



CODE OF ETHICAL CONDUCT

For the Use of Animals for Research, Testing and Teaching

MPI Approved Version

19 December 2022 to 19 December 2027

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Abbreviations

AEC	Animal Ethics Committee
ANZCCART	Australian and New Zealand Council for the Care of Animals in Research and Teaching
AUP	Animal Use Protocol
AWA	Animal Welfare Act 1999
AWA Amendment	The Animal Welfare Act (No 2) 2015
AWO	Animal Welfare Office
CEC	Code of Ethical Conduct (this document)
DCO	Drug Control Officer
DVC (R&E)	Deputy Vice-Chancellor (Research and Enterprise)
HSECC	Health & Safety and Ethics Compliance Committee
HSNO	Hazardous Substances and New Organism Act 1996
IARMS	Integrated Animal Research Management System
LGOIMA	Local Government Official Information and Meetings Act 1987
MPI	Ministry for Primary Industries
NAEAC	National Animal Ethics Advisory Committee
Operations Manual	Animal Care and Use Programme Quality Operations Manual
PI	Principal Investigator
RTT	Use of animals in research, testing and teaching
RVM	Restricted Veterinary Medicine
SOP	Standard Operating Procedure
Three Rs	Replacement, reduction, and refinement of use of animals in research

1. Introduction/background on the activities of the organisation

The University of Otago is approved as the Code Holder as consented of the Director-General of MPI, for the use of animals in teaching and research at the University of Otago.

1.1. Organisational activities

The University of Otago recognises the need for animal experimentation and that the use of animals in teaching and research has a cost that must be weighed against the potential benefit obtained. Animals used in research have made major contributions to biological knowledge for the welfare of humans and animals, in the treatment or prevention of diseases, and in the understanding of ecosystems, biodiversity and species conservation. In addition, many courses in the University, across diverse departments, depend on the use of animals for teaching purposes.

1.2. RTT and Te Tiriti o Waitangi

The University of Otago is committed to advancing the principles of partnership, participation and protection implied by the Treaty of Waitangi in everything it does, including its animal-based research. This includes all of those involved in conducting or regulating animal use in RTT at Otago having regard to relevant Māori ethical values and other knowledge, as permitted by current law and policy.

1.3. RTT and the Three Rs

As a part of the CEC and Animal Ethics Committees' (AECs') processes, researchers are required to demonstrate why there is no alternative for the animal model and what will be done to minimise animal numbers and distress. The principles of the Three Rs will be applied and described in the application process:

- a. **Replace** the use of animals with alternative techniques or avoid the use of sentient animals.
- b. **Reduce** the number of animals used in an experiment and AUP to a minimum required to achieve the scientific requirements.
- c. **Refine** the way experiments are carried out to reduce harm and enhance the welfare of animals used.

1.4. Responsible persons

The University of Otago (the 'Code Holder') must meet its legal responsibilities as defined by the Animal Welfare Act (AWA) and Amendments. The Vice Chancellor retains the institutional responsibility to ensure the University is compliant with the CEC throughout the following delegated responsibilities for ensuring the code requirements are met:

- Deputy Vice Chancellor (Research and Enterprise) (DVC R&E).
- Chairs of each AEC.
- Members of each AEC.
- All individuals named on AEC-approved animal use protocol (AUP).
- All individuals named on parenting agreements with external organisations.

- All University of Otago employees and students responsible for any aspect of care and welfare of animals used in RTT.

1.5. Persons/organisations under the CEC

The CEC applies to all University of Otago staff and students, and animals used for RTT within New Zealand under an AEC-approved AUP. Where parenting agreements are approved by a University of Otago AEC, those parenting organisations are required to adhere to the conditions in this CEC. For research that occurs in collaboration with other New Zealand Code Holders, only one AEC will approve the research and only the CEC under which the approving AEC is appointed will apply.

2. Establishment, functions, powers, and membership of the Animal Ethics Committees

2.1. Functions, duties, and powers of the committees

The key functions of each AEC are as follows:

- To consider application for use of animals in research, testing and teaching (RTT).
- To monitor the conduct of approved applications.
- To inspect facilities used for RTT.
- To investigate adverse events/non-compliances and to take appropriate actions.
- to ensure that the highest ethical standards are observed by all persons associated with each AEC in relation to the manipulation and use of animals.
- to ensure compliance with the AWA 1999 including the Amendment Act No.2 (2015) by all persons named on approved AEC protocols.

2.2. Membership of each AEC

The University of Otago shall operate up to two (2) AECs to provide sufficient coverage for AUP assessment and approval. Each AEC shall be established, in accordance with the Act, to consider ethical matters pertaining to the manipulation of animals, by University of Otago staff as well as parenting organisations covered by the University of Otago AEC(s). Each committee will consist of a Chair and Deputy Chair who are academic representatives of the University, plus statutory members (minimum four) and organisational members (minimum five). There is no maximum number of AEC members; the membership will reflect the range of expertise needed. Individuals may serve on more than one AEC should they have the required expertise and capacity.

2.2.1 Statutory members

Each AEC includes four (4) statutory members:

- a senior academic representative of the University appointed by the Code Holder, who is qualified to evaluate proposals, the qualifications and skills of the applicant and others involved in the project, and the scientific and teaching value of the proposal, as appropriate, as delegated by the DVC (R& E).

- a veterinarian nominated by the New Zealand Veterinary Association (NZVA) who is not employed by or associated with the University of Otago.
- a person nominated by the Royal New Zealand Society for the Prevention of Cruelty to Animals (RNZSPCA), who is not employed by or associated with University of Otago, or involved in the use of animals for research, testing or teaching.
- a person nominated by a territorial authority or regional council, not employed by, or associated with the University of Otago or associated with the scientific community or an animal welfare agency.

2.2.2 Organisational members

Each AEC will consist of minimum of four (4) organisational members :

- a Chairperson, who is a senior academic representative of the University appointed by DVC (R& E) and is qualified to evaluate applications,
- a Deputy Chairperson,
- a Facility Manager or delegate,
- the Animal Welfare Officer or delegate.

