

## CODE OF ETHICAL CONDUCT

For the Use of Animals in Research, Testing and Teaching (section 88 of the Animal Welfare Act 1999)

20 November 2024 – 19 November 2029

## Contents

1. Background on the Activities of the Code Holder	2
1.1 Organisational Activities .....	2
1.2 RTT and Te Tiriti o Waitangi Obligations and Principles .....	3
1.3 The Three Rs.....	4
1.4 Responsible Individuals.....	5
1.5 Individuals/Organisations under the CEC .....	6
2. Functions, Powers and Membership of the Animal Ethics Committee (AEC)	6
2.1 Functions and Powers of the AEC .....	6
2.2 Membership of the AEC.....	7
2.3 AEC Appointment Procedures .....	9
3. AEC Standard Processes	11
3.1 General.....	11
3.2 Meeting Procedures.....	12
3.3 Consideration Between Meetings.....	14
3.4 Secretarial Support .....	15
3.5 Record Keeping Requirements .....	15
4. AEC Technical Processes	16
4.1 Consideration of Applications by the AEC .....	16
4.2 Standard Operating Procedures considered by the AEC .....	19
4.3 Amend, Suspend or Revoke the CEC.....	20
5.0 Monitoring by the AEC	21
5.1 Monitoring during the Approval Period.....	22
<b>Scheduled visits</b> .....	22
<b>Non-scheduled visits</b> .....	22
5.2 Monitoring by Proxy .....	22
5.3 Monitoring across Impact Grades.....	22

5.4 Monitoring Specific Manipulations.....	23
5.5 Monitoring Animal Facilities .....	23
6. Responsibilities of organisations/individuals with AEC Approved Applications	23
6.1 Reporting to the AEC.....	23
6.2 Records Management.....	25
6.3 Appropriate Qualifications.....	26
6.4 Sick and Injured Animals .....	26
6.5 Standard Operating Procedures developed by the Code Holder .....	27
6.6 Management of Animal Facilities .....	27
6.7 Euthanasia for Tissue Collection .....	28
6.8 Rehoming.....	28
7. Compliance Breaches & Complaints Procedures	29
7.1 Compliance Breaches.....	29
7.2 Animal Welfare Complaints .....	29
7.3 Procedural Complaints.....	30
8. Arrangements for External Parties to Use the CEC and AEC	31

## **1. Background on the Activities of the Code Holder**

(Section 89 and Section 93 of the Animal Welfare Act 1999)

### **1.1 Organisational Activities**

This Code of Ethical Conduct (CEC) for the Use of Animals in Research and Teaching aims to ensure that all animal use related to research and teaching at Wintec and by parented organisations is conducted in accordance with the Animal Welfare Act 1999 (the Act).

At Wintec, research and teaching (RTT) activities include manipulations on animals, guided by this CEC and under the approval of the Wintec Animal Ethics Committee (AEC). Research and teaching activities at Wintec may be carried out in the fields of animal health and husbandry, animal biology, and anatomy and physiology.

The AEC will maintain standards of animal management that meet the purposes of Part 6 of the Animal Welfare Act 1999. The AEC will ensure that standards of animal management meet or exceed those detailed in the National Animal Ethics Advisory Committee (NAEAC): *Good Practice Guide for the Use of Animals in Research, Testing and Teaching*. No animals will be used for teaching or research purposes without having approval from the AEC.

## 1.2 RTT and Te Tiriti o Waitangi Obligations and Principles

### **Treaty of Waitangi Obligations and Principles**

Wintec is committed to upholding the principles of partnership, participation and protection implied by The Treaty of Waitangi / Te Tiriti o Waitangi (Te Tiriti). Meeting Wintec obligations under Te Tiriti encompasses articulating the ethical dimensions of tikanga as they relate to research and teaching and to guide researchers and educators more generally with respect to Māori ethical understandings and perspectives.

While Te Tiriti principles are not specific to the use of animals in research and teaching they nonetheless provide guidance for general obligations and considerations of relevance. Four key principles from these guidelines can be adapted to the animal ethics environment.

#### **Whakapapa (relationships and connectedness to mana whenua)**

Consulting meaningfully and developing authentic relationships contributes to the ethical tenor of all research and teaching. Wintec expects all researchers and/or educators to consult with relevant stakeholders in a culturally appropriate manner prior to undertaking any animal manipulations.

#### **Tika (purposefulness)**

Research and teaching involving animals should only be carried out in circumstances where the perceived benefits outweigh the harms caused. In this context, purposefulness is the expectation that the research and/or teaching is well designed and carried out to a sufficient standard to be able to deliver these benefits (i.e. that it is fit for purpose).

#### **Manākitanga (cultural and social responsibility)**

All participants in research and teaching should act with respect for others. This respect extends to all sentient beings involved in the research, be they human or members of other species.

#### **Mana (justice and equity)**

When research and/or teaching involves animals, the benefits of the work often accrue to a different group than those that bear the costs. Under these circumstances, particular care should be taken to ensure that the group bearing the costs is treated with as much care as possible to minimise this imbalance.

In recognition of these principles, this CEC integrates and incorporates mātauranga Māori by drawing on a foundation of tikanga Māori to enhance understanding of Māori ethical concepts, support decision-making around Māori ethical issues, assist with/identifying ways to address Māori ethical concerns and help support kaitiaki roles of Māori ethics committee members. It aims to improve the capacity of key personnel within the system of ethical review to respond more appropriately to Māori issues and, in doing so, enhance Māori communities' confidence and trust in the decisions made by Wintec.

Wintec recognises that Māori have specific interests in the way their land is used and in the indigenous fauna of New Zealand. This CEC, therefore, ensures that Wintec operates with tiaki and whakaute when using these resources, and provides a useful guide to educators, researchers, ethics committee members, and those who engage in consultation or advice about animal ethical issues.

*Ref: 1 Hudson, M., Milne, M., Reynolds, P., Russell, K. & Smith, B. (2010). Te Ara Tika Guidelines for Māori research ethics: A framework for researchers and ethics committee members. Health Research Council of New Zealand, Auckland.*

### 1.3 The Three Rs

Wintec's Philosophy towards Research and Teaching and the Four Rs (based on the Three Rs plus Respect)

Wintec has an overall mission to build a stronger community through education, research and career development. The use of animals makes an important contribution to all three of these areas. Animal research and teaching is an integral part of maintaining Wintec's mission and the Wintec recognises there must be a responsible balance between the desire to use animals and the need to maintain the welfare of the animals used.

The guiding principles underpinning the humane use of animals is the Four Rs policy (Replace, Reduce, Refine and Respect). The Four Rs will be carefully considered when evaluating proposals for research and teaching. Researchers, and educators at Wintec are required to apply the following guiding principles based on the Three Rs and reflect the Wintec core value of Respect and manākitanga.

**Replace:** Replace the use of animals where possible, by substituting non-sentient or non-iving alternatives.

**Reduce:** Reduce the number of animals manipulated to a minimum required to achieve teaching and scientific requirements. Wondering – human ethics are in a different code – so only include 'animals' in this code?

**Refine:** Animal use will be refined to reduce pain or suffering as much as possible and enhance animal welfare.

**Respect:** Respect animals, as sentient beings, enforcing and living the values of manākitanga, recognising that all animals used in teaching and research should have their welfare needs as the first priority. We recognise the perspective that all animals have inherent value while remaining compatible with the science perspective that animals have instrumental value.

#### **Manipulation of Live Animals**

In accordance with the principles above, manipulation of live animals must consider section 3 of the Act - definition of manipulation. Manipulation must only be undertaken:

- i. Where an alternative to the use of live animals is not appropriate or feasible.
- ii. Where there is a good reason to believe that the findings will add to the scientific understanding of biological functions and behaviour or will extend the body of knowledge aimed at improvement in the health and welfare of animals.
- iii. Where manipulation is a required part of the educational curriculum and/or research project.
- iv. Where animals can be appropriately housed, handled, and cared for in a way that promotes their physical and psychological well-being. This includes proper nutrition, housing conditions, and social interactions where appropriate.

#### **Consideration for Teaching using live animals**

In accordance with the principles above, consideration for teaching using live animals includes:

- i. The value of the proposed manipulation is beneficial to the learning outcomes of the students.
- ii. Whether a non-animal alternative can be used, or used alongside live animals, to reduce numbers.

- iii. The choice of appropriate animal species and individual animals that are used for manipulations, to minimise stress.
- iv. Management of animal to student ratios to maximise student learning and minimise individual animal stress.

