

EthicoNZ Ltd

CODE OF ETHICAL CONDUCT

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

19 December 2024 – 18 December 2029

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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 EthicoNZ Ltd (EthicoNZ) implements and gives effect to the Animal Welfare Act 1999 (the Act), the Animal Welfare (Records and Statistics) Regulations 1999, and any other relevant legislation. Within this document, the term "animal" refers to any species defined as an animal by the Act and "manipulation" applies to any procedure defined as a manipulation by the Act.

EthicoNZ Ltd is a consultancy and research company that carries out contract research, testing and teaching on animals as defined in the Animal Welfare Act (1999). The research is broadly aimed to improve the welfare and lives of animals and humans.

EthicoNZ may choose to allow other organisations to parent to its AEC to obtain approval to undertake research, testing, or teaching (RTT). This will be done on a case-by-case basis, depending on the scope of research the organisation wishes to conduct and the ability of the EthicoNZ AEC to consider and monitor the research according to the Act.

1.2 RTT and Te Tiriti o Waitangi Obligations and Principles

As with NAEAC, EthicoNZ is committed to upholding the principles of Te Tiriti o Waitangi, specifically partnership, participation, and protection for all projects undertaken by EthicoNZ and parented organisations. While Te Tiriti does not explicitly address animal ethics, it provides clear obligations around partnership and consultation with Māori, which are relevant to all work conducted in RTT in Aotearoa New Zealand. These obligations extend to ensuring that Māori perspectives are integrated into decision-making processes that involve animals and the environment.

Specifically where relevant, this CEC requires engagement in genuine and meaningful partnerships with Māori, including regular consultation with iwi and hapū, to ensure that Māori values and perspectives are appropriately reflected. Consultations should occur first with the community closest to the research, likely at a hapū level, to ensure that research aligns with Māori values.

Engaging with Māori on matters concerning RTT, particularly when research may involve taonga (treasured) species or Māori land is critical. EthicoNZ recognises that engaging with Māori is not a one-time obligation but an ongoing commitment to co-governance and shared decision-making, which should be embedded in all stages of research.

Māori Worldview and its Relevance to Animal Ethics

In Te Ao Māori (the Māori worldview), animals, like all aspects of the natural world, are seen as interconnected with humans and hold intrinsic value within whakapapa (genealogy). This holistic view emphasises the relationships between humans, animals, and the environment, recognising that humans are responsible for caring for and respecting all living beings. Animals are considered part of the collective ecosystem, and their welfare is tied to the wellbeing of people and the land.

Key Māori values that are particularly relevant to animal ethics in RTT include:

- **Whakapapa** – Relationships and connectedness between all living beings are central in Māori thought. In the context of RTT, this means fostering meaningful partnerships with iwi and hapū, especially where research impacts animals or the environment in ways concerning Māori. Researchers should acknowledge the place of animals within the broader whakapapa and the spiritual and cultural importance this holds for Māori.
- **Tika** – Research must be just, purposeful, and beneficial. In animal research, this means ensuring that any harm caused is outweighed by significant benefits and that the research team has the skills and experience necessary to carry out the work ethically and effectively. It also requires ensuring that the research aligns with the values of kaitiakitanga and does not compromise Māori perspectives on animals or the environment.
- **Manaakitanga and Whakaute** - Care and respect must be shown in all aspects of the research, from the committee processes to interactions with animals and tangata whenua. This value requires that all interactions be conducted with integrity and respect for the cultural and spiritual significance animals may hold for Māori communities.
- **Kaitiakitanga** – As stewards of the natural world, Māori place high value on the guardianship of animals and the environment. Research proposals must demonstrate a commitment to minimising the impact on animal welfare and ensure that all actions are consistent with kaitiakitanga principles, ensuring the care and protection of the natural world for future generations.

EthicoNZ acknowledges that the 3 Rs (and a proposed 4th R, discussed in section 1.3) can be informed by Māori values, particularly with regard to the concept of respect, and that animals are significant beings in their own right, and thus desiring respect from us.

Taonga and Indigenous Species

Although EthicoNZ does not currently research indigenous species, it acknowledges the special significance of taonga species to Māori. Taonga species are not only ecologically important but also hold deep cultural and spiritual significance for Māori as part of their identity and whakapapa. Any research that potentially affects taonga species must involve consultation with iwi and hapū to ensure that their mana (authority) and kaitiaki (guardianship) responsibilities are respected.

For projects involving taonga species or work on Māori land, applicants must identify and appropriately address Māori perspectives in their research proposals. This involves active engagement with relevant iwi and hapū to discuss potential impacts, provide evidence of meaningful consultation, and ensure that Māori cultural values are not compromised. Evidence of these discussions must be included with applications for ethical approval.

To apply for ethical approval, all applicants must identify and appropriately address Māori perspectives in relation to their research. Projects which have aspects of interest to Māori must discuss these with relevant iwi or hapū and provide evidence of these discussions demonstrating that Māori perspectives are not compromised.

Guidance for Engagement with Māori

A structured approach to engaging with Māori, will help ensure that all engagement is genuine and is consistent with the principles of partnership. This includes:

- Early and proactive engagement with iwi and hapū before any research proposal is finalised.

