



Waipapa Taumata Rau | The University of Auckland

CODE OF ETHICAL CONDUCT
For the Use of
Animals for Research, Testing and Teaching

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1. Introduction / Background on the Activities of the Applicant

1.1 Organisational Activities

Waipapa Taumata Rau | the University of Auckland (the University) Animal Ethics Committee (AEC) is established as a Committee of the University Council and is responsible for ensuring that protocols for use of animals in research, testing and teaching are executed in accordance with legislative requirements. No member of staff or any student shall use animals for research, testing or teaching without the prior approval of the AEC.

It is also the role of the AEC to ensure that all Acts of Parliament, codes of welfare, regulations or bylaws which pertain to the obtaining, holding, possession, care and treatment of animals are complied with by regularly reviewing amendments to relevant Acts and updating documentation and training material.

The AEC oversees a diverse range of research, testing and teaching activities spanning but not limited to biomedical, environmental, wildlife, and animal welfare.

The purpose of this Code of Ethical Conduct (CEC) is to ensure that members of the University treat all animals in their control with due care and consideration for their welfare.

The University's Taumata Teitei, Vision 2030 and Strategic plan 2025 expresses a commitment to fundamental Te Ao Māori principles and working in a way consistent with the emerging Waipapa framework. The principles reflect the University's foundational relationship with tangata whenua and commitment to Te Tiriti o Waitangi. Embedded in the framework is a commitment also to mana enhancing relationships, represented as 'Kia whakamana i te tangata':

- i. Manaakitanga - Caring for those around us in the way we relate to each other
- ii. Whanaungatanga - Recognising the importance of kinship and lasting relationship
- iii. Kaitiakitanga - Valuing stewardship and guardianship and our relationship with the natural world

Researchers proposing to carry out research involving issues of significance to Māori are advised to consult the research framework outlined in *Te Ara Tika* (see [Te Ara Tika Guidelines for Māori Research Ethics](#): A framework for researchers and ethics committee members for more information) that addresses ethical issues for Māori within the context of decision-making by ethics committees. This framework was developed by the Pūtaiora writing group for the Health Research Council (HRC). *Te Ara Tika Guidelines for Māori research ethics: A framework for researchers and ethics committee members*. Health Research Council of New Zealand, Auckland). The framework draws on Tikanga Māori and provide general obligations and considerations of relevance to all working in RTT in Aotearoa.

The Te Ara Tika principles and their application to animal research ethics:¹

¹ These points are adapted from Massey University's Code of Ethical Conduct.

Whakapapa (relationships): Developing authentic relationships through meaningful consultation and putting in place structures or processes that have been established to support these relationships. Where research is of direct relevance to iwi, researchers are required to consult with relevant stakeholders in a culturally appropriate manner prior to undertaking any research.

Tika (purposefulness): Research 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 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).

Manaakitanga (cultural and social responsibility): All participants in research 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 involves animals, the benefits of the research 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 in order to minimise this imbalance.

1.2 Research, Testing and Teaching (RTT) and the Three Rs (3Rs)

The carefully regulated use of animals in research is essential for discoveries to improve the health and well-being of humans, animals and the environment and make a vital contribution to understanding biological processes.

Animals are used at the University in research, testing and teaching only when it can be justified on scientific, ethical, and legal grounds and when no satisfactory or reasonable alternative is available. The University is committed to the principles of the 3Rs: replacement, reduction, and refinement. Researchers are therefore expected to carefully plan their experiments and manipulations to ensure i) that replacement of animals by non-sentient or non-living alternatives are sought when appropriate, ii) that the minimum numbers of animals are used to scientifically achieve the objectives of the experiment, and iii) that all approved techniques are designed to minimise harm and increase positive welfare of the animals.

1.3 Responsible Persons

The code holder is Waipapa Taumata Rau | University of Auckland. The AEC is established as a Committee of Council and is responsible for reporting to the Vice-Chancellor through the Deputy Vice-Chancellor (Research) (DVCR).

1.4 Persons/Organisations under the CEC

The CEC applies to members of the University, including:

- Anyone employed under a University or Auckland UniServices Limited employment agreement, or as an independent contractor,

- Any student enrolled at the University,
- Anyone else who is undertaking, piloting or supporting research, testing and teaching in association or affiliation with the University, including anyone subject to the Honorary and Adjunct Appointment Policy and Procedures or holding a University title such as Emeritus Professor.

The CEC also applies to members of approved parented organisations.

2. Establishment, Functions, Powers and Membership of the Animal Ethics Committee

2.1 Functions, Duties and Powers of the Committee

The functions, duties and powers of AEC are set out in the Animal Welfare Act 1999, section 99.

The AEC oversees the use of animals for research, testing and teaching by members of the University. The AEC may also agree to act on behalf of other organisations.

The AEC reviews written applications for the use of animals for research, testing and teaching according to the criteria outlined in the Animal Welfare Act 1999, section 100. It issues approvals only if it is satisfied that animal use complies with the Animal Welfare Act 1999, as well as any enacted Animal Welfare Amendments, and all other Acts of Parliament, regulations and bylaws relating to the obtaining, holding, possession, care and treatment of animals in a research, testing and teaching environment.