### **Consideration for Researching using live animals**

In accordance with the principles above, consideration for research using live animals includes:

- i. Appropriate experimental design and analyses to provide statistically valid results with the minimum necessary number of animals. Consultation with a biostatistician may be required.
- ii. The choice of animal species. This will depend on scientific and technical criteria and animal welfare. Expediency and economic factors must not be allowed to distort these criteria.
- iii. The source of animals. Animals must be lawfully acquired, maintained, and used in strict compliance with all legislation which relates to their welfare and humane treatment. Endangered, threatened, and indigenous species should not be used unless under the guidance or permission of the Department of Conservation, and only with appropriate iwi consultation.
- iv. Minimising of distress and suffering. The manipulation of live animals should only be undertaken in accordance with the Ministry for Primary Industries Guidance Document for Animal Use Statistics and the National Animal Ethics Advisory Committee: *Good Practice Guide for the Use of Animals in Research, Testing and Teaching*.

### **1.4 Responsible Individuals**

The code holder shall be the Wintec Executive Director/Chief Executive, or other appropriate delegated authority. They shall retain the institutional responsibility to ensure Wintec meets its legal responsibilities as defined by the relevant legislation.

The protocol holder is responsible for administration of Animal Use Protocols (AUPs) in research projects.

In practice, the code holder may choose to delegate the day-to-day administration to relevant personnel within the organisation.

The tutor in charge of the class at the time the teaching is taking place is responsible for ensuring AUPs and Standard Operating Procedures (SOPs) are followed. The protocol holder has overall responsibility to ensure that individual tutors are aware of, and follow, the applicable AUP.

Other responsible persons include all Wintec staff and students, contractors, visitors, volunteers and AEC members.

The AEC members carry out monitoring during the use of animals to ensure ethics AUPs are being followed.

Wintec may, from time to time, grant permission to other organisations to operate under this CEC. In this instance a Parenting Agreement will be agreed to, outlining all requirements. All organisations that enter into a Parenting Agreement with Wintec will undertake to comply with this CEC, including that all individuals using this CEC are familiar with responsibilities and administration therein.

## 1.5 Individuals/Organisations under the CEC

This CEC applies to the following:

- i. All employees (kaimahi), contractors, volunteers, visitors and learners (ākonga) of Wintec or parented organisations.
- ii. Members of Wintec AEC.
- iii. Persons named on Wintec approved AEC AUPs and associated documents.
- iv. Persons responsible for any aspect of care and welfare of animals used in RTT at Wintec or parented organisations.
- v. All animals used in RTT at Wintec or parented organisations.

All individuals in either Wintec or parented organisations that use animals for RTT under the approval of a Wintec AEC must comply with this CEC.

All members will be provided with training as per induction.

## 2. Functions, Powers and Membership of the Animal Ethics Committee (AEC)

### 2.1 Functions and Powers of the AEC

Pursuant to section 99 of the Animal Welfare Act 1999 (the Act), and amendments, Wintec will have a single functioning AEC that shall be guided by this CEC.

The AEC shall be established and maintained by Wintec in accordance with the Act, and in consideration of the NAEAC *Good Practice Guide for the Use of Animals in Research, Testing and Teaching*.

The purpose of the AEC is to consider ethical matters pertaining to the manipulation of animals for teaching and research at Wintec, as well as the manipulation of animals by parented organisations.

Responsibilities of the AEC are:

- i. To ensure that the highest ethical standards are observed by all persons associated with it, in relation to the manipulation and use of animals by Wintec or parented organisations.
- ii. To ensure compliance with the Act, and amendments, and all other relevant legislation, by all persons named on approved AEC AUPs, procedures, and associated documents.
- iii. To act in accordance with the NAEAC *Good Practice Guide for the Use of Animals in Research, Testing and Teaching*.
- iv. To respond to, and respect, ethical dimensions of tikanga Māori involving animal use; identifying and responding to key ethical concerns for Māori; and implementing effective and responsive decision-making around Māori ethical issues relating to animal use.
- v. To advise the Code Holder of all matters pertaining to the welfare of animals involved in manipulation within the organisations covered by this CEC
- vi. To promote a culture of care which fosters integrity and accountability of the actions and decisions of all staff, learners, contractors, committee members, and parented organisations.

These responsibilities extend equally to all teaching and manipulation of animals, projects and facilities approved by the AEC.

Section 99 of the Animal Welfare Act 1999 outlines the functions and powers of the AEC:

(1) The functions of an animal ethics committee are:

- (a) to consider and determine on behalf of the code holder applications for the approval of projects:
- (b) to consider and determine, under Section 84(1)(a), applications for the approval of projects:
- (c) to set, vary, and revoke conditions of project approvals:
- (d) to monitor compliance with conditions of project approvals:
- (e) to monitor animal management practices and facilities to ensure compliance with the terms of the code of ethical conduct:
- (f) to consider and determine applications for the renewal of project approvals:
- (g) to suspend or revoke, where necessary, project approvals:
- (h) to recommend to the code holder amendments to the code of ethical conduct.

(2) Each Animal Ethics Committee has such powers as are reasonably necessary to enable it to carry out its functions.

The AEC has the power to inspect animals used in teaching and research including their fitness, welfare, housing, environment, and related experimental records at any time to satisfy itself that approved procedures are being properly carried out. The AEC has the power to direct that any procedure, whether approved or not, be stopped or modified on ethical grounds. The AEC can also direct that animals be properly cared for or, if appropriate, euthanised.

The Ministry of Primary Industries must be notified in writing regarding any parenting arrangements.

Should the AEC be disbanded, all current projects, and any obligations under the CEC relating to those projects will be formally transferred to another organisation with an approved CEC and AEC.

## 2.2 Membership of the AEC

### **Members**

The AEC shall have of a maximum of nine (9) members, including:

### **Statutory Members**

Wintec AEC will include four statutory members, including:

- The code Holder or, if the code holder is an organisation, a senior representative of the company/organisation appointed by the chief executive who is qualified to evaluate applications.
- A veterinarian nominated by the New Zealand Veterinary Association (NZVA) who is not employed by or associated with the code holder.
- A person nominated by an approved animal welfare organisation (the Royal New Zealand Society for the Prevention of Cruelty to Animals (RNZSPCA)), who is not employed by or associated with the code holder or involved in RTT.
- A person nominated by a territorial authority or regional council, not employed by or associated with Wintec, or associated with the scientific community or an animal welfare agency.

## **Organisational/Internal Members**

- I. A senior member of staff capable of evaluating each proposal for a project, the qualifications and skills of the proposer of a project, and the scientific value or the teaching value, as the case may require, of a project.
- II. A person with experience in laboratory animal management.
- III. An animal facility representative who is directly responsible for hands-on animal care. (This may be the Animal Welfare Officer (AWO)).
- IV. A veterinarian who conducts surgery and maintains animal welfare standards.
- V. A person with experience in sheep and cattle husbandry.

Organisational/internal members shall be employees of Wintec, and their selection should reflect the diversity and inclusiveness of Wintec. They will be supported by Wintec to perform their duties in relation to the AEC.

The chairperson will establish an appropriate remuneration system for external members for their time, expenses related to travel, meeting preparation and monitoring activities, subject to Wintec remuneration protocols. This will be reviewed from time to time as required, and in consultation with the committee, and will be documented by the AEC Administrator.

### **Facility Animal Welfare Officer**

At least one AWO shall be appointed by the code holder and shall be a registered veterinarian or registered veterinary nurse/technician/technologist, employed by Wintec, and endorsed by the AEC. The AWO is not an official member of the AEC.

The AWO may be invited to attend AEC meetings to provide animal welfare advice, updates, and reporting as required to the AEC regarding Wintec animal manipulations, animal facilities, animal health, student training, and welfare and advances in relation to the Four Rs.

Parented organisations must meet this same requirement stated above, with an AWO selected and endorsed by their Chief Executive, or equivalent.

### **AEC Administrator**

The AEC shall have an AEC Administrator who shall be appointed by Wintec. The AEC Administrator will organise and attend AEC meetings to provide administrative assistance. Any parented organisation must provide administrative support within their organisation for the efficient and timely management of information through to Wintec's AEC.

The Administrator supports the work of the AEC but does not have full membership and does not contribute to decision-making.

### **Māori Representation**

The work undertaken under this CEC does not routinely necessitate Māori representation on the AEC. However, in line with Wintec Research Ethics Framework, all AUP applications must consider Te Tiriti obligations. If it is found that an issue is of specific interest to Māori, Iwi, Hapu or Whānau, the applicant is required to consider these aspects to ensure they include evidence in the submitted AUP application that Māori perspectives have been identified, responded to, and are not compromised. The Māori Representative is not an official member of the AEC and does not contribute to decision-making.



### *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 AUP or SOP applications, the species of animal or similar situations. Co-opted advisors do not contribute to decision making.

If the co-opted additional expert is a Wintec representative, this will occur as part of their role so no additional remuneration will apply. If the co-opted additional expertise is external to Wintec, they will be remunerated commensurate with their skills and the complexity of the advice sought.

