



## **CODE OF ETHICAL CONDUCT**

**For the Use of**

**Animals for Research, Testing and Teaching**

**MPI Approved Version**

**1 January 2018 to 20 December 2022**

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

# 1. Introduction/Background on the Activities of the Applicant

## 1.1 Scope of Activity

The University of Otago recognises the need for animal experimentation and that the use of animals in research, testing and teaching (RTT) 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.

This Code of Ethical Conduct (CEC) is designed to comply with all the requirements of the Animal Welfare Act (AWA) 1999, including the Amendment to the Animal Welfare Amendment Act No. 2 (2015), particularly Part 6: “Use of Animals in RTT”, so that the specified animals can be used in RTT at the University of Otago. “Animals” refers to the definition provided in the AWA.

## 1.2 Research, Teaching and Testing and the Three Rs

As a part of the CEC and Animal Ethics Committee (AEC) 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 3Rs will be applied and described in the application process:

- (i) **Replace** the use of animals with alternative techniques or avoid the use of animals.
- (ii) **Reduce** the number of animals to a minimum required to achieve the scientific requirements.
- (iii) **Refine** the way experiments are carried out to reduce animal suffering and enhance animal welfare.

## 1.3 Responsible Persons

The University (the ‘Code Holder’) must meet its legal responsibilities as defined by the Animal Welfare Act and amendments. The Vice-Chancellor retains the institutional responsibility to ensure the University is compliant with the CEC through the following delegated responsibilities for ensuring the code requirements are met (including individuals as delegated by 1.3.1 or 1.3.2):

1.3.1. Deputy Vice-Chancellor (Research and Enterprise) (DVC (R&E))

1.3.2. Chairs of the Wellington, Dunedin and Christchurch AECs

1.3.3. Members of the AECs

1.3.4. All individuals named on approved AEC protocols

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

## 1.4 Persons/Organisations under the CEC

The CEC applies to all University of Otago staff and students, and animals used for RTT within New Zealand. 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 NZ CEC 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 Committee

### 2.1 Functions, Duties and Powers of the Committee

The key functions of the AEC are as follows:

- to ensure that the highest ethical standards are observed by all persons associated with it, in relation to the manipulation and use of animals
- to ensure compliance with the Animal Welfare Act 1999, including the Animal Welfare Amendment Act No. 2 (2015), by all persons named on approved AEC protocols.

### 2.2 Membership of the AEC

The University of Otago shall operate three AECs, one at each of the Dunedin, Christchurch and Wellington campuses.

Each AEC will consist of a minimum of five members including the following:

- 2.2 (a)* a chairperson who is a senior representative of the University, endorsed by the AEC and appointed by the Code Holder
- 2.2 (b)* a person appointed by the Code Holder on the nomination of an approved animal welfare organisation, such as the Royal New Zealand Society for the Prevention of Cruelty to Animals (RNZSPCA), who is not employed by, or associated with, the University or involved in the use of animals for RTT
- 2.2 (c)* a person appointed by the Code Holder on the nomination of a territorial authority or regional council who is not employed by, or associated with, the University, or associated with the scientific community or an animal welfare agency
- 2.2 (d)* a veterinarian appointed by the Code Holder on the nomination of the New Zealand Veterinary Association (NZVA) who is not employed by, or associated with, the University
- 2.2 (e)* up to eight additional institutional members appointed by the Code Holder.

#### 2.2.1 Organisational members

Institutional members of the AEC are selected based on experience with animal research to provide a range of knowledge on topics covered by the AEC. At least one senior member must be appointed based on capability of evaluating scientific validity of projects. These members are appointed as per section 2.2 (e) and approved by the chairperson and Code Holder.

### 2.2.2 *External members*

External members appointed under section 2.2 will be remunerated at the University of Otago Committees of Council honorary payment schedule.

