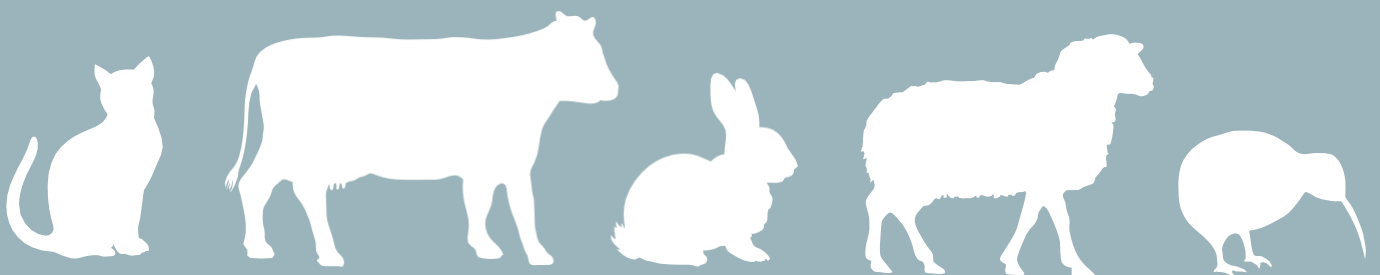




Good Practice Guide for the use of animals in research, testing and teaching

January 2022



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While every effort has been made to ensure the information in this guide is accurate, the Ministry for Primary Industries (MPI) and the National Animal Ethics Advisory Committee (NAEAC), their employees and consultants expressly disclaim all and any liability to any person in respect of anything, and the consequences of anything, done or omitted to be done in reliance, whether wholly or partly, upon the whole or any part of the contents of this publication.

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Animal welfare in New Zealand is safeguarded by the Animal Welfare Act 1999 (the Act). The Act requires those in charge of animals to provide adequately for their physical, health and behavioural needs. These needs include:

- proper and sufficient food and water;
- adequate shelter;
- opportunity to display normal patterns of behaviour;
- physical handling in a manner which minimises the likelihood of unreasonable or unnecessary pain or distress;
- protection from, and rapid diagnosis of, any significant injury or disease.

The nature of the research, testing or teaching (RTT) may mean that the general obligations under the Act cannot be met. For instance, some pain or distress to a small number of animals may occur. This may however, result in significant benefits to people, other animals or the environment. For this reason, the use of animals in RTT is governed by a separate set of provisions (Part 6) within the Act.

Within the constraints of any project, all reasonable steps must be taken to ensure that the physical, health and behavioural needs of those animals are met in accordance with both good practice and scientific knowledge, as is stated in section 80(2)(a)(i) of the Act.

Traditional acceptance of the use of animals in RTT has come under increasing scrutiny. Both the public and the scientific community are concerned that standards of husbandry and care of animals in RTT should at least parallel those required in other areas.

For this reason, the use of animals in RTT carries significant responsibilities and strict legislative obligations. Part 6 of the Act allows such activities only where there is good reason to believe:

- that the findings of the research or testing or the results of the teaching will enhance the understanding of human beings, animals, or ecosystems; the maintenance or protection of human or animal health or welfare; the management, protection, or control of ecosystems, plants, animals, or native fauna; the production and productivity of animals; or the achievement of educational objectives; and
- that the benefits derived from the use of animals in research, testing, and teaching are not outweighed by the likely harm to the animals.

NAEAC is committed to upholding the principles of partnership, participation and protection implied by the Treaty of Waitangi. The Treaty principles are not specific to the use of animals in research, testing and teaching (RTT), but they nonetheless provide general obligations and considerations of relevance to all working in RTT in Aotearoa.

1.1. Purpose of this Guide

It is intended that this guide will be useful to:

- people or organisations wishing to establish an AEC;
- code holders, or members of current AECs, in discharging their responsibilities;
- investigators, preparing to submit an application to an AEC;
- members of the public, wanting to understand more about how RTT is managed in New Zealand.

Additional intentions are that the guide will:

- promote the humane and responsible use of animals for scientific purposes;
- encourage the highest standard of husbandry and animal care;
- set guidelines for what constitutes “good practice” in managing of animals in the RTT environment.

1.2. Scope of this Guide

This guide covers the use of animals for scientific purposes in medicine, biology, agriculture, aquaculture, veterinary and other animal sciences, industry and teaching. It includes their use in research, teaching, field trials, and product testing.

The guide provides general principles for the care and use of animals and specifies the responsibilities of investigators and teachers. It also provides guidelines for the humane conduct of experiments, and the acquisition of animals.

Throughout this guide:

- “shall” means that there is a statutory requirement;
- “must” denotes a minimum standard in a code of welfare;
- “should” and “may” denote a recommendation.

1.3. Feedback on this Guide

Comments on this guide are invited and should be sent to the NAEAC Secretary:

NAEAC@mpi.govt.nz or

The Secretary
NAEAC
PO Box 2526
Wellington 6140

DEFINITIONS OF TERMS & ABBREVIATIONS USED IN THIS GUIDE

(The) Act: Animal Welfare Act 1999 (including any amendments).

Analgesia: The temporary abolition or diminution of pain perception.

Anaesthesia: A state of controllable, reversible insensibility in which sensor perception and motor responses are both markedly depressed.

Animal: The Animal Welfare Act 1999 defines “animal” as:

Any live member of the animal kingdom that is:

- a mammal; or
- a bird; or
- a reptile; or
- an amphibian; or
- a fish (bony or cartilaginous); or
- any octopus, squid, crab, lobster, or crayfish (including freshwater crayfish); or
- any other member of the animal kingdom which is declared from time to time by the Governor-General, by Order in Council, to be an animal for the purposes of this Act; and
- includes any mammalian foetus, or any avian or reptilian pre-hatched young, that is in the last half of its period of gestation or development; and
- includes any marsupial pouch young.

It does not include any other prenatal, pre-hatched, larval or developmental stage.

AEC: Animal Ethics Committee.

Approved project: A project which has been formally approved following evaluation of a written proposal by a properly constituted AEC.

Cachexia: Severe generalised weakness, malnutrition and emaciation.

CEC: Code of ethical conduct.

Distress: Acute or chronic response of an animal caused by stimuli that produce observable biological stress as shown by abnormal physiological or behavioural responses.

Embryonated egg: An egg in the last half of incubation.

Endangered species: A species named as endangered in the Wildlife Act 1953, the Trade in Endangered Species Act 1989, or any other Act of the Parliament, or in the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES).

EPA:	Environmental Protection Authority.
Euthanasia:	The humane termination of life.
Experiment:	Any test or trial for a scientific purpose, including any activity to test a hypothesis or demonstrate a known fact.
Foetus:	An unborn mammal in the post-embryonic stage of development.
Genetic modification	
(GM):	The deletion, change or moving of genes within an organism, or the transfer of genes from one organism to another, or the modification of existing genes or the construction of new genes and their incorporation into any organism.
Humane endpoint:	The point at which an experimental animal's pain and/or distress is terminated, minimised or reduced by taking actions such as humanely killing the animal, terminating a painful procedure, or treating to relieve pain and/or distress. (Canadian Council for Animal Care)
HSNO Act:	Hazardous Substances and New Organisms Act 1996.
IATA:	International Air Transport Association.
IBSC:	Institutional Biological Safety Committee.
IDAO:	Internal Drug Administration Order.
In vitro:	Outside the living body and in an artificial environment.
In vivo:	In the living body.
Investigator:	A person approved by an AEC to be responsible for the conduct of an approved project involving animals.
IOP:	Institutional Operating Plan.
MPI:	Ministry for Primary Industries.
Moribund:	Approaching death; about to die.
Manipulation:	This is defined by the Act in relation to any live animal as meaning interfering with the normal physiological, behavioural or anatomical integrity of the animal by deliberately

subjecting it to a procedure which is unusual or abnormal when compared with that to which animals of that type would be subjected to under normal management or practice and which involves:

- exposing it to any parasite, micro-organism, drug, chemical, biological product, radiation, electrical stimulation, or environmental condition; or
- enforced activity, restraint, nutrition, or surgical intervention; or
- depriving it of usual care.

The term defined by subsection (1) includes

- the killing of an animal (other than an animal in a wild state) for the purpose of interfering with the animal's body or its tissues;

- the breeding or production of an animal using any breeding technique (including genetic modification) that may result in the birth or production of an animal that is more susceptible to, or at greater risk of, pain or distress during its life as a result of the breeding or production.

It does not include:

- any therapy or prophylaxis necessary or desirable for the welfare of the animal; or
- the killing of an animal as the end point of research testing or teaching if the animal is killed in such a manner that it does not suffer unreasonable or unnecessary pain or distress; or
- the hunting or killing of any animal in a wild state by a method that is not an experimental method;
- any killing of an animal that is carried out by any person:
 - while exercising powers under the Biosecurity Act 1993 for the purposes specified in section 121(1A) of that Act; or
 - while exercising powers or performing functions for the purposes of a response activity carried out under the Biosecurity Act 1993.

NAEAC: National Animal Ethics Advisory Committee

Organisation: Any individual, company, institution or organisation that might apply for approval of a code. In the case of an organisation, the code holder is the organisation, not a person such as a chief executive. The code is not transferable to another organisation if companies are sold or merge, unless the Director-General of MPI gives specific approval to the transfer prior to the sale or merger.

Pain: An awareness of acute or chronic discomfort, occurring in varying degrees of severity, and resulting from injury, disease, or emotional distress as evidenced by biological or behavioural changes or both.

Parenting: Any person or organisation operating under a CEC held by another organisation.

Project: A series of related experiments that forms a discrete piece of research.

Proposal: A written outline of a research project put forward for consideration by an AEC.

RTT: Research, testing and teaching.

Scientific purposes: All those activities performed to acquire, develop or demonstrate knowledge or techniques in any scientific discipline, including activities for the purposes of teaching, research, diagnosis, product testing, and the production of biological products.

SOP: Standard operating procedure

Tranquillisers: Drugs which are used to treat anxiety or produce sedation.

THE NATIONAL ANIMAL ETHICS **3**

ADVISORY COMMITTEE

3.1. Functions of NAEAC

The National Animal Ethics Advisory Committee (NAEAC) is established under s62 of the Act to:

- advise the Minister on ethical issues and animal welfare issues arising from RTT;
- make recommendations to the Minister under section 3(3) (which relates to manipulation);
- make recommendations to the Director-General under section 85 (which relates to restrictions on use of non-human hominids);
- provide advice and information on the development and review of CECs;
- make recommendations to the Director-General concerning the approval, amendment, suspension, or revocation of any CEC;
- make recommendations to the Minister concerning the setting of standards and policies for CECs;
- provide information and advice to AECs;
- recommend for approval by the Director-General under section 109, such persons as are, in the opinion of the Committee, suitable for appointment as accredited reviewers;
- consider the reports of independent reviews of code holders and AECs;
- make recommendations to the Minister under section 118(3) (which relates to the power of the Minister to approve research or testing).

3.2. Membership of NAEAC

NAEAC consists of no more than 10 members, including a chairperson, appointed by the Minister. In appointing members other than the chairperson, the Minister shall have regard to:

- the public interest in relation to the manipulation of animals in research, testing, and teaching; and
- the need for the Committee to possess knowledge and experience in the following areas:
 - veterinary science:
 - medical science:
 - biological science:
 - the commercial use of animals in research and testing:
 - ethical standards and conduct in respect of animals:
 - education issues, including the use of animals in schools:
 - the manipulation of animals in research, testing, and teaching:
 - environmental and conservation management:
 - animal welfare advocacy:
 - any other area the Minister considers relevant; and
- achieving a balance between members who are currently involved in RTT and members who are not.

3.3. Keeping in Touch with NAEAC

Contact with NAEAC can be maintained in a number of ways:

- Write to:
NAEAC@mpi.govt.nz or

The Secretary
NAEAC
PO Box 2526
Wellington 6140
- Read the NAEAC newsletter.
- Attend a NAEAC workshop. Watch the NAEAC newsletter for details.
- Site visits. NAEAC visits places where RTT is being carried out. These visits aim to:
 - familiarise NAEAC members with actual RTT work being carried out;
 - allow NAEAC members to understand the challenges and experiences of AEC members;
 - educate AEC members about the role of NAEAC.

The selection of the sites to visit are made in consultation with MPI. The visit is NOT an audit exercise. There is a broad range of experience on the committee and there may be opportunity to discuss various aspects of welfare, research or teaching strategy.

Individual NAEAC members may also, from time to time, ask to attend an AEC meeting as an observer. Such visits are for the member's personal development only and are not made to critique the AEC's operation. The NAEAC member will not participate in any discussion uninvited.

4.1. Requirement for a CEC

Any person who engages in RTT and wishes to use animals for such purposes shall:

- have an approved CEC; or
- work for a person who holds such a code; or
- have a formal arrangement to use another person's code pursuant to section 84 of the Act.

Codes must be approved by the Director-General of MPI prior to commencing RTT activities. Approvals are for a maximum of five years.

An application would normally be made by the chief executive of the organisation requiring a code.

4.2. Recommended Content for a CEC

The CEC lists the responsibilities of the code holder, the steps to be undertaken in setting up an AEC, and the policies and procedures to be adopted and followed by the code holder and the AEC.

At a minimum the CEC shall meet the requirements specified in section 88 of the Act. A system of keeping records and monitoring all activities involving animal use and husbandry is essential.

Every code holder shall also comply with the Animal Welfare (Records and Statistics) Regulations 1999.

The NAEAC template for drafting a CEC can be found here: <https://www.mpi.govt.nz/protection-and-response/animal-welfare/national-animal-ethics-advisory-committee/> Applicants may vary the content of the CEC to suit their organisation, but should retain the order of sections, and shall meet the requirements of the Act. Having a consistent internal sectional order will assist the Director-General and NAEAC when assessing applications.

4.3. Applying for a CEC

The following documents shall be submitted to the Director-General of MPI:

- a draft CEC;
- a completed application form;
- independent references as specified in section 89(2)(b) of the Act.

If the application is for a renewal of an approved CEC, a report from an accredited reviewer shall have been submitted to MPI and NAEAC by the reviewer.

4.4. Consideration of an Application to Approve a CEC

The Director-General shall consult with NAEAC on each application for a CEC. The Director-General shall notify the applicant of the decision within 40 working days of the application being lodged. This can be extended to 80 working days if the Director-General requires more information or needs to consult with the applicant. If the Director-General does not notify the applicant of the decision within the required time period, the Director-General is deemed to have refused to approve the proposed code.