## 2.3 AEC Appointment Procedures

### *Members, Chair/Deputy Chair*

Pursuant to section 101 of the Act, and section 4.11 of the NAEAC: *Good Practice Guide for the Use of Animals in Research, Testing and Teaching*, all members of the AEC shall be appointed by the Code Holder, or their nominee.

In appointing members of the AEC, Wintec, with endorsement of the Chairperson of the AEC shall have regard to:

- i. Their personal attributes; and their ability to contribute to the functions of the AEC.
- ii. At least one statutory member must be appointed based on their capability to evaluate the scientific validity of projects, and in accordance with section 4.11.1 of the NAEAC: *Good Practice Guide for the Use of Animals in Research, Testing and Teaching*.

The Chairperson shall be appointed by the code holder, and subject to the endorsement of the AEC. Where the AEC is being established for the first time, the code holder may appoint the Chairperson without AEC endorsement, so that they may function to assist with operationalising the CEC and establishing the first AEC. This appointed role may serve one term, after which reappointment would require AEC endorsement.

A Deputy Chairperson shall be elected by the AEC members at the start of the term of the CEC and will chair the meeting and perform other chairperson's duties as required should the Chairperson be unavailable for any meeting. They also may serve as Chair if the Chairperson declares a conflict of interest.

Persons not eligible to be an AEC member include anyone who has a conviction against any of the following Acts of Parliament or any replacement, substituted or added Act of Parliament, as specified in section 89(1)(c) of the Animal Welfare Act 1999, including, 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, and The Veterinarians Act 2005.

### *Term of Appointment*

Every member of the AEC shall be appointed for a term of three (3) years. Term limits apply to both organisational and external members.

Upon the completion by any person of three consecutive terms as a member of AEC, that person shall cease to be eligible for reappointment as a member of the AEC until after the lapse of three years during which that person did not hold office as a member of the AEC.

### *Reappointments*

Renewals of the term are possible, but external committee members will need to be re-nominated by the appropriate external body. When members are replaced, every effort shall be made to ensure that the new committee member is a person with suitable knowledge and experience.

### *Vacancies*

If there is a vacancy, the AEC Administrator will initiate the recruitment process for internal and external members.

Vacancies and unexpected/prolonged absences are managed by continued functioning with no less than the relevant quorum. If there are fewer members than the quorum, then the AEC cannot legally fulfil its duties. In such a case, AEC meetings and relevant decisions will need to be postponed until the vacancies are filled, by way of advertising and endorsement by the appropriate authorities.

If a member has protracted inactivity on the committee for two consecutive months that member must resign their position from the committee and a replacement will be proactively recruited. If the replacement is an external member they must be nominated by the appropriate authority.

### *Induction and Training*

It is the responsibility of the Chair to ensure all members of the AEC are fully prepared for their role on the AEC. New members meet with the Chair prior to beginning duties and are given an orientation session on the functions and procedures of the AEC, and the roles performed by the members of the AEC.

The AEC Administrator will inform MPI of any new committee members so they can be registered and be provided with the most up-to-date NAEAC welcome pack.

The AEC Administrator will provide new members with the following for Chairperson induction and new member induction respectively:

The Chair will be provided with:

- List of current committee members, their role and brief bio.
- List of parented organisations, Parenting Agreements, and contact details.
- List of key contacts, including but not limited to, MPI and NAEAC.
- Access to the CEC, Animal Welfare Act 1999 and NAEAC *Good Practice Guide for the use of animal in research, testing and teaching*.
- Copy of the previous two meeting minutes.
- List of current AUPs and SOPs.
- The new Chair may meet with current members, in person or online prior to the first scheduled AEC meeting.
- Physical tour of animal facilities, surgery, and anywhere else relevant to the management and care of animals on the premises, wherever practicable.

New members will be provided with:

- A welcome letter, including contact details for the Chair and AEC Administrator.
- A copy of the minutes of the last meeting, including a summary of active AUPs and SOPs.
- A copy of/access to the current CEC.
- Instructions on how to access the Act, and other relevant legislation.

- An outline of expectations for attendance and engagement with the AEC.
- An introductory list of AEC membership and their respective roles.

Members may be required to attend NAEAC workshops, conferences and/or training courses. Ongoing continuing education shall be facilitated by the distribution of relevant literature. The Chair can also facilitate contact of AEC members with outside experts if requested.

Members must provide a personal profile detailing experience for which a sample format will be supplied.

### **3. AEC Standard Processes**

#### **3.1 General**

##### *Protection of AEC Members*

In accordance with section 104 of the Act regarding the protection of AEC members: no member of an animal ethics committee 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.

##### *Conflict of Interest*

Members of the AEC are expected to perform their duties in good faith, honestly, and impartially, and avoid situations that might compromise their integrity or otherwise lead to conflicts of interest.

At the start of each meeting, AEC members must declare any actual or potential conflict of interest to be recorded in the minutes, which may be audited by accredited reviewers. A conflict of interest is generally accepted to exist when an AEC member's duties or responsibilities to the AEC's entity could be affected by some other interest or duty that the member may have.

The recorded minutes should reflect the expression of a specific conflict of interest, what it is in relation to, and how the conflict is being handled. Actions in response to the conflict of interest depend on the individual case, and may include:

- i. The conflicted member participates in discussion but not in any contribution to decision-making; or
- ii. The conflicted member responds to questions but does not participate in the discussion or decision.
- iii. The conflicted member withdraws from all discussions and deliberations, and is usually asked to leave the meeting, particularly when decisions are made.

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

##### *Confidentiality*

AEC meetings will be subject to the requirements of the Local Government Official Information and Meetings Act 1987. A Wintec designated officer will deal with any requests under the Official Information Act in consultation with the Chairperson and any persons who may be involved.

All information pertaining to minutes of proceedings, project applications, committee decisions, operations and records is to be stored and maintained satisfactorily for not less than 7 years. Access to this information will only be with the approval of the Chairperson or the CE.

AEC members are required to sign a Wintec confidentiality agreement at the time of their appointment to the AEC and must treat all information submitted to the AEC, and any related documentation and correspondence, as confidential. Members are expected to keep all documents. (either electronic or hardcopy) in a secure place. Documentation held by members of the AEC shall be returned when no longer required and destroyed by the AEC Administrator. No documentation shall be released unless approved by the Chairperson.

### 3.2 Meeting Procedures

#### *Scope of AEC Meeting*

The following items will be covered during each AEC meeting:

##### Standing agenda items

- Opening Karakia
- Mihi (Welcome)
- Introduction of new attendees
- Attendees and apologies
- Confirmed quorum
- Declaration of actual or potential conflicts of interest
- Review of minutes of the previous meeting
- Matters arising and Action List from the previous meeting
- Confirmation of date of the next meeting

##### For review

- Research - New applications (including linked approvals (e.g., ACVM, DOC))
- Research - Amendments to approved applications
- Research - Interim & final project reports
- SOPs and AUPs
- Ratifications
- Adverse events
- Non-compliances
- Monitoring reports
- Complaints
- General Business
- Correspondence
- Closing Karakia

##### End of Year Meetings

- End of Year teaching reports
- Animal Use Statistics

Completed meeting minutes will be checked with the Chairperson and made available to the AEC at the next meeting. Meeting minutes are forwarded to the Wintec Komiti Akoranga/Academic Committee or equivalent thereof. Meeting minutes shall be retained for no less than 7 years.

### *Frequency of Meetings*

The AEC will meet at least twice a year and on additional occasions when required to enable it to fully carry out its responsibilities including reviewing teaching and research AUP and SOP applications.

A schedule of meetings will be approved by the AEC. Notice of planned meeting times, dates, and places will be provided to all AEC members in writing at least two weeks prior to the first meeting of each year. There is provision for out of schedule meetings to be called by the AEC Chairperson when required. A minimum of two weeks' notice of such meetings will be given to all members. The minimum notice period for providing information ahead of any extra meetings is two weeks.

### *Circulation of Meeting Papers*

Meetings will be organised by the AEC Administrator who sets and distributes the AEC agenda, AUP and SOP applications, and all other appropriate information by email to AEC members at least two weeks prior to the meeting. If AUP or SOP applications are not received on time they will not be accepted as agenda items for the meeting. The AEC Administrator will record the meeting minutes and distribute minutes to members for approval.

Procedures are the same for internal applicants and parented organisations.

### *Quorum*

A quorum will be achieved through attendance of 50% +1 members including two external statutory members. Meetings may not proceed without a quorum. It is not appropriate for the committee to make decisions with half or more of the committee absent.

### *Decision Making*

Decisions will be made by consensus after all AEC members present have had the opportunity to express their views.

With AUP applications, appointed members will discuss the matter and a consensus needs to be reached. Discussion is revised until all members are satisfied. If consensus cannot be reached, the default should be to reject the AUP application.

All decisions will be recorded in the minutes and the applicant advised of the outcome in writing with the reasons for any rejection clearly outlined. The applicant can seek guidance from the AEC Chair regarding the AEC concerns and recommendations. If the outlined issues are addressed, then the AUP can be resubmitted.