AEC activities include but are not limited to reviewing and approving applications and amendments, conducting post-approval monitoring, and overseeing any remedial actions in relation to animal use.

2.2 Membership of the AEC

The AEC consists of a minimum of four statutory members plus up to 8 internal and other members appointed for a period of three years.

2.3 Statutory Members

- The Chair is a senior representative of the University who is qualified to evaluate applications. The Chair is nominated by the University's Vice-Chancellor following consultation with the AEC, Animal Welfare Officer (AWO) and DVCR, and the appointment is formally approved by the University Council,
- A person nominated by an approved animal welfare organisation (for example, 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 research, testing or teaching,
- A person nominated by a Territorial Authority or Regional Council, not employed by or associated with the University, or associated with the scientific community or an animal welfare agency,

- A veterinarian nominated by the New Zealand Veterinary Association (NZVA) who is not employed by or associated with the University.

2.4 Organisational Members

Organisational members are nominated members from within the University who are experienced in the fields of research and/or animal management (as applicable) and have a working knowledge of animal ethics applications. At least one of the organisational members is a senior member of staff capable of evaluating project proposals as well as the qualifications and skills of the applicant, and the scientific or teaching value of a project.

Nominated members of the AEC consist of:

- The Dean of the Faculty of Medical and Health Sciences or their nominee,
- The Dean of the Faculty of Science or their nominee,
- A senior member of animal facility staff or a senior technical staff member responsible for animals in research,
- Two representatives of the Faculty of Medical and Health Sciences,
- One representative of the Faculty of Science,
- The Animal Welfare Officer (AWO) *ex officio* (non-voting). All references in this Code to the AWO shall be read as including the AWO or delegate

The Animal Ethics Committee Coordinator attends all AEC meetings to provide secretarial support.

2.5 External Members

External members are paid a fee for every half day attendance at AEC meetings or other AEC business at the University's set rate. This rate is set annually by the University Council according to fees prescribed by the Tertiary Education Commission.

2.6 Additional Members

The AEC has the power to co-opt additional members for a period of up to three years when the Committee requires additional expertise regarding specific areas where the AEC itself may not have sufficient knowledge. These co-opted members may if required be granted voting rights by the consensus of the AEC members. It may also seek advice intermittently from specialist roles (for example, Behaviour Technologist, Training and Compliance Specialist), as appropriate. Any additional external members are paid a fee for every half day attendance at AEC meetings or other AEC business at the University's set rate.

2.7 Appointment Procedures

2.7.1 Appointment of AEC members

Institutional members are identified by the Chair or by an AEC member; potential members may also declare their interest to a Committee member or be recommended by a Head of School/Department or the relevant Associate Dean Research. The nomination will give regard to their qualifications and experience. The new members are notified to the University Council.

External statutory members are nominated by the relevant bodies outlined in Section 2.3 (Statutory members) and formally approved by the University's Council.

2.7.2 Appointment of the Chair and Deputy Chair

The Chair is nominated following discussions by the AEC, AWO and the DVCR and formally approved by the University Council upon recommendation of the DVCR.

Committee members are invited to nominate another member or themselves as Deputy Chair, and if there is more than one nominee, the Deputy Chair is elected by voting. The appointment is notified to the University Council at their next meeting. The Deputy Chair assumes all the roles and powers of the Chair in the absence of the Chair.

2.7.3 Reappointments

External members can be reappointed at the expiry of their term through a formal nomination by the relevant bodies outlined in Section 2.3 (Statutory members). There is no limit to the number of terms served by an external member as long as they remain a nominee of their organisation according to requirements under the Act.

Institutional members can be reappointed at the expiry of their term through the appointment process outlined in Section 2.7.1 (Appointment Procedures).

2.8 Term of Appointment

AEC members are appointed for a term of three years and can be reappointed without restriction.

2.9 Induction and Training of New Members

The Chair and AWO manage an induction process for all new AEC members. 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 Committee. An information package, containing the CEC and other relevant documents for participating in the AEC are provided. All AEC members are also referred to appropriate literature, including relevant publications from the National Animal Ethics Advisory Committee (NAEAC), the National Animal Welfare Advisory Committee (NAWAC) and the Australian and New Zealand Council for the Care of Animals in Research and Teaching (ANZCCART), and provided with access to the University library. Members are subsequently encouraged and supported to attend conferences, workshops, or relevant meetings.

2.10 Vacancies

Where an unexpected vacancy arises, the member appointed to fill the vacancy is appointed for either a portion or the remainder of the vacancy. External members can only be replaced following nomination of a new member from their sponsoring organisation.

If an AEC member is absent for more than half of the scheduled annual meetings without justification, their membership will be terminated. If there is notice of absence in advance (for example, due to taking study leave, illness, or parental leave) for more than three consecutive meetings during the year, they will be replaced either temporarily or permanently.