Up to eight (8) additional academic representatives for each AEC may be appointed by the DVC (R&E), based on nomination by the relevant Heads of Departments and/or Deans, based on experience with animal research to provide a range of knowledge on topics covered by each AEC. Membership will include at least one (1) senior member of UO staff capable of evaluating proposals, the qualifications and skills of the applicant and others involved in the project, and the scientific and teaching value of the proposal, as appropriate.

The AEC may consult with expert advisers on a one-off basis for individual research projects or on specific issues. These advisers are not members of the AEC.

2.2.3 External members

Statutory external members appointed under Section 2.2.1 will be remunerated at the University of Otago Committees of Council honorary payment schedule.

2.2.4 Additional members

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

2.3. Appointment procedures

Appointments are made by the DVC (R&E) on behalf of the code holder, and shall be made after consultation with the committee, and in the case of statutory external appointments, with the relevant nominating agency. Further consideration of eligibility for the role will consider time availability and any conflicts of interest (such as related funding or involvement in AUPs).

2.3.1. Statutory external members

For external AEC statutory members, the association/territorial authority will be approached by the AEC Chairperson requesting nomination of a member for the AEC under the AWA.

2.3.2. Chairperson

The Chairperson shall be appointed by the Vice Chancellor in consultation with the DVC (R&E). Each AEC will elect a Deputy Chairperson.

2.3.3. Reappointment process

The reappointment process is required to be initiated six months before the expiry of the term. In the first instance, if the individual and Chairperson is agreeable, the individual will be approached for a repeat term.

In the case of external statutory members, a further nomination must be received, and the appointment made by the DVC (R&E) on behalf of the Code Holder.

2.4. Term of appointment

The term of appointment is three years.

2.5. Induction and training of new members

Each AEC member shall receive a formal induction provided by the AEC Chairperson and nominated AEC members. The University of Otago AEC materials and NAEAC induction pack will be provided and access to the Operations Manual. External members will be provided the opportunity to tour the animal facilities. Members may also be required to attend NAEAC workshops, conferences and/or training courses during their term on the AEC.

Enhancement of the knowledge and skills of AEC members shall be facilitated by the distribution of appropriate literature, access to the University of Otago resources, attendance at conferences (e.g., ANZCCART), AEC workshops (e.g., NAEAC), and contact with University of Otago staff and outside experts. Literature such as the ANZCCART News, NAEAC reports and guidelines, and Welfare Pulse are distributed among all AEC members in addition to the AEC document, to complement their knowledge of relevant matters. Other training material, such as the ANZCCART ComPass training modules, shall be made available. AEC members are encouraged to ask for support and training should they be aware of an opportunity they wish to take.

2.6. Vacancies

Vacancies in the membership of an AEC will not invalidate its actions, as long as a quorum of members is still available for committee meetings. Vacancies must be filled as promptly as possible in accordance with Section 2.3 of this document.

Resignations from the AECs will allow sufficient time for replacement appointment.

If a member has a protracted and/or unexplained absence from the committee of longer than four consecutive meetings, the Chairperson will contact the member in the first instance to identify any barriers to participating in the AEC. If unable to contact the AEC member, the member will have been deemed to have resigned their position on the AEC and the vacancy filled in accordance with Section 2.3 of this document.

3. AEC processes

3.1. AEC meetings

The primary function of each AEC meeting is to consider for approval AUPs submitted by Principal Investigators (PIs) for assessment and to advise on matters relating to animals used in RTT, to ensure the highest ethical standards are required for the care and use of animals at the University of Otago.

In accordance with the AWA, including the amendment, AUPs must be submitted for the following:

- the manipulation of live animals in RTT;
- the killing of animals for their tissue;
- the breeding or production of animals for RTT that may result in the birth or production of animals that are more susceptible to, or at greater risk of, pain or distress during its life.

At each meeting, the AEC may review new AUP applications including modifications and response to AEC provisos, ratify any decisions on new AUPs made by the relevant subcommittee, review the minutes of the previous meeting and action items, review reports from the Animal Welfare Officer or delegate including reports on clinical cases, adverse events and non-compliances, review Project Evaluation Reports (PERs) or end of study reports and any other relevant documentation, review Standard Operating Procedures (SOPs), discuss any other business brought to the attention of the AEC.

Each AEC is responsible for the review of monitoring animal welfare during protocol procedures and end of project reports.

Each AEC is required to review and comment on Committee activities related to animal use for RTT at the University of Otago, to the Health and Safety and Ethical Compliance Committee, University Council, and the University Senior Leadership team.

The AECs are responsible for the monitoring of animal facilities used for RTT and animal welfare and husbandry, as outlined in the NAEAC Good Practice Guide for the Use of Animals in Research, Testing and Teaching. An annual timetable will be generated by the AEC Chairs to allocate facility monitoring to specific AECs to ensure all facilities are monitored. A report will be generated at the completion of the monitoring visit and a copy provided to each AEC and the Code Holder. Where corrective actions or improvements are identified, these will be documented, time bound and reviewed at each AEC meeting until closed out fully.

3.2. Frequency of meetings

The AECs will be scheduled to meet monthly, with a minimum of four meetings per year. The schedule will be set annually and available to researchers and AEC members. At least two (2) weeks' notice will be given to AEC members of the meeting time and place.

3.3. Timing for circulation of agenda items

The AEC Administrator sets the agenda in conjunction with the AEC Chairperson. The AEC Administrator shall make available the agenda, meeting documents and the AUPs to be reviewed for the Committee to view at least a week before the AEC meeting. Electronic copies of the meeting documents are made available through a shared folder or attached to an email. AUPs to be reviewed are accessible to AEC members through the University's online Integrated Animal Research Management System (IARMS). The AEC Administrator will record the meetings and keep minutes.

3.4. Quorum

The quorum requirements are 50% +1 of committee members, including at least two (2) external statutory members described in Section 2.2.1.

3.5. Decision process

All approvals by the AECs will be by consensus. At the committee's request, additional conditions and/or requests may be made to the applicant in order to promote consensus. If consensus cannot be reached the application will be declined. Additional conditions and/or requests will be defined by the AEC and documented by the AEC Administrator. The requests will be made in writing to the applicant with a time frame for response to be received. Responses will be tabled at an AEC meeting for consideration as a part of the AUP, and formally recorded in AEC business minutes.