- Providing clear information on the research, its potential impacts, and how Māori perspectives will be incorporated.
- Establishing long-term partnerships with Māori rather than engaging in one-off consultations.
- Ensuring that Māori voices are represented in decision-making processes, including at the governance level of ethics committees.
- Training researchers in mātauranga Māori (Māori knowledge) and tikanga (customary practices) to foster a deeper understanding of the cultural context of their work.

By upholding these principles, EthicoNZ will ensure that RTT under this CEC will be conducted in a way that respects Māori perspectives and the deep connections between humans, animals, and the environment

1.3 The 3 Rs

Approval will be given to use animals in RTT only when it can be justified on scientific, ethical, and legal grounds, and when no satisfactory or reasonable alternative is available.

EthicoNZ is committed to the principles of the 3 Rs: replacement, reduction, and refinement. This means that when submitting a proposal, researchers must:

- Describe how they have explored ways to *replace* animals with non-sentient or non-living alternatives whenever possible
- Describe how their proposed experiments and manipulations have *reduced* numbers of animals used to the minimum that can achieve the objectives of the project
- Describe how the techniques proposed have been *refined* to minimise harm and increase positive welfare of the animals

EthicoNZ will promote the concept of a 4th R – “Respect” and this is referred to in Section 1.2 Manaakitanga and Whakaute. Researchers must demonstrate through their application and behaviour that their research will be carried out with care and respect for animals, environment, and the ethical process.

1.4 Responsible Individuals

The code holder is EthicoNZ and responsibility for the administration of the CEC is delegated to its directors, James Robert Webster and Gosia Anna Zobel.

Both directors have significant experience in animal research and ethics.

EthicoNZ may from time to time enter into an animal ethics parenting agreement with other organisations who request and are granted permission to operate under this CEC. In this instance a contract will be signed outlining the requirements of the parented organisation to adhere to this CEC.

1.5 Individuals/Organisations under the CEC

This CEC applies to the following:

- All persons employed by or contracted to EthicoNZ and all approved parented organisations
- Members of the EthicoNZ animal ethics committee (AEC)

- Persons responsible for care and welfare of animals in RTT at any parented organisation
- All animals under an approved application or in a facility approved by the EthicoNZ AEC

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

2.1 Functions and Powers of 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.

EthicoNZ will have a single functioning AEC that will enact the provisions and intentions of the Act stated above and any amendments to the Act. The AEC shall be established, operate, and be maintained by EthicoNZ in accordance with the Act and the NAEAC Good Practice Guide for the Use of Animals in Research, Testing and Teaching.

The AEC will consider ethical matters on the use of animals in RTT as proposed by EthicoNZ and parented organisations. The duties of the AEC include, but are not limited to:

- Granting or removing approval for the use of animals in RTT
- Setting and varying conditions on how manipulations are carried out
- Confirming that the 3 Rs, and the proposed 4th R, are implemented
- Monitoring approved projects and facilities
- Reviewing adverse events
- Issuing non-compliances
- Determining the suitability of staff to carry out the manipulations and deliver on the outcomes proposed

Should the AEC be disestablished, all currently approved applications, and any obligations under this CEC relating to those applications, will be formally transferred to another organisation with an approved CEC and AEC.

2.2 Membership of the AEC

Statutory members

- A senior representative of the EthicoNZ appointed by the directors 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 EthicoNZ or associated with the scientific community or an animal welfare agency

The senior representative of the EthicoNZ will be chairperson of the AEC.

External members will be reimbursed for meeting attendance, monitoring visits, report writing (when requested), and reasonable travel expenses. Financial support to attend educational events and conferences (e.g., NAEAC AEC Workshop, ANZCCART Conference) will be made on a case-by-case basis.

Organisational members

In addition to the chairperson from EthicoNZ, there may be a minimum of one and up to three other members on the AEC nominated by EthicoNZ to assist the AEC carry out its duties. These additional organisational members will participate fully in decision-making and may include:

- a senior scientist
- an expert in Māori worldview, its relevance to animal ethics, and in engaging with Māori
- a person with statistical expertise
- a veterinarian/ animal welfare officer

The EthicoNZ AEC will comprise a minimum of five and a maximum of eight members.

Subject Matter Experts

The AEC may engage persons with specific skills to act as Subject Matter Experts (SME) on an *ad hoc* basis and who may be remunerated on a case-by-case basis. The SME acts in an advisory capacity to the AEC only and does not participate in decision-making.

2.3 AEC Appointment Procedures

Members, Chair/Deputy Chair

All appointments and replacements on the AEC, including chairperson, deputy chairperson, statutory members and organisational members are made by the code holder. External statutory members are nominated by the relevant bodies outlined in Section 2.2 (Statutory members) and formally approved by the code holder. Additional members and SMEs may be nominated by the AEC and approved by the code holder.

When making appointments, the code holder will consider the background of the appointee and any potential conflicts of interest which must be declared when signing a confidentiality agreement. The goal of all appointments is to achieve views on the AEC that represent unbiased members of the public, however specific skills will be sought to aid understanding of the RTT, its impact and the benefits proposed.

Term of Appointment

All appointments are for the term of the current CEC in effect at the time of the appointment, thus the maximum appointment term is 5 years.

Reappointments

Reappointments are made by the code holder with no limit to the number of terms a person may serve on the AEC. All members are reappointed when a new CEC is issued.

