australian Code requirements (2.1.1(x) and 2.2.8) that all aspects of confidentiality arrangements be fairly discussed with all members of the AEC, and that provision is made for AEC members to seek advice without breaching confidentiality. Institutions are advised to seek their own legal advice regarding confidentiality and provide members, particularly independents, with any advice pertaining to their situation, especially the provision of any indemnity.

Conflict resolution

Grievance procedures for both AEC members and investigators should be clearly defined in the Terms of Reference or operating procedures of the AEC. The Code states that 'where possible, decisions on approvals of proposals should be made on the basis of consensus' (Section 2.2.22).

Where two or more members oppose a proposal it should not be approved until the AEC has explored ways of modifying the project that may lead to consensus. In most instances consensus can be reached. A majority decision should only be undertaken after a review period.

(a) Conflict between an investigator and the AEC

Disputes between an investigator and an AEC may arise, and in the first instance the Chairperson of the AEC should try to resolve the dispute. If, however, the Chairperson is unable to resolve the dispute, then the dispute should be referred to the governing body of the institution for review.

The Bureau of Animal Welfare may be consulted on these matters if the AEC, investigator or institution so desires.

(b) Conflict involving a member of the AEC

From time to time, members of the AEC may become dissatisfied with the functioning of the Committee or aspects of animal welfare, and/or have ideas on how the functioning of the Committee or animal welfare could be improved. The Chairperson should listen to these complaints seriously, and carefully consider ideas for improvements.

Members of the AEC are advised that if their concerns are not sufficiently addressed they should take their concerns in the first instance to the head of the institution, and if still unresolved, to the Bureau of Animal Welfare.

Terms of Reference

The AEC must have Terms of Reference that are publicly available and describe procedures required by the Code (see 2.2.1). Terms of reference should be regularly reviewed and all processes described should be compliant with the Act, Regulations and the Code. They should be accepted in writing by each AEC member on appointment and whenever they are revised.

A proforma Terms of Reference has been developed by the AEC Advisory Committee and is available at www.dpi.vic.gov.au/animalwelfare/procedures.

Responsibilities of AEC Members, Institutions and Affiliates:

Specific information regarding the responsibilities of each member of the AEC, the Institution, the Institution Animal Welfare Office, the Licence Nominee, and the AEC Executive Officer are outlined in the following Appendices to this Animal Ethics Note.



Appendix 1

Responsibilities of institutions

Animal Ethics Note: 3.1 September 2010

Introduction:

Institutions that use animals for scientific purposes (research and/or teaching) must implement processes that ensure the governing body of the institution complies with the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes (2004)* and the *Prevention of Cruelty Act Victoria (1986)*. The institution's delegate (Licence Nominee) is responsible for ensuring that the Institution fulfils its obligations under the Code.

Responsibilities of Institutions towards their AEC under the Code:

At minimum the Institution or its representative must:

- nominate an AEC, directly responsible to the governing body of the institution or its delegate, to manage project applications falling under each of their licences;
- ensure, through the AEC, that all scientific and teaching activities involving the use of animals comply with relevant legislation and the Code;
- respond promptly and effectively to recommendations from the AEC to ensure that all care and use of animals for scientific purposes within the institution remains in accordance with the Code;
- address concerns raised by the AEC regarding non-compliance with the Code which may include disciplinary action upon advice of the AEC. The institution and the AEC should prepare written procedures, to deal with non-compliance and any grievance related to the AEC process. **The written procedures must clearly define the reporting mechanisms and the responsibilities of all parties to ensure fair and effective processes;**
- seek comment from the AEC on all matters that may affect the welfare of animals used for scientific purposes by the institution, including the building or modification of animal facilities;
- ensure that the AEC approves guidelines for animal care and use within the institution and that these are implemented, including those which ensure that emergencies, such as fire and power failure, are detected promptly and dealt with effectively;
- provide the AEC with the resources required to fulfil its terms of reference and operational requirements. This includes provision of resources for orientation and education of AEC members, administrative assistance and, where appropriate, the reimbursement of out-of-pocket expenses and/or payment of an allowance to AEC members;
- conduct an annual review of the operation of the AEC, including an assessment of the AEC's Annual Report and a meeting with the AEC chairperson (see [Annual AEC Self-Audit](#));
- provide all relevant personnel including AEC members with details of the institution's policy on the care and use of animals, confidentiality, Freedom of Information legislation, legal requirements, privacy policy and commercial considerations;
- establish and make known procedures for the fair resolution of disagreements between AEC members, between the AEC and investigators or teachers, or between the AEC and the institution;
- provide personnel and AEC members with information on potential disease hazards and other Occupational Health and Safety (OH&S) issues associated with the care and use of animals;



Responsibilities of Licence Nominees/Institution Representatives towards the AEC:

The following responsibilities should form a major part of the Licence Nominees interactions with the AEC:

- respond promptly and effectively to recommendations from the AEC to ensure that all care and use of animals for scientific purposes within the institution remains in accordance with the Code;
- address concerns raised by the AEC regarding non-compliance with the Code which may include disciplinary action upon advice of the AEC;
- seek comment from the AEC on all matters that may affect the welfare of animals used for scientific purposes by the institution, including the building or modification of animal facilities;
- ensure that the AEC approves guidelines for animal care and use within the institution and that these are implemented, including those which ensure that emergencies, such as fire and power failure, are detected promptly and dealt with effectively;
- provide the AEC with the resources required to fulfil its terms of reference and operational requirements
- conduct an annual review of the operation of the AEC, including an assessment of the AEC's Annual Report and a meeting with the AEC chairperson (see [Annual AEC Self-Audit](#));

AEC Executive Officers/AEC Secretaries:

Institutions may need to appoint one or more AEC Executive Officers to help the Chairperson manage the administrative aspects of AEC functioning and decrease the AECs workload.

Responsibilities of Executive Officers/AEC Secretaries:

The main responsibility of an AEC Executive Officer is to ensure that records are in order and to assist the Chair. This will enable efficiency and well-focused decision making.

An AEC Executive Officer may:

- liaise with the AEC Chairperson and members to determine appropriate meeting dates and corresponding project application deadlines;
- liaise with scientists and teachers submitting application regarding incomplete or incorrect applications and outcomes of project application assessments;
- schedule facilities inspections and meetings with Institution Representatives and Licence Nominees;
- record, collate and distribute meeting Agenda, Minutes and Reports;
- collate and maintain the register of approved projects and the Adverse Event log;
- manage correspondence with the Bureau of Animal Welfare.

A complete outline of Institution and Institution representative's responsibilities under the Act can be found in the following Animal Ethics Note 2.1: Responsibilities of Institutions Towards Ensuring the Welfare of Animals in Research and Teaching.



Appendix 2

Chairperson responsibilities

Animal Ethics Note: 3.1 September 2010

Introduction:

The Chairperson can be of any category. The Code stipulates only that:

The Chairperson should hold a senior position in the institution, or, if an external appointee, be given a commitment by the institution to provide the necessary support and authority to carry out the role. It is recommended that the chairperson is an additional appointee to the category A – D members.

The Code sets out a number of attributes that the Chairperson should have (Section 2.2.9). Critically, an effective Chairperson will need to be able to elicit the views and participation of all members of the AEC and to summarise and fairly balance these in arriving at acceptable group decisions.

Ideally, the Chairperson will be committed:

- to the spirit of ethical science,
- to disseminating that ethical view to the institution and the wider community, and
- to understanding the issues and conflicts involved in balancing the costs and benefits of the use of animals in research and/or teaching.

It is essential that the Chairperson:

- be skilled in leading groups of people to a consensus (see Code definition and Section 2.2.22),
- be willing to devote time and energy to ensuring
 - o the smooth running of the AEC,
 - o liaison with other bodies, and
 - o the welfare of animals.

If the AEC does not have a supporting Executive Officer (Appendix 1), it is part of the Chairperson's role to make sure that all applications to the AEC contain all the main relevant information. This will assist efficiency and well-focused decision making.

When reviewing a project application the AEC Chairperson should ascertain the licence authorising the investigator to carry out scientific procedures. If the investigator is from an external institution, the Chairperson should ensure formal authorisation has been obtained from the license holders of the investigator's institution and institution with which the AEC is affiliated.

Responsibilities of the Chair:

The key responsibilities of the Chairperson are to:

- ensure that the AEC operates in accordance with the principles and requirements of the Code, the relevant policies of the institution, and the agreed AEC procedures;
- ensure that the process by which decisions about applications are made is fair to investigators and acceptable to all AEC members;
- ensure that minutes are maintained that record decisions and all other aspects of the AEC's operation; ensure that a register of approved projects is maintained;
- ensure that AEC members inspect animal housing and laboratory areas regularly and that records of these inspections are maintained;



- ensure that AEC recommendations are acted on / carried out;
- maintain frequent communication with the institution's management to ensure
 - o the AEC is adequately resourced, and
 - o the institution's management is aware of any problems occurring;
- ensure that the AEC submits an annual report to the governing body or head of the institution in accordance with Section 2.2.40 of the Code (see Annual AEC Self-Audit);
- recommend corrective measures / discipline to accompany breaches of protocol;
- ensure that the Department Head via the Bureau of Animal Welfare is notified of approved fieldwork (as per the Prevention of Cruelty to Animals Regulations).

For the smooth operation of the AEC, the Chairperson may also find it useful to:

- encourage investigators to attend AEC meetings when their applications are under consideration - this provides Committee members the opportunity to address questions and concerns directly to the investigators;
- ensure that each member of the Committee has ample opportunity to ask questions of, and discuss issues with, the investigators;
- ensure that a quorum is maintained if any member of the AEC is required to leave the room during discussion of any proposal;
- ensure that the discussion of scientific aims, justification and technical details are understood by to the non-scientific members of the AEC;
- encourage questions and discussion from the non-scientific members on the Committee;
- ensure that Committee members receive applications and any other papers at least seven days before each meeting;
- ensure that any person with a conflict of interest has left the room when their proposal is discussed by the AEC;
- support the dissemination of information on issues of animal ethics within the institution and the community;
- coopt additional expertise to the Committee if required.

Finally, if the Chairperson is a scientist/investigator whose applications are considered by the AEC, then a deputy should assume the chair when such applications are under consideration, and the chairperson will have left the room.

To be effective, a Chairperson will need to be readily accessible to AEC members and investigators and to be able to respond quickly to matters that arise.



Appendix 3

Category A member - Veterinarian

Animal Ethics Note: 3.1 September 2010

Introduction:

The Code stipulates particular attributes of the Category A member. The Category A person is 'a person with qualifications in veterinary science and with experience relevant to the activities of the institution'. A Category A member will possess a degree that enables them to register as a veterinary surgeon in Australia.

Veterinarians are members of AECs because they have specialised knowledge of animals, and of advances in their care, health and general welfare. AECs rely very much on veterinarians for information on the variations between species in their reaction to procedures or drugs, on their housing needs, and on their post-operative care.

They can be particularly useful in helping the Committee to assess the progress of a project or the impact of a specific procedure on the animals, by visiting an investigator and watching experiments. In addition, they are trained to communicate complex physiological processes in lay terms. This is essential to ensuring that all committee members fully understand the impact of any procedures being proposed.

It is preferable, but not essential, for the veterinarian to have had some previous experience with laboratory animals in a research environment. Where veterinarians do not have training and experience in the husbandry of the species used in the institution, they must familiarise themselves with the biology and clinical characteristics of the species used. They should seek assistance, where necessary, from others and remain up to date with the relevant issues in the care and welfare of laboratory animals, including the recognition and control of pain in laboratory species. Ideally, a Category A member will have a good understanding of issues relevant to experimental design and the scientific method.

Responsibilities of the category A member:

Category A persons should note that the responsibility for determining the adequacy of the experience, qualifications, and technical skills of investigators rests entirely with the AEC.

The Category A member should:

- ensure that conditions provide for the humane care of animals used for scientific purposes;
- consider the potential impact on the welfare of animals against the potential scientific or educational value of the research proposal;
- advise on the nature of procedures proposed and their impact on the well being of animals involved and, where necessary, suggest more humane alternatives;
- advise the AEC whether the use of local or general anaesthetic, analgesic or tranquillising agents in the protocol is appropriate to the species, and parallels use in current veterinary practice;
- ensure that proposals for animals to be used in research involve subjecting animals to the minimum of pain and distress consistent with the needs of the experiment, and where possible, promote techniques that enhance wellbeing; in particular, provide technical advice on:
 - animal husbandry
 - anaesthesia and analgesia
 - techniques for obtaining blood and tissues samples
 - surgery and post operative care
 - assessment and monitoring of pain



- humane killing of animals
- adjuvants
- sources of information on best practice, alternatives and the 3Rs;
- regularly inspect the institution's animal care facilities, including those for breeding animals, and advise on their suitability and impact on the welfare of animals;
- ensure that those involved in the care and handling of experimental and breeding animals have the necessary skills and expertise;
- consider adverse incident reports;
- seek assistance, where necessary, from others and remain up to date with the relevant issues in experimental design and the care and welfare of laboratory animals, including the recognition and control of pain in laboratory species;
- assess and discuss with the AEC the scientific merit of research proposals, experimental design and necessity for animal usage.

Useful Resources for Category A Members:

1. ANZCCART Fact sheet : The role of veterinarians in the care and use of animals in research and teaching
2. Scott, L.R. and Carter, P.D. (1996) The role of veterinarians on animal experimentation ethics committees. *Australian Veterinary Journal* **74(4)**: 309-310.
3. ANZCCART Fact sheet: Pain-assessment, alleviation and avoidance in laboratory animals
4. The Victorian Code of Practice for the housing and care of laboratory animals

Note: These resources are available at www.dpi.vic.gov.au/animalwelfare/procedures.



Appendix 4

Category B member - Scientist

Animal Ethics Note: 3.1 September 2010

Introduction:

The Code stipulates particular attributes of the Category B member. The Category B person is 'a suitably qualified person with substantial recent experience in scientific or teaching activities. This will usually entail possession of a higher degree in research.'

The Category B member should be seen as the communication link between investigators or teachers and the AEC, particularly Category C and D members. **The role of the scientist is to assess and if necessary help explain the scientific merit of the application in terms of both experimental design and importance of contribution to knowledge base.**

Pitfalls with regard to animal welfare may be particularly obvious to an investigator with current or recent experience of animal experimentation, as is the balance between benefit and cost of a given protocol.

It is important that the Category B member is committed to the spirit of ethical science. He/she should be able to understand the issues and conflicts involved in balancing the costs and benefits of the use of animals for scientific purposes.

Responsibilities of the category B member:

Category B persons should note that the responsibility for determining the adequacy of the experience, qualifications, and technical skills of investigators rests entirely with the AEC.

The Category B member should:

- assess the scientific merit of proposals in terms of both experimental design and importance of contribution to knowledge base;
- ensures that the experiments proposed are of the highest standard;
- ask questions of the investigators relating to all aspects of the scientific process, including aims, previous studies, experimental design, choice of species, statistical methods, availability of non-animal alternatives, use of alternative procedures, anaesthesia, analgesia, endpoints, euthanasia, and so on;
- provides scientific expertise to the Committee;
- explains details of the science in lay terms to the non-scientific members of the Committee (where required);
- considers available alternatives to animal use and implementation of the 3Rs wherever possible; and
- considers whether proposals are justified weighing the scientific or educational value of the study against the potential effects on the welfare of animals;
- consider adverse incident reports;
- participate in scientific premises site visits at least once per year.

Useful Resources for Category B Members:

1. Rogers, L. (1994) What do animals think and feel? *ANZCCART News* **7(4)**: 1-3.
2. Rose, M.A. (1996) The problem of pain: concepts and issues. *ANZCCART News* **9(4)**: 2-4





Appendix 5

Category C member - Animal welfarist

Animal Ethics Note: 3.1 September 2010

Introduction:

The Code stipulates particular attributes of the Category C member. The Category C person is *'a person with demonstrable commitment to, and established experience in, furthering the welfare of animals, who is not employed by or otherwise associated with the institution, and who is not involved in the care and use of animals for scientific purposes. Veterinarians with specific animal welfare interest and experience may meet the requirements of this category are appropriate as Category C members'* (for example, through working in pounds and shelters, other animal welfare organisations or with further qualifications in animal welfare).

In general, the Category C person, **while not representing an animal welfare organisation, should, where possible, be selected on the basis of active membership of, and nomination by, an animal welfare organisation.** Although they can be expected to share the views of the organisation nominating them, welfarists participate in AEC meetings as members of the AEC, not as representatives of an animal welfare organisation. So, if they are members of an anti-vivisection society it is not their role to oppose every application on philosophical grounds, but to ensure that if a protocol is accepted the animals are well cared for and there are no unethical procedures.

The Category C member should bring an ethical and animal welfare perspective to the deliberations and activities of the Committee. It is not necessary that welfarists have a background in veterinary science or animal care, though this may be the case; but they should have awareness of current community expectations and concerns about animal welfare, and an ability to communicate these concerns.

Through the Category C member of AECs, the animal welfare movement will become more knowledgeable about how work is undertaken on animals in research institutions. Similarly, researchers and teachers using animals will become more aware of the concerns of the animal welfare community.

Responsibilities of the category C member:

The Category C member should:

- promote the reforms known as the '3Rs' (see section 4) whenever possible. Most animal welfare organisations see this as the crucial role of AECs and look to Category C members to promote the 3Rs. This is not an easy role, particularly considering the diversity and complexity of research topics and research methods;
- ask questions about:
 - o the aims of the proposed research; considering and discussing the purpose and likely benefits of the proposed research;
 - o the reasons for using animals, the number requested, evidence of use and consideration of alternatives, and reasons for rejection of known alternatives;
 - o the likely effect on the animals; discussing the invasiveness of procedures, repetitive procedures, analgesia, anaesthesia, the fate of the animals, arrangements for humane death, and other matters which affect the day-to-day existence of the animals;
- consider adverse incident responses.



Ultimately, it is the role of all members of the AEC to consider whether proposals are justified weighing the scientific or educational value of the study against the potential impact on the welfare of animals.

Category C members may also wish to visit the animal holding area, and inspect caging/ housing, feeding rosters, monitoring rosters, bedding, lighting, etc; and take particular interest in any aspect of proposal assessment or meeting business that coincides with their area(s) of expertise. Category C members should also consider the guidelines for Category D members.



Appendix 6

Category D member - Lay member

Animal Ethics Note: 3.1 September 2010

Introduction:

The Code stipulates particular attributes of the Category D member. The Category D member is 'a person both independent of the institution and who has never been involved in the use of animals in scientific or teaching activities using animals, either in their employment or beyond their under-graduate education. Category D members should be viewed by the wider community as bringing a completely independent view to the AEC, and must not fit the requirements of any other Category'.

Independence from the institution requires that the member avoid any conflict of interest that may affect their ability to perform their duties according to the Code. This does not preclude the institution providing the member with sitting fees or remuneration of travelling or office expenses.

Suitable Category D members may be distinguished public figures, business people, teachers, retirees, accountants and lawyers. In any case the person will need to have the presence to articulate a reasonable community perspective undaunted by other members who have scientific, veterinary and animal welfare expertise and interest. This person should bring an independent perspective and impartial view to the deliberations and activities of the AEC and should see himself /herself as representing the broad community.

Ultimately, it is the role of all members of the AEC to consider whether proposals are justified weighing the scientific or educational value of the study against the potential effects on the welfare of animals. Ethical science maximises scientific value and minimises effects to welfare of animals.

Responsibilities of category D members:

Much of the role of the independent member of the AEC will be achieved by considering the manner in which the AEC operates and how it meets the requirements of the Code. Other members of the AEC will be able to provide specialist information about veterinary and scientific details.

Category D members may wish in particular to:

- consider and discuss the purpose and likely benefits of the proposed research;
- consider meeting procedures, executive power, decision-making procedures, dispute resolution procedures and so on, to ensure that all AEC activities are fair and reasonable;
- ensure that scientific details are presented and explained in a manner which is understandable to you and to other lay members of the AEC;
- consider the need for animals, the number requested, evidence of use and consideration of alternatives, and reasons for rejection of known alternatives;
- visit the animal holding area, and inspect caging/housing, feeding rosters, monitoring rosters, bedding, lighting, and so on;
- discuss the invasiveness of procedures, repetitive procedures, analgesia, anaesthesia, arrangements for humane death, and other matters which affect the day-to-day existence of the animals;
- take particular interest in any aspect of proposal assessment or meeting business that coincides with their area(s) of expertise;
- consider annual and final research reports and adverse incidence reports.

A lay member who has difficulty understanding an application should contact the Executive Officer or the Chairperson, who will be able either to clarify it, or to consult the investigator. Usually, if one committee member has difficulty following an application, so do others.





Appendix 7

Category E member - Animal care staff

Animal Ethics Note: 3.1 September 2010

Introduction:

Category E membership on AECs is strongly recommended, but not mandated by the Australian Code of Practice. Animal care staff bring to the AEC an unrivalled knowledge of the institution's animals, their housing and care, the ways in which they are used in experiments or teaching, and the requirements of the various investigators. Through their networks (e.g., ANZLAA, professional contacts), they have access to valuable information on what is happening elsewhere, and can be of enormous assistance to investigators and to the AEC. Animal Care attendants bring a fresh perspective to the practical aspects of a proposed project.

Ideally the Category E member will contribute an experienced and professional point of view, and hold a position in the institution that will enable them to promote the AEC's recommendations.

Responsibilities:

Animal Care staff are responsible for the day-to-day management of animals by an institution and should contact the AEC Executive Officer or Chairperson where facilities and/or a scientific procedure are at risk of breaching or have breached the Code and/or caused concern for animal welfare.

It is the duty of the AEC, particularly the Chairperson, to liaise with the Animal Care Attendants/Animal Laboratory/Facility Manager/s to ensure that all animals are cared for adequately at all times and that the animals have good welfare.





Animal Ethics Committees

Guidelines for the conduct of AECs

Animal Ethics Note: 3.2 September 2010

Introduction:

Under Australian State and Territory law we have a duty to provide for animals' physical and emotional needs. This document was developed by the AEC Advisory Committee (AECAC) and the Victorian Bureau of Animal Welfare (BAW) to assist AECs and institutions with AEC function and institutional responsibility.

It is based on principles of the Victorian legislation, 7th edition of the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes, and considers commonly accepted practice, and legal advice where relevant. Policy pertaining to additional matters can be added to these guidelines on request to the Bureau of Animal Welfare.

It is important to remember that the primary responsibility of AECs is to ensure that all care and use of animals is conducted in compliance with the Code. AECs apply a set of principles that govern the ethical conduct of people whose work involves the use of animals for scientific purposes. The role of the AEC is to ensure that the use of animals is justified, provides for the welfare of those animals and incorporates the principles of Replacement, Reduction and Refinement (the Three R's).

AEC Approval of scientific procedures:

The Act and Regulations require that AEC approval be received before Scientific Procedures are performed in Victoria. That approval must be given by an AEC that is nominated on the licence issued. An exception is if AEC approval is formally delegated to another AEC.

The Licence Nominee should be satisfied that AEC approval has been given before:

- i) members of their institution conduct scientific procedures anywhere in Victoria, or
- ii) people from another institution conduct scientific procedures at their premises, or
- iii) visiting overseas investigators or students conduct work with the approval of the institution.

Levels of response to new applications

The following guidelines are suggested to assist AECs with standard procedures for responding to new applications. The AEC may have 4 levels of response:

- (a) accepted without modification;
- (b) accepted with conditions; that is, when the Committee makes a decision about alterations to the activities proposed in the application and the agreed modifications to the project are to be recorded in the minutes as a decision of the Committee. The investigator should be made aware that exact conformity with those alterations is a condition of approval and the conditions of approval should be noted in the letter of approval or by incorporating the modifications in the application;
- (c) accepted with modification to the satisfaction of the Executive. In this case the applicants must resubmit their application incorporating the modifications and or additional information requested by the Committee. The Committee must then consider the potential impact of the information on the wellbeing of the animals involved. For information with potentially high animal welfare impact (justification for inducing pain in the absence of analgesia, single housing for social species, queries as to why valid alternatives are not used), the information must return to the full AEC for appraisal. If the Committee are satisfied with the changes, they can then approve the application;
- (d) rejected, may be re-submitted with required modifications.



The AEC may delegate to the Executive authority to approve minor amendments ONLY. For example:

- i) addition of suitably experienced personnel;
- ii) minor changes to procedures: where “minor” is defined as any change that has little or no impact on the wellbeing of the animals involved in the project; for example, verifying dose rates for drugs, needle sizes, routes of administration;
- iii) opportunistic diagnostic or veterinary activities intended to benefit the animals;
- iv) re-activation of paused projects.

Please remember that the Executive must constitute at least one independent member (ie. at least a Category C or D member). The Executive can not approve new projects or major modifications.

All such minor amendments must be recorded and subject to ratification by the full AEC at the next meeting. The AEC may also place conditions on approval of a project. For example, the AEC may require six monthly progress reports, limited initial animal numbers etc. Regardless, final project approval or rejection should be a clear decision by consensus and promptly conveyed to the applicant.

AEC approval for breeding animals:

Approval by an AEC for breeding animals may be included in either a) an individual project application for conducting ‘scientific procedures’ or b) SOPs for well established and routine practices and procedures associated with breeding ‘specified animals’.