3.6. Effective input of committee members

To ensure effective input by all members of the AECs, all members will have equal opportunity to contribute to the business of the meeting. Chairpersons will ensure that all members, particularly statutory external representatives, have contributed and are satisfied with the discussion prior to any decisions being made.

3.7. Establishment and membership of subcommittees

The AEC may require the formation of a subcommittee to further assess or investigate animal related issues or AUPs. Subcommittee membership must include as a minimum the Chairperson (or delegate), one (1) of the statutory external members, and the Animal Welfare Officer (or delegate).

If consideration of new AUPs between meetings is required the AEC Chair may authorise formation of an AEC subcommittee for this. The membership of this subcommittee must always include at least two (2) of the statutory external members and decisions made by the subcommittee are conditional on ratification at the next AEC meeting.

All subcommittee decisions are to be recommended to the AECs for ratification at the next full meeting and any outcomes confirmed in writing by the AEC.

3.8. Conflicts of interest

The University of Otago Conflicts of Interest Policy applies to all organisational members of the AEC and will be administered accordingly. Committee members must declare any actual or potential conflicts of interest at the beginning of every meeting, and these must be recorded in the minutes. The up-to-date list of potential or actual conflicts of interest will be reviewed at each meeting, as a standing agenda item.

Where a member of an AEC is the Principal Investigator or has a significant contribution to an AUP being considered, the member may provide information if asked but must retire from the deliberation on the approval or non-approval of the AUP. This decision will be made by AEC consensus. If the AEC Chair is conflicted, the Deputy Chair will administer the meeting and the Chair must retire from the deliberations. If both are conflicted, a suitable Chair will be elected from the committee members.

Where a member of an AEC is named on a proposal but is acting in a largely advisory or supply capacity, this shall not be deemed a conflict of interest.

3.9. Confidentiality

All AEC members are required to sign a University of Otago confidentiality agreement at the time of their appointment to the AEC and must treat all information submitted to the AEC as confidential.

Meetings may be audio recorded solely for the purpose of recording the minutes, and only by the designated administrator. The administrator is responsible to ensure the recording is deleted after 14 days. Members will not record minutes on their individual computers. Written notes will be submitted to the AEC Administrator at the conclusion of the meeting for destruction.

All Official Information Act 1982 requests must be managed by the University of Otago Office of the Registrar.

3.10. Use of video conferencing

All meetings are attended by members either face to face or by online (e.g., Zoom, Skype or Teams) for a quorum of AEC members. Calling in (audio only) may be used in case of technical difficulties but is not to be counted for quorum. Each member's method of attendance will be recorded in the meeting minutes.

Decisions can only be made at a quorate meeting.

Where an AEC member is not able to attend the face-to-face meeting or participate by video conference, written notes may be submitted by the AEC member. These notes entered into the University Integrated Animal Research Management System (IARMS) for AUP review. Written notes may be used should a member have difficulty accessing IARMS (such as technical difficulties) and will be provided at the meeting by the Administrator for

consideration. The notes will be retained by the Administrator at the conclusion of the meeting and destroyed.

3.11. Consideration between meetings

It is the preference of the University of Otago that all decisions are made in a quorate meeting. However, it is recognised that there are times when an AEC decision is required between meetings to comply with the Three Rs and preserve animal welfare. Where minor changes or alterations are required between meetings, this may be managed through the Designated Members Review process (see Section 4.7). The Designated Members Reviewers are the AEC Chairperson and Deputy Chairperson.

3.12. Public presence at meetings

Meetings will not be open to the public. Information about AEC meetings is official information under the terms of the Official Information Act 1982, and requests by members of the public for its release are to be treated as requests pursuant to that Act and must be made through the University of Otago Office of the Registrar.

3.13. Applicant presence at meetings

The AECs support the attendance of the AUP applicant (Principal Investigator) at the meeting, to present their application and answer any questions the committee may have. Applicants can write to the AEC Administrator requesting attendance at the meeting, which will be at the discretion of the Chairperson.

The applicant is welcome to bring a support person to the meeting. This shall be arranged with the AEC Administrator. This person is required to sign a University of Otago confidentiality agreement prior to attending the meeting to ensure there is no discussion of the AEC meeting processes by the attendee outside the meeting.

Where the committee has an unexpected request for detailed information during discussions that can be best answered by the AUP applicant or personnel, they may be invited to the meeting or called by videoconference.

In all cases, the AUP applicant or personnel must not be present in any capacity during AEC deliberations on the AUP. All attendance at meetings is recorded on the meeting agenda and minutes.

3.14. Administration support

Persons with appropriate skills shall be employed by the University of Otago to act as the AEC Administrator. The AEC Administrator shall prepare the agenda, draft the minutes, and provide access to the documentation and correspondence used by the committee. The AEC Administrator shall not contribute to the AEC deliberation except for clarification of details for minutes and decision recording.

3.15. Recordkeeping and information management

Records of the AEC meetings shall include:

- Agendas
- Minutes
- Correspondence with investigators

- Site visit reports
- Study protocols/AUPs
- AEC Approvals
- Manipulations carried out and actual impact grade resulting
- Details of the husbandry routines and actual environmental conditions
- Variations approved
- Deviations/non-compliances
- Adverse events
- Staff training records
- Veterinary treatment
- Results of manipulations/treatments

Records will be kept in compliance with Animal Welfare (Records and Statistics) Regulations 1999 S4. They will be securely destroyed or deleted at the end of this period. Audio recordings will be deleted 14 days after the AEC meeting by the AEC administrator.

All AUP applications must be submitted through the University's online Integrated Animal Research Management System (IARMS). Any proposed change to an AUP needs to be approved by an AEC.

3.16. Reporting of animal use statistics to MPI

The AECs (through the AEC Administrator) will report statistics on animal use and impact of use using the prescribed MPI form(s) on or before 28 February each year to MPI, or within seven (7) days of a request from MPI (or any inspector appointed under the Act) for information.