Vacancies

Vacancies of statutory members on the AEC must be filled as promptly as possible by contacting the nominating agency. The procedure for replacement of an AEC member due to resignation or absence during the term of the CEC shall follow the appointment procedures in 2.3. An unexplained absence from the AEC for two consecutive scheduled meetings constitutes abandonment of the role and this member will have been deemed to have resigned their position on the AEC. The vacancy will be filled in accordance with the appointment procedures describe above. Vacancies will not invalidate the actions of the AEC if a quorum of members, as specified in Section 3.2, is present at an AEC meeting.

Induction and Training

The chairperson is responsible for ensuring that AEC members are sufficiently skilled to undertake their duties and can freely contribute to consideration of all AEC business. Training will include a discussion with the chairperson covering operations and projects open at the time of appointment, and access to the following resources:

- The current CEC
- NAEAC Induction pack
- NAEAC Good Practice Guide for Use of Animals in Research, Testing and Teaching
- The Act, and other relevant legislation
- Access to information and operation of any specific software required to perform their duties

Members will be given additional resources (such as updates in the resources above) as required during their appointment term and will be encouraged to attend educational events such as NAEAC workshops and ANZCCART conferences.

If the chairperson leaves the AEC, there will be a crossover period with the incoming chairperson to provide an effective induction to AEC chairing processes and training with other required processes of the workflow and EthicoDB.

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 AEC is personally liable for any act done or omitted by the member or the AEC in good faith during the operations of the AEC.

Conflict of Interest

AEC members must declare any potential conflict of interest with an item to be discussed at the start of the meeting. Details of all conflicts of interest will be formally recorded in the minutes of the meeting. If the AEC chairperson is conflicted, the deputy chairperson will administer the discussion and the chairperson must retire from the deliberations. If both are conflicted, a suitable chairperson will be elected from the committee members.

Conflicts of interest can be handled in various ways as determined by the AEC and the circumstances of the specific conflict.

- The conflicted member participates in discussion on the item, but not in the final decision;
- The conflicted member responds to questions regarding the item, but does not participate in the discussion or decision.
- The conflicted member withdraws from all discussions and deliberations on the item, and will be normally asked to leave the meeting, including when decisions are made.

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

Confidentiality

To ensure open disclosure of details in an application, the confidentiality of sensitive information will be maintained at all times. All AEC members, internal and external, shall sign a confidentiality agreement at the time of appointment, a breach of which may give rise to personal liability in civil law. Applicants attending a portion of the meeting are bound by confidentiality agreements in the parenting arrangement and will be specifically reminded of that fact when joining the meeting. AEC meetings are not open to the public, as described in Section 3.2, but should circumstances deem that a member of the public did attend, a confidentiality agreement would be obtained prior by the AEC coordinator.

All documents, including forms and correspondence, will be maintained in a secure location and access controlled. The secure location will be on the EthicoDB or Microsoft Sharepoint/Google storage which is encrypted with 2-factor authentication and regularly backed up. Any physical documents tabled at the meeting will be collected and securely destroyed. Email communication to AEC members must be deleted by the AEC members when no longer needed, such as after the relevant meeting or decision has been made.

No documentation shall be released to external parties 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
 - Apologies
 - Review of minutes of the previous meeting

- Matters arising
- Correspondence
- Conflicts of interest
- General business
- Confirmation of date of the next meeting
- For review
 - New applications, including linked approvals (e.g., ACVM, DOC)
 - Modifications to approved applications
 - Interim & final project reports
 - Standard operating procedures
 - Adverse events
 - Non-compliances
 - Monitoring reports
 - Complaints
 - Animal welfare reports (animal use statistics)
 - Any other relevant matters

Frequency of Meetings

The AEC will meet face-to-face or online in scheduled meetings at least twice a year, even if there are no new applications to discuss. In addition, additional meetings may be called by the AEC Chairperson between scheduled meetings, when required to enable the AEC to carry out its functions on submitted proposals. Meeting times, dates, and places will be provided to all AEC members in writing at the start of the year for the two scheduled meetings and at least two weeks prior to an additional required meeting.

Circulation of Meeting Papers

Meeting packs containing all agenda items will be either sent to members electronically by the AEC coordinator (as described in 3.4) or electronic access will be available to members at least 1 week prior to a meeting.

Quorum

An AEC meeting quorum required for any decisions will be achieved through attendance of 50% +1 of the current members including two external statutory members. One member of the quorum must be the chairperson or deputy chairperson.

Decision Making

The AEC will make decisions by consensus only, and if consensus cannot be reached, an application will not be approved. In this case, the application may be returned to the applicant with clear feedback for revision, or be rejected.

Effective Input of Committee Members

The chairperson will ensure that all members have the opportunity to provide effective input into deliberations of the AEC and are all in agreement with any decisions made.

Online Meetings

All meetings shall be face-to-face (in person, by video conference or hybrid) for the quorum of AEC members as defined above. Members joining the meeting by video conference must have cameras turned on and the attendance (online or in-person) will be recorded in the

minutes. Written notes may be used to enable contributions by AEC members if they cannot attend face-to-face, but these notes cannot contribute to a quorum.