4.5. New AECs - Where to Get Assistance

When a new AEC is being formed, NAEAC will, on request, arrange assistance from a local NAEAC member. This is intended to ensure the new committee:

- develops procedures that are both appropriate for the nature of RTT involved, and compliant with the Animal Welfare Act; and
- is familiar with the literature available to provide support.

Generally, the NAEAC member would attend an AEC meeting as an observer, for the purpose of advising, and may be able to arrange for members of the new committee to attend a meeting of another AEC to gain further experience (this is considered to be particularly valuable for 'external' members of AECs). Such a visit is made in an advisory capacity only and will not fulfil any review function.

This is an area in which NAEAC can provide valuable assistance to AECs, establishing a personal connection that will have long-lasting benefits.

4.6. Using Another Organisation's CEC

Organisations or individuals that, for whatever reason, elect not to have their own CEC may arrange to use the CEC and AEC of an organisation that does have them.

Allowing other parties to use your CEC.

This is termed a parenting arrangement. It is the code holder's decision as to whether external parties will be allowed to do this.

NAEAC recommends that where code holders do not permit parenting arrangements, they state this in their code.

If the code holder intends to allow use by external parties the following expectations apply:

- The CEC must detail the policies and procedures it will implement to manage such arrangements.
- The code holder must ensure that members of its AEC are qualified to evaluate all projects submitted by a parented organisation.
- The code holder must be satisfied that the personnel who will manipulate animals on behalf of that parented organisation are appropriately qualified.
- The AEC must have a review process in place for all relevant operating SOPs of the parented organisation, such as those used to manage animal facilities.

- AEC responsibilities for monitoring and oversight described below, apply equally to the work and facilities of parented organisations.
- The code holder may wish to appoint a nominee of the parented organisation to the AEC.

Note: The code holder must notify MPI of the arrangement in writing and before the external party begins any RTT using animals. Notification should include the (registered if appropriate) name of the person or organisation, postal and physical addresses of the parented organisation and contact details for the person to whom correspondence should be addressed.

4.7. Amendments, Suspension or Revocation of the CEC

4.7.1 Amendments

Establish a procedure to enable the AEC to recommend amendments of the CEC to the code holder. When it is intended to amend the code:

- Minor Amendments - shall be notified to MPI annually (and no later than 31 March after the year in which they were made).
- Significant Amendments - shall be approved by MPI, prior to implementation.
- Suspension or Revocation - an organisation, under section 95 of the Act, may request the suspension or revocation of its CEC if it decides to cease manipulating animals for RTT.

4.7.2 Suspension and Revocation

Irrespective of an application under section 95, the Director-General has the power to revoke a CEC as a response to a conviction under:

- the Animal Welfare Act 1999;
- the Animals Protection Act 1960;
- the Agricultural Compounds and Veterinary Medicines Act 1997;
- the Biosecurity Act 1993;
- the Companies Act 1993;
- the Crimes Act 1961;
- the Dog Control Act 1996;
- the Serious Fraud Office Act 1990;
- the Trade in Endangered Species Act 1989;
- the Veterinarians Act 2005.

The Director-General also has the power to suspend or revoke a CEC if the code holder:

- is no longer carrying out RTT or no longer wishes to enable RTT to be carried out by another person;
- no longer has the capability and skills to carry out RTT or to enable RTT to be carried out by another person;
- has failed to comply in a material respect with the CEC, the Act or any regulations made under the Act;
- provided false information in, or with the CEC application.

In either case, the welfare of animals under a current approval must be maintained and each approval must either be terminated or submitted to another AEC for approval.

4.8. CEC Expiry and Statutory Review

Approved CECs expire after a maximum of 5 years. In order to renew a CEC, a statutory review of the CEC and the AEC's compliance with it, is required during the fifth year.

Key components of the review are:

- the review is conducted by an MPI-accredited reviewer who is independent of the organisation and MPI;
- the reviewer audits and reports on compliance with the Act and CEC; including reviewing how the AEC(s) constituted under the CEC operate;
- a formal report is provided to MPI and NAEAC;
- NAEAC reviews the report, assesses the adequacy of the submitted CEC and makes a recommendation to the Director-General of MPI, as to whether a new code should be approved.

The statutory review is a key part of the RTT control process. Evidence of AEC activities (e.g. minutes of meetings and monitoring information) provides a tangible basis on which code-compliance can be assessed, and consequently contributes to the process by which regulators, the Minister and the public are assured of the ethical scientific use of animals.

Any recommendations that the reviewer makes relating to the CEC should be considered when revising the CEC. The new CEC must be submitted to MPI. Submission must allow sufficient time for the review of the existing CEC to be assessed and the new CEC considered by NAEAC, within a timeframe that allows the new CEC to come in to force immediately after the previous code expires. If this is not done in a timely manner, the code holder risks having no current CEC, and therefore will be unable to undertake any animal manipulations until such time as a new code is approved.

It is NAEAC's advice to have the review completed, and a new CEC drafted and submitted at least 4 months prior to expiry of any current CEC.

4.9. Animal Ethics Committee (AEC)

The use of animals under section 6 of the Act shall be approved by an AEC. A code holder is permitted to set up one or more AECs to consider applications to carry out RTT.

Key responsibilities of an AEC are:

- considering applications to use animals for RTT;
- setting appropriate conditions on approved projects;
- monitoring approved protocols;
- approving & monitoring adherence to standard operating procedures;
- reviewing the results of approved projects;
- monitoring of animal facilities used for RTT;
- monitoring routine animal husbandry and welfare.

The AEC has the power to inspect animals, their accommodation, and related experimental records at any time to satisfy itself that approved procedures are being properly carried out.

These responsibilities extend equally to all projects and facilities approved by the AEC.

Part 6 of the Act also sets out criteria that the AEC shall consider when reviewing proposals. This includes examination of the opportunities for refinement of the method, reduction in animals used and replacement of animals with another process (the Three Rs).

4.10. Jurisdiction of AECs

4.10.1 Authority is within New Zealand only

AECs are constituted under the Act. This legislation has force only within New Zealand (which includes New Zealand's territorial waters). An AEC cannot approve a project in a jurisdiction where it is unable to comply with all relevant parts of the CEC under which it operates.

AECs must not issue formal approvals for work performed wholly in another country. Where projects involve work undertaken both within and outside New Zealand jurisdiction, only animals used within New Zealand are to be reported to MPI in annual statistics.

4.10.2 Animal Work Performed across Several Code Holders

Routinely, the person wishing to undertake RTT should apply to the AEC associated with their host institution. However, situations sometimes arise where more than one organisation is involved in a RTT project. For example:

- where a student from one organisation intends to carry out RTT with a second organisation.
- where two organisations work together on a project involving RTT.
- where one organisation (that has its own AEC) intends collaborative or contracted work with a second organisation that also has an AEC.
- where several AECs are established under a single CEC.

The AEC that is best placed to assess the application according to the criteria in s100 and monitor any approval in accordance with s99 of the Act should be the AEC which considers the application. This would usually be the organisation that is the primary host for the RTT. This AEC must be advised of names, affiliations and suitability of all researchers involved in the project including any not employed by the primary host.

Where a protocol is going to involve activities occurring at more than one organisation associated with an AEC, and there is no obvious primary host institution, the investigators may choose which AEC they use. It may help to examine the CEC from each organisation, looking for the best fit with respect to expertise of the AEC.

For all applications to an AEC, the applicant shall be a suitable person with respect to s82 of the Act and the CEC for that AEC must allow for the arrangement.

4.11. AEC Membership

4.11.1 Statutory Members

1. A senior member of staff, capable of evaluating the scientific value of proposals in accordance with s101(3) & (4) of the Act.
2. Veterinarian nominated by the New Zealand Veterinary Association. This person must not be in the employ of, or otherwise associated with, the code holder in accordance with s101(5) of the Act.
3. Nominee of an approved animal welfare organisation. The Royal New Zealand Society for the Prevention of Cruelty to Animals is the only approved organisation in New Zealand.

This person shall not be in the employ of, or otherwise associated with, the code holder in accordance with s101(6) & (7) of the Act.

4. Lay person nominated by the local territorial authority or regional council, not associated with the scientific community in accordance with s101(8) & (9) of the Act. See Appendix 2, for a useful 'A Guide for Lay Members of Animal Ethics Committees'.

Notes on Independence:

- The background and previous employment history of any statutory external nominee should be carefully considered. Do not appoint anyone where the public might perceive institutional, scientific, financial or philosophical biases.
- The phrase 'associated with the scientific community' is not easily defined and should be considered on a case-by-case basis. However, the following points should add clarity:
 - the aim is to appoint a lay member whose views represent an unbiased member of the public;
 - some understanding and knowledge of science in a general context would not necessarily imply that the person was associated with the scientific community and would clearly assist the appointee with understanding the complexities of RTT project applications.
- If unsure of the suitability of a potential appointee, seek advice from NAEAC.

4.11.2 The Importance of Statutory External Members

The Act mandates a minimum of three non-institutional members on each AEC. Statutory external members bring different skills but are all intended to bring credibility and transparency to RTT in New Zealand. These outcomes are maximised when the members fully participate in the decision process. The views of external members should be sought in each case, and fully considered.

4.11.2 Remuneration

Statutory external members should be remunerated for the time spent on AEC business. Refund of travel and other expenses is also expected.

Additional Members

Additional members may be appointed to the AEC by the code holder. Additional appointees should bring useful expertise to the committee.

AEC Chair

The code holder decides on how the Chair and Deputy Chair will be determined. The code holder may appoint them directly or allow the AEC to choose them. The process may be described in the code.

Period of Appointment

The period of appointment for each type of AEC member should be specified in the CEC. It is useful to include the eligibility criteria for reappointment in the code.

Induction of New Members

A formal process should be followed to induct new members including at least:

- a copy of the CEC;
- the NAEAC induction pack;
- a summary of the key AEC approvals open at the time;
- encouragement to attend NAEAC workshops.

Protection of Members

Section 104 of the Act states no member of an AEC is personally liable for any act done or omitted by the member or the committee in good faith in the course of the operations of the committee.

4.12. AEC Meetings and Decision Making

NAEAC expects that all new applications and amendments to existing projects will be considered at face-to-face meetings. However, NAEAC accepts that it may occasionally be necessary to consider a new applications, or variations to existing approvals under urgency, when meeting face to face is not possible. The process for managing such contingencies should be described in the CEC.

4.12.1 Public Access to Meetings

Some public organisations are subject to the Local Government Official Information and Meetings Act 1987. In this case, meetings must be open to the public, unless there is good reason for their exclusion. The committee shall apply section 48(1)(a)(ii) of the Local Government Official Information and Meetings Act. This means sections 6, 7 and 9 of the Official Information Act 1982 apply including commercial sensitivity and legal professional privilege. However, section 9(2)(g)(i) of the Official Information Act (which relates to free and frank expression of opinion between members of an organisation) is not available.

4.12.2 Timing for Circulation of Agenda Items

There is a need to provide members of an AEC adequate time to assess any application. The CEC should state the minimum period allowed (prior to the meeting) for circulation of materials. Phrases such as 'well in advance' are vague and not suitable.

4.11.3 Frequency of and Attendance at Meetings

Meeting frequency should be stated. A minimum of one face to face meeting a year should be held to maintain continuity and the relationships between AEC members. Even if there are no applications to consider, there will be monitoring reports to consider, or monitoring visits to carry out.

The CEC should also document the expectation on members for meeting attendance.

4.12.4 Quorum

The requirements for a quorum should be clearly documented, should be at least 50% +1 of the membership, and should include at least two of the statutory external members.

4.12.5 Vacancies

The CEC should detail how vacancies and unexpected/prolonged absences are managed. While it appreciates the difficulties that lack of a quorum can pose, NAEAC requires CECs to detail how this will be managed. If there are insufficient members present to constitute a meeting then NAEAC considers that those members present could, in effect, act as a subcommittee and be governed by the process outlined for subcommittees in the CEC. If vacancies render the AEC inquorate this would invalidate its actions. The CEC should outline how this will be avoided.

4.12.6 Consensus

NAEAC strongly recommends that decisions are made by consensus, with applications revised until all members are satisfied. If consensus cannot be reached the default should be to reject the application.

4.12.7 Conflict of Interest

The CECs should include direction as to how all conflicts of interest are declared, managed and recorded.

Members of AECs are expected to perform their functions in good faith, honestly and impartially, and to avoid situations that might compromise their integrity or otherwise lead to conflicts of interest. At the start of each meeting, a general declaration of whether conflict of interest exists or not, should be made by each member and held on record. It is recommended that members err on the side of caution in disclosing perceived or actual conflicts of interest to ensure transparency.

Members are expected to declare any area where there is a potential conflict of interest to the AEC Chair in advance of any committee work on a matter, where a conflict of interest could occur, or be perceived to occur.

The AEC should consider how to handle each conflict on a case-by-case basis.

As a minimum, the AEC membership should be advised of the conflict of interest and committee records should reflect the expression of a specific conflict of interest, what it is in relation to, and how the conflict is being handled.

Additional remedies, when the matter relating to the conflict of interest is discussed in committee, could include:

- the conflicted member participates in discussion but not in any vote or final decision; or
- the conflicted member responds to questions, but does not participate in the discussion or decision.
- the conflicted member withdraws from all discussions and deliberations.

Where the Chair has the conflict of interest, then the Deputy Chair should assume the chair for the duration of the matter where conflict has been declared.

NAEAC members can provide guidance or training on the management of conflict of interest to AEC committees, where requested. Further guidance on conflicts of interest is available at: <http://www.oag.govt.nz/>.

Accredited reviewers will review conflicts of interest as part of their normal auditing process, therefore AECs should record adequate documentation of declarations for this purpose.

4.12.8 Appropriate Use of Teleconferences and Videoconferences

- The CEC should state the AECs policy on the use of teleconferences and videoconferences in their decision-making process.
- With adequate software, videoconferences can be an appropriate format for meeting.

NAEAC recommends the following practices.

- All normal meeting procedures must be adhered to.
- Chairs should take particular care to ensure active participation of all members

- Individuals attending meetings by telephone should be the exception, and only occur when other means of attendance are not available.
- A minimum of one face to face meeting should occur every year.
- Initial consideration of applications graded as D or E should occur at a face-to-face meeting.

Accredited reviewers will review the use of telephone and videoconferencing as part of their normal auditing process, therefore, AECs should maintain adequate records of meeting type & nature of attendance, discussion and decisions made.

