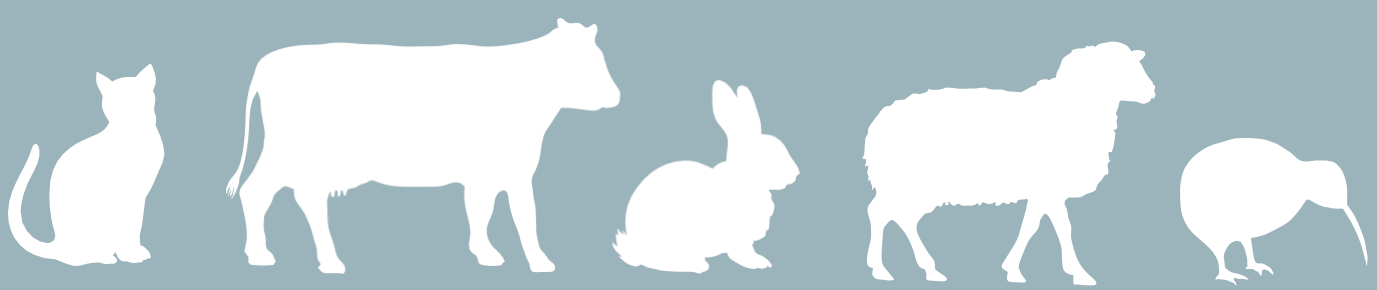
Ministry for Primary Industries
Manatū Ahu Matua

Good Practice Guide

for the use of animals in research, testing and teaching

March 2024



New Zealand Government

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Preface

The National Animal Ethics Advisory Committee acknowledges that the use of animals for research testing and teaching is contentious. The animal ethics committees who administer codes of ethical conduct are in place to ensure that societal expectations are met in relation to minimising the impact of such use on the animals. Our relationship with animals comes with high expectations that animals under human care are well looked after. Animals play an important role in our lives – they offer food and fibre, income and companionship, education, research opportunities, and entertainment. In general, these relationships are accepted, as long as they are humane.

There is an expectation that if animals are to be used for research, testing or teaching, every effort is made to:

- **Reduce** *numbers so that as few animals are used while still providing meaningful information*
- **Refine** *the way experiments are carried out in order to reduce pain or suffering as much as possible*
- **Replace** *animals with non-animal alternatives.*

When animals are kept and housed, they must be able to live and behave in a way that allows them to express natural behaviours. This guide describes accepted good practice for housing and managing animals, developing codes of ethical conduct, establishing effective process for animal ethics committees and underpinning compliance with the requirements of the Animal Welfare Act 1999.

Kei te mārama te Komiti Tohutohu Matatika Kararehe he take e tohea nuitia ana te whakamahi i te kararehe mō te rangahau me te ako. He mea whakatū ngā komiti matatika kararehe e whakahaere nei i ngā waehere matatika mā rātau e whakarite ka tutuki ngā tūmanako pāpori mō te whakaiti i te whai pānga o ngā mahi nei ki ngā kararehe.He teitei tonu ngā tūmanako tērā ka āta tiakina ngā kararehe e whakamahia ana e te tāngata. He nui te wāhi ki ngā kararehe i tō tātau oranga – ka whakawhiwhi mai i te kai, te kaka, te hua moni, te hoatanga, te mātauranga, ngā huarahi rangahau me te whakangahau hoki. Mō te nuinga, ka whakaaetia ēnei āhuatanga, mēna kāore he tūkinotanga.

Tērā te kawatau mehemea ka whakamahia ngā kararehe mō te rangahau, mō te whakamātautau, mō te ako rānei, kā āta whakapautia te kaha ki te:

- **Whakaiti** *i te nui o ngā kararehe ka whakamahia kia hua mai he mōhiohio e whai take ana*
- **Whakarite** *i te tikanga whakamātautau kia whakaitia te mamae o te kararehe ki tōna iti ka taea*
- **Whakamahi kē** *i ngā kōwhiringa kore kararehe.*

Ina ka pupuritia ngā kararehe, ka whakanōhia ki te whare kararehe, me āhei rātau kia ora, kia mahi i runga i ngā āhuatanga me ngā wheako tonu o taua momo kararehe. Ka whakamārama tēnei aratohu i ngā mahi tōtika mō te whakanoho me te whakahaere kararehe, mō te whakarite waehere mahi matatika, mō te whakarite hātepe whai take mā ngā komiti matatika kararehe, mō ngā mahi tautuku hoki i ngā āhuatanga o te Te Ture Tiaki Kararehe 1999.

Animal welfare describes what an animal experiences, how it performs, or whether it lives in keeping with its nature. Animal welfare is often a compromise between animals' needs and humans' needs and desires – it is society that determines what compromises to animal welfare are accepted as necessary and reasonable.

All people who own or manage animals have obligations to care for those animals.

Sentience is the ability to perceive or feel things. Animals have emotions, feelings, perceptions, and experiences that matter to them. These can be negative (such as pain or boredom) as well as positive (such as pleasure or comfort). Understanding that animals are sentient is integral to minimising the impact of the use of animals for scientific purposes.

We don't know whether animals' emotions, feelings, and experiences are similar to those of humans. We also don't know if they are felt with the same intensity. But they matter to individual animals and have an impact on their welfare. Animals with compromised welfare may respond in ways that in turn compromises the results of manipulations undertaken for research, testing or teaching.

This Good Practice Guide is intended to support New Zealand's robust animal welfare system that demands close scrutiny of the use of animals in research, testing and teaching and expects accountability.

Ko te tiaki kararehe ka aro ki ngā wheako a te kararehe, āna mahi, me tōna ora hoki i runga i ngā āhuatanga o taua momo kararehe. Ko te tiaki kararehe, he tauritenga ki waenga i ngā hiahia o te kararehe me ngā hiahia o te tāngata – ko te pāpori tonu ka whakarite he aha ngā tauritenga tiaki kararehe e rite ana, e tika ana.

Ka whai kawenga ngā tāngata katoa e whai kararehe ana, e whakahaere kararehe ana rānei mō te tiakitanga o aua kararehe.

Ko te rongo āhuatanga ko te āheinga ki te rongo i ngā āhuatanga o te ao. He kare ā-roto, he māramatanga, he wheako ō ngā kararehe e whai take ana ki a rātau. He āhuatanga kino ētahi (pēnei i te mamae me te takeo), he āhuatanga takatika hoki ētahi (pēnei i te koa me te hāneanea). Ko te mārama ki ngā āhua o te rongo āhuatanga o ngā kararehe tētahi wāhi nui o ngā mahi hei whakaiti i te pānga kino o te whakamahitanga i te kararehe mō ngā take pūtaiao.

Kāore tātau i te mōhio mehemea he ōrite ngā kare ā-roto me ngā wheako a ngā kararehe ki ērā o te tāngata. Kāore hoki tātau i te mōhio mehemea kei te rite tonu te kaha o te rongo. Engari he take nui tonu tēnei mō ia kararehe ka whai pānga ki tōna hauora. Mehemea kāore e pai ana te hauora o te kararehe, tērā pea ka whakamōreatia ngā hua o ngā rangahau, whakamātautau, akoranga rānei.

Ko te whāinga o tēnei Aratohu Mahi Tōtika, ko te tautoko i te pūnaha tiaki kararehe tōtōpū o Aotearoa, ko ia ka āta titiro ki ngā āhuatanga o te whakamahi i te kararehe mō te rangahau, te whakamātautau me te ako, ka whai kawatau hoki mō te takohanga.

Introduction

Animal Welfare in Aotearoa New Zealand

Animal welfare in Aotearoa New Zealand is safeguarded by the Animal Welfare Act 1999 (the Act). The Act requires those in charge of animals to provide for their physical, health, and behavioural needs as appropriate to the species, environment, and circumstances of the animal. 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; and
- protection from, and rapid diagnosis of, any significant injury or disease.

The Use of Animals in Research, Testing and Teaching

The Act specifies what constitutes the manipulation (section 3 of the Act) of an animal for the purposes of research, testing, or teaching (RTT) (section 5 of the Act). The nature of manipulation for 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 strictly governed by a separate set of provisions within Part 6 of the Act.

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

Within the constraints of any project, all reasonable steps should 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.

The 3 Rs

The 3 Rs principles in RTT provide a framework for performing more humane RTT work with animals.

The 3 Rs refer to:

- **reduction** in the numbers of animals to the minimum necessary to achieve a robust result;
- **refinement** of procedures and animal environments to minimise pain or distress; and
- **replacement** of animals with a non-sentient or non-living alternative wherever possible.

One of the purposes of Part 6 of the Act is to promote efforts to implement the 3 Rs in RTT. Additionally, animal ethics committees (AECs) are required to take the 3 Rs into consideration when considering RTT applications (section 100).

Background 1

1.1. Purpose, Scope & Intended Audience of this Guide

Purpose

This Guide provides information regarding the use of animals in research, testing, and teaching in Aotearoa New Zealand, and includes:

- promoting the humane and responsible use of animals for scientific purposes;
- guiding the highest standard of husbandry and animal care; and
- setting guidelines for what constitutes "good practice" in managing animals in the RTT environment.

Scope

This Guide covers the use of animals in research, testing, and teaching activities where animals are used in subject areas like medicine, biology, agriculture, aquaculture, veterinary, and other animal sciences, industry, field trials, product testing, and teaching.

This Guide provides general principles for the care and use of animals and specifies the responsibilities of project leads and any personnel using animals in RTT. It also provides guidelines for the humane conduct of projects, and the acquisition of animals.

Throughout this guide:

- "must" denotes a statutory requirement in the Act, a regulation, or a minimum standard in a code of welfare;
- "should" and "may" denote the National Animal Ethics Advisory Committee's (NAEAC) recommendations for best practise.

The Act, regulations and codes of welfare should be referred to for clarification of any statutory requirements.

Intended Audience

This Guide is a resource for a range of stakeholders including:

- organisations that use animals in research, testing, or teaching;
    - those that hold a code of ethical conduct, including members of their animal ethics committees;
    - organisations that have an arrangement to use another organisation's code of ethical conduct;
    - project leads preparing an application for submission to an AEC, including teachers/instructors;
- organisations that are considering developing a code of ethical conduct or arranging to use another organisation's code of ethical conduct; and
- members of the public who are interested in understanding more about the RTT system in Aotearoa New Zealand.

The National Animal Ethics Advisory Committee 2

2.1. Functions of NAEAC

The National Animal Ethics Advisory Committee (NAEAC) is established under section 62 of the Act. The functions of NAEAC outlined in section 63 of the Act are 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 codes of ethical conduct (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 animal ethics committees (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).