### 2.2.3 *Additional members*

The AEC has the power to co-opt additional expertise where additional skills or knowledge gaps are identified. This may be in relation to the science involved in applications, the species of animal or similar situations.

## 2.3 Appointment Procedures

The Code Holder will appoint the chairperson, and the AEC will elect the deputy chairperson.

Reappointment of statutory external members at the expiry of their term must be through a formal nomination by the relevant body as outlined in section 2.2.

Reappointment of Institutional members at the expiry of their term must be through the formal appointment process as outlined in section 2.2.

The secretary of the AEC should be an employee of the University and approved by the Code Holder. The secretary is 'in attendance' only and does not form part of the consensus decision-making processes of the AEC.

## 2.4 Vacancies

Vacancies in the membership of the committee 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 of this CEC.

If a member has a protracted and unexplained absence from the committee of longer than four consecutive meetings, this member will have been deemed to have resigned their position on the AEC and the vacancy filled in accordance with section 2 of this CEC.

## 2.5 Induction and Training of New Members

The Code Holder will provide new AEC members with the NAEAC induction pack and additional Institutional information as deemed necessary. Members may also be required to attend NAEAC workshops, conferences and/or training courses during their term on the AEC.

## 2.6 Term of Appointment

Appointments shall be for a period of three years. Reappointment for consecutive terms is subject to the appointment process as outlined in section 2.2 of the CEC.

## 3. AEC Procedures

### 3.1 AEC Meetings

The primary function of the AEC meeting is to review animal users protocols (AUPs), submitted by Principal Investigators (PIs) for assessment and advice on matters relating to animals used in RTT, to ensure the highest ethical standards are required for the manipulation and use of animals at the University of Otago.

In accordance with the Animal Welfare Act 1999, including the Animal Welfare Amendment Act No. 2 (2015), AUPs must be submitted for the following:

- (i) the manipulation of live animals in RTT
- (ii) the killing of animals for their tissue
- (iii) 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

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

The AEC reviews and comments on other business related to animal use for RTT at the University of Otago.

### 3.2 Frequency of Meetings

AECs will meet at least twice a year as organised by the chairperson. At least two weeks' notice will be given to AEC members of the meeting time and place.

### 3.3 Timing for Circulation of Agenda Items

Each chairperson will ensure that the secretary records and keeps the minutes, and that the agenda, AEC applications and all other appropriate information is forwarded to the AEC members at least one week prior to the meeting.

### 3.4 Quorum

A quorum is 50% of membership + 1, including two external statutory members appointed as per section 2 of the CEC.

### 3.5 Decision Process

All decisions of the AEC will be by consensus.

### 3.6 Conflicts of Interest

Committee members must declare any actual or potential conflict of interest to the chairperson for consideration, prior to the matter concerned being discussed by the AEC. When a conflict of interest is declared, it will be recorded, and the member will recuse



themselves from all AEC business relating to that matter, including discussion and decision-making.

### 3.7 Effective Input of Committee Members

To ensure effective input by external members, all members will have equal opportunity to contribute to the business of the meeting. Decisions will be made after all committee members present have had the opportunity to express their views. External members will have access to researchers and staff involved in the manipulation of animals so that they can obtain information and answers to questions they have regarding applications made to the AEC.

### 3.8 Confidentiality

Committee 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.

### 3.9 Use of Tele/Video Conferencing

The University of Otago considers face-to-face meetings the preferred method of reaching a consensus agreement. Where no other option is practical, video conferences/teleconferences are acceptable alternatives. Modifications of existing protocols (but not consideration of new protocols) may be discussed by email.

### 3.10 Consideration between Meetings

It is the preference of the University of Otago that all AEC decisions are made in a quorate meeting. It is recognised that on certain occasions an AEC decision is required between meetings. There are two situations where interim approval between meetings may apply:

- modifications to existing protocols
- fast tracking new proposals.