In line with section 4 of 7th edition of The Australian Code, the Act and Regulations require that ‘practices or procedures to be conducted on **specified animals** which involve the surgical, medical or physical treatment of **specified animals** or the extraction or derivation of any tissue, material or substance from the body of a **specified animal** must be approved and monitored by the Animal Ethics Committee’.

The following guide is provided for the requirement and form of AEC approval required for breeding animals:

- a) Individual project applications would be required for any practices and procedures involving the introduction of a Genetically Modified (GM) line not previously held by the institution and/or the creation or breeding of new lines of GM animals, congenics, mutants or cloned animals or novel use of breeding procedures as these activities are considered ‘scientific procedures’. Refer also to The Australian Code section: 3.3.79 and 3.3.56-3.3.64.
- b) A Standard Operating Procedure would be required for established or routine practice or procedures associated with breeding of non-GM specified animals and well phenotyped and understood GM specified animals.

It is noted that the breeding of GM lines of specified animals that are initially novel to the institution may over time become established. Reporting to the AEC on the outcome of phenotype testing and other relevant data, including measures put in place to monitor and care for animals that develop adverse side effects is essential to allow an assessment of the status of breeding animals. As per Australian Code section 3.3.60 the AEC can determine the transition of the status of these animals from breeding of novel animals to established breeding stock, and thus the requirement for approval by method a) or b).

When phenotypes are well understood, phenotype reports should be made to the AEC including information on monitoring of and care for animals displaying adverse affects due to the modification.



AEC monitoring of interstate activities:

The Australian Code of Practice for the care and use of animals for scientific purposes states that AEC members should inspect all animal housing and laboratory areas regularly and record their findings (Section 2.2.29). Where an institution nominates an AEC based outside Victoria, it is required to demonstrate in the Terms of Reference how this requirement will be fulfilled.

Approvals by an interstate AEC / remote monitoring:

Interstate AECs must provide details of how they intend to fulfil their monitoring responsibilities, as outlined in section 2 of The Australian Code, when approving and forwarding a fieldwork notification to the Bureau of Animal Welfare. This may include delegation of monitoring to a Victorian AEC or suitable proxy (eg. a vet, wildlife ranger or Category C person), digital images or video plus annual report of activities and any adverse events. If welfare and liability concerns remain, there is the additional option of approval by both an interstate and a relevant Victorian AEC. This may be particularly pertinent for projects involving wildlife studies.

Scavenging versus secondary use versus re-use of animals:

Scavenging is the use of an entire animal or organ or tissue from an animal already killed as part of an AEC approved project. It may also involve the use of surplus project or breeding animals that have already been humanely killed. It is inherent that there is no additional impact on the animal thus AEC approval is not required.

In line with the principles of Reduction and Replacement, 'scavenging' is strongly encouraged. Institutions should implement strategies to promote scavenging whenever possible. For example, project application templates should routinely ask whether animals/tissues will be available for scavenging, a strategy should be developed to communicate to internal investigators and potential external bodies available dead animals/tissues as appropriate, and the use of scavenged animals for surgical or other teaching activities should be considered in the first instance.

Secondary use, however, is considered by AECAC to access potential additional impact on a live animal or additional use of a live animal under anaesthesia (terminal or not). Examples of secondary use often occurs with surgical training and practice, live animal organ or tissue extraction. Secondary use of animals should be in line with the principles of Reduction and/or Refinement of the number and impact on the animals proposed and requires AEC approval.

For example, if an AEC approved project involves procedures under anaesthesia, and an additional procedure is requested to be done at a later date, these procedures should be considered either as an independent project application or a modification of the existing project, depending on ethical/ welfare assessment. **It is imperative that the AEC understand the entire history of the animal(s) in considering repeat procedures.**

Re-use of animals may involve using one cohort of animals to be first a control group and then, after the appropriate interlude, a treatment group. This 're-use' of animals should be considered together in one project application and the cumulative impact on the animals considered. Alternatively re-use of animals may involve a number of totally separate projects, and thus life histories records on animals are essential to enable assessment of the cumulative impact on these animals.

Minimising the production of surplus laboratory animals:

The UK Laboratory Animal Science Association and the Animal Procedures Committee (APC) have investigated the issue of animals surplus to scientific requirements, and have concluded that even when well managed some surplus may be inevitable. However, it was also recognised that breeders and scientists continue to review their breeding and use requirements regularly to minimise numbers of surplus animals.



The UK APC produced a report in July 2004 in which the following principles for minimising the production of surplus animals were recommended:

- a) ensuring that, where scientists have exacting and specific requirements for animals, this is scientifically justified;
- b) discouraging small, in-house rodent breeding colonies wherever possible (and where this does not add to welfare costs) and particularly for commonly available species and strains;
- c) encouraging sharing and cryo-preservation of 'tick over' strains;
- d) ensuring full cooperation between users, both those that use animals under a license and those that use ex vivo tissues or organs (ie. scavenging);
- e) finding uses (within or outside the institution) for surplus animals;
- f) planning projects as far in advance as is reasonably possible so as to enable the optimum management of animal colonies.

For further information on the above-mentioned report and 'Breeding and supply of laboratory animals in the UK' in general, please refer to the UK Home office website:

http://www.homeoffice.gov.uk/docs4/breeding_supply.pdf

Please note in Australia there may be some restrictions on the scavenging of GM Animals. Institutions can apply to the OGTR for exemptions for release of non-GM animals from GM breeding schemes/projects. Please refer to the relevant Institutional Biosafety Committee and/or Office of Gene Technology Regulator www.ogtr.gov.au.

Self-Auditing your AEC:

According to Section 2.2.40 of the Code, each AEC must develop an annual report reviewing the operation of the AEC and detailing numbers of applications, types of applications, numbers of animals, adverse incidents, site inspections etc. conducted by the AEC. In addition, the Australian Code requires that the Chairperson meet with the Institution representative of Licence Nominee to discuss the progress of the AEC and any incidents and/or recommendations the AEC has to ensure the institution continues to comply with the Australian Code and the Act.

To try and provide a more rounded review of AEC function, the BAW has developed a Self-Audit form that will partially fulfil Section 2.1.1 (ix), conducting an annual review of the operation of the AEC and a meeting with the AEC Chairperson, and replace the AEC Annual Report (Section 2.2.40).

A copy of the Self-Audit is included in this Guide.

Payment of external AEC members:

External members of AECs are those who participate in the activities of the committee but who are not employed by the licensed institution that established the Committee. The presence of external members is required by legislation, according to the Australian Code (minimum category C and D members) and is vital to the functioning of the AEC and the institution's research and teaching involving live animals.

The Australian Code (7th edition, section 2.1 (viii)) and the Victorian AECAC consider it reasonable but optional for external members of AECs to be offered:

- (i) Reimbursement for personal expenses incurred in carrying out AEC activities and;
- (ii) An honorarium or sitting fee for attendance at meetings and inspections.



The AECAC and the BAW recognise that participation in AEC activities involves considerable commitment from external members in terms of the costs involved in foregoing wages and personal time. It is also recognised that institutions are independent in their decisions regarding the payment of external members; remembering that the amount paid should not be seen as constituting employment by the institution or be of sufficient size to sway decisions of the member. Members may elect to receive the sitting fee directly or donate it to an organisation of their choice.

The following sitting fees were set by the Department of Premier and Cabinet for advisory committees in 2008 and may be of use to institutions contemplating paying external members for their services:

Fees per day for:

- (a) chair \$150-\$291
- (b) member \$155-\$226

Password protected electronic signatures:

There is no actual legal requirement for project applications upon approval to be signed by AEC members (or signatory delegated to the chair). This does, however, commonly occur in practice at the discretion of the AEC.

Legal advice provided to the BAW conveys that the *Electronic Transactions Act 2000* (ETA) permits the use of a password protected electronic signature where the law requires a signature. The ETA conveys a legislative endorsement of the legitimacy of a password protected electronic signature. Accordingly, even if a signature is not legally required, it is recommended that where a password protected electronic signature is used, it is done so in compliance with the ETA.





Animal Ethics Committee

Project proposal assessment guide

Animal Ethics Note: 3.3 September 2010

Introduction:

The aim of this guide is to provide a checklist to assist members of the Animal Ethics Committees (AEC) to decide whether the use of animals is justified, based on whether the scientific or educational value of the work outweighs the potential impact on the animals being used.

To do this the committee must know:

- why the work is proposed
- why animals are needed
- what will be done to the animals
- what impact the work will have on the welfare of the animals

Project justification and description:

The project justification should clearly state:

- the broad context of the work
- the aim/s of the work
- the significance of the work
- why animals are needed
- what will be done to the animals in broad terms

The project description should provide:

- details of what will be done to the animals
- what impacts the interventions may have on animal welfare
- how the animals will be monitored and cared for
- a description of the endpoint of each experiment
- the phenotypes of any genetically modified animals and any special requirements they may have

An example of the difference between the project summary and the project description is that the summary would say that the animals will be anaesthetized, whereas the project description would say exactly how the animals are going to be anaesthetized (agents, route, dose rate) and how they are going to be monitored during and after the anaesthetic.



The AEC should be satisfied that it knows what is happening to individual animals within a project from the time of issue for use until the endpoint of the experiment.

The numbers of animals requested for use must be clearly justified. The application should include, as appropriate, power analysis or an explanation of numbers based on requirements for tissue sampling, logistics/equipment etc. In some cases it may be better to use more animals to minimise the pain and distress caused to an individual animal.

The AEC must know who is responsible for the work with animals. For each person named in a proposal there must be **details** about:

- what they will do to the animals
- what experience they have with the procedure(s) they will carry out on live animals
- what training they will need, and how such training will be provided (i.e. who will provide the training)



Assessing an application to the Animal Ethics Committee – What questions should I ask?

Do I really understand the application?

- 1.1 Is it written in plain English?
- 1.2 Is it easy to follow?
- 1.3 Is there minimal use of acronyms and abbreviations or where acronyms and abbreviations are used, are they explained?
- 1.4 Are there any words that I don't understand and need clarification on?

Justification for this activity

- 2.1 Do I clearly understand why this activity is being done?
- 2.2 Do I consider this activity to be essential for the achievement of the stated objectives?

Replacement principle

- 3.1 Is it necessary to use live animals to achieve the stated objectives?
- 3.2 Have alternatives to the use of animals been considered for this activity?
- 3.3 Are there good reasons provided for not using alternatives to live animals in this activity?

Reduction principle

- 4.1 Do I know exactly how many animals are being used in the activity?
- 4.2 Is the number of animals to be used appropriate to achieve the stated objectives, or is it too many or too few?
- 4.3 Is the activity, or any part of it, a repeat of work already done? If so, do I consider the reasons good enough for repeating it?

Refinement principle

- 5.1 What species and class/type of animal are being used in the activity?
- 5.2 Are there measures in place to minimise any pain or distress to the animals?
- 5.3 Are the species and type of animal to be used appropriate for achieving the stated objectives of the activity?
- 5.4 Do I understand what exactly will be happening to the animals at all times during the activity, including where they will be housed?
- 5.5 Am I satisfied that the Standard Operating Procedures fully describe the procedures to be used on the animals during the activity?
- 5.6 Am I satisfied the people carrying out the procedures are competent to do so?
- 5.7 Am I satisfied that the stated monitoring program is thorough enough and that the nominated people are competent to monitor the animals and treat them as required?
- 5.8 Am I satisfied that the parameters for withdrawing animals from the activity sufficiently protect the welfare of the animals?
- 5.9 If there is an animal emergency, are there appropriate measures in place to deal with it and minimise any suffering to the animals?
- 5.10 What happens to the animals at the end of the activity? Do I consider this appropriate?

The following checklist may also be useful....



Scientific procedure application checklist

Project title	Yes	No
Does it describe the work proposed?		
Project duration	Yes	No
Is the proposed duration stated?		
Safety	Yes	No
Are there any safety issues for humans or other animals?		
Justification for the use of animals	Yes	No
Are the aims clearly stated?		
Is the significance of the work clear?		
Is the outline of the project design clear?		
Do I know...	Yes	No
Broadly what is going to be done to the animals?		
Replacement	Yes	No
Is it clear why alternatives are not being used?		
Reduction	Yes	No
Are the numbers requested justified?		
Refinement	Yes	No
Do I know...	Yes	No
Where the animals will be housed and who will care for them at all stages of the project?		
Whether any genetically modified animals have phenotypes which require special care?		
Project description	Yes	No
Do I know...	Yes	No
The meaning of all the terms used?		
The details of what will happen to each individual animal or group of animals from the beginning to the end of the project? (agents, dose rates, routes and frequency of administration, actions, anaesthesia, surgery, number of procedures per animal etc)		
The potential impacts on the animals' welfare of each procedure?		
What criteria will be used to monitor the animals?		
What will be done if welfare problems are identified?		
How the animals will be euthanased and disposed of?		
Whether early and subsequent inspections by the AWO are needed?		
Investigators	Yes	No
Do I know...	Yes	No
Who will be doing the work?		
What experience the named personnel have in the specific techniques described in the proposal?		
What training is needed?		
Who will provide the training?		
How the training will be provided?		



Application assessment for school based projects – Questions to ask:

1) Do I really understand the application?

- a) Is it written in plain English and easy to follow?
- b) Is there minimal use of acronyms, abbreviations and jargon?

2) Justification for this activity

- a) Do I clearly understand why this activity is being done?
- b) Do I consider this activity essential to achieve the stated educational outcome?
- c) Do I know how the achievement of the educational outcome will be assessed?

3) Replacement principle

- a) Is it necessary to use live animals to achieve the stated educational outcome?
- b) Have alternatives to animals been considered for this activity?
- c) Are there good reasons provided for not using alternatives to live animals in this activity?

4) Reduction principle

- a) Do I know how many animals are being used in this activity?
- b) Is the number of animals to be used appropriate to achieve the educational outcome, or is it too few or too many?
- c) Do I know the ratio of students to teachers and animals to students? Is it acceptable?
- d) Do I know the maximum and minimum animals to be used by each student?
- e) Do I know the maximum number of times an animal will be used?
- f) If this is a repeated activity, has the principle of the 3Rs continued to be applied with each application?
- g) Is it clear whether these animals have been used in previous activities? What is a reasonable limit to the number of activities the animal will be involved with?

5) Refinement principle

- a) What species and class/type of animal is being used in the activity?
- b) Are there measures in place to minimise any distress or pain to the animals?
- c) Are the species and type of animal to be used appropriate for achieving the stated educational outcomes?
- d) Do I understand exactly what will be happening to the animals at all times during the activity, including where they will be housed?
- e) Am I satisfied that housing is safe and appropriate for the animals?
- f) Am I satisfied that the Standard Operating Procedures fully describe the procedures to be used on the animals during the activity?
- g) Am I satisfied that the people carrying out the procedures are competent to do so?
- h) Is it clear to me who is responsible for care and welfare of the animals during the entire activity? When this passes between teacher and student, is that well documented?



- i) If the animals are to be kept for a period of time, am I satisfied that the people caring for the animals are competent to do so?
- j) Am I satisfied that the stated monitoring programme is thorough enough and that the nominated people are competent enough to monitor the animals and treat them as required? Are there clear steps outlined in response to an adverse event?
- k) Am I satisfied that the parameters for withdrawing animals from the activity sufficiently protect the welfare of the animals?
- l) If there is an animal emergency, are there appropriate measures in place to deal with it and minimise any suffering by the animals?
- m) What happens to the animals at the end of the activity? Do I consider this appropriate?



AEC guidelines

for management of adverse incidents

Animal Ethics Note: 3.4 September 2010

Background:

The *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* (7th edition) requires prompt reporting of adverse incidents to the AEC. The AEC is responsible for investigation of adverse incidents and for making recommendations to its institution to ensure that all care and use of animals for scientific purposes within the institution remains in accordance with the Code. AECs should develop policies regarding the reporting, investigation of and response to adverse incidents and, with support from the institution, implement procedures to promote compliance with the Code and the recommendations of the AEC. These guidelines are intended to assist AECs with these responsibilities.

Definition of an 'adverse incident'

'Adverse events' are any events having a negative effect on animal's wellbeing; as evidenced by abnormal physiological or behavioural response. They may be predictable consequences of research activities, or they may occur unexpectedly. It is **where they are unexpected, and particularly where they have not been anticipated in an AEC approval**, that they are considered 'adverse incidents' and require investigation.

Some examples of adverse incidents may include:

1. Unexpected death of an animal/group of animals;
2. Unexpected welfare deterioration either during/post procedure including diarrhoea, vomiting, respiratory issues, collapse, abdominal swelling, rapid weight loss or neurological symptoms;
3. Adverse effects in a larger number of animals than was expected;
4. Unforeseen levels of pain/distress.

It should be noted that the cause of these events does not bear any influence on whether an outcome is defined as an adverse incident or not. For example, power failure may lead to an increase in room temperature beyond the animals' normal capacity to cope. Prolonged drought may mean fieldwork populations have a greater incidence of mortality than predicted. Although these things may not be under the control of the principal investigator, they are nonetheless adverse incidents for the animals and should be reported and managed as such.

An adverse incident may be a breach of AEC approval

Many adverse incidents are entirely unexpected and occur despite extensive planning and risk mitigation. However, an adverse incident may occur as a result of a failure to adhere to the approved protocol, for example inadequate supervision of trainees or infrequent monitoring of post-operative animals. It is important to note that an approved AEC application is a 'contract' between the investigators named on the application and the AEC. This contract forms the basis of an exemption from the *Prevention of Cruelty to Animals Act 1986*. Deviation from the approved procedures constitutes an offence under this Act and exposes investigators to the full extent of the law.

Failing to respond to an adverse incident (eg, by refusing to treat or euthanase an animal in pain or distress) is also a breach of the Act. **Any person** who finds an animal in pain or distress has a statutory obligation to initiate action to address the situation.

In exceptional circumstances, a person may feel unable to take action despite an animal's pain or distress. In these cases, and where all institutional avenues have been exhausted, the Bureau of Animal Welfare (Principal Veterinary Officer) should be contacted on 9217 4200.



The major phases of Adverse Incident Management are:

1. Prevention of Adverse Incidents
2. Initial Response to an Adverse Incident
3. Investigation and preparation of an Adverse Incident Report (AIR)
4. AEC review of Adverse Incident

1. Prevention of adverse incidents

Experimental design supported by appropriate risk management can prevent or contain adverse incidents. For each protocol, it is essential that the AEC is aware of all potential impacts on animal welfare. Investigators must not assume that the AEC is aware of any side-effects of any substances or potential for harm in any procedures. They must describe each possibility in lay terms.

Prior to giving its approval, the AEC must be satisfied that the investigator has frankly disclosed:

- i. The effect of each procedure on the animals and any welfare impact;
- ii. The nature of known or reasonably expected animal welfare impact and the cumulative impact of a series of procedures for each cohort and control group;
- iii. How experimental design techniques such as pilot studies, sequential dosing, progressive staging of experimental phases or sequential terminal sampling have been incorporated to minimise animal welfare impact and the risk of adverse events;
- iv. Potential sources of risk to animal welfare; and
- v. How risk factors will be monitored and controlled during the project.

In addition to compliance with the Australian Code, compliance with the AEC policy on adverse incident management may be made a condition of AEC approval.

Training of investigators and animal care staff to anticipate and respond to adverse events is essential to minimising risk. Many adverse incidents can be prevented if staff are aware of the right course of action. The precedence of animal welfare over completion of the project should be emphasised.

2. Initial response to an adverse incident

2.2. Address animal welfare first

When welfare is no longer consistent with AEC approval, immediate action is required of the person that first notices the problem. The investigator, their delegate, or, in their absence, a person nominated by the AEC (Australian Code section 2.2.35) should be notified and direct the response. The welfare interest of the individual animal must take precedence over continuation or completion of the research or teaching protocol. Each AEC should formalise its own procedures but the following recommended steps will have relevance for most situations:

- i. The experimental or teaching activity using affected animals must cease and all welfare issues addressed without delay. This may involve euthanasia or treatment of the animals involved, with appropriate advice. Veterinary advice or advice from animal care personnel may be mandated by the Adverse Incident policy.
- ii. Potential risks to animals in other cohorts or arms of this or related projects must be assessed and a risk management plan instituted.

There should be a contingency in the Adverse Incident policy for disagreement on whether the event is adverse to the animal or not. A possible solution is that an Animal Welfare Officer or veterinarian be made available to independently assess the animals in the case of serious disagreement between staff responsible for the animals.



2.2. Prompt initial reporting

As soon as immediate animal welfare issues have been addressed, the Investigator should advise the Chair of the AEC. The Animal House Manager and Animal Welfare Officer/institutional veterinarian should also be advised if not already aware of the situation.

If other cohorts or arms of this or other projects may be affected, the investigator should consult the AEC Chair and Executive to clearly determine which areas of work are suspended pending finalisation and review of the Adverse Incident Report.

2.3. Responsibility for reporting to the AEC

Adverse incidents are reported because the standard of animal welfare has departed from that approved by the AEC. The primary responsibility for reporting an adverse incident to the AEC is that of the investigator or teacher. From a practical perspective, adverse incident reporting of morbidity and mortality which stem from non-experimental activities such as colony management or facility-wide equipment failure are more appropriately the reporting responsibility of the Animal Facility Manager. Failure to report promptly to the AEC represents a breach of the Code of Practice (§2.2.28).

3. Investigation and preparation of an Adverse Incident Report

Incident reporting is a well established method of obtaining information about errors to assist in the identification of causal and contributing factors. A thorough investigation is required to produce a useful Adverse Incident Report (AIR). Investigation of an adverse incident should include where applicable:

- i) Post mortem examinations and/or necropsies, with the assistance of the institutional veterinarian or other competent personnel, to clearly establish the cause of death;
- ii) A review with all personnel involved in the research and animal care teams to document the timeline and gather full details of the incident;
- iii) Rigorous analysis to identify causes or factors contributing to the adverse incident, and
- iv) Submission of an AIR to the AEC including recommendations to prevent recurrence.

In some instances the preparation of the report may be a lengthy process. Frequent contact with the AEC Chair and Executive Officer may be necessary to provide regular progress reports.

At a minimum, an AIR should include:

- i) a brief lay summary of the experimentation originally approved by the AEC (including total number of animals approved) and brief details of any previous incidents relating to the application,
- ii) a concise description of the adverse incident including location, dates and times,
- iii) details of the animal welfare impact by animal (morbidity and mortality) and the total number of animals affected by the incident,
- iv) details of personnel present and/or involved,
- v) a summary of the initial response to the incident,
- vi) identification of potential causal factors including materials, methods and/or environment,
- vii) analysis and assessment of contributing factors, and
- viii) conclusions and recommended actions to prevent future such incidents.



4. AEC Review of an adverse incident

The purpose of the AEC review of the Adverse Incident Report is to determine whether the benefits of the project predicted in the application continue to outweigh the costs to the animal, given the nature and scale of the adverse incident. The AEC must also make recommendations to ensure that all care and use of animals for scientific purposes within the institution remains in accordance with the Code and to manage any non-compliance. If causal or contributing factors have not or cannot be dealt with by the investigator or teacher, the AEC must make recommendations to the institution to resolve the matter.

In making its recommendations, the AEC should consider, in addition to the AIR and any discussions with the investigator and/or other personnel:

- i) The seriousness of the harm caused
- ii) The level of culpability of the personnel involved (for example, was the adverse event intentional, reckless, negligent, or a mistake?)
- iii) Whether sufficient information was disclosed at the time of the original application for AEC approval
- iv) Whether or not the person, facilities or equipment involved have a history of prior adverse events
- v) Whether or not the personnel involved have complied with the Adverse Incident policy
- vi) The potential for conflict of interest with respect to the personnel involved
- vii) The likelihood of the adverse event continuing or being repeated
- viii) The prevalence of the type of adverse event
- ix) The likely public perception of the adverse event and the manner with which it is dealt
- x) The deterrent effect

It is important that institutions and their AECs encourage a culture of transparency and disclosure to promote continuous improvement, quality management and compliance. The way in which an AEC investigates and reviews adverse incidents will have a significant effect on compliance with the Adverse Incident policy.

Having considered the AIR, the AEC may determine that:

- i) All necessary steps have been taken to prevent a recurrence and experimentation or teaching can resume with or without additional conditions, or
- ii) Further action must be taken by the AEC or the institution.

In determining an appropriate course of action, the AEC should consider the following hierarchy of responses:

- i) Warnings (including listing on the Adverse Incidents register)
- ii) Directions by the AEC (training, restoration, improvements in facilities or equipment)
- iii) Temporary suspension of the project (while directions are carried out)
- iv) Reporting to the Bureau of Animal Welfare
- v) Increased inspection or reporting frequency
- vi) Withdrawal of project approval
- vii) Formal discipline

Adverse Incident Register

The AEC should record the incident and the determination in a central register to allow for future reference and an overview of all adverse incidents. Depending on the nature and/or the gravity of the incident, they may inform and make recommendations to the institution, the licence nominee, the investigator and, where appropriate, the Bureau of Animal Welfare.



AEC guidelines

for site inspections

Animal Ethics Note: 3.5 September 2010

Introduction:

Site inspections and monitoring are an important aspect of AEC membership that allow members to gain a first hand knowledge of the AEC approved animal housing and projects. It is also a good opportunity to meet investigators and teachers carrying out those projects plus animal facility/care staff.

The Code requires that AECs monitor all animal facilities and laboratory areas, preferably on an annual basis. By carrying out site inspections, the AEC can be assured that the general welfare of the animals is considered and that investigators and teachers are carrying out their activities according to the requirements of the Code and any conditions specified by the AEC.