4.12.9 Consideration between Meetings and Subcommittees

The CEC should indicate how decisions will be made between meetings. AEC members may allow a subcommittee to make decisions on their behalf. If subcommittees are used, procedures should describe their appointment and function.

For consideration of a new application, the membership of a subcommittee should always include at least two of the statutorily appointed external members. Decisions made by a subcommittee are conditional on ratification at the next AEC meeting. NAEAC advises that interim decisions should only be made for fast-tracking studies that:

- have a legitimate requirement for urgency; and
- are for manipulations of grades A and B only.

Any fast-tracking procedures should not circumvent proper consideration of the application.

For consideration of amendments to an existing application, the CEC should state who will have delegated authority to make such decisions. Any subcommittee should always include at least one of the statutorily appointed external members. A subcommittee review is appropriate for alterations to current studies where:

- the changes do not involve a major departure from the approved study design;
- there is no change to the impact grading;
- any request to change numbers is the minimum necessary to retain the statistical validity of the original approval. (Larger changes in numbers and any increase over 10% of the original number requested should be agreed by a quorum of the committee).

Accredited reviewers will review the consideration between meetings as part of their normal auditing process, therefore AECs should record the discussion and decisions made in such circumstances for this purpose.

4.12.10 Confidentiality

CECs should describe how confidentiality will be managed. Commercially sensitive information may be included in applications to the AEC. Applications must contain sufficient information so the AEC can ensure that the review criteria set out in the Act are met.

4.12.11 Applicant Presence at Meetings

The CEC should describe whether an applicant may be present or not.

4.12.12 Secretarial Support

The CEC should describe how the AEC is supported with secretarial functions.

4.13. Applications to the AEC

Applications should be on a standard form to ensure no important information is missed. This will allow the AEC to maintain consistency in its consideration of the criteria specified in s100 of the Act. The application template (Appendix 1) includes the criteria NAEAC considers central for AECs when considering applications. AECs in New Zealand deal with animal models and facilities including rodents in cages, fish in tanks, livestock on pasture, and populations of animals in the wild. It is acknowledged that not all categories in the template will be applicable for all proposals.

The Act requires that RTT will be undertaken only by suitably qualified and trained persons. The application shall detail the qualifications of all key personnel involved in the project.

4.13.1 Criteria for Consideration of Applications

The key principle underlying the assessment process is that the benefits that are likely to be derived from using animals in RTT must outweigh the foreseeable harm to those animals. The CEC should therefore contain policies and procedures to ensure that relevant criteria (below) are considered both by project applicants in writing applications, and by the AEC in evaluating applications. This information forms the basis for assessing likely benefit/harm of the work.

The CEC should describe the criteria used in the consideration of applications to the AEC, paraphrased below. The Act specifies in s100 the criteria that AECs can have regard to in considering any application for approval of a project and in setting, varying or revoking conditions of approval, noting that they must have regard to such of these that are relevant.

- To ensure that the use of animals in research, testing, and teaching is confined to cases in which there is good reason to believe
 - that the findings of the research or testing or the results of the teaching will enhance—
 - the understanding of human beings, animals, or ecosystems; or
 - the maintenance or protection of human or animal health or welfare; or
 - the management, protection, or control of ecosystems, plants, animals, or native fauna; or
 - the production and productivity of animals; or
 - the achievement of educational objectives; and
 - that the benefits derived from the use of animals in research, testing, and teaching (whether the direct benefits of a project or the likely benefits of that project when combined with the findings of other related projects that have been undertaken in the past or that are currently being undertaken or are planned for the future) are not outweighed by the likely harm to the animals. Note that this does not apply to the killing of an animal (other than an animal in a wild state) for the purpose of interfering with the animal's body or its tissues.
 - that, where the research, testing, or teaching involves the use of a non-human hominid, that research, testing, or teaching may be carried out only where either—
 - it is in the best interests of the non-human hominid; or
 - it is in the interest of the species to which the non-human hominid belongs and the benefits to be derived from the use of the non-human hominid in the

research, testing, or teaching (being benefits of the kind described in paragraph (b)) are not outweighed by the likely harm to the non-human hominid.

- And to ensure that, —
 - in relation to animals used in research, testing, and teaching, all reasonable steps are taken to ensure that the physical, health, and behavioural needs of those animals are met in accordance with both good practice and scientific knowledge; and
 - where animals used in research, testing, and teaching are ill or injured, they receive, where practicable, treatment that alleviates any unreasonable or unnecessary pain or distress:
 - where, because of the nature of the research, testing, or teaching, the physical, health and behavioural needs cannot be fully met or treatment cannot be provided, any degree of pain or distress is reduced to the minimum possible in the circumstances:
- And to promote efforts —
 - to reduce the number of animals used in research, testing, and teaching to the minimum necessary:
 - to refine techniques used in any research, testing, and teaching so that the harm caused to the animals is minimised and the benefits are maximised:
 - to replace animals as subjects for research, and testing by substituting, where appropriate, non-sentient or non-living alternatives:
 - to replace the use of animals in teaching by substituting for animals, where appropriate, non-sentient or non-living alternatives or by imparting the information in another way.
- Other criteria are:
 - any matters that the AEC is required to consider by regulations made under the Act; and
 - the scientific or educational objectives of the project; and
 - the harm to, or the distress felt by, the animals as a result of the manipulation, and the extent to which that harm or distress can be alleviated by any means (including, where the pain or distress cannot be held within reasonable levels, the abandonment of the manipulation or the humane destruction of animals), but this paragraph does not apply to the killing of animals for the purpose of any project where research, testing, and teaching are to be performed on their bodies or tissues; and
 - whether the design of the experiment or demonstration is such that it is reasonable to expect that the objectives of the experiment or demonstration will be met; and
 - the factors that have been taken into account in the choice of animal species; and
 - the extent to which there has been—
 - assessment of the suitability of using non-sentient or non-living alternatives in the project; and

- replacement of animals as subjects with suitable non-sentient or non-living alternatives; and
- whether the number of animals to be used is the minimum necessary to ensure a meaningful interpretation of the findings and the statistical validity of the findings; and
- whether adequate measures will be taken to ensure the general health and welfare of animals before, during, and after manipulation; and
- whether suitably qualified persons will be engaged in supervising and undertaking the research, testing, or teaching; and
- whether any duplication of an experiment is proposed and, if so, whether any such duplication will be undertaken only if the original experiment—
 - is flawed in a way that was not able to be predicted; or
 - needs to be duplicated for the purpose of confirming a result that was unexpected or has far-reaching implications; and
- whether the same animals are to be used repeatedly in successive projects, and, if so, the cumulative effect of the successive projects on the welfare of the animals; and
- whether there is a commitment to ensuring that findings of any experiment will be adequately used, promoted, or published;
- and any other matters that the AEC considers relevant.

AECs should consider where relevant: the potential for experiments and manipulations to cause compassion fatigue in animal care personnel, investigators, and students, that might impact on the welfare of the animals under care.

4.13.2 Impact Grading

The AEC should document how it will assess impact grading of proposed RTT. It is recommended that AECs adopt the MPI grading guidelines.

4.13.3 Development of Standard Operating Procedures for Manipulation of Animals

The use of SOPs for routine manipulations will minimise technique ‘drift’ and the welfare impact of such manipulations. The AEC must have a review process in place for all SOPs used in the conduct of an RTT project.

4.13.4 Avoiding Duplication of Animal Research

Scientific experiments involving animals are sometimes repeated by the same or other research groups. In considering whether the repetition of experiments is desirable, it is essential to distinguish between ‘replication’, ‘repetition’, and ‘duplication’.

Replication refers to the repeating of experiments or tests to increase the reliability (by replication within experiments) and generality (by replication of entire experiments) of the findings. Replication is a fundamental component of the scientific method. The degree of replication required will depend on the level of scientific precision demanded, the natural variation in the

variables measured, and the range of circumstances in which findings are to be applied. The level of replication required to achieve the desired statistical precision can be predicted by power analyses of pilot data.

Repetition of product testing is sometimes required by regulatory agencies. Such repeat testing may occur:

- where routine testing of different batches of products is required;
- where product stability or shelf life is being determined;
- where 'generic' companies commence manufacture of products coming off-patent and are required by regulators to provide evidence of efficacy and safety using animal models; and
- where the claimed efficacy of products is extended (e.g. an existing parasiticide is shown to be effective against an additional parasite).

All cases entail, either or both, novelty and uncertainty. Therefore, repetition of the animal tests is necessary to ensure that products are fit for purpose (i.e. both efficacious and acceptably safe).

Duplication of animal experiments, where neither replication nor repetition (as defined above) are being carried out, would be pointless. If the outcomes are predictable from previous experiments, such duplication is unacceptable because animals are needlessly manipulated. However, it could occur when a researcher, and those scrutinising the researcher's proposal, are unaware that the experiment or test has already been done because results have not been published. This may be because:

- the research 'failed' and was not considered worth publishing, or
- the research findings were commercially sensitive, or
- the research is still in progress.

The Act permits 'duplication' only where the original experiment was found to be flawed, or for confirmation (i.e. as replication or repetition).

The following guidelines should be followed to avoid needless duplication of animal use:

- AECs need to be aware of the important distinction between 'replication', 'repetition', and 'duplication' as defined above.
- AECs need to avoid approving research that involves 'duplication' unless previous studies were flawed.
- Researchers should be asked by AECs to provide evidence, in research applications, of the efforts made to avoid duplication of past research. Evidence could include for example: the literature and patent databases searched including keywords used, and reference to previous searches.
- Researchers should be asked to consider the likelihood that the research is currently being undertaken elsewhere, and if so, to make every effort to ensure they are aware of, and not duplicating such research.
- Researchers should be encouraged by AECs to follow the ARRIVE Guidelines (see: <https://www.nc3rs.org.uk/arrive-guidelines>) when reporting the results of in vivo animal research.

4.13.5 Outcomes of Consideration

The CEC should state clearly the possible outcomes of the consideration process. These are commonly:

- approved with conditions;
- returned to the applicant for revision;
- rejected.

4.13.6 Conditions of Approval

The AEC may set conditions of approval and may vary or revoke such conditions (s99(1)(c)). Such conditions may include matters such as:

- the time period for which approval is granted;
- reporting requirements of project applicants to the AEC;
- monitoring requirements - See NAEAC Occasional Papers, number 4 & 5;
 - “No. 4: Compliance monitoring: The University of Auckland approach”
 - “No. 5: Monitoring methods for animal ethics committees”.

4.13.7 Maximum Approval Period

The CEC should set the maximum approval periods for all types of AEC approvals. The CEC should specify that no animal shall be manipulated unless under a current approval.

4.13.8 Power to Suspend/Revoke/Vary Approvals

The AEC has the power to set, vary or revoke conditions of project approval and to suspend, or revoke approvals if required. The CEC should specify how these decisions will be made and how the processes are managed.

4.13.9 Compliance with Other Legislation

The AEC should be provided with evidence that, for any activity which must be approved by other regulatory authorities, such approval has been obtained.

This includes where appropriate:

- confirmation that advice from the institution’s biological safety committee has been sought and that appropriate measures for containment, disposal and decontamination have been established;
- evidence of compliance with the organisation’s Institutional Operating Plan.

AEC POST-APPROVAL RESPONSIBILITIES

5

5.1. Compliance Reporting

A procedure should be established to allow:

- staff members to raise a concern over the conduct of work;
- reporting of non-compliances;
- reporting of deviations from the intended protocol.

This provides a structured means of informing the AEC and key staff when things do not go to plan. Non-compliance may be considered justifiable in hindsight; on other occasions there may be a need to make changes to how work is conducted. The aim should be to firstly consider the action that may be needed to address any animal welfare concerns, and secondly to address procedural and personnel matters based on a clear understanding of the nature of, and reasons for non-compliance. Serious cases of non-compliance should be addressed by disciplinary procedures, as determined by management of the host institution in conjunction with the AEC.

A clear process for regulator notification should be set out in the CEC, for cases of non-compliance against the Act.

5.2. Project Monitoring

Monitoring includes a range of activities undertaken by various members of the committee and/or the Animal Welfare Officer. As a minimum NAEAC expects the AEC to actively monitor at least 10% of all projects graded A or B and all projects graded C-E.

Accredited reviewers will review monitoring of projects as part of their normal auditing process, therefore AECs should record adequate documentation for this purpose.

Monitoring may include the following activities:

- Observations at unscheduled times i.e. not premeditated for compliance monitoring. This could be conducted by any member of the AEC who happens to be visiting animal holding facilities and observes animal practices as an unintended consequence of their primary activity. Examples of this type of visit include, but are not limited to, a visit to an animal facility by an AEC member in their capacity as an investigator undertaking their own manipulations, the animal facilities member during their management activities or the Animal Welfare Officer (AWO) during a scheduled training session. Veterinary visits and facility checks lead to the most frequent unplanned observations as the AWO walks past investigators performing manipulations.
- Veterinary care: each facility must have an approved procedure for reporting and treatment of sick (ill, injured, distressed) animals. Reporting of animals with conditions which were not anticipated during the planning phase ensures that information on models is transferred back to the AEC and can, often, be “fed back” to improve and refine the model, reduce variability and ultimately perhaps animal usage.

- A structured post-approval review of procedures relating to projects should be developed. This should include conditions set by the AEC at the time of approval for new models, new procedures and new personnel. This aspect of post-approval review focuses more on individual procedures or components of an approval, rather than review of the whole project. It ensures that new models have been set up properly and that personnel are trained appropriately for the work at hand.
- Reviews of projects and experiments where:
 - numbers of animals for which approval is given are large
 - an investigator has been liable for welfare incidents or breaches of approval. If such incidents occur this should prompt an immediate project review as part of the non-compliance procedure.

5.3. Interim Reports

Where projects run over a number of years, the lead investigator should submit an annual interim report. This will allow the AEC to remain engaged and familiar with the progress of the project. Contents should at least:

- summarise the aims and projected benefits of the project;
- state the number of animals of each species approved;
- restate the expected grading for animal impact;
- summarise any variations to the original project approved by the AEC;
- summarise any deviations, non-compliances, or adverse events that have occurred to date;
- report the actual number used, and the actual impact grading;
- summarise the current status of the project, and any results in hand.

An AEC may also request interim reports during the course of an approval as a means of monitoring the progress of a new manipulation, or the ongoing welfare of the animals.

