EpiVets Ltd - Tika Ethics

CODE OF ETHICAL CONDUCT

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

14 May 2025 to 13 May 2030

Table of Contents / Ngā Ihirangi

1. Background on the Activities of the Code Holder / He Kōrero Whakamārama mō ngā Mahi a te Kaipupuri i te Tikanga

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

1.1 Organisational Activities / Ngā Mahi a te Whakahaere

Tika Ethics Ltd is a wholly owned subsidiary of EpiVets Ltd. EpiVets is a research and epidemiology business based in Te Awamutu. We have four main engines of our business:

1. Regulatory – We have a team of people who help businesses navigate through the process of getting products registered through the ACVM (Agricultural Compounds and Veterinary Medicines). Sometimes involves designing a full regulatory pathway for clients, other times it may be doing an assessment of products that have been submitted for registration.

2. Research – We have five veterinary epidemiologists, five research technicians, a senior scientist and four regulatory specialists who make up this part of our business.

We carry out trial work on New Zealand production animal farms for sheep (meat and milk), beef, dairy cattle and deer.

These can be:

a.) Welfare-based studies (e.g. the prevalence of lameness in dairy cattle nationally, prevalence of tail damage in cattle nationally, leaving calves on the dam)
b.) Product registration studies (e.g. a new teat seal, methane mitigation products). Existing product studies that need some more research (e.g. pain relief used for disbudding cattle or goats).
c.) Pilot studies – Studies that are cutting edge in new technology or products that are going through their first round of animal testing.
d.) Test validation studies (e.g., utilising bulk milk to determine the selenium status of cattle).

3. Epidemiology (Statistical analysis) – We analyse all sorts of data from children to chickens, cattle to horses, sheep to deer, and bees to plants. We build databases and carry out machine-learning projects on colossal data sets.

4. Epidemiology (Disease modelling)—Here, we study exotic diseases and model their outbreaks or outcomes (e.g., foot and mouth disease in Indonesia).

1.2 RTT and Te Tiriti o Waitangi Obligations and Principles / Te Rangahau, Te Whakamātautau me te Whakaako (RTT) me ngā Herenga me ngā Mātāpono o Te Tiriti o Waitangi

Our organisation recognises and is committed to the principles of partnership, participation, and protection as outlined in the Treaty of Waitangi. While we are not a university or a

Crown Research Institute, we understand the importance of these principles in guiding ethical conduct and relationships with Māori. This is in part why we chose the name that we did as Tika means “Correct”, “True”, or “right”, often related to doing what is just or proper in accordance with cultural and spiritual practices.

Partnership: We actively seek to build and maintain partnerships with Māori communities. We acknowledge that engagement should be based on mutual respect and understanding. This involves consulting with local iwi or hapū on research projects, especially those that might influence areas of particular interest to Māori, ensuring their perspectives are integrated and respected in our ethical conduct.

Participation: We are committed to facilitating the meaningful participation of Māori in our activities related to RTT. This includes creating opportunities for Māori input on projects that may affect indigenous species or culturally significant animals. Although we may not have Māori representation on our Animal Ethics Committee directly, we ensure that all research proposals consider and reflect Māori views and interests.

Protection: We ensure that our practices uphold the protection of Māori values, particularly when it involves indigenous species or lands. Research activities are conducted with care (tiaki) and respect (whakaute), ensuring that Māori cultural relationships with fauna and the environment are not compromised. In cases where research may potentially impact indigenous species, we require our researchers to engage with Māori communities, providing evidence of these engagements.

We encourage our team to continually seek guidance from cultural advisers to ensure our understanding and implementation of the Treaty principles are both respectful and effective. By embedding these principles throughout our ethical conduct code, we strive to promote a harmonious and respectful relationship with Māori in all aspects of our work.

1.3 The 3 Rs / Ngā R e 3

Our organisation is committed to ethical practices in Research, Testing, and Teaching (RTT). We adhere to the principles of the 3 Rs—Replacement, Reduction, and Refinement—as integral to our operational philosophy, guiding all aspects of our work involving animals.

Replacement: We prioritise the use of non-animal models and methods whenever possible. Our goal is to minimise reliance on animal involvement by exploring innovative alternatives, such as in vitro models, computer simulations, and other technological methodologies that do not require the use of sentient creatures. We collaborate with others to ensure that we have the required relationships to look for alternatives.