2.2. Membership of NAEAC

Under section 64 of the Act, NAEAC consists of no more than 10 members, including a chair appointed by the Minister. In appointing members other than the chair, the Minister must have regard to the public interest in relation to the manipulation of animals in RTT; 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.

2.3. RTT and Te Tiriti o Waitangi Obligations and Principles

Beyond the functions outlined in the Act, NAEAC is committed to upholding the principles of partnership, participation, and protection implied by Te Tiriti o Waitangi. Te Tiriti principles are relevant to the use of animals in RTT and provide general obligations and considerations to all working in RTT in Aotearoa New Zealand.

2.4. Contact NAEAC

If you have a query or feedback on this Guide please contact NAEAC via email or direct written correspondence to the address below.

Email: **NAEAC@mpi.govt.nz**

Mailing address:
The Secretary
NAEAC
PO Box 2526
Wellington 6140

2.5. Keeping Up to Date

NAEAC provides regular updates as well as opportunities for learning and development as outlined below.

- Visit the NAEAC website.
- Read the NAEAC newsletter.
- Attend a NAEAC-hosted AEC workshop.

- Also, NAEAC visits organisations that undertake RTT. 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;
    - inform AEC members about the role of NAEAC.

Site visits are made in consultation with MPI. These visits are NOT for auditing purposes. 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.

Codes of Ethical Conduct & Arrangements 3

3.1. Requirements for Undertaking RTT

Under section 82 of the Act, any person or organisation who engages in RTT and wishes to use animals for such purposes must:

- have an approved code of ethical conduct (CEC) (see following sections for recommended content and application process); or
- work for a person or organisation who holds a CEC; or
- have a formal arrangement to use another person's code under section 84 of the Act (see section 3.6 of this guide for more information regarding arrangements).

All individuals or organisations that engage in RTT must adhere to the requirements set out in the Act as well as the CEC under which they operate. This applies equally to organisations that have their own CEC as well as organisations that have an arrangement to use another organisation's CEC.

Both CECs and arrangements must be formally in place prior to commencing any RTT activities. For CECs, this requires approval by the Director-General of MPI. For organisations operating under an arrangement, this must be confirmed between the two parties and the code holder must notify MPI in writing regarding the arrangement.

3.2. Codes of Ethical Conduct (CEC)

A CEC outlines the responsibilities, policies, and procedures of the code holder, including the setup and operation of an AEC (see section 4 of this guide for more information regarding AECs).

At a minimum a CEC must 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 (and any parented organisations), must also comply with the Animal Welfare (Records and Statistics) Regulations 1999 (see section 4.4.15 of this guide for more information regarding animal use statistics).

NAEAC and MPI have developed an application pack to assist organisations when applying for a CEC. Applicants may vary the content of the CEC to suit their organisation, but should retain the order of sections, and must meet the requirements of the Act. Having a consistent internal sectional order will assist the Director-General and NAEAC to assess applications.

3.3. CEC Application Process

3.3.1. Application Submission

Under section 89 of the Act, any individual or organisation applying for a CEC must provide the following documents to the Director-General of MPI:

- a draft CEC;
- a completed application in accordance with the requirements under section 89(1) of the Act; and
- independent references and appropriate qualifications as specified in section 89(2)(b) of the Act.

An application would normally be made by a high-level person in the organisation (e.g., the chief executive, Vice-Chancellor etc) requiring a CEC. Approvals are for a maximum of five years (under section 94(1) of the Act).

If the application is for a subsequent CEC (the organisation has had a previous CEC), a report from an accredited reviewer must be submitted to MPI and NAEAC by the reviewer (see section 3.5 of this guide for more information regarding CEC reviews).

3.3.2. Application Review & Decision

The Director-General must consult with NAEAC on each CEC application (section 89(3) of the Act). The Director-General must notify the applicant of the decision within 40 working days of the application being lodged (section 92(1) of the Act). This can be extended a further 40 working days if the Director-General requires more information or needs to consult with the applicant (section 92(3) of the Act). If the Director-General does not notify the applicant of the decision within 40 days, the Director-General is deemed to have refused to approve the proposed code (section 92(2) of the Act).

The Director-General may, before deciding whether to approve, or to refuse to approve, a proposed CEC, change the contents of the code if NAEAC so recommends after consultation with the applicant (section 90 of the Act). Where the Director-General refuses to approve a proposed code of ethical conduct, the Director-General must give the applicant written notice to that effect, along with the reasons for the refusal (section 91(4) of the Act).

3.4. CEC Amendments, Suspension, or Revocation

3.4.1. Amendments

Each CEC should include a process where the AEC can recommend CEC amendments to the code holder. Section 95 of the Act sets out the requirements of applications for amendment, suspension, or revocation of a CEC. Regarding amendments to the CEC:

- Minor amendments (those that do not affect the meaning of the CEC) must be notified to MPI annually (and no later than 31 March after the year in which they were made).
- Major amendments must be approved by MPI, prior to implementation.

3.4.2. Suspension and Revocation

An individual or organisation may request the suspension or revocation of its CEC if it decides to cease manipulating animals for RTT under section 95 of the Act.

Additionally, the Director-General has the power to suspend or revoke a CEC under section 96(2) of the Act if the Director-General believes on reasonable grounds, that 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.
- has been convicted of an offence 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;
- any Act passed in substitution of the above Acts.

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

3.5. CEC Expiry and Statutory Review

After a CEC is approved for the first time, an independent review must be completed within two years and then again at five years from the date of initial approval. Then subsequent CECs from the same organisation can be approved for (a maximum of) 5 years. In order to apply for a new CEC, an independent review must be completed prior to the expiry of the current approved CEC (section 105 of the Act).

Well in advance of CEC expiry, MPI liaises directly with each organisation to ensure they understand the requirements around the statutory review of their current CEC as well as applying for a new CEC. MPI will specify exact timeframes for these steps to ensure timely review and processing ahead of the CEC expiry date. 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.

Independent reviews:

- are conducted by an MPI-accredited reviewer who is independent of the organisation and MPI;
- cover and report on compliance with the Act and the CEC (including how the AEC operates); and
- include a formal report that is provided to MPI and NAEAC.

NAEAC reviews the report and provides feedback to MPI. This includes any concerns that the committee may have regarding the content of the report. MPI takes this information into consideration when assessing whether or not an organisation has achieved a satisfactory level of compliance.

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 regarding the use of animals in RTT.

Any recommendations that the reviewer makes should be considered when an organisation is applying for a new CEC.

3.6. Arrangements to Use Another Organisation's CEC

Individuals or organisations that do not have their own CEC may arrange to use the CEC and AEC of another organisation. Allowing for such arrangements (termed 'parenting') is specified in the CEC (where some code holders allow arrangements whereas others do not).

Code holders, who permit other organisations to use their CEC, have the following responsibilities:

- The code holder must notify MPI of the arrangement in writing before any work is undertaken.
  - Notification information should include:
    - name of the individual/organisation
    - postal and physical addresses
    - contact details for a primary contact person (name, email, phone).
- The CEC must detail the policies and procedures it will implement to manage such arrangements.

- The conditions of the parenting agreement are documented in a written agreement.
- Prior to the arrangement, the code holder must ensure that members of its AEC are qualified to evaluate all projects submitted by the parented organisation.
- The code holder must provide the CEC to parented organisations as well as notification of any amendments to the CEC.
- The code holder must ensure that parented organisations fully comply with the CEC.
- The AEC should have a review process in place for all relevant standard operating procedures (SOPs) of the parented organisation.
- AEC responsibilities for monitoring and oversight (described in sections 7.1 & 7.2 of this guide) apply equally to the RTT work undertaken at parented organisations.

Parented individuals/organisations, who have a notified arrangement to use another organisation's CEC, have the following responsibilities:

- No RTT work may be undertaken until the arrangement is fully in place and notified to MPI in writing.
- The individual/organisation must comply fully with the CEC and the conditions of the parenting arrangement.
- Individual/organisation SOPs relating to RTT projects and management of animal facilities should be presented to the AEC for review.
- Animal use statistics must be reported directly to MPI unless the parenting arrangement provides for the code holder to do so on behalf of the individual/organisation (more information regarding animal use statistics can be found in sections 4.4.15 & 8.1.3 of this guide).

3.7. Contact MPI for Assistance

If you have a query relating to CECs, arrangements, or the CEC application process, please contact MPI via email or direct written correspondence to the address below.

Email: animalwelfare@mpi.govt.nz

Mailing address:

Animal Welfare

Agriculture & Investment Services

Ministry for Primary Industries

PO Box 2526

Wellington 6140

Animal Ethics Committee Function & Administration

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4.1. Animal Ethics Committee (AEC)

Any use of animals for RTT must be considered by an animal ethics committee (AEC). A code holder is permitted to set up one or more AECs to consider applications to carry out RTT. The functions and powers of the AEC are set out in section 99 of the Act.

In summary, functions of the AEC are:

- reviewing, approving, renewing, revoking RTT project applications;
- setting, varying, or revoking conditions of project approval;
- monitoring compliance with project conditions and monitoring animal facilities and management practices to ensure compliance with the CEC.
- recommending changes to the CEC to the code holder.

The AEC possesses the powers to carry out whatever is reasonably necessary for it to effectively execute its functions. These powers and functions apply to the organisation that holds the CEC as well as all organisations with which it has a parenting arrangement.

4.2. AEC Jurisdiction

4.2.1. Authority is Within Aotearoa New Zealand

AECs are constituted under the Act. This legislation has force only within Aotearoa New Zealand (which includes territorial waters). An AEC cannot consider 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 Aotearoa New Zealand jurisdiction, only animals used within this country should be reported to MPI in annual statistics (more information regarding animal use statistics can be found in sections 4.4.15 & 8.1.3 of this guide).

4.2.2. RTT Work Performed Across Organisations

Routinely, the individual wishing to undertake RTT should apply to the AEC associated with their institution. However, situations may 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 more than one AEC is established under a single CEC.

The AEC that is best placed to assess the application according to the criteria in section 100 of the Act and monitor any approval in accordance with section 99(d) and (e) of the Act should be the AEC which considers the application.

4.3. AEC Membership

4.3.1. Statutory Members

Under section 101 of the Act, each AEC must consist of at least four members (as described below).

1. The code holder, or a senior staff member of the code holder organisation, capable of evaluating the scientific value of applications.
2. A veterinarian nominated by the New Zealand Veterinary Association. This person must not be in the employment of, or otherwise associated with, the code holder.
3. A nominee of an approved animal welfare organisation. The Royal New Zealand Society for the Prevention of Cruelty to Animals is currently the only approved organisation in Aotearoa New Zealand. This person must not be in the employment of, or otherwise associated with, the code holder.
4. A lay person nominated by a territorial authority or regional council, not associated with the scientific community. Please see A Guide for Lay Members of Animal Ethics Committees for more information.