#### *3.10.1 Modifications to existing protocols*

For modifications/alterations to existing protocols to be considered and approved by the chairperson (or nominee), the following criteria must be met:

- The changes do not involve a major departure from the approved study design.
- There is no increase to the impact grading.
- Additional staff and students are required to be added to an existing protocol.
- Any change to numbers is the minimum necessary to retain the statistical validity of the original approval. Any increase over 10% of the original number requested must be agreed by a quorum of the committee.

#### *3.10.2 Fast tracking new proposals*

A fast track approval (interim approval) for a new protocol may be issued on a well-justified case-by-case basis, where there are sufficient grounds for the urgency of the approval. The requirements for considering a fast track approval are as follows:

- There is a legitimate requirement for urgency.

- The manipulation is grades A and/or B.
- The AUP is brought to the next meeting of the AEC, which may endorse, endorse with conditions or not endorse the decision.

A subcommittee of the AEC shall consider these proposals. Subcommittee membership must include as a minimum the chairperson (or nominee), one of the statutorily appointed external members and a co-opted animal welfare officer (or nominee).

The fast track approval shall be considered for ratification at the next AEC meeting and the approval confirmed in writing by the AEC.

### 3.11 Public Presence at Meetings

Meetings will not be open to the public.

### 3.12 Applicant Presence at Meetings

The AEC may invite applicants to be present at the meeting in support of their application and to answer any questions the AEC may have. Applicants are welcome to bring a support person to the AEC meeting. Applicants may write to the chairperson requesting attendance at the AEC meeting to present on their protocol and answer questions from the AEC, which will be at the discretion of the chairperson.

### 3.13 Secretarial Support

Persons with appropriate skills shall be employed by the University of Otago to act as secretary to the AEC. Each secretary shall maintain records of agendas, minutes, decisions, correspondence with investigators, site visit reports, application forms and all other relevant documentation consistent with the University of Otago minute keeping guidelines for Council, Senate and their Committees.

### 3.14 Record-keeping and Information Management

Information management protocols are defined in section 3.13 of the CEC and in the University of Otago Records Management policy. Records are archived and destroyed in accordance with University of Otago policy.

### 3.15 Reporting of Statistics to MPI

The AEC will report statistics on animal use and impact of use on completed protocols annually to the MPI.

## 4. Consideration of AUPs

### 4.1 Criteria for Consideration of Submitted Protocols

When considering submitted proposals, the AEC shall ensure that the protocol meets the criteria set out in section 100 of the AWA.

### 4.2 Outcomes Following Consideration by the AEC

The AEC may:

1. **Approve**

*This includes the following options:*

- (i) Work on the research may commence as per the protocol.
- (ii) There are modifications to be made to the protocol. Work may commence, or a specified portion of work may commence, provided the modifications needed do not impact on animal welfare. The modifications must be submitted to the AEC in writing within six weeks of receipt of the approval notification.

2. **Require revision**

**No** work is to commence, as the protocol requires revision on ethical grounds.

3. **Decline**

**No** work is to commence in any capacity in relation to the protocol.

For modifications to existing protocols, refer to section 3.10. All decisions will be recorded in the minutes and the applicant advised of the outcome in writing.

### 4.3 Maximum Approval Period

The maximum approval period for an application is three years. At this time all animal manipulations must stop. Where there is sufficient justification, an extension of up to two years may be granted by the AEC on application.

### 4.4 Power to Suspend, Revoke and Vary Approvals

The AEC has the authority to suspend or revoke protocols, or vary conditions of approvals temporarily or permanently.

### 4.5 Minor Changes to Approved Applications

The AECs recognise that there may be the requirement for minor modifications to the protocol manipulation procedures or other aspects. Such requests (for items other than those specified in section 3.10.1 – minor modifications between AEC meetings) should be submitted to the AEC with supporting documentation.

### 4.6 Protection of AEC Members

Members of the AEC 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.