3.17. Protection of AEC members

Members of the AECs are protected under Section 104 of the AWA and are not 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. Consideration of applications by the AECs

4.1. Criteria for consideration

When considering submitted AUP applications, the AECs shall ensure that the protocol meets the criteria set out in Section 100 of the Act, any matter that the AECs require to consider by regulations made under the Act, and the relevant section of the NAEAC Good Practice Guide for the Use of Animals in Research, Testing and Teaching. Prior assessment and consultation on AUP applications is available to all PIs through the AWO or AEC members (through the AEC Administrator or the AEC Chair).

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Guide for the Use of Animals in Research, Testing and Teaching. Prior assessment and consultation on AUP application is available to all PIs through the AWO or AEC members (through the AEC Administrator or the AEC Chair).

The key principle underlying the assessment process is that the benefits that are likely to be derived from using animals in RTT must outweigh the foreseeable harm to those animals. In considering any AUP application for approval the AECs shall have regard to the following to ensure that the use of animals in RTT is confined to cases in which there is good reason to believe:

- that the findings of the research or testing or the results of the teaching will enhance:
 - the understanding of human beings, animals, or ecosystems; or
 - the maintenance or protection of human or animal health or welfare; or
 - the management, protection, or control of ecosystems, plants, animals, or native fauna; or
 - the production and productivity of animals; or
 - the achievement of educational objectives; and
- that the benefits derived from the use of animals in RTT (whether the direct benefits of a project or the likely benefits of that project when combined with the findings of other related projects that have been undertaken in the past or that are currently being undertaken or are planned for the future) are not outweighed by the likely harm to the animals. Note that this does not apply to the killing of an animal (other than an animal in a wild state) for the purpose of interfering with the animal's body or its tissues.

And to ensure that:

- in relation to animals used in RTT all reasonable steps are taken to ensure that the physical, health, and behavioural needs of those animals are met in accordance with both good practice and scientific knowledge; and
- where animals used in RTT are ill or injured, they receive, where practicable, treatment that alleviates any unreasonable or unnecessary pain or distress:
- where, because of the nature of the RTT, the physical, health and behavioural needs cannot be fully met or treatment cannot be provided, any degree of pain or distress is reduced to the minimum possible in the circumstances,

And to promote efforts:

- to reduce the number of animals used in RTT to the minimum necessary:
- to refine techniques used in any RTT so that the harm caused to the animals is minimised and the benefits are maximised:
- to replace animals as subjects for research, and testing by substituting, where appropriate, non-sentient or non-living alternatives:
- to replace the use of animals in teaching by substituting for animals, where appropriate, non-sentient or non-living alternatives or by imparting the information in another way.

Other criteria are:

- any matters that the AEC is required to consider by regulations made under the Act; and
- the scientific or educational objectives of the project; and
- the harm to, or the distress felt by, the animals as a result of the manipulation, and the extent to which that harm or distress can be alleviated by any means (including, where the pain or distress cannot be held within reasonable levels, the abandonment of the manipulation or the humane destruction of animals), but this paragraph does not apply to the killing of animals for the purpose of any project where research, testing, and teaching are to be performed on their bodies or tissues; and
- whether the design of the experiment or demonstration is such that it is reasonable to expect that the objectives of the experiment or demonstration will be met; and
- the factors that have been taken into account in the choice of animal species; and
- the extent to which there has been:
 - assessment of the suitability of using non-sentient or non-living alternatives in the project; and
 - replacement of animals as subjects with suitable non-sentient or non-living alternatives; and
- whether the number of animals to be used is the minimum necessary to ensure a meaningful interpretation of the findings and the statistical validity of the findings; and
- whether adequate measures will be taken to ensure the general health and welfare of animals before, during, and after manipulation; and
- whether suitably qualified persons will be engaged in supervising and undertaking the research, testing, or teaching; and
- whether any duplication of an experiment is proposed and, if so, whether any such duplication will be undertaken only if the original experiment:
 - is flawed in a way that was not able to be predicted; or
 - needs to be duplicated for the purpose of confirming a result that was unexpected or has far-reaching implications; and
- whether the same animals are to be used repeatedly in successive projects, and, if so, the cumulative effect of the successive projects on the welfare of the animals; and
- whether there is a commitment to ensuring that findings of any experiment will be adequately used, promoted, or published,
- and any other matters that the AEC considers relevant.

The AEC will consider where relevant: Māori ethical values and other knowledge; the potential for experiments and manipulations to cause compassion fatigue in animal care personnel, investigators, and students, which might impact on the welfare of the animals under care.

4.2. Impact grading

The AECs will grade applications according to the ethical grading set out by MPI.

4.3. Outcomes after consideration

The AECs' decision on the AUP application shall be one of the following:

- a. approve in full (with or without conditions);
- b. approve in principle, with **no animal manipulations** to be started until the approval of minor or technical modifications accepted by the AEC Chairperson, a specified sub-group of the AEC, or the full AEC;
- c. defer an application until requested specified details are provided to the AEC Administrator and agreed as acceptable to the Chairperson, a specified sub-group of the AEC, or the full AEC;
- d. decline the application.

Decisions are recorded in writing by the AEC Administrator in the meeting minutes and provided to the AUP applicant (Principal Investigator) through an electronic notification, via the Integrated Animal Research Management System (IARMS).

4.4. Conditions of approval

The AECs may set conditions of approval and may vary or revoke such conditions. Such conditions may include matters such as:

- the time period for which approval is granted;
- reporting requirements of AUP applicants to the AEC;
- monitoring requirements or site visits.

Conditions will be conveyed to AUP applicant (Principal Investigator) through the Integrated Animal Research Management System (IARMS) or an email from the AEC Administrator. Response to conditions will be reviewed by a designated AEC member or a specified sub-group of the AEC and ratified at a quorate meeting. The response may also be reviewed by the full AEC.

4.5. Maximum approval period

All applications for continuing research and teaching must be resubmitted for consideration at least every three (3) years.

Applications will initially be approved for up to three years and can be extended by up to 1 year per extension application (subject to AEC review and approval) for a maximum of 2 years extension.