Statutory external members should be remunerated for the time spent on AEC business (e.g., preparation, travel for/attendance of meetings and training as well as other activities like monitoring visits).

4.3.2. Additional Members

Additional members may be appointed to the AEC by the code holder to bring useful expertise to the committee. These may be individuals who are full members of the committee (i.e., participate in decision-making) or they may be appointed to provide advice only (and do not participate in decision-making).

4.3.3. AEC Appointment Procedures

Statutory External Members

The background and previous employment history of any statutory external nominee should be carefully considered. Caution is advised where the public might perceive institutional, scientific, financial, or philosophical biases.

"Associated with the scientific community" is not easily defined and should be considered on a case-by-case basis. When considering statutory external nominees consider the following:

- the aim is to appoint a lay person whose views represent an unbiased member of the public;
- some understanding/knowledge of science in a general context would not necessarily mean that the person was associated with the scientific community and would be useful for understanding the complexities of RTT applications.

If you are unsure of the suitability of a potential appointee, seek advice from NAEAC (see section 2.4) or MPI (see section 3.7).

Chair/Deputy Chair

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

Term of Appointment & Reappointments

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

Vacancies

The CEC should detail how vacancies and unexpected/prolonged absences are managed. This is particularly important as vacancies have the potential to impact the meeting quorum.

Induction & Training

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 current approved applications;
- encouragement to attend NAEAC workshops.

NAEAC strongly encourages ongoing development and upskilling for AEC members. This may include attendance at workshops or conferences (e.g., NAEAC workshops, Australian & New Zealand Council for the Care of Animals in Research and Teaching (ANZCCART) conferences) and provision of other information including RTT resources developed and distributed by MPI.

4.4. AEC Meeting Procedures

4.4.1. 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.

4.4.2. Confidentiality

CECs should describe how confidentiality and protection of confidential information will be managed. This includes all AEC-related documentation (e.g., applications, reports, correspondence, adverse events, non-compliances, etc.). Confidentiality also extends to applicant and public attendance at AEC meetings (see section 4.4.12 of this guide).

4.4.3. Conflict of Interest

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. In general, they should declare any area where there is a potential conflict of interest to the AEC Chair in advance of any AEC work on a matter.

At the start of each meeting, a general declaration of any conflicts of interest (perceived or real) should be made to the AEC and recorded in the minutes. The AEC should consider and decide how to handle each conflict on a case-by-case basis.

Additional approaches, when the AEC discusses matters relating to a conflict of interest, could include:

- the conflicted member participates in discussion but not in any 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, the Deputy Chair should assume the Chair role for the duration of the matter for which a conflict has been declared.

NAEAC and MPI can provide advice on the management of conflict of interest to AECs (more information regarding conflicts of interest can be found on the Controller and Auditor-General website).

When CECs are reviewed, accredited reviewers will inspect for conflicts of interest as part of this process; therefore, AECs should adequately document conflicts of interest for this purpose.

4.4.4. Scope of AEC Meetings

AEC meetings cover a wide range of topics including but not limited to:

- Standing agenda items
    - Apologies
    - Review of minutes of the previous meeting
    - Matters arising
    - Correspondence
    - Conflict of interest
    - Confirmation of date of the next meeting
- For review
    - New applications (including linked approvals (e.g., ACVM, DOC)
    - Modifications to approved applications
    - Interim & final project reports
    - Standard operating procedures
    - Adverse events
    - Non-compliances
    - Monitoring reports
    - Complaints
    - Any other relevant matters

4.4.5. Meeting Frequency and Attendance

Meeting frequency as well as notice that is given to AEC members regarding meeting time and place should be stated in the CEC. Even if there are no new applications to consider, there will be other matters to discuss, like monitoring reports, adverse events, etc., including monitoring visits to carry out.

The CEC should also document expectations for AEC members regarding meeting attendance.

4.4.6. Circulation of Meeting Papers

The CEC should state the minimum time prior to the meeting for circulation of/access to the meeting paper pack. This should be clearly stated (e.g., two weeks prior rather than 'in advance of the meeting') and provide AEC members adequate time to assess any application or other AEC documentation.

4.4.7. Quorum

The requirements for a quorum should be clearly documented in the CEC (i.e., at least 50% +1 of the AEC and must include at least two of the statutory external members).

4.4.8. Decision-Making

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

4.4.9. Effective Input of Committee Members

All members of the AEC should be actively supported to undertake their work. As described above, 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 Aotearoa New Zealand. These outcomes are maximised when the members fully participate in the decision process. The views of statutory external members should be actively sought by the AEC chair and fully considered.

4.4.10. Online Meetings

NAEAC expects the AEC meeting format to be face-to-face but recognises that different approaches may be needed for the AEC to progress its work. As such, appropriately managed meetings can be undertaken via in-person, online or hybrid formats. Telephone conferencing is not an acceptable meeting format (more information below). For organisations that predominantly use online meetings, NAEAC recommends that at least one face-to-face meeting is included each year to maintain continuity and the relationships between AEC members.

Online meetings should adhere to the following practices:

- The process for managing this type of approach should be described in the CEC.
- All normal meeting procedures and quorum requirements must be adhered to.
- Chairs should take particular care to ensure active participation of all members.
- Cameras should be turned on, to allow better communication between members.
- Individuals should only attend meetings (face to face or online) by telephone in exceptional circumstances (i.e., when other means of attendance are not available).

Accredited reviewers will review the use of online meetings as part of their normal review process; therefore, AECs should maintain adequate records of meeting type and nature of attendance, discussion and decision making.

4.4.11. Subcommittees

The AEC may choose to use subcommittees to undertake various types of work. If subcommittees are used, the CEC should include a description of their appointment and function. When decision-making is required (e.g., consideration of a new application), the membership of a subcommittee should always include at least two external statutory members. Decisions made by a subcommittee are conditional on ratification at the next AEC meeting.

4.4.12. Meeting Attendance by Other Parties

There may be instances where other parties attend AEC meetings (e.g., applicants or members of the public). The CEC should clearly outline how attendance is managed, including how confidentiality is maintained. Applicants must not be present when a decision is being made regarding their application.

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 as outlined in the Act. In such instances the AEC should seek guidance from the code holder.

4.4.13. Consideration between Meetings

The CEC should indicate how decisions will be made between meetings. AECs may allow a subcommittee to make decisions between meetings however these are conditional on ratification at the next AEC meeting (see section 4.4.11 of this guide for more information regarding subcommittees).

NAEAC advises that consideration between meetings should only be made for projects that:

- have a legitimate requirement for urgency; and
- are for manipulations of grades A and B only (see Animal Use Statistics for additional guidance regarding manipulation grades.

The process for consideration of projects between meetings should not circumvent proper review of the application.

For consideration of modifications to an existing application, the CEC should state who will have delegated authority to make such decisions. A subcommittee review is appropriate for modifications to current applications 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).

Any subcommittee considering minor modifications to existing applications should include at least one external statutory member. Any subcommittee considering new applications or major modifications to existing applications

should always include at least two external statutory members. Any subcommittee decisions should then be ratified by the full committee.

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

4.4.14. Secretariat Support

Under section 102 of the Act, the CEC should describe how the AEC is supported with secretarial functions, including:

- role competency and responsibilities;
- organisation of meetings;
- setting the agenda; and
- recording and keeping of the minutes.

4.4.15. Record Keeping Requirements

Information Management

The CEC should outline clear processes regarding the management of all AEC documents to meet the requirements of the Act. These should include maintenance, storage, including specifying a minimum storage period, and destruction of meeting minutes, decisions, operations, and records as well as how security and access to this information is managed.

The code holder must retain the following records, including:

- CEC and any amendments;
- policies and procedures of the AEC;
- minutes of meetings;
- appointments of members;
- project applications;
- project approvals;
- project reports, amendments;
- standard operating procedure approvals;
- adverse event notifications;
- project and procedure monitoring, site visits;
- complaints log;
- and other relevant records.

Animal Use Statistics

As required by the Animal Welfare (Records & Statistics) Regulations 1999, organisations (code holders and parented organisations) that use animals in RTT must report animal use statistics each year to MPI on or before 28 February (see the Animal Use Statistics guidance document for more information). Code holders may elect to submit animal use statistics for their parented organisations. However, these must be submitted separately to the code holder's animal use statistics and only if the two parties have explicitly agreed to this arrangement.

Project Planning & AEC Application Preparation

5

5.1. Responsibilities of Teachers/Instructors

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 in RTT.

5.1.1. Aotearoa New Zealand Schools

Use of animals in all Aotearoa New Zealand schools must be covered under an approved CEC. The New Zealand Association of Science Educators holds a CEC that can provide cover for early childhood centres, kindergartens, schools (both teachers and students), and 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 CEC; it considers RTT project applications and can provide advice on when AEC approval is necessary.

The standard of care for animals that are housed at schools must meet the requirements of this guide or the relevant code of welfare for the species. This includes care for such animals over weekends and holiday periods. Students should not be allowed to take animals home unless there is a clear written agreement from a parent or guardian that the animals will be cared for adequately and responsibly.

The following resources are of particular relevance to schools who undertake RTT. Additional resources can be found in Appendix 4.

Ethical guidelines for students in laboratory classes involving the use of animals or animal tissues

Caring for Animals in the Classroom

5.1.2.Tertiary Institutions

Tertiary institutions may use animals in a variety of teaching applications. Project leads should engage with an AEC early in their planning process to ensure all preparations are in place prior to undertaking teaching with animals.

The project lead must:

- obtain AEC approval for use of all animals for the entire project period and ensure that activities are conducted as approved by the AEC;
- 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 the 3 Rs (reduction, refinement or replacement) in the use of animals, provided such methods are compatible with the educational objectives;
- 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.

5.2. Considerations for the Use of Non-Human Hominids

Section 85 of the Act outlines specific requirements for the use of non-human hominids in RTT. The requirements are summarised below.

- No person may carry out RTT using non-human hominids unless they have approval (including conditions) from the MPI Director-General.
- The Director-General may set conditions upon the approval as they see fit.
- The Director-General may revoke, replace (with another condition), or amend conditions of approval.
- The Director-General must consult with NAEAC regarding any RTT application to use non-human hominids.
- The Director-General must be satisfied that RTT is in the best interests of the non-human hominid or in the interests of the species overall.
- The Director-General must monitor approved RTT using non-human hominids.

As described above, the use of non-human hominids in RTT does not follow the regular AEC approval process that applies to all other animals. AEC approval is not a requirement under the Act; however, it may be a condition of approval, as specified by the Director-General.