Establishment and Membership of Sub-Committees

Subcommittees will not be used. All decisions will require a quorum of the AEC. Rules for consideration between meetings, (as described in 3.3.), will be followed for any application that urgent consideration is requested by the applicant.

Meeting Attendance by Other Parties

AEC meetings are not open to members of the public, however, there may be circumstances when the AEC may agree to allow members of the public to attend.

Application personnel may attend AEC meetings only when the committee deem it to be valuable such as an application in a new area of research or to present results of a study. Applicants or personnel must not be present in any capacity during AEC deliberations on the application.

All attendance at meetings by applicants or public is recorded in the meeting agenda and minutes with the reasons for the attendance. Confidentiality of applicants and public will be maintained as described in 3.1.

3.3 Consideration Between Meetings

The AEC will only consider applications at meetings, whether scheduled or additional. Requests for urgent consideration of an application before the next scheduled meeting will require an ad hoc meeting with at least a quorum (3.2) of the AEC present.

Amendments to an application can be considered outside of meetings as follows;

Major amendments are those which may have affected the deliberations of the application by the AEC and include changes to methodology, design, species, animal numbers (>10%), applicant or project leader, project outcomes or facilities.

- Major amendments to an approved application may be considered between meetings if the following conditions are in place:
 - There must be a valid reason for urgency;
 - The requested amendment is to an approved application with an impact grade of A or B;
 - The requested amendment does not increase the impact grading of the application;
 - AEC members will be notified of an urgent amendment to review by email and decisions must be made by consensus of a quorum (3.2) of members.
- Minor amendments include change in approval dates, personnel or timing of events and may be approved by the chairperson as delegated by the AEC.

Decisions made between meetings are ratified and recorded in the minutes of the subsequent AEC meeting.

3.4 Secretarial Support

Secretarial support will be managed and provided by EthicoNZ. An AEC coordinator will arrange and send out agendas, confirm attendance and payment of members, compile the meeting minutes, arrange attendance for applicants at meetings and any other tasks required for the smooth operation of the AEC. The Coordinator role is not a decision-making one on the AEC.

3.5 Record Keeping Requirements

Information Management

All records and documentation associated with the operation of the AEC are stored securely in electronic form in the AEC database or an alternate secure location (see Confidentiality) to which the code holder controls access, for not less than ten years. When deleted, this will be done securely.

The animal ethics process and information storage is done in a workflow and database system, EthicoDB. This system is built on a secure commercial platform that has been customised for EthicoNZ requirements. It meets the needs of online access, form submission, reminders, reporting and data storage required for an efficient ethics management system.

Responsibility for maintenance of the database and management of all records is with the chairperson and coordinator.

Records stored will include but are not limited to:

- CEC and any amendments
- Policies and procedures of the AEC
- Agendas of meetings
- Minutes of meetings
- Appointments of members
- Formal correspondence
- Applications
- Approvals and other AEC decisions
- Amendments
- Reports
 - Animal Use
 - Adverse events
 - Final reports
 - Monitoring visits
 - Site visits
- Standard operating procedures and approvals
- Adverse event records
- Training records
- Non-compliances
- Complaints records

Animal Use Statistics

Applications must contain all details of proposed animal use. Within one month of the approval end date, the Animal Use Statistics must be completed and submitted to the AEC in an Animal Use report. The AEC may revise the impact grade at any time during discussion of

the project or reports, and the final grading will be recorded with acceptance of the Animal Use report. This information will be stored as detailed in 3.5.

Animal Use Statistics for EthicoNZ will be provided to MPI in the requested format on or before 28 February each year or within seven days of a request for information from MPI or any inspector appointed under the Act.

Parented organisations must provide their animal use statistics directly to MPI unless there is an agreement in place with EthicoNZ to provide their animal use statistics to MPI on their behalf.

4. AEC Technical Processes

4.1 Consideration of Applications by the AEC

Criteria for Consideration

When considering submitted applications, the AEC shall ensure that the application meets the criteria set out in Section 100 of the Act. The main principles of consideration is that the benefits proposed must outweigh the foreseeable harm to those animal used in the application and that the 3 Rs (and proposed 4th R) have been implemented. A standardised application form is used to facilitate the collection of information from the applicant and the relevance to the criteria that the AEC must consider. The application form is designed so that it cannot be submitted without all the required criteria provided.

Criteria for consideration include but is not limited to:

- Personnel and their competency to undertake named procedures
- Facilities and locations of animals
- Implementation of the 3 Rs (and proposed 4th R)
- Science quality, duplication, justification, and outputs
- Materials and methods, including manipulations, dates, surgical details and drugs and compounds administered
- Animal use and re-use, treatments and groups
- Impact grade
- Biometric evaluation
- Monitoring, endpoints, and handling of contingencies and adverse events
- Potential for, and management of, compassion fatigue
- Any other matters the AEC deems relevant

The AEC will not consider an application that includes the Porsolt Swim Test for rodents or somatic cell cloning of ruminants.

Impact Grading

The MPI Animal Use Statistics guide will be used for impact grading of an application. Applicants will be requested to use this guide to propose a grading and the AEC will accept or revise this grading when considering an application.

At any time during an approval period, in response to adverse events or monitoring, or following subsequent reporting, the AEC may revise the grading of the application.

Outcomes after Consideration

Following consideration of an application using the criteria outlined in 4.1., the AEC may make the following decisions and place the application in the corresponding status.