Decisions made between meetings will be communicated via email to AEC members and the applicant and ratified at the next formal meeting.

All decisions regarding AUPs will be recorded in the AEC correspondence to be presented at the end of year AEC meeting, as well as being recorded at the end of the related AUP.

### *Effective Input of Committee Members*

To ensure effective input, all members will have equal opportunity to contribute to the business of the meeting. Members will have access to applicants involved in the manipulation of animals so that they can obtain information and answers to questions they have regarding the AUP application. The views of external members should be sought in each case, and fully considered. External members will be provided with support from the AEC Administrator including the NAEAC induction pack and monitoring guidelines. External members are provided with support to fully participate in the work of the AEC

(they are heard, and their views are considered). The Chairperson has the right to ask visitors to leave the meeting at any time. All members will otherwise have normal speaking rights.

### *Online Meetings*

#### *Use of Audio/Video Conferencing*

While the AEC prefers face-to-face meetings, it recognises that with adequate software, videoconferences can be considered the equivalent of face-to-face meetings. For any meeting format, all meeting procedures must be adhered to, and a quorum must be reached for the meeting to proceed.

Online meetings will adhere to the following practices:

- All normal meeting procedures and quorum requirements will be adhered to
- The Chair will take particular care to ensure active participation of all members
- Cameras will be turned on, to allow better communication between members.

### *Establishment and Membership of Sub-Committees*

Subcommittees may be established by the AEC to bring in external expertise, improve effectiveness of operational processes, and ensure efficiency of the AEC processes.

The process for establishing subcommittees includes endorsement by consensus of the AEC, establishment of an outline for the terms of reference of the subcommittee listing the purpose, chair and membership, meeting schedule, level of administrative support, conditions of work, and dispute resolution processes. Sub-committees will include at least two statutory external members and decisions made will be ratified at the next full AEC meeting. Sub-committees may be disestablished, or members added/removed at any time by consensus of the AEC.

### *Meeting Attendance by Other Parties*

**Public Presence:** Meetings will not be open to the public and are invitation only. 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.

### **Applicant Presence at Meetings**

The AEC may invite applicants to be present at the meeting in support of their AUP application and to answer any questions the AEC may have. This may consist of a face-to-face meeting, a web conference, or a phone call, and it may be scheduled, or unscheduled. 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 AUP and answer questions from the AEC, which will be at the discretion of the Chairperson. In all cases, applicant or project personnel must not be present in any capacity during AEC deliberations on the project.

### **3.3 Consideration Between Meetings**

The AEC may give consideration between meetings to urgent AUP applications for A and B gradings or for simple proposals involving minimal animal welfare concerns. This may be by email collaboration or an extra meeting. The written request, with associated supporting documents, will be made available to all AEC members at least ten days prior to discussion. Feedback and revisions will then be circulated to AEC members, and if a consensus can be reached, the AUP application will be tentatively approved

as an Interim Decision, allowing work to commence, and will be ratified at the next face-to-face meeting.

Urgent AUP applications received with C or higher gradings trigger an out of sequence meeting to be held within the following month to ensure they are dealt with in line with the applicant's required timeframe.

### 3.4 Secretarial Support

In addition to AEC members, an administrator with appropriate skills shall be appointed by the Chair and endorsed by the AEC for the purpose of overseeing administration matters of the AEC. The AEC Administrator will attend all meetings and does not form part of the decision-making processes of the AEC.

Duties of the AEC Administrator include:

- i. Organising meetings, including preparing videoconference links, agendas, and memos; distributing materials; taking meeting minutes; coordinating subcommittee meetings.
- ii. Maintaining secure records of agendas, minutes, decisions, correspondence with investigators, site visit reports, AUP and SOP application forms and all other relevant documentation.
- iii. Recording correspondence (and forwarding to members if relevant).
- iv. Collating animal use data and forwarding statistics on animal use to the Ministry for Primary Industries each year.
- v. Notifying AUP holders if their AUPs or SOPs are coming up for renewal.

### 3.5 Record Keeping Requirements

#### *Information Management*

AEC documentation shall be maintained in order to meet the requirements of the Animal Welfare (Records & Statistics) Regulations 1999. All sensitive information pertaining to minutes of proceedings, project applications, committee decisions, operations and records is stored in Wintec's secure database, accessible by AEC members only. Approved AUPs, SOPs, the CEC and other approved documents will be accessible to select Wintec staff or other people that require access to fulfil their duty of care. Historical paper records are to be stored in a locked archive room and maintained for not less than 7 years, and access will require approval from the Chairperson or the Executive Director/Chief Executive. Destruction after 7 years will be through a secure document destruction and recycling company.

#### *Animal Use Statistics*

Animal use statistics will be recorded by AUP holders, including those within parented organisations, and data from Animal Use forms will be collated by the AEC Administrator at the end of every year.

The AEC Administrator will submit animal use statistics for Wintec RTT to MPI annually by 28th February, as per legislative requirements.

Parented organisations provide their own animal use statistics to the Ministry for Primary Industries unless they have an arrangement for the Code Holder to provide them.

Parented organisations will be made aware of the requirements set out under the Animal Welfare (Records and Statistics) Regulations 1999 to keep 'readily accessible' records regarding animals used in research, testing and teaching.

Annual returns to MPI must include:

- i. Detail of records kept for every AUP ending in the calendar year. For AUPs extending past three years, details of records kept must be submitted in the year following every third year of the project, or in the year following the year that the project ends - whichever is soonest.
- ii. If no animals have been manipulated or no projects have ended in the preceding year, a nil return must be submitted.

#### **4. AEC Technical Processes**

##### **4.1 Consideration of Applications by the AEC**

###### *Criteria for Consideration*

To help ensure compliance with the Act and NAEAC recommendations, applications for AUPs must be presented on the AUP application. It is acknowledged that not all categories in the template will be applicable for all AUPs. The AEC may implement a pre-screening process. Pre-screening will be completed by an AEC member experienced in the assessing of AUP applications, to ensure AUP applications contain all required information prior to consideration at a formal meeting.

###### **Criteria for Consideration**

Pursuant to section 100 of the Act, the AEC must consider specific criteria as outlined below.

- i. The Three Rs as outlined in section 1.3 of this CEC.
- ii. Scientific or education objectives of the project.
- iii. The means by which harm or distress related to the manipulation is alleviated and risks of adverse events are identified and eliminated or managed to significantly minimise risks of adverse events occurring.
- iv. The adequacy of proposed animal handling, husbandry, and health care measures.
- v. Whether the expected use and benefits outweigh the impact on the animals, and the likelihood that the use benefits will be realised.
- vi. The reasons for selecting the proposed animal species, and whether animals will be used repeatedly.
- vii. The biostatistical justification of proposed numbers to be used; or for teaching basic animal handling, whether there are enough animals for appropriate animal to student ratios, to reduce stress on individual animals.
- viii. The qualifications and experience of personnel involved in the proposed use.
- ix. Whether duplication of an experiment is proposed, and, whether it still meets conditions under section 100 of the Act.
- x. Whether findings will be adequately used, promoted, or published.
- xi. That the applicant has rightful ownership/guardianship of the animals or has obtained approval from the animal supplier.
- xii. Any other matters that the AEC considers relevant, including required approvals like ACVM, DOC.

Consideration is given to 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 have impact on the welfare of the animals under their care.

A short report will be required at the end of each year to confirm the conditions of approval have been met, and to record any incidents. A standard end of year report template will be provided for



these purposes. Any incidents that occur with an adverse effect on an animal's welfare shall be promptly reported to the AEC in the form of an Unexpected Adverse Event (UAE) report.

### *Impact Grading*

All AUPs submitted to the AEC will be assessed for impact grading of manipulations guided by the Animal Use Statistics documents issued by MPI.

The impact grading of a project will be assigned by the applicant prior to the meeting, and at the amendment of a project if changes are required. Researchers, educators, and AECs should use their knowledge and judgement in determining the impact of procedures on animals. The AEC may adjust the grading at the time of approval, after the work has started, or when the actual impact on the animals has been evaluated via the monitoring report or on the animal statistics form.

### *Outcomes after Consideration*

Possible AEC outcomes of AUP application review:

- Approved
- Approved with amendments or conditions
- Returned to the applicant for revision
- Declined.
  
- **Approved**  
Proposals that have been approved will be numbered and approved for the timeframe agreed by the AEC. The Chairperson, applicant and other personnel must sign and date the AUP. Research cannot commence until after the document has all required signatures and been returned to the AEC Administrator. An email to the AUP holder confirming all these have been met, and with the completed AUP attached, will thereby confirm start date.
  