Who should attend a site inspection?

- The AEC Chair is responsible for organising a site inspection.
- As many members of an AEC as possible should attend site inspections. The AEC Chair should give sufficient notice of site inspections so that members can talk to the investigators about their projects.
- The Code requires that at least one independent committee member (that is, not associated with the institution) attend each site inspection.
- The animal facility staff should also be present, and a report of the site inspection made to the Licence Nominee.

Inspections:

Site inspections will vary in their length and assessment criteria depending on the type of animal facility, the type of research being conducted there and stage of current projects.

Where possible site inspections should include the monitoring of some individual projects in the inspection. Records should be examined to confirm that researchers and teacher are meeting the commitments that they have made in their applications

Some key aspects to consider during inspections are:

Facilities:

- Are the animal facilities in good repair and of adequate standard?
- Are general hygiene, husbandry, pest control, food storage, etc. appropriate?
- Are good records kept with respect to the maintenance of the facility, animal husbandry, health and monitoring?

Animals:

- Are individual animals (wherever possible) as well as cages/pens identified to indicate whether they are part of a specific project or not?
- Is individual animal housing appropriate and necessary?
- Are the animals coping with situation they are in? For example, are they showing signs of stress/distress such as abnormal behaviour, weight loss, injuries etc.
- Are pain and stressors minimised?
- Is there opportunity for social contact and appropriate environmental complexity (enrichment)?



- Are the animals adequately monitored (regularly as well as associated with particular procedures) and are the relevant records available?
- Do the paddock animals have satisfactory shade/shelter, water and body condition?

Risk management:

- Are there appropriate security and emergency backup systems (for power, water failure) in place?
- Is there adequate after hours/weekend monitoring?
- Are there sufficient emergency contacts and are their details readily available/displayed in a prominent position?
- Are there contingency procedures for emergency treatment and euthanasia established and are the readily available/displayed in a prominent position?

Continual improvement:

- Have any problems identified in previous audits/inspections been adequately addressed?
- Is there an open and accountable attitude?
- Is communication effective amongst teachers/ investigators and animal facility/care staff?

Individual projects:

- Is the project being conducted according to the Code and the approved application including any specific conditions?
- Are records available?

Recording the inspection

The outcome of the inspection and any resulting actions should be discussed at the following AEC meeting and recorded in the minutes. The Australian Code (2.2.29) describes the necessary inclusions: "Records of inspections should include the names of those who attended, observations, any identified problems, follow-up and outcomes."

Useful Resources:

The CCAC have a series of site inspection templates that may be useful as a guide for developing paperwork for your own inspections. These templates can be found at the following link

http://www.ccac.ca/en/CCAC_Programs/Assessment/review_form.htm in Section 6 of the Preparation Form.



Applications involving multiple AECs

Animal Ethics Note: 3.6 September 2010

Introduction:

Research projects involving more than one institution and Animal Ethics Committee (AEC) can create confusion over the extent of responsibility and oversight by each institution and AEC. There are various scenarios where multiple AECs might have an interest in an application to use animals:

- a. Where animal use is conducted at a site not licensed to the researcher's employer, with or without collaborative ties to a researcher at that site;
- b. Where animal use is conducted partly at the researcher's employer's site and partly elsewhere, with or without collaborative ties to a researcher at the second site.
- c. Where animal use may be conducted by employees of a large institution with multiple licences and AECs, in multiple sites.

Animals may spend a brief period at either site (eg, for imaging or other specialised procedures); or they may be held for long periods at both sites. Animals may be cared for by animal care staff or by researchers, and this may change during the project and/or depending on the site. Standard operating procedures may exist for specialised facilities that are unknown to the approving AEC. Emergency and adverse incident reporting must be directed to the authority with the capacity to respond.

To ensure the best outcome for animals used in these projects, a clear delineation of responsibilities of all parties involved is essential. This guideline is intended to provide institutions, researchers and AECs with suggestions for meeting their statutory obligations and ensuring the welfare of animals used in their projects.

What is the legal framework?

In Victoria, the licensing of animal use in research and teaching depends on the places where the animal use occurs. Premises usually used for scientific procedures (the use of animals for research or teaching) must be authorised for that use by a Scientific Procedures Premises Licence (SPPL). The 'occupier' (owner or tenant) of the premises holds the licence. Where scientific premises are not used (eg, field research, the use of veterinary clinics or farms), a Scientific Procedures Fieldwork Licence must be held by the legal entity (institution or person) performing the scientific procedures. All use of animals under a scientific procedures licence must comply with the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes (2004, 7th edition) (The Australian Code).

Each licence must establish a relationship with an AEC. The AEC is linked to the licence which is itself (if it is an SPPL) linked to the premises.

The Principal Investigator is responsible for ensuring that all animal use is first approved by an AEC, and is primarily responsible for the welfare of the animals during the project.

The licence holder is liable for non-compliance on the licensed premises. In the event of non-compliance, the licence holder for the site, the licence nominee responsible for the site, the Principal Investigator and potentially the AEC may be in breach of the legislation. There are penalties associated with breaches by the licence holder, licence nominee and principal investigator. The legislation requires non-compliant AECs to be replaced by the licence holder.

More information regarding the role of AECs may be found in Animal Ethics Note 3.1, *Animal Ethics Committee Membership*. More information on the responsibilities of institutions may be found in Animal Ethics Note 2.1, *Responsibilities of Institutions Towards Ensuring the Welfare of Animals in Research and Teaching*.



The Australian Code makes reference to projects involving more than one AEC:

§2.2.41: *Where projects are to be conducted at more than one institution, procedures must be in place to ensure that:*

- (i) *animals will be well cared for in all phases of the project;*
- (ii) *the responsible AECs are in a position to inspect the animals during all phases of the project;*
- (iii) *before any work commences each AEC approves, or delegates approval of, scientific and teaching activities being conducted by members of its institution;*
- (iv) *clear communication channels are established between all involved AECs and investigators and teachers; and*
- (v) *such arrangements between institutions should be as a formal agreement that ensures that all parties involved are aware of and can meet their respective responsibilities under the requirements of the Code and relevant legislation; and*

§2.2.42: *Where parts of a project take place at different institutions, each AEC may choose to approve and monitor only those parts that take place at their institution. Notwithstanding this arrangement, it is essential that each AEC is cognisant of all aspects of the project and ensures that any cumulative impact of procedures on animals is considered. Such arrangements should be part of a formal agreement between the institutions involved, and*

§3.1.5: *When seeking approval for a project, investigators and teachers must inform the relevant AEC of other scientific and teaching institutions participating in the project (see 2.2.41).*

§3.1.6: *Investigators and teachers must notify their institutional AEC in writing when seeking approval to participate in scientific and teaching activities at another institution through that institution's AEC (see 2.2.41).*

Defining the responsibilities of researchers and AECs

There is a clear need to reduce duplication of ethical review of applications. Victorian AECs are formally audited by the Bureau of Animal Welfare every 3 years, providing an independent assessment of their compliance with the Australian Code and, if necessary, recommendations for improvement. AECs and researchers must have confidence in the auditing and review system if the risk of overloading the AEC system is to be avoided.

To meet their obligations under the legislation and the Australian Code, researcher(s) should, in consultation with their employing institution, elect a primary AEC to review their application. The secondary AEC must be informed of the work to be conducted at their site. The level of detail required by the secondary AEC will vary depending on the nature of the work and the individual sites to be used. As a minimum, it is recommended that the researcher(s) use the Bureau of Animal Welfare Fieldwork Notification Form (see Appendix 1) to communicate essential information regarding the project and monitoring arrangements to the secondary AEC. This will establish that the secondary AEC has delegated its role as per 2.2.41(iii). Secondary AECs may request a copy of the full AEC application for noting or endorsing if they wish.

Secondary AECs taking on a duplicate review of the approved application risk introducing confusion as well as legal uncertainty about the status of each approval. Serious concerns about the approved application should be negotiated with the primary AEC and researcher directly. Secondary AECs requesting minor amendments, for example accommodating local conditions or existing SOPs, should request the researcher to incorporate these into their original application, by applying to the primary AEC. It is an offence to carry out procedures not described in the approved application.



Interstate researchers and AECs: all scientific procedures carried out in Victoria must be performed under the auspices of a Victorian Scientific Procedures Licence. In some cases it may be acceptable for an interstate AEC to approve activities conducted under a Victorian licence – please consult the Bureau of Animal Welfare for specific advice regarding these arrangements.

Researchers accessing multiple AECs in large institutions

Occasionally researchers employed by large institutions may use animal facilities that are licensed to their employer, but not linked to the licence under which they normally work. These animal facilities are overseen by the AEC associated with the licence which authorises the use of those facilities.

In order to maintain compliance with the Australian Code, researchers working across licences within their employing organisation should follow the same principles as those working with AECs from different institutions. Generally, the AEC responsible for the premises, or its delegate (institutional veterinarian or Animal Welfare Officer formally delegated by the AEC), should be notified of the work and any modifications to the application made accordingly.

Communication with animal facility staff

To complete the chain of communication regarding the multi-AEC project, information must be provided to animal care staff at all facilities where the animals are to be held. This information must include emergency contacts for the project, monitoring responsibilities and any other relevant information. The complete AEC application, or the Fieldwork Notification, may be displayed where the animals are held.

What if something goes wrong?

Adverse events must be reported to the approving AEC as soon as possible. See Animal Ethics note 3.4, *AEC Guidelines for the Management of Adverse Incidents*, for more information on the investigation and resolution of adverse incidents.

Common sense must be exercised in the reporting of adverse incidents that occur outside the remit of the approving AEC. For example, if failure of equipment, essential services or local monitoring leads to an adverse incident, it is essential that the AEC responsible for monitoring those facilities be informed, so that they may take appropriate action.



Examples of solutions to multi-AEC applications

Scenario	Primary AEC	Secondary AEC	Monitoring
<ul style="list-style-type: none"> • Researcher X takes animals that are already under experimentation at Institution X to Institution Y for further experimentation • Researcher X is collaborating with Researcher Y • Researchers X and Y both perform procedures on live animals 	X	Y	X then Y
<ul style="list-style-type: none"> • Researcher X goes to Institution Y to collaborate with Researcher Y • Animals are supplied by and housed at Institution Y • Researcher X and Y <u>both</u> perform procedures on live animals 	Y	X	Y
<ul style="list-style-type: none"> • Researcher X goes to Institution Y to collaborate with Researcher Y • Animals are supplied by and housed at Institution Y • Researcher X only perform procedures on live animals 	Y	X	Y
<p>Researcher X is contracted by Institution Y to produce a biological product at institution Y</p> <p>Animals are supplied by and housed at Institution Y</p> <p>Technicians from Y & Researcher X perform procedures on live animals</p>	Y	-	Y
<ul style="list-style-type: none"> • Researcher X takes animals that are already under experimentation at Institution X to Institution Y to use equipment available at that Institution Y • Researcher X is <u>not</u> collaborating with Researchers at Institution Y • Researchers at Institution Y do or do not handle the live animals in order to help Researcher X use the equipment. 	X	Y	X then Y
<ul style="list-style-type: none"> • Researcher X takes animals that are already under experimentation at Institution X for contract services at Institution Y • Researcher X is <u>not</u> collaborating with Researchers at Institution Y • Researchers at Institution Y carry out the contract service (eg. scanning, specialised behavioural testing) 	X (nb researchers at Y need to appear on the application)	Y	X then Y
<ul style="list-style-type: none"> • Researcher X provides animals that had been subjected to experimentation at Institution X to researchers at Institution Y • Researcher X is <u>not</u> collaborating with Researchers at Institution Y • Researchers at Institution Y carry out a separate set of experiments on live animals 	Y	-	Y



Post-approval monitoring

Animal Ethics Note: 3.7 September 2010

Introduction

The care, handling, housing and use of animals in research and teaching in Victoria is regulated through the Prevention of Cruelty to Animals Act 1986, associated Regulations 2009, and through the following mandatory Codes of Practice:

- The Australian Code of Practice for the Care and Use of Animals for Scientific Purposes, 7th edition;
- The Victorian Code of Practice for the Housing and Care of Laboratory Mice, Rats, Guinea Pigs and Rabbits; and
- The Victorian Code of Practice for the Use of Animals from Municipal Pounds in Scientific Procedures.

The governance role of the organisation using animals in research and teaching is outlined in the Australian Code (section 2.1) and is complemented by the governance roles of the institutional Animal Ethics Committee (AEC). As a scientific procedures licence holder or a specified animal breeding licence holder, the institution has further responsibilities (conditions of licence) that are described in the *Prevention of Cruelty to Animals Act 1986* and Regulations. The Bureau of Animal Welfare within the Department of Primary Industries administers the legislation and the licensing system and carries out its own inspections and enforcement activities.

The Australian Code requires that institutions “implement processes so that the governing body of the institution or its delegate is assured of compliance with the Code and relevant legislation”.

In order for institutions to meet their obligations with respect to ensuring compliance there needs to be a system of validating that the commitments made to the AEC with respect to animal care and use have actually been carried out; a *post-approval monitoring system*.

Benefits of a post-approval monitoring program

Aside from compliance benefits, a properly resourced and conducted post-approval monitoring program enables:

- detection of problems at an early stage when they are easier to manage;
- greater communication between applicants and AECs, with flow-on effects such as improved application quality, feedback on the impact of AEC decisions, prompt adverse incident reporting;
- increased ability to assess and monitor researcher competency, identify training needs and training opportunities (eg, skilled researchers who might be able to train others in specialised procedures);
- better scientific outcomes through consistency and good animal welfare.

Setting up for success

A post-approval monitoring program will reap the most rewards when the institutional framework is set up to prevent non-compliance. For a post-approval monitoring program to run smoothly there needs to be a clear understanding by researchers, teachers, students, animal care staff and AEC members as to their roles and responsibilities in the care and use of animals in research and teaching.

An institutional training program should inform all parties of their legal obligations and provide support to meet those obligations (for example, provision of record-keeping templates on intranet, easy access to AEC information, supplying hard copies of the Australian Code).

Clear policies should be in place to outline the management of non-compliance with AEC approvals.



Designing a post-approval monitoring system

While post-approval monitoring systems will vary between the institutions, some fundamental principles will universally apply.

- The program must have explicit support from senior institutional management. AECs are central to an institution's oversight of compliance with the legislation and Australian Code. Any post-approval monitoring program will need to be approved by and conducted in association with an AEC. However, AECs are not always able to act unassisted to ensure that projects are adequately monitored or that non-compliance is dealt with appropriately. Hence, a clear reporting line from the AEC to the controlling body of the organisation (CEO, Council etc) is essential.
- Consistency, transparency and commitment to following issues up are essential.
- Data management is important and allows 'corporate memory' to be passed on easily when key personnel change.

There are 3 basic models for post-approval monitoring. The option adopted by an institution will largely depend on resources available but should relate principally to the volume of animal work being conducted.

1. AEC members conduct all post-approval monitoring: this arrangement will work well in smaller institutions without the resources to fund independent officers with animal welfare responsibility. However, AECs are becoming busier with more projects, collaborations, facilities upgrades and construction taking place. Essential to the AEC process is the involvement of independent volunteers, many of whom have busy professional and personal lives but give a significant amount of time to considering applications and attending meetings. AECs generally come together at regular intervals to consider applications and standard operating procedures (SOPs); but are unlikely to be present when animal use is being carried out. A productive and useful post-approval monitoring programme should be designed and implemented jointly by the AEC and its institution, and should not over-burden the Committee with unsupported responsibility or unreasonable demands on volunteer time.
2. An Animal Welfare Officer conducts post-approval monitoring on behalf of the AEC and the institution: The Australian Code advises that institutions "consider appointing an officer with veterinary or other appropriate, qualifications who is authorised by the AEC to ensure that projects are proceeding in compliance with the Code and the decisions of the AEC." This option can be very worthwhile as it additionally provides a resource of contemporary veterinary information into the organisation for the benefit of AEC members and researchers.
3. In large institutions an independent office may be established specifically to uphold animal welfare standards. This option provides an institution with excellent risk-control and the capacity to encourage best practice. It may or may not stand separately to the management of animal facilities but there are advantages to independence. There is the potential for this office to contribute substantially to the institutional training program, both in legal obligations and technical skills, as well as providing leadership within the organisation on animal welfare standards. Note that the office must work cooperatively with the AEC to achieve the requirements of the Australian Code with respect to AEC monitoring responsibilities.



Dealing with non-compliance

A policy, supported by the management structure of the institution, should be in place prior to establishing a post-approval monitoring program.

The Australian Code requires that the institution implement processes to:

- address concerns raised by the AEC regarding non-compliance with the Code which may include disciplinary action upon advice of the AEC;
- respond promptly and effectively to recommendations from the AEC to ensure that all care and use of animals for scientific purposes within the institution remains in accordance with the Code.

The Australian Code requires AECs to:

- establish fair and effective procedures to deal with non-compliance with the Code and to ensure that there is appropriate reporting to the institution;
- ensure that non-compliant activities immediately cease and remedial action is initiated.

Reporting on findings

The findings of the post-approval monitoring may be included in the annual report of the AEC to the institution. This emphasises the important service provided by the members of the AEC to the institution and keeps senior managers apprised of any trends in compliance that may need to be addressed more widely than at the project level. Non-compliance with critical animal welfare impact should be reported on an individual basis.

Reporting to the Bureau of Animal Welfare should be considered if the AEC is unsure about appropriate action to take or if they are concerned that serious non-compliance has taken place. The Bureau of Animal Welfare can offer advice to institutions and AECs on management of non-compliance and appropriate actions to take to ensure that similar situations do not arise again.







The Three R's

Animal Ethics Note: 4.1 September 2010

Background:

Investigators are required by law to minimise any pain or other harm to the animals used for research and teaching. The *3Rs Principle* must be applied at the planning stages of any animal work.

The purpose of the Three R's is to provide a framework to address the ethical dilemma created by the use of animals for research and teaching, by ensuring that animals which might suffer are only used when necessary (Replacement), that no more animals are used than are required to achieve the objectives of the work (Reduction), and that any noxiousness arising from the work is kept to a minimum (Refinement).

Planning a project

When planning a project, scientists must ask themselves 3 questions:

Question 1: "Do I need to use higher order animals at all?" This is the principle of Replacement. If the answer is "Yes" then Reduction and Refinement must be applied.

Replacement means that animals should not be used at all if the same aim can be achieved in other ways. The word "animal" refers to those higher order animals that are capable of suffering or feeling pain.

Examples of replacement of higher order animals in research and teaching:

- Computer modelling, in vitro methodologies, human volunteers
- Established animal cell lines and animal cells, tissues and organs where the animal was killed by a humane technique before collection of the material
- Non-sentient invertebrates, such as *Drosophila* and nematode worms

Question 2: "What is the lowest number of animals needed for this work?" This is the principle of Reduction.

Reduction means keeping the number of animals used to the minimum necessary to achieve the purposes of the work. It is equally important to avoid using too few animals. The use of too few animals may result in insignificant or inconclusive results.

Examples of reduction in animals used in research and teaching:

- Improved experimental design and statistical analysis
- Techniques, such as imaging, which require smaller numbers of animals
- Pilot studies, which may help define endpoints (refinement) as well as indicating whether a particular course of study is worth pursuing

Question 3: "How will these procedures impact on the animals?" This is the principle of Refinement.

Refinement refers to minimising any pain, suffering or other harm, which may be caused by the work. This means that every aspect of the work must be reviewed carefully and great care taken to minimise any noxious effects on the animals. It is worth noting that many studies cause very low or no pain, suffering or other harm to the animals involved.

Examples of refinement of the use of animals in research and teaching:

- Providing appropriate anaesthetic and analgesic regimes
- Training animals to co-operate with certain procedures (e.g. taking blood samples) so the animals are less stressed
- Ensuring that accommodation meets the animals' needs (e.g. providing opportunities for nesting for rodents)



Balancing harm and benefit

Conducting a harm-benefit analysis is an essential part of planning to use animals for research or teaching. The main ethical principle that guides most animal use in science is:

“Using animals for scientific purposes is acceptable only when any harm done to the animals is very greatly outweighed by the benefits of their use”.

Scientists and Animal Ethics Committees (AECs) must work together to ensure three things before a project proposal can be approved.

1. They must make sure that any harm caused to the animals is minimised – as low as it can be.

This is achieved by applying the Three Rs Principle when developing and reviewing the proposed procedure. Application of the Three Rs Principle helps to ensure that animals are only used when that is really necessary, that no more and no fewer animals are used than are required to achieve the objectives of the work, and that if any noxiousness or harm is caused during the work, it is kept as low as possible.

2. They must make sure that the expected benefits of the work are achievable and maximised - as great as possible

This is achieved in two steps:

- The first step is to carefully examine the precise scientific aims of the procedure, ensuring that the aims are achievable; that is, can those aims be fully realised using the methodology and animals described?
- The second step is to carefully assess the benefits of the proposed project by:
 - o For research projects, what value the new knowledge will or might have in helping to solve the health, welfare, practical, economic or other problem it is designed to address.
 - o For teaching exercises, how the proposed procedure will enhance students’ learning about body processes. For testing procedures, whether they are legally required and can appropriately assess the safety or effectiveness of chemicals, drugs, medicines, vaccines and other substances.

3. They must weigh any expected harm to the animals against the anticipated benefits of the work by weighing the most important principle:

“The greater the harm or noxiousness the greater must be the expected benefits before a procedure can be approved”.

While a proposal may be expected to bring very great benefits that could justify causing greater harm to the animals used, scientists and AECs must still conscientiously apply the Three Rs. Similarly, even when any harm is already quite low, all attempts to further reduce the level of harm should be made.

Statistics and experimental design

Where there is no alternative to the use of animals in research and teaching, it is important that experiments are well designed and correctly analysed in order to maximize the chance of obtaining scientifically valid results with the minimum number of animals. Experiments that use too few animals may fail to pick up biologically important effects.

If the potential impact on the animal is unknown, it is appropriate to incorporate a pilot study into the project design to allow a staged assessment of the impact on animal welfare and how it will be managed. Pilot studies should be regarded as integral to the overall project and should be assessed by the AEC according to the usual criteria applied to project approval.

For further information please refer to Animal Ethics Note 4.3: *“Interpreting Experimental Design and Statistical Analysis.”*



Understanding and interpreting a research plan

Animal Ethics Note: 4.2 September 2010

Background:

Scientists and teachers intending to use animals for research or teaching purposes have a legal and ethical obligation to ensure the well-being of the animals destined for use in their activities. An essential element of ensuring the welfare of animals used for research or teaching purposes is **good planning**. It is important that all AEC members are capable of interpreting a research plan developed by a scientist. This document will attempt to guide AEC members through the planning process and explain the reasons for each step.

What is the research question?

What does the researcher wish to find out?

A clearly defined research question or teaching objective is essential; providing the investigator with a specific purpose or direction. Usually the research question can be found in the “aims” of the project. It is important that a thorough literature search is conducted to determine what information is already available and to try to narrow the focus of the question or objective. There is no point in repeating work that has been done before; nor is there any point in making the same mistakes or leaving the same gaps in knowledge as previous research.

In some studies the research question may have multiple components, in other cases there may not be a question per se, rather the investigator may want to demonstrate something or establish that an assumption does actually hold under laboratory or field conditions.

What is the hypothesis?

The hypothesis is essentially an assumption or an educated guess about the likely answer to the research question based on evidence gathered from previous research, anecdotal evidence or theoretical conjecture. It is usually written in a statement form that addresses the research question.

A hypothesis includes two variables:

- an independent variable and
- a dependent variable.

(A variable is anything that changes in the course of an investigation.)

In constructing a hypothesis, **one variable at a time** is selected and a suggestion is put forward as to how this might influence the event under investigation. The variable selected is called the Independent variable.

Usually there are two different hypotheses stated: the “null hypothesis” and the “alternative hypothesis”. These are relatively complex statistical concepts, but in short, a null hypothesis states that the “independent variable” will **not** influence the event under investigation. The alternative hypothesis states that the independent variable **will** influence the event under investigation and, depending on the nature of the research question, the alternative hypothesis may state how the independent variable will influence the event.

It is important to note, that **not all research questions** will be accompanied by a hypothesis, particularly if the research questions is a statement or a demonstration. In addition, the hypothesis is often assumed within the research question itself, and is not stated separately.



How does the investigator plan to answer the question?

After developing the research question or objective and the hypotheses, the investigator needs to determine the best way to answer that question. Again, the literature can help to guide the development of the research proposal and methodology. It is important to utilise previous research to determine what may or may not work with a particular species or with specific procedures – knowing the mistakes of others means that these mistakes are more likely to be avoided.

Once the investigator has established how they plan to answer the research question, the most important question you need to ask is “Do they really need to use animals to answer the research question, or can the question be answered by interpreting existing data in the literature? [This is also known as the principle of Replacement – see “Three R’s” Information Note].

If the answer is “Yes” then a review of the literature should provide them with the answers they seek.

If the answer is “No”, then the scientist needs to determine (if they have not already done so) which species would be optimal for answering the question. Returning, again, to the literature the investigator should review whether this species has been used in this type of research; asking questions such as:

- how have different studies managed the species?
- what were the procedures undertaken on the species?
- were all procedures/experimental activities successful? Why, why not?
- why were the outcomes from those studies not sufficient to answer your research question?

[This is the first step towards the principles of Reduction and Refinement – see “Three R’s” information note.]