For more information regarding the use of non-human hominids in RTT or to submit an application please contact MPI for assistance (see section 3.7 of this guide).

5.3. Project Planning

It is essential that project leads carefully plan their projects and ensure relevant project information is provided in an application to an AEC. The PREPARE Guidelines provide useful information regarding planning and preparation of projects. Additional information regarding outcomes for animals and animal facilities can be found in sections 8.4 & 9, respectively.

5.3.1. Project Personnel

Any person who uses animals in RTT, including project leads and all project personnel, has an obligation to treat the animals humanely and to consider their welfare while undertaking projects (see A Culture of Care).

Project leads have direct and ultimate responsibility for all matters related to the welfare of the animals under their projects, including general husbandry and housing as well as project manipulations. This begins when animals are allocated to the approved project and ends at the conclusion specified in the application (e.g., euthanasia, rehoming).

Project leads are also 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. Any application to the AEC must clearly outline information for project personnel including their qualifications, skills and any training that is still required.

5.3.2. Consultation with Technical Experts

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

5.3.3. Development of Standard Operating Procedures by the Organisation

Organisations that undertake RTT should develop standard operating procedures. These may be included/referenced in an AEC application. As such, the organisation should have an internal process in place for developing and reviewing SOPs. SOPs should always be available to relevant staff at the organisation.

5.3.4. Animal Species

General Information

Project leads should 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, project leads must 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 project 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.

Use of Taonga Species

Where any proposed RTT work involves (or may involve) taonga species, the applicant should discuss these aspects with local iwi or hapū. 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.

5.3.5. Transportation

Transportation can cause distress due to confinement, movement, noise and changes in the environment and personnel. The extent of any distress will depend on various aspects related to the animal and the journey. These include animal health, temperament, species, age, sex, the number of animals travelling together and their social relationships. It also includes 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.

Animals must be transported in accordance with the Code of Welfare: Transport in New Zealand. Other species-specific codes of welfare also contain information relating to the transport of animals. These can be found on the MPI website.

5.3.6. Avoiding Duplication of Animal RTT

Projects involving animals are sometimes repeated by the same or other research groups. In considering whether the repetition is justified, it is essential to distinguish between 'replication', 'repetition', and 'duplication'. (see Avoiding Duplication of Research Involving Animals).

Replication refers to the repeating of projects to increase the reliability (by replication within projects) and generality (by replication of entire projects) of the findings. Replication is a fundamental component of the scientific method. The required degree of replication will depend on the level of scientific precision that is needed, natural variation in the variables, and the range of circumstances in which the findings will be applied. The level of replication that is needed to achieve the desired statistical precision can be predicted by power analyses of 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 novelty, uncertainty, or both. Therefore, repetition is necessary to ensure that products are fit for purpose (i.e., both efficacious and acceptably safe).

Duplication of projects, where neither replication nor repetition are being carried out, is pointless. If the outcomes are predictable from previous experiments, such duplication is unacceptable because animal use is unnecessary. However, it could occur when a project lead, and those scrutinising their proposed project, 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.

Section 100 of 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'.
- AECs need to avoid approving projects that involve 'duplication' unless previous projects were flawed.
- AECs should ask project leads to provide evidence in their application regarding the efforts they have made to avoid duplication of past projects. Evidence could include the literature and patent database searches including keywords and reference to previous searches.
- Project leads should consider the likelihood that the project is currently being undertaken elsewhere, and if so, to make every effort to ensure they are not duplicating such projects.
- Project leads should follow the PREPARE Guidelines when developing project applications and the ARRIVE Guidelines when reporting the results of *in vivo* RTT.

5.4. Important Considerations regarding Pain & Distress

The following sections include information regarding considerations around pain and distress that apply to all projects. Information regarding specific manipulations can be found in Appendix 2.

5.4.1. Limiting Pain and Distress

Appropriate procedures to minimise pain and distress and to promote the welfare of the animals should be provided during/after projects.

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

The project lead should anticipate potential adverse events of a manipulation and take all possible steps to avoid or minimise pain and distress. These things should be clearly accounted for in the application to the AEC.

These steps should include:

- choosing the most appropriate and humane methods for manipulations;
- ensuring that all persons involved in animal use or care are competent and have appropriate technical skills;
- using pre-emptive analgesia when pain is anticipated;
- ensuring that animals are appropriately monitored to allow prompt alleviation of pain or distress;
- developing a plan to manage any adverse events, this may include:
    - increased monitoring frequency;
    - consultation with a veterinarian;
    - administration of appropriate medication;
    - using anaesthetic, analgesic and tranquillising agents appropriate to the species;
    - removal from the project or humane euthanasia;
- developing study endpoints that minimise pain and distress;
- conducting projects over the shortest time practicable; and

- using appropriate methods of euthanasia.

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

Distress can sometimes be avoided or minimised by non-pharmacological means. Before a project begins, animals should be appropriately conditioned to the environment, procedures, and animal care personnel.

5.4.2. Duration of Projects

Project duration should be the minimum necessary to address the project questions/objectives.

Projects that involve any pain or distress should be as brief as practicable. The continued long-term use of individual animals must be approved by the AEC.

5.4.3. Animal Outcomes & Study Endpoints

All project applications should clearly specify ultimate outcomes for the animals and study endpoints. Outcomes may include animals being retained by the institution, rehomed, or euthanised (see section 8.4 of this guide for more information).

Study endpoints are used to judge when an animal should be removed from a project or euthanised in order to ensure animal welfare.

Death as an endpoint is generally unacceptable and should be fully justified in the project application. All animals found in a moribund state should be euthanised unless specifically approved by the AEC. Endpoints earlier than the moribund condition should be used. Unexpected deaths should be reported as adverse events to the AEC and included in end of project reporting (see sections 8.3.2 and 8.1.2 for more information regarding adverse events and end of project reporting, respectively).

Animals should be euthanised 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); or
- they self-mutilate; or
- they have a condition (e.g., an abscess) where pain and suffering cannot be alleviated through veterinary care (unless specifically approved by the AEC).

5.4.4. Repeated Use of Animals (Re-use)

Individual animals should not be used more than once, either in the same or different projects, without the express approval of the AEC. However, there are instances where re-use of animals may be appropriate (and reduce the total number of animals that are used).

Project leads should carefully consider the benefits of reusing animals against any potential adverse effects. They should include information in their application to account for:

- the pain or distress and any potential long-term or cumulative effects caused by any previous manipulations (including recovery time);
- the pain or distress likely to be caused by foreseeable future manipulations; and
- the total time across all projects.

5.4.5. Handling & Restraining Animals

Animals should only be handled by those who are competent with the project methods to minimise pain, injury, or distress. Specific information regarding skills and competency of all project personnel should be provided in the application to the AEC.

When the use of restraint devices is necessary they should be appropriate to the animal, well-maintained, and used to the minimum extent and time period. Where appropriate animals should be trained with the restraint prior to the start of the trial. This is important for both the welfare of the animal and the safety of the handler.

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

Periods of prolonged restraint or confinement should be avoided. However, where prolonged restraint is proposed (e.g., housing livestock in metabolism cages), the applicant should describe how the biological and behavioural needs of the animal will be met. Such animals should be assessed regularly by a veterinarian or other qualified person not otherwise involved in the project. If any negative impact is detected, the animal should be removed from the restraint, or the method modified to minimise the impact.

5.4.6. Pre-Operative Preparation

Surgical success can be improved by careful attention to pre-operative preparation including the following:

- Animals that are fit for purpose will ensure more reliable research data. Project leads should consult the institutional veterinarian or other qualified person to assist in obtaining such animals.
- Pre-operative physical examination can often identify potential problems (e.g., 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 some species to minimise complications of anaesthetic administration.
- Practice on cadavers enables familiarisation with anatomical landmarks and can streamline surgical procedures (i.e., reduce the amount of anaesthetic, reduce surgery time, and minimise tissue damage).
- All surgical procedures should have a pain management plan for prevention or alleviation of pain that is appropriate for the procedures and the animal species.

5.4.7. Surgical Procedures

General Information

Information regarding pre-operative preparation, surgical procedures and post-operative care should be clearly outlined in the application to the AEC.

Anaesthesia and surgery should be performed by competent personnel with appropriate training and experience. Training should only be given by competent persons 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 (e.g., hypothermia, and cardiovascular/respiratory depression).

Anaesthetic, analgesic, and tranquillising agents should be suitable for the species and appropriate for the purpose of the project. The use of such agents should mirror what is used in current medical, laboratory animal or veterinary practice.

Aseptic Technique

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.

Anaesthetic Trials

Project leads 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 welfare in subsequent study animals.

Multiple Surgeries

When an animal will undergo more than one surgical procedure, it should recover between each procedure. Every effort should be made to reduce the total number of procedures on one animal.

Non-Survival Surgery

Non-survival surgeries should be undertaken using the same procedures as those for animals that will regain consciousness (i.e., pre-operative preparation and pain relief). Animals should be unconscious for the whole procedure, with euthanasia either by overdose of the general anaesthetic or by inducing brain death (e.g., exsanguination or disruption of the thorax).

5.4.8. Post-Operative Care

Animals should be provided with appropriate post-operative care to ensure prompt recovery. This should include care regarding warmth, hygiene, fluids and food intake, and control of infection. Pain relief is critical, and 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.

Project leads should ensure that animals are adequately monitored, and accurate records are kept. The duties of all personnel should be clearly defined in the application to the AEC (including how emergencies will be managed).

5.4.9. Modifying Animal Behaviour

Procedures used to modify animal behaviour depend on motivation of the animal. The preferred method is positive reinforcement, but in some projects biological stress may be part of what is being studied. 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 distressing stimuli should be minimised and escape from the stimuli should be available. All procedures should be clearly described in the application to the AEC.

5.4.10. Withholding Food or Water

Projects involving the withholding of food or water should not lead to detrimental effect on the animals. In these projects, the fluid balance and/or body weight must be monitored, recorded, and maintained as indicated in the application to the AEC.

5.5. Project Proposal Review by the Organisation

When project planning is completed, the project lead should recheck the project proposal to ensure that the 3 Rs as well as the following points have been considered.

- Do the potential benefits outweigh any ethical concerns regarding the impact on animal welfare?
- Can the aims be achieved without using animals (replacement)?
- Are there different ways (with less impact to animal welfare) of achieving the same aims (refinement)?
- Are suitable holding facilities, equipment, and competent personnel available (refinement)?
- Have all relevant personnel been informed of the planned husbandry and project procedures?
- Has the most appropriate animal species been selected?
- Is the biological status (genetic, nutritional, microbiological, general health) of the animals appropriate?
- Are the environmental conditions (e.g., photoperiod/temperature/density) appropriate (refinement)?
- Can valid results be obtained using the minimum number of animals (reduction)?