- **Approved with Amendments or Conditions**  
Proposals that have been *approved with amendments* require changes to be made to the AUP before they can be fully approved. Work may not commence until the amendments have been approved. The amendments must be submitted to the AEC in writing within two weeks of receipt of the approval notification. Proposed amendments will be written into the AUP before it is numbered and signed, as above.
  
- **Revision Required**  
Proposals where revision is required are prohibited from commencing work as the AUP requires revision and resubmission to the AEC for review.
  
- **Declined**  
Proposals that are declined are prohibited from commencing work under that AUP in any capacity.

All decisions will be notified in writing or emailed to the AUP applicant. If approved, the work may commence once the AUP has been signed by the AEC Chair, AUP applicant and other listed personnel, dated and numbered. Notification will include the start and end date.

### *Conditions of Approval*

The AEC (or nominated subcommittees, as appropriate) will discuss all AUP applications to make decisions regarding 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 justification for the use of animals, appropriate impact grading, and specifications for monitoring and reporting

On approval of an AUP, an inspection may be undertaken by a veterinarian (not the AUP holder) to ensure that facilities comply with minimum standards and legislative requirements for both animals, including daily care of animals, and personnel.

The AEC will ensure that for all AUP approvals all conditions have been met, including for specific manipulations.

### *Maximum Approval Period*

The AEC will require a definite endpoint, by way of an expiry date, for all AUP approvals. When the expiry date for an approval is reached, all animal manipulations must stop.

The maximum approval period for an AUP application is three years. If an applicant wishes to continue with the project beyond the three-year period, a new application must be submitted. Extensions, if required, must be resubmitted 30 working days before the approval is due to expire. Extensions do not exceed the three-year timeframe.

Where AUPs extend beyond one year, the principal investigator (PI) for the AUP must submit an annual interim compliance report as per section 5.1.

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

The AEC has the power to suspend or revoke approvals or set, vary, or revoke conditions of project approval. This includes new information provided to the AEC, or as a result of the AEC's monitoring of the AUP, or where the AEC has concerns about the welfare of animals being used, failure to meet reporting requirements or any other aspect considered to be of concern by the AEC Chairperson.

In the case of imminent danger to the welfare of the animal, any AEC member, staff veterinarian, veterinary nurse/technician, or teacher may halt a procedural manipulation while seeking further advice from the AEC Chairperson. Any of these people may also report directly to the AEC if there is danger to animal welfare.

The Chairperson will determine what immediate action is required, including immediate revocation, in accordance with the Act. The AEC will be informed of any such action as soon as practicable. At the next meeting, the AEC may decide to revoke or vary the approval. If a decision is required sooner, the Chair may call an out-of-schedule meeting of the AEC, or, details may be circulated by email to all members of the AEC for feedback and confirmation of outcome. Revocation, suspension, or variation of an approved AUP will be notified in writing to the applicant, applicant's manager and DCE responsible for research and teaching, or their delegate, with the decision and reasons clearly outlined. The AEC may notify MPI depending on the severity of the situation.

### *Amendments to Approved AUPs*

After approval, any amendments to AUPs will require submission on the Wintec Amendments to AUP Request form along with the original Application for Use of Animals in Research, Testing, and Teaching with the proposed amendments included. Amendment applications are considered at a scheduled AEC meeting, or, if a decision is required sooner, the application may be circulated by email to all members of the AEC for feedback and approval.

There are two categories of amendments, major amendments, and minor amendments, as detailed below.

**Minor Amendments** – An amendment to an existing approved AUP is considered minor if all the following criteria are met:

- i. The original AUP contains impact grade A or B manipulations.
- ii. There is no proposed change to the impact grading (as defined in section 4.2).
- iii. There is no proposed change to the approved study design.
- iv. Proposed increases to animal numbers are no more than 10% greater than the original number from the original approved AUP.
- v. Proposed decreases to animal numbers clearly demonstrate the number of animals being used is the minimum necessary to retain the statistical validity of the original approved AUP.
- vi. There is a low residual risk of adverse welfare outcomes for the animals.
- vii. Additional staff and students are required to be added to an existing AUP.
- viii. Time extension requests are within 3 years from start of the original approval.

Minor amendments approved by the AEC will be then adopted, signed and dated by the Chair and the applicant and given a version number. A copy will be sent to the applicant and held on AEC file. It will be active from the date signed. It will be ratified at the following AEC meeting with a record of AEC feedback and approval.

**Major Amendments** – An amendment to an existing AUP is considered major if any of the following criteria are met:

- i. The original AUP contains impact grade C-E manipulations.
- ii. There is a proposed increase or decrease in the impact grading (as defined in section 4.1).
- iii. There is a proposed change to the previously approved study design.
- ix. There is a proposed increase in animal numbers over 10% of the original number from the original approved AUP.
- x. Proposed decreases to animal numbers fail to demonstrate the number of animals being used is the minimum necessary to retain the statistical validity of the original approved AUP.
- iv. There are potential risks of adverse welfare outcomes for animals.
- v. There is a change of project lead.

Minor amendments to existing AUP may be considered between meetings.

Major amendments require automatic consideration at the next AEC meeting. If there is an urgent request for an amendment, a special meeting may be called by the AEC Chair.

### 4.2 Standard Operating Procedures considered by the AEC

The AEC may review/approve SOPs for animal husbandry practices or routine procedures that relate to the manipulation of animals in RTT. The appropriate Code of Welfare and the *NAEAC Good Practice Guide for the Use of Animals in Research, Testing and Teaching* will be used as a standard reference when developing and reviewing SOPs.

All new SOPs must be brought to the next AEC meeting for consideration and to register formal review/approval.

#### **Development of SOPs**

All SOPs must 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 for review/approval.

#### **SOP Approval and Amendment Process**

Applications for review/approval of SOPs are submitted for approval at any time. Any minor interim amendments must be approved by the AEC using an *Amendments to Approved AUP or SOP* form. Any more than minor, and interim changes to the SOP will need to be resubmitted in full, with word document track changes visible.

#### **Periodic review of SOPs**

Periodic review, and re-approval of SOPs is required, to allow review and incorporation of improvements. This shall occur at 3-year intervals; however, in rapidly evolving areas, or with SOPs that have a very high ethical cost, more frequent review is appropriate.

#### **4.3 Amend, Suspend or Revoke the CEC**

(1) Every Code Holder may apply to the Director-General for their approval to the amendment, suspension, or revocation of the approval of the code of ethical conduct in respect of which the code holder holds the Director-General's approval.

(2) Every such application must be in writing and must state the reason why the code of ethical conduct should be amended, suspended, or revoked.

(3) The Director-General must refer to the National Animal Ethics Advisory Committee for its comments every application made under subsection (1) for their approval to the amendment of a code of ethical conduct and must consult with that Committee with regard to every such application.

(4) Despite subsections (1) to (3), nothing in this section prevents a code holder from making minor amendments to a code of ethical conduct (being minor amendments that would not materially affect the purposes of the code) without the approval of the Director-General.

(5) Where, in any year ending with 31 December, a code holder makes minor amendments to a code of ethical conduct, that code holder must, as soon as practicable after the end of that year but not later than 31 March in the succeeding year, give to the Director-General in writing particulars of those minor amendments.

#### **Process to Amend the CEC**

The AEC may recommend to the code holder that the CEC be amended. Where the code holder agrees to the amendment, after sufficient consultation with stakeholders including staff, students, and parented organisations, then minor amendments will be notified in writing to the Director-General of MPI and must state the reason the code of ethical conduct should be amended. Any amendments which are not minor must be approved by the Director-General of MPI. Any changes to the CEC will be communicated directly to parented organisations as well as to staff and students and the amended CEC will be appended to the Wintec website.

## 5.0 Monitoring by the AEC

Pursuant to section 99 of the Act, the AEC has the authority and responsibility to carry out regular monitoring of activities related to approved AUPs and SOPs, including reviewing and overseeing animal management practices and facilities to ensure compliance with the terms of this CEC.

Monitoring of the activities of applicants, the facilities for housing animals, animal health and welfare and proper documentation, particularly in relation to observing the conditions of project approvals, will be carried out following the recommendations in the *NAEAC Good Practice Guide for the Use of Animals in Research, Testing and Teaching*.

Monitoring activities may include:

- i. Inspection of animal health, and welfare.
- ii. Inspection of animal facilities.
- iii. Observing procedures when/where applicable.
- iv. Inspection of experimental records and documentation to ensure that procedures are being properly carried out as approved.
- v. Reporting compliance reviews to ensure proper reporting is being carried out by approval holders.

Monitoring visits may be carried out by:

- i. The Animal Welfare Officer (AWO).
- ii. The staff veterinarian, veterinary nurse, or animal welfare expert.
- iii. The veterinarian (external statutory member of the AEC who is nominated by the New Zealand Veterinary Association).
- iv. Any member of the AEC has authority to carry out annual inspections as a core activity of the AEC.
- v. Any member of the AEC who happens to be visiting animal facilities and observes animal practices as an unintended consequence of their primary activity.