Interpreting a methodology

Once it has been established that the existing literature is insufficient to answer the research question/objective, and the existing literature has been reviewed to help determine which animal species and which scientific procedures may be necessary to answer the question, you need to review the proposed methodology, taking the following into consideration:

- What experimental procedures are included in the methodology?
- What is known/does the investigator know about the behaviour of the animal species?
- Will the natural behaviours of the animal impact on the ability to use the proposed experimental procedures? If yes, how is the investigator planning to deal with this?
- Does the investigator know if the animal species has specific housing and husbandry requirements; and if yes, how might these requirements impact on the investigator’s ability to answer the research question and the design of my experimental procedures?
- What types of stressors will the proposed methodology put upon the animals?
- Will any stress experienced by the animals impact on the validity of the research results?
- At what point will an animal be removed from the study when they begin to show signs of stress or distress?
- How many animals are needed and has the investigator consulted a biometrician to help utilise the variation (the estimated differences between individual animals) reported in the literature to determine the minimum number of animals required to provide me with statistically powerful results?



Further information on experimental design and statistical interpretation can be found in Animal Ethics Note 4.3: *“Interpreting Experimental Design and Statistical Analysis.”*

[Again, these questions are helping to address the principles of Reduction and Refinement – see “Three R’s” Information note.]

Having answered all these questions and gathered as much information about the behaviour and housing and husbandry needs of the animals, you should assess the proposed methodology on the merits of benefits versus harm to the animals.

Where new procedures or untested procedures are being planned, particularly the procedures which are likely to have a great impact on the animal, you may wish to suggest that the investigator conduct a small pilot study to test whether the proposed methodology is suitable for answering the research question.

Assessing the suitability of the proposed experimental site

Often animal housing and experimental equipment need to be modified to ensure that they meet all the experimental requirements. It is important to assess a research proposal or plan to determine whether the investigator has adequately considered the implications of housing, husbandry and the experimental procedure on the day-to-day care and welfare of the animals.

Some questions the investigator needs to answer:

- Housing:
 - o What housing is available?
 - Is it suitable? Does it need modification?
 - o How are food and water provided?
- Husbandry:
 - o What are the feed, water and shelter requirements of the animals?
 - o Who will primarily be responsible for the day to day management of the animals?
 - Are they completely familiar with the proposed experiment and its objectives?
 - Are they familiar with the species of animal and do they require training in the behaviour, management and handling of the species?
 - o What are the emergency contingency plans for the management of the animal (eg. loss of power, loss of water, fire, staff illness etc.)?
- Equipment:
 - o Is the equipment appropriate for the species, age and sex of the animal? If not, has testing on modified equipment been conducted to determine its suitability/ability to fulfil its original function.
 - o Do all the personnel involved in the experiment understand how to use and maintain the equipment?
 - o What are the emergency contingency plans for failures in equipment?

Once these questions have been answered it is recommended that the investigator develops a **Manual of Procedures** for the running and maintenance of the animals and the experiment. This manual should provide answers to all the questions above, include a complete methodology, emergency contact numbers, and a general husbandry schedule. This manual should be available to all personnel involved in the study and should be available at the experimental site and the animal housing site to anyone who may need to attend to the animals.



Standard Operating Procedures:

Where appropriately applied, Standard Operating Procedures (SOPs) may facilitate consistency of procedures, breeding related activities and the preparation of proposals by investigators and teachers.

There is a risk; however, that the use of SOPs may reduce the rigour with which procedures are considered by the AEC and, therefore, SOPs should only be referred to in proposals under the following circumstances:

1. new SOPs must be approved by the AEC before implementation;
2. SOPs must only list **one** method of performing the described procedure, so that the AEC may know exactly what is happening to each animal;
3. SOPs must include in the title the date on which they were last approved or reviewed and be reviewed regularly by the AEC at least every three years;
4. AEC members must have ready access to copies of all current SOPs;
5. investigators or teachers named on a proposal must have the necessary skills to implement a SOP; and
6. any variation to an SOP must be detailed in the proposal.



Interpreting experimental design and statistical analysis

Animal Ethics Note: 4.3 September 2010

Background:

Sometimes it is difficult to understand why an investigator has requested a specific number of animals for their study. AEC members need to be assured that there are neither too many nor too few animals for the purposes of the study. In most cases, investigators will provide some statistical justification for their numbers, but this can be difficult for AEC members to interpret. This information note will aim to shed some light on some of the terminology and rationale behind different statistical methods. The aim is to provide you with enough information to make an informed decision about the proposed project.

The independent and dependent variables

A variable is anything that changes in the course of an investigation. There are two kinds of variables: the independent and the dependent variable. The independent variable is the variable that the investigator is manipulating and the dependent variable is the outcome they are measuring. For example, if I wanted to determine the effect of age of a person on the efficacy of a drug for treating asthma, **age** would be my **independent** variable (I would manipulate the ages of the people in the drug trial), and number, severity and duration of asthma attacks would be my *dependent* (measurable) variables.

The hypothesis/research question

The hypothesis is essentially an assumption or an educated guess about the likely answer to the research question based on evidence gathered from previous research, anecdotal evidence or theoretical conjecture. It is usually written in a statement form that addresses the research question.

A hypothesis includes two variables:
an independent variable and
a dependent variable.

In constructing a hypothesis, **one variable at a time** is selected and a suggestion is put forward as to how this might influence the event under investigation. The variable selected is called the Independent variable.

Usually there are two different hypotheses stated: the “null hypothesis” and the “alternative hypothesis”. These are relatively complex statistical concepts, but in short, a null hypothesis states that the “independent variable” will **not** influence the event under investigation. In the above example, the null hypothesis would be that age has *no* effect on the efficacy of the drug used for treating asthma. It is easier to disprove something than it is to prove that it is universally applicable, hence the use of the null hypothesis. The alternative hypothesis states that the independent variable **will** influence the event under investigation and, depending on the nature of the research question, the alternative hypothesis may state how the independent variable will influence the event.

It is important to note, that *not all research questions* will be accompanied by a hypothesis, particularly if the research question is a statement or a demonstration. In addition, the hypothesis is often assumed within the research question itself, and is not stated separately.

Factors and treatments

Conditions controlled by the investigator may also be called factors. These may or may not relate directly to the independent variables of interest to the study, but they may still have an effect on the outcome and must be considered. In the asthma drug example, the researcher may choose to only include males in the study. The gender of the subjects is a factor which is controlled by the researcher.



Where factors relate to the project outcomes they are the independent variable(s) under examination. They are then compared using treatments, where their effect is directly measured. If the asthma drug is given by two different routes, then the drug is a factor with two treatments. The treatments/levels can be qualitative such as routes A and B, or quantitative, such as the dose levels of the drug.

The experimental unit

The experimental unit is the animal/s that is/are assigned to a specific treatment within an experiment. Often the experimental unit is a single animal, but sometimes, particularly, where group effects could be very important to the outcome of the research question, the experimental unit will be a specific group of animals. When this occurs, measurements are taken from each animal in the group and then their results are pooled and averaged to provide a single data point for that group for the experiment. The single data points from each of the groups in the trial are then analysed statistically.

When the group is an experimental unit the number of individual animals required for the experiment is likely to be higher than when the experimental unit is a single animal. At first this may seem to be a bad experimental design, inconsistent with the 3Rs, but if to achieve the same outcomes with individual animals, the animals need to be housed individually, then the impact of the study on the animals may be far greater than allowing the animals to remain in groups and using more animals.

Therefore, it is important to understand the behaviour, particularly the social behaviour, of the animals that are to be part of the study to determine which is the best method of testing the animals.

It is also important to note that in some studies, for one part of the study the animal is the experimental unit and for another part the group is the experimental unit. This is often true for 'split-plot' or 'nested' designs; for example, a drug company may wish to determine the influence of a new vitamin supplement for preventing rickets in lambs fed either a general pasture diet or a calcium enriched diet.

Pasture Group		Pasture + Calcium enriched grain	
Saline injection	Vitamin injection	Saline injection	Vitamin injection

To determine the impact of the calcium enriched grain on the incidence of rickets, the experimental unit would be the group; to compare the effects of the vitamin injection and any interactions between the vitamin injection and the diet, the experimental unit is the individual lamb.

Sample size

The determination of the sample size could be seen as the most important part of designing an experiment. It is also often the most difficult because many of the statistical equations used for determining the most appropriate sample size are based on factors that are mostly unknown at the time of planning the experiment. In addition, while statisticians and biometricians can work with an investigator to utilise previous research to help narrow down an appropriate sample size, there may be practical constraints on the researcher owing to the nature of working with animals.

For example, the most appropriate sample size for determining the behavioural responses of young calves to a range of fear tests may be 800 per treatment, but within a given calving period, a farm may only be giving birth to 200 calves.

The experiment could be conducted on 4 separate farms, but then additional factors come into play that may confound/complicate the statistical analysis beyond the original study plan, further increasing the number of animals required; such as differences between farm routines, staff, feeding times, and genetics of the calves.



However, for AEC purposes, it is important to observe that an investigator has thought about and justified their animal numbers using the best knowledge available. Some important factors to consider when determining the appropriateness of a sample size are:

- The objectives of the study

The sample size will vary depending on the specific aims of a study: consider what the aims are, how many experimental groups will be required to test the aims; is the experimental unit an individual animal or a group; the outcomes of previous research.

- The type of data being collected

There are several different types of data that can be collected: categorical, or qualitative, data, such as dead/alive, male/female, old/young; or numerical data. Numerical, or quantitative, data can be further divided into discrete data, which involves “the number of something” for example, the number of times an animal walks past a particular post in a paddock; or continuous data where something is measured and can take on any intermediate value, such as height.

The type of data generally determines the type of statistical analysis that can be performed and provides guidelines for the sample size. Categorical data often results in larger sample sizes compared with continuous numerical data.

- The uniformity of the experimental subjects

The larger the variation between experimental subjects, such as farm of origin, genetics, husbandry procedures etc, the larger the sample size. Being able to control the environment and the animal’s genetics as much as possible will reduce the variability between subjects and reduce the number of animals required for a study.

- The design of the experiment

The experimental design also influences the sample size. The experimental design will depend on the nature on the question/s being asked and the animals being used. The more complex the question; that is, the greater the number of treatments, the greater total number of animals required for the study, but the number per treatment group may actually reduce.

Useful definitions:

Statistical Power

The statistical power of an experiment is the probability that the statistical analysis of the data collected will detect differences between treatments at a specified rate. That is, if I arbitrarily set the probability of detecting a difference between treatments of 95% then, I expect that 95% of the time I will accurately accept the null hypothesis and 5% of the time I will make an error in accepting the null hypothesis. Statistical power is arbitrarily set by the investigator and affects the sample size. The higher the power, the greater the sample size required.

Type 1 Error Rate

The Type I error rate(also known as α) is the rate at which the experiment is willing to be wrong in accepting the null hypothesis when the alternative hypothesis is true. Again, this error rate is arbitrarily set by the investigator, however, 0.05 (or 5%) and 0.01 (1%) are most commonly used. Essentially a Type I Error Rate of 0.05 says that the investigator is willing to be wrong in accepting the null hypothesis 5% of the time.

P value

The “p value” is the probability that the difference between means of different groups, is at least as extreme as the difference that could have been found if the null hypothesis were true. Put more simply, it is the probability that the result could have occurred by chance.



Biological Significance versus Statistical Significance

It is important to remember that while an experiment/study may find that a certain treatment results in a statistically significant change in an outcome, the change may not be biologically significant.

For example, if I were to feed dairy cows prone to mastitis a new vitamin combination to determine whether it influenced the incidence of mastitis over 3 calving seasons. I might find that, of those animals receiving the vitamin, a statistically significant proportion has a lower incidence of mastitis, but biologically, the improvement in the incidence of mastitis was 0.01, meaning only 1 cow in every 100 cows would have a reduced level of mastitis infection over 3 calving seasons or 1/3 of a cow per calving season. Therefore, while my vitamin had a statistically significant impact on the incidence of mastitis it had little effect biologically.

ANOVA (Analysis of Variance)

The ANOVA is a highly versatile statistical method that is capable of determining the difference between two or more groups in their responses to a specific treatment. ANOVA can be used to analyse very simple studies involving two groups and one treatment or highly complex studies involving factorial designs, randomised blocks and/or repeated measures.

ANOVA takes the variation between responses of individual experimental units to a treatment and estimates the probability that the difference between the means of the two treatments is due to chance as opposed to the treatment itself. ANOVA utilises the Type I Error Rate as the cut off point. If the Type I Error Rate is set at 0.05, then a "p value" less than 0.05 is considered significant; that is, it is more than random chance that the two means of the treatment groups are different.

Additional resources:

- Festing, M.F.W., Overend, P., Das, R.G., Borja, M.C., and Berdoy, M. (2002). The design of Animal Experiments. Reducing the use of animals in research through better experimental design. *Laboratory Animal Handbooks*, 14. Published by The Royal Society of Medicine Press Limited.
- www.isogenic.info Author: Michael F.W. Festing



Guidelines

for the euthanasia of animals

Animal Ethics Note: 4.4 September 2010

For full details on the recommended methods for humane euthanasia of animals used for Scientific Purposes, please refer to:

- **The Code of Practice for the Housing and Care of Laboratory Mice, Rats, Guinea Pigs and Rabbits, and**
- **The NHMRC Guidelines to Promote the Wellbeing of Animals used for Scientific Purposes.**

Use of carbon dioxide for euthanasia of laboratory animals:

At its meeting in December 2006 the Chairs Committee discussed the findings of the Newcastle Consensus Meeting on Carbon Dioxide Euthanasia of Laboratory Animals.

The full report of the Newcastle Consensus Meeting can be found at [www.nc3rs.org.uk/CO2Consensus Report](http://www.nc3rs.org.uk/CO2Consensus%20Report) and is recommended reading for all Victorian AECs.

The essential feature of the report was that there is no 'ideal' method of using CO₂ as a euthanasia agent. Immersion of the animal in a pre-filled container (pre-fill method) and exposure to rising concentrations of CO₂ (slow-fill method) both potentially cause welfare problems.

The report suggests that, given the current level of knowledge of the effects of CO₂, it may be more humane to use a 'slow-fill' method of CO₂ euthanasia for rats and mice. Filling the euthanasia chamber at a rate of 20% of its volume per minute is the most likely method of achieving loss of consciousness before aversive effects are experienced by the animal.

The AECAC advises Victorian AECs to use the Newcastle report to formulate Standard Operating Procedures for the euthanasia of animals using CO₂. Given the findings of the report it would be expected that the slow-fill method form the basis of these SOP's, with any variations to be specifically approved by an institution's AEC.





Planning the use of animals for research or teaching

Animal Ethics Note: 4.5 September 2010

Background:

Scientists and teachers intending to use animals for research or teaching purposes have a legal and ethical obligation to ensure the well-being of the animals destined for use in their activities. An essential element of ensuring the welfare of animals used for research or teaching purposes is **good planning**. This document outlines the basic steps involved in planning activities that involve the use of live animals.

Step 1: What is the research question?

A clearly defined research question or teaching objective is essential; providing the investigator with a specific purpose or direction.

It is important that a thorough literature search is conducted to determine what information is already available and to try to narrow the focus of the question or objective. There is no point in repeating work that has been done before; nor is there any point in making the same mistakes or leaving the same gaps in knowledge as previous research.

Step 2: How do I best answer my research question?

After you have developed your research question or objective you need to determine the best way to answer that question. Again, the literature can help to guide the development of your research proposal and methodology. You can use previous research to determine what may or may not work with a particular species or with specific procedures.

Once you have determined what you would like to do to answer your research question, the most important question you need to ask is “Do I really need to use animals to answer my question, or can my question be answered by interpreting existing data in the literature? [This is also known as the principle of Replacement – see “Three R’s” Information Note].

If the answer is “yes” then a review of the literature should provide you with the answers you seek.

If the answer is “No”, then you need to determine (if you have not already done so) which species would be optimal for answering the question. Returning, again, to the literature you can review whether this species has been used in this type of research. You need to ask question such as:

- how have different studies managed the species?
- what were the procedures undertaken on the species?
- were all procedures/experimental activities successful? Why, why not?
- why were the outcomes from those studies not sufficient to answer your research question?

[This is the first step towards the principles of Reduction and Refinement – see “Three R’s” information note.]



Step 3: Developing a methodology

Once you have determined that the existing literature is insufficient to answer your research question/objective, and you have reviewed existing literature to help determine which animal species and which scientific procedures may be necessary to answer your question, you need to develop your methodology.

When developing the methodology you need to take the following into consideration:

- What experimental procedures would I like to include in my methodology?
- What do I know about the behaviour of my animal species?
- Will the natural behaviours of my animal impact on my ability to use the proposed experimental procedures in the method I have determined will best answer my research question/objective? If yes, how am I planning to deal with this?
- Does my animal species have specific housing and husbandry requirements; and if yes, how might these requirements impact on my ability to answer my research question and the design of my experimental procedures?
- What types of stressors will my proposed methodology put upon my animals?
- Will stress experienced by the animals impact on the validity of my research results?
- At what point will I remove an animal from the study when they begin to show signs of stress or distress?
- How many animals do I need?
- Have I consulted a biometrician to help me utilise the variation reported in the literature to determine the minimum number of animals required to provide me with statistically powerful results?

[Again, these questions are helping you to address the principles of Reduction and Refinement – see “Three R’s” Information note.]

Having answered all these questions and gathered as much information about the behaviour and housing and husbandry needs of your animals, you should develop your proposed methodology.

Where new procedures or untested procedures are being planned, particularly the procedures which are likely to have a great impact on the animal, you may wish to conduct a small pilot study to test whether the methodology you propose is suitable for answering your research question.

Step 4 – Assess and modify your proposed experimental site

Once your methodology and animal numbers are firmly set, your next step is to determine whether you have a suitable experimental site to house your animals and to conduct your studies. Often animal housing and experimental equipment need to be modified to ensure that they meet all your requirements. It is essential that you make these alterations **before** you obtain your animals.

Some questions you need to answer:

- Housing:
 - o What housing is available?
 - o Is it suitable? Does it need modification?
 - o How are food and water provided?



- Husbandry:
 - o What are the feed, water and shelter requirements of my animals?
 - o Do I need to order food? If yes, what type of food is suitable for the species and age/developmental stage of my animals and how will it be delivered to the experimental facility and to my animals?
 - o Who will primarily be responsible for the day to day management of my animals?
 - Are they completely familiar with the proposed experiment and its objectives?
 - Are they familiar with the species of animal and do they require training in the behaviour, management and handling of the species?
 - o What are the emergency contingency plans for the management of the animal (eg. loss of power, loss of water, fire, staff illness etc.)?
 - o What are the emergency contingency plans for failures in equipment?
- Equipment:
 - o Is the equipment you are planning to use appropriate for the species, age and sex of the animal you have chosen? If not you will need to arrange modification and test that the modified equipment still fulfils its function.
 - o Do all the personnel involved in the experiment understand how to use and maintain the equipment?

Once you have answers to all these questions you should develop a **Manual of Procedures** for the running and maintenance of your animals and your experiment. This manual should provide answers to all the questions above, include a complete methodology, emergency contact numbers, and a general husbandry schedule. This manual should be available to all personnel involved in the study and should be available at the experimental site and the animal housing site to anyone who may need to attend to your animals.

Step 5 – Develop and submit your AEC application

It is at this point that you are ready to develop and submit your AEC application.

Once you have received AEC approval you can move on to ordering/obtaining your animals and beginning your experiment.

Remember:

- You must plan ahead!
- You must understand the behavioural and husbandry requirements of your animals and how these may impact on your ability to answer your research question.
- You must be familiar with the Code of Practice outlining the minimum standards of animal care for the species of animal you are working with.



Standard Operating Procedures:

Where appropriately applied, Standard Operating Procedures (SOPs) may facilitate consistency of procedures, breeding related activities and the preparation of proposals by investigators and teachers.

There is a risk; however, that the use of SOPs may reduce the rigour with which procedures are considered by the AEC and, therefore, SOPs should only be referred to in proposals under the following circumstances:

- i. new SOPs must be approved by the AEC before implementation;
- ii. SOPs must only list *one* method of performing the described procedure, so that the AEC may know exactly what is happening to each animal;
- iii. SOPs must include in the title the date on which they were last approved or reviewed and be reviewed regularly by the AEC at least every three years;
- iv. AEC members must have ready access to copies of all current SOPs;
- v. investigators or teachers named on a proposal must have the necessary skills to implement a SOP; and
- vi. any variation to an SOP must be detailed in the proposal.

Useful resources:

The CCAC Experimental Animal User Training Modules (particularly Topic 5) may be useful as a guide for developing your experiment. The training modules can be found at the following link http://www.ccac.ca/en/CCAC_Programs/ETCC/Intro-coretopics-Web11.htm.



Guidelines

for investigator record keeping

Animal Ethics Note: 4.6 September 2010

Background:

Section 2.2.27 of the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* (the Code) indicates that investigators and/or animal facility managers must maintain records that “will enable the AEC to verify that the welfare of animals has been monitored as agreed {in the Animal Ethics Committee Project Application}”. These records provide information that enables “critical investigation of the cause(s) of unexpected adverse events as a basis for future prevention strategies”; or, in other words, a means for developing standard operating procedures and contingency plans to avoid adverse events in future research involving animals.

The Code also stipulates that “Investigators and teachers must ensure that records of the use and monitoring of animals used for scientific purposes are maintained” (**Section 3.1.9**). These records for every given AEC approval should include:

- the origin and fate of animals,
- how animal welfare was assessed,
- any unexpected negative impact on animal well being,
- notations of procedures carried out on the animal/s, and
- additional information to be recorded required by the AEC.

The Code also stipulates that, “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 the AEC, external auditors, other investigators, animal carers, etc. to trace the use of an animal from acquisition to the conclusion of the approved protocol.

The following guidelines are a minimum standard with respect to record keeping and should not be viewed as an exhaustive list.

Record keeping

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

- Animal Ethics Committee approval number, date and duration of approval.
- Records relating to adherence to specific conditions which the 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 & personnel involved (eg, records of daily monitoring, completed checklists).
- Place & 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) & 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.

Evidence of preparation for adverse events and adherence to SOPs:

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



Contingency planning

Animal Ethics Note: 4.7 September 2010

Contingency planning can:

- prevent the loss of animal life,
- prevent the loss of valuable research resources and income,
- reduce the time of emergency recovery and thus provide cost savings, and
- reassure the general public that measures are in place to protect the animals in emergencies.

The Australian code of practice for the care and use of animals for scientific purposes stipulates that institutions are responsible for ensuring that the AEC approves guidelines for animals care within the institution and that these are implemented, including those which ensure that emergencies, such as fire and power failure, are detected promptly and dealt with effectively (2.1.1 (viii)).

Contingency plans should encompass common emergencies such as power outages and faulty Heating, Ventilation and Air Conditioning (HVAC) systems as well as fires and the extreme weather conditions or natural disasters the facility is most likely to experience.

Special attention must be given to mitigating the impact of common emergencies. Institutions must develop and document plans that ensure the early detection and notification of power and HVAC failure. Such plans must include provision of backup systems and alternative methods for regulating temperature and ventilation as well as procedures for waste disposal and evacuation and relocation of animals if required.

Plans for more major emergencies such as fire, extreme weather and natural disasters must include mitigation, preparedness and response and recovery procedures.

Facilities need to have a good communication plan in place, including in the event of personnel evacuation.

Emergency Response Preparations

Emergency Response Leaders

The team should be made up of the various managers and supervisors of the animal facility as well as personnel from support areas such as facilities management, OHS and IT. These key personnel should be involved in establishing the procedures required for each type of emergency situation. During an emergency, this team may bring in other emergency response personnel to provide technical expertise and information and animal care as required.

Emergency Response Centre

The emergency response centre should allow ready access to the area, or areas, of concern. For large facilities, several locations may need to be identified. An area in the centre(s) should be devoted to storing items that will be used by emergency response personnel. If storage space is limited, consider making arrangements with other facilities that may be able to provide supplies during emergencies.



Emergency Response Personnel

Facilities Management

There must be a system for early detection and warning of plant or facilities failure that impact on the functioning of the animal facility. Contingency plans should be developed and communicated such that facilities management personnel are aware of the particular requirements of the animal facility and of the need to act promptly should plant or facilities failures occur. Of particular importance is the necessity for up-to-date contact lists to be maintained such that facilities management know who, within the animal facility, they need to contact when plant and facilities failures occur.

Likewise, animal facility management and staff must have access to a contact list for the facilities management department and know who to contact in the event of plant or facilities failures.

Occupational Health & Safety

Contingency plans should be developed and communicated such that OHS personnel are aware of the particular requirements of the animal facility. Contact lists should clearly indicate the OHS personnel who are responsible for the animal facility.

Information Technology

Contingency plans should be developed and communicated such that IT personnel are aware of the particular requirements of the animal facility. In particular, the plan should incorporate strategies for ensuring communication can be maintained during emergencies. Contact lists should clearly indicate the IT personnel who are responsible for the animal facility.

Laboratory Personnel

Laboratories that employ their own animal care personnel and/or use animals outside the animal facility should have their own plan, based on the animal facility contingency plan, to handle emergency situations.

Animal Facility Staff

Determine ahead of time how many staff members are needed to deal with an emergency. This should be the minimum number possible but consider creating two separate teams so that one can act as a relief. Contact lists, available to all animal facility staff, should clearly indicate the staff responsible during emergencies and should be available to all. Establish a mechanism for bringing staff in if there is no phone service.