Reduction: When the use of animals is necessary, we focus on rigorous experimental design and statistical practices to minimise the number of animals involved. Each research proposal undergoes a thorough review to ensure that any use of animals is fully justified and that the smallest number necessary is employed to achieve sound scientific outcomes. Our farming backgrounds and close links within these communities allow us to understand results that will “matter” in the industry, not just what may be interesting. This allows us to do sample size calculations on outcomes that are realistic and practical, often reducing the number of animals required.

Refinement: We continuously strive to enhance the welfare of animals under our care. This includes refining procedures and techniques to reduce pain and distress, ensuring humane housing and handling conditions, and enhancing the overall quality of life for animals involved in research. We draw on the latest scientific advancements to inform and improve our practices.

Additionally, our organisation encourages the inclusion of a fourth R—Respect—into our RTT philosophy. This involves fostering a culture of respect and ethical responsibility towards all living creatures.

1.4 Responsible Individuals / Ngā Tāngata Takitahi e Whai Takohanga ana

The Managing Director of EpiVets Ltd ("Code Holder") is ultimately responsible for the administration of the Code of Ethical Conduct (CEC) through the AEC (Tika Ethics). The Managing Director delegates this authority to the AEC Chair (nominated person) via the EpiVets Board of Directors. The CEC is administered by the AEC.

1.5 Individuals/Organisations under the CEC / Ngā Tāngata Takitahi / Ngā Whakahaere i roto i Te Tikanga Mahi Matatika

This CEC applies to EpiVets Ltd and its employees. In addition, Tika Ethics may enter into parenting agreements with other organisations that elect to operate under and comply with this CEC. All individuals in either EpiVets Ltd or parented organisations that use animals for research, testing or teaching (RTT) under the approval of the AEC must be familiar with and comply with this CEC.

The CEC will be available on the Tika Ethics SharePoint site and is provided to all organisations before they enter a parenting arrangement with Tika Ethics.

2. Functions, Powers and Membership of the Animal Ethics Committee (AEC) / Ngā Kawenga, Ngā Mana me te Noho Mema ki te Komiti Matatika Kararehe (AEC)

2.1 Functions and Powers of the AEC / Ngā Kawenga me Ngā Mana o te Komiti Matatika Kararehe (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 the 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.

Under sections 1(d) &1(e) above, the AEC reserves the right to inspect animals, the facilities where they reside, and related experimental records at any time to satisfy itself that approved procedures are being properly carried out.

2.2 Membership of the AEC / Te Noho Mema ki te Komiti Matatika Kararehe (AEC)

The AEC will consist of five members, four of whom will be statutory members (section 101 of the Animal Welfare Act 1999) and one chair. Other members may be appointed by the code holder if other skill sets are required to reach a maximum of seven members.

The Chair is a contracted staff member, appointed by the Managing Director of EpiVets to work on behalf of Tika Ethics. This individual has a contract with EpiVets Ltd to work for Tika Ethics. This individual is capable of evaluating projects, the skills of the applicants and the scientific or teaching value of the project.

Statutory members

- 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 EpiVets Ltd, or associated with the scientific community or an animal welfare agency
- A senior member of EpiVets

External Members will be paid an agreed amount per AEC meeting for the time involved in reading material and attending meetings. Additional costs associated with monitoring projects and farms, and all associated travel costs, will be paid. Payments for meeting attendance are arranged quarterly. Processing of payments for monitoring and travel costs will be arranged by the administration of EpiVets Ltd every month.

Organisational members

EpiVets Ltd is choosing to put one senior staff member onto Tika Ethics as per the statutory requirements. To minimise bias, this member will not have any involvement in the research

side of EpiVets, so they will have no contact with the clients or have any idea of the study that is being proposed before being part of the assessment team of the committee.

Additional members

The AEC may, from time to time, seek expert advice from additional individuals external to the organisation or (in the situation where biometric support is required internally) in cases where expertise is not otherwise represented on the committee. These advisors do not participate in decision-making. External advisors will be remunerated on the same basis as Statutory External Members.