5.4. Changes to Approved Applications

There should be a policy to manage variations to approved projects. The process to handle minor and significant variations may vary, in which case they should be clearly stated. In the case of minor modifications this could be done by a subcommittee of the AEC.

Accredited reviewers will review approval amendments and the process used as part of their normal auditing process, therefore AECs should record adequate documentation for this purpose.

5.5. Adverse Event Reporting

Adverse events (AEs) are atypical incidents that occur to an animal as a result of :

- the experimental manipulation
- animal husbandry failures
- disease.

Where unexpected adverse events or outcomes occur during RTT, rapid reporting is essential, primarily from the point of view of animal welfare.

(Note: expected adverse events should have been detailed in the original application, and do not require immediate reporting).

Basic components of an AE system are:

- a recording system to document any AE;
- reporting timelines. These may vary depending on the seriousness of the event.
- notification of the project leader & AEC;
- establishing responsive and preventative actions. These could range from additional observations, review of procedure, through to termination of the project.

5.6. End of Approval Reports

An important step in the approval cycle is the examination of results of approved projects. This allows the AEC to determine whether the proposed benefits of the work were realised. The best way to achieve this is to require investigators to submit an end of project report. This report should:

- summarise the aims and projected benefits of the project;
- compare the number of animals of each species approved with the number actually used;
- compare the expected grading for animal impact with actual grading;
- summarise any variations to the original project approved by the AEC;
- summarise any amendments, non-compliances, or AEs that occurred during the project;
- summarise the results and actual value realised by the project;
- indicate if any further work is being considered.

Reports should be submitted within 3 months of the trial conclusion. If the AEC meets infrequently, reports should be reviewed either by the Chair or a subcommittee in a timely manner. The reviewer(s) should call a meeting of the full committee if matters of concern are identified.

Organisations should consider adopting the ARRIVE guidelines for improved reporting of research using animals (<https://www.nc3rs.org.uk/arrive-guidelines>).

5.7. Non-compliance

The CEC should detail processes for dealing with non-compliance with any AEC approved protocol, including Standard Operating Procedures.

5.8. Complaints Procedure

The code holder shall ensure that there are procedures to deal promptly and fairly with complaints.

Procedures should cover:

- complaints from AEC members, staff members or members of the public;
- complaints against the Chairperson.

The procedure should specify how complaints, and the outcomes of the complaints process are recorded and stored.

5.9. Record Keeping

The code holder shall retain records relevant to its approvals, operations and functions under the Animal Welfare (Records and Statistics) Regulations 1999. These records form part of the statutory review of CEC and must include a record of the actual “impact” of the manipulation on each animal used.

Records kept should include (but not limited to):

- CEC and any amendments
- policies and procedures of the AEC
- minutes of meetings
- appointments of members
- project applications
- project approvals
- project reports, amendments
- AE notifications
- project and procedure monitoring, site visits
- complaints log.

The CEC should indicate how these records are managed and stored.

5.10. Reporting of Statistics to MPI

Every year the code holder shall inform MPI of the numbers of animals it has used in RTT.

Returns are required to be submitted by 28 February for the preceding calendar year. For details, see the MPI document: “Animal Use Statistics – Guidance for Completing Statistical Returns”

<https://www.mpi.govt.nz/dmsdocument/1477>

Facilities include the buildings, cages, tanks, aquaria, yards or paddocks in which animals are kept. Investigators, AECs and the institutions must ensure that facilities are appropriately designed, constructed, equipped, staffed and maintained to ensure the health and welfare of the animals and to fulfil scientific requirements.

The design and management of facilities will depend on the type of animals to be kept and the experiments to be undertaken. The overall condition and management of facilities should permit effective maintenance and servicing and be compatible with maintaining good health and welfare.

6.1. Monitoring of Animal Facilities

Under section 99 of the Act, a key function of the AEC is to monitor animal management practices and facilities to ensure compliance with the terms of the CEC. This applies also to any facilities operated by an organisation parented by an AEC.

Accredited reviewers will review monitoring of animal facilities as part of their normal auditing process, therefore AECs should record adequate documentation for this purpose.

6.1.1 Scheduled Visits

AEC members should visit each animal facility every year. These visits should be programmed and scheduled. The purpose and scope should be clear. This may vary from, for example, inspection of a specific aspect of animal husbandry practice or the adequacy of a particular building, to a complete assessment of all practices and facilities. Complete assessments are probably most beneficial at a point midway between scheduled statutory reviews. A checklist should be used.

6.1.2 Non-scheduled Visits

Experience shows that a collaborative approach between the AEC and facility staff is key to genuine transparency in the use and care of animals. Non-scheduled monitoring visits should be considered where an AEC holds unresolved concerns over the conduct of an RTT activity.

6.1.3 Periodic Review of SOPs

The scientific body of knowledge underpinning animal management practices and experimental technique is constantly expanding. Periodic review, and resubmission to the AEC of SOPs is required, to allow incorporation of improvements. Typically, review occurs at 3-year intervals. However, in rapidly evolving areas, or protocols with very high ethical cost, more frequent review may be appropriate.

6.1.4 Animal Carer on the AEC

The most direct means for the AEC to monitor the day-to-day operation of an animal facility is by appointment of an animal carer from the host institution to the AEC. This enables the AEC to gain insight into the culture, commitment, capability and effectiveness of the staff responsible for animal welfare. Many AECs have a regular part of meetings devoted to discussion of items raised by the animal care representative.

6.2. Facility Personnel

6.2.1 Facility Manager

Animal facilities used for RTT should be supervised by persons with appropriate veterinary or animal care qualifications or experience with the species involved.

The facility manager should:

- ensure that veterinary care is available at all times, for animals held for both breeding, and for experimental manipulations;
- be responsible for the management of the day-to-day care of the animals;
- supervise the work of other personnel in the facility;
- liaise between investigators, teachers, and facility personnel;
- communicate with the AEC on facility management, and any adverse events;
- continually develop the institution's animal care policies and procedures. See Standard Operating Procedures (SOPs) section 6.5;
- be knowledgeable regarding signs of pain, distress and illness specific to the species housed;
- ensure the well-being of all animals is regularly assessed. (After animals are allocated to an approved project, the investigator has primary responsibility for ensuring adequate monitoring of the animals' well-being.);
- ensure that all ill or injured animals are treated promptly;
- investigate the cause of all adverse events including when animals die unexpectedly;
- provide appropriate protective clothing to facility personnel;
- identify, assess and manage any duties that may cause compassion fatigue among facility personnel;
- enforce high standards of personal hygiene, and ensure staff do not eat, drink or smoke in animal areas;
- establish an effective cleaning/sanitation schedule for housed animals;
- ensure that the equipment and facility is clean and well maintained;
- keep adequate records of:
 - the source, transport and use of animals received;
 - identification of animals, where this is part of normal care (e.g. livestock);
 - health status (including health management plans), genetic constitution and the physical environment of animals held, when definition of these is required;
 - fate or disposal details of all animals held;
 - fertility, fecundity, morbidity and mortality in animal breeding groups;
 - routine disease screening results;
 - diseases developed and treatment provided.

Records related to the use of animals in RTT must be made available to accredited reviewers, the AEC, and its nominated representatives.

6.2.2 Personnel

Having sufficient numbers of well-trained, committed staff is key to achieving high standards of animal care.

Institutions should encourage and promote formal training in animal science or technology.

Personnel employed in the care of animals should:

- be trained in the care and maintenance of those animals;
- understand how their actions will affect the animals' well-being, and the outcome of experiments;

- be able to recognise early-stage changes in animal behaviour, performance and appearance;
- have clear instruction in their duties, and in institutional policy and procedures;
- have their training documented.

Any research facility using fish should ensure that the staff have sufficient experience and training to guarantee good welfare standards are maintained. All staff working with fish and housing systems should be familiar with basic fish husbandry and water quality management. Staff who are to undertake new manipulations or procedures should be signed off as competent and initially supervised by experienced staff to ensure the welfare of the animals is not compromised during training.

Personnel should be informed of allergy hazards and the important zoonotic diseases of animals under their care and of precautions that should be taken. Personnel should be informed of any compassion fatigue hazards from their duties, and how these may be avoided, reduced or otherwise managed. Regular health checks and appropriate immunisation (e.g. against tetanus and other zoonoses) of all personnel who handle animals are recommended in the interests of both personnel and animals.

6.3. Routine Monitoring of Animal Health

As a minimum, NAEAC expects that all animals housed in a facility undergo daily visual health checks and more thorough assessment checks at least once a week as part of routine husbandry.

The advantages include:

- prevention of unnecessary impact on animal welfare;
- ensuring scientific data is not compromised by animals behaving or functioning abnormally;
- avoiding costly and disruptive disease outbreaks.

Animal carers must be appropriately trained, and capable of designing and implementing the monitoring programme. There is a large body of literature to assist this process.

6.4. Food and Water

As a minimum:

- provide species-appropriate, clean and nutritionally correct food;
- provide sufficient food to allow normal growth of immature animals, the maintenance of adult animals, and the requirements of pregnancy or lactation;
- remove uneaten perishable food promptly unless contrary to the needs of the species;
- alteration to dietary regimes should be gradual;
- allow sufficient trough space or feeding points when feeding groups. This will avoid undue competition for food which is especially important if feed is restricted;
- for fish:
 - The use of live feeds should be done with some caution as they are a significant risk factor in introducing parasites into the system.
 - Feeding should be done in a predictable regular manner, the number of feeding events necessary to ensure good welfare is often related to the fish species or stage of life cycle.
 - Feeding can result in increased aggression between individuals if insufficient food is presented.
- for land animals, supply clean, fresh, and uncontaminated drinking water continuously.

6.5. Standard Operating Procedures (SOPs)

Facility management should develop SOPs to enable consistent performance of routine tasks. Where they relate to holding and breeding facilities for animals used in RTT, SOPs should be submitted to the AEC for consideration.

Facility SOPs should cover:

- animal husbandry;
- animal transport;
- facility sanitation;
- health checking, disease diagnosis and treatment;
- breeding colony management;
- restraint and manipulation of animals;
- emergency management;
- euthanasia;
- reporting of non-compliance and adverse events;
- staff health and safety.

Where available, MPI codes of welfare should be followed, unless alternative procedures have been approved by the animal ethics committee.

SOPs should be reviewed regularly and resubmitted to the AEC if amended.

6.6. Acquisition of Animals

Animals should be obtained from breeding and supply facilities that maintain conditions consistent with this guide and/or a relevant industry code.

6.7. Animals Collected from their Natural Habitats

Most species of indigenous fauna are protected by law. The Department of Conservation must be consulted when these species are required. Permits are usually necessary to collect, keep, release or kill protected fauna, and further permits are usually required to import or export such species. Any conditions imposed on permits must be observed.

Endangered species must not be used unless the research will be of direct benefit to the conservation of that species or a closely related species and will not further endanger the species.

Animals should be taken from natural habitats only if animals bred in captivity are not available or are unsuitable for the specific scientific purpose.

The definition of a manipulation specifically excludes (in s3 (2) (d) of the Act) the hunting or killing of any animal in a wild state by a method that is not an experimental method. Nonetheless, capture and restraint is clearly stressful. Distress felt by the animals will vary depending on the species, physiological state and experience of contact with humans. Strategies should be employed to minimise distress during capture such as:

- careful choice of capture techniques;
- use of skilled operators;
- choice of appropriate and safe enclosures, devices or caging;
- monitoring for signs of distress following capture;
- treatment of any capture-induced trauma.

Where live traps are used, their operation shall comply with section 36 of the Act, which states:

- traps shall be inspected within 12 hours after sunrise every day beginning on the day immediately after the day on which the trap was set or, where a reliable remote monitoring system is used, be inspected within 24 hours after an animal is captured;
- at each inspection any living animal shall be removed.

Fish may be caught using commercial harvesting practices. Note though that catching fish by an experimental method requires AEC approval.

Fish are easily injured when netted. Consider the following factors:

- minimising the time taken is critical to reducing stress;
- use soft mesh nets and avoid chasing fish around systems. Once caught either keep the fish in the net to manipulate or gently drop the fish out of the net, do not roll fish out of nets as this increases damage to the skin.
- covering the eyes with a wet cloth will quieten most fish species for handling. Ensure anything that touches the fish (including hands, cloths etc) are wet, to avoid damaging the critical mucus layer.

6.8. Animals Obtained from Other Countries

Under the Biosecurity Act 1993, the exit and entry of animals or animal tissues can be restricted.

Permits must be obtained from MPI for the importation of live animals, and their genetic material.

The IBSC must be consulted when genetically modified animals are to be imported and approvals obtained from EPA through the institutional committee. The housing and use of GM organisms and animals requires specialised transitional and containment facilities for vertebrate laboratory animals. MPI approval must first be obtained for the establishment of transitional/containment facilities. This approval requires an on-site inspection by MPI inspectors.

Permits must be obtained from MPI for the importation of specimens from dead animals.

Permits must be obtained from the Department of Conservation for the import/export of both live and dead specimens of all native New Zealand fauna and animals or plants subject to the Trade in Endangered Species Act 1989 or regulations.

6.9. Transport of Animals

Transportation can cause distress due to confinement, movement, noise and changes in the environment and personnel. The extent of any distress will depend on the animals' health, temperament, species, age, sex, the number travelling together and their social relationships, the period without food or water, the duration, the mode of transport, environmental conditions (particularly extremes of temperature) and the care given during the journey.

The CEC should require that animals are transported under humane and hygienic conditions at all times. The Transport within New Zealand Code of Welfare can be found at the following link:

<https://www.mpi.govt.nz/document-vault/1407/direct>

6.10. Animal Housing

All animal housing should provide a safe and appropriate environment for the animals held.

A documented pest control programme should be in place to monitor and control vermin.

The sections below provide an overview of requirements. For greater detail refer to a recognised reference such as:

- the Universities Federation for Animal Welfare (UFAW);
- the Guide for the Care and Use of Laboratory Animals (The Guide);
- Canadian Council on Animal Care: Guide for the Care and Use of Experimental Animals.

6.11. Outdoor Holding Areas

Outdoor areas for housing animals should:

- be compatible with the needs of the species;
- provide adequate shelter and water;
- protect the animals from predation;
- meet any species-specific needs;
- comply with established farm or zoological garden practice.