- **Approved.** The application is approved as written and manipulations take place for the period defined by the start and end dates;
- **Approved with conditions.** Conditions of Approval may be placed on the project and communicated to the applicant along with the decision. Similarly, should minor information be required that is unknown at the approval date (e.g., farm locations), an application may be approved with explicit directions to provide that information;
- **Amendments required.** The application requires amendments which can then be considered following the pathway for major and minor amendments to an application as described in section 3.3. Manipulations must not start until the amendments have been made, the application is resubmitted and approved;
- **Revise.** The application requires major revisions which must be made and submitted following the process of a new application for consideration at a meeting of the AEC;
- **Declined.** The application is considered to be unable to be revised due to major issues with the ethical justification for the work and is declined by the AEC. The manipulations must not take place.

Decisions made by the AEC will be recorded in the minutes of the meeting and stored as described in 3.5. Applicants will be advised of decisions, conditions and requirements by email and these will also be recorded and available to the applicant in EthicoDB.

Conditions of Approval

The communication to the applicant that an application is approved includes the approved start and end dates, reporting dates, monitoring requirements or other conditions as the AEC decides. During the approval period, the AEC may set, vary or revoke conditions of approval based on information received from the monitoring and reporting process and communicate this to the approval holder.

Maximum Approval Period

The maximum approval period for an application is three years. Interim reports, using a standardised report form in EthicoDB, will be required at least annually for applications approved for over one year. Interim reports must be submitted to the AEC for formal acceptance and include the following:

- Progress on the project and any changes in delivery of outcomes
- Number of animals manipulated and impact grade, compared to numbers approved
- Reference to amendments, adverse events or non-compliances

Any proposal for work with a period of over three years will require a new application to be submitted and approved before the previous approval period ends.

Power to Suspend, Revoke, and Vary Approvals

The AEC can suspend, revoke, and vary approvals during the approval period, based on information received from the monitoring and reporting process and communicate this to the approval holder. If approval is suspended or revoked, all manipulations must cease, and arrangements must be made to safeguard the welfare of the animals. If there are specific concerns regarding the welfare of animals on a project, the AEC or persons delegated by the AEC have the power to immediately access a project for monitoring purposes at any time deemed necessary. Manipulations can be stopped anytime, and animals managed to safeguard their welfare, and approval revoked.

If the concerns of the Committee are resolved, the project may be approved to continue. Otherwise, the approval is ended permanently.

Modifications to Approved Applications

Requests to amend an application can be submitted electronically via EthicoDB during an approval period. These are categorised as follows:

- Major amendments to an approved application are those that may have affected the consideration of the application by the AEC and include changes to methodology or design, species, animal numbers >10%, approval holder or project leader, project outcomes or facilities
- Minor amendments are unlikely to have affected the consideration of the application by the AEC and include change in approval dates, animal numbers <10%, personnel or timing of events

Major amendments must be considered by at least a quorum (3.2) of AEC members. The applicant may request urgent consideration of an amendment and this may be done between scheduled meetings providing:

- There is a valid reason for urgency
- The amendment is to an application with an impact grade of A or B
- The amendment does not increase the impact grade of the application.

For urgent consideration between meetings, the AEC will be notified that an amendment is available for review and an appropriate time frame (based on the urgency of the request and AEC availability to review) given for consideration by the AEC. If necessary, a video conference may be requested by the AEC.

In all other cases amendments must be considered at a scheduled meeting of the AEC.

Minor amendments may be approved between meetings by the chairperson as delegated by the AEC but must be ratified at the next scheduled meeting of the AEC.

4.2 Standard Operating Procedures considered by the AEC

SOPs are submitted to the AEC via EthicoDB and are reviewed and approved with an expiry date by either a veterinarian/AWO who is delegated to do so by the AEC or by the AEC itself. If an SOP is being followed in an application, the SOP, operators and their competency must be referenced. The AEC considers the use of an SOP by the named competent persons when the application is discussed and new and amended SOPs may be approved at that time.

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 CEC 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 CEC 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 CEC 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 CEC (being minor amendments that would not materially affect the purposes of the CEC) without the approval of the Director-General.

(5) Where, in any year ending with 31 December, a code holder makes minor amendments to a CEC, 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.

During the approval period for this CEC, the code holder or the AEC may recommend changes (amendment, suspension, or revocation) in discussion with the other party.

MPI will be notified of all amendments, whether minor (do not materially affect the meaning or operation of the CEC) or major for acceptance or approval before they are implemented.

If the CEC is changed, all users at EthicoNZ and parented organisations will be notified and provided with a copy of the new CEC. After approval, a copy of the new CEC will be available on the EthicoNZ public website as soon as possible.

5. Monitoring by the AEC

([Section 99](#) of the Animal Welfare Act 1999)

All members of the AEC, veterinarian/AWO and any other person delegated to do so by the AEC have the authority to inspect animals, their accommodation, and to view manipulations or experimental records of currently approved applications, at any time to ensure that procedures are consistent with the approval and that facilities meet requirements. This applies whether the approval holder is from EthicoNZ or a parented organisation. While the approval holder is usually notified of such visits in advance, this is not a requirement. All monitoring visits are recorded on a monitoring form which contains details of the visit, recommendations, non-conformances, actions required and commendations. Monitoring forms and any required actions are reviewed and accepted by the AEC at scheduled meetings. If there is an urgent need for action from a monitoring visit, for example if animal welfare is compromised, the AEC may exercise its powers to suspend, revoke or vary an approval.