4.6. Power to suspend, revoke and vary approvals

The AECs may direct that any procedure on animals be stopped or modified on ethical grounds and the animal(s) be either euthanised or otherwise properly cared for. Between

meetings, this power is vested in the AEC Chairperson, or their delegate, in consultation with the Animal Welfare Officer.

4.7. Changes to approved applications

Designated Member Review

The Designated Member Review (DMR) process allows for minor refinements to existing AUPs between meetings to maintain animal welfare, reduce the number the animals used and to prevent delays in teaching and research. The DMR application must be reviewed by the AWO, the AEC Chairperson or delegate, and any other member of the AEC identified by the AEC Chairperson. All must be in agreement with the DMR outcome.

The criteria for a DMR are:

- the changes do not involve a major departure from the approved study design; or
- there is no increase to impact grading; or
- additional staff and students are required to be added to an existing protocol.

Modifications must be submitted to the AEC Administrator, who will forward the request to the AWO in the first instance. The AWO will review whether the modification is suitable for DMR based on the potential animal welfare impact, and if so, it is forwarded to the AEC Chairperson (or delegate) for a final decision. If approval is granted, details of the modification will then be provided to the next AEC meeting for ratification.

5. Responsibilities under AEC-approved applications

The University of Otago, its personnel and officers are subject to the Animal Welfare Act 1999 and this Code of Ethical Conduct. The use of animals at the University of Otago shall be carried out in accordance with this CEC and the AEC-approved animal use protocol. Failure to comply with any aspect of the AUP is a non-compliance and may involve changes or deviations with personnel, techniques, or manipulations for which a modification to the AUP has not been requested or approved. On such occasions, these variations represent non-compliances that require corrective actions.

The AECs have the responsibility to ensure the highest ethical standards are upheld for the manipulation and use of animals on approved AUPs. Authority has been delegated to the Animal Welfare Office (or designee) and the Animal Practices and Compliance Officer (APCO) for animal welfare and AUP compliance monitoring. The AWO and APCO have the responsibility to:

- Stop any procedure immediately that they consider to be causing unnecessary distress or pain to the animal
- Stop any animal use immediately that they believe deviates from any approved use, which involves any non-approved procedure, or which causes unforeseen distress to an animal
- Humanly euthanise an animal if it is considered necessary.

Upon receiving a report of a potential non-compliance event, the AWO (or delegate) or APCO will conduct an initial investigation immediately to determine if it is:

- i) A potential non-compliance with impact on animal welfare
- ii) A potential non-compliance with no impact on animal welfare.

In the case of (i), the AWO, designee or APCO may temporarily suspend work on all/part of the AUP and/or immediately treat or euthanise the animals, ensuring there is no ongoing risk of adverse events or other animal welfare concerns. A report will be sent immediately to the AEC Chair and the PI.

In the case of (ii), the AWO, designee or APCO will prepare a report for the next AEC meeting. A copy of the report will also go to the PI in a timely manner to allow the PI to prepare a response letter for the AEC meeting.

The AEC Chair will contact the PI to address the key concern(s). Contact by phone is recommended in the first instance, if this is impractical, email may be used.

The phone call will be followed up by a letter or email to the PI to confirm the details of the phone call and any immediate course of action, or to address the key concern(s) in the first instance. A copy of the letter or email, and any subsequent correspondence, will be provided to the AWO and AEC Administrator, and will normally be sent to the PI's Head of Department (HOD) and Dean of the academic unit (if applicable).

At the next AEC meeting, the reports will be reviewed to determine if there has been a non-compliance and the significance of the event. The AEC will review any discussions/correspondence held with the PI and make a recommendation to the most appropriate course of action. This may include a meeting between the PI and AEC or a subcommittee to discuss the concerns in detail and plan remedial measures. The final minutes of such a meeting will be distributed to all personnel involved for comment and revision.

The PI will be required to address all concerns within a time frame stipulated by the AEC.

The PI, HOD, and AWO will be advised in writing by the AEC Administrator of the outcome. Copies of notifications and reports on the outcome of significant non-compliance events and any AUP suspension will be provided to the appropriate Dean, Pro-Vice-Chancellor (PVC), Deputy Vice-Chancellor Research and Enterprise (DVC R&E) and the Health and Safety and Ethics Compliance Committee.

The PI may appeal the decision of the AEC by addressing their concerns in writing to the DVC (R&E) in the first instance.

When significant non-compliance events occur, the National Animal Ethics Advisory Committee (NAEAC) may be notified (as determined by the AEC and confirmed by the DVC R&E).

If an individual appears to have committed an offence against the Animal Welfare Act 1999, the University will conduct an investigation and disciplinary procedures will be implemented, if considered necessary. The Ministry of Primary Industries (MPI) will be notified through NAEAC.

5.1. Compliance

5.1.1. Project reporting

The PI is responsible for complying with the Animal Welfare Act, this code of ethical conduct, any AUP approval conditions and the collection of accurate animal use data.

Interim and final reports shall be submitted by the Principal Investigator to the AEC Administrator using the prescribed form, as soon as the AUP is closed or completed. The AEC Administrator shall send reminders to the Principal Investigators to ensure submission of the report(s).

5.1.2. Compliance reporting

The Principal Investigator shall report to the AEC any non-compliance or potential non-compliance. Where corrective actions are identified, these must be time framed, with specific responsibilities allocated.

The AECs, or their delegated authority, have responsibility for the monitoring of all approved protocols, as outlined in Section 7, which always includes monitoring for compliance.

5.2. Appropriate qualifications

All animal users must have the appropriate skills to perform the manipulations they are authorised to perform under the protocol. The approving AEC will specify any required training at the time of AUP consideration and the timeframes for completion of training. Evidence of training must be reviewed by the AEC prior to work commencing on the AUP.

All personnel who are responsible for animal manipulations must be trained and declared competent by a trainer approved under the AWO Training Programme Framework as described in the Operations Manual. The Drug Control Officer (DCO) will specify Restricted Veterinary Medicine training.

The AWO is responsible for allocating the required training of personnel based on the protocol. Training is species- and manipulation-specific. The AEC approves all required training, and a register is maintained on IARMS.