Veterinarians

An on-call veterinarian should be available at all times. The veterinary staff should develop a process by which other veterinarians can be brought in to help with emergency situations. The on-call vet should have the authority to determine when additional assistance is needed.

Communication

When planning for emergencies, take into account how communication can occur, or not occur, within and outside the animal facility during various emergency situations. Consider the following communications options; landline and mobile phones, pagers, walkie-talkies, email, social networking websites and runners.

Up-to-date contact lists are an essential element of communication. All animal facility staff and emergency response personnel must know who they need to contact when emergencies occur.

Standardised communication templates such as form emails may be a useful way of providing quick but consistent information to animal facility staff, laboratory personnel and staff in other departments such as facilities management, OHS and ITS.



Supplies

Emergency Response Personnel Supplies

Depending of the likelihood and type of major emergency planned for, supplies of water, non-perishable food, torches, radios, batteries, basic tools etc should be available to help provide for the emergency response team's needs. This should include the materials and equipment required for euthanasia and disposal of animals if required.

These supplies should be kept accessible in the areas where individuals will be deployed. Extra supplies should be kept in the emergency response centre to be distributed as needed.

Emergency Animal Supplies

- Water
- Food
- Bedding
- Clean cages

Action Checklists

Checklists should be prepared to direct decision making during and after an emergency. This should include checking of animals, environmental safety, plant and equipment and communication protocols.

Evacuation

A specific action checklist should be prepared for use during an evacuation. This should include how the evacuation of animals will be prioritised based on such things a value, vulnerability, manageability, relocation ease and hazard.

Mechanisms to ensure that animals can be cared for after personnel evacuation must be considered.

Having an ordered list of facilities and facility plans can assist fire/rescue crews in deciding what to focus on, in case such decisions need to be made. These lists and plans should clearly indicate areas which contain animals and how these may be accessed.

Recovery/Redeployment Guidelines

A specific action checklist should be prepared for use during recovery or redeployment from an emergency. This should include how environmental safety will be assessed and how and in what order animals, plant and equipment will be checked both immediately and as recovery proceeds.

Practice

Procedures for handling an emergency should be practiced so that staff are comfortable and confident with them.

Communication strategies should be included in any practice and simulated emergency responses should aim to test all aspects of the emergency plan. This should include following procedures for checking and recording outcomes of plant and equipment assessments, as well as personnel evacuation and re-entry protocols.

After practising, debrief with staff to refine and improve the plan if needed.







Effective communication skills

Animal Ethics Note: 5.1 September 2010

Introduction:

For Animal Ethics Committee members, investigators, teachers and institutions to work well together, they need to be able to effectively communicate both verbally and in written formats. It is important that ALL forms of communication are **clear, simple** and **respectful**. This Information note provides some basic guidelines to effective communication.

Chip Rose commented, *"We all use language to communicate, to express ourselves, to get our ideas across, and to connect with the person to whom we are speaking. When a relationship is working, the act of communicating seems to flow relatively effortlessly. When a relationship is deteriorating, the act of communicating can be frustrating as climbing a hill of sand."* (www.directionservice.org/cadre).

Written communication:

Often the appropriate design and thorough completion of application and information forms can be the most effective communication tool between investigators, teachers and AECs. It is essential that **all** forms of written communication are clear, concise and *respectful*.

Developing a new application form or altering an existing one:

The development of new forms should take into consideration all possible interpretations of the questions being asked.

- The provision of information or explanation boxes can be helpful and ensure that important information is not left out.
- The provision of contact numbers for a person/s who can be called if the applicant needs advice on completing sections of the form can also ensure that forms are submitted complete and reduce the added work created when information is left out or insufficient information is provided.
- Ensure that each of the questions asked is distinct and there is as little repetition as possible; this reduces the length of the form and reduces the risk of the applicant becoming confused about the information required.

Completing an application form:

One of the greatest sources of confusion for Animal Ethics Committees is the way in which a proposed experiment is communicated in the application form. There are three golden rules to ensuring that researchers and teachers communicate well through the application form:

1. Complete **all** sections of the form that are relevant to the project carefully and concisely/succinctly.
2. Use **plain** language wherever possible and where not possible, provide definitions in plain language. – Remember, the people responsible for assessing the project proposal may not have any background in the area of research and may or may not have extensive experience with this species of animal.
3. If in doubt **ask!** A contact from the AEC (Chair or Executive Officer, or other member) should be available to answer applicant questions before they submit their application.



Using standard template responses:

If AECs wish to use standard communication templates to respond to project applications it is essential that those templates are also clearly and concisely written.

- Provide the applicant with a step-by-step outline of what they need to do next.
- If a project's requirements do not meet one of the standard templates, then carefully alter the template to fit the project requirements or write a new response.
- Provide clear deadline dates.
- Ensure there are no contradictory statements in your response, or partial statements that can be interpreted incorrectly – **be very clear!**

Verbal communication:

There are in fact three parts to verbal communication that we need to be aware of:

1. Verbal messages – the words we choose to use and how they are arranged;
2. Paraverbal messages - how we say those words, our tone, the pace at which we speak and the volume of our speech; and
3. Nonverbal messages – the body language we display.

In order to communicate effectively we need to use all three components to achieve two goals:

1. Send a clear and concise message, and
2. Hear and correctly interpret the message someone else is sending to you.

Good communication skills = mutual respect:

The following information is adapted from : Barriers to Every Day Communication by *Nancy J. Foster, J.D.* Sourced at: <http://www.directionservice.org/cadre/foster.cfm>

Good communication skills are **mutual respect skills**. Ideally, each person will show respect for the other as well as respect for self. You show respect for the other person by listening fully and demonstrating that you hear and understand what that person means; and you respect yourself when you assert or send a clear and concise message without aggression. To have a complete communication, each person must both "hear" and "send."

Let us look at some of the conversational bad habits which often interfere with full and complete communication. Anything which blocks the meaning of a communication is a barrier to communication. These usually fall into one of three categories: judging, sending solutions or avoiding the other person's concerns. Some common examples follow:

- **Criticizing** "Well, despite your very long application, you really haven't provided us with anything we can use to make a decision."
- **Name-calling** "You really are a very poor scientist."
- **Diagnosing** "You are avoiding answering the question because you know we won't like the answer."

All of these responses judge the other person and therefore impose the speaker's point of view. The other person will often feel misunderstood and unsafe, and is more likely to react in a defensive or self-protective manner.

- **Ordering** "You need to become familiar with this immediately."
- **Threatening** "If you can't understand this, I can't see how you can contribute to this conversation in a meaningful way."



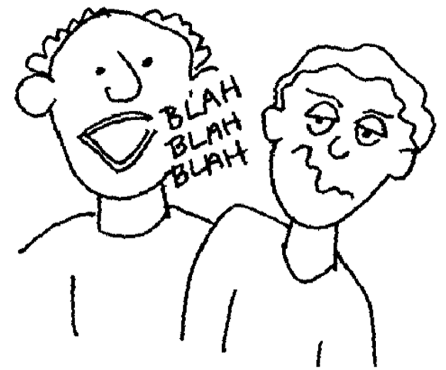
- **Moralizing** “You ought to have done some research so you can understand what we are talking about.”
- **Excessive/inappropriate questioning** “What don’t you understand?” “What do you understand?”
- **Advising** “If I were you, this is what I would do...”

Each of the above are attempts to solve the other person’s problem. They are manipulative, self-righteous or coercive but vary in how direct they are. Even when caringly intended, the solution is often proffered without a full understanding of the problem. Such responses may make the problem worse, or create a new issue without resolving the original problem. They also demean the other person’s capacity to handle his or her own problems, and are likely to foster anxiety and resentment.

The barriers to communication listed above do not always have a negative impact on communications. However, they are high-risk responses when people are interacting under stress. They tend to block the feeling of the other person, who then is less likely to express his or her true feelings in a constructive way. Rather than fostering understanding, they may diminish the other’s self-esteem, or foster resentment, defensiveness, withdrawal or dependency in the other, and inhibit their problem solving ability. Unfortunately, it has been estimated that people use these responses 90% of the time when they are discussing a problem or need.

Nonverbal communication barriers

1. Flashing or rolling eyes
2. Quick or slow movements
3. Arms crossed, legs crossed
4. Gestures made with exasperation
5. Slouching, hunching over
6. Poor personal care
7. Doodling
8. Staring at people or avoiding eye contact
9. Excessive fidgeting with materials



Sending messages:

Adapted from Communication Skills by Rod Windle and Suzanne Warren
(<http://www.directionservice.org/cadre/section4>)

Effective verbal messages:

1. Are brief, succinct, and organized
2. Are free of jargon
3. Do not create resistance in the listener

Our use of language has tremendous power in the type of atmosphere that is created during a discussion. Words that are critical, blaming, judgmental or accusatory tend to create a resistant and defensive mindset that is not conducive to productive problem solving. On the other hand, we can choose words that normalise the issues and problems and reduce resistance. Phrases such as “*in some studies, investigators have tried . . .*”, “*it is not uncommon for . . .*” and “*similar studies have shown*” are examples of this.

Sending effective messages requires that we state our point of view as briefly and succinctly as possible. Listening to a rambling, unorganized speaker is tedious and discouraging - why continue to listen when there is no interchange?

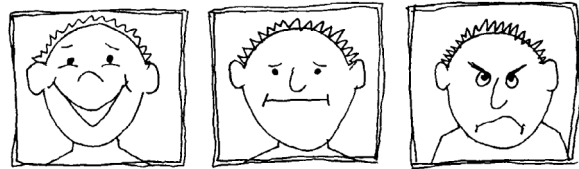


Lengthy explanations can be confusing to the listener and the message loses its concreteness, relevance, and impact. This is your opportunity to help the listener understand **your** perspective and point of view. Choose your words with the intent of making your message as clear as possible, avoiding jargon and unnecessary, tangential information.

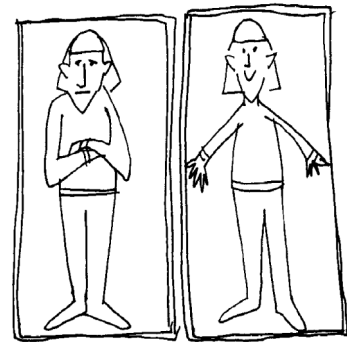
Nonverbal messages are the primary way that we communicate emotions:

1. Account for about 55% of what is perceived and understood by others.
2. Are conveyed through our facial expressions as well as our postures and gestures.

Facial Expression: The face is perhaps the most important conveyor of emotional information. A face can light up with enthusiasm, energy, and approval, express confusion or boredom, and scowl with displeasure. The eyes are particularly expressive in telegraphing joy, sadness, anger, or confusion.



Postures and Gestures: Our body postures can create a feeling of warm openness or cold rejection. For example, when someone faces us, sitting quietly with hands loosely folded in the lap, a feeling of anticipation and interest is created. A posture of arms crossed on the chest portrays a feeling of inflexibility. The action of gathering up one's materials and reaching for a purse signals a desire to end the conversation.



Paraverbal messages:

1. Account for about 38% of what is perceived and understood by others.
2. Include the tone, pitch, and pacing of our voice.

Paraverbal communication refers to the messages that we transmit through the tone, pitch, and pacing of our voices. It is how we say something, not what we say. Professor Mehrabian states that the paraverbal message accounts for approximately 38% of what is communicated to someone. A sentence can convey entirely different meanings depending on the emphasis on words and the tone of voice. For example, the statement, "I didn't say you were stupid" has six different meanings, depending on which word is emphasised.

"I didn't **SAY** you were stupid."
"I didn't say **YOU** were stupid."
"I didn't say you were **STUPID**."

Some points to remember about our paraverbal communication:

- When we are angry or excited, our speech tends to become more rapid and higher pitched.
- When we are bored or feeling down, our speech tends to slow and take on a monotone quality.
- When we are feeling defensive, our speech is often abrupt.

The importance of consistency:

In all of our communications we want to strive to send consistent verbal, paraverbal and nonverbal messages. When our messages are inconsistent, the listener may become confused. Inconsistency can also create a lack of trust and undermine the chance to build a good working relationship.

When a person sends a message with conflicting verbal, paraverbal and nonverbal information, the nonverbal information tends to be believed. Consider the example of someone, through a clenched jaw, hard eyes, and steely voice, telling you they're not mad. Which are you likely to believe? What you see or what you hear?



Receiving messages:

Adapted from *Communication Skills* by Rod Windle and Suzanne Warren
(<http://www.directionservice.org/cadre/section4>)

Listening:

1. Requires concentration and energy
2. Involves a psychological connection with the speaker
3. Includes a desire and willingness to try and see things from another's perspective
4. Requires that we suspend judgment and evaluation

The key to receiving messages effectively is **active listening**. Active listening requires more than hearing words. It requires a desire to understand another human being, an attitude of respect and acceptance, and a willingness to open one's mind to try and see things from another's point of view.

Active listening requires a high level of concentration and energy. It demands that we set aside our own thoughts and agendas, put ourselves in another's shoes and try to see the world through that person's eyes.

True listening requires that we suspend judgment, evaluation, and approval in an attempt to understand another is frame of reference, emotions, and attitudes. Listening to understand is, indeed, a difficult task!

Often, people worry that if they listen attentively and patiently to a person who is saying something they disagree with, they are inadvertently sending a message of agreement. When we listen effectively we gain information that is valuable to understanding the problem as the other person sees it. We gain a greater understanding of the other person's perception. After all, the truth is subjective and a matter of perception. When we have a deeper understanding of another's perception, whether we agree with it or not, we hold the key to understanding that person's motivation, attitude, and behaviour. We have a deeper understanding of the problem and the potential paths for reaching agreement.

Learning to be an effective listener is a difficult task for many people. However, the specific skills of effective listening behaviour can be learned. It is our ultimate goal to integrate these skills into a sensitive and unified way of listening.

Key listening skills:

Nonverbal:

- Giving full physical attention to the speaker;
 - o Effective attending is a careful balance of alertness and relaxation that includes appropriate body movement, eye contact, and "posture of involvement". Fully attending says to the speaker, "What you are saying is very important. I am totally present and intent on understanding you".

We create a posture of involvement by:

- o Leaning gently towards the speaker;
 - o Facing the other person squarely;
 - o Maintaining an open posture with arms and legs uncrossed;
 - o Maintaining an appropriate distance between us and the speaker;
 - o Moving our bodies in response to the speaker, i.e., appropriate head
- Being aware of the speaker's nonverbal messages;



When we pay attention to a speaker's body language we gain insight into how that person is feeling as well as the intensity of the feeling. We can then, through our reflective listening skills, check the accuracy of our interpretations by expressing in our own words, our impression of what is being communicated.

Verbal:

- Paying attention to the words and feelings that are being expressed;

In order to understand the total meaning of a message, we must be able to gain understanding about both the feeling and the content of the message. We are often more comfortable dealing with the content rather than the feelings (i.e., the relationship), particularly when the feelings are intense. Our tendency is to try and ignore the emotional aspect of the message/ conflict and move directly to the substance of the issues.



This can lead to an escalation of intense emotions. It may be necessary to deal directly with the relationship problem by openly acknowledging and naming the feelings and having an honest discussion about them prior to moving into the substantive issues. If we leave the emotional aspect unaddressed, we risk missing important information about the problem as well as derailing the communication process.

- Using reflective listening tools such as paraphrasing, reflecting, summarizing
 - o Paraphrasing - a brief, succinct statement reflecting the content of the speaker's message.
 - o Reflecting Feeling - a statement, in a way that conveys understanding, of the feeling that the listener has heard.
 - o Summarizing - a statement of the main ideas and feelings to show understanding.
- Questioning to increase understanding of the message and help the speaker tell his story.
- Asking open questions to gain information, encourage the speaker to tell her story, and gain clarification.

Effective communication . . .

It is two way.

It involves active listening.

It reflects the accountability of speaker and listener.

It utilizes feedback.

It is free of stress.

It is clear.



Dispute resolution

Animal Ethics Note: 5.2 September 2010

Adapted from Communication Skills

by Rod Windle and Suzanne Warren (<http://www.directionservice.org/contents.cfm>)

Note: we encourage you to go to the website and read through the entire book

Conflict:

Conflict is the main vehicle through which change takes place in our society. When we disagree, it helps us sharpen our focus and define what the important issues are for us. Unless we have reached a utopian society, there will always be conflict, as there will always be disagreement about what is fair and best for all of us. If we accept the inevitability of conflict, it becomes obvious that it is in our best interest to gain the skills to be successful dispute resolvers.

Successfully resolving a conflict can be an enjoyable and empowering experience. Becoming more skilled in resolving disputes and solving problems can also help us to understand the workings of the human mind in relationships, which can lead to better relationships overall. This is not to say that problem solving is always fun or easy; in fact, many times it is hard work. The rewards, however, usually are worth it.

A preliminary step in resolving conflict is to understand what the conflict is actually about. Having a clear picture of what the issues are reduces the chance of a mismatch between the problem and the solution. Conflicts can be complex, and they may not always be about what they seem. For example, a disagreement that seems to be about data may actually have elements of relationship or values embedded within it. It's necessary to observe carefully to determine the true combination of elements that are involved.

The seven types of conflict:

1. Data conflicts will have data solutions:

There are conflicts which exist primarily over *data* or facts. Most data conflicts have data or factual solutions, either through obtaining more information or through new data collection.

Example: The insertion of indwelling jugular catheters has long-term pain consequences for sheep and pigs, but not for cattle.

Discussion: Some methods of using "data" to help resolve the issue could include providing more information regarding ability of these species of animals to feel pain, reviewing the literature about the pain associated with minor surgical procedures, reviewing data about the effectiveness of post-operative analgesia in different livestock species and reviewing the proposed protocol to allow to determine whether pain relief or anaesthesia has been proposed to determine a research protocol that everyone can agree on.

2. Relationship conflicts will have relationship solutions:

Conflicts can arise over a *relationship*, or over a communication style.

Example: A category E is upset because he believes that the Category B Member is not taking into consideration the impact of the proposed research on the ability of laboratory technical staff to maintain day-to-day husbandry activities and good general animal welfare. He states that an agreement to have a tour of the facility and a demonstration of the impact of the proposed study has not been kept. Finally, he feels that the Category A and B members are condescending and diffident in their dealings with him, often failing to acknowledge his concerns and responding to correspondence and phone calls.



Discussion: Relationships can often be improved by clearly stating needs, developing clear expectations, and writing agreements down for the parties to follow. Many times people are unaware of how they come across to others. “You can’t change if you aren’t told what’s wrong!”

3. Values conflicts will have values-based solutions

Conflicts can occur over *values*, where the parties have perceived or actual incompatibilities in their belief systems. This is a common conflict situation on Animal Ethics Committees and it is important that members recognised that all value systems have merit and must be treated with respect.

Example: The category C member on your AEC is morally opposed to the infection of animals with human diseases in order to establish a disease model for trialling a new drug.

Discussion: Our values help us define what is “right” or “wrong” in any situation, and provide a moral compass for our lives. Different values do not need to cause conflict; people can live together in harmony with different value systems. The keys to successful resolution are improvement and expansion of tolerance, understanding, and acceptance of others’ points of view.

4. Resources conflicts will have solutions that address resources

Conflicts often occur over real or perceived scarcity of *resources*:

Example: An investigator would like to purchase a new piece of equipment that will reduce the number of animals required to carry out a single replicate of a drug trial. However, the Institution has just allocated funds to building a new animal house to accommodate more animals for the trial and cannot afford to purchase the equipment. The investigator and the AEC want the Institution to reroute the funding, but the Institution’s administration says that money for capital works cannot be used to purchase equipment.

Discussion: A key concept useful to work with when scarce resources are at stake is that of “expanding the pie”. Expanding the pie involves brainstorming ways to use existing resources more effectively. Perhaps the technology can be leased instead of bought; perhaps it can be shared between a series of institutions. The institution could apply to the funding source to have the funds diverted or apply for grants from a different funding institution or the government. The possible solutions are limited only by the flexibility and creativity of those involved.

5. Conflicts generated by past history must address that history

Conflicts occasionally result from a *history* of slights or “bad blood” between investigators, and the AEC or between individual AEC members and associated staff.

Example: John, a Category E member has difficulty communicating with the Category A and B members on his AEC. He comes to meetings stiffly, with his arms folded, and says little. Privately, he feels that they do not take his concerns about the practical implications of proposed research on the welfare of the animals he cares for; he feels they behave in a superior way and he feels inferior as a result.

Discussion: In such cases, it’s most important to communicate person to person, to allow the person carrying the “history” a chance to vent and tell his story, to stay away from evoking “rules” as justification for decisions, and to ultimately allow a new perspective to emerge overtime. It’s important to remember that histories weren’t created overnight and usually won’t be resolved overnight. Building trust takes time.



6. Conflicts about the underlying *structure* of a situation must deal with that *structure*

Conflicts can occur over how to deal with structural realities which exist outside the immediate world of the AEC but which are having an impact on them.

Example: An institution is in the process of downgrading its research facilities and research support personnel. Animal facilities at the institution recently fell into disrepair and, due to the loss of staff that would have in the past been responsible for rectifying the situation; the facilities have not been repaired in a timely manner, leaving the welfare of the animals housed inside at risk. The AEC has made a recommendation to suspend all further research in this facility until repairs are made, but the investigators would lose their current work and need to start again, resulting in substantial additional costs and time.

Discussion: It can be helpful to assist those involved with this type of problem to appreciate the external forces and constraints bearing upon them. Their appreciation that a conflict has an external source can have the effect of everyone coming together to jointly address the imposed difficulties. Structural conflicts will often have structural solutions.

7. *Psychological* elements which cause problems in resolving issues must be dealt with creatively and must address the underlying *psychological* needs.

Conflicts can be caused or maintained by the *psychological* needs of humans: the desire for power, control, autonomy, recognition or love.

Discussion: These conflicts are often difficult to identify and it is important that dispute resolvers not engage in excessive psychoanalysis of others. Still, there are times when these basic human tendencies and drives will be contributing to a conflict, often masquerading as some other, more tangible issue. Few people are going to be able to come out and say "I'm in this conflict with you because you're not giving me enough recognition." Sometimes it is wisest to not deal with these issues directly; people hate to feel as if they are being "analysed". If you become aware of these issues, it may be useful to search for a viable solution that will help some of these needs to actually be met, and will thereby reduce the need to create more conflict.

The most common responses to conflict:

When faced with a conflict, people most commonly employ one or a combination of three basic response styles. These responses have parallels with the survival tactics of earlier humans:

1. a *fighting* response which mirrors the ancient fight response;
2. an *avoiding* response which is a variant of the flight response, and
3. the *acquiescing* response which resolves conflict by choosing to give in to the other's demands, i.e. by "playing dead".

In real life, most people tend to have one main response style but may react with any variant of these, depending upon the situation, the timing, and their mood. Each of these three responses to conflict has its appropriate time and place, and is not necessarily good or bad.

Rather than judging a particular response, the question we might want to ask is this: "Does what we are doing represent the best approach we can use right now in order to most successfully solve the problem at hand?"



People generally resolve conflict using what skills they have learned and are most comfortable with. This means that most of our learning about how to resolve conflict has taken place through experiencing one or more of the three common problem solving styles. However, there are methods of resolving conflict which are inherently different from any of the three common responses.

Ultimately, in evaluating the appropriateness of any approach, we will always want to ask ourselves the basic question:

“Is the approach I am using the very best I can use to resolve this conflict or solve this problem?”

How to deal with difficult people:

The ‘spongehead’ technique

One day, a physician was in his office, writing out reports after seeing patients all day. Suddenly, without warning, an irate man burst into the office, stormed past the receptionist (who made valiant attempts to stop him), strode directly into the doctor’s inner office, and slammed the door behind him. The shaken receptionist could hear the man yelling, screaming, and pounding his fist on something. This seemed to go on for a very long time. Finally, the man opened the door and came out, slammed it loudly, and ignored the receptionist as he ploughed out into the street.

All was quiet. It took quite some time for the receptionist’s heart to stop pounding in her chest. There was no noise from the doctor’s inner office. She was, naturally, very concerned about how the doctor must be feeling.

After a few minutes, she thought she heard a noise from behind the doctor’s door...it sounded like someone was whistling a happy tune! She opened the door and peeked in, and was greeted with the sight of the doctor peacefully working on his records and, indeed, humming a happy tune. His face was serene and his manner, relaxed.

“I was so worried about you”, she said, “That man was just ripping you up one side and down the other!”

“Yes, he certainly did” replied the doctor. “But you know, it is very difficult to be upset by a spongehead!”.

Steps in the spongehead technique:

1. Listen carefully to the content of the attack against you.
2. Do not respond verbally to the points that are made. Try not to be defensive, just listen.
3. As you are listening, be brutally honest with yourself. What parts of what the other is saying have shreds of truth to them, no matter how distorted?
4. Mentally, sincerely thank the other for pointing those out to you, and giving you the opportunity to improve yourself. When you have completed this step, you will have “separated out” the truth in what was said.
5. The rest of the other’s diatribe is obviously not true, and the arguments that are made are full of holes. Visualize the other’s head as a giant, blue-green sponge. From the holes, the inaccurate, misleading and untrue statements pour out, as water from a leaky jug. The other now looks absurd, and, far from being threatening, it may be all you can do to keep from breaking out in laughter. It is, truly, very difficult to get upset with a spongehead!