5.1 Monitoring during the Approval Period

The application form requires the applicant to specify how animals will be monitored and their welfare safeguarded during the project. The monitoring details required include what is to be monitored, how it will be monitored and the frequency of monitoring. If a specific recording form is used, it must be attached to the application form and submitted with the application. Monitoring questions are mandatory, and an application cannot be submitted unless answered.

In addition to monitoring during the project by the approval holder, at the time of approval the AEC will determine if the project is to be monitored by the AEC or its delegates and schedule this at an appropriate stage of the project.

In addition to scheduled visits the AEC or its delegates may monitor a project at any time during the approval period.

Monitoring visits and reports will include but are not limited to:

- Appropriateness of facilities
- Skills of project staff relevant to the manipulations and approval
- Health and welfare of animals
- Project records in line with approval
- Application of the Three Rs in line with approval
- Non-compliances with approval conditions
- Recommendations for improvement
- Commendations on any aspect of the project carried out particularly well
-

5.2 Monitoring by Proxy

Where timing or geographic location makes monitoring by the AEC or veterinarian/AWO difficult, the AEC may contract an independent veterinarian to perform a monitoring visit. The veterinarian must have the required skills to complete a monitor visit, have no conflict of interest with the project and sign a confidentiality agreement before the visit. As delegates of the AEC, contracted personnel have the same authority as AEC members.

The monitoring veterinarian will be supplied with the relevant application, other documentation, and access to complete the monitoring report online. Alternatively, they may provide it to EthicoNZ for entry into EthicoDB. Monitor reports are reviewed, actions determined from recommendations and any non-compliances found during the monitoring visit and the report accepted at an AEC meeting.

5.3 Monitoring across Impact Grades

The AEC will monitor a minimum of 10% of all approved projects with an impact grade of A or B and 100% of projects graded C-E. If a project these requirements it will be monitored at least once and if it has a duration of longer than one year, it will be monitored annually.

5.4 Monitoring Specific Manipulations

Monitoring of any project or specific manipulations outside the impact grade requirements will be determined by the AEC, considering factors such as the novelty of the manipulation, facilities, research team or perceived risks to animal welfare. These monitoring visits may be scheduled or unscheduled and a monitoring report will be completed for AEC review.

5.5 Monitoring Animal Facilities

Animal Facilities are those where animals are specifically housed or kept for RTT purposes. All facilities including those owned by EthicoNZ or parented organisations will be operated according to an approved SOP as in 4.2. and monitored during a project as required by the impact grading, or at least once in each year that the facility is used.

Monitoring visits may be scheduled or unscheduled and reports will be completed and approved by the AEC as in 5.1.

6. Responsibilities of organisations/individuals with AEC Approved Applications

6.1 Reporting to the AEC

Project Reports

Approval holders must meet all reporting requirements associated with their project.

Interim reports are required annually for projects over one year or at specified points in the project, containing project details as requested by the AEC.

Approval holders must submit a report on the animal welfare outcomes and complete animal use statistics according to Animal Welfare (Records and Statistics) Regulations 1999 and MPI Guidance Document: Animal Use Statistics, within one month after the approval end date.

Final reports covering the project's scientific outcomes, benefits and further work planned must be submitted within six months of the end of the approval period.

End of Approval Grading & Animal Use Statistics

End of approval grading will be reported to the AEC in the animal use report within one month of the end of the approval period. The impact grade at the end of the approval period must take into account the proposed grading, any change in impact assessed during the project and the impact of any adverse events where the event is related to the project and has altered the impact on the affected animals. The final decision on grading is determined by the AEC when the animal use report is accepted.

Non-Compliance

EthicoNZ and all parented organisations must have a procedures in place to report and manage any non-compliances that are identified during monitoring or reported during projects. Non compliances may include, but are not limited to omissions or deviations from;

- The Act, regulations or codes of welfare;
- The CEC;
- All details, conditions, procedures and requirements of the approval;

All non-compliances, whether they are identified during monitoring or by the organisations themselves must be reported within one week of a request from EthicoNZ or AEC, using a non-compliance form on EthicoDB. The non-compliance form describes the circumstances of the non-compliance and actions required to prevent it from reoccurring. If the non-compliance has impacted or put animal welfare at risk, the situation must be also managed as an adverse event (see below).

Non compliances will be considered by the AEC and any corrective actions required by the AEC must be responded to and actioned within 30 days. The appropriate severity of the non-compliance (Minor or Major, see 7.1) will be communicated to the organisation(s) concerned to manage, and if deemed necessary by the AEC, escalated to MPI.

Adverse Events

Adverse events may occur during a project due to causes as diverse as extreme weather events, unpredicted side effects of a treatment or manipulation or if approved animal

welfare thresholds are exceeded. All adverse events must be reported (via phone, email or EthicoDB) to the AEC within 24 hours of the event. An adverse event report must be submitted within 30 days by the appropriate person (approval holder, facility manager, program manager or veterinarian). The person(s) responsible for the animals (in consultation with a veterinarian if necessary) must take appropriate action, including treatments, management practices, or post-mortem.