5.3. Daily care of animals

The PI, or the Animal Facility Manager, may delegate authority for named competent person(s) to visually complete a health and wellbeing inspection of all animals' health in institutional facilities daily. There may be situations where daily observations are not practicable (e.g., captive wildlife studies); where this is the case, the AUP must specify how animal monitoring (frequency and by whom) will occur.

5.4. Sick and injured animals

All applications must have veterinary oversight, whether by the AWO veterinarians, or a nominated external veterinarian or practice named on the application and approved by the AWO. This includes parented AUPs. If the health or wellbeing of an animal or animals is compromised during a project, veterinary advice must be sought and implemented as soon as practicable.

Illness or injury shall be reported via IARMS online sick reporting procedures, with appropriate actions taken. All sick reports shall be viewed by AWO veterinarians as soon as possible and statistics reported at the next AEC meeting.

Where the sick report identifies health issues that threaten the ethical justification of the project, or may undermine the validity of the project, the AWO veterinarians must escalate the issue to the PI and AEC Chair immediately for their consideration and action.

The AWO veterinary staff employed by the Code Holder have the authority to visit animal holdings and use areas at any time, and without prior notice, provided reasonable steps are taken to comply with any access requirements that may apply. The AWO will provide reports to the AECs on any matters and issues arising.

5.5. Standard Operating Procedures (SOPs)

University of Otago SOPs for the care, welfare and use of animals, animal husbandry and management, and AUP-specific procedures are developed through the **SOP Development and Approval Guidelines** and are submitted to the AECs for review and approval. The AEC shall review SOPs 2 years from first approval, then every 5 years thereafter, or earlier if required.

The main SOP categories are Research SOPs, Husbandry-related (Facility Management) SOPs, Veterinary Care SOPs, Drug Control and Storage SOPs.

The SOPs shall be drafted by the topic/category lead writer (researcher/animal care personnel/animal facility manager/veterinarian/Drug control officer) and developed in consultation with the relevant affected parties. AEC members may also be consulted. Processing SOPs for review and related documents is managed by the Animal Welfare Office. Finalised SOPs for AEC approval are sent to the AEC Administrator for the AEC to review and approve at the next meeting.

5.6. Adverse events

Any animal welfare adverse events during an AUP approval period shall be dealt with promptly. Animal welfare adverse events include any unanticipated or atypical incidents that occur to an animal as a result of experimental manipulation, routine husbandry, or diseases. Adverse events (including but not limited to incidents resulting to the experimental manipulation, disease, or animal husbandry failures) are detailed in the AEC approved AUP.

Adverse events may also result from unexpected events not foreseen when the project started, such as natural events (e.g., extreme weather/earthquake).

Where an adverse event occurs, it is the responsibility of the person(s) handling the animals (in consultation with a veterinarian if necessary) to establish and administer the appropriate treatments or management practices, as soon as possible.

If an animal is injured or sick as a consequence of an unexpected adverse event, this must be dealt with immediately, and the PI and AWO veterinarian notified to establish any additional immediate responsive and preventive actions. This shall also be reported primarily through IARMS or via email. Phone calls must be made for urgent cases. The Animal Welfare Officer (or delegate) shall contact the relevant AEC Chair.

The AWO reports adverse events monthly to the AECs for further discussion for the identification of any improvements and preventive actions required.

Actions identified in response to an adverse event may include:

- Treatment and management of the health of the animal
- Additional observational requirements for the protocol
- Review of any procedures
- Review of competence and training of staff to continue with manipulations or animal related activities
- Termination of the project.

5.7. Recordkeeping

Study records

AUP-specific study records are kept by the approval holders (PIs and personnel under AUP). This may include for all animal approved under the AUP:

- individual animal behavioural records
- monitoring records
- laboratory notes
- site visit reports
- animal usage numbers
- impact gradings
- variation requests
- non-compliance notifications
- adverse event reports.

These shall be kept for seven years on completion of the AUP and should be made available for review and auditing purposes. Records are archived and destroyed in accordance with the University of Otago Information and Records Management Policy. Animal records (animal identification including date of birth, date of arrival/delivery, source, veterinary and research history, fate of animal) entered in IARMS can also be retrieved.

5.8. Euthanasia for tissue collection/dissection

Animals that will be euthanised solely for harvesting of tissues are required to have an AEC approval and will be under an AUP. However, tissues or organs from these already euthanised animals may be utilised for research and teaching by other groups within the University without requiring an AUP. This will be a part of the University of Otago's animal

tissue/organ sharing programme. This will be documented and reported as part of the openness in research and teaching initiative.

5.9. Rehoming

Opportunities to rehome animals at the conclusion of their use in research and teaching will be considered in accordance with the University of Otago's Guidelines on Rehoming Animals Used in Research and Teaching Programmes.

6. Animal facilities

All animals housed must be in accordance with the NAEAC Good Practice Guide for the Use of Animals in Research, Teaching and Testing, and to the authorised SOPs relating to husbandry.

Standards shall be maintained by the provision of in-house training and external training for animal care staff. Animal husbandry will be provided at each facility seven days a week. All caged indoor-housed animals shall be visually inspected by a trained and/or experienced animal care staff at least one each day, seven days a week.

6.1. Management of animal facilities

6.1.1. Policies and procedures

Animal facilities shall operate as per the authorised SOPs to ensure that all facilities and practices are in accordance with good practice and scientific knowledge (as recommended by NAEAC in their Good Practice Guide for the use of Animals in Research, Testing and Teaching) and the relevant codes of welfare issued under Section 75 of the AWA.

6.1.2. Emergency management

The Code Holder, or delegated authority, shall ensure that protocols and procedures have been put in place by the institution to manage any impacts on welfare of animals caused by emergency events.

6.2. Development of SOPs for facility management

Standard Operating Procedures (SOPs) shall be developed in accordance with the University guidelines. The guidelines require SOP development in consultation with subject matter experts. The standard template must be used including recording who wrote the SOP, date of approval by the AEC, version control numbers and the review date. There are three main groups of SOPs requiring AEC approval:

- Researcher SOP
- Husbandry related SOP
- Veterinary care related SOP.