Collaborative problem solving:

In spite of the fact that we frequently engage in negotiation, for many of us, our repertoire of negotiating skills is limited. Out of habit and lack of knowledge about alternative strategies we try to solve problems by stating, and sticking to, our position. When we insist on our position as a way to solve the problem, in order for one party to be



satisfied with the outcome, the other party must be dissatisfied. Reaching an agreement depends on who can be the most powerful, the most persuasive, and/or the most willing to endure until “the bitter end”. If neither party is willing to “back down”, the problem solving process may become stalled with no agreement being reached at all. This type of “positional bargaining” is limited in its effectiveness in the following ways:

1. *It can be inefficient.* Hagglng, attempting to convince, and resorting to tactics such as stonewalling or holding out often result in multiple meetings which invariably extend over a long period of time..
2. *It can produce unwise agreements.* When we bargain from two positions - yours and mine - we are essentially considering only two possible solutions to a problem. By putting our efforts into trying to convince the other side of our solution, we forfeit the opportunity to consider other possibilities that may meet our needs and be more satisfying for everyone.
3. *It can be hard on the relationship.* This type of problem solving creates stress, anger and resentment for all participants. Bitter feelings may impact future problem solving.

The advantages of working collaboratively to solve problems:

- Working with interests often results in the identification of more possible solutions than were originally considered. An interest is the underlying need or concern that a party is trying to have satisfied. It is the thing that is motivating someone to seek a solution. A statement that describes one possible solution to meet that need or concern is a position;
- By “expanding the pie”, we end up with fair agreements that potentially meet more of our needs and are “win-win” rather than “win-lose”;
- Creates greater satisfaction for all of the parties and promotes a foundation for future problem solving that is respectful and energizing rather than negative and depleting.

Prepare for collaborative problem solving by:

1. Figuring out your interests
2. Figuring out their interests
3. Thinking of some options that would meet the interests
4. Considering what a fair standard might be
5. Keeping an open mind

A model for collaborative problem solving:

Collaborative problem solving is not a linear process. Identifying all of the interests of the parties must be accomplished before generating options. However, in order to do this effectively, we may need to move back and forth through the first steps, i.e., sharing information, defining issues, sharing more information, etc. in order to develop a clear picture of the interests. Reaching agreement often proceeds in a series of baby steps. One’s best “next step” is the step that will take us most effectively in that direction.

1. Share perspectives

* Use our communication skills to understand the other’s perception of the situation, their needs, and desires. See “Effective Communication Skills” Information Note.

The process of perspective sharing allows each party to gain a clear understanding of the other’s *perception* of the problem situation, for this is at the heart of collaborative problem solving.



Too often we focus on uncovering more data, facts, and objective information in an effort to reveal the “truth” and convince the other side to see things as we do. Parties may actually agree on the objective data, but it is their differences in how they *perceive* the data that causes the conflict.

Seeking to understand how the other side sees the situation may not only help us see potential solutions that will meet many of our needs, but may also allow us to revise how WE see the problem. Consequently, the area of conflict may actually be reduced.

2. Define the issues

- * Clarify the topics for discussion

How an issue is described or “framed” is important because it can have an impact on the ensuing discussion. Framing issues in neutral language that does not reflect the perceptions of either party will set the stage for productive discussions.

It is helpful in organizing an agenda for discussion, to list the issues and have some discussion about the best place to begin. There are a variety of ways to structure a discussion. Experience shows that “agreement begets agreement” so it is often desirable to begin with the easier issues that can be resolved quickly. The parties then have the positive experience of reaching agreement that can build momentum and the feeling of success.

3. Identify the interests

- * Go beyond the stated positions or solutions to figure out what the parties really need to have satisfied in order to reach agreement

- * Look for the common ground between all parties

Once the issues have been framed, the parties are ready to figure out the interests that they need to have satisfied in order to reach agreement. Recall that an interest is a party’s concern, need, desire or goal behind a position. It is what an individual wants to have satisfied - it expresses why the party cares.

Interests provide the motivation for people to seek solutions. When we are able to discover our underlying interests, we are able to move away from our positions and consider other options for meeting our needs. There is almost always more than one solution that will satisfy any interest.

Also, by focusing on what it is that we really need to have satisfied we may find that the other party shares some of our interests - it just wasn’t obvious when we looked at the positions.

4. Generate options

- * Brainstorm and generate ideas, looking at the problem from all angles and considering as many different ideas as possible

By this stage in the process, parties have had an opportunity to share, listen and develop an understanding of their interests as well as the interests of the other side. They have moved from an adversarial, entrenched posture to a problem solving, interest-based mode and are ready to brainstorm potential options and solutions.



The goal of brainstorming is to generate as many ideas and options as possible. Most of us are not accustomed to inventing options and we slip easily into critiquing and judging as soon as possibilities are put on the board. This curtails the flow of ideas, people's willingness to take risks, and suppresses creativity. Therefore it is wise before beginning with this step, to establish ground rules for brainstorming. People need to be reminded that this is not the time for deciding - it is the time for inventing and discussing.

Rules of brainstorming

1. **Make no criticism:** judging is not allowed.
2. **Be free-wheeling:** use your creativity and imagination, take risks.
3. **Go for quantity:** the more and varied the ideas the better. Avoid thinking in terms of a single answer.
4. **Combine and expand:** modify and build on other's ideas.

People are accustomed to searching for the one answer to a problem and often maintain a mindset that if one party wins, the other one loses. During the brainstorming process, record ideas on large pieces of newsprint so everyone has a clear view - this helps stimulate ideas and helps maintain a collaborative atmosphere by focusing everyone together.

Guidelines for generating options:

- Allow time for people to "warm up" and get comfortable with the creative process.
- Encourage looking at the problem from all angles.
- Encourage dovetailing, piggybacking, combining and revising ideas.
- Look for ideas with mutual gain.

5. Develop a fair standard or objective criteria for deciding

* Using agreed upon criteria, combine and reduce options

* Strive to "expand the pie" and create agreements for mutual gain.

Once the brainstorming has taken place, the parties need to decide on the criteria against which the options will be evaluated.

Why use objective criteria?

1. It protects the relationship from a contest of wills;
2. Allows the parties to use the time more effectively, focusing rather on standards and solutions rather than on defending their positions;
3. Enables parties to alter their perceptions without "losing face";
4. Enables parties to strive toward mutual fairness and decisions that are in the best interest of the all.
5. Creates agreements that are fair and wise.

Objective criteria may:

1. Be as simple as your collective interests;
2. Include budgetary standards, legal standards, scientific merit, procedural guidelines, etc.



6. Evaluate options and reach agreement

With a comprehensive list of brainstormed ideas and mutually agreeable objective criteria, you are ready to evaluate the options and move toward creating agreements that will meet as many of your collective needs and interests as possible.

Techniques for narrowing the field of options:

Thumbs up/Thumbs down

This method provides a general sense of the parties' views on any particular item. Using the objective criteria, the parties go through the list of items and give a thumbs up, thumbs down, or thumbs neutral sign. Some items will obviously not meet the objective standard and can be eliminated with unanimous thumbs down.

Using stars

Star the items that the group thinks are best.

Can any of the favoured options be reworked to create even better options?

Combining items for mutual gain

Some items may partially meet the objective criteria. Can some of these ideas be combined to create agreements for mutual gain? Can they be combined to actually meet more of the parties needs and interests, thereby expanding the total pie?

When an agreement is reached, ask the question:

**“Is this the best job we can do? Is there room for improvement?
Do we have a maximized solution or one that is marginally acceptable?”**

Knowing what to do next:

It is also true that each dispute between people is unique. Problem solving and dispute resolutions are organic processes which exist at the interface of art and science; it's impossible to follow a fixed set of rules to guarantee success. One of the worst feelings during a problem solving session or a negotiation comes when we perceive that we are stuck, or that the process is going badly. What should we do now?

Mediation teacher Jim Melamed has a foolproof formula to follow for how to think about what to do next. Jim recommends that the dispute resolver ask a simple question:

“What is the very best thing I could be doing right now to help move this process along?”

By asking this question, we may be able to cut through our frustration and “stick” to or focus on the practical tasks at hand.

While we ponder this question, we may want to buy ourselves some time. We can always say something like, “I wonder if someone wouldn't mind just summarising where we are right now”, or we can just ask for a short time out for everyone.



Solutions for common problems:

1. There is overt negativity or resistance.

Defuse the resistance.

The secret of dealing with resistance is not to fight it, but to *join* it; because ultimately it gives us control over the situation, and the chance to return all participants to calmness and clarity. It is important to understand that joining is not simply giving in. It is rather a process of, from a balanced position, moving to align with the “attacking” energy so that it is possible to begin to change the direction of that energy.

When we *join*, there are profound effects both on ourselves and on the other party. If we are successful, we get back an increased appreciation of where they are coming from; we understand their point of view, even if we hold different views ourselves. We also can better understand what will work in order to persuade the others to come to agreement.

The other party may begin to feel that they are understood and more importantly that perhaps we are a bit more like them. As people come to feel that they are more like each other, it becomes more difficult to attack, because it becomes like attacking oneself.

2. The process is becoming unfocused or veering off direction.

Refocus or clarify the track in terms of the goals of the negotiation.

3. Other people’s emotions are getting in the way.

Deal with their emotional needs.

4. People do not seem to understand certain aspects of the issues or the consequences of a given course of action.

Educate.

When we feel that the people we are working with are just not understanding and dealing with essential facts of a case, it may be time to try to *educate*. This is done not by berating, putting down or accusing but by educating. one of the best ways to be an effective educator is to use the Socratic Method: ask questions.

Example questions:

1. Questions to make people think or challenge them:

“What do you suppose would happen if...(insert factual content)?”

2. Questions to gather, clarify, or provide information:

“Am I correct in my understanding of this issue, which is..(insert factual content)..”

3. Questions which have a “reality check” quality:

“So if we spent all the money now, what would be the consequences of that?”







Useful resources

The following list of useful resources is adapted from the ANZCCART Website:

<http://www.adelaide.edu.au/ANZCCART/resources/>.

Useful background for members of AECs, particularly members in categories C and D. All are available from ANZCCART's Adelaide office.

- Australian Code of Practice for the Care and Use of Animals for *Scientific Purposes*. 7th Edition. Australian Government – National Health and Medical Research Council, Canberra. (The 'Information Sources' pages at the back of this Code provide an excellent list of further resources specific to various subjects associated with the care and use of animals in research and teaching.)
- Australian Senate Select Committee on Animal Welfare (1989). *Animal Experimentation*. Australian Government Publishing Service, Canberra. *ANZCCART News* 8(3). September, 1995. Special Issue for Schools on the Use of Animals in Education.
- Baker, R.M., Burrell, J.H. and Rose, M.A. (eds.) (1994). *Effective Animal Experimentation Ethics Committees*. Proceedings of ANZCCART's 1992 Conference. ANZCCART, Adelaide.
- Brennan, A. (1996). Australian AEECs: some proposals for effectiveness. *ANZCCART News* 9(2): 1-3.
- Campbell, A. (1995). The animal rights debate. *ANZCCART News* 8(1): 1-3.
- Einstein, R. (1997). The value of animal ethics committees. *ANZCCART News* 10(1): 3-5.
- Hassall, G (1999) Committees and conflict resolution. *ANZCCART News* 12(1) 1-3.
- Johnson, K. (1996). Making ethical decisions when the balance keeps swinging. *ANZCCART News* 9(3): 9-10.
- Johnston, N.E. (ed.) (1993). *Animal Welfare Conference Proceedings*. Monash University.
- Johnston, N.E. (ed.) (1995). *Animals in Science Conference: Perspectives on their Use, Care and Welfare*. Monash University.
- Mellor, D. (1993). Animals in science: ethics, obligations and ANZCCART. *ANZCCART News* 6(1): 1-3.
- Monamy, V. (1996). *Animal Experimentation: A Student Guide to Balancing the Issues*. ANZCCART, Adelaide.
- Montgomery, J. (1995) NHMRC Animal Welfare Committee Newsletter. No. 9: 18-19.
- Morton, D.B. and Griffiths, P.H.M. (1985). Guidelines on the recognition of pain, distress and discomfort in experimental animals and an hypothesis for assessment. *The Veterinary Record*. April 20, 1985. pp. 431-436.
- Oogjes, G. (1996). The need for change. *ANZCCART News* 9(3): 4-5.
- Perry, M. (1997). Review of the Australian Code of Practice for the Care and Use of *Animals for Scientific Purposes*. *ANZCCART News* 10(1): 1-2.
- Rogers, L. (1994). What do animals think and feel? *ANZCCART News* 7(4): 1-3.
- Rose, M. (1992). Russell and Burch revisited. *ACCART News* 5(4): 1-2, 6-7.
- Rose, M. (1996). Striking the balance: the practitioner and the AEC. *ANZCCART News* 9(3):1-4.
- Rose, M.A. (1996). The problems of pain: concepts and issues. *ANZCCART News* 9(4): 2-4.
- Russell, W.M.S and Burch, R.L. (1959). *The Principles of Humane Experimental Technique*. Reprinted edition (1992). UFAW, London.



- Schuppli, C (2004) The role of the Animal Ethics committee in achieving humane animal experimentation. PhD University of British Columbia. (Pdf version on request from BAW).
- Scott, L.R. and Carter, P.D. (1996). The role of veterinarians on animal experimentation ethics committees. *Australian Veterinary Journal* **74**(4): 309-310.
- Singer, P. (1990). *Animal Liberation*. New York Review of Books. Second edition. New York.
- Stiles, K. (1995). NHMRC Animal Welfare Committee Newsletter No. **9**:15-17. December.
- Stiles, K. and Edwards, K. (1994). *Guidelines for Lay Members of Animal Experimentation Ethics Committees, or, What Do I Do Now I'm Here?* ANZFAS, Melbourne.
- The Nuffield Council on Bioethics. *The ethics of research involving animals*. May 2005 www.nuffieldbioethics.org (for a printed copy email bioethics@nuffieldbioethics.org)

Journals

- Animal Welfare
- Anthrozoos
- ATLA (Alternatives to Laboratory Animals)
- ILAR Journal
- Lab Animal
- Laboratory Animals

Newsletters

- ANZCCART News
- ANZSLAS Newsletter
- Animal Welfare Information Center of the US National Agricultural Library
- CAAT (Center for Alternatives to Animal Testing), USA
- Canadian Council on Animal Care *Resource* 20
- Ethics Committee News, from the Animal Welfare Information Network (ANZFAS)
- FRAME (Fund for Replacement of Animals in Medical Experiments), UK
- NHMRC Animal Welfare Committee
- Research Defence Society, UK
- SCAW (Scientists' Center for Animal Welfare), USA
- UFAW (Universities Federation for Animal Welfare), UK



Resources relating to Animal Care and Housing

- **Environmental Enrichment for Captive Animals**, (Robert J Young) 2003, ISBN 0 632 06407 2. UFAW/Blackwell Publishing.
- **Housing for laboratory rats, mice, guinea pigs and rabbits** (A. Hargreaves) 2000. ISBN 0 958621 3 5. ANZCCART Australia.
- **Physiology and Behaviour of Animal Suffering**, (Neville G Gregory) 1994 ISBN 0 632 06468 4. UFAW/Blackwell Publishing
- [Policy on the Care and Use of Sheep for Scientific Purposes based on Good Practice](#)

Resources for Australian Animal Ethics Committee Members

- [Information package for Australian Animal Ethics Committee \(AEC\) members \(pdf 194kB\)](#)
- [Universities Federation for Animal Welfare \(UFAW\)](#)
- [Policy on the Care and Use of Sheep for Scientific Purposes based on Good Practice](#)

Resources for Researchers and University Students

- **Useful Information about Experimental Design** The aim of this web site is to help you to reduce the numbers of animals used in research by better choice of animals and better experimental design.
- **Animal Experimentation: A Student Guide to Balancing the Issues** (V Monamy) 1996. ISBN 0 9586821 0 0. ANZCCART Australia
- **Careful How You Hold Me CD-ROM** - The University of Melbourne
A multi media program for investigators, honours and postgraduate students, animal technicians and others new to the field of laboratory animal science and animal welfare - a resource for collective use or self paced learning. Look under **Animal Science** in the Catalogue List.
- **7th edition of the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes** (pdf 472kB)
Following extensive public consultation and review by a national working party made up of industry, government and animal welfare representatives, in 2004 the NHMRC has released the 7th edition of the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes (The Code). Click [here](#) (pdf 472kB) to download a pdf of the new edition of the Code. A hardcopy may be purchased from National Mail and Marketing on 1800 020 103.
- **Euthanasia of Animals Used for Scientific Purposes** (ed. J Reilly) 2nd edition (2001). ISBN 0 9586821 4 3. ANZCCART Australia.
- **'From Guinea Pig to Computer Mouse: Alternative Methods for a Humane Education' (2nd ed.)** InterNICHE book. The groundbreaking publication is now available for free download as a pdf document. First published in 2003, with minor updates made in February 2006, the 520-page book provides full details of over 500 alternatives, including description, specification and source. It also offers background information on the diversity of alternative tools and approaches, a review of published studies that assess alternatives through learning performance, and an exploration of curricular design. Seven case studies written by university heads of department who have fully replaced harmful animal use describe the experience of developing and implementing best practice teaching methods. The book also provides links to over 600 further resources.



- **New Zealand Code of Practice for the Use of Veterinary and Human Medicines in Research, Testing and Teaching Organizations** (pdf 151kB) The Royal Society has sponsored this Code to ensure it is written on behalf of the research community in New Zealand. Click [here](#) (pdf 151kB) to download a copy of the NZ code.
- **Ethical guidelines for Australian students using animals or animal tissues for educational purposes, for use by universities and other research organizations** (pdf 64kB) Using animals or their tissues in laboratory classes is a privilege which brings with it responsibilities that go well beyond the need to avoid cruelty to the animals. This pamphlet gives some advice to help students and teachers meet these responsibilities and to help them gain maximum benefit from using animals in laboratory classes.
- **New Zealand Ethical guidelines for students in laboratory classes involving the use of animals or animal tissues.** Using animals or their tissues in laboratory classes is a privilege which brings with it responsibilities that go well beyond the need to avoid cruelty to the animals. This pamphlet gives some advice to help students and teachers meet these responsibilities and to help them gain maximum benefit from using animals in laboratory classes. Available from ANZCCART NZ.

Resources for School Children

- **Animals, scientists and you.** An information resource for primary school students. There is also a teachers' book and a video (10 min). The video is designed to be used with the book as an introduction to individual chapters or to the complete course. It can also be used separately as an interdisciplinary visual aid on the topic of animals. Available from the Baker Medical Research Institute, PO Box 348, Prahran, Vic 3181, Australia.
- **Ethical guidelines for Australian school students using animals or animals for educational purposes** (pdf 63kB) Using animals or their tissues in laboratory classes is a privilege which brings with it responsibilities that go well beyond the need to avoid cruelty to the animals. This pamphlet gives some advice to help students and teachers meet these responsibilities and to help them gain maximum benefit from using animals in laboratory classes.
- **Investigating vertebrates, an animal study for 7th Form biology.** Available from P. Davie, IVABS, Massey University, PO Box 11-222, Palmerston North.
- **FRAME resources: *Issues—animal experiments; Animal experimentation—what are laboratory animals used for?*; and *Alternatives to animal testing.*** Excellent resource material for senior secondary students. The aims of the series are to inform young people about issues of concern and to develop skills of analysis and investigation, debate, and communication. A range of informed opinion is presented to enable pupils to form their own judgments. Published by FRAME (Fund for the Replacement of Animals in Medical Experiments), Russell and Birch House, 96-98 North Sherwood St, Nottingham NG1 4EE, United Kingdom.
- **Using Animals in Science.** An information resource for children, teachers, tertiary students & parents, prepared jointly by ANZCCART NZ and Massey University in New Zealand.



Resources for School Teachers

- **Animals and society – how simple are the issues?** Beta pamphlet. Suitable for intermediate and secondary students. Available for the Royal Society of New Zealand, PO Box 598, Wellington.
- **Animals, scientists and you.** An information resource for primary school students. There is also a teachers' book and a video (10 min). The video is designed to be used with the book as an introduction to individual chapters or to the complete course. It can also be used separately as an interdisciplinary visual aid on the topic of animals. Available from the Baker Medical Research Institute, PO Box 348, Prahan, Vic 3181, Australia.
- **The alternatives to dissection resource kit.** A practical aid for secondary school teachers. Published by SAFE (Save animals from exploitation). Available from SAFE Resource and Information Centre, 133 Worcester St, Christchurch. Email: safe@chch.planet.co.nz
- **Ethical guidelines for Australian school students using animals or animals for educational purposes** (pdf 63kB). Using animals or their tissues in laboratory classes is a privilege which brings with it responsibilities that go well beyond the need to avoid cruelty to the animals. This pamphlet gives some advice to help students and teachers meet these responsibilities and to help them gain maximum benefit from using animals in laboratory classes.
- **The facts.** A series of pamphlets about the use of animals in research. Suitable for intermediate and secondary students. Further information from Animals in Medicines Research Information Centre (AMRIC), 12 Whitehall, London, SW1A 2DY, United Kingdom.
- **NAWAC Codes of recommendations and minimum standards.** Resource for teachers. The National Animal Welfare Advisory Committee (NAWAC) to the Minister of Agriculture has now produced 20 codes outlining the minimum standards which are currently acceptable to the informed New Zealand public and make recommendations to ensure good animal welfare. These codes are available from Animal Welfare and Environment Section, MAF Biosecurity Authority, PO Box 2526, Wellington







AEC Annual Self-Audit

Purpose:

Completion of this audit form annually will partially fulfil Section 2.1.1 (ix), conducting an annual review of the operation of the AEC and a meeting with the AEC chairperson, and replace the AEC Annual Report (Section 2.2.40).

The self-audit will only be deemed complete if all sections have been completed and signed off by the relevant person.

The original self-audit document must be retained by the institution for inspection during the triennial review by the Bureau of Animal Welfare. In addition, copies should be provided to the AEC members to ensure continuous improvement in AEC activities and encourage continued training for relevant staff within the Institution and AEC members in accordance with Section 2.2.1 (iii and viii).

Section 1. General information

1.1 Licence Number

1.2 Institution name

1.3 Postal Address

1.4 Licence Nominee's details

Name and Title (Prof., Dr., Mr., Ms., etc)	
Position: Department:	
Postal Address (if different from above)	
Phone:	()
Fax:	()
Email:	

1.5 Financial Year of this Self-Audit Report (eg 08/09)

1.6 Date of Last Bureau of Animal Welfare Audit:

Section 2. Animal Ethics Committee Composition

Please add additional boxes for categories as required.

2.1 Chairperson's Details:

Name and Title (Prof., Dr., Mr., Ms., etc)	
Position: Institution & Department:	
Postal Address	
Phone:	()
Fax:	()
Email:	

2.2 Category A Member's Details:

Name and Title (Prof., Dr., Mr., Ms., etc)	
Position: Institution & Department:	
Postal Address	
Phone:	()
Fax:	()
Email:	

2.3 Category B Member's Details:

Name and Title (Prof., Dr., Mr., Ms., etc)	
Position: Institution & Department:	
Postal Address	
Phone:	()
Fax:	()
Email:	

2.4 Category C Member's Details:

Name and Title (Prof., Dr., Mr., Ms., etc)	
Position: Institution & Department:	
Postal Address	
Phone:	()
Fax:	()
Email:	

2.5 Category D Member's Details:

Name and Title (Prof., Dr., Mr., Ms., etc)	
Position: Institution & Department:	
Postal Address	
Phone:	()
Fax:	()
Email:	

2.6 Category E Member's Details: (If applicable)

Name and Title (Prof., Dr., Mr., Ms., etc)	
Position: Institution & Department:	
Postal Address	
Phone:	()
Fax:	()
Email:	

**2.7 Other regular attendees of committee meetings
(including co-opted members and/or invited experts that have contributed to the quorum during the past 12 months):**

Name and Title (Prof., Dr., Mr., Ms., etc)	
Position: Institution & Department:	
Postal Address	
Phone:	()
Fax:	()
Email:	
Role within the AEC:	

Name and Title (Prof., Dr., Mr., Ms., etc)	
Position: Institution & Department:	
Postal Address	
Phone:	()
Fax:	()
Email:	
Role within the AEC:	

2.8 AEC Secretary's Contact Details:

Name and Title (Prof., Dr., Mr., Ms., etc)	
Position: Institution & Department:	
Postal Address	
Phone:	()
Fax:	()
Email:	

For additional regular committee member's in each category please attach a separate sheet.