- If the potential impact on the animal is unknown, is it appropriate to incorporate a pilot study (refinement)?
- What will be done to minimise or avoid pain and distress (refinement)?
- What arrangements will be made to monitor the animals (refinement)?
- If projects have been completed previously, 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, to avoid unnecessary duplication?
- If animals are used repeatedly, what will be done to minimise the cumulative effects of re-use (refinement)?
- Are there required permits for the importation, capture, use, destruction, or release of the animals?
- What arrangements have been made for the fate of all animals at the completion of the project?

5.6. AEC Application Preparation

Applications to the AEC should be submitted on a standard form to ensure all relevant information is included. This will allow the AEC to maintain consistency in its consideration of the criteria specified in section 100 of the Act (see Appendix 3 for an example of the criteria NAEAC considers central for AECs when considering applications). Considering the wide range of RTT activities across Aotearoa New Zealand, NAEAC acknowledges that AEC standardised application forms may differ. AECs may also elect to include questions to query if applicants have submitted their application to another AEC including their decision regarding the application.

All AEC applications should include the following information:

- background, aim and significance of the project;
- justification for the use of animals;
- information regarding the consideration and incorporation of the 3 Rs;
- the names, roles, and qualifications of the key personnel;
- the numbers, types, and life-stages of animals to be used;
- the procedures that will occur;
- the impact on the animals;
- what will be done to mitigate the impact;
- the fate of the animals which demonstrates that the project will comply with the Act.

If AEC approval is granted, project leads must comply with all conditions of approval imposed by the AEC. These may include:

- supervision of all aspects of the project (including project personnel) to ensure good animal welfare standards are met;
- compliance with all conditions imposed by the AEC;
- documentation of the numbers of animals used, and the actual impact grading they experienced;
- alerting the AEC to any adverse events;
- informing the AEC when the project is completed or discontinued; and
- providing a written report to the AEC at the conclusion of the project.

Animal Ethics Committee Consideration of Applications 6

6.1. Applications to the AEC

No RTT work may be undertaken until project applications have been reviewed and approved by an AEC.

6.1.1. Consideration of RTT Applications

Purposes of Part 6 of the Act

AECs must consider the overall purposes of Part 6 of the Act (section 80 of the Act) regarding animals used in RTT when reviewing applications.

Section 80 stipulates that for any animals used in RTT:

- There is good reason to believe the benefits outweigh the likely harm to those animals.
- The physical, health, and behavioural needs of animals are met in accordance with both good practice and scientific knowledge.
- Treatments are provided that alleviate any unreasonable or unnecessary pain and distress.
- Efforts relating to the 3Rs are promoted to:
    - **reduce** the number of animals used in research, testing, and teaching;
    - **refine** RTT techniques so that the harm is minimised, and the benefits are maximised;
    - **replace** the use of animals using appropriate alternatives.

The CEC should contain policies and procedures to ensure that relevant criteria are considered both by project applicants when writing applications and by the AEC in evaluating applications. This information forms the basis for assessing likely benefit/harm of the work.

Criteria for Consideration

Section 100 of the Act (given below) specifies criteria that AECs must have regard to in considering any application for approval of a project and in setting, varying, or revoking conditions of approval. These criteria are, as written in Section 100 of the Act:

- the purposes of this Part [being Part 6 of the Act], but the committee need not have regard to the purpose stated in section 80(1)(b) for any part of the project that involves manipulation to which section 3(1A) applies; and
- 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)[1]; 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

[1] 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 (Section 3(1A)). When an AEC considers approving a RTT project that involves manipulation to which section 3(1A) applies, the committee must be satisfied that every animal that will be subject to that manipulation will be killed in such a manner that the animal does not suffer unreasonable or unnecessary pain or distress.

- the factors that have been considered 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.

Compliance with Other Legislation

Some types of RTT require additional approvals to comply with other pieces of legislation. As such, AECs should be provided with evidence that, for any activity which must be approved by a regulatory authority, such approval has been obtained.

This includes, where appropriate:

- Animal Welfare (Care and Procedures) Regulations 2018;
- Agricultural Compounds and Veterinary Medicines (ACVM) and Environmental Protection Agency (EPA) approvals;
- Department of Conservation approvals;
- 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.

Compassion Fatigue

AECs should also consider the potential that RTT work may cause compassion fatigue in animal care personnel, project leads, and students. This is a serious consideration and may also impact on the welfare of the animals under their care. The 3 Rs Collaborative has developed a useful resource regarding this topic.

6.1.2. Impact Grading

The CEC should describe how the AEC will assess impact grading of proposed RTT. AECs should reference the MPI resource, Animal Use Statistics, for guidance regarding impact grading.

6.1.3. Outcomes of Consideration

The CEC should clearly state the possible outcomes when reviewing RTT applications. This should also include specifications around when RTT can commence and how this is communicated to applicants.

These are commonly:

- approved;

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

6.1.4. Conditions of Approval

The AEC may set conditions of approval and may vary or revoke such conditions (section 99(1)(c) of the Act). Such conditions may include:

- the time period for which approval is granted;
- requirements for reporting to the AEC;
- monitoring requirements (see the following NAEAC Occasional Papers and sections 7.1, 7.2 and 8.3 of this guide for more information related to monitoring)
    - No. 4: Compliance monitoring: The University of Auckland approach
    - No. 5: Monitoring methods for animal ethics committees.

6.1.5. Maximum Approval Period

The CEC should provide specific guidelines regarding maximum approval periods for RTT work.

- Set the maximum approval periods for all types of AEC approvals (often 3 years).
- Clarify that extensions for current approvals are not permitted beyond the maximum period for that type of approval. If a project extends beyond the approval period, a new application must be submitted.

6.1.6. 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 (section 99(1)(g) of the Act). The CEC should specify how these decisions will be made and how these processes are managed.

6.2. Modifications to Approved Applications

The CEC should state how modifications to approved applications are managed (see Table 1). NAEAC recommends a proportionate approach, depending on the expected impact of the modification. Please note examples may vary between organisations.

Table 1: Example Modifications

Type	*Scope*	*Example Modifications*	*Example Actions*
Minor	Does not change the impact grade Does not fundamentally change the study	Change in timing of manipulations (no impact) Change in monitoring personnel Change in numbers <10% Change in location of activity Change in trained personnel carrying out manipulations	Notify the AEC within 2 business days and include in the final report submitted to the AEC

Major	Has potential to impact the outcome of the study Increases the impact grading	Change in species Change to numbers > 10% Change to manipulation timing Change to test or control material Change in project lead Change in the number of groups Changes to study plan or design	AEC approval required prior to implementation

Use of a standardised form can aid in consistency when considering proposed modifications.

Accredited reviewers will review approved modifications and the associated process as part of their normal review process; therefore, AECs should keep adequate records for this purpose.

6.2.1. Standard Operating Procedures Considered by the AEC

NAEAC recommends that individuals/organisations that undertake RTT use Standard Operating Procedures (SOPs) to ensure consistency across projects. SOPs may cover procedures for the care and use of animals, training of staff, standard RTT manipulations (e.g., behavioural testing), as well as the management of animal facilities. The AEC should have a review process in place for SOPs (including periodic review).

Animal Ethics Committee Post-Approval Responsibilities 7

7.1. Project Monitoring

Under in section 99(1)(d) and (e) of the Act, AECs are required to monitor approved projects as well as animal management practices and facilities. This includes projects approved for parented organisations.

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

7.1.1. Monitoring during the Approval Period

Monitoring may include the following activities:

- Observations at unscheduled times (i.e., not pre-scheduled for compliance monitoring). This could be conducted by any member of the AEC who happens to be visiting RTT animal facilities and observes animal practices as an unintended consequence of their primary activity. This type of visit may include, but is not limited to:
    - a visit to an RTT animal facility by an AEC member in their capacity as project lead or project personnel undertaking their own manipulations;
    - an animal facilities AEC member during their regular management activities;
    - the Animal Welfare Officer (AWO), as a member of the AEC, during a scheduled training session. Veterinary visits and facility checks may also provide opportunities for the AWO to monitor RTT activities. Please note that if an AWO is not a member of the AEC any monitoring they do would be considered proxy monitoring (see section 7.1.2).
- A structured post-approval review of project procedures. This should include conditions set by the AEC at the time of approval. This aspect of post-approval review focuses more on individual procedures rather than review of the whole project. It ensures that new procedures have been set up properly and that personnel are trained appropriately.
- Reviews of projects where:
    - numbers of animals for which approval is given are large;
    - a project lead or project personnel have 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 (see section 7.3 of this guide for more information regarding compliance procedures).

7.1.2. Monitoring by Proxy

On occasion the AEC may nominate another person to undertake some monitoring activities on their behalf; this is considered proxy monitoring. The CEC should outline how proxy monitoring is managed including how individuals are selected/appointed as well as how monitoring visits are documented and reported back to the AEC.

7.1.3. Monitoring across Impact Grades

NAEAC expects that annually the AEC will actively monitor:

- at least 10% of approved projects graded A and B; and
- 100% of projects graded C-E.

7.1.4. Monitoring Specific Manipulations

The AEC may require additional monitoring for specific manipulations. This could include procedures that are high impact or new. The CEC should outline the process for monitoring specific manipulations.

7.2. Monitoring Animal Facilities

Under section 99(1)(d) and (e) of the Act, a key function of the AEC is to monitor animal management practices and facilities to ensure compliance with the CEC. This also applies to any facilities operated by parented organisations. All visits should be documented using a standardised form or checklist.

Organisations should develop SOPs for their animal facilities as described in section 5.3.1 of this guide.

Accredited reviewers will review monitoring of animal facilities as part of their normal review process; therefore, AECs should keep adequate records for this purpose.

7.2.1. Scheduled Visits

AEC members should visit each animal facility every year. These visits should have a clear purpose and scope. They may include inspection of a specific aspect of animal husbandry practice, the adequacy of a particular facility, or be used to do an assessment of all practices and facilities. Comprehensive assessments may be most useful midway between scheduled statutory reviews. A checklist should be used.

7.2.2. Non-Scheduled Visits

Experience shows that a collaborative approach between the AEC and facility staff is key to genuine transparency in the care and use of animals. Non-scheduled monitoring visits should be considered where an AEC holds unresolved concerns regarding adherence to agreed husbandry or facility SOPs.

7.2.3. Animal Welfare Liaison

AECs often work closely with animal welfare liaisons (this may include AWOs, veterinarians, or animal technicians from the organisation). These individuals can provide a direct means for the AEC to monitor the day-to-day operation of animal facilities. This enables the AEC to gain insight into the culture, commitment, capability, and effectiveness of the staff responsible for animal welfare. These individuals may be appointed to the AEC (and participate in decision-making), or they may serve in an advisory capacity only.