The application form must describe monitoring methods, endpoints, contingency plans for adverse events, and animal welfare thresholds. A contingency plan must include the action to be taken and the procedure for emergency euthanasia.

The adverse event report requires the approval holder to consider how the risk of the same or similar event can be reduced and to determine if the application or SOP need to be modified considering the adverse event. The adverse event report and actions taken or proposed are accepted by the AEC at a meeting. The approval holder must make any required change to an application that is detailed in the adverse event form through an amendment to the application.

The adverse event report requires the approval holder to consider whether the event has increased the impact grading of the study. If so, this must be accounted for in the post-approval reporting.

6.2 Records Management

All parented organisations and applications must have a person responsible for keeping the following required records:

- Applications
- AEC approval documents
- Number of animals used, all manipulations undertaken and actual impact grade
- Details of animal husbandry routines and environmental conditions
- Amendments approved during the project
- Non-compliances
- Adverse events, monitoring, animal use and final reports
- SOPs
- Staff training records
- Veterinary consultation and treatment
- Project results

6.3 Appropriate Qualifications

All personnel who undertake animal manipulations must be trained in the procedure or in an approved relevant SOP. Competency or qualifications of personnel must be declared on the application and is subject to monitoring. Training may occur on an application if stated, providing the trainer is either a veterinarian/AWO or another suitably qualified person who has the competency of trainer.

A register of SOPs, trained personnel, competency and expiry is kept in EthicoDB.

6.4 Sick and Injured Animals

All applications must have a veterinarian or veterinary practice named on the application. If the health or well-being of an animal is compromised during a project, veterinary advice must be sought and implemented.

6.5 Standard Operating Procedures developed by the Code Holder

All SOPs are created and stored in EthicoDB, reviewed and approved with an expiry date by the AEC or a veterinarian delegated to do so. EthicoNZ will provide reminders to the approval holder within 30 days of the SOP expiry date and unlock the SOP so it can be reviewed and edited if necessary. SOP renewals and updates will be approved by the AEC.

If an approval holder wishes to change an SOP during the approved period, or a change has been requested by the AEC as a result of monitoring, adverse event, non-compliance or new knowledge, the SOP will be unlocked by EthicoNZ for editing and approval.

6.6 Management of Animal Facilities

Policies & Procedures

If animals are housed, the housing must be managed following the NAEAC Good Practice Guide for the Use of Animals in Research, Testing and Teaching. Housing facilities must ensure that animals' general health is safeguarded, and undue stress is avoided. Sufficient space, according to the species, must be allocated for each animal. Environmental needs such as temperature, humidity, ventilation, lighting, and social interaction must also be consistent with the species' needs. Appropriate enrichment (e.g. environmental complexity) for caged or housed animals must be provided unless it can be demonstrated that the enrichment will interfere with the research objectives, and the AEC accepts this justification. Animals must be fed appropriate to their requirements and of the quality and quantity adequate to preserve their health, with free access to water, unless an application objective is to study the effects of variation in these nutritional requirements and the variation is approved by the AEC.

Facility standards shall be maintained by providing in-house training and access to external training for animal care staff. The AEC monitors facilities and approves SOPs for the operation of the facility as described in 5.5.

The facility manager and the approval holder are responsible for ensuring that the person caring for the day-to-day needs of animals is appropriately trained and has access to a registered veterinarian should the need arise. Animal husbandry and care shall be provided at each facility daily. All caged indoor-housed animals shall be visually inspected by an approved operator at least daily.

The manager of a facility must review and sign off all applications prior to manipulations taking place in that facility. Managers are responsible for ensuring their staff are aware of their roles and responsibilities on a project.

Animals in a commercial farming environment must be cared for following good farming practice that aligns with the relevant codes of welfare for the species. The AEC must be notified of farm locations.

Emergency Management

Facilities must have a current SOP that is provided to the AEC for review that includes but is not limited to:

- Routine animal husbandry and handling procedures;
- Animal transport;
- Cleaning and sanitation;
- Animal health plan and identification appropriate to the species and location;
- Breeding colony management (if appropriate);
- Emergency management including fire, natural disasters and pandemics;
- Euthanasia;
- Reporting of adverse events and non-compliances;
- Staff health and safety.

Housing of Animals

Animal facilities and practices (design, hygiene and management) shall be managed following good practice and scientific knowledge (as recommended by NAEAC in its Good Practice Guide for the Use of Animals in Research, Testing and Teaching, to the relevant codes of welfare issued under section 75 of the Animal Welfare Act 1999) and following the specific SOP for the facility.

Transportation of Animals

Animals must be transported following relevant legislation and codes of welfare (Code of Welfare: Transport within New Zealand | NZ Government (mpi.govt.nz)). Animals imported from overseas must meet all applicable regulatory requirements.

6.7 Euthanasia for Tissue Collection

Killing animals for the purpose of tissue collection/dissection requires an application to the AEC documenting the justification, method of killing and disposal. Methods of killing appropriate to the species and life cycle must be used and The American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals used as a guide.

6.8 Rehoming

The potential to rehome animals at the end of studies must be considered and described in all applications and approved by the AEC. Where there is potential for rehoming, this will be explored by the AEC on a case-by-case basis.