6.12. Indoor Housing

Buildings for the indoor housing of animals must:

- have an emergency action plan;
- be compatible with the physical, health and behavioural needs of the species and stage of animal to be housed;
- suit the project undertaken;
- allow for free movement;
- provide for group contact where this is appropriate;
- be designed and operated to supply environmental factors suitable to the species;
- prevent cross-contamination between different groups/types of animals;
- allow for the delivery and adequate storage of food, water, bedding and appropriate enrichment;
- facilitate the entry of people and other animals;
- restrict access to the animal quarters to authorised persons only;
- be maintained in good repair;
- have durable, impervious and easily sanitised walls;
- be kept clean and tidy, and operated to achieve maximum possible hygiene;
- allow for effective and humane pest control;
- have a reticulated water supply and proper facilities for drainage.

6.13. Environmental Factors

Provide environmental conditions suitable for the behavioural and biological needs of each species held. Consider:

- air exchange;
- temperature;
- humidity;
- noise;
- light intensity and duration;
- water quality.

Effective ventilation is essential for the comfort of housed animals and the control of temperature, humidity and odours. Ventilation systems should distribute air uniformly and achieve adequate air exchange, both within cages and within a room. There should be a means of alerting the facility manager when ventilation systems are not working correctly, or there is an interruption to power supply, so that remedial action can be taken.

Noxious odours, particularly ammonia must be kept to a level compatible with the health and comfort of the animals and personnel.

The adequacy of the ventilation system, the design, construction and placement of cages and containers, population densities both within cages and within a room, the effectiveness of the cleaning and the frequency of bedding changes will all influence the level of noxious gases.

Attention should be given to the balance between the need for cleanliness and the potential impact of cleaning procedures on the animals.

Environmental factors potentially affect the welfare of the animals and may affect the results of experiments. Investigators should be consulted prior to any planned changes to the environmental conditions of their animals.

Fish (special considerations)

It is important to consider:

- Respiration; this includes providing both enough oxygen and sufficient de-gassing to remove CO₂ from the environment.
- Temperature; the inverse relationship between temperature and oxygen saturation in water can be problematic, especially as increasing temperatures drive higher levels of oxygen demand in fish.
- Osmotic balance.
- Thermal regulation; Fish have a wide range of thermal tolerance as a group; however, each species of fish will have preferred ranges.
- Water quality; key factors are dissolved oxygen, temperature, pH, ammonia, nitrite and water hardness.
- Appropriate systems must be in place to remove contaminants from water in fish tanks and ponds.

6.14. Pens, Cages and Containers

The enclosure must be designed and managed to meet species-specific needs, unless otherwise signed off as part of an AEC approved project.

Consider the following, for each species held.

- Sufficient space allocation:
 - Population density within enclosures, and the placement of these in rooms should ensure that acceptable social and environmental conditions for the species are maintained.
 - Single house animals only when appropriate for the species or if required by the experiment, e.g. during recovery from surgery or collection of samples.
- Appropriate substrate:
 - Wire floor cages for rodents should only be used when essential to the research protocol, and

- then only for brief periods.
 - Cages with wire floors should include a solid resting area.
 - Bedding (litter) should be appropriate to the species, comfortable, absorbent, dust-free, non-palatable, non-toxic, able to be sterilised if required by the research project.
- Nesting/sleeping areas:
 - All animals should be routinely provided with bedding material so that they can rest in dry comfortable sleeping areas.
 - Pregnant animals should be provided with nesting materials where appropriate.
- Social interaction
- Opportunity to perform a species-specific behavioural repertoire
- Hiding/retiring zones
- Appropriate environmental conditions
- Ready access to food and water
- Cleaning:
 - Cleaning should be frequent enough to ensure a healthy environment, without creating unnecessary disturbance.
 - Choice of detergents, disinfectants and pesticides should be made in consultation with investigators.
 - Deodorants designed to mask odours should not be used in animal facilities. They are not an acceptable substitute for good cleaning practices and may interfere with breeding cycles and metabolic processes.
 - Cleaning practices should be monitored regularly to ensure effective sanitation. Methods include visual inspection, monitoring water temperatures and microbiological testing of surfaces after cleaning.
 - Spot cleaning should be used where appropriate.
- Measures to prevent the spread of pests and disease
- Requirements of the project
- Ability to observe the animals readily.

6.14.1 Pens, Cages, Enclosure Requirements

Animal containers and enclosures must be:

- constructed of durable, impervious materials;
- kept clean;
- well maintained;
- secure and escape-proof;
- sized to allow animals to stretch out when recumbent and to stand upright and must:
 - protect the animals from climatic extremes;
 - prevent injury to the animals.

6.14.2 Farm Animals (Special Considerations)

As well the above criteria, the following points must be noted when housing farm animals:

- housing and management practices must meet the requirements of the code of welfare for the species concerned;
- material used for indoor facilities should be impervious to moisture, insects and vermin. Concrete and metal are the preferred building materials;
- pipes supplying drinking water should not be copper or galvanised;
- adequate trough space must be provided so all animals have access to feed and water supplies
- any paint/sealer applied to wood where cleaning and disinfection is required must be non-toxic to livestock;

- floors (paved or concrete) surfaces should be 'textured' to prevent slipping;
- Concrete is not suitable for areas where livestock stand for lengthy periods of time and should be covered with rubber matting or other suitable substrate such as wood chips;
- Faecal material and urine should drain away or be cleaned away regularly to prevent animals standing in dirty areas;
- fencing must be maintained to prevent escape or injury;
- ruminants require a resting area either in a well-drained outside area or bedded shelter;
- plan how to manage ventilation, temperature, relative humidity, air velocity, moisture, dust, light, gas accumulation, odours, space and manure. These become increasingly important when large animals are housed indoors.

6.14.3 Fish (Special Considerations)

The challenge with housing and caring for fish is their diverse nature. The environmental range of fish varies from deep oceans to the highest lakes in the world. They might live in water from near freezing, to over 40°C.

The housing and welfare programme should give consideration to the following areas, in relation to the species to be used:

- Nutrition, and feed delivery systems;
- Managing waste;
- Oxygen & CO₂ levels in water;
- Osmotic balance;
- Thermal regulation;
- Water quality, filtration, and flow;
- Holding systems;
- Lighting;
- External stimuli;
- Disease management;
- Environmental enrichment;
- Stocking density;
- Handling.

For more information, see NAEAC Occasional Paper No. 14: Fish Welfare.

6.15. Enrichment and Environmental Complexity

Most animals used in RTT are housed in unnatural environments. Wherever possible such animals should be provided with an environment that can accommodate the behavioural and physiological needs of the species.

Many of the species of animals used in RTT have well defined social structures and prefer to live in groups, although care must be taken to ensure that the animals are socially compatible. Individual housing is stressful for social animals, therefore social isolation should be avoided whenever possible and limited to meet the specific research objectives as approved by an AEC. The effects of physical isolation should be minimised where possible by the use of non-contact communication, whether visual, auditory or olfactory. Judicious use of mirrors can also be helpful, as can an environment of increased complexity.

The living areas of the animals should be set up and provisioned with the means that will enable them to perform a behavioural repertoire appropriate to the species.

6.16. Admission of New Animals into Holding Areas

Consider the following general points for new animals:

- quarantine and inspection by a qualified person;
- evaluate their health, and treat if required;
- determine suitability for the proposed experiments;
- hold for sufficient time to acclimatise to the facility and personnel;
- experimental manipulations are not normally permitted while animals are held in quarantine. This may vary, depending on the nature of the project. Animals may be bred while in quarantine;
- animals that do not adapt to their new environment should not be kept.

6.17. Routine Husbandry Procedures

Routine husbandry procedures should meet any code of welfare for the species involved and be performed by competent personnel.

Procedures for the care of normal healthy breeding stock and supply of animals are viewed as routine husbandry and fall outside the definition of manipulation.

When special breeding requirements are integral to a research or teaching project such as the creation of a genetically modified animal, then procedures applicable to breeding are regarded as a manipulation and should be included in the proposal to the AEC.

Variations to normal procedure as part of an experimental project must receive prior AEC approval.

Fish (special considerations)

- Handling: thought should be given to minimising the impact on their welfare. Training and habituation is possible.
- Anaesthesia: two of the greatest risks for fish under anaesthesia are overdose and hypercapnia. If fish are kept in the anaesthetic too long, they can receive too great a dose. The hypercapnia risk comes from prolonged anaesthesia which reduces breathing rate.
- Frequency: there is a risk from cumulative stressful events, leading to increased disease susceptibility and death. Fish that are regularly handled will acclimate and handling impacts reduce with time.

6.17.1 Identification of Animals

The method of identification should be reliable, appropriate for the species and project, and cause the least possible stress to the animal. Available methods include:

- tattoo;
- neck-band;
- leg band;
- individual tag, usually place in the animal's ear;
- electronic numbering device (microchip);
- physical mark e.g. tail paint on cattle, permanent marker stripes on rodent's tail;
- box/enclosure label.

Less invasive methods should be chosen when suitable. Invasive identification procedures should be performed, or closely supervised, by an experienced practitioner under appropriate anaesthesia/analgesia.

6.18. Euthanasia

The method and procedures used for killing an animal must be humane and:

- i. minimise pain or distress and produce rapid loss of consciousness until death occurs
- ii. be compatible with the purpose and aims of the project or activity
- iii. be appropriate to the species, age, developmental stage and health of the animal
- iv. require minimum restraint of the animal
- v. be reliable, reproducible and irreversible
- vi. ensure that animals are killed in a quiet, clean environment away from other animals
- vii. ensure that death is established before disposal of the carcass, foetuses, embryos and fertilised eggs.

Dependent offspring of animals to be killed must be cared for or humanely killed.

NAEAC recommends AECs refer to the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals.

6.18.1 Disposal of Animal Carcasses and Waste

Provide for prompt and sanitary disposal of animal carcasses and waste material in accordance with Hazardous Substances and New Organisms (HSNO) and EPA legislation, local council by-laws and community standards.

6.19. Emergency Management

Every animal facility should have a documented emergency recovery plan, to cover such emergencies as flooding and fire, or the breakdown of lighting, heating, cooling or ventilation.

The AEC should:

- work with the organisation to ensure adequate contingency arrangements for the care of animals are in place;
- ensure adequate consideration is given to special classes of animals. For example, does containment of genetically modified (GM) animals require special attention?
- ensure provision is made for emergency euthanasia of animals;
- require facility staff to be trained against the emergency plan.

RESPONSIBILITIES OF INVESTIGATORS

7

People who use animals for scientific purposes have an obligation to treat the animals humanely and to consider their welfare and the Three Rs as essential factors when planning and conducting experiments.

Investigators have direct and ultimate responsibility for all matters related to the welfare of the animals under their control, including the general husbandry and housing of those animals as well as the specific manipulations. They should act in accordance with their specific AEC approval.

The responsibility of investigators extends over all facets of the care and use of animals in projects approved by the AEC, beginning when the animal is allocated to the approved project and ending with its fate at the end of the project.

Investigators are responsible for the standard of animal care and use by all other persons involved in the project. They should ensure that the extent of supervision is compatible with the level of competence of each person and the responsibilities they are given.

In many institutions the daily animal husbandry is delegated to professional animal care personnel. In this case, the investigator should implement strategies for effective communication with the facility manager.

Investigators have a legal and ethical responsibility to ensure that animals on a project are manipulated using medical and surgical techniques which are consistent with the principles of good practice and scientific knowledge in the discipline of laboratory animal veterinary medicine. Investigators should consult with veterinarians whenever unexpected adverse effects occur in order that appropriate veterinary care and treatment regimens are immediately implemented. This responsibility is consistent with the public's duty of care to seek veterinary management of any sick animals in their charge.

Where an application is likely to involve or impinge on indigenous species, the applicant should discuss these aspects with local iwi or hapu. The application should include evidence that these discussions have taken place and that Māori perspectives are not compromised. If there is any uncertainty, the applicant should approach local Māori representatives for clarification.

7.1. Responsibilities of Teachers

Animals should only be used for teaching activities when there are no suitable alternatives for achieving all of the educational objectives. Students should be given the opportunity to discuss the ethical, legal, social and scientific issues involved in the use of animals for scientific purposes, including teaching.

7.1.1 All New Zealand Schools

Use of animals in all New Zealand schools must comply with the approved CEC of the New Zealand Association of Science Educators. This CEC covers early childhood centres,

kindergartens, schools (both teachers and students) home-schooled students and their families. It is administered by the association on behalf of the Ministry of Education.

An animal ethics committee is established under the code. It approves appropriate projects and is able to provide advice on when AEC approval is necessary.

Any animals that are housed at schools must be well cared for at all times, including during weekends and holidays. The standard of care should meet the requirements of this guide or the relevant code of welfare for the species. Students should not be allowed to take animals home unless there is a clear written undertaking from a parent or guardian that the animals will be cared for adequately and responsibly.

There are two resources of particular relevance to schools:

1. Ethical guidelines for students in laboratory classes involving the use of animals or animal tissues, an ANZCCART publication.
2. Caring for Animals – A Guide for Teachers, Early Childhood Educators and Students, published by the Ministry of Education.

7.1.2 Tertiary Institutions

The person in charge of animals used to achieve educational objectives should:

- accept ultimate responsibility for ensuring that the care and use of the animals is in accordance with this guide and all relevant legislation;
- have relevant training and qualifications;
- incorporate into the proposed activities any methods for the replacement, reduction or refinement in the use of animals, provided such methods are compatible with the educational objectives;
- obtain prior AEC approval for use of all animals for the entire course and ensure that activities are conducted as directed and approved by the AEC;
- instruct students appropriately in the care and use of animals before those students participate in experiments with live animals and, where possible, use alternative methods in that preparation;
- ensure that there is close, competent supervision of all students;
- allow students to anaesthetise animals or carry out surgery only if it is essential for their training;
- ensure that in the event of injury to animals, prompt treatment is provided;
- be responsible for the humane killing of the animals, if required.

7.2. AEC Approval

Before any project begins, investigators shall receive approval from the AEC. This requires a formal application to the AEC that:

- explains the value of the project;
- explains why non-animal models cannot be used;
- documents the names, roles and qualifications of the key personnel;
- specifies the numbers, types, and stages of animals to be used;
- specifies the procedures that will occur;

- estimates the impact on the animals;
- stipulates what will be done to mitigate the impact;
- describes the fate of the animals which demonstrates that the project will comply with the Act. Moreover, the investigators must satisfy the AEC of their competence to conduct the techniques described in the experiment.

Species requiring special permission from other organisations (e.g. Department of Conservation) must not be obtained and held before such approval is granted.