Record keeping for monitoring includes:

- i. A Monitoring Report template must be filled out for every planned monitoring visit.
- ii. The completed Monitoring Report must be sent to the AEC no later than 30 calendar days after the monitoring visit has been completed.
- iii. All monitoring reports and notes will be included as agenda items for the AEC meeting. Upon receipt of any additional information, the AEC may rescind its approval of a project or request the approval holder attend an AEC meeting to explain the manipulation in more detail and answer questions.

The monitoring of Wintec and parented animal facilities, manipulations, and approval holders will be carried out at least annually. For distant locations, monitoring will be carried out by a registered veterinarian nominated by the AEC external veterinarian. The external veterinarian or nominated person will be provided with a Monitoring Template and a copy of the relative AUP. Monitoring reports will be sent to the AEC Administrator for recording purposes and presented by the monitor at the next AEC meeting.

Monitoring responsibilities apply equally to any parented organisations and approvals. When animal manipulations are undertaken at a parented organisation or remote site where access is difficult, monitoring of animals is the responsibility of the staff in liaison with the veterinarian or Primary Investigator (PI) nominated as supervising the project. In these situations, the AEC may request additional reporting requirements (e.g., Interim Reports) to the approval holder, and request monitoring visits be carried out by an independent veterinarian approved by the AEC. Monitoring visits may be carried out by the AEC itself or with remote monitoring (via camera).

## 5.1 Monitoring during the Approval Period

Ongoing monitoring during the approval period shall be completed by the approval holder and sufficient records kept. In addition, approval holders must report annually as per section 4.1/6.1. Records may be audited at any time by any authorised AEC member. The AEC may conduct a monitoring visit at any time and without notice.

### **Scheduled visits**

Monitoring shall be completed by AEC members or a delegated Wintec monitor with related qualifications, knowledge and experience, that visit each animal facility every year. These visits shall be scheduled, and the purpose and scope made clear.

### **Non-scheduled visits**

Non-scheduled monitoring visits shall be considered where the AEC holds unresolved concerns over the conduct of any RTT activities.

### **Frequency of Monitoring**

Annual monitoring of internal and parented organisations shall be carried out for facilities and manipulations related to approved AUPs including the following:

Any member of the AEC can undertake monitoring (not only external members), provided that any conflicts of interest are appropriately managed.

- i. A Reporting Compliance Checklist must be carried out by the AEC annually for every AUP, verifying all reporting obligations have been met.
- ii. Every animal facility must be monitored annually to ensure compliance with the CEC and AUP.

## 5.2 Monitoring by Proxy

Monitoring by proxy may be undertaken in exceptional circumstances but the AEC should conduct most monitoring activities as it is a core function of the AEC.

To assist the AEC to meet the required monitoring frequency, and where the timing or geographic location make monitoring difficult, the AEC may contract an independent veterinarian or other suitable veterinary or animal welfare professional to perform the monitoring visit. As representatives of the AEC, contracted personnel have the same authority as AEC members. The monitoring veterinarian will be supplied with the relevant AUP, SOPs, other relevant documentation, and a monitoring form. They will be either given access to complete the monitoring report online or submit a hard copy to the AEC to be included as agenda items for the AEC meeting.

## 5.3 Monitoring across Impact Grades

### **Monitoring of Manipulations Grade A & B**

Monitoring will be carried out annually by AEC members (not the approval holder) for at least 10% of AUPs impact graded A or B. Monitoring reports are provided to the AEC for review and acceptance.

### **Monitoring of Manipulations Grade C-E**

All grade C impact manipulations (includes manipulations of minor impact and long duration or moderate impact and short duration) to grade E manipulations (manipulations of high impact and long duration), will be monitored annually by an AEC appointed registered veterinarian. Monitoring reports are provided to the AEC for review and acceptance.

## 5.4 Monitoring Specific Manipulations

The AEC may request to observe specific activities or manipulations carried out as part of an approved amendment, either as a condition of approval, or as part of its routine monitoring. Where a technique is new or particularly invasive, the AEC may request the manipulation be trialed first as a pilot study before incorporation into a larger AUP.

Monitoring of specific manipulations is carried out as explained in other sections above, and as frequently as deemed necessary by the AEC according to legislative requirements.

## 5.5 Monitoring Animal Facilities

All animal facilities for approved projects, manipulations, and handling/teaching will be monitored annually, for all grades. See section 7 of the NAEAC *Good Practice Guide for the Use of Animals in Research, Testing and Teaching* for more about monitoring across impact grades. Animal facility monitoring will follow the procedures outlined in approved SOPs that include the following conditions:

- i. All Wintec animal facilities are regularly audited by an external AEC member to ensure that facilities comply with minimum standards and legislative requirements for both animals, including daily care of animals, and personnel. An external AEC member will undertake a minimum of one visit per year to inspect each animal facility with approved AUPs or SOPs, as well as manipulations and animals. The AEC member shall arrange visits to inspect animals and facilities. These visits may be undertaken with minimal notice or by prior arrangement. The AEC will receive and retain animal facility audit reports appropriate to sites under their jurisdiction and will accept these as independent monitoring reports.
- ii. Facilities of parented organisations that have an approved, current project will be inspected by an AEC member, or delegated authority, at least once per year.
- iii. All facility audit reports will be viewed by the facility managers, the code holder (or delegate) and the AEC. Corrective actions will be monitored, with minimal notice, until a satisfactory outcome is achieved.
- iv. Non-scheduled visits by an AEC member may also be carried out at the discretion of the AEC.

## 6. Responsibilities of organisations/individuals with AEC Approved Applications

### 6.1 Reporting to the AEC

#### *Project Reports*

To help the AEC fulfil its monitoring obligations under the Act, a short report will be required at the end of each teaching, testing, or research AUP to confirm that conditions of approval have been met.

Final reports will be presented to the AEC using a format that focuses on study achievement and animal welfare considerations. It must be sent to the AEC Chair within three months of the project being completed. The report should include:

- i. Manipulations carried out and the actual impact grade resulting.
- ii. Amendments approved.
- iii. Numbers of animals manipulated and an explanation if the number differs from the approved AUP.

- iv. Non-compliances occurring.
- v. Adverse events.
- vi. A discussion on how the Four Rs, as outlined in section 1.3 were applied, including how improvements could be made to respect, reduce, replace, or refine animal use in future projects/teaching.
- vii. Other learnings or changes the approval holder would make on future applications including what worked well/didn't work well that could be used to inform future animal manipulations.
- viii. For research/testing projects, a discussion about the outcomes/findings of the work and whether future ongoing work is planned.
- ix. Any additional requests, with justifications and outcomes.

The report must be formally accepted by the AEC before a project is closed. Study completion and reporting details will be entered into records maintained by the Chairperson. Final reports must be reviewed by the AEC before applications for continuation of such work under an existing approved AUP will be considered.

#### *End of Approval Grading & Animal Use Statistics*

The AEC will be informed of the impact gradings at the completion of the project. This information will enable the AEC to compare the actual gradings from the manipulations performed against those proposed in the initial AUP application. The AEC may change the impact grading. This information will be supplied at the first AEC meeting after the completion of a project.

To assess appropriateness of impact grading, the AEC will require annual reports for teaching AUPs, and annual interim reports for research/testing based AUPs, which will include adverse events (as outlined in section 5.5) and untoward occurrences which will already have been notified to the AEC as they occur. Monitoring reports received from AEC members will also provide feedback on the appropriateness of the AUP grading.

As part of the final report, AUP holders are responsible for reporting animal use statistics for completed projects to the AEC prior to 28<sup>th</sup> February for the previous calendar year (under the Animal Welfare (Records & Statistics) Regulations 1999. The AUP final report must contain details of the species used during the approval period of the AUP, including any additional requests, with justifications and outcomes. The AEC is responsible for the reporting of Wintec animal use numbers to the MPI.

Parented organisations are responsible for submitting their own animal use returns to MPI (unless they have a specific arrangement for the code holder to submit them on their behalf). The code holder will support parented organisations to ensure they submit their animal use statistics to MPI on time.

Annual reports will be reviewed by the AEC to ensure conditions have been met.

#### *Non-Compliance*

The AEC is responsible for monitoring compliance of all approved AUPs, procedures, and animal facilities. Compliance breaches are notified to the AEC within 5 days. Anyone can report a non-compliance.

#### *Adverse Events*



Adverse Events (AEs) are unanticipated or atypical incidents that occur to an animal because of a planned manipulation, routine husbandry, or diseases. In all cases where an AE occurs, it is the approval holder's responsibility to establish and implement a management plan, as required, to minimise the effects on animals. All Adverse Events must be evaluated, and a plan put in place to eliminate risk of recurrence. Details of the evaluation, and elimination plans must be submitted with the Adverse Event report. Anticipating potential adverse events and eliminating/managing risks of adverse welfare outcomes must be part of every AUP application, as per section 4.1.