7.3. Compliance Breaches

7.3.1. Identifying Non-Compliances

Compliance breaches or non-compliances may be omissions or deviations against:

- The Act, regulations, or minimum standards in codes of welfare;
- The CEC;
- An AEC approval;
- SOPs named in an approval.

Non-compliances may be minor, major, or critical depending on their severity and circumstances (Table 2). It should be noted that multiple minor non-compliances may sum to a major non-compliance and multiple major non-compliances may sum to a critical non-compliance.

Table 2: Non-Compliances Guidelines

Type	*Description*
Minor	A deviation or omission which is unlikely to materially reduce the ability to meet acceptable requirements

Major	Significant deviation or omission from a specification or standard where maintenance of requirements is inhibited without constituting an overall failure
Critical	Severe deviation, omission or failure from a specification or standard with a direct and adverse effect on meeting requirements

7.3.2. Managing Non-Compliances

The code holder must ensure that there are procedures in place (including documentation in the CEC) to deal with any type of non-compliance promptly. Procedures should cover:

- how to report non-compliances (including timelines for reporting);
- how non-compliances will be handled and investigated (including timelines for investigation and response) as well as recording of actions;
- a pathway to escalate serious non-compliances to the regulator (MPI).

When managing non-compliances, actions to address any animal welfare concerns should be undertaken first. Then any procedural and personnel matters can be addressed with an aim to improve the overall process and decrease the likelihood that similar non-compliances reoccur. Major or critical cases of non-compliance should be addressed by disciplinary procedures, as determined by the organisation's senior leadership team in conjunction with the AEC.

More information regarding AEC members reporting code holder or AEC non-compliance can be found in section 103 of the Act.

7.4. Complaints Procedures

The code holder must ensure that there are procedures in place (including documentation in the CEC) to deal with both animal welfare and procedural complaints promptly.

Procedures should cover:

- how to express concern over conduct of work;
- how to report complaints (including timelines for reporting);
- how complaints will be handled and investigated;
- pathway to escalate to the code holder where appropriate.

7.4.1. Animal Welfare Complaints

The CEC should specifically outline management procedures relating to animal welfare complaints received from the following parties:

- Members of the public;
- Employees (this includes employees of any organisation with a parenting arrangement);
- Members of the AEC.

7.4.2. Procedural Complaints

The CEC should specifically outline management procedures relating to procedural complaints received from the following parties:

- Applicants;
- Members of the AEC.

This should also include information regarding the management of complaints made against the Chair, Deputy Chair or Administrator.

Responsibilities of Organisations/Individuals with AEC Approved Applications 8

8.1. Project Reports

8.1.1. Interim Reports

Where projects run over a number of years, the project lead should submit an annual interim report to the AEC. The AEC may also request interim reports during a project. Interim reports may include the following:

- the aims and expected benefits of the project;
- the number of animals of each species that were approved;
- the expected impact grading across manipulations;
- any variations to the original project (as approved by the AEC);
- any deviations, non-compliances, or adverse events that occurred;
- the number of animals that have been used and the impact grade they experienced; and
- the current status of the project (this may include preliminary results).

8.1.2.Final Reports

At the conclusion of each project a final report should be submitted to the AEC (typically within 3 months). Final reports may include the following:

- the aims and expected benefits of the project;
- the number of animals that were used (compared to the number specified in the application);
- the impact grading that animals experienced (compared to what was specified in the application);
- any variations to the original project (as approved by the AEC);
- any amendments, non-compliances, or adverse events that occurred;
- the final results;
- if any further work is being considered.

Organisations should consider adopting the ARRIVE guidelines for improved RTT reporting.

8.1.3.End of Approval Grading & Animal Use Statistics

As part of the final report, project leads are responsible for providing end of approval grading (as this may differ from the impact grades specified in the application to the AEC). They are also responsible for reporting animal use statistics for completed projects to MPI by February 28th for the previous calendar year (under the Animal Welfare (Records & Statistics) Regulations 1999).

8.2. Organisation Management Systems

8.2.1.Records Management

Project leads must accurately document the conduct and outcomes of each project. This should include:

- applications;
- AEC approvals;
- number of animals that are used, all manipulations that are undertaken and actual impact grade;
- details of animal husbandry routines and environmental conditions;
- modifications that were approved during the project;
- non-compliances;
- adverse events;
- staff training records;
- veterinary consultation and treatment; and

- project results.

8.2.2. Emergency Management

Every organisation should have a documented emergency management plan to cover emergencies such as flooding and fire, or the breakdown of lighting, heating, cooling, or ventilation systems, as well as critical staff shortages. This should be referenced in the organisation's CEC. The plan should include:

- appropriate contingency arrangements for the care and welfare of animals (including considerations for special classes of animals (e.g., genetically modified));
- provision for emergency euthanasia of animals;
- staff training so they can effectively carry out the plan.

8.3. Monitoring by the Organisation during the Project

Animals should be monitored at least daily to assess their health and welfare. Monitoring is also beneficial to ensure project data or teaching demonstrations are not compromised and may help to avoid costly and disruptive disease outbreaks.

Project leads should ensure arrangements are made for contacting key personnel in the event of emergencies. Any adverse effects that impact on animal welfare must be reported to the AEC (see section 8.3.2 of this guide for more information regarding adverse events).

Project personnel should be familiar with normal behaviour and knowledgeable of signs of pain or distress specific to each animal species.

8.3.1. Sick and Injured Animals

Monitoring provides an opportunity to identify deviations from normal behavioural patterns which can indicate 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 also be monitored appropriately for clinical signs of pain or distress. These include but are not limited to the following:

- abnormal stance or movements;
- abnormal sounds;
- abnormal appearance (e.g., changes to coat);
- altered cardiovascular and/or respiratory function;
- abnormal appetite;
- rapid decline in body weight;
- altered body temperature; and/or
- vomiting and abnormal defecation or urination.

Animal welfare monitoring sheets should be used to record observations regarding the information listed above. If animals develop signs of severe pain or distress, they should be provided with appropriate treatment immediately or euthanised. Alleviation of such pain or distress takes precedence over continuing/finishing the project. If in doubt, project leads should seek a veterinary opinion.

8.3.2. Adverse Events

Adverse events are unanticipated or atypical incidents that occur to an animal as a result of:

- experimental manipulation; and/or
- animal husbandry failures; and/or

- disease.

Importantly, this does not include expected adverse events that have been anticipated and where mitigations have been included in the application to the AEC.

Where adverse events or outcomes occur during RTT, rapid reporting is essential, to minimise negative animal welfare impacts. Project leads should consult with veterinarians whenever adverse effects occur to ensure that appropriate veterinary care and treatment regimens are immediately implemented. Unexpected deaths during a project should be investigated by a veterinarian/other qualified person to determine the cause and initiate remedial action. The AEC should also be notified. Additionally, project leads should readily engage with the AEC when adverse events occur. Each AEC will have a set process for managing adverse events that includes:

- clear thresholds when reporting of an adverse event is required;
- processes for recording, including who to report to and the timeline for reporting;
- AEC actions and timelines (which may vary depending on the severity of the adverse event).

8.3.3. Non-Compliance

Every organisation should have procedures in place to manage any non-compliances that are identified during monitoring or reported during projects. These processes should be outlined in the organisation's CEC and made available to relevant personnel. Non-compliances should be reported to the AEC even if they are resolved internally between staff.

8.4. Outcomes for Animals at the End of the Project

Upon completion of the project, animals may be returned to normal husbandry conditions, returned to their natural habitat (if permitted), rehomed or euthanised.

8.4.1. Rehoming

Opportunities to rehome animals should be considered wherever possible. Rehoming should be the preferred choice if the animal is suitable for rehoming (i.e., it can be introduced to a new environment with little/no impact on its welfare).

8.4.2. Euthanasia

In some circumstances, euthanasia is the most appropriate outcome for animals that have been used in RTT. The euthanasia method should:

- minimise pain or distress and produce rapid loss of consciousness until death occurs;
- be compatible with the purpose and aims of the project;
- be appropriate to the species, age, developmental stage, and health of the animal;
- require minimum restraint of the animal; and
- be reliable, reproducible, and irreversible;

Animals should be euthanised in a quiet, clean environment away from other animals. Death should be established before disposal of the carcass or foetuses/embryos/fertilised eggs. Dependent offspring of animals to be euthanised should be cared for or euthanised.

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

8.4.3. Necropsy

A necropsy should be performed when animals die unexpectedly (see section 8.3.2 of this guide regarding adverse events) or are euthanised due to unforeseen complications. The necropsy should be carried out by

a person with appropriate qualifications. Project leads should consider the value of a necropsy 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.

8.4.4. Tissue Sharing

Tissue from an animal killed for another purpose can be used for unrelated RTT activities without seeking AEC approval. For instance:

- Animal tissues from an abattoir can be obtained and used without the need for AEC approval.
- Spare tissues from an animal killed under an AEC approval can be obtained and used without the need for an additional AEC approval.

Wherever practicable, tissue samples from animals that have died or been euthanised should be made available to other investigators (e.g., through a tissue bank).

8.4.5. Disposal of Animal Carcasses and Waste

Project leads are responsible for the 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.

Animal Facilities 9

Facilities include the buildings, enclosures, cages, tanks, aquaria, yards, or paddocks where animals are kept. Project leads, AECs, and the institutions should ensure that facilities are appropriate to protect the health and welfare of the animals.

9.1. Facility Personnel

9.1.1. Facility Manager

RTT animal facilities should be supervised by persons with appropriate veterinary or animal care qualifications or experience with the species that are housed there.

The facility manager should:

- 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 project leads, teachers/instructors, and facility personnel;
- communicate with the AEC on facility management and any adverse events;
- participate in the ongoing development of standard operating procedures (see section 9.2);
- ensure the welfare and health of all animals is regularly assessed;
- ensure that veterinary care is available at all times for all animals at the facility;
- have knowledge of pain, distress, and illness specific to the species housed at the facility;
- ensure that all ill or injured animals are treated promptly;
- investigate the cause of all adverse events including when animals die unexpectedly;
- ensure health and safety procedures are followed (e.g., PPE, reduce risk of zoonotic disease, etc.);
- enforce high standards of personal hygiene and ensure staff do not eat/drink/smoke in animal areas;
- establish an effective cleaning/sanitation schedule for housed animals;
- ensure that the equipment and facility is clean and well maintained; and
- keep adequate records of:
    - the source, transport, and use of animals at the facility;
    - identification of animals, where this is part of normal care (e.g., livestock);
    - health status, genetic constitution, and the physical environment of animals;
    - fate or disposal details of all animals;
    - fertility, fecundity, morbidity, and mortality in animal breeding groups;
    - routine disease screening results;
    - diseases identified and treatment provided; and
    - routine preventative health treatments.