As detailed in Section 5.5, all SOPs, including those for facility management, shall be developed in accordance with the University of Otago SOP Development and Approval Guidelines and be submitted to the AECs for review and approval.

6.3. Transportation of animals

All transportation of animals will be humane and hygienic and in accordance with regulatory requirements (e.g., PC2 Animals, Hazardous Substances and New Organisms Act, IATA). This will be achieved through compliance with an approved transportation SOP or an approved AUP.

6.4. Housing of animals

Housing facilities shall ensure that the general health of animals is safeguarded, and that undue stress is avoided. Sufficient space, according to the species, must be allocated for each animal. Environmental needs, such as temperature, humidity, ventilation, and enrichment must be consistent with the species concerned. Wherever possible, animals in unnatural environments should be provided with an environment that can accommodate the behavioural and physiological needs of the species. Animals must receive a supply of foodstuffs appropriate to their requirements and of the quality and quantity adequate to preserve their health, with free access to water, unless the objective of the experience is to study the effect of variation in these nutritional requirements.

Details, including any deviations (with adequate justification) must be provided in the AUP for AEC review and approval.

6.5. Monitoring animal facilities

All animal holding facilities, where animals under AEC-approved AUPs are held, shall be inspected by AEC members at least once per year, using an AEC-approved animal facility inspection checklist as a guide. The AEC members or their delegates undertaking such inspections, and any other institutional oversight functions, will be selected from both AECs through agreement of both of the AEC Chairs.

All facility inspection reports will be reviewed by both AECs at the next meeting. A report will be sent back by the AEC Administrator to the Facility Manager. Corrective actions will be monitored by the AEC and the code holder until a satisfactory outcome is achieved. The annual AEC facility visit is scheduled with one of the two Animal Facility Managers internal audits (conducted at six monthly intervals). Staff from the AWO may accompany the Facility Manager during these audits to provide assistance. The AEC may conduct non-scheduled facility visits as part of the monitoring and follow-up on any unresolved concerns of the facility and its operation.

Animal facilities of Parented Organisations shall also be inspected by the AEC. Parented Organisations are required to submit a semi-annual report through the AWO, which shall be reviewed at each following AEC meeting.

This includes any parented organisational facilities. All inspections will be conducted using the animal facility inspection checklist authorised by the AECs as the guide.

7. Monitoring

The AECs have the power to conduct inspections and observations at unscheduled times (i.e., not premeditated for compliance monitoring).

7.1. Monitoring during the approval period

The AECs have the power to inspect animals, their accommodation, and related experimental records at any time to satisfy itself that approved procedures are being properly carried out. The AECs, or their delegated authorities, are responsible for the monitoring of all approved protocols. Monitoring records and other research-related study records (such as in Section 7.6) maintained by researchers must be made available to the AECs (or delegated authorities) for review. Other relevant animal records can be accessed in IARMS.

All individuals listed on the approved protocols are required to comply with the conditions of the AEC approval and this code.

7.2. Monitoring by proxy

The approving AEC shall allocate site visits during the AUP review. Monitoring by the AEC is normally delegated to the APCO, the AWO or the clinical veterinarian for routine procedures. Any AEC member from either AEC can elect to conduct the site visit themselves, depending on their availability. This must be declared at the AEC meeting and recorded by the AEC Administrator. All monitoring events, such as site visits, will be documented and reviewed at the AEC meeting.

7.3. Frequency of monitoring

The AEC or their delegated authorities shall conduct at least one (1) annual monitoring site visit for every approved AUP with impact Grade C, D, and E manipulations, and at least 10% of protocols with Grade A and/or B manipulations per annum. AEC-allocated site visit report/checklist (which may also be incorporated into the AWO report) will be reviewed by the AEC at the next meeting and shall highlight any deviation from the AUP or non-compliance. Any further action required by the AEC shall be recorded and monitored by the AEC until a satisfactory outcome is achieved.

7.4. Monitoring of manipulations Grades A and B

The AEC will allocate a monitoring site visit to at least 10% of Grade A & B protocols during the approval period annually.

7.5. Monitoring of manipulations Grades C-E

The AEC will allocate a monitoring site visit to all Grade C – E approved applications to be monitored at least annually by the AEC or their delegate.

7.6. Specific manipulations

The AEC, at the time of AUP review, may allocate the site visit on specific high impact manipulations or personnel performing such manipulations. This follows the standard AEC site visit allocation procedure.

7.7. End of approval reporting

The AEC requires an end of protocol completion report to be submitted by the PI within three months of the end of the project. The report must include the value of the study, any modifications made to the protocol and all reports of inspections, site visits, sick animal

reports or similar. The report will include the initial grading of the approved protocol, and an assessment from the PI on the grade during the progress of the protocol.

Reports must be submitted to the AEC at the meeting that follows completion of the protocol.

7.8. End of approval grading

With the end of protocol completion report, the Principal Investigator shall report to the AEC (using the prescribed form) the initial grade approved in the AUP and the actual grade as recorded in the IARMS Animal Management system. Where changes have occurred, the AEC will review the information for consideration of future AUPs.

7.9. Compliance breaches

7.9.1. Non-compliance with an AEC approval

Non-compliances will be managed in accordance with the University of Otago AEC Management of Animal Non-Compliance Events Procedure.

7.9.2. Non-compliance with legislation or regulations

If a PI is found non-compliant with legislation or regulations, or non-compliant with this CEC, an immediate cessation to further work may be issued and only reinstated upon further consideration of the AEC. The Chair will report to the AEC, Deputy Vice-Chancellor (Research and Enterprise) and the Head of Department for further action if warranted, including the involvement of regulatory authorities. The AEC may also consider whether disciplinary measures are required. Such a process would follow the University of Otago's Policy for disciplinary procedures.

Non-compliance with legislation or regulations (including non-compliance with this CEC) as determined by the AEC or another competent authority within the University of Otago, will be reported to MPI by the AEC or by the DVC (R&E) (on behalf of the Code Holder).