If approval is granted, investigators should:

- supervise all aspects of the project to ensure good animal welfare standards are met
- comply with all conditions imposed by the AEC
- document the numbers of animals used, and the actual impact grading experienced
- alert the AEC to any adverse events
- inform the AEC when the project is completed or discontinued;
- provide a written report to the AEC at the conclusion of the project.

7.3. Planning Projects

It is essential that investigators carefully plan their experimental protocol. This guide raises important issues for consideration which may lead to adjustments to the final protocol for submission to the AEC.

7.3.1 Choice of Species

Ensure the choice of species is appropriate for the purpose of the project. Requirements for known genetic constitution, freedom from specific diseases, documented health, nutritional and environmental histories, and other relevant factors should be taken into account. When the definition of the biological status of animals is necessary, investigators should ensure that the supplier can provide adequate proof that any requirements can be met. Where relevant, species and individual animals should be chosen on the basis that the proposed experiments will result in the least pain and distress. In making this decision, all aspects of the biological nature of the animals, including their behavioural characteristics and their cognitive development, should be taken into account.

7.3.2 Monitoring of Animals on Approval

Observe intensively managed animals as frequently as circumstances require, but at least daily, to assess their health and welfare. Ensure satisfactory arrangements are made for contacting key personnel in the event of emergencies. Any unexpected adverse effects that impact on animal welfare must be reported to the AEC.

7.3.3 Record-keeping

Investigators must accurately document the conduct and outcomes of the trial. Records maintained should include:

1. Study protocol
2. AEC approval
3. Manipulations carried out and actual impact grade resulting.

4. Details of animal husbandry routines & actual environmental conditions
5. Variations approved
6. Deviations/non-compliances
7. Adverse events
8. Staff training records
9. Veterinary treatment
10. Results of manipulations/ treatments

Animal use records shall meet the statistical reporting requirements of the Animal Welfare (Records and Statistics) Regulations 1999, as detailed in MPI's publication "Animal Use Statistics".

7.3.4 Consultation

Investigators should consult other experienced scientists, veterinarians, or laboratory animal, livestock or wildlife specialists when necessary.

7.3.5 Checklist

When planning is completed, the investigator should recheck the protocol to ensure that the following points have been adequately covered and the Three Rs (replacement, refinement and reduction) have been considered.

- a. Do the potential benefits outweigh any ethical concerns about the impact on animal welfare?
- b. Can the aims be achieved without using animals (replacement)?
- c. Are there better ways of achieving the same ends (refinement)?
- d. Are suitable holding facilities, equipment and competent personnel available (refinement)?
- e. Have all involved personnel been informed of the planned experimental and other procedures?
- f. Has the most appropriate species of animal been selected?
- g. Is the biological status (genetic, nutritional, microbiological, general health) of the animals appropriate?
- h. Are the environmental conditions (including caging or pen type, noise, photoperiod, temperature, humidity, ventilation, density of housing and social structures) appropriate (refinement)?
- i. Are the experiments designed so that statistically valid results can be obtained or the educational objectives achieved using the minimum necessary number of animals (reduction)?
- j. If the potential impact on the animal is unknown, is it 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 (refinement)?
- k. If the scientific activity could cause the animals any pain or distress, what will be done to minimise or avoid this (refinement)?
- l. What arrangements will be made to monitor the animals adequately, in terms of both their general health and welfare and their response to manipulation (refinement)?

- m. If any of the experiments have been performed previously, why should they be repeated (reduction)? Is this required for quality control or legislative reasons (repetition, replication)? Have you checked to see if similar work has been done before, so that you can avoid duplicating previous work and thus using animals unnecessarily?
- n. If any animals are to be used repeatedly, what will be done to minimise the cumulative effects of such use (refinement)?
- o. Are there any permits that must be obtained for the importation, capture, use, destruction or release of the animals?
- p. What arrangements have been made for the fate of all healthy animals at the completion of the project?

7.4. Conduct of Experiments

7.4.1 Limiting Pain and Distress

Pain and distress cannot always be adequately evaluated in animals and investigators should therefore assume that animals experience pain in a manner similar to humans. Decisions regarding their welfare in experiments should be based on this assumption unless there is evidence to the contrary.

The investigator should anticipate any potentially adverse effects of a manipulation and take all possible steps to avoid or minimise pain and distress.

These steps should include:

- choosing the most appropriate and humane method for manipulations
- ensuring the technical skills and competence of all persons involved in animal care and use
- using pre-emptive analgesia when pain is anticipated
- ensuring that animals are adequately monitored to allow prompt alleviation of pain or distress
- developing a plan to manage any adverse effects of a manipulation e.g. increase in frequency of observation, consultation with a veterinarian, administration of appropriate medication, removal from the project or humane euthanasia
- using anaesthetic, analgesic and tranquillising agents appropriate to the species and the experimental purposes
- developing study endpoints that minimise pain and distress
- conducting projects over the shortest time practicable; and
- using appropriate methods of euthanasia.

The use of local or general anaesthetics, analgesics or tranquillisers must be appropriate to the species, and should meet the criteria generally accepted in current medical, laboratory animal or veterinary practice.

Manipulations which are liable to cause pain of a kind and degree for which anaesthesia would normally be used in medical or veterinary practice must be carried out under anaesthesia.

Distress can sometimes be avoided or minimised by non-pharmacological means. Before an experiment begins, animals should be appropriately conditioned to the experimental environment and procedures and be familiar with animal care personnel. During and after experiments

appropriate nursing procedures to minimise pain and distress and to promote the well-being of the animals should be provided.

If animals develop signs of severe pain or distress despite the precautions outlined above, they should have the pain or distress alleviated promptly or be killed humanely and without delay. Veterinary consultants involved in the animal care programme should be informed immediately. Alleviation of such pain or distress takes precedence over continuing or finishing the experiment. If in doubt, investigators should always seek a professional veterinary opinion before continuing an experiment.

Unexpected deaths occurring during a project must be properly investigated by a veterinarian or other qualified person to determine the cause and initiate remedial action. If the deaths are due to manipulations, these must cease. The AEC must be notified and the project protocol resubmitted with appropriate modification.

7.4.2 Animal Welfare Monitoring of Pain or Distress

Investigators should be familiar with the normal behaviour of the animal species chosen, be knowledgeable of signs of pain or distress specific to that species, and must regularly monitor their animals for these signs.

Animals should be monitored to allow detection of deviations from normal behaviour patterns. Such deviations are often the first indications that animals are experiencing pain or distress. Any changes in patterns of sleeping, feeding, drinking, grooming, exploratory behaviour, performance in learning or discriminatory tasks, reproduction or social behaviour should be noted, assessed and acted on if appropriate. Animals must be monitored appropriately for clinical signs of acute pain or distress. These may include one or more of the following:

- abnormal behaviour;
- abnormal stance or movements;
- abnormal sounds;
- altered cardiovascular and/or respiratory function;
- abnormal appetite;
- rapid decline in body weight;
- altered body temperature; and
- vomiting and abnormal defecation or urination.

Animal welfare monitoring score sheets should be used to document the observations and collection of data listed above. For example, variations in body weight, water intake, and grooming behaviour can be recorded every 24 hours or more often as needed during the immediate post-operative period for surgical manipulations.

7.4.3 Study Endpoints

For all but the most minor of manipulations, the investigator should develop humane study endpoints when preparing a project application. These can be used to judge when an animal should be removed from a project or euthanised in order to promote animal welfare.

Death as an endpoint is generally unacceptable and should be fully justified. All animals found in a moribund state must be euthanised unless specifically justified as above and approved by the AEC. It is generally accepted that moribund animals give unreliable research data because they are frequently in a state of multiple organ failure. Attention to good practice indicates that endpoints earlier than the moribund condition should always be used. Typically, these are based

on changes in body weight, tumour size, and/or body temperature combined with abnormal clinical condition.

For example, animals should be killed when:

- they have lost more than 20% of their pre-study body weight; or
- they have lost more than 10% in 24 hours; or
- a tumour grows to more than 10% of the animal's weight; or
- body temperature falls below a pre-set level (as determined by pilot studies which indicate that the level set is predictive of death); or
- animals self-mutilate limbs and feet; or
- animals develop abscesses.

7.4.4 Repeated Use of Animals in Experiments (Reuse)

Individual animals should not be used in more than one experiment, either in the same or different projects, without the express approval of the AEC. However, appropriate reuse of animals may reduce the total number of animals used in a project, result in better design of experiments, and reduce stress or prevent pain in other animals.

The benefits of reusing animals should be balanced against any adverse effects on their well-being, taking into account the lifetime experience of the individual animal.

Applications involving the reuse of animals should take into account:

- the pain or distress and any potential long-term or cumulative effects caused by any previous manipulations;
- the total time taken;
- the pain or distress likely to be caused by the next and subsequent manipulations; and
- whether the animal has recovered fully from the first experiment before further experiments are carried out.

7.4.5 Duration of Experiments

Experimental duration should be the minimum required to provide answers to the questions asked.

Experiments which involve any pain or distress, should be as brief as practicable. AEC approval should be sought for the continued long-term use of individual animals. The decision to continue must be based on the clinical well-being of the animal and the absence of aversion to the experimental situation.

7.4.6 Handling and Restraining Animals

Animals should be handled only by persons instructed and competent in methods which minimise pain, injury or distress.

When the use of restraint devices is necessary for the welfare of the animal and the safety of the handler, they should be used to the minimum extent, for the minimum period required to accomplish the purpose of the experiment, and be appropriate for the animal. Restraint devices such as cattle crushes should be maintained regularly and operated as intended by the manufacturer.

Tranquillisers or anaesthetics may aid restraint but may prolong recovery from the procedure.

When these agents have been used, greater attention may be required in assessing the recovery of the animals.

Periods of prolonged restraint or confinement should be avoided. However, where prolonged restraint or confinement is proposed, such as housing livestock in metabolism cages, consideration should be given to their biological needs, including their behavioural requirements and the need for appropriate exercise. Such animals should be assessed regularly by a veterinarian or other qualified person not otherwise involved in the project. If any negative impact on an animal is detected, the animal should be removed from the restraint or the method modified to minimise the impact.

7.4.7 Fate at Completion of Projects

Upon completion of the project, animals should be either:

- returned promptly to either normal husbandry conditions or,
- if appropriate and permitted, to their natural habitat or,
- rehomed where appropriate or,
- when necessary, be euthanised.

7.4.8 Rehoming

Opportunities to rehome animals should be considered wherever possible, especially when the project or manipulation has had minimal impact on the welfare of the animal. Rehoming should be the preferred choice if the physiological condition and behavioural attributes of the animal indicate that it can be introduced to a new environment with little, or no, transient impact on its well-being.

An animal should not be released to a person at the conclusion of its use unless:

- the AEC has approved such release;
- safeguards are in place and approved by the AEC to ensure the ongoing well-being of the animal;
- transport of animals between sites is appropriate.

7.4.9 Tissue Sharing

Investigators and animal carers should ensure that, if practicable, tissue samples from animals that have died or been humanely killed are provided or made available to other investigators for their work or deposited in a tissue bank for subsequent distribution.

7.4.10 Autopsy

An autopsy should be performed when animals die unexpectedly or are euthanised due to unforeseen complications. The autopsy should be carried out by a person with appropriate qualifications.

Investigators should consider the value of an autopsy for all animals that die for reasons other than approved euthanasia during a project. Post-mortem evaluation may identify one or more non-experimental variables which could compromise the remaining, or future, research subjects.

7.4.11 Pre-operative Planning

Surgical success can be improved by careful attention to the following.

- The use of animals that are fit for purpose will ensure more reliable research data. Investigators should consult the institutional veterinarian or other qualified person to assist in obtaining such animals.
- Pre-operative physical examination can often identify potential problems, such as increased anaesthetic risk, which may compromise the surgical procedure. Animals that are not in an appropriate state of health should be rejected.
- Pre-surgical fasting is necessary for many species to minimise complications of anaesthetic administration.
- Pre-experimental practice on cadavers enables investigators to familiarise themselves with anatomical landmarks and streamline the experimental surgical procedures, thereby reducing the quantity of anaesthetic required, reducing operative time and minimising tissue damage. This will speed post-operative recovery and promote animal well-being.
- For any surgical procedure, a pain management plan aimed at prevention or alleviation of pain and which is appropriate for the procedures and the species should be developed, implemented and reviewed if necessary.

7.4.12 Surgery

Anaesthesia and surgery should be performed by competent personnel with appropriate training and experience. Training should only be given by competent personnel with relevant expertise in surgery and anaesthesia.

Surgical procedures should be carried out under appropriate local or general anaesthesia. There should be adequate monitoring of the depth of anaesthesia and effects such as hypothermia, and cardiovascular and respiratory depression.

The choice and administration of anaesthetic, analgesic and tranquillising agents should be suitable for the species and appropriate for the purpose of the experiment. The use of such agents should parallel that used in current medical, laboratory animal or veterinary practice.

Investigators should consider the value of a limited anaesthetic trial to familiarise themselves with new anaesthetic or analgesic drug combinations. Species and strain variation in drug metabolism can result in unexpected morbidity and mortality when dosages are extrapolated from published data. A limited trial, when combined with a non-survival surgical practice session, can provide invaluable information and promote surgical success and animal well-being in subsequent study animals.

When more than one surgical procedure is to be performed the animal should have recovered to good general health between each procedure. Every effort should be made to reduce the total number of procedures on one animal and the AEC should be informed specifically of the need for more than one procedure.

When the animal is not to recover from the surgery, it should be unconscious for the whole procedure, with euthanasia either by overdose of the general anaesthetic or by inducing brain death by a variety of methods e.g. exsanguination or disruption of the thorax.

When the animal is to recover from the anaesthetic, surgical procedures should conform to accepted standards in laboratory animal and veterinary practice. All tissues should be handled with care and particular attention should be given to haemostasis. Aseptic technique should be used for animals which undergo any survival surgery which involves disruption of the skin's barrier function. Aseptic technique includes aseptic preparation of the surgical field, use of sterilised instruments, wearing of sterile surgical gloves, gowns, caps, and face masks.

The use of post-operative antibiotics should not be a substitute for correct aseptic technique.

7.4.13 Post-operative Care

The comfort of animals must be promoted throughout the post-operative period. Attention should be given to warmth, hygiene, fluid and food intake, and control of infection. Consideration of pain relief is paramount in post-operative care. The use of analgesics and tranquillisers may be needed to minimise post-operative pain or distress. Care should be taken that animals recovering from anaesthesia are housed to prevent injury and that conditions are such that they are not disturbed, attacked or killed by other animals in the same enclosure.