3. AEC Processes

3.1 AEC Meetings

AEC meetings are held to assess project applications and amendments for the use of animals in research, testing and teaching. Other items for consideration may be end of approval reports, 3Rs initiatives, Standard Operating Procedures (SOPs), teaching evaluations, NAEAC and Ministry for Primary Industries (MPI) information, conference attendance, monitoring reports, adverse event reports, any other relevant legislation, etc. The Chair leads the meeting and ensures that each member is provided with ample opportunity to present their views and to respond to the views of other members.

3.2 Frequency of Meetings

There are eleven scheduled AEC meetings per year. These meetings are held monthly from February to December.

Committee members are provided with a meeting schedule for the year, and the schedule is also available on the AEC and Council webpages of the University website. If a meeting is to be held at a different location or format (for example, Zoom), Committee members are notified as soon as possible ahead of time as well as on the agenda for that meeting.

3.3 Timing for Circulation of Agenda Items

Meetings are organised by the Animal Ethics Coordinator who sets and distributes the agenda, AEC applications, and all other appropriate information to members at least eight days prior to the meeting via email. A final agenda is sent no less than three days prior and may include any urgent last-minute items. Rarely, and only if urgent, may items be tabled for consideration at the meeting. The Animal Ethics Coordinator minutes all meetings.

3.4 Quorum

A quorum for a meeting of the AEC is half of the appointed members plus one, including at least two of the statutory external members.

For a meeting of the AEC where half of the appointed members plus one are present but includes only one statutory external member, the meeting may still proceed with the agreement of the attending external member and Chair. All decisions from that meeting will be *pro tem* and formally ratified at the next quorate meeting.

3.5 Decision Process

The AEC decision making process is by consensus. The Chair ensures all members have an opportunity to offer opinion or ask questions about all applications. The technical aspects of applications are usually explained to the rest of the committee by the specific committee members who have relevant scientific expertise. This helps all participate in the discussion and decision-making process.

If a decision cannot be reached by consensus in the initial Committee meeting, then the Committee will ask the applicant for further information to assist the decision-making process and to reach a final consensus position.

The Chair will consider consensus reached only once satisfied that due process has occurred.

3.6 Effective Input of Committee Members

All AEC members are provided with the applications to be reviewed and any other necessary information. All members are strongly encouraged to ask for further information about any part of an application and to fully participate in all AEC discussions. The Chair particularly ensures that every external member is provided with the opportunity to present their views, to engage in discussion with the other members of the AEC and to ask other AEC members to explain their assessment. The Chair endeavours to provide any further information requested by external members.

External members are granted access to the electronic ethics review system used by the University to manage submissions and the review of animal ethics applications. These members also have access to other Committee documentation through a secure AEC shared site.

If hard copies of applications, the agenda and other information pertinent to AEC meetings are requested by AEC members, then this will be distributed by tracked postage or courier.

3.7 Establishment and Membership of Subcommittees

For review of urgent new applications of welfare grading A and B, a subcommittee of the AEC comprises a minimum of the Chair, one University member and two external members based on availability and expertise. AEC members will be contacted to assess availability and members may be approached due to a specific area of expertise or known availability. New applications of welfare grading C, D, or E will be considered at the next fully quorate AEC meeting.

For review of urgent major amendments, the subcommittee of the AEC comprises a minimum of the Chair, one University member and one external member based on availability and expertise (see Section 4.7 for the Major and Minor amendments process). AEC members will be contacted to assess availability and members may be approached due to a specific area of expertise or known availability.

Urgency is decided by the Chair and the AWO after speaking with the PI and assessing the submitted application. Examples of urgent amendments may relate to (but are not limited to) timing of experiments/manipulations, animal welfare improvements, wildlife work that is seasonal, student

work that is time limited, and teaching. All decisions made by these subcommittees are by consensus and ratified at the next quorate meeting.

3.8 Conflict of Interest

The Chair asks at the start of each meeting for AEC members to declare any real or perceived conflicts of interest as required by the University's Conflicts of Interest Policy and their significance will be assessed. Depending on the level of conflict, the Chair may request the member to absent themselves from the meeting or the part of the meeting that covers the specific conflict.

In cases where the Chair has a conflict of interest, the Chair absents themselves from the meeting and the Deputy Chair fulfils the role of Chair during the discussion.

All conflicts of interest, and a member's absence during discussion or decision-making are recorded in the minutes of the meeting.

3.9 Confidentiality

All applications and AEC related documentation are treated as confidential. Records are kept secure in the University's electronic ethics review system.

Requests by members of the public for information about AEC applications are subject to the Official Information Act 1982 (OIA) and referred to the University's General Counsel. Any information released under the OIA shall have confidentiality maintained on the identity and contact details of applicants and AEC members where applicable.

Where applications contain commercially sensitive information, the General Counsel may request further details in confidence so that the review criteria set out in the OIA can be met. Commercially sensitive information given in confidence may be released under the OIA after consultation with the applicant.