2.3 AEC Appointment Procedures / Ngā Tukanga Kopou Mema ki te Komiti Matatika Kararehe (AEC)

Members, Chair/Deputy Chair

1. General Member Appointments:
    - Appointments to the AEC are made from the code holder following consultations between the Committee, the code holder, and any relevant nominating bodies or agencies for statutory external appointments.
    - For organisational membership, the current AEC evaluates its existing composition to identify areas where additional expertise is needed. Recommendations for new members are based on their skills, experience, availability, and potential conflicts of interest to ensure a balanced representation within the committee.
2. External Member Appointments:
    - External members are appointed by the code holder upon the recommendation of their respective nominating bodies. This collaboration ensures the inclusion of a wide range of perspectives and expertise relevant to ethical animal research.
3. Chair and Deputy Chair Appointments:
    - The code holder appoints the AEC Chair for the term outlined in the Code of Ethical Conduct (CEC). The appointed individuals must demonstrate leadership skills, considerable experience, and a comprehensive understanding of ethical practices and regulations.
    - In instances where the Chair is unavailable, the Deputy Chair is nominated to fulfil the Chair's responsibilities as chosen by the Chair or the code holder in their absence, ensuring seamless continuity of leadership and decision-making. The AEC or Code Holder will appoint the Deputy Chair if the Chair is recused due to a potential conflict of interest.
4. Replacement During the CEC Term:
    - Should a replacement of any AEC member be necessary during the term of the CEC, the procedure as outlined above for the relevant member category will be followed to maintain the committee's functionality and integrity.

Term of Appointment

Members are appointed for a term of 3 years and may be reappointed for up to two additional terms with the approval of the nominating body.

Reappointments

Reappointments will be made by the Code holder or their nominee on the recommendation of the AEC and with the approval of the nominating body.

Vacancies

In the event of any member being absent for a planned period of more than three months, their position will be deemed vacant, and nominations for a replacement shall be sought from the appointing/nominating party concerned. Where the duration of absence is uncertain, the AEC will decide whether to appoint a replacement person for that duration.

Induction and Training

1. Initial Orientation and Meetings: New members will meet with the AEC Chair before their first meeting to discuss the committee's structure, functions, and expectations. This provides a foundation for understanding their new roles. This meeting may be online.
2. Training Sessions: Group training sessions will cover the operational aspects of the AEC and the use of our management systems, including any relevant databases or tools for managing submissions and reviews. If required, further one-on-one training will be carried out online if further individual training is required.
3. Resource Provision:
    - Access to EpiVets Ltd.'s Code of Ethical Conduct (CEC).
    - NAEAC's induction pack and Good Practice Guide for Use of Animals in Research, Testing, and Teaching.
    - Relevant communications, newsletters, and documents that aid in ongoing education.

Ongoing Development for Current AEC Members:

We emphasise the importance of continual learning and development for our AEC members through:

1. Educational Resources and Participation: Members are encouraged to engage in webinars, workshops, and conferences related to animal ethics, research, and welfare. Support is provided to facilitate attendance and participation.
2. Access to Literature and Guides: Continuous updates and literature relevant to the field are circulated among members, ensuring they are informed of the latest developments and best practices.
3. Professional Networking and Support:
    - Opportunities to network with peers from similar organisations and participate in NAEAC workshops.

- Encouragement to seek additional training or support for professional growth.

4. Mentorship for Leadership Transitions: When there's a transition in the AEC Chair position, the outgoing Chair or the longest-serving committee members will provide mentorship and guidance to ensure a smooth transfer of responsibilities.

Through these structured approaches, EpiVets Ltd ensures that both new and current members of the AEC are equipped with the skills, knowledge, and resources necessary to uphold the highest ethical standards in animal research and welfare.

3. AEC Standard Processes / Ngā Hātepe Whakahaere a te Komiti Matatika Kararehe (AEC)

3.1 General / He Hātepe Whānui

Protection of AEC Members

In accordance with Section 104 of the Animal Welfare Act 1999, members of the Animal Ethics Committee (AEC) at Tika Ethics are protected from personal liability for actions undertaken in good faith during the operations of the committee. This provision ensures that AEC members can perform their duties with confidence, knowing that they are not personally liable for acts or omissions made in the honest exercise of their responsibilities.

Furthermore, all members of the AEC are covered under EpiVets Ltd Professional Indemnity Insurance policy. This coverage applies when members are conducting their roles and responsibilities associated with the AEC, adhering to the terms, conditions, exclusions, and limitations specified by the policy. This insurance provides an additional layer of protection, underscoring our commitment to the support and security of our AEC members as they uphold the highest ethical standards in animal research.

Conflict of Interest

At Tika Ethics, we are committed to maintaining impartiality and integrity within our Animal Ethics Committee (AEC), which is of particular importance given the potential real and perceived bias of being a research organisation that also has an ethics committee. To ensure this, several measures are in place to identify and manage conflicts of interest effectively:

1. Committee Composition: While there will be a senior member of EpiVets on the committee, this member does not work in the research part of the business. This ensures they bring institutional knowledge but ensures that the committee operates independently and that all evaluations are conducted without influence from internal stakeholders of the organisation. The Chair is employed by EpiVets, but does not work day-to-day in the EpiVets business, so can stay completely removed from the projects for unbiased evaluation.