## 5. Institutional Monitoring and Compliance Responsibilities

### 5.1 Code Holder Responsibilities

The Code Holder is responsible for monitoring compliance of protocols with all Acts of Parliament, regulations or bylaws pertaining to the care and treatment of animals. Particular attention will be given to sections 80 and 100 of the AWA.

### 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 AEC will specify any required training and the timeframes for completion of training, evidence of which will be provided to the AEC. The drug control officer will specify Restricted Veterinary Medicine training.

### 5.3 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). This will be achieved through compliance with an approved transportation standard operating procedure (SOP) or an approved AUP.

### 5.4 Housing of Animals

Animal facilities and practices shall be in accordance with good practice and scientific knowledge (as recommended by NAEAC in its *Good Practice Guide for the Use of Animals in Research, Testing and Teaching* (June 2010)) and to the relevant codes of welfare issued under section 75 of the AWA. This is to ensure that the animals' health is safeguarded and that undue stress is avoided. All requirements of the AWA and Amendment 2015 shall be met.

This will be achieved through the adherence to University of Otago approved SOPs or an approved AUP, including housing, feeding, water access, enrichment, etc.

### 5.5 Daily Care of Animals

An approved, competent person with delegated authority must visually inspect all animals held in institutional facilities daily, where practicable. Where daily observation is not practicable (e.g. wildlife studies) this shall be documented in the protocol.

### 5.6 Vet Care and Animal Health Management

Veterinary assistance and advice is available 24 hours per day, seven days per week. The veterinary staff employed by the Code Holder have the authority to visit animal holding and use areas at any time, and without prior notice, provided reasonable steps are taken to comply with any access requirements that may apply. If any issues are identified, an

inspection report will be forwarded to the AEC, relevant PI and associated line managers as appropriate.

Illness or injury shall be reported in a 'sick report' with appropriate actions taken. All sick reports shall be reviewed by institutional veterinarians and statistics reported monthly to the AEC (if animals are on an approved AUP) and the facility manager.

## 5.7 Standard Operating Procedures

University of Otago staff may develop SOPs for animal husbandry practices or routine procedures that relate to the manipulation of animals in RTT. These SOPs will be developed in consultation with the relevant affected parties, peer reviewed by an individual(s) with expertise in the procedure and submitted to the AEC (or their delegated authority) for authorisation, based on that due process has occurred.

## 5.8 Adverse Events

Any animal welfare adverse events during an approval shall be dealt with promptly. If an animal is injured or sick as a consequence of manipulation, this should be dealt with appropriately and reported to the Animal Welfare Office (AWO) immediately. The AEC must be notified of the adverse event. The adverse event will be discussed at the next AEC meeting and procedures will be developed to prevent the event happening in future RTT if the AEC believes the adverse event is preventable.

## 5.9 Grading

All protocols submitted to the AEC will be assessed for grading of manipulations as outlined in the *Animal Use Statistics* documents as issued by MPI.

# 6. Animal Facilities

## 6.1 Management of Animal Facilities

Animal Facilities shall document SOPs as per section 5.7 to ensure that all animal facilities and practices are in accordance with good practice and scientific knowledge (as recommended by NAEAC in its *Good Practice Guide for the Use of Animals in Research, Teaching and Testing* (June 2010)) and the relevant codes of welfare issued under section 75 of the AWA.

## 6.2 Monitoring Animal Facilities

Animal facility managers shall audit the facilities at six monthly intervals. University veterinary staff from the AWO may accompany the facility manager during these audits to provide assistance. At least one audit per annum must be conducted including an AEC representative(s). All facility audit reports will be viewed by the facility managers, the Code Holder (or delegate) and the AEC. Corrective actions will be monitored until a satisfactory outcome is achieved.