9.1.2.Other Facility Personnel

Having sufficient numbers of well-trained, committed staff is key to achieving high standards of animal care. Organisations should encourage and promote formal training in animal science or technology.

Personnel employed to care for the animals should:

- be trained in the care and maintenance of those animals;
- understand how their actions will affect the animals' welfare 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 documented training; and
- have regular health checks and immunisations where appropriate.

9.2. Facility Procedures

9.2.1. Standard Operating Procedures (SOPs)

The organisation should develop SOPs to enable consistent performance of routine tasks. SOPs should be submitted to the AEC for review; they should also be reviewed regularly and resubmitted if amended.

Facility SOPs should cover:

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

MPI Codes of Welfare detail species- or situation-specific minimum standards and recommended best practice and should be followed unless deviations from standard care or alternative procedures have been approved by the AEC.

9.2.2. Routine Husbandry Procedures

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. Routine husbandry procedures should meet relevant Codes of Welfare and be performed by competent personnel.

When there are special breeding requirements for a project (e.g., creation of a genetically modified animal), these procedures are considered a manipulation and must be included in the application to the AEC.

Modifications to normal procedure as part of a project must receive prior AEC approval (see section 6.1.7 of this guide regarding modifications to approved applications).

9.2.3. Identification of Animals

The method of identification should be reliable, appropriate for the species, and cause minimal stress. Less invasive methods should be chosen when suitable. Invasive identification procedures should be performed or closely supervised by an experienced practitioner and under appropriate anaesthesia/analgesia.

Identification methods can include:

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

9.3. Acquisition of Animals

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

If RTT animal use requires authorisation from other organisations (e.g., Department of Conservation), the animals should not be transported or held before such authorisation is granted.

9.3.1. Animals Collected from Natural Habitats

Legal Requirements

Many endemic animal species are protected by law. The Department of Conservation must be consulted when these species are used. Permits are usually necessary to collect, keep, release, or kill protected species, and additional permits are usually required to import or export these species. Any conditions imposed on permits must be observed.

Endangered species should not be used unless the project 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 only be taken from natural habitats if animals bred in captivity are not available or are unsuitable for the specific purpose of the project.

Exclusions & Considerations regarding Capture and Restraint

The definition of a manipulation specifically excludes (in section 3(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. Regardless, capture, and restraint can be very stressful. Distress felt by animals will vary depending on the species, physiological state, and experience of contact with humans. Strategies should be employed to minimise pain and distress during capture including:

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

Use of Live Traps

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

- traps must 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; and
- at each inspection any living animal must be removed.

At each inspection any living animals must be handled according to the requirements set out in section 36 of the Act.

Special Considerations for Fish

Fish that experience cumulative stressful events may be more likely to develop disease or die. As such, any handling should be carefully undertaken to minimise pain and distress. Done correctly, fish that are regularly handled will acclimate over time. It is important to note that fish under anaesthesia can be at risk of overdose and hypercapnia (build-up of carbon dioxide).

Fish may be caught using commercial harvesting practices. However, catching fish by an experimental method requires AEC approval. As fish can be easily injured when netted the following factors should be considered:

- minimise the pursuit and capture time as much as possible;
- use soft mesh nets and after capture either manipulate the fish in the net or gently drop the fish out of the net (do not roll fish out of nets as this can increase skin damage).
- cover the eyes with a wet cloth as this can soothe most fish species during handling.

- Ensure anything that touches the fish (e.g., hands) are wet, to avoid damage to the mucus layer.

9.3.2. Animals Obtained from Other Countries

Under the Biosecurity Act 1993 and the Animal Products Act 1999, the exit and entry of animals or animal products including animal tissues into Aotearoa New Zealand can be restricted. Permits or approvals must be obtained from MPI for the importation of live animals, and their genetic material.

Genetically Modified Animals

The Institutional Biological Safety Committee (IBSC) and the Environmental Protection Agency (EPA) must be consulted regarding approvals around the importation of genetically modified (GM) animals. The housing and use of GM organisms or animals requires specialised transitional and containment facilities for vertebrate laboratory animals. MPI approval must be obtained for the establishment of transitional/containment facilities prior to housing GM organisms/animals. This includes on-site review by MPI inspectors.

Specimens from Dead Animals

Permits must also 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 endemic Aotearoa New Zealand animal or plant species subject to the Trade in Endangered Species Act 1989 or regulations.

9.3.3. Admission of New Animals into Holding Areas

The following should be considered when new animals arrive at a facility:

- quarantine and inspection by a qualified person/team;
- evaluation of health, and treatment if required; and
- sufficient holding time to acclimatise to the facility and personnel.

Normally, projects do not commence while animals are held in quarantine. This may vary, depending on the nature of the project. If appropriate, animals may be bred while in quarantine. If facility personnel note that animals are not adapting to their new environment or have any other concerns they should consult the facility manager and the project lead.

9.4. Food and Water

Each facility should consider the following, as a minimum, regarding the provision of food and water:

- food should be species-appropriate, nutritionally correct, and clean;
- food should be provided in sufficient quantities to allow normal growth as well as to support the requirements of pregnancy/lactation and any species-specific needs;
- uneaten perishable food should be removed promptly;
- alteration to dietary routines should be gradual;
- when feeding groups, sufficient trough space/feeding points should be provided to reduce competition;
- clean drinking water should be available continuously for terrestrial animals; and
- when providing food to fish:
    - care should be taken with live feed as there is a risk of introducing parasites into the system;
    - feeding should be done in a routine manner where the number of feeding events is appropriate to the fish species or stage of life.
    - appropriate quantities are provided to reduce the likelihood of aggression.

9.5. Animal Environments

All animal environments should provide a safe and appropriate space for the species. Each animal facility should have a documented pest control programme to monitor and control vermin.

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

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

9.5.1. Enrichment and Environmental Complexity

Most animals used in RTT are housed in unnatural environments. Animals should be provided with an optimised environment that meets the behavioural and physiological needs of the species unless other conditions are required to meet the objectives of the project.

Some RTT species have well defined social structures and normally live in groups. If possible, RTT animals should be housed in appropriate/socially compatible groups. Individual housing may be stressful for social animals but may be required to meet a project objective. This should be for the minimum time necessary and fully justified in the application to the AEC. If animals are housed individually during a project they may benefit from non-contact communication (visual/auditory/olfactory) with other compatible animals of the same species.

9.5.2. Environmental Factors

Environmental conditions should be suitable for the behavioural and biological needs of each species. The environmental conditions can potentially affect the welfare of the animals and may affect project results. Project leads should be consulted prior to any planned changes to the environment of their animals.

The following general environmental factors should be carefully considered:

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

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

Noxious odours, particularly ammonia, should be kept at a low level to ensure the health and comfort of the animals and facility personnel. Numerous factors influence the levels of noxious odours with a space, including the quality of the ventilation system, enclosure design and placement, animal density within cages/rooms, and the frequency of cleaning/bedding changes. With that said, facility staff should aim to balance the need for cleanliness and the potential impact of cleaning procedures on the animals.

Special Considerations for Fish

To ensure their health and welfare fish require specific environmental conditions including the following:

- Environments should have enough oxygen and sufficient de-gassing to remove carbon dioxide from the environment to ensure fish maintain normal respiration.

- Temperature should be carefully controlled with knowledge that increasing temperature drives higher levels of oxygen demand in fish. Fish have a wide range of thermal tolerance; however, each species will have preferred ranges.
- Factors that affect water quality are critically important including dissolved oxygen, temperature, pH, ammonia, nitrite, and water hardness which contribute to osmotic balance (across membranes).
- Appropriate systems must be in place to remove contaminants from water in tanks and ponds.
- Fish should be provided with appropriate systems for feed delivery and holding as well as disease management, environmental enrichment, and handling.

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

9.5.3. Indoor & Outdoor Housing

Indoor Housing

Buildings for the indoor housing of animals should:

- be compatible with the physical, health, and behavioural needs and stage of the animal(s);
- provide for group contact where 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;
- allow for free movement;
- suit the requirements of the project;
- 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;
- restrict access to the animal quarters to authorised persons only;
- facilitate the entry of people and other animals (where appropriate); and
- have an associated emergency management plan (see section 8.2.2 of this guide regarding emergency management).

Outdoor Housing

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; and
- comply with established farm or zoological garden practice.

9.6. Animal Enclosures

Enclosures should be designed and managed to meet species-specific needs, unless otherwise approved as part of an application approved by the AEC.

The following should be considered regarding animal enclosures for each species:

- Sufficient space allocation:
    - Population density in enclosures and within rooms should ensure acceptable social and environmental conditions including zones for hiding/retiring.

    - Single housing only when appropriate for the species or if required by the project (e.g., during recovery from surgery or collection of samples).
- Appropriate substrate:
    - Wire floors for rodents should only be used when essential, and then only for brief periods. Cages with wire floors should include a solid resting area.
    - Bedding (litter) should be appropriate to the species, absorbent, dust-free, non-palatable, non-toxic, and be sterilised if required by the project.
- Nesting/sleeping areas:
    - All animals should be routinely provided with bedding and nesting material.
    - Pregnant animals should be provided with a wider range of nesting materials that best suit their nest building needs.
- Ready access to food and water.
- Hygiene practices:
    - should ensure a healthy environment, without creating unnecessary disturbance.
    - include appropriate choice of detergents/disinfectants made in consultation with project leads.
    - do not include deodorants designed to mask odours as these can impact animal behaviour.
    - should be monitored regularly to ensure effective sanitation (e.g., visual inspection, monitoring water temperatures and microbiological testing of surfaces after cleaning).
    - include spot cleaning where appropriate.
- Measures to prevent the spread of pests and disease.
- They should be appropriate to support the requirements of the project.
- Animals should be readily observed in the enclosures.

9.6.1.Enclosure Requirements

Animal enclosures should:

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

9.6.2. Special Considerations for Farm Animals

As well the considerations above, the following should be considered when housing farm animals:

- housing and management practices must meet the requirements of the relevant Codes of Welfare;
- any paint/sealer applied to wood where cleaning/disinfection is required must be non-toxic;
- material used for indoor facilities should be impervious to moisture, insects, and vermin;
- pipes supplying drinking water should not be galvanised or made of copper;
- adequate trough space must be provided so all animals have access to feed and water supplies;
- floors (paved or concrete) surfaces should be “textured” to prevent slipping;
- ruminants require a resting area either in a well-drained outside area or bedded shelter;
- concrete should be covered with rubber matting or other suitable substrate such as wood chips;
- faeces/urine should drain away or be removed regularly to prevent animals standing/lying in dirty areas;
- fencing must be maintained to prevent escape or injury;
- plans should be in place to manage ventilation, temperature, relative humidity, air flow, moisture, dust, light, gas accumulation, odours, space, and manure. These become increasingly important when large animals are housed indoors.