2.9 Has the membership of this committee changed during the past 12 months?

Yes , please specify below

No

Please detail how the composition of the committee has altered in the past 12 months:

2.10 Each Committee member must individually complete the APPENDIX 1 form to be attached to this Self-Audit form.

Section 3. AEC Activities Report

3.1 How many formal, minuted meetings has the AEC conducted this year?

3.2 Please provide the dates of each of the formal meetings held during the past 12 months (day/month/year):

- | | | | |
|----|-----|-----|-----|
| 1. | 7. | 13. | 19. |
| 2. | 8. | 14. | 20. |
| 3. | 9. | 15. | 21. |
| 4. | 10. | 16. | 22. |
| 5. | 11. | 17. | 23. |
| 6. | 12. | 18. | 24. |

3.3 Are all meetings minuted?

Yes

No

If No, please detail reasons below (note that minutes of AEC decisions and other actions must be maintained, §2.2.12 of the Australian Code)

3.4 Please complete the following table outlining the number of research proposals your AEC has reviewed in the past 12 months:

Project Type	Number Approved	Number Approved with minor revisions	Number approved with major revisions	Number Approved out of Session	Number rejected	Total:
Understanding human/animal biology						
Improving human/animal welfare						
Improve animal management/ production						
Educational objectives						
Environmental objectives						
Total:						

3.5 Please list and provide details for any project applications that involve more than one AEC :

	Project Type	Additional AEC's involved (list Institution and licence/s involved)	Communication between AEC's Established? Yes/No	Additional Comments
1				
2				
3				
4				
5				
6				

Please add lines to the table where necessary

3.6 Please detail any project outcomes that have resulted in *conflict* between an Investigator and the AEC

	Project Type	Outline Issues raised in the dispute	Outline steps taken to resolve conflict	Detail outcome : Resolved/Not resolved
1				
2				
3				

Please add lines to the table where necessary

3.7 Please detail any project outcomes that have resulted in *conflict* between AEC Members

	Members involved (names and/or category)	Outline Issues raised in the dispute	Outline steps taken to resolve conflict	Detail outcome: Resolved/Not resolved
1				
2				

Please add lines to the table where necessary

3.8 Please detail any *adverse incidents* reported by investigators

	Project Number	Summary of incident	AEC Action	Outcome: resolved to AEC satisfaction
1				
2				

Alternatively, attach adverse incident register

3.9 Please detail any administrative difficulties faced by the AEC:

3.9.1 Please outline recommendations to improve administrative function of the AEC

3.10 Please detail any other difficulties experienced by the AEC in the past 12 months

3.10.1 Please outline recommendations for improving/correcting/avoiding future difficulties:

3.11 Please provide details of any other matters impacting on the institution's ability to maintain compliance with the Code:

3.12 Please provide recommendations for returning or maintaining compliance with the Code

Section 4. Institutional Animal Care/Use Facilities

4.1 Does your institution have animal facilities?

Yes

No , please go to Section 5

4.2 Are all the facilities where animals are housed /used visited at least once a year by all or some of the AEC members?

Yes

Yes and No

No

Please provide further detail if your answer was "Yes and No" or "No":

4.3 Are all visits conducted by the AEC documented in committee minutes or in a written report?

Yes

Yes and No

No

Please provide further detail if your answer was "Yes and No" or "No":

4.4 Does each AEC Member attend at least 1 Facility visit per year?

Yes

Yes and No

No

Please provide further detail if your answer was "Yes and No" or "No":

4.5 Are the results of Facility visits discussed and followed up with the Facility Manager/director or the relevant institutional person?

Yes

Yes and No

No

Please provide further detail if your answer was "Yes and No" or "No":

4.6 Are any serious concerns noted during a facility visit or meeting discussed with the licence nominee or appropriate institution representative?

Yes

Yes and No

No

Please provide further detail if your answer was "Yes and No" or "No":

4.7 Do the Licence Nominee /Appropriate institution representative and the AEC work together the address concerns identified by the AEC?

Yes

Please provide some brief examples:

Yes and No

Please provide details:

No

Please provide details:

4.8 Please provide an additional comments or recommendations regarding animal care/use facilities held/used by the institution

Section 5. Continuing Education and Training & Occupational Health and Safety

5.1 Please specify training and continuing education opportunities (eg conferences, workshops, training sessions etc.) *provided by the institution for the following groups* (where applicable):

- A. AEC Members

- B. Animal Carers

- C. Scientists/investigators

- D. other animal users/students

5.2 Please outline training and continuing education opportunities recommended for each of the following groups:

- A. AEC Members

- B. Animal Carers

- C. Scientists/investigators

- D. other animal users/students

5.3 Comment on the ability of the AEC to accurately assess the competence of staff in procedures relevant to project requirements for each of the following groups:

- A. Animal Carers

- B. Scientists/investigators

- C. other animal users/students

5.4 Comment on the ease of obtaining adequate training for animal carers/users

5.5 Comment on the ease of obtaining adequate training for AEC Members

5.6 Is the institutional OH&S program sufficient to provide AEC Members with good health and safety during meetings and facilities visits?

Yes

Yes and No

No

Please provide recommendations if your answer was "Yes and No" or "No":

Section 6. Summary and Recommendations

This section is to be completed by the Chairperson the committee in consultation with the Licence Nominee

6.1 Please outline the main strengths of your AEC

6.2 Please provide an analysis of the weaknesses of your AEC, indicating provisions for improvements in the next 12 months.

6.2.1 Please indicate any further resources or training that the Bureau of Animal Welfare could provide to assist you in meeting your challenges

6.3 Please detail any recommendations you have for improving the Institution's animal care program and facilities and note any resources required:

6.4 Additional information/comments

Section 7. Declarations

To be completed by the AEC Chairperson/s and the Licence Nominee or Institution Representative

I declare that the information contained in this AEC Annual Self-Auditing Document is an accurate account of the functioning of this AEC. I understand that completion of this report meets the reporting requirements set out in Section 2.2.40 of the Australian Code of practice for the care and use of animals for scientific purposes.

I declare that the content of this report, particularly recommendations regarding animal facilities, training and continuing education requirements and opportunities and AEC functioning have been the subject of discussion between the AEC Chairperson/s and the Institution's Licence Nominee/Representative signed below.

We agree to undertake as many of the recommendations as practical in the coming year to ensure continual improvement in the functioning of our AEC and to ensure continued ethical and humane use of animals for scientific and teaching purposes.

Signed by Chairperson/s: _____ / _____

Name/s in Full: _____ / _____

Date: _____ / _____

Signed by Licence Nominee/Institution Representative: _____

Name in Full: _____

Date: _____

Appendix 1: AEC Member Summary

Name:

Position on AEC:

Date:

Signature _____

A1.1 In the past 12 months, how many meetings did you attend?

A1.2 Please provide dates of each meeting you attended over the past 12 months (day/month/year):

- | | | | |
|----|-----|-----|-----|
| 1. | 7. | 13. | 19. |
| 2. | 8. | 14. | 20. |
| 3. | 9. | 15. | 21. |
| 4. | 10. | 16. | 22. |
| 5. | 11. | 17. | 23. |
| 6. | 12. | 18. | 24. |

A1.3 Please provide details of Animal Use/Care facilities held by the institution that you reviewed as part of your AEC membership responsibilities: (include: date, name of facility, facility manager, outcome of meeting, personal comments regarding the conduct of the facility inspection and any recommendations for future inspections)

A1.4 Please provide details of any TRAINING relevant to your role as an AEC member you have obtained in the past 12 months:

A1.5 Please detail any references and/or additional training you would like to improve your ability to contribute effectively to your AEC:

A1.6 Please provide your analysis of the main STRENGTHS of your AEC Program:

A1.7 Please provide your analysis of the main WEAKNESSES of your AEC Program:

A1.8 Comments or additional information:

Application for approval to use animals in a Research Project

Background

All scientific procedures using animals must be carried out in accordance with the Prevention of Cruelty to Animals Act 1986 (the *Act*), associated Regulations and the Australian code of practice for the care and use of animals for scientific purposes (the *Code*).

These legislative requirements specify that an Animal Ethics Committee (AEC) must verify that the use of animals for research or teaching is justified and adheres to the principles of Replacement, Reduction and Refinement. All proposed animal use must be approved by an AEC before commencing the project.

Before completing this application form investigators should be familiar with the following as applicable:

- The *Australian code of practice for the care and use of animals for scientific purposes*
- The Code of practice for the housing and care of laboratory mice, rats, guinea pigs and rabbits
- The Code of practice for the use of animals from municipal pounds in scientific procedures
- Part III of the *Prevention of Cruelty to Animals Act 1986 and Regulations 1997*

Knowledge of these legal requirements will assist you in completing this application in a satisfactory manner. The above documents can be found at www.dpi.vic.gov.au/animalwelfare/

Notes on the completion of this Application Form

1. Insert your answers in the boxes provided below each question. When necessary boxes will expand to accommodate the length of your answer.
2. A response is required for each question. Write "Not applicable", if necessary.
3. **Applications must be written in plain English.** It should be assumed that assessors have either no scientific knowledge or no knowledge of your area of research. Where scientific language is unavoidable, it must be supported by a suitable lay description or a glossary of terms. **It is not appropriate to include sections from grant applications containing excessive detail of procedures unrelated to the use of animals.**
4. It is highly recommended that you ask a colleague and a person with a non-scientific background to read the application before it is submitted.

Note: Please do not copy and submit this page with your application.

Institution name

Animal Ethics Committee

Office Use Only

Office Use Only

Scientific Institution

AEC Register Number

Office Use Only

--	--	--	--	--

Conditions of approval

All matters pertaining to the conduct of the approved project are to be reported to the Animal Ethics Committee, which maintains oversight in accordance with licence conditions for the Licence SPPL****.

Any variation proposed to the project, and the reasons for that change, must be submitted to the AEC for approval and must not be implemented until approval is granted.

A record of details of any animals used in the project must be retained.

The project should only be conducted in approved premises nominated on the Licence SPPL ***. Use of other premises would constitute a variation and relevant details are to be notified to the AEC for approval as "field work".

The AEC must also be notified in writing of:

- Any changes to approved investigators
- Any unexpected incidents or complications that result in deaths, euthanasia or pain and suffering for the animals used in the project. Details of the steps taken to deal with adverse incidents must be included in the notification.

The total numbers of animals approved for use in the project are:

Species (and common name)	Strain Name (Indicate with an {*} if Genetically Modified)	Sex	Age	Total Number

Declaration by Nominated Signing Officer for the AEC

I certify that this project has been considered and approved by the (insert institution name) Animal Ethics Committee

The period of approval for the project is **/ **/ ** to **/ **/ **

Nominated Signing Officer Name:	
Nominated Signing Officer Signature:	
Date:	

Section 1. Administration

1.1. Title

The title of the project should be concise and expressed in lay language. Do not use abbreviations or scientific jargon.

1.2. Project Supervisor (primary investigator)

The project supervisor will have legal responsibility for the welfare of the animals.

Name (Title, given name, family name)	
Name of Employing Institution	
Scientific Procedures Licence (name, number if known)	

1.3. Primary Contact

The primary contact must be an investigator on the project whose details are given in Section 4.

Name (Title, given name, family name)	
---------------------------------------	--

1.4. Duration of Project

Applicants may request approval for a project up to three (3) years. **DO NOT** nominate a date before that of the AEC meeting. Scientific activities involving the use of animals must not start before receipt of written approval.

Proposed commencement date:	Day:	Month:	Year:
-----------------------------	------	--------	-------

Expected completion date:	Day:	Month:	Year:
---------------------------	------	--------	-------

1.5. Animals Requested

Species (and common name)	Strain Name (Indicate with an {*} if genetically modified)	Sex	Age	Total Number

1.6. Funding and Contracts

(i) Indicate with a {√} the principal source of funding for this project.

Source of funding	Peer reviewed	Not peer reviewed
Internal		
External agency		
Commercial/Private		

(ii) Name funding source and, if applicable, the scheme.

(iii) Is this project commercial-in-confidence?

<input type="checkbox"/>	No
<input type="checkbox"/>	Yes

1.7. Risk Management

Does this project involve procedures or agents that might pose a health risk to other animals and/or personnel?

<input type="checkbox"/>	No	
<input type="checkbox"/>	Yes	If Yes, please explain the risk and describe what precautions will be taken.

1.8. Permits

Is the acquisition, holding, or use of the animals subject to any permit, law or regulation of the State or Commonwealth (eg. OGTR, protected native or imported)?

<input type="checkbox"/>	No	
<input type="checkbox"/>	Yes	If yes, please specify the permit number.

Section 2. Justification for the Use of Animals

Animal Ethics Committees (AECs) must be satisfied that the use of animals is justified, based on whether the scientific or educational value of the work outweighs the potential impact on the animals being used.

Unsatisfactory completion of this section will result in a request for revision of the application.

Overall, answers provided in the following subsections should provide AEC members, particularly external lay and welfare members, with a clear idea of why the experiments are necessary and what will happen to animals.

All information provided in this section must be in language that can be understood by an interested, intelligent person without a scientific background. Do not use scientific jargon and abbreviations.

2.1. Project Summary

(i) Provide a brief discussion of the background of the course. If applicable, describe how this project relates to any previously approved projects.

(ii) State the aim/s of the project.

(iii) Briefly outline how the project is designed to achieve its aims, in particular what will happen to the animals.

NOTE: This section is a summary only. Expanded detail of procedures on animals is required in Section 3.3.6.

2.2. Potential Benefit of the Project

Explain the significance and the potential benefit of the proposed project

2.3. Potential Impact on the Animals

(i) What will be the potential impact on the well-being of animals to be used in the proposed project?

	Minor
	Moderate
	Substantial

(ii) Briefly explain the reason for this classification.

(iii) Please indicate if the project involves any of the following:

	<u>Death as an end point (as defined in The Code) * AEC approved project to be forwarded to Bureau of Animal Welfare under Regulation 12 (2) for final approval.</u>
	Production of monoclonal antibodies by ascites method
	Prolonged restraint or confinement

2.4. Repeated Studies

Does this project duplicate work that has been carried out previously?

	No	
	Yes	If yes, please explain why it is necessary to duplicate the work.

2.5. Repeated Use of Animals

Have any of the animals been the subject of a previous research or teaching activity?

	No	
	Yes	If yes, provide AEC Register Number/s of the other project/s, describe what was done to the animals previously and justify their use in this project.

Section 3. Project Details

The purpose of the *Australian of practice for the care and use of animals for scientific purposes* (the Code) is to ensure the ethical use and the humane care of animals used for scientific purposes.

The Code emphasises the responsibilities of investigators, teachers and institutions using animals to:

- ensure that the use of animals is justified, taking into consideration the scientific or educational benefits and the potential effects on the welfare of the animals;
- ensure that the welfare of animals is always considered;
- promote the development and use techniques which replace animal use in scientific and teaching activities wherever possible;
- minimise the number of animals used in projects; and
- avoid pain or distress for each animal used in scientific and teaching activities;

To this end, there is a need in scientific and teaching activities to consider:

- the *replacement* of animals with other methods
- the *reduction* in the number of animals used; and
- the *refinement* of techniques used to reduce the impact on animals.

Where scientific language is deemed unavoidable it must be supported by a suitable lay description in the text or in a glossary of terms.

Glossary of Terms

Scientific term	Lay description

3.1. Replacement

The Code specifies that techniques that totally or partially replace the use of animals for scientific purposes must be sought and used wherever possible. In order to complete this section a search of alternatives websites and databases will be required. Suitable websites and databases include:

altweb.jhsph.edu/databases.htm

www.nca-nl.org/

www.nal.usda.gov/awic/alternatives/alternat.htm

www.vetmed.ucdavis.edu/Animal_Alternatives/databaseapproach.html

3.1.1. Alternatives

(i) Provide details of the search conducted to find alternatives to the use of animals for this project. Include a list of the websites and databases visited, the date visited and the years and key words that the search encompassed.

(ii) Have alternatives that totally or partially replace the use of animals been incorporated into this project?

	No	If no, provide a list of potential alternatives and explain why they are unsuitable for use in this project.
	Yes	If yes, please describe what alternatives are to be used in this project.

3.2. Reduction

3.2.1. Justification for Number of Animals Requested

(i) Justify the number of animals requested in terms of statistical considerations and/or other considerations in the experimental design. Where appropriate, present the numbers in table form.

(ii) To reduce animal use, would the animals or their tissues, at the conclusion of your experiments, be suitable for use in another project?

3.2.2. Endorsement of Statistician / Biometrician

Wherever possible, applications should be endorsed by a Statistician / Biometrician or Reference to an appropriate statistical text provided.

Has a statistician / Biometrician been consulted about the design of this project?

	No	If no, please explain why this was not considered necessary.
	Yes	If yes, please have the declaration below completed.

I am aware of and support the proposed experimental design and number of animals to be used as outlined in this application.

Statistician /Biometrician Name:	
Statistician /Biometrician Signature:	
Date:	

3.3. Refinement

3.3.1. Choice of Animal

Refer to the NHMRC Policy on the care and use of non-human primates for scientific purposes if using these animals.

Justify your choice of animal (species/strain/sex/age).

3.3.2. Genetic Modification of Animals

Does the project involve the use or production of genetically modified animals eg. transgenic, knockout, or of animals with spontaneous genetic mutations?

	No	
	Yes	If yes, please complete Appendix 1

3.3.3. Cloning of Animals

Does the project involve the use or production of cloned animals?

	No	
	Yes	If yes, please complete Appendix 1

3.3.4. Source of Animals

If animals are to be sourced from municipal pounds, you must comply with the Code of practice for the use of animals from municipal pounds in scientific procedures.

(i) From where will the animals be obtained?

(ii) Will animals need to be transported from the source location to the location where they will be held for this project?

	No	
	Yes	If yes, provide details of transportation and acclimatisation procedures.

3.3.5. Location of Animals and Housing

Refer to the Code of practice for the housing and care of laboratory mice, rats, guinea pigs and rabbits (Housing Code) if using these species

(i) Where will animals be housed? If outdoors, please give details of shelter provided. If, contrary to the needs of the species, no shelter is provided, justify the lack of shelter.

(ii) Where will procedures be performed? If animals need to be transported from where they are housed to where the procedures are carried out provide details of how this will be done.

(iii) What type of housing will be used? Include details of methods used to ensure that housing meets the specific requirements of the animals being held. Describe any special housing requirements.

(iv) Will any animals need to be housed individually?

	No	
	Yes	If yes, explain why, for how long and how the impact of social isolation be minimised?

3.3.6. Project Description

This section should explain the scientific rationale of the project and provide a detailed description of the experimental design. Particular emphasis should be placed on describing what will happen to each animal or group of animals (including controls) from the time the animals are obtained until the time the project is completed.

It is not necessary to include excessive detail about procedures that do not involve the use of live animals.

When multiple procedures are to be performed on individual animals, consider using a flow diagram to illustrate the number of procedures to be performed and the time interval between each procedure. The expected effect of the procedures on the animals should be described.

If performing non-terminal surgical procedures describe how asepsis will be maintained during surgery and the pain management strategies that will be used to minimise post-surgical pain and distress.

If trapping, marking or tracking wildlife or fish, provide details of the type of trap and marking or tracking device.

If agents are to be administered, provide details of dose rates, volumes, needle gauges, routes and methods of administration. Also provide a brief description of the mechanism of action and expected effects of any agents to be administered.

3.3.7. Monitoring

Investigators are responsible for monitoring the welfare of their animals. This responsibility begins when an animal is allocated to the approved project and ends with the specified fate of the animal at the completion of the project.

Unexpected incidents that impact on the welfare of any individual animal or group of animals must be responded to immediately and reported to the AEC.

All personnel identified in this section of the proposal must be aware of the criteria for monitoring the welfare of the

animals and of how records are to be kept.

For housed animals, welfare monitoring checklists must be kept with the animal so as to be readily accessible to all nominated personnel and to animal facility staff.

(i) Day-to-day monitoring: Who will monitor the animals?

On weekdays:

After hours (including weekends and holidays):

(ii) Day-to-day monitoring during the project: What specific signs will be monitored and how frequently? Attach a copy of the monitoring *checklist you will use to record these observations (* see Housing Code for example).

(iii) Monitoring during and after procedures/interventions: What specific signs will be monitored and how frequently? Attach a copy of the monitoring *checklist you will use to record these observations (* see Housing Code for example).

(iv) What clinical, behavioural or other signs will be used to indicate that intervention is needed to alleviate an animal's pain or suffering? What action will be taken if these indicators are reached? (eg. increase in the frequency of observations, consultation with a veterinarian, administration of analgesics or other appropriate medication, withdrawal from the project, euthanasia etc)?

(v) Who is responsible for the management of emergencies?

3.3.8. Fate of the Animals

(i) What is be the maximum period of time that an individual animal or group of animals will be used in this project?

(ii) What will happen to the animals at the completion of the project?

(iii) If the animals are to be killed, how will this be done and by whom? Include information about agents, dose rates, method and route of administration and experience of personnel.

(iv) What will be the method of disposal of dead animals?

Section 4. Details of Personnel Involved in the Project

Investigators have personal responsibility for the welfare of the animals they use and must act in accordance with all requirements of the Act, the Regulations, the Code and the AEC. This responsibility begins when an animal is allocated to the approved project and ends with the specified fate of the animal at the completion of the project.

The AEC must be assured that all personnel working on live animals in this project are appropriately experienced, or will be adequately trained and supervised in the techniques described. A global statement of experience with animal related techniques e.g. "10 yrs experience" is not sufficient.

4.1. Project Supervisor (primary investigator)

Name (Title, given name, family name)			
Qualifications			
Department/ Organisation			
Position			
Internal Telephone No. (direct contact number)			
Internal E-mail address			
INVOLVEMENT IN THE PROJECT			
Will you be carrying out techniques/procedures on live animals?	Yes	<input type="checkbox"/>	If yes, complete details below.
	No	<input type="checkbox"/>	If no, details of expertise are not required.
<i>For each species and technique, describe the level of expertise and number of years of experience the named investigator possesses. If no experience, please complete the arrangements for training section below.</i>			
Species	Technique/Procedure	Level of Expertise Approx. number of times you have performed the technique/procedure in this species	
ARRANGEMENTS FOR TRAINING			
<i>For each species and technique, nominate the person who will provide training and describe the level of expertise of that person.</i>			
Species	Technique/Procedure	Level of Expertise Approx. number of times you have performed the technique/procedure in this species	
Trainer(s) Declaration: I/We have the relevant expertise and I/We accept responsibility to train and supervise the above person until I/We consider them to be competent in the necessary procedures.			
Trainer(s) signature:		Date:	

4.2. Other Investigators

Name (Title, given name, family name)		
Qualifications		
Department		
Position		
Internal Telephone No. (direct contact number)		
Internal E-mail address		
INVOLVEMENT IN THE PROJECT		
<i>For each species and technique, describe the level of expertise and number of years of experience the named investigator possesses. If no experience, please complete the arrangements for training section below.</i>		
Species	Technique/Procedure	Level of Expertise
		Approx. number of times you have performed the technique/procedure in this species
ARRANGEMENTS FOR TRAINING		
<i>For each species and technique, nominate the person who will provide training and describe the level of expertise of that person.</i>		
Species	Technique/Procedure	Level of Expertise
		Approx. number of times you have performed the technique/procedure in this species
Trainer(s) Declaration: I/We have the relevant expertise and I/We accept responsibility to train and supervise the above person until I/We consider them to be competent in the necessary procedures.		
Trainer(s) signature:		Date:

Name (Title, given name, family name)	
Qualifications	
Department	
Position	
Internal Telephone No. (direct contact number)	
Internal E-mail address	

INVOLVEMENT IN THE PROJECT

For each species and technique, describe the level of expertise and number of years of experience the named investigator possesses. If no experience, please complete the arrangements for training section below.

Species	Technique/Procedure	Level of Expertise Approx. number of times you have performed the technique/procedure in this species

ARRANGEMENTS FOR TRAINING

For each species and technique, nominate the person who will provide training and describe the level of expertise of that person.

Species	Technique/Procedure	Level of Expertise Approx. number of times you have performed the technique/procedure in this species

Trainer(s) Declaration: I/We have the relevant expertise and I/We accept responsibility to train and supervise the above person until I/We consider them to be competent in the necessary procedures.

Trainer(s) signature:

Date:

Section 5. Project Supervisor Declaration

I hereby declare that:

- (i) I have read Part III of the *Prevention of Cruelty to Animals Act 1986* (the *Act*), the Regulations 1997 and the current version of the *Australian code of practice for the care and use of animals for scientific purposes* (the *Code*), and accept the responsibilities detailed therein.
- (ii) I accept responsibility for the conduct of all experimental procedures detailed in this application, in accordance with requirements of the *Act*, Regulations, the *Code*, the Animal Ethics Committee.
- (iii) I have listed each person engaged in this project under Section 4 and consider that they have the qualifications, experience and training appropriate for their role in the project; and that they are competent to perform procedures described to the extent of their role. If any person is not already skilled in the procedures, I will ensure that they obtain all necessary training in advance of performing any procedure independently. All personnel have been made aware of their role and responsibilities in this project, and have been given copies of all necessary documentation.
- (iv) The Animal Facility Manager has been made aware of requirements for this application.

Project Supervisor Signature:	
Date:	

Section 6. Other Investigator Declaration

I hereby declare that:

- (i) I am familiar with Part III of the *Prevention of Cruelty to Animals Act 1986* (the *Act*), associated Regulations and the current version of the *Australian code of practice for the care and use of animals for scientific purposes* (the *Code*) and accept the responsibilities detailed therein to the extent of my involvement in this project.
- (ii) I accept responsibility for the conduct of all experimental procedures detailed in this application that I undertake, in accordance with the requirements of the *Act*, the *Regulations* and the *Code* and the Animal Ethics Committee.

Investigator's Name	Investigator's Signature	Date

Section 7. Animal Facility Manager Declaration

The signature of the animal facility manager is required if animals are to be obtained from or housed in the animal facility.

I confirm that the required animals can be obtained from and/or housed in the animal facility:

Animal Facility Manager's Name:	
Animal Facility Manager's Signature:	
Date:	

Section 8. Conflict of Interest

Is there any affiliation or financial interest for researchers in this research or its outcomes or any circumstances which might represent a perceived, potential or actual conflict of interest?