All Adverse Events must be reported to the AEC and handled as follows:

#### **Minor Events**

Minor events are those typically related to non-urgent issues with housing, nutrition, or husbandry of animals on an approved AUP. These must be addressed appropriately to minimise the likelihood for animal distress or ill health. An Adverse Event Report must be completed immediately and reviewed by the staff veterinarian within 7 working days of being reported. Appropriate actions in response to the event are recorded on the form and the form is filed with the AEC within 30 days of being reported.

#### **Major Events**

Major events are those related to injury or illness of animals on an approved AUP. These must be reported to the staff veterinarian immediately and appropriate actions taken, including communication with the AEC Chair. An Adverse Event Report must be completed immediately and appropriate actions in response to the event are recorded by the staff veterinarian and the form is submitted to the AEC within 7 working days of being reported.

#### **AEC Response to Major Events**

Any major event must be reported to the AEC within 7 days of being reported. The Chairperson, or nominated representative will determine what, if any, additional action is required, in accordance with the Act. Depending on the severity of the event, additional observations, review of procedure, or pause/termination of the project may be considered. The adverse event will be discussed at the next AEC meeting to determine if procedures are needed to prevent similar events from happening in future, and if required a management plan will be put in place and recorded in the minutes. The AEC may notify MPI depending on the situation.

### **6.2 Records Management**

Records are to be maintained by holders of approved AUPs and SOPs or by Facility Managers on behalf of the holders, to include data as per the NAEAC *Good Practice Guide for the use of animals in research, testing, and teaching*. Records will readily accessible, collected annually, and reported to the AEC each year.

Records 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
- amendments that were approved during the project
- non-compliances
- adverse events
- staff training records
- veterinary consultation and treatment; and

- project results.

### 6.3 Appropriate Qualifications

The Act requires that RTT will be undertaken only by suitably qualified and trained persons who have experience with the species and manipulations included in the application. Every application must clearly identify the persons primarily engaged in carrying out the animal manipulation, including details of the qualifications and experience of personnel involved in the proposed use. All personnel responsible for the manipulations must understand their obligations as outlined in their application and acknowledge this by signing the application (digital signatures are acceptable).

Approval holders are responsible for ensuring that all personnel involved in the proposal and the care of animals are aware of their obligations under the CEC. The AEC will specify any required training and the timeframes for completion of training, evidence of which will be provided to the AEC.

### 6.4 Sick and Injured Animals

Animals used in an AEC approved AUP must receive responsive and thorough care if they are sick or injured. Detailed record-keeping and reporting must take place as outlined below. Reports of sick and injured animals are sent to and retained by the principal researcher/approval holder and facility manager. These will be included in the annual and interim compliance reporting.

The AEC requires animal users to keep records of animal health and adverse events. The AEC reserves the right to review these records at any time.

Each AUP and animal facility must have an approved SOP or process for reporting and treatment of sick (ill, injured, distressed) animals and must include the following points:

- i. Facility managers, staff, or students under staff supervision, shall monitor all animals covered under SOPs and AUPs daily (including weekends and holidays).
- ii. Veterinary assistance and advice shall be available 24 hours per day, seven days per week.
- iii. Sick and injured animals must receive prompt and appropriate care by a veterinarian, or designated person under supervision by a veterinarian.
- iv. Response to, and management of sick/injured animals must be humane and hygienic and in accordance with regulatory and legislative requirements.
- v. Veterinary staff, or any of the AEC, shall 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, and associated managers as appropriate.
- vi. Adverse events (such as illness, injury, or death) must be addressed as outlined in the section for Adverse Events.

### **Euthanasia**

Euthanasia of any animal must follow the current approved Euthanasia SOP, guided by the NAEAC *Good Practice Guide for the use of animals in research, testing, and teaching*, and must be referenced to the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals for informing appropriate methods of euthanasia. Euthanasia for tissue collection for the purpose of research, testing, or teaching is only permitted if it is covered by an approved AUP.

It is acknowledged that the Four Rs, as in section 1.3 welfare extends into death, as in te ao Māori when an animal dies, parts of its body may be seen to have mana or mauri of their own. Under this principle, respect and manaakitanga for animals shall extend into death.

Each animal facility will ensure prompt and sanitary disposal of animal carcasses and waste material in accordance with Hazardous Substances and New Organisms (HSNO) and Environmental Protection Agency legislation, local council bylaws, and community standards.

#### 6.5 Standard Operating Procedures developed by the Code Holder

##### **Development of SOP for RTT**

All SOPs must be developed by the end user institution in consultation with the relevant affected parties, peer reviewed by an individual(s) with expertise in the procedure and submitted to the AEC for review/approval.

##### **Development of SOPs for facility management**

The AEC exercises oversight of the operation of SOPs relating to the care and use of animals maintained in Wintec animal facilities. SOPs will be developed in consultation with the AEC. SOPs must be reviewed and approved by the responsible AWO prior to submitting to the AEC for review/approval.

##### **Proxy Monitoring**

Monitoring by proxy may be undertaken in exceptional circumstances but the AEC should conduct most monitoring activities as it is a core function of the AEC.

To assist the AEC to meet the required monitoring frequency, and where the timing or geographic location make monitoring difficult, the AEC may contract an independent veterinarian or other suitable veterinary or animal welfare professional to perform the monitoring visit. As representatives of the AEC, contracted personnel have the same authority as AEC members. The monitoring veterinarian will be supplied with the relevant AUP, SOPs, other relevant documentation, and a monitoring form. They will be either given access to complete the monitoring report online or submit it hardcopy to the AEC to be included as agenda items for the AEC meeting.

#### 6.6 Management of Animal Facilities

All animal facilities and practices shall be with reference to good practice and scientific knowledge as recommended by the current version of the NAEAC *Good Practice Guide for the Use of Animals in Research, Testing and Teaching* and to the relevant codes of welfare issued under section 75 of the Act, and amendments.

##### *Policies & Procedures*

Animal facilities shall be managed in accordance with SOPs which have been written with regards to monitoring by external AEC members; staff monitoring during routine activities; newly identified hazards to animals and monitoring of known hazards.

The facility and animal management practices shall be designed to ensure the physical and mental health, as well as species specific behavioural needs of animals are met including:

- i. Provision of appropriate and sufficient food and water.
- ii. Provision of adequate and appropriate housing including shade and shelter.
- iii. Opportunity to display normal patterns of behaviour related to positive welfare.
- iv. Physical handling in a manner which does no harm and minimises the likelihood of any unreasonable or unnecessary pain or distress.
- v. Prevention of, protection from, rapid diagnosis of, and treatment of any significant injury or disease.

These needs will be met in a manner that is appropriate to each species of animal kept at the facility, recognising the environment and circumstances required for research or teaching. The aim for Wintec animal facilities and animal management staff, will be to ensure that animals have the opportunity to live a good life, by taking account of the latest research regarding best practice animal handling and facility design, and looking for opportunities to improve animal welfare.

### *Emergency Management*

In the event of an emergency, the Wintec facility Animal Care Programme Co-ordinator or equivalent will be responsible for activating the Wintec Animal Emergency Plan, ensuring animals housed at Wintec are well cared for during the emergency, including critical staff shortages.

### *Housing of Animals*

Animal housing and husbandry will follow the procedures outlined in approved AUPs and SOPs and following guidance in the NAEAC *Good practice Guide for the use of animals in research, testing, and teaching*. Sufficient living space must be allocated, and environmental conditions must be consistent with the needs of the species concerned. Unless otherwise covered by an approved AUP, animals will receive free access to water and adequate food to meet their nutritional requirements, and ways of enriching the environment of captive animals must be utilised.

An approved, competent person with delegated authority must visually inspect all animals held in institutional facilities at least daily.

### *Transportation of Animals*

Collection and transport of animals will be humane and hygienic and in accordance with regulatory and legislative requirements, including the Code of Welfare Transport of Animals within New Zealand and Codes of Welfare for the individual species, and following procedures outlined in approved AUPs and SOPs, and following guidance in the NAEAC *Good practice Guide for the use of animals in research, testing, and teaching*. This is to ensure that the animals' health is safeguarded, and that undue stress is avoided. All adverse events shall be reported to the AEC, in accordance with section 6, and records of animal movements will be kept as required.

## 6.7 Euthanasia for Tissue Collection

Wintec will consider tissue sharing where appropriate.

## 6.8 Rehoming

Animals that are used for research or teaching purposes may be privately owned, or owned by Wintec. For animals that are owned by Wintec, opportunities to re-home animals at the end of an AUP will be considered wherever possible, especially when the project or manipulation has had minimal impact on the welfare of the animal. Re-homing must follow the approved SOP.