### 6.3 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.

## 7. Monitoring of Approved AUPs

### 7.1 AUP Compliance Monitoring

The AEC, or their delegated authority, is responsible for the monitoring of all approved protocols. Where a delegated authority is nominated by the AEC to provide this monitoring function, this must be recorded in writing. All monitoring events, such as site visits, will be documented and formal reports received by the AEC. Where corrective actions are identified, these must be time framed with specific responsibilities allocated. Compliance with corrective actions will be monitored by the AEC, and where non-compliance is significant or ongoing, the AEC will escalate the matter to the Code Holder or their delegated authority.

All individuals listed on approved protocols are required to comply with the conditions of AEC approval and this code. Prior assessment and consultation on AUPs is available to all PIs through the AWO or AEC members.

Site visits and/or post approval monitoring will be conducted on at least 10% of grade A – C approved protocols, and all grade D and E protocols.

### 7.2 Powers of the AEC

The AEC has the power to inspect animals, their accommodation and related experimental records at any time to satisfy itself that approved procedures are being properly carried out. Between meetings, this power is vested in the chairperson and at least one other member appointed according to section 2 of this code, or staff of the AWO on behalf of the AEC. Any member of the AEC can request access to animals or facilities at any time as long as they are accompanied by the AEC chairperson or their nominee.

### 7.3 Monitoring of Manipulations

The AEC will require monitoring of at least 10% of Grade A – C protocols and all Grade D and E protocols as per section 7.1.

### 7.4 End of Approval Reporting

The AEC will be provided with an end of protocol completion report submitted by the PI. The report must include the outcome of the research, any modifications made to the protocol and all reports of inspections, site visits, sick animal reports or similar. Reports should be submitted to the AEC at the meeting that follows completion of the protocol. The

end of protocol completion 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.

#### 7.5 End of Approval Statistics

The protocol completion report must contain details of the numbers of animals used during the life of the protocol, including any additional requests, with justifications and outcomes. The AEC is responsible for the reporting of animal use numbers to the MPI on behalf of the Code Holder.

### 8. Arrangements for External Parties to Use the CEC and AEC

Arrangements for external parties to use this this CEC and the AEC (parenting agreement) shall be considered by the AEC 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.

### 9. Complaints Procedures

#### 9.1 Reporting of Complaints

All complaints regarding animal welfare must be reported to the chairperson and recorded in the minutes. A log of complaints will be held by the AEC.

#### 9.2 Procedural Complaints

In accordance with section 103 of the AWA, any member of the AEC who believes that the committee or the University of Otago is failing to comply with material in respect of the CEC may report such non-compliance to the Director General of MPI. An AEC member who makes such a report in good faith shall not be liable to any discipline or civil proceedings from the University of Otago because of having made the report.

Complaints shall be written to the chairperson of the appropriate AEC. The chairperson may consult with other personnel as needed to complete any required investigation. If the matter cannot be resolved by the AEC, or to the satisfaction of the complainant, it shall be referred to the DVC (R&E). The outcome of the reconsideration is final.

#### 9.3 Animal Welfare Complaints

##### *9.3.1 Complaints from members of the public*

Complaints made by members of the public shall be referred to the AEC chairperson who may 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. A complaint report will be entered into the AEC complaints log at the next AEC meeting. 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 provided to 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 Ethics Compliance Committee shall be notified.

#### *9.3.2 Complaints made by University of Otago staff*

Complaints made by University of Otago employees shall be directed 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.

#### *9.3.3. Complaints regarding the AEC Chairperson*

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, the MPI shall be notified.

## 10. Process to Amend the CEC

Proposed CEC amendments must be submitted to the AEC in writing, outlining the proposed changes, the reasons for the changes 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 changes 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 secretary. The DVC (R&E) will notify the Pro-Vice-Chancellor (Health Sciences) and Pro-Vice-Chancellor (Sciences), who are required to notify all Heads of Departments and employees responsible for any aspect of animals used in RTT in their division of the updated CEC. All minor amendments to the CEC shall be notified to MPI by the Code Holder.

### 10.2 Major Modifications

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 shall occur. Where the modification is declined, an alternative strategy will be discussed with the AEC and Code Holder.