3.10 Use of Tele/Video Conferencing

It is intended that meetings occur in person, entirely by video or as a hybrid of these mediums. Teleconferencing may be used in exceptional cases or if one of the members is unable to join in person or by video.

3.11 Consideration between Meetings

It is the preference of the AEC that all decisions about new applications and major amendments are made at the scheduled monthly AEC meetings. However, on certain occasions an AEC decision is required between meetings.

Where there are sufficient grounds to justify the urgency for obtaining the approval outside of the normal meeting schedule, a review of a new protocol or major amendment may be considered between meetings on a case-by-case basis.

The decision to allow an interim review is made by the Chair and AWO after discussion with the researcher.

Any consideration of urgent matters must have a legitimate requirement for urgency and not circumvent proper consideration of the application.

All subcommittee approvals are ratified at the next Committee meeting.

3.11.1 Urgent Consideration of New Applications with Impact Grades A or B

Interim review of a new application with an impact grade A or B are evaluated by a subcommittee following the process indicated in Section 3.7 (Establishment and Membership of Subcommittees).

3.11.2 Urgent Consideration of a New Applications for Studies of Grades C, D or E.

Urgent review of a new application with an impact grade C, D, or E only occurs at an extraordinary quorate AEC meeting.

3.11.3 Urgent Consideration of Amendments.

The process to assess minor or major amendments under urgency is described in Section 4.7 (Changes to Approved Applications).

3.12 Public Presence at Meetings

Generally, AEC meetings are not open to the public, however, there may be circumstances when doing so is agreed. The AEC may also resolve that one or more specified persons may remain after the public has been excluded if, in the opinion of the AEC, they have knowledge that will assist the AEC. The minutes of the meeting note this resolution and state the knowledge possessed by that person or persons which will be of assistance to the AEC in relation to the matter to be discussed and how it is relevant. Members of the public are not present during the decision-making process.

3.13 Applicant Presence at Meetings

The AEC may allow Principal Investigators (PIs) to be present during the discussion of their application if that is considered necessary to provide explanations to questions raised by Committee members. Applicants are not present during the decision-making and will be notified of the decision about their application through the normal notification process.

If one of the AEC members is listed as personnel on any application being considered at an AEC meeting, they must declare a conflict of interest at the beginning of the meeting and will be asked to leave the room while the application is discussed, and the decision of outcome made.

3.14 Secretarial Support

The University Ethics and Integrity Team provides administrative support to the AEC. The Animal Ethics Coordinator is responsible for receiving applications (new applications and amendment requests), preparing and circulating the agenda, writing draft meeting minutes and coordinating the final minutes, sending out correspondence, keeping all records, and other duties required to support the AEC.

3.15 Record Keeping and Information Management

AEC documentation is maintained in order to meet the requirements of the Act. All minutes of AEC meetings, its decisions, operations and records of the AEC are stored securely and held in an electronic ethics review system for a minimum of seven years. Access to these records is restricted to members of the Ethics and Integrity Team, the AWO, the AEC, and the Code Holder.

Records maintained include:

- Study protocol
- AEC Approval
- Manipulations carried out and actual impact grading
- Approval amendments
- Relevant staff training records
- End of Approval Reports
- Animal Usage Returns
- Agendas and Minutes of the meetings

3.16 Reporting of Statistics to MPI

Applicants are responsible for submitting their animal usage numbers and required statistics to the Animal Ethics Coordinator by the end of January of the year after an approval ends, when approved animal numbers are reached, or when the project is concluded or discontinued. Animal usage numbers are also required in any subsequent year for which an extension was granted. The Animal Ethics Coordinator consolidates these figures into a University-wide return for submission to MPI by 28 February. Parented organisations are required to submit their own animal usage returns to MPI each year.

3.17 Protection of AEC Members

Members of the AEC will not be held 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 AEC.

3.18 Process to Amend the CEC

Any requests for changes to the CEC are discussed and approved by the AEC and referred with a Committee recommendation to the code holder. The process to amend the CEC and notify relevant parties is described in Section 10 (Process to Amend, Suspend or Revoke the CEC).

4. Consideration of Applications by the AEC

4.1 Criteria for Consideration

A harm-benefit analysis of a proposal is undertaken to assess whether the harm to the animals in terms of pain and distress is justified by the expected outcomes. Ethical considerations, and reviewing how the research, testing or teaching may ultimately benefit human beings, animals or the environment or contribute to basic biological understanding is examined.

The AEC shall ensure that any proposals meet the criteria set out in Section 100 of the Act, including whether the design of the study is such that the objectives of the experiment will be met, that the number of animals to be used is the minimum necessary to ensure a meaningful interpretation of the findings, whether suitably qualified persons will be engaged in supervising and undertaking the research, testing or teaching, and whether the work has been conducted previously. The AEC considers whether the applicant has adequately addressed the 3Rs, and whether throughout the course of the approval, adequate measures will be taken to ensure the general health and welfare of the animals before, during and after any manipulation.

The following conditions are also noted and addressed in applications:

4.1.1 Animal Use Justification

There are no practical alternative approaches to the research, testing or teaching that would avoid the use of sentient animals. Additionally, that the correct species and numbers of animals are used.