2. Declaration and Management: If any AEC member, including the Chair, finds themselves listed as an applicant on a proposal or identifies a conflict of interest that could question their impartiality, they are required to declare the conflict and withdraw from the assessment process for that application.

3. Chair Conflict Protocol: In instances where the Chair declares a conflict of interest, the Deputy Chair will assume the Chair's duties for the assessment of the affected application to maintain objectivity in decision-making.
4. Confidentiality Measures: All applications and communications regarding assessments are managed confidentially and separately from EpiVets Ltd employees. This ensures that information is shared only within the AEC and relevant parties, safeguarding against any potential conflicts related to confidentiality breaches.
5. Documentation: All declared conflicts of interest and subsequent actions are meticulously recorded in the minutes of the AEC meetings. This transparency is crucial for maintaining trust and accountability in all ethical evaluations conducted by the committee.

By implementing these measures, Tika Ethics strives to uphold a robust framework for ethical oversight, ensuring that all research involving animals is assessed fairly and without bias.

Confidentiality

This is an area that Tika Ethics takes very seriously, both with the applications we are submitting, but also for those organisations that are parented.

1. Non-Disclosure Agreements (NDAs): An NDA will be established with any new business for which EpiVets is applying on behalf of or that is being parented under the CEC and Tika Ethics. This ensures that all parties are legally bound to protect confidential information and intellectual property shared during the AEC processes.
2. Employment and Subcontracting Agreements: All individual members of Tika Ethics, including employees and subcontractors, are bound by employment or subcontracting agreements that explicitly detail their obligations regarding confidentiality. These agreements emphasise the responsibility to protect proprietary and sensitive information encountered in the course of their duties.
3. Secure Information Systems: Utilising SharePoint as our secure platform, we restrict access to AEC documents and communications to only those members with the necessary permissions. This protection ensures that confidential information is handled exclusively by authorised individuals.
4. Confidentiality Protocols for Meetings:

   Applicants: All applications are reviewed under strict confidentiality during AEC meetings, with applicants reassured that their sensitive information remains secure.

   Public Attendance: Members of the public who may attend AEC meetings are required to sign confidentiality agreements to prevent unauthorised disclosure of any proprietary or sensitive information discussed.
5. Training and Policy Awareness: Regular training sessions for AEC members and stakeholders reinforce the importance of confidentiality. Emphasising awareness around data protection protocols helps maintain high standards across the organisation.

6. **Breach and Dismissal Policies:** Any breaches of confidentiality by AEC members, employees, or subcontractors are taken seriously and are subject to investigation. Depending on the severity of the breach, disciplinary actions may include dismissal or termination of employment or subcontracting agreements. This policy underscores our commitment to safeguarding information integrity and maintaining the trust placed in our organisation.

3.2 Meeting Procedures / Ngā Tukanga Hui

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
    - Confirmation of the 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

Frequency of Meetings

Meetings will be held at a minimum of monthly online. These will be booked in advance for the full year with a set time and will be cancelled by the Chair if there are no applications or items to discuss. Additional meetings may be required, and these will be booked in advance at a frequency appropriate to the demand.

One meeting per year will be attempted to be conducted in person to strengthen the committee and combine this with training.

Circulation of Meeting Papers

Meeting papers will be distributed by the Secretary to members of the AEC a minimum of one week prior to each meeting by providing a link to a document folder in the AEC's online resource (SharePoint).

Quorum

The quorum for meetings shall be 50% of the number of AEC members plus one, with at least two from the Statutory External Membership category.

Decision Making

The AEC will reach decisions by consensus. If consensus cannot be reached, the applicant or another person (advisor) with relevant expertise may be invited to present additional information and respond to members' questions, or the application will be declined. If an application is declined, applicants will be provided with the reasons for decline and may subsequently submit a revised application. The AEC reserves the right to decline an application without the option to resubmit.

Effective Input of Committee Members

The key to effective input is to ensure that members are well-supported and resourced to effectively contribute to committee discussions:

1. Access to Information: All committee members are provided with access to all agenda items and relevant documentation well in advance of meetings. This ensures that every member is fully informed and prepared to engage meaningfully in discussions.
2. Equal Opportunity for Contribution: The Chair actively facilitates an inclusive environment where all members, especially statutory external representatives, are encouraged and expected to participate fully in the committee's business. Every member's input is valued, and discussions are structured to allow ample opportunity for contributions before any decisions are made.
3. Professional Development and Support: Members are provided with opportunities for upskilling and professional development. This includes access to workshops, seminars, and additional training resources to enhance their contribution to the AEC.
4. Requesting Additional Information: To support informed decision-making, research staff and resources are available to committee members upon request. They can provide additional information and answer any questions regarding applications, ensuring clarity and understanding of complex issues.
5. Facilitated Feedback Mechanisms: The Chair ensures that mechanisms for providing feedback are actively facilitated. This includes soliciting input during meetings, as well as offering additional channels for feedback, such as surveys or follow-up meetings, to capture any suggestions or concerns members might have.