Investigators should ensure that animals are adequately monitored. They should ensure that they, or other experienced personnel, are fully informed of the animals' condition. The duties of all personnel should be clearly defined and ways of dealing with emergencies established.

Appropriate clinical records, including observations and administration of any drugs, fluids or other treatments, should be kept, and made accessible to all involved in the post-operative care of the animal.

Regular observation of surgical wounds is essential to check the progress of healing. Any problems must be attended to immediately.

Any post-operative animal observed to be in a state of severe pain or distress that cannot be alleviated must be killed humanely immediately and the consultant veterinarian informed without delay.

7.4.14 Modifying Animal Behaviour

Procedures used to modify an animal's behaviour or to induce it to perform specific tasks depend on motivation of the animal. The preferred inducement is positive reinforcement, but in some cases the inducement may need to be some form of biological stress. This stress should be as mild as possible. Severe deprivation of water, food, social interaction or sensory stimuli should not be used.

The level and duration of painful or noxious stimuli should be minimised and escape from the stimuli should be available. Behaviour can usually be modified using procedures that involve no more of a stressor than that normally experienced by the species. When noxious stimuli are used to modify behaviour, the AEC should be aware of the duration and possibility of escape from the stimuli.

7.4.15 Withholding Food or Water

Projects involving the withholding or severe restriction of food or water should produce no continuing detrimental effect on the animals. In these experiments, the fluid balance and/or body weight should be monitored, recorded and maintained within the limits approved by the AEC.

7.5. Guidelines for Specific Manipulations

7.5.1 Production of Genetically Modified Animals

The breeding or production of an animal using genetic modification that may result in the birth or production of an animal that is more susceptible to, or at greater risk of, pain or distress during its life as a result of the breeding or production is considered a manipulation under the Act.

Resulting pregnancies can have an impact on the dam as well as the foetus and require close monitoring for problems such as hydrallantois and dystocia.

Genetic modification is defined as the deletion, change, or moving of genes within an organism, or the transfer of genes from one organism to another, or the modification of existing genes, or the construction of new genes and their incorporation into any organism (as defined in the Royal Commission Report 2001).

Reproductive or therapeutic cloning is the genetic modification of animals, in particular livestock or rodents, to establish desired traits for food production (e.g. meat quality), livestock health, or medicine production (e.g. induce cows to produce medical compounds in milk). Alternatively, animals can be produced with genetic mutations to better understand disease process. Cloning uses a process called somatic cell nuclear transfer (SCNT). Scientists take an immature egg or oocytes from a female animal, often by inducing superovulation. Instead of combining it with sperm, they remove the nucleus (which contains the oocyte's genes). This leaves behind the other components necessary for the initial stages of embryo development. Scientists then add the nucleus or cell from the donor animal that has the desirable or modified traits they wish to copy. The donor nucleus is fused with the ooplast (the oocyte whose nucleus has been removed), and an embryo begins to form. The embryo is then implanted in the uterus of a surrogate dam which carries it to term.

7.5.2 Animal Models of Disease

The scientific validity of animal models of human diseases rests in part on how closely a given model resembles a particular disease. Thus, the attendant pain and distress of the human disease may also occur in the animal. Special care should be taken in selecting the appropriate species, and the investigator must accept responsibility for ensuring that any pain or distress is minimised and that the AEC is informed of the potential effects of the disease on the animals.

Investigators must not allow the experiments to proceed to the painful or distressful or lingering death of animals unless no other experimental endpoint is feasible and the goals of the experiments are the prevention, alleviation, treatment or care of a life-threatening disease or situation in human beings or animals.

Investigators must avoid using death as an experimental endpoint whenever possible. When death as an endpoint cannot be avoided, the experiments should be designed to result in the deaths of as few animals as possible.

7.5.3 Experimental Induction of Neoplasia

The site for induction of tumours should be chosen carefully. Subcutaneous sites on the back or flank should be chosen when possible. Prior to the use of footpad, brain and eye sites, specific justification as to the lack of any alternative should be made to the AEC.

Investigators should monitor their animals regularly for signs of pain or distress, especially sudden changes in body condition and signs that tumour growth is impacting on the well-being of the animals.

Animals with experimentally induced tumours should be euthanised before predictable death occurs, cachexia becomes advanced or the tumour becomes large enough to cause ulceration or severe limiting of normal behaviour. Animals should be used when tumours are at the minimum size necessary to obtain valid results.

In tumour therapy experiments, the endpoints chosen should be as early as possible, compatible with reliable assessment of the therapy. Weight changes should be monitored closely. Death from the tumour should not be an endpoint.

7.5.4 Production of Monoclonal Antibodies

In vitro methods should be used for the routine amplification of hybridomas for the production of monoclonal antibodies. Investigators wishing to use the in vivo (ascites) method should provide in their proposal to the AEC recent laboratory evidence to show that in vitro methods are unsuitable for the specific monoclonal antibody that is the subject of the proposal.

In the immunisation phase, investigators should ensure the minimisation of pain and distress to animals from factors such as the type, volume, site and frequency of the injection of adjuvants, and the methods and frequency of blood sampling.

With ascitic tumours, including hybridomas, investigators should ensure that the volume of ascitic fluid does not cause gross abdominal distension, and the volumes of solid tumours and cachexia do not become distressful to the animals. Careful monitoring is necessary because body weight loss can be difficult to discern in the presence of ascites and abdominal tumours.

7.5.5 Lesions of the Central Nervous System

Anatomical or chemical lesions of the central nervous system have been widely used to study its structure and function in health and disease. These experiments demand special consideration when the lesion produces loss of function, including impairment of limb or trunk movements, loss of sensibility to touch, temperature or pain, impairment of the animal's awareness of its surroundings or impairment of appetite or injury mechanisms. Special animal care, caging, and other facilities may be needed and the AEC, in approving such experiments, has a particular responsibility to ensure that these facilities are available and that the condition of the animals is closely monitored.

7.5.6 Implanted Devices

Investigators should be aware of the need for strict attention to aseptic technique when foreign bodies are surgically implanted. Contamination of prosthetic devices frequently requires their removal after antibiotic therapy has failed.

Skilled and specialised attention is required in the care of animals following an operation in which monitoring or sampling devices have been implanted, or a fistula created. Regular observation is essential to determine signs of distress, pain or infection which must be treated immediately.

7.5.7 Organ and Tissue Transplantation

Skilled and specialised attention is required for animals following organ or tissue transplantation. Animals must be assessed frequently for any signs of pain, distress, infection and tissue rejection and treated immediately if these occur. Special attention should be given to the management of immunosuppression and the disease hazards and adverse outcomes that may be associated with organ and tissue transplantation between species (xenotransplantation). Death as an endpoint is unacceptable when determining recipient survival times.

7.5.8 Neuromuscular Paralysis

Neuromuscular blocking agents may only be used with adequate general anaesthesia. When these agents are used, specialist advice on anaesthesia should be obtained.

Immobilisation of an animal solely with a neuromuscular blocking agent is not acceptable. When these agents are used with general anaesthesia, special care must be taken to ensure the maintenance of an adequate plane of anaesthesia. Since the usual criteria such as character of respiration and corneal and flexor withdrawal reflexes cannot be used, continuous or frequent intermittent monitoring of physiological variables such as heart rate, blood pressure, oxygen saturation, pupil size and electroencephalogram is necessary, together with the effects of these of mild sensory stimuli. Care is required to ensure that drugs used in the procedures do not interfere with this monitoring.

7.5.9 Electro-immobilisation

Electro-immobilisation must not be used as an alternative to analgesia or anaesthesia. When its use is proposed for the restraint of animals, AECs should carefully evaluate published evidence to assess whether it may cause distress. If so, an alternative restraint method should be used.

7.5.10 Toxicological Experiments

If suitable non-animal tests are available, they shall be used. In particular, in vitro methods should be used as an initial screening test wherever possible.

Investigation of the safety of agents intended for use in human beings, animals, the household or the environment, or of naturally occurring toxins, or of agents to be used as poisons for pest control should be performed by persons with appropriate training.

The endpoint of such experiments should be as early as is compatible with reliable assessment of toxicity and must minimise the extent of any pain and distress.

When death as an endpoint cannot be avoided, the experiments must be designed to result in the deaths of as few animals as possible.

All such tests should be undertaken in accordance with internationally recognised guidelines such as an OECD Guideline for the testing of chemicals.

Investigators must not allow the painful, distressing or lingering deaths of animals unless no other endpoint is feasible and the goals of the project are the prevention, alleviation or cure of a life-threatening disease or situation in humans or animals.

7.5.11 Foetal Experimentation

Under the Act, the definition of an animal includes mammalian, avian and reptilian prenatal or pre-hatched young in the second half of their developmental stage. Any projects involving such animals require AEC approval.

When foetal experimentation or surgery compromises the ability of the neonate to survive and be without pain or distress, it must be euthanised before or immediately following birth unless such pain or distress can be relieved.

Although there is increasing evidence that fetuses do not feel pain under normal conditions, investigators should ensure adequate anaesthesia for both mother and foetus when the latter is undergoing surgical or other manipulation in utero.

During surgery of the mother consideration must be given to any special requirements for anaesthesia of the foetus.

Eggs must be destroyed before hatching, unless hatching is a requirement of the experiment. The AEC must approve the arrangements made for hatchlings.

7.5.12 Research on Pain Mechanisms and the Relief of Pain

In experiments in which unanaesthetised animals are to be subjected to stimuli designed to produce pain or when pain is to be inflicted on animals as part of normal management, investigators should:

- ensure that these stimuli limit pain at all times to levels comparable to those which do not distress human beings;
- ensure that the animals are exposed to the minimum pain necessary for the purpose of the experiment;
- provide treatment for the relief of pain, or allow self-administration of analgesics, or escape from repetitive, painful stimuli when possible.

7.5.13 Animal Welfare and Animal Health Research

When studying ways of improving the health and welfare of animals, investigators may need to design experiments that replicate a problem such as injury, trauma, nutritional disorder, physical exertion, disease or environmental stress.

Thus, the attendant pain and distress may also be replicated. When such experiments are necessary, the investigator must ensure that:

- the principal aim of the project is to improve animal health or welfare;
- alternative methods, such as the use of animals already experiencing the problem, are not possible;
- all possible steps are taken to minimise any pain or distress;
- the experiments do not proceed to the painful or distressful or lingering death of animals unless no other experimental endpoint is feasible and the goals of the experiments are the prevention, alleviation, treatment or care of a life-threatening disease or situation. When death as an endpoint cannot be avoided, the experiments must be designed to result in the deaths of as few animals as possible.

7.5.14 Experiments Involving Hazards to Humans or Other Animals

Hazards may arise from sources that include:

- viruses;
- bacteria;
- fungi;
- parasites;
- radiation;
- radioactivity;
- corrosive substances;
- toxins;
- allergens;
- carcinogens;
- recombinant DNA;
- anaesthetic gases; and
- physical injuries.

Any potential pathogenic effects of these hazards when used in experiments should be explained as far as possible to all personnel. Tests before, during and after the experiments may be required for personnel.

Protocols submitted to the institution's AEC should include a description of any intended use of hazardous compounds or organisms. They should describe specific safety measures and disposal protocols used to prevent contamination of caging, other animals, research personnel and students.

Investigators must not allow the experiments to proceed to the painful or distressful or lingering death of animals unless no other experimental endpoint is feasible and the goals of the experiments are the prevention, alleviation, treatment or care of a life-threatening disease or situation in human beings or animals. When death as an endpoint cannot be avoided, the experiments must be designed to result in the deaths of as few animals as possible.

Precautions, security and emergency plans to contain hazardous agents must be appropriate to a "worst-case" situation.

APPENDIX 1 – EXAMPLE OF A TEMPLATE FOR ANIMAL USE APPLICATIONS

1. Project description

Section 1: Project Header
Project Title and Reference number
Name of submitter/ Principal Investigator
Contact Details
Proposed Start date
Requested duration of approval
Has the application been considered by another AEC?

Section 2: Project Lay Summary
Explain the project purpose/ goals
Explain what will happen to the animals during the study
Is this application related to others? If so, provide a diagram or other explanation of the relationships
Explain how the findings will be promoted or published

Section 3: Animal Numbers and Justification
Include a table of species and numbers, requested, along with predicted impact grading
Previous RTT use of the animals, and consideration of the possible cumulative effects
Justification for species & numbers requested

Section 4: The Three Rs
What consideration has been given to: <ul style="list-style-type: none">• Replacement with non-sentient, or non-living methods• Reduction in animals required• Refinement of procedures
Describe the methods used to determine that the application does not duplicate previous studies

Section 5: Background
Supply background information, which provides context for the application
Projected benefits to animals, humans or ecosystems vs cost to the project animals

Section 6: Study design

Describe the objectives

Detail the methods

Include a table of proposed manipulations & timings

Provide details of sample sizes and justification, randomisation, blinding

Provide a list of any AEC approved SOPs followed during manipulations

Section 7: Animals, husbandry and welfare

Source of animals

Transport requirements

Animal housing and locations including address of facility or farm

Husbandry to ensure general health and welfare

Health status assessment of animals before, during and after manipulation

Specific requirements of animals bred with potential for compromised welfare e.g. transgenic animals

Harm or distress that may be experienced by animals resulting from manipulations, whether this can be alleviated and, if so, the methods to be used

Environmental manipulation including lack of enrichment, single housing of social species, confinement e.g. in metabolic crates

Provide a list of any AEC approved husbandry SOPs that will be followed

Provide a list of all drugs and animals remedies being used during the experimental work

Section 8: Monitoring

Who will monitor the project animals?

Detail the monitoring methods and frequency

Explain provisions for emergency care of project animals (including nights & weekends)

Section 9: Adverse Events

Are adverse events anticipated?

Does any manipulation include administration of a material potentially toxic to the recipients?

Plan to manage any adverse events

Method for real-time recording of adverse events

Process for notifying AEC of adverse events

Section 10: Surgical and other manipulations

Justification for multiple surgeries on a single animal

Anaesthetics proposed, dosing rates and frequency

Monitoring of depth of anaesthesia*

Proposed pain management*

Peri-surgical support to maximise welfare outcomes e.g. use of fluid therapy, heat pads

Other manipulations with the potential to impact on welfare e.g. use of muscle relaxants

Personnel involved

Section 11: Endpoints and animal disposition
Study endpoints – at what point will the study end for animals?
Humane endpoints – where animals will be euthanised within the study to avoid suffering, how will certainty of outcome be balanced against animal welfare considerations?
Death as an endpoint – if death is the required endpoint, this must be fully justified
What will happen to the animals at the end of the trial?