4.1.2 Anaesthesia and Analgesia

Appropriate anaesthesia and analgesia are provided in consultation with a veterinarian at the University.

4.1.3 Source of Animals

The animals are lawfully acquired and appropriate for the proposed use. Where possible, animals used have been specifically bred for research, testing and teaching.

4.1.4 Neuromuscular Blockade

The AEC only approves the use of a neuromuscular blocking agents when administered with concurrent use of appropriate analgesia, anaesthesia, mechanical pulmonary ventilation and monitoring.

4.1.5 Endangered Species

The AEC does not approve the use of an endangered or threatened species unless the findings are expected to assist the management and conservation of that species. The appropriate permission by the relevant government department must be obtained prior to approval of the AEC application.

4.1.6 Transportation of Animals

Transportation of animals is included as a procedure in applications to the AEC.

4.1.7 Housing of Animals

Routine housing is normally managed by the facility, and details of non-standard housing or that varies from the routine animal housing must be included in applications to the AEC.

4.1.8 Fate of Animals

The fate of all animals is stated at the end of the protocol.

4.2 Impact Grading

The AEC uses the impact grading system in the most recent MPI Animal Use Statistics Guidance document together with the expertise and knowledge of the AEC members to determine whether the impact grading proposed in an application is correct.

4.3 Outcomes after Consideration

The AEC review new research, testing or teaching applications, requests for amendment to approved applications, and end of approval reports.

There are four possible outcomes:

- **Approved:** Approval is given, but minor administrative changes may be undertaken.
- **Conditionally approved:** The Committee has identified straightforward matters for clarification or revision. No work may commence until the clarification or revisions have been approved.
- **Major Revisions Required:** The Committee requires significant revisions and will review the revised application at a future AEC meeting. In the case of a new application or amendment request, no work may commence until approved.
- **Declined:** The application, amendment, or report is declined and a new application must be submitted.

An AWO report is presented at AEC meetings and includes information for the noting of the Committee regarding any adverse events (see Section 5.5 for more information).

Decisions are recorded in the AEC Minutes and conveyed in writing to applicants. In some cases, members of the AEC may also meet with an applicant to explain a decision and how the application could be revised to meet the Committee requirements.

4.4 Conditions of Approval

The Committee may require various conditions to be fulfilled on approved applications. These are conveyed to the applicant in writing.

These conditions may include:

- A requirement to put in place additional training, consultation or other procedural matters
- Pilot studies and initial reports back to the Committee before allowing a larger study to be completed,
- The applicant to have the AWO or appropriate nominee attend when a procedure is performed,
- Some of these conditions may require a report back to the AEC on outcomes before progressing to a subsequent part of the study.

4.5 Maximum Approval Period

The maximum approval is given for a period of three years, or any such lesser period as the AEC may determine as appropriate.

Applicants may also apply to the AEC for approval of a time only extension to an animal ethics approval. This amendment must include details on progress to date and the rationale for the extension. Usually, the extension period given is 3-6 months to a maximum of 18 months.

4.6 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 if the applicant is found to be carrying out procedures not set out in the approved application and/or failing to adhere to specific operating procedures and/or failing to provide adequate care and veterinary support of animals. This power is usually held by the Chair but can be delegated by the Chair to the AWO or any member of the Committee.

4.7 Changes to Approved Applications

After approval, any amendments to protocols must be approved by the AEC prior to the changes coming into effect. This requires submission of an amendment request in the electronic ethics review system, or on the appropriate document form for amendment requests from parented organisations with no access to the electronic ethics review system.

4.7.1 Minor Amendments

Minor amendments involve minimal changes to a protocol and no change in welfare impact grade. These are dealt with by the Chair or their nominee between AEC meetings and are ratified at the next AEC meeting.

Minor amendments are restricted to:

- An increase of up to 10% over the number of animals originally approved,
- Any protocol changes where the additional welfare impact(s) will be minor,
- No increase of overall project manipulation grading,
- Change of wild type strain of animal to be used,
- Personnel changes (not including change of PI amendments),
- Other matters from time to time pre-approved by the AEC for the Chair to approve between meetings.

4.7.2 Major Amendments

All other amendments where there is a substantive change of welfare impact, or the changes are considered by the Chair and AWO to be of a significant nature will be considered as major amendments.

Major amendments will be assessed by full Committee review at the next quorate AEC meeting but if urgent, the Chair and AWO will determine if they are suitable for either a subcommittee review (see Committee definition and process as described in Section 3.7 (Establishment and Membership of Subcommittees)) or by an extraordinary full quorate AEC meeting.

5. Responsibilities under AEC Approved Applications

5.1 Compliance

The PI is responsible for all work undertaken on an approved application. Prior to the submission of an application, the PI must have completed a course of training as specified by the AEC to ensure that they understand their responsibilities and the expectations as a PI.

In addition, all other members of a research team must attend a course of training as specified by the AEC to ensure that they understand their legislative and institutional responsibilities.