8. Arrangements for external parties to use the CEC and AECs

Arrangements for external parties to use this CEC and the AECs (parenting agreements) shall be considered by the AECs on a case-by-case basis, and on formal ratification with the DVC (R&E). A documented memorandum of understanding is required to be signed by both parties, outlining the responsibilities of each party for the agreement, including the requirement of the external party to comply with this code. MPI will be informed in writing by the AEC Administrator when any parenting agreement is completed.

9. Complaints procedures

Note: maximum penalties for individual and corporate offences against the Animal Welfare Act 1999, the Animal Welfare (Records and Statistics) Regulations 1999 and other legislation and regulations that apply to the use of animals for research, testing and teaching are included in the text of each Act and Regulation.

Complaints will be logged by the AEC Administrator for the attention and action of the AEC and Code Holder.

9.1. Animal welfare complaints

Procedures are in place to allow:

- staff members to raise concerns over the conduct of animal work
- reporting of non-compliances; and
- reporting of deviations from the approved AUP.

Staff, students, members of the public and visitors are encouraged to report any complaints or concerns immediately. Verbal and written complaints will be accepted by the University. Complaints will be allocated a contact person who will follow up the complainant. Expected actions include:

- taking immediate steps to ameliorate and if possible, remedy the situation
- investigation of the concerns/complaints by the AEC or their delegate
- the AEC reporting back to the complainant in writing on the investigation findings and actions taken

If the matter is not resolved to the satisfaction of the complainant, the matter will be escalated to the DVC R&E.

Where the complainant is not satisfied with the outcome, or where the nature of the complaint has a significant impact on animal welfare, the Code Holder will notify MPI of the situation, the investigation, and the outcome.

9.1.1. Complaints by the public

Complaints made by members of the public shall be logged by the AEC Administrator and referred to the next available AEC meeting for discussion. The AEC Chair may choose to correspond directly with those concerned to inform them of the University's position and/or to advise them that further correspondence may be addressed to MPI. The report of actions taken will be logged by the AEC Administrator and the DVC (R&E) provided with a monthly update.

If the committee agrees that there is evidence of a potential non-compliance, the Chairperson shall arrange an investigation by AEC member(s) with a formal report to be provided at the next AEC meeting. Where non-compliance with the CEC or AWA is identified, corrective actions shall be recorded and monitored by the AEC. The DVC (R&E) and the Health, Safety and Ethical Compliance Committee shall be notified.

9.1.2. Complaints by employees

Complaints made by University of Otago employees shall be logged by the AEC Administrator and forwarded to the AEC Chairperson. If there is evidence of a potential non-compliance, the Chairperson shall arrange an investigation by AEC member(s). A report of the investigation will be provided to the next AEC meeting and the Code

Holder. Corrective actions will be identified and monitored by the AEC and reported to the DVC (R&E) and the Health & Safety and Ethics Compliance Committee.

9.1.3. Complaints by AEC members

Complaints from AEC members, on potential non-compliance with the CEC or AWA, shall be directed to the AEC Administrator. The Code Holder will be notified, and an investigation pathway identified. A report shall be provided to the Code Holder and corrective actions identified if required. MPI will be notified of the complaint and resulting actions by the Code Holder. The Code Holder will escalate and provide a report to the Health & Safety and Ethics Compliance Committee.

Any member of an AEC who believes that the committee or the Code Holder is failing to comply in a material respect of the Animal Welfare Act or regulations may report the non-compliance to the Director-General. Any AEC member that makes such a report is considered to be acting in good faith and to not be liable to any civil or criminal proceedings or any disciplinary proceedings as a result of that report (AWA 103).

9.1.4. Breaches of the Act

Serious breaches of the AWA and any potential for prosecution will be notified to the Code Holder as soon as practicable. The Health, Safety and Ethical Compliance Committee will be notified immediately, and a course of action identified. MPI will be notified of the occurrence.

9.2. Procedural complaints

9.2.1. Complaints by applicants

Procedural complaints from applicants (Principal Investigators) will be submitted to the AEC Administrator who will notify the AEC Chairperson. The complaint will be investigated by AEC member(s). If the complaint is found to be substantiated, the DVC R&E will be notified, who may request a formal investigation. Any corrective actions will be documented.

9.2.2. Complaints by AEC members

Complaints from AEC members will be logged by the AEC Administrator who will notify the AEC Chairperson and DVC (R&E). The complaint will be investigated by AEC member(s) as directed by the DVC (R&E). If there is evidence of non-compliance, the DVC (R&E) will escalate to the Health, Safety and Ethical Compliance Committee with a prescribed action plan to address any deficiencies.

9.2.3. Complaints against the Chair

Complaints made by University of Otago employees, AEC members or members of the public regarding the Chairperson shall be directed to the Code Holder, who may correspond directly with the Chairperson to resolve the issue. Where the Code Holder believes the complaint justifies escalation, MPI shall be notified.

10. Process to amend, suspend or revoke the CEC

Proposed CEC amendments must be submitted to the AEC in writing, outlining the proposed changes, their reasons for the change and the name(s) of those proposing the change. The AEC will review the proposal and may seek input from other University of Otago staff to decide if the proposed modification is minor or major.

10.1. Minor amendments

Where minor amendments to the CEC are required, the AEC shall submit the recommended change to the DVC (R&E) for Code Holder approval. Minor changes will be incorporated, and the CEC modification record maintained. The updated CEC will be placed on the institutional web page by the Administrator. The DVC (R&E) will notify Senior Management who are required to notify all Heads of Departments and employees responsible for any aspect of animal used in RTT in their Division. All minor amendments to the CEC shall be notified to MPI and any parenting organisations by the Code Holder within seven days of the modification to the CEC.

10.2. Major amendments

Where major modifications to the CEC are required, the request and justification shall be submitted to the Code Holder or delegated authority. The Code Holder will apply to the Director-General of the MPI for amendment. Where the modification is approved, the AEC will be advised and the notification to University staff and any Parented Organisation shall occur within seven days of approval. The updated CEC will be placed on the institutional web page by the AEC Administrator. Where the modification is declined, an alternative strategy will be discussed with the AEC and Code Holder.