Section 12: Euthanasia
Methods proposed
Drugs, doses, and routes*
Personnel involved

*Note: the AEC may instead require attachment of supporting documentation of authorised use of veterinary medicines (e.g. if the applicant already holds an approved Institutional Drug Administration Order (IDAO)).

Section 13: Project Personnel
Name, organisational position, and project role (including investigators, veterinary support, husbandry personnel)
Contact details – including emergency contact details
Qualifications, training experience
Additional training required

Section 14: Animals used in teaching
Preparation of students for animal use, especially consideration of ethics e.g. cost versus benefit
Extent of student supervision
Relevant experience of students
Copy of laboratory handout

Section 15: Signatures
Signatures of approval as appropriate: <ul style="list-style-type: none"> • Principal investigator • Delegated study investigators • Science reviewer • Biometrician • Animal facility manager • Head of department or equivalent
Statement that project leaders signature commits to: <ul style="list-style-type: none"> • Not commencing work until formal approval is received • Ensuring all personnel have read the protocol and are trained to carry out their roles • Adverse events will be notified to the AEC • Variations to this project will be approved by the AEC • All AEC recording and reporting requirements will be met

APPENDIX 2 – A GUIDE FOR LAY MEMBERS OF ANIMAL ETHICS COMMITTEES

1. Introduction

The use of animals in research, testing and teaching (RTT) in New Zealand is controlled by the Animal Welfare Act 1999 (the Act). Part 6 of the Act requires the establishment of Animal Ethics Committees (AEC), to weigh the merit of proposed animal use. The Act mandates four individuals who at a minimum, shall make up the AEC. Of these four, three shall be independent of the AEC's parent organisation, and are:

- A New Zealand Veterinary Association nominee
- An approved animal welfare organisation nominee
- A territorial authority or regional council nominee

The role played by these statutory external members is seen as key to the AEC remaining objective when assessing proposals.

Many of those who undertake this important role will have limited knowledge of scientific method, or the usage of animals in RTT in New Zealand. This guide is intended to provide an overview of the New Zealand system, and reassure lay members of the importance and legitimacy of their roles within AECs.

2. Legislation

Part 6 of the Act acknowledges that in the course of RTT, the welfare of animals may be compromised in ways that are unacceptable under other circumstances. Because of public interest in the welfare of experimental animals, a system has been set in place that requires closer scrutiny than for any other use of animals.

Under this system, any individual or institution wanting to use animals in RTT, shall hold or operate under a code of ethical conduct (CEC), approved by the Director-General of MPI. Further, no project can be undertaken unless it has been approved by an AEC, constituted under the CEC. Compliance with the CEC and the legislation by both the institution and its AEC is subject to independent review, at least every five years.

Note: There are two exceptions to the requirement for AEC approval of projects:

- Research, testing or teaching involving non-human hominids (gorillas, chimpanzees, bonobos, and orangutans). Any use of these animals in RTT can only be approved by the Director-General of MPI.
- Research or testing in the national interest may be approved by the Minister of Agriculture.

3. Role of AECs

The functions of the AEC as set down in the legislation are:

- Considering and making decisions on project applications including renewals, suspensions and revocations;

- Setting conditions on project approvals;
- Monitoring compliance; and
- Monitoring animal management and facilities.

When making its decisions on particular projects, the AEC is required to consider the following (refer to section 7 for more detail):

- The scientific or educational objectives;
- The likely harm and distress to the animal/s and its potential alleviation;
- A weighing of the costs and benefits in the first two considerations;
- Whether the experimental design allows the objectives to be met;
- Whether the choice of species is appropriate;
- Whether the number of animals has been appropriately justified;
- Measures to be taken to ensure the animals' general health and well-being;
- Whether the personnel involved in manipulations are suitably qualified;
- Whether the project duplicates previous work, and if so, whether the duplication is justified;
- Whether the work involves repeated use of animals, and if so, whether this is justified and managed appropriately; and
- Whether there is a commitment to use, promote or publish the results.

4. Role of Lay Members

Lay members of AECs play a key role in ensuring the appropriate use of animals in RTT, and contribute in the following ways:

Independence: Lay members shall be independent of the parent organisation. As such, they ensure the broader scrutiny that is important in maintaining the integrity of the system. Note: while independent, it is expected that institutions will recompense external members for time spent, and travel costs incurred in meeting their AEC responsibilities.

Public representation: With their various backgrounds, lay members are representative of the public. While public opinion on the use of animals in RTT varies greatly, an independent survey conducted for MAF in 2005 (Williams et al 2007) showed that a majority of the respondents (68% for research and testing; 72% for teaching) accepted the use of animals provided there was no unnecessary suffering involved. However, the survey also showed that only 21% of the respondents knew about legislation covering this area, with only about a third of those (i.e. 8% of the total respondents) knowing either "a lot" or "a fair amount" about this legislation. This means that you are representing a public that has little knowledge of the controls on the use of animals in RTT. Many lay members feel daunted by what they perceive as a lack of knowledge on their own part. This should not be regarded as a handicap. You are there to provide a broader societal input, not specific scientific knowledge.

Animal advocate: Being independent of the aims and procedures of the parent institution, lay members may more readily see issues from the animals' point of view, with a focus on improving welfare.

Fresh perspective: Familiarity with issues and procedures can obscure opportunities for improvements. The different and valuable perspective of the lay member has often been demonstrated.

5. Use of Animals in RTT in New Zealand

Institutions in New Zealand carry out a wide range of activities that require AEC approval. To determine if a procedure requires approval, some words need to be understood in their legal context. For example, “animal” has a meaning in the Act, that is narrower than in general usage. The Act defines “research, testing and teaching”, “manipulation” and “animal” in the following specific terms:

“Animal” is defined as any:

- Mammal, bird, reptile, amphibian, fish, octopus, squid, crab, lobster, crayfish; and
- Mammalian, avian or reptilian pre-hatched young in the last half of gestation or development, and marsupial pouch young.

“Research, testing and teaching” includes:

- Any work (investigative experimental diagnostic, toxicity testing or potency testing) that involves the manipulation of any animal; or
- Any work involving the manipulation of any animal to produce antisera or other biological products; or
- Any teaching that involves the manipulation of any animal.

“Manipulation” means:

interfering with the normal physiological, behavioural, or anatomical integrity of an animal by:

- Subjecting it to a procedure which is unusual or abnormal when compared with that to which animals of that type would be subjected under normal management or practice;
- Depriving an animal of usual care;
- Exposing the animal to any parasite, micro-organism, drug, chemical, biological product, radiation, electrical stimulation, or environmental condition; or
- Enforced activity, restraint, nutrition, or surgical intervention.

Animals are “manipulated” in RTT in New Zealand in the following areas:

- Medical research, for example the investigation of treatments for brain damage at the time of birth;
- Veterinary and agricultural research, for example investigations into methods of pain relief for on-farm procedures;
- Biological research including conservation research, for example investigation into the relative humaneness of poisons used in pest control;
- Education – training of doctors, veterinarians, animal technicians and nurses, university and school students, for example the teaching of methods of pregnancy diagnosis to veterinary students;
- Development of veterinary and medical drugs and vaccines, including the:
 - testing of their efficacy and safety, for example the development and testing of worming products for farm animals;
 - toxicity testing of food and household products, e.g. testing for marine biotoxins in shellfish;
 - commercial production of antisera and blood products e.g. blood agar for microbiological use.

Most AECs tend to have a particular focus although some universities for example, may cover a number of different areas.

6. The Three Rs

In 1959, in a book entitled *Principles of Humane Experimental Technique*, two scientists, William Russell and Rex Burch, introduced the concept of the “Three Rs”. This has become the fundamental principle underlining the humane use of animals in science and teaching. The “Three Rs” are replacement, reduction and refinement.

Replacement: To replace animals with a non-sentient alternative. For example:

- Use of non-sentient organisms e.g. using invertebrate animals such as earthworms for dissection instead of rats.
- Use of in-vitro techniques like tissue cultures to screen products for toxicity.
- Use of non-biological alternatives. Veterinary schools use sophisticated models for the teaching of procedures such as intubation and intravenous injections.
- The use of volunteer human subjects for drug testing.

Reduction: To reduce both the numbers of experiments, and the number of animals used within experiments, to the minimum possible. This might include:

- Ensuring that experiments are necessary in that there is no other way to find the information sought.
- Ensuring that experiments are not repeating work previously done.
- Ensuring that statistical analyses are used to reduce numbers of animals within experiments to the minimum consistent with achieving meaningful results.

Refinement: To minimise or eliminate animal suffering. This might include:

- Improving animal husbandry and environmental conditions.
- The use of anaesthesia and analgesia where appropriate.
- The use of humane endpoints.

7. Considering Proposals

a. Ensure you are familiar with the way your particular AEC operates. You should be given a copy of the CEC which will detail committee processes.

For example, you need to know whether your committee makes its decisions on a consensus or a majority basis. There should also be mechanisms in place to ensure that all members, including lay members, have opportunities to express their opinions, ask questions or air concerns. You should also be given a copy of any standard operating procedures (SOPs) your AEC uses.

b. Do not be afraid to ask questions. In order to fulfil your role on the AEC, it is essential that you ask as many questions as needed, to understand what is being proposed in terms of the research, testing or teaching. While other members of the committee may be familiar with scientific terms and procedures, they will understand that lay members may not be, and will welcome your questions.

c. What to look for. Refer to section 3 for the list questions AECs should be asking, when assessing RTT proposals. Further clarification is given below.

The scientific or educational objectives

These should be clearly stated. They should be given in plain English. You need to be able to understand the benefits of any RTT proposal, if a sound assessment is to be made.

The likely harm and distress to the animals and its potential alleviation

Information may be available from other committee members with appropriate experience, or from the AEC veterinarian (or animal technician). If this cannot be adequately determined, it is common practice for AEC members to request to observe the procedure. When procedures are expected to have a significant impact on the animals, methods to minimise pain and distress need to be considered. Also, the frequency of animal monitoring must be acceptable to the AEC members. Committee members need to be satisfied that those who will be doing the monitoring are skilled in identifying pain in the relevant animal species. Harm and distress should be considered in terms of overall impact on the animal, including both the invasiveness and duration of any procedures. Researchers should also have contingency plans in place in case of unexpected outcomes. Where appropriate, humane endpoints, and methods of euthanasia should form part of the proposal detail.

Weighing of the costs and benefits in the first two considerations

This is a balancing of the benefits of the proposal against the cost to the animals. Generally speaking, the higher the cost in terms of harm and distress to the animal, the greater the justification in terms of expected benefits.

Whether the experimental design allows the objectives to be met

The way the research is to be carried out should be both logical and practicable. If the objectives cannot be met, the animals will have been exposed to pain or distress, unnecessarily.

Whether the choice of species is appropriate

The type of animal chosen needs to be justified, including why animals need to be used at all.

Whether the number of animals has been appropriately justified

It is important that the numbers of animals used is the minimum necessary to obtain statistically valid results. Too few animals will result in wastage if results are statistically invalid.

What measures will be taken to ensure general health and well-being

It is part of the role of the AEC to monitor the institution's animal management and facilities. This means that the AEC must be satisfied that the environmental, nutritional, and behavioural needs of animals are considered.

Whether the personnel involved in manipulations are suitably qualified

Experience of personnel should be specified. If personnel are inexperienced, a system of training and monitoring should be specified.

Whether the project duplicates previous work, and if so, whether the duplication is justified

Researchers should be aware through literature searches, collegiality and journal reading as to developments in their particular field of research. While it is not always possible to ascertain duplication of work (issues such as commercial sensitivity, or failure of the research to achieve meaningful results, may preclude publication of results), researchers should be able to justify their proposed work as novel to the best of their ability.

Whether the work involves repeated use of animals, and if so, is this justified and managed appropriately

There are situations where it is appropriate to reuse animals a number of times. However, reuse of animals should be adequately justified.

Whether there is a commitment to use, promote or publish the results

In order to justify the use of animals in this way, the work being done should have some meaning that will impact on the lives of humans or animals, or ecosystems.

Resources and references

Monamy V. (1996) *Animal experimentation: a student guide to balancing the issues*. ANZCCART.

Smith, JA and Jennings, M. (2003) *A resource book for lay members of local ethical review processes*. Royal Society for the Prevention of Cruelty to Animals.

Wells, N. *Animal Law in New Zealand* Published by Thomson Reuters (Brookers Ltd, New Zealand), 2011, paperback, 988 pages, Price NZ\$ 128.00, ISBN: 978 0 86472 689

Williams VM, Dacre IT, Elliott M. (2007) Public attitudes in New Zealand towards the use of animals for research, testing and teaching purposes. *New Zealand Veterinary Journal*

<http://altweb.jhsph.edu/index.htm> - Altweb, the Alternatives to Animal Testing Web Site, was created to serve as a gateway to alternatives news, information, and resources on the Internet and beyond and is based in Johns Hopkins University in the United States of America

<http://www.nc3rs.org.uk/> - website of the National Centre for the *Replacement, Refinement and Reduction of Animals in Research* (NC3Rs)

<https://www.understandinganimalresearch.org.uk/> Understanding Animal Research is a Mutual Society (not-for-profit organisation) that explains why animals are used in medical and scientific research. We aim to achieve a broad understanding of the humane use of animals in medical, veterinary, scientific and environmental research in the UK. We are funded by our members who include universities, professional societies, industry and charities. The information provided by Understanding Animal Research is based on thorough research and understanding of the facts, historical and scientific.

<https://anzccart.org.nz/> The Australian and New Zealand Council for the Care of Animals in Research and Teaching (ANZCCART) is an independent body which was established to provide a focus for consideration of the scientific, ethical and social issues associated with the use of animals in research and teaching. ANZCCART (NZ) seeks to promote effective communication and co-operation between all parties and to assist in the resolution of potential conflicts by promoting awareness of concerns and solutions to problems in New Zealand.

<https://www.aaalac.org/resources/resource-library/> The Association for Assessment and Accreditation of Laboratory Animal Care International, or AAALAC, is a private, non-profit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs.

<https://www.mq.edu.au/research/ethics-integrity-and-policies/ethics/animal-ethics/research-animal-care-and-ethics-training-race-research-office> Compass is an animal welfare training program, which has replaced RACE. Developed in conjunction with ANZCCART

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