5.1.1 Project Reporting

The AEC may request an interim report, for example, for pilot studies.

Final reporting by submitting an End of Approval report (EOA) is required within three months of the end of an approval or conclusion of work. The EOA includes information as indicated in Section 7.7 (End of Approval reporting).

5.1.2 Compliance Reporting

The PI or a member of the research team must report any non-compliance to the AEC by way of the AWO, as soon as they become aware of the non-compliance.

For the process of reporting non-compliances refer to Section 7.9.1.

5.2 Appropriate Qualifications

Applicants are required to list their qualifications and experience with animals in a research setting, including their experience with the specific species and manipulations as indicated in the application.

Applicants without appropriate training must receive training and PIs must be able to demonstrate to the AEC evidence of this training. Training required as part of an application must be supervised by a qualified person. The AEC must be satisfied that an applicant has or will receive sufficient training in all approved manipulations, prior to the start of animal work. The AEC may stipulate that the AWO and/or an appropriately trained supervisor be present for any procedures.

5.3 Sick and Injured Animals

Applicants must treat animals in their control with due care and consideration for their welfare. Sick or injured animals must be attended to immediately, including obtaining veterinary advice and/or care. The AEC, AWO and veterinary staff can direct how that sick or injured animals be properly cared for, and if appropriate, euthanised.

These events are reported through the facility and veterinary team and dealt with appropriately. The monthly AWO report may include any anomalies, disease outbreaks, and situations of adverse events.

5.4 Standard Operating Procedures

The application submission and approval process for an SOP is the same as for research, testing and teaching applications. Forms for approval of an SOP are available on the University intranet and electronic ethics review system. Any new SOPs are only written following consultation with the AWO.

SOPs are reviewed at least every three to five years by the AEC, depending on the nature of the subject. The owner of the SOP (in consultation with the AWO) will ensure that all policies and procedures are up to date.

5.5 Adverse Events

Unexpected adverse events (AEs) are unanticipated or atypical incidents that impact (or could impact) the welfare of an animal(s). They can result from many situations, including but not limited to, experimental manipulation, routine husbandry or disease and have not been addressed in the animal ethics approval. These situations may have arisen due to accidental events, events outside the researchers control or may have been intentional.

Any unexpected adverse events before, during or after manipulations, that affect the animals or their welfare are reported to and dealt with by the AWO as soon as possible. Responses may vary

depending on the seriousness of the event. The PI will be notified and included in the discussion about what transpired (if not involved). Interventions could range from additional observations, review of procedures, through to termination of the project. This is captured by completion of the appropriate report and notification to the AEC via the monthly AWO report.

Urgent welfare concerns must be acted upon immediately by contacting a senior facility staff member or facility manager and AWO or veterinary team as applicable. If an event is considered to involve a serious compromise of animal welfare or breach of conditions, the AWO reports the incident to the Chair or Deputy Chair as soon as possible to help decide on an appropriate course of action.

5.6 Record Keeping

All PIs are required to keep training records and records of their approval activity and animal usage. Records maintained should at least include relevant items from the following list: 1. Study protocol 2. AEC approval 3. Manipulations carried out and actual impact grade resulting. 4. Details of animal husbandry routines and actual environmental conditions 5. Variations approved 6. Deviations/noncompliances 7. Adverse events 8. Staff training records 9. Veterinary treatment. 10. Results of manipulations/treatments.

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

5.7 Euthanasia for Tissue Collection/Dissection

Euthanasia for the purposes of tissue collection/dissection requires an AEC application to be submitted to and approved by the AEC.

Surplus tissues not being used by a particular research group may be made available to other research groups or used for teaching purposes via a tissue sharing board, digital database and/or word of mouth between colleagues.

5.8 Rehoming

All non-GMO animals may be made available for rehoming. This occurs via the animal facility, AWO and veterinary staff. Animals on approved project applications that may be suitable for rehoming (e.g., tissues not required, minimal impact of manipulations) should be returned to the facility for assessment. Rehoming is the preferred choice if the physiological condition and behavioural attributes of the animal indicate that it can be introduced to a new environment with little, or no, transient impact on its well-being. Animals bred and not used are also rehomed as appropriate.

Rehoming is accomplished through work with various organisations or to competent individuals. Rehoming activities will be documented.

6. Animal Facilities

6.1 Management of Animal Facilities

Where appropriate, animal facilities use SOPs to manage aspects of their activities. The SOPs must be approved by the AEC and take into account relevant legislation and guidelines.

6.1.1 Policies and Procedures

The AEC, AWO, veterinarians, facility staff and associated facility management committees review best practice internationally and base practices, SOPs, and procedures to be approved on this information. Topics include (but are not limited to) specific manipulations, health and welfare, husbandry, breeding, enrichment, 3Rs, transportation, and euthanasia.

6.1.2 Emergency Management

Emergency Business Continuity Plans (BCPs) are in place for every University faculty and research institute. There are also local crisis management teams for facilities, as well as an incident management team(s) for the University. The AWO is involved in any decision-making processes that will impact animals and animal facilities at the University.