7. Compliance Breaches & Complaints Procedures

([Section 103](#) of the Animal Welfare Act 1999)

7.1 Compliance Breaches

Non-Compliance with an AEC Approval

All staff using this CEC must familiarise themselves with it and all other policies and procedures that apply to using animals for research testing and teaching. By signing a parenting contract, organisations agree to follow this CEC.

All Acts of Parliament, regulations or by-laws on the obtaining, holding possession, care and

treatment of animals are to be complied with. AEC approval is limited to approving the use of animals in Research, Testing and Teaching under the Animal Welfare Act 1999 (Part 6) and does not override individuals' obligations under legislation or regulation other than the Animal Welfare Act. Approval holders and personnel are therefore responsible for compliance with all other legislation and regulations. Specific questions in the application are asked to ensure compliance requirements outside the Animal Welfare Act have been met. These questions are included so the AEC can be confident that any other potential compliance issues have been addressed and if compliance with other legislation may influence any details required in the application or approval conditions.

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

Minor non-compliances are those where there has been a small (unlikely to impact the study or animal welfare), accidental non-compliance with legislation, regulations or approval conditions as described in the application or any conditions imposed by the AEC. Minor non-compliances are recorded and dealt with by the AEC and organisations as described in 6.1.

Major Non-Compliance with Legislation or Regulations

A major non-compliance with legislation, regulations or approval conditions as described in the application or any conditions imposed by the AEC is one that would have impacted the current approval of the study or adversely affected animal welfare. Major non-compliances are recorded and dealt with by the AEC and organisations as described in 6.1. with additional conditions put on subsequent applications from the research team or organisation, as determined by the AEC.

All non-compliances, whether they are major or minor must be reported within one week of a request from EthicoNZ or the AEC, using a non-compliance form on EthicoDB. Corrective actions arising from the non-compliance must be actioned with 30 days of a request from the AEC.

7.2 Animal Welfare Complaints

By the Public

Complaints made by members of the public shall be reported to the chairperson, who may correspond directly with those concerned or with the parented organisation concerned. If not resolved the complainant may be advised that further correspondence can be addressed to the Ministry for Primary Industries.

By Employees

Any person employed by EthicoNZ or a parented organisation can raise a complaint with the AEC in any instance where they believe that the welfare of animals (whether or not they are being managed under a current AEC approval) is compromised. This communication can be made directly to the chairperson or an AEC member in person or by email.

The AEC can direct that any procedure, whether approved or not, be stopped or modified on ethical grounds. The AEC can also require that the animals be appropriately cared for or euthanased.

All complaints will be handled by EthicoNZ as a priority with an initial response to the complainant within seven days outlining the process that will be followed. The complaint will

be formally reviewed at the next meeting of the AEC, recorded in EthicoDB and action will be taken in line with the severity of the issue. If the complaint leads to non-compliance, it will be dealt with as outlined in 6.1 and 7.1. If the complaint is serious an urgent meeting of the AEC may be called.

Complaints will be closed once the complainant, code holder and AEC are satisfied with the outcome or it has been referred to the Ministry for Primary Industries for further action.

By AEC Members

Any member of the AEC who believes that the Committee, EthicoNZ or a parented organisation is failing to comply in a material respect with the CEC may report this non-compliance to the Director-General of the Ministry of Primary Industries.

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

7.3 Procedural Complaints

([Section 103](#) of the Animal Welfare Act 1999)

By approval holders

If an approval holder wishes to make a procedural complaint, the complaint will be directed to the chairperson, who will decide if a formal investigation or other action is required.

Any employee of EthicoNZ or a parented organisation who makes such a report in good faith shall not be liable to any disciplinary or civil proceedings because of having made that complaint.

By AEC Members

The chairperson and other members of the AEC will initially investigate procedural complaints from any member of the AEC and If the complaint is substantiated, a formal investigation will be initiated and appropriate action taken, including notification to the Ministry for Primary Industries.

Against the Chair/Deputy Chair/Administrator

If a complaint from any person concerns the chairperson of the AEC, it can be made directly to the Ministry for Primary Industries for appropriate action to be taken.

The complainant will be notified of the process that will be followed within seven days of EthicoNZ receiving a complaint. The timeframe for the formal investigation may depend on the nature of the complaint and the parties involved but will be handled as a priority.

Complaints will be closed once the complainant, code holder and AEC are satisfied with the outcome or it has been referred to the Ministry for Primary Industries for further action.

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

([Section 84](#) of the Animal Welfare Act 1999)

Parenting arrangements with other organisations shall be entered into on a case-by-case basis and only if the AEC has the appropriate expertise to review applications and monitor the approvals by that organisation.

The parented organisation, through its nominated representative, must sign a parenting contract, valid until the end of the current CEC. In signing this contract, the organisation agrees to abide by the CEC, confidentiality, monitoring requirements and a declaration of other or prior arrangements with an AEC or offences against the Animal Welfare Act. A parented organisation must also demonstrate commitment and a culture consistent with this CEC.

The Ministry for Primary Industries will be notified in writing of all parenting arrangements before the organisation can submit an application to the Committee.

Parented organisations must provide their animal use statistics directly to the Ministry for Primary Industries unless there is an agreement in place with EthicoNZ to provide animal use statistics on their behalf.