Re-homing is acceptable if the physiological condition and behavioural attributes of the animal indicate that it can be introduced to a new environment with little, or no, transient impact on its welfare or well-being, and biosecurity requirements are met.

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

- i. The AEC has approved the release.
- ii. Safeguards are in place and approved by the AEC to ensure the ongoing well-being of the animal.
- iii. Transport of animals between sites is appropriate.

Evidence of ongoing wellbeing once the animal passes into someone else's ownership should be evidenced.

## **7. Compliance Breaches & Complaints Procedures**

(Section 103 of the Animal Welfare Act 1999)

### **7.1 Compliance Breaches**

The AEC is responsible for monitoring compliance of all approved AUPs, procedures, and animal facilities. Compliance breaches are notified to the AEC. Anyone can report a non-compliance.

#### *Non-Compliance with an AEC Approval*

Non-compliance with any AEC approved AUP will be addressed with an immediate assessment of risk for animals used under that AUP followed by suspension of the AUP, if warranted. An audit of animal use procedures related to the AUP will be carried out, including but not limited to, reviewing reporting, monitoring, training, and education processes under the AUP. Results of the audit will be assessed by the AEC and communicated to the AUP holder. A clear outline of corrective actions, including time frames will be established, and specific responsibilities allocated. Compliance with corrective actions will be monitored by the AEC. Where non-compliance is significant or ongoing, the AEC will take immediate action to suspend or revoke the AUP followed by escalation of the matter to the Code Holder.

#### *Minor Non-Compliance with Legislation or Regulations (including the CEC)*

Non-compliance with any AEC approved SOPs, activities and legislative requirements, the CEC, applications (including conditions set by the AEC) and/or approved SOPs will be addressed with a clear outline of corrective actions including time frames and 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.

#### *Major Non-Compliance with Legislation or Regulations*

The AEC can recommend that a non-compliance relating to SOPs, activities, legislative requirements, the CEC and applications (including conditions set by the AEC) is escalated to MPI, or they can notify MPI directly. Where non-compliance with the Code or Act is identified, corrective actions shall be recorded and monitored by the AEC. The Code Holder shall be notified.

Where the Code Holder believes the compliance breach justifies escalation, the MPI shall be notified.

### **7.2 Animal Welfare Complaints**

Animal welfare complaint and appeal procedures will be set up by the Chairperson to deal fairly and promptly with complaints from applicants, AEC members, staff, students, parented organisations and the public.

All complaints regarding animal welfare, at Wintec or any parented organisation, must be made in writing to the AEC chairperson or AWO, or via a specific complaint to the code holder. All complaints must be reported to the chairperson of the AEC who will log the complaint into the AEC complaints log that is managed separately to AEC meeting minutes. Complaints will be formally reviewed by the AEC and recorded in the meeting minutes. The Principle Investigator shall be notified.

Disciplinary action for non-compliance with the CEC shall be in accordance with the Wintec

employment and complaints policies or, in the case of external personnel, with the policy of the organisation concerned. Serious non-compliances with the CEC or Act (e.g. cases of animal cruelty), or any complaint that otherwise requires escalation will be referred by the AEC or code holder to MPI.

#### *By the Public*

Animal welfare complaints made by members of the public shall be referred to the AEC chairperson who may consult with the members of the AEC and act as appropriate. A complaint report will be entered into the AEC complaints log at the next AEC meeting. If the AEC 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 Act is identified, corrective actions shall be recorded and monitored by the AEC. The code holder shall be notified. If the matter cannot be resolved within the AEC, it shall be reported to the code holder or their representative.

#### *By Employees*

Animal welfare complaints made by Wintec employees shall be directed to the AEC chairperson who may consult with AEC members as appropriate and may call a special meeting of the AEC to resolve the matter. 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 code holder. If the matter cannot be resolved within the AEC, it shall be reported to the Code Holder or their representative. Where possible, the AEC shall treat complaints as confidential.

#### *By AEC Members*

Animal welfare complaints made by AEC members shall be directed to the chairperson or to the code holder, who may correspond directly with the chairperson to resolve the issue. The chairperson may consult with members of the AEC as appropriate and may call a special meeting of the AEC to resolve the matter. Where non-compliance with the CEC or Act is identified, corrective actions shall be recorded and monitored by the AEC. Complaints raised by the AEC must be notified to the code holder or their representative, along with corrective actions taken.

#### *By Parented organisations*

Animal welfare complaints made by parented organisations shall be referred to the AEC chairperson who may consult with the members of the AEC and act as appropriate. A complaint report will be entered into the AEC complaints log at the next AEC meeting. If the AEC 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 Act is identified, corrective actions shall be recorded and monitored by the AEC. The code holder shall be notified. If the matter cannot be resolved within the AEC, it shall be reported to the code holder or their representative.

### **7.3 Procedural Complaints**

In accordance with section 103 of the Act, any member of the AEC who believes that the AEC (including the Chairperson) or Wintec is failing to comply with 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 by reason of having made the report.

#### *By Applicants*

Any applicant who wishes to make a complaint must do so in writing via the AEC Administrator. Procedural complaints made by applicants shall be directed to the chairperson or the code holder, who may correspond directly with the chairperson to resolve the issue. Procedural complaints may be raised at the next regular meeting of the AEC. Where a complaint is deemed valid, the AEC may seek guidance from the code holder or their representative to ensure a fair, prompt resolution to the complaint. Where non-compliance with the CEC or Act is identified, corrective actions shall be recorded and monitored by the AEC. Actions taken as a response to a complaint will be recorded in the AEC minutes. The Code Holder shall be notified. Where the code holder believes the complaint justifies escalation, the MPI shall be notified.

#### *By AEC Members*

Any member of an AEC who believes that the AEC or code holder is failing to comply in a material respect with the CEC may lodge a formal complaint in writing to the chairperson or code holder. Complaints by AEC members to the chairperson must always be communicated to the code holder or their representative who may take legal advice on any further actions to be taken. In exceptional circumstances, a report may be made directly to the Director-General of MPI in accordance with section 103 of the Act.

An AEC member employed by Wintec who makes such a report in good faith shall not be liable to any discipline or civil proceedings due to having made that report.

#### *Against the Chair/Deputy Chair/Administrator*

Procedural complaints made by Wintec employees, AEC members or members of the public regarding the AEC chairperson shall be directed to the code holder. Where applicable, the code holder or their representative may choose to handle a complaint through Wintec's policies, or as deemed appropriate if the complaint falls outside of standard policy. Complaints made to the code holder may be reported back to the AEC subject to legal advice. Where the code holder believes the complaint justifies escalation, MPI shall be notified.

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

### **Permitted Arrangements**

The AEC will consider parenting arrangements (for consideration of external AUP applications) from outside organisations on a case-by-case basis. The AEC may accept such parenting arrangements only if it believes the AEC has the appropriate expertise and resources to review the AUP application and provide monitoring and other relevant services. The conditions for monitoring of animal manipulations, as set out by the AEC, need to be outlined by the external party and judged as satisfactory by the AEC. Parenting arrangements are a formal agreement between the two parties.

Parented organisations entering into this formal agreement with Wintec shall comply with this CEC. The conditions for monitoring of animal manipulations, as set out by the AEC, shall be confirmed with the applicant.

Members of the AEC shall perform local supervision, including carrying out monitoring of animal manipulations.

Wintec will notify MPI, in writing, of all arrangements for external parties to use the Wintec CEC. This will be done before the external party begins any animal research, testing, or teaching. Notification will include the name of the person or organisation, postal, and physical address of the parented

organisation and contact details for the person to whom correspondence shall be addressed. Such outside organisations shall comply with the CEC, and the arrangement must be re-confirmed when a new CEC is approved.

Full cost recovery shall apply in the absence of a collaborative agreement.

Parented organisations are responsible for submitting their own animal use statistics to the Ministry for Primary Industries no later than 28th February annually.

Wintec	Waikato Institute of Skills and Technology
Code / CEC	Code of Ethical Conduct
Code Holder	Wintec as owner of the Code / Chief Executive / Executive Director
NAEAC	National Animal Ethics Advisory Committee
MPI	Ministry for Primary Industries
DOC	Department of Conservation
AEC	Animal Ethics Committee
AUP	Animal Use Protocol
SOP	Standard Operating Procedure
The Act	Animal Welfare Act 1999
RTT	Research, testing, and teaching
AWO	Animal Welfare Officer
CE	Chief Executive
Chairperson	Chair of the Animal Ethics Committee
DC	Deputy Chairperson
RNZSPCA	Royal New Zealand Society for the Prevention of Cruelty to Animals
NZVA	New Zealand Veterinary Association
AVMA	American Veterinary Medical Association
ANZCCART	Australian & New Zealand Council for the Care of Animals in Research and Teaching
PI	Principal Investigator/Protocol Holder
UAE	Unexpected adverse event
HSNO	Hazardous Substances and New Organisms