Animal facilities have documents that outline responses to various emergency situations (including but not limited to such things as pandemic response, water being cut off, natural disasters). The AWO, veterinary staff, facility managers and senior facility staff are also on call 24/7 in case of emergencies. Staff rosters would be detailed at the time, based on the nature of the crisis.

6.2 Development of SOPs for Facility Management

All SOPs of animal facilities are approved by the AEC and are regularly reviewed. Procedures for the approval of SOPs are the same as for project applications and amendments and are outlined in Section 5.4 (Standard Operating Procedures).

6.3 Transportation of Animals

All animal transport managed by the facilities is carried out in accordance with the relevant SOPs or guidance documents held by each animal facility, AWO or University (as appropriate), unless specific approval is obtained from the AEC. The Transport within New Zealand code of welfare may also be used, if relevant.

6.4 Housing of Animals

All animal housing is in accordance with the relevant SOPs or guidance documents held by each animal facility unless specific approval is obtained from the AEC. Details of animal housing that vary from the standard usually provided are included in applications to the AEC.

6.5 Monitoring Animal Facilities

The AWO, veterinary staff and/or any member of the AEC may make regular informal visits to each animal facility over the course of a year. These visits are communicated to the AEC in the monthly AWO report or via reporting by AEC members at the monthly meeting.

A formal visit by a member of the AEC occurs once annually and is reported to the AEC for discussion and noting. A copy of the report is sent to the animal facility manager.

Monitoring of animal facilities includes any animal facility run by a parented organisation.

7. Monitoring

7.1 Monitoring during the Approval Period

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 and to deal with any breaches found as appropriate to their particular circumstances as set out in Section 4.6 (Power to Suspend, Revoke or Vary Approvals). This includes the power to monitor approved protocols, require animal users to report back to the AEC, monitor adherence to specific operating procedures, and to monitor animal facilities, routine animal husbandry and animal welfare.

Monitoring includes a range of activities undertaken by various members of the AEC and/or the AWO or veterinary staff, including unscheduled observations, veterinary care, a structured postapproval review of procedures, videos, requested reports, and formal review of projects and experiments.

The AEC monitors approvals through site visits to animal breeding and holding facilities, visits to users of animals, and visits to locations where approved manipulations are being performed (on and off campus). Between meetings of the AEC, the Chair can unilaterally undertake site visits and inspections, and/or appoint another member of the AEC or the AWO to undertake this task. Other reviews may be undertaken as noted in Section 7 (Monitoring). Reports on site visits and reviews are presented at a subsequent meeting of the AEC for discussion and noting.

If anything is identified that needs follow up, then this will be done in consultation with the researcher and may include a range of options, based on the nature of the findings. This may include but is not limited to: training, progress report, amendment to the approval, non-compliance reporting, additional interim reporting and further site visits.

7.2 Monitoring by Proxy

In the event the AEC requires monitoring by a proxy, the appropriate person and nature of the review are determined by the AEC. Evidence and/or a written report is submitted to the AEC for review.

7.3 Frequency of Monitoring

At a minimum 10% of all Grade A and B, 30% of all Grade C approvals will be monitored during their approval period. All active approvals of Grade D or E will be monitored annually. The Committee will work toward increasing monitoring as time and resource allows.

7.4 Monitoring of Manipulations Grade A & B

Monitoring of manipulations Grade A & B is undertaken by the AWO, the AEC or nominee. Monitoring includes a range of activities, for example unscheduled and scheduled observations, progress reports, veterinary care, a structured post-approval review of procedures, and projects and experiments. Where the location of the procedures makes a site visit problematic, the AEC can request applicants provide a video record of procedures and/or use a live video link to facilitate monitoring of the approval. The AEC is made aware of this monitoring via formal monitoring visit reports, items notified in the appropriate section of the monthly AWO report or via AEC member reports.

7.5 Monitoring of Manipulations Grade C-E

Monitoring of manipulations Grade C-E will be undertaken by the AWO, the AEC or nominee. This includes unscheduled and scheduled observations, veterinary care interactions, structured postapproval reviews of procedures, and projects and experiments. Where the location of the procedures makes a site visit problematic, the AEC can request applicants provide a video record of procedures and/or use a live video link to facilitate monitoring of the approval. The AEC is made aware of this monitoring via formal monitoring visit reports, items notified in the appropriate section of the monthly AWO report or via AEC member reports.

7.6 Specific Manipulations

The AWO and veterinary/welfare staff take part in monitoring of projects as indicated in Sections 4.4 (Conditions of Approval), 6.5 (Monitoring Animal Facilities), and the other relevant subsections of Section 7 (Monitoring). Any reviews of new, high impact, or specific manipulations, are reported in the appropriate section of the monthly AWO report to the AEC.

7.7 End of Approval Reporting

Applicants submits an EOA report at the end of the approval period. These reports include information on progress, unexpected adverse events, improvements for future work, animals used and outputs, and are included in an AEC meeting agenda for approval.