No	
Yes	If Yes, provide brief details

Section 9. Nominated Person on Licence Declaration

I acknowledge that it is my responsibility to ensure that staff of the department and those working under their supervision who use animals for scientific purposes comply with the conditions laid down by:

- (i) The *Prevention of Cruelty to Animals Act 1986 and Regulations 1997*;
- (ii) The current version of the *Australian code of practice for the care and use of animals for scientific purposes*; and
- (iii) The Animal Ethics Committee.

I certify that the animals required for this project can be provided, housed and maintained at a standard consistent with the requirements of the *Act*, the *Regulations*, the *Code* and any other condition laid down by the Animal Ethics Committee and that approval of this project will not compromise the conditions under which other animals in the institution are held.

Nominated Person's Name:	
Nominated Person's Signature:	
Date:	

Check list:

Project Title		
Does it describe the work proposed?	Yes	No
Project duration		
Is the proposed duration stated?	Yes	No
Safety		
Are there any safety issues for humans or other animals?	Yes	No
Justification for the use of animals		
Is the project summary easily understood by people who do not have a scientific background?	Yes	No
Are the aims clearly stated?	Yes	No
Is the significance of the work clear?	Yes	No
Replacement		
Is it clear why alternatives are not being used?	Yes	No
Reduction		
Are the numbers requested justified?	Yes	No
Refinement		
Are all terms clearly defined?	Yes	No
Where will the animals be housed and who will care for them at all stages of the project?	Yes	No
Do any genetically modified or cloned animals have phenotypes which require special care?	Yes	No
What will happen to each individual animal or group of animals from the beginning to the end of the project? (agents, dose rates, routes and frequency of administration, actions, anaesthesia, surgery, number of procedures per animal etc)	Yes	No
What is the potential impact on the animals' welfare of each procedure?	Yes	No
What criteria will be used to monitor the animals?	Yes	No
What will be done if welfare problems are identified?	Yes	No
How will the animals will be killed and disposed of?	Yes	No
Investigators		
Who will be doing the work?	Yes	No
What experience do the named personnel have in the specific techniques described in the proposal?	Yes	No
What training is needed?	Yes	No
Who will provide the training?	Yes	No
How the training will be provided?	Yes	No

Appendix 1: Genetic Modification or Cloning of Animals Report

This report must be completed for all projects involving the use or production of genetically modified animals.

A. Animal Details (A separate report is required for each strain)

Species (and common name)	Strain Name	Background Strain

B. Genotype (If applicable for cloned animals)

(i) Describe the function/s of the gene/s that have been/will be modified

(ii) Explain the relevance of the genetic modification to the project

(iii) Will tissue be collected to use for genotyping?

	No	
	Yes	If yes, describe how and when.

(iv) What will be the fate of animals that are not of the appropriate genotype?

C. Phenotype

(i) Is the phenotype of this strain well characterised?

	No	If no, briefly describe the <i>potential</i> or <i>anticipated</i> behavioural, physiological, reproductive and developmental features of the strain and identify whether the modification/s will affect the health, welfare, breeding or lifespan of the animals.
	Yes	If yes, briefly describe the <i>known</i> behavioural, physiological, reproductive and developmental features of the strain and identify whether the modification/s will affect the health, welfare, breeding or lifespan of the animals.

(ii) Does the strain require any special husbandry?

	No	
	Yes	If yes, describe the particular requirements for care.

D. Breeding

Describe the breeding program (e.g. heterozygous, homozygous, back-crossing) that will be used to produce the genetically modified or cloned animals to be used in the project. Provide estimates of the number of animals that will be used in the breeding program.

NOTE: Records of the number of animals used as part of the breeding program (including animals culled because of inappropriate genotype) must be maintained and provided to the AEC and Bureau of Animal Welfare on request.

Application for approval to use Animals in a Teaching Project

Background

All scientific procedures using animals must be carried out in accordance with the Prevention of Cruelty to Animals Act 1986 (the *Act*), associated Regulations and the Australian code of practice for the care and use of animals for scientific purposes (the *Code*).

These legislative requirements specify that an Animal Ethics Committee (AEC) must verify that the use of animals for research or teaching is justified and adheres to the principles of Replacement, Reduction and Refinement. All proposed animal use must be approved by an AEC before commencing the project.

Before completing this application form investigators should be familiar with the following as applicable:

- The *Australian code of practice for the care and use of animals for scientific purposes*
- The Code of practice for the housing and care of laboratory mice, rats, guinea pigs and rabbits
- The Code of practice for the use of animals from municipal pounds in scientific procedures
- Part III of the *Prevention of Cruelty to Animals Act 1986 and Regulations 1997*

Knowledge of these legal requirements will assist you in completing this application in a satisfactory manner. The above documents can be found at www.dpi.vic.gov.au/animalwelfare/

Notes on the completion of this Application Form

1. Insert your answers in the boxes provided below each question. When necessary boxes will expand to accommodate the length of your answer.
2. A response is required for each question. Write "Not applicable", if necessary.
3. **Applications must be written in plain English.** It should be assumed that assessors have either no scientific knowledge or no knowledge of your area of research. Where scientific language is unavoidable, it must be supported by a suitable lay description or a glossary of terms. **It is not appropriate to include sections from grant applications containing excessive detail of procedures unrelated to the use of animals.**
4. It is highly recommended that you ask a colleague and a person with a non-scientific background to read the application before it is submitted.

Note: Please do not copy and submit this page with your application.

Institution name

Animal Ethics Committee

Application for Approval to use Animals in a Teaching Project

Office Use Only

Office Use Only

Scientific Institution

AEC Register Number

Office Use Only

--	--	--	--	--

Conditions of approval

All matters pertaining to the conduct of the approved project are to be reported to the Animal Ethics Committee, which maintains oversight in accordance with licence conditions for the Licence SPPL****.

Any variation proposed to the project, and the reasons for that change, must be submitted to the AEC for approval and must not be implemented until approval is granted.

A record of details of any animals used in the project must be retained.

The project should only be conducted in approved premises nominated on the Licence SPPL ***. Use of other premises would constitute a variation and relevant details are to be notified to the AEC for approval as "field work".

The AEC must also be notified in writing of:

- Any changes to approved teachers.
- Any unexpected incidents or complications that result in deaths, euthanasia or pain and suffering for the animals used in the project. Details of the steps taken to deal with adverse incidents must be included in the notification.

The total numbers of animals approved for use in the project are:

Species (and common name)	Strain Name (Indicate with an {*} if Genetically Modified)	Sex	Age	Total Number

Declaration by Nominated Signing Officer for the AEC

I certify that this project has been considered and approved by the (insert institution name) Animal Ethics Committee

The period of approval for the project is **/ **/ ** to **/ **/ **

Nominated Signing Officer Name:	
Nominated Signing Officer Signature:	
Date:	

Section 1. Administration

1.1. Course/Subject Code

--

1.2. Course/Subject Title

--

1.3. Course/Subject Coordinator

The person nominated as the course/subject co-ordinator will have legal responsibility for the animals
--

Name (Title, given name, family name)	
Department	

1.4. Duration of Project

DO NOT nominate a date before that of the AEC meeting. Teaching activities involving the use of animals must not start before written approval is given.

Proposed commencement date:	Day:	Month:	Year:
-----------------------------	------	--------	-------

Completion date: The course/subject will expire three years from the approved commencement date.

1.5. Animals Requested

Species (and common name)	Strain Name (Indicate with an {*} if genetically modified)	Sex	Age	Number/ year	Total Number requested

1.6. Risk Management

Does this course/subject involve procedures or agents that might pose a health risk to other animals and/or personnel?
--

No	
Yes	If Yes, please explain the risk and describe what precautions will be taken.

1.7. Permits

Is the acquisition, holding, or use of the animals subject to any permit, law or regulation of the State or Commonwealth (eg. OGTR, protected native or imported)?

	No	
	Yes	If yes, please specify the permit number.

Section 2. Justification for the Use of Animals

Animal Ethics Committees (AECs) must be satisfied that the use of animals is justified, based on whether the educational value of the work outweighs the potential impact on the animals being used.

Unsatisfactory completion of this section will result in a request for revision of the application.

Overall, answers provided in the following subsections should provide AEC members, particularly external lay and welfare members, with a clear idea of why it is necessary to use animals and what will happen to animals during the teaching project.

All information provided must be in language that can be understood by an interested, intelligent person without a scientific background. Do not use scientific jargon or abbreviations.

2.1. Course/Subject Summary

(i) Provide a brief discussion of the background of the course/subject. If applicable, describe how this course/subject relates to any previously approved courses/subjects.

(ii) State the educational objectives of the course/subject.

(iii) Briefly outline how the course/subject is designed to achieve its objectives, in particular, why it is necessary to use animals and what will happen to the animals.

NOTE: This section is a summary only. Expanded detail of procedures on animals is required in section 3.3.6.

(iv) Describe how the course/subject is evaluated to determine that the educational objectives are achieved.

2.2. Potential Benefit of the Course/Subject

Explain the significance and the potential benefit of the proposed course/subject.

2.3. Potential Impact on the Animals

(i) What will be the potential impact on the well-being of animals to be used in the proposed project?

	Minor
	Moderate
	Substantial

(ii) Briefly explain the reason for this classification.

(iii) Please indicate if the project involves any of the following:

	<u>Death as an end point (as defined in The Code) * AEC approved project to be forwarded to Bureau of Animal Welfare under Regulation 12 (2) for final approval.</u>
	Production of monoclonal antibodies by ascites method
	Prolonged restraint or confinement

2.4. Repeated use of animals

(i) Have any of the animals been the subject of a previous research or teaching project?

	No	
	Yes	If yes, provide AEC Register Number/s of the projects, describe what was done to the animals previously and justify their use in this course/subject..

(ii) If animals are being used in multiple projects, describe how records are kept so that the cumulative impact of the procedures performed on the animals in all projects can be monitored and managed.

Section 3. Project Details

The purpose of the *Australian of practice for the care and use of animals for scientific purposes* (the Code) is to ensure the ethical use and the humane care of animals used for scientific purposes, including teaching.

The Code emphasises the responsibilities of investigators, teachers and institutions using animals to:

- ensure that the use of animals is justified, taking into consideration the scientific or educational benefits and the potential effects on the welfare of the animals;
- ensure that the welfare of animals is always considered;
- promote the development and use of techniques which replace animal use in scientific and teaching activities;
- minimise the number of animals used in course/subjects; and
- avoid pain or distress for each animal used in scientific and teaching activities;

To this end, there is a need in scientific and teaching activities to consider:

- the *replacement* of animals with other methods
- the *reduction* in the number of animals used; and
- the *refinement* of techniques used to reduce the impact on animals.

Where scientific language is deemed unavoidable it must be supported by a suitable lay description in the text or in a glossary of terms.

Glossary of Terms

Scientific term	Lay description

3.1. Replacement

The Code specifies that techniques that totally or partially replace the use of animals for scientific purposes must be sought and used wherever possible. Before completing this section a search of alternatives websites and databases should be undertaken. Suitable websites and databases include:

altweb.jhsph.edu/databases.htm

www.eurca.org/

www.nca-nl.org/

www.nal.usda.gov/awic/alternatives/alternat.htm

www.vetmed.ucdavis.edu/Animal_Alternatives/databaseapproach.html

3.1.1. Alternatives

(i) Have alternatives that totally or partially replace the use of animals been incorporated into this course/subject?

No	If no, identify potential alternatives and explain why they are unsuitable for use in this course/subject.
Yes	If yes, please describe what alternatives are to be used in this course/subject.

(ii) Are alternatives that totally or partially replace the use of animals being considered or developed for incorporation into this course/subject?

	No	If no, explain why this is not possible.
	Yes	If yes, please describe what alternatives are to being considered or developed and indicate when they may be incorporated into this course/subject.

3.2. Reduction

3.2.1. Justification for Number of Animals Requested

(i) The numbers of animals requested must be clearly justified. Justification may be based, as appropriate, on statistical considerations or on student:teacher ratios, student:animal ratios etc. In some cases it may be better to use more animals in order to minimise the impact on individual animals. Where appropriate, present the numbers in table form.

(ii) To reduce animal use, would the animals or their tissues be suitable for use in another project at the end of your course/subject? Identify the suitable project, if known.

3.3. Refinement

3.3.1. Choice of Animal

Justify your choice of animal. Why is it necessary to use the species/strain/sex/age requested?

3.3.2. Genetic Modification of Animals

Does the course/subject involve the use of animals with spontaneous genetic mutations or the use or production of genetically modified animals eg. transgenic, knockout?

	No	
	Yes	If yes, please complete Appendix 1

3.3.3. Cloning of Animals

Does the course/subject involve the use or production of cloned animals?

	No	
	Yes	If yes, please complete Appendix 1

3.3.4. Source of Animals

If animals are to be sourced from municipal pounds, you must comply with the Code of practice for the use of animals from municipal pounds in scientific procedures.

(i) From where will the animals be obtained?

(ii) Will animals need to be transported from the source location to the location where they will be held for this course/subject?

	No	
	Yes	If yes, provide details of transportation and acclimatisation procedures.

3.3.5. Location of Animals and Housing

Refer to the *Code of practice for the housing and care of laboratory mice, rats, guinea pigs and rabbits* if using these species

(i) Where will animals be housed? If outdoors, please give details of shelter provided. If, contrary to the needs of the species, no shelter is provided, justify the lack of shelter.

(ii) Where will procedures be performed? If animals need to be transported from where they are housed to where the procedures are carried out provide details of transportation methods and acclimatisation procedures.

(iii) What type of housing will be used? Describe any special housing requirements?.

(iv) Will any animals need to be housed individually?

	No	
	Yes	If yes, explain why, for how long and how the impact of social isolation be minimised?

3.3.6. Project Description

This section should provide a detailed description of the design of the course/subject and the procedures that will be performed. Particular emphasis should be placed on describing what will happen to each animal or group of animals (including controls) from the time the animals are obtained until the time the course/subject is completed.

When multiple procedures are to be performed on individual animals, consider using a flow diagram to illustrate the number of procedures to be performed and the time interval between each procedure.

The expected effect of each of the procedures on the animals should be described.

If performing non-terminal surgical procedures describe how asepsis will be maintained during surgery and the pain management strategies that will be used to minimise post-surgical pain and distress.

If trapping, marking or tracking wildlife or fish, provide details of the type of trap and marking or tracking device.

If agents are to be administered, provide details of dose rates, volumes, needle gauges, routes and methods of administration. Also provide a brief description of the mechanism of action and expected effects of any agents to be administered.

For each procedure please specify:

- Whether or not students will carry out the procedure
- What will be the maximum number of students supervised by each teacher?
- What will be the number of animals used by each student or group of students?
- What will be the maximum number of times each animal will be used by a student?

It is not necessary to include excessive detail about procedures that do not involve the use of live animals.

3.3.7. Monitoring

Teachers are responsible for monitoring the welfare of their animals. This responsibility begins when an animal is allocated to the approved course/subject and ends with the specified fate of the animal at the completion of the course/subject.

Unexpected incidents that impact on the welfare of any individual animal or group of animals require an immediate response and must be reported to the AEC.

All personnel identified in this section of the proposal must be aware of the criteria for monitoring the welfare of the animals and of how records are to be kept.

For housed animals, welfare monitoring checklists must be kept with the animal so as to be readily accessible to all nominated personnel and to animal care staff.

(i) Day-to-day monitoring: Who will monitor the animals?

On weekdays:

After hours (including weekends and holidays):

(ii) Day-to-day monitoring during the course/subject: What clinical, behavioural or other signs will be monitored and how frequently? Attach a copy of the monitoring checklist you will use to record these observations.

(iii) Monitoring during and after procedures/interventions: What clinical, behavioural or other signs will be monitored and how frequently? Attach a copy of the monitoring checklist you will use to record these observations.

(iv) What clinical, behavioural or other signs will be used to indicate that an animal is unwell or in pain? What action will be taken if these indicators are reached?

(v) Who is responsible for the management of emergencies?

3.3.8. Fate of the Animals

(i) What is be the maximum period of time that an individual animal or group of animals will be used as part of this course/subject?

(ii) What will happen to the animals at the completion of the course/subject?

(iii) If the animals are to be killed, how will this be done and by whom? Include information about agents, dose rates, method and route of administration and experience of personnel.

(iv) What will be the method of disposal of dead animals?

Section 4. Details of personnel involved in the Course/Subject

Teachers have legal responsibility for the welfare of the animals they use and must act in accordance with all requirements of the Prevention of Cruelty to Animals Act 1986 (the *Act*), associated Regulations, the *Code* and the AEC. This responsibility begins when an animal is allocated to the approved course/subject and ends with the specified fate of the animal at the completion of the course/subject.

The AEC must be assured that all personnel working on live animals in this course/subject are appropriately experienced, or will be adequately trained and supervised in the techniques described. A global statement of experience with animal related techniques e.g. "10 yrs experience" is not sufficient.

4.1. Course/Subject Subject Coordinator

Name (Title, given name, family name)				
Qualifications				
Department				
Position				
Telephone No. (direct contact number)				
E-mail address				
Involvement in the Course/Subject				
<i>For each species and technique, describe the level of expertise and number of years of experience the named investigator possesses. If no experience, please complete the arrangements for training section below.</i>				
Species	Technique/Procedure	Approximate number of times this person has performed the technique/procedure in this species		
		<5	5-20	>20
Arrangements for training				
<i>For each species and technique, nominate the person who will provide training and describe the level of expertise of that person.</i>				
Species	Technique/Procedure	Name of Trainer	Level of Expertise/Number of Years Experience	
Trainer(s) Declaration: I/We have the relevant expertise and I/We accept responsibility to train and supervise the above person until I/We consider them to be competent in the necessary procedures.				
Trainer(s) signature:			Date:	

4.2. Other Teachers

Name (Title, given name, family name)				
Qualifications				
Department				
Position				
Telephone No. (direct contact number,)				
E-mail address				
Involvement in the Course/Subject <i>For each species and technique, describe the level of expertise and number of years of experience the named investigator possesses. If no experience, please complete the arrangements for training section below.</i>				
Species	Technique/Procedure	Approximate number of times this person has performed the technique/procedure in this species		
		<5	5-20	>20
Arrangements for training <i>For each species and technique, nominate the person who will provide training and describe the level of expertise of that person.</i>				
Species	Technique/Procedure	Name of Trainer	Level of Expertise/Number of Years Experience	
Trainer(s) Declaration: I/We have the relevant expertise and I/We accept responsibility to train and supervise the above person until I/We consider them to be competent in the necessary procedures.				
Trainer(s) signature:			Date:	

Name (Title, given name, family name)				
Qualifications				
Department				
Position				
Telephone No. (direct contact number,)				
E-mail address				
Involvement in the Course/Subject				
<i>For each species and technique, describe the level of expertise and number of years of experience the named investigator possesses. If no experience, please complete the arrangements for training section below.</i>				
Species	Technique/Procedure	Approximate number of times this person has performed the technique/procedure in this species		
		<5	5-20	>20
Arrangements for training				
<i>For each species and technique, nominate the person who will provide training and describe the level of expertise of that person.</i>				
Species	Technique/Procedure	Name of Trainer	Level of Expertise/Number of Years Experience	
Trainer(s) Declaration: I/We have the relevant expertise and I/We accept responsibility to train and supervise the above person until I/We consider them to be competent in the necessary procedures.				
Trainer(s) signature:			Date:	

Section 5. Course/Subject Coordinator Declaration

I hereby declare that:

- (i) I have read Part III of the *Prevention of Cruelty to Animals Act 1986* (the *Act*), the Regulations 1997 and the current version of the *Australian code of practice for the care and use of animals for scientific purposes* (the *Code*), and accept the responsibilities detailed therein.
- (ii) I accept responsibility for the conduct of all procedures detailed in this application, in accordance with requirements of the *Act*, the *Code*, the University of Melbourne Animal Welfare Committee and the relevant University of Melbourne Animal Ethics Committee.
- (iii) I have listed each person engaged in this course/subject under Section 4 and consider that they have the qualifications, experience and training appropriate for their role in the course/subject; and that they are competent to perform procedures described to the extent of their role. If any person is not already skilled in the procedures, I will ensure that they obtain all necessary training in advance of performing any procedure independently. All personnel have been made aware of their role and responsibilities in this course/subject, and have been given copies of all necessary documentation.
- (iv) The Animal Facility/Farm Manager has been made aware of requirements for this application.

Course/Subject Co-ordinator's Signature:	
Date:	

Section 6. Teacher Declaration

I hereby declare that:

- (i) I am familiar with Part III of the *Prevention of Cruelty to Animals Act 1986* (the *Act*), associated Regulations and the current version of the *Australian code of practice for the care and use of animals for scientific purposes* (the *Code*) and accept the responsibilities detailed therein to the extent of my involvement in this course/subject.
- (ii) I accept responsibility for the conduct of all procedures detailed in this application that I undertake, in accordance with the requirements of the *Act* and the *Code* and any other conditions laid down by the University of Melbourne Animal Welfare Committee or the relevant University of Melbourne Animal Ethics Committee.

Teacher's Name	Teacher's Signature	Date

Section 7. Animal Facility Manager Declaration

The signature of the animal facility/farm manager is required if animals are to be obtained from or housed in the animal facility or on a University farm.

I confirm that the required animals can be obtained from and/or housed in the animal facility/farm:

Animal Facility Manager's Name:	
Animal Facility Manager's Signature:	
Date:	

Section 8. Head of Department Declaration

I acknowledge that it is my responsibility to ensure that staff of the department and those working under their supervision who use animals for scientific purposes comply with the conditions laid down by:

- (i) The *Prevention of Cruelty to Animals Act 1986* (the *Act*) and *Regulations 1997*;
- (ii) The current version of the *Australian code of practice for the care and use of animals for scientific purposes* (the *Code*); and
- (iii) The University of Melbourne's Animal Welfare Committee.

I certify that the animals required for this course/subject can be provided, housed and maintained at a standard consistent with the requirements of the *Act*, the *Code* and any other condition laid down by the University of Melbourne Animal Welfare Committee or the relevant University of Melbourne Animal Ethics Committee and that approval of this course/subject will not compromise the conditions under which other animals in the department are held.

Head of Department's Name:	
Head of Department's Signature:	
Date:	

Check list:

Course/Subject Title		
Does it describe the work proposed?	Yes	No
Course/Subject duration		
Is the proposed duration stated?	Yes	No
Safety		
Are there any safety issues for humans or other animals?	Yes	No
Justification for the use of animals		
Is the course/subject summary easily understood by people who do not have a scientific background?	Yes	No
Are the aims clearly stated?	Yes	No
Is the significance of the work clear?	Yes	No
Replacement		
Is it clear why alternatives are not being used?	Yes	No
Reduction		
Are the numbers requested justified?	Yes	No
Refinement		
Are all terms clearly defined?	Yes	No
Where will the animals be housed and who will care for them at all stages of the course/subject?	Yes	No
Do any genetically modified or cloned animals have phenotypes which require special care?	Yes	No
What will happen to each individual animal or group of animals from the beginning to the end of the course/subject? (agents, dose rates, routes and frequency of administration, actions, anaesthesia, surgery, number of procedures per animal etc)	Yes	No
What is the potential impact on the animals' welfare of each procedure?	Yes	No
What criteria will be used to monitor the animals?	Yes	No
What will be done if welfare problems are identified?	Yes	No
How will the animals will be killed and disposed of?	Yes	No
Investigators		
Who will be doing the work?	Yes	No
What experience do the named personnel have in the specific techniques described in the proposal?	Yes	No
What training is needed?	Yes	No
Who will provide the training?	Yes	No
How the training will be provided?	Yes	No

Appendix 1: Genetic Modification or Cloning of Animals Report

This report must be completed for all projects involving the use or production of genetically modified animals.

A. Animal Details (A separate report is required for each strain)

Species (and common name)	Strain Name	Background Strain

B. Genotype (If applicable for cloned animals)

(i) Describe the function/s of the gene/s that have been/will be modified

(ii) Explain the relevance of the genetic modification to the course/subject

(iii) Will tissue be collected to use for genotyping?

No	
Yes	If yes, describe how and when.

(iv) What will be the fate of animals that are not of the appropriate genotype?

C. Phenotype

(i) Is the phenotype of this strain well characterised?

No	If no, briefly describe the <i>potential</i> or <i>anticipated</i> behavioural, physiological, reproductive and developmental features of the strain and identify whether the modification/s will affect the health, welfare, breeding or lifespan of the animals.
Yes	If yes, briefly describe the <i>known</i> behavioural, physiological, reproductive and developmental features of the strain and identify whether the modification/s will affect the health, welfare, breeding or lifespan of the animals.

(ii) Does the strain require any special husbandry?

No	
Yes	If yes, describe the particular requirements for care.

D. Breeding

Describe, or attach Standard Operating Procedures that describe, the breeding program (e.g. heterozygous, homozygous, back-crossing) that will be used to produce the genetically modified or cloned animals to be used in the course/subject.

NOTE: Actual numbers of animals used as part of the breeding program (including animals culled because of inappropriate genotype) must be maintained and provided to the AEC and Bureau of Animal Welfare on request.

The breeding estimates table available at www.research.unimelb.edu.au/animalethics/approval/forms/ may be used as an aid to designing the breeding schedule and estimating animal numbers.