Appendix 1

Definitions & Abbreviations

(The) Act	Animal Welfare Act 1999.
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. The statutory definition does not include any other prenatal, pre-hatched, larval, or developmental stage. For NAEAC's position on use of larval fish, see Appendix 2.
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.
Code holder	An individual or an organisation that holds an approved code of ethical conduct (CEC) and has an established AEC. Where an organisation holds a CEC, the organisation must specify an individual or individuals within the organisation who will be responsible for administering the CEC.
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, 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.
IOP	Institutional Operating Plan.
MPI	Ministry for Primary Industries.
Moribund	Approaching death; about to die.
Manipulation	Defined in section 3 of the Animal Welfare Act 1999. The term manipulation, in relation to any live animal means interfering with the normal physiological, behavioural, or anatomical integrity of the animal by deliberately depriving the animal of usual care or 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. The term manipulation 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 in a manner specified above;

	▪ 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; or ▪ any procedure that the Minister declares not to be a manipulation; or ▪ 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	An individual or corporate entity and also includes a body of persons whether corporate or unincorporate.
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	A mutual agreement between a code holder (the parent) and a non-code holder (the parented), whereby the parented carries out and regulates their RTT activities under the AEC and CEC established and held by the parent.
Project	An individual or series of related experiments or demonstrations that form a discrete piece of research or are undertaken for testing or teaching purposes.
Project Lead	A person approved by an AEC to be responsible for the conduct of an approved project involving animals.
Proposal	A written outline of a research project put forward for consideration by an AEC.
Protocol	A written plan outlining the objectives, design, and procedures involved in the carrying out of a particular project. A protocol may include standard operating procedures for specific tasks.
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.
Standard Operating Procedures (SOP)	A set of written instructions that describe the step-by-step process for carrying out a routine task or manipulation.

Tissue Sharing	Provision of tissue obtained under an AEC approval to another party, to prevent the need to kill additional animals
Tranquillisers	Drugs which are used to treat anxiety or produce sedation.

Appendix 2

Guidelines for Specific Manipulations

The use of larval fish in RTT

Zebrafish are typically used during the larval phase which is not covered by the Act. NAEAC considers that fish larvae meet the criteria for sentience and have developed a position statement regarding to their use.

Production of Genetically Modified Animals

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).

The breeding or production of an animal using genetic modification that may result in the production of offspring that are more susceptible to, or at greater risk of, pain or distress during their life is considered a manipulation under the Act. Pregnancies can have an impact on the dam as well as the foetus(es) and they require close monitoring for problems such as hydrallantois and dystocia.

Animal Models of Disease

The scientific validity of animal models of human diseases is related to how closely a given model resembles a particular disease. Special care should be taken in selecting appropriate species for the project. The project lead is responsible 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.

Project leads should not allow experiments to proceed to the painful, distressful, or lingering death of animals unless the experimental endpoint is completely justified and approved by an AEC. The goals of such projects may be the prevention, alleviation, treatment, or care of a life-threatening disease or situation in human beings or animals. Death as an experimental endpoint should be avoided whenever possible.

Experimental Induction of Neoplasia

Experimentally induced tumours should be the minimum size necessary to obtain valid results. Animals 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. Project leads should ensure animals are monitored regularly for signs of pain or distress. Sudden changes in body condition and signs that tumour growth is impacting on the welfare of the animals are particularly important.

The site for induction of tumours should be carefully considered. Subcutaneous sites on the back or flank should be utilised when possible. Specific justification should be made to the AEC for the use of footpad, brain, and/or eye sites.

Production of Monoclonal Antibodies

In vitro methods should be used for the routine amplification of hybridomas for the production of monoclonal antibodies. Project leads applying to use the *in vivo* (ascites) method should provide recent laboratory evidence to show that *in vitro* methods are unsuitable for the specific monoclonal antibody required for the project.

In the immunisation phase, project leads should ensure pain and distress is minimised. This can be influenced by the type, volume, site, and frequency of the injection of adjuvants, and the methods and frequency of blood sampling.

With ascitic tumours, including hybridomas, project leads 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 weight loss can be difficult to discern in the presence of ascites and abdominal tumours.

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. These experiments demand special consideration when the lesion produces loss of function (e.g., impairment of limb/trunk movements), loss of sensibility to touch/temperature/pain, impairment of the animal's awareness of its surroundings or appetite. Special 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.

Implanted Devices

Specialised care is required 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 and should be treated immediately. Project leads should be aware of the need for strict attention to aseptic technique when foreign bodies are surgically implanted. Contamination of prosthetic devices may require removal if antibiotic therapy has failed.

Organ and Tissue Transplantation

Specialised care is required following organ or tissue transplantation. Animals should be assessed frequently for any signs of pain, distress, infection, and/or 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.

Neuromuscular Paralysis

Neuromuscular blocking agents should only be used with appropriate general anaesthesia in line with specialist advice to ensure 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 (e.g., heart rate, blood pressure, oxygen saturation, pupil size and brain function as measured by an electroencephalogram) is necessary alongside the effects of these of mild sensory stimuli. Care is required to ensure that pharmaceuticals used in the procedures do not interfere with this monitoring. Immobilisation of an animal solely with a neuromuscular blocking agent is not acceptable.

Electro-immobilisation

Electro-immobilisation should 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.

Toxicological Experiments

The safety of agents intended for use in human beings/animals/the household/the environment, naturally occurring toxins, or agents to be used as poisons for pest control should be investigated by persons with appropriate training, and in accordance with internationally recognised guidelines such as an OECD Guideline for the testing of chemicals.

Additionally, *in vitro* methods should be used as an initial screening test wherever possible.

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.

Like with animal models of disease, project leads should not allow experiments to proceed to the painful, distressful, or lingering death of animals unless the experimental endpoint is completely justified and approved by an AEC. The goals of such projects may be the prevention, alleviation, treatment, or care of a life-threatening disease or situation in human beings or animals. Death as an experimental endpoint should be avoided whenever possible.

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 these 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 foetuses do not feel pain under normal conditions, project leads should ensure adequate anaesthesia for both dam and foetus(es) when the latter is undergoing surgical or other manipulation *in utero*. During surgery of the dam, consideration must be given to any special requirements for anaesthesia of the foetus(es).

Eggs must be destroyed before hatching unless hatching is a requirement of the experiment. AEC approval must be obtained for arrangements made for hatchlings.

Research on Pain Mechanisms and the Relief of Pain

In experiments in which unanaesthetised animals are subjected to painful stimuli, or when pain is applied as part of normal management, project leads 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.

Animal Welfare and Animal Health Research

When studying ways of improving the health and welfare of animals, project leads may design experiments that replicate an issue (e.g., injury, trauma, nutritional disorder, physical exertion, disease, or environmental stress). When such experiments are necessary, the project lead should 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 the experimental endpoint is completely justified and approved by an AEC.

Experiments Involving Hazards to Humans or Other Animals

Some projects may include the use of potential hazards (e.g., viruses, bacteria, fungi, parasites, radiation, radioactivity, corrosive substances, toxins, allergens, carcinogens, recombinant DNA and/or anaesthetic gases).

Information regarding these hazards as well as safety measures/mitigations should be included in the application to the AEC and provided to all project personnel.

Appendix 3

Sample AEC Application Information

Project General Information	• Project title • Project lead/institution and personnel, including qualifications and intended role within the project • Project start date and duration • Has the application been considered by another AEC?
Animal Information	• Type, number, and origin of animals • Any re-use of animals from other projects and potential cumulative impacts • Anticipated impact grade of manipulations in the proposed project
Project Justification	• Project purpose • Projected benefits to animals, humans, or ecosystems vs cost to the project animals • Potential expected harms to animals in terms of suffering, pain, and distress? • Is this application related to others? If so, provide an explanation of the relationships. • How will any findings be promoted or published?
Project Proposal	• Background information proving sufficient context for the project • Objectives and methods • Justification for the use of animals, including species, number, and life stage, including any randomisation or blinding strategies • A table of proposed manipulations and timings (including any AEC approved SOPs) • Experimental or observational strategies and statistical design to minimise pain, suffering, distress, and where appropriate, environmental impact • Consideration of the 3Rs and methods to ensure the project will not duplicate previous studies
Animal Husbandry & Welfare	• Animal housing and locations including address • Husbandry to ensure general health and welfare • Health status assessments to be performed • Specific requirements of animals bred with potential for compromised welfare • AEC approved husbandry SOPs that will be followed • Drugs and animals remedies being used during the experimental work • Study endpoints for animals used (including information on euthanasia methods if applicable), and fate after project completion if applicable
Monitoring	• Monitoring methods, frequency, and responsible personnel • Provisions for emergency care of project animals
Adverse Events	• Anticipated adverse events including management plans and record-keeping strategies • Process for notifying AEC of adverse events
Surgery/Other manipulations	• Surgical procedures (including repeated surgeries on a single animal) and responsible personnel • Anaesthetics, dosing rates and frequency • Monitoring of depth of anaesthesia • Proposed pain management • Peri-surgical support to maximise welfare outcomes • Other manipulations with the potential to impact on welfare

Signatures	• Signatures of approval: project lead, delegated project personnel, science reviewer, biometrician, animal facility manager, head of department or equivalent
	• Statement that project leaders signature commits to:
	  ○ 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 submitted for consideration by the AEC
	  ○ all AEC recording and reporting requirements will be met.

Appendix 4

Resources & 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., Rodriguez-Ferrere, M. (2011). Animal Law in New Zealand (2nd ed). Thomson Reuters (Brookers Ltd, New Zealand).

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. 55(2). 61-68. DOI: 10.1080/00480169.2007.36743.

https://www.naeac.org.nz/ The NAEAC website

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.mpi.govt.nz/animals/animal-welfare/animals-research-testing-teaching/ Access to the code of ethical conduct application pack.

https://www.legislation.govt.nz/ New Zealand legislation website.

https://www.anzccart.org.nz/pages/schools ANZCCART Information for New Zealand Schools.

https://www.anzccart.org.nz/pages/animal-ethics-in-new-zealand-schools ANZCCART Animal Ethics Approval in New Zealand Schools.

https://www.anzccart.org.nz/pages/information-for-new-zealand-teachers ANZCCART Secondary School Resources for New Zealand Teachers.

https://www.anzccart.org.nz/pages/general-info ANZCCART New Zealanders' Attitudes to Animal Research in 2023.