7.8 End of Approval Grading

At the completion of the project, reports are submitted to the AEC as described in Section 7.7 (End of Approval Reporting) and include the grading initially approved as well as any amendments approved that resulted in a change of grading.

7.9 Compliance Breaches

7.9.1 Non-Compliance with an AEC Approval

When a non-compliance is found, it must be reported to the AWO as soon as possible. After an investigation and depending on the nature of the non-compliance, the non-compliance is dealt with by the AWO or their nominee. If the non-compliance has the potential to be significant or there is any question of severity, an investigation is done in consultation with the Chair or Deputy Chair and

subsequently reported to the AEC. Corrective actions may include education, retraining or disciplinary action. The non-compliance may be escalated to the DVCR. All non-compliances will be reported to the AEC in the monthly AWO report.

If anything is identified that needs follow up, then this will be done in consultation with the researcher and may include a range of options, based on the nature of the finding. This may include but is not limited to: training, progress reports, amendments to the approval, formal noncompliance reporting, additional interim reporting, further site visits, suspension or revocation of approval, communication with MPI and/or suspension of further animal research activities. The line manager of the person (or more senior institutional management) may be involved in the discussions, depending on the nature and severity of the breach.

7.9.2 Non-Compliance with Legislation or Regulations (*Including Non-Compliance with this CEC*).

Non-compliance with the Act or other associated Acts and Regulations will be investigated by the AEC and may be escalated to the DVCR and/or MPI if required.

7.10 End of Approval Statistics

At the end of the approval period, the PI submits an Animal Usage Report (AUR) using a bespoke form in the electronic ethics review system form based on the MPI AUR report form. These statistics are reviewed at an AEC meeting.

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

The code holder may agree to enter into parenting arrangements with other organisations, including commercial enterprises, who wish to submit applications to use animals for research, testing or teaching. Applications for parenting arrangements are approved by the DVCR, and once approved, a written formal parenting agreement will be signed by the code holder and the organisation. The organisation will exercise all responsibilities as per the CEC and must comply with this CEC.

Approval of these parenting arrangements are notified in writing to MPI and to the AEC, in accordance with legislative requirements.

9. Complaints Procedures

9.1 Animal Welfare Complaints

9.1.1 Complaints by the Public

Members of the public may submit written complaints about animal welfare directly to the University. The Chair, in conjunction with the AWO, the Deputy Chair, and the DVCR investigate the matter and determine if an animal welfare breach occurred and any corrective action that may be required. Complainants are notified of the outcome of the investigation in writing (unless the complaint was made anonymously). All complaints are kept in a secure online folder and reported to the AEC.

9.1.2 Complaints by Employees

Animal welfare complaints made by employees are managed in the same manner as for a public complaint (see Section 9.1.1).

9.1.3 Complaints by AEC Members

Animal welfare complaints made by AEC members are managed in the same manner as for a public complaint (see Section 9.1.1).

9.1.4 Breaches of the Act

Any person who believes that the AEC or the code holder is failing to comply in a material respect with the Animal Welfare Act 1999, reports this to the Director-General of MPI.

9.2 Procedural Complaints

9.2.1 Complaints by Applicants

Complaints made by applicants about AEC procedural matters are directed to the Chair in writing. An applicant 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.

Any applicant who believes that the AEC or the code holder is failing to comply in a material respect with the Animal Welfare Act 1999 or with the CEC may also report this to the Director-General of MPI.

9.2.2 Complaints by AEC Members

Complaints made by AEC members about AEC procedural matters are directed to the Chair in writing. An AEC member who makes such a report in good faith is not liable to any discipline or civil proceedings by reason of having made the report.

Any AEC member who believes that the AEC or the code holder is failing to comply in a material respect with the Animal Welfare Act 1999 or with the CEC may also report this to the Director-General of MPI.

9.2.3 Complaints against the Chair

Complaints made by AEC members, the University staff members/students or the public that concern the Chair of the AEC can be directed to the DVCR in writing. The DVCR, in conjunction with the AWO and the Deputy Chair, investigate the matter and the DVCR will determine any corrective action. Complainants are notified of the outcome of the investigation in writing (unless the complaint was made anonymously).

10. Process to Amend, Suspend or Revoke the CEC

The AEC recommends CEC amendments to the code holder via the office of the DVCR.

If amendments are major in nature, once internally approved, the amended CEC is submitted to the Director-General of MPI for approval (as required in accordance with the Animal Welfare Act 1999).

Where the proposed amendments are minor in nature (i.e., amendments that would not materially affect the purposes of the CEC), the amendments can be made with approval from the code holder but without requiring prior approval from the Director-General. In this situation, the proposed amended CEC is submitted to the Vice-Chancellor via the DVCR for approval. Any such amendments made during a calendar year are reported in writing to the Director-General prior to 31 March of the following year.

The code holder applies in writing to the Director-General to suspend or revoke the CEC, stating the reason for the request.

Staff and students of the University are notified of changes to the CEC by newsletters and a notification added to the AEC website. Parented organisations are formally notified of changes to the CEC by email directly.