Online Meetings

Online (face-to-face) meetings will be the preferred method for meetings to allow for suitable representation across the country (e.g. South Island).

Establishment and Membership of Sub-Committees

Subcommittees will not be established given the small number of members of the Tika Ethics Committee.

Meeting Attendance by Other Parties

1. Meeting Structure: AEC meetings are structured in two parts to balance public access with confidential deliberation:
    - Part I: This section covers general business and may be attended by the public, allowing transparency and access to non-sensitive discussions.

- **Part II:** This section is reserved for confidential discussions where the public is excluded. This ensures that sensitive matters are handled with the appropriate level of confidentiality. If external advisors or members of the public are invited to attend Part II, they must adhere to the same confidentiality requirements as AEC members.

2. **Applicant Attendance:** Applicants or project personnel may be invited to attend AEC meetings under specific circumstances:
    - When an application involves a new area or subject matter unfamiliar to the AEC, inviting applicants can provide valuable insights before their application is formally considered.
    - To deliver presentations on project results, enriching the committee's understanding of ongoing research.
    - To facilitate discussions by addressing specific questions directed to the applicant.
    - Any other instances deemed necessary by the AEC to enhance deliberations.
3. **Confidential Deliberations:** Regardless of their involvement, applicants or other personnel must not be present during the AEC's deliberative sessions on their applications to preserve fairness and confidentiality.
4. **Documentation:** All instances of visitor attendance, including applicants and members of the public, are documented in the meeting agenda and minutes. This ensures a transparent record of participation while maintaining confidentiality standards.

3.3 Consideration Between Meetings / Te Whai Whakaaro ki te Take ki Waenga i ngā Hui

At Tika Ethics, we have a structured process in place to manage matters that arise between scheduled meetings of the Animal Ethics Committee (AEC), ensuring that urgent requests are handled efficiently while maintaining high ethical standards:

1. **Between-Meeting Decisions:** When decisions are necessary between scheduled AEC meetings, applications and amendments can be considered under the following conditions:
    - Urgent requests involving manipulations graded 'C' or amendments that do not alter the application's impact grading may be reviewed by a quorum of the committee. The urgency must be justified, and teleconferencing can facilitate discussions for amplitude-grading up to 'C', while email communication handles those up to 'B'.

    Research considered grades 'D' and 'E' will not be considered between full meetings.
2. **Urgency and Prioritisation:** Urgent applications are those scheduled to commence within two weeks or less and must detail the reasons for urgency. These applications may be prioritised for review through available preview processes and addressed at the next full AEC meeting if necessary.

3. Temporary Consents and Subsequent Review:

   All temporary consents or amendments that were approved between scheduled meetings will be compiled and presented at the next scheduled Animal Ethics Committee (AEC) meeting. During this meeting, AEC members will review the temporary consents to ensure that they meet ethical standards and that the circumstances necessitating their approval are valid. The AEC members will confirm the temporary consents by consensus. If the members agree that the consents were justified and meet ethical guidelines, they are ratified and remain in effect. If the AEC members find issues with any temporary consent, they have the authority to revoke it or suggest modifications. In case of revocation, all related work must cease immediately, except for necessary actions to ensure animal welfare. The outcomes of the AEC meeting, including ratifications, revocations, or modifications, will be documented in the meeting minutes for transparency and future reference.

4. Documentation and Transparency: Decisions made between meetings are meticulously recorded in the appropriate documentation systems and ratified in the minutes of the subsequent AEC meeting, ensuring transparency and accountability in interim decision-making.

Through these procedures, Tika Ethics ensures that urgent matters are addressed promptly, maintaining the integrity and operational effectiveness of the AEC by balancing flexibility with rigorous oversight.

3.4 Secretarial Support / Te Tautoko a te Ringa Āwhina

The secretary's support is designed in accordance with Section 102 of the Animal Welfare Act 1999, ensuring effective administration and compliance with regulatory standards.

The secretary will be employed part-time by Tika Ethics Ltd.

1. Role of the Secretary:
   - Competencies: The appointed secretary possesses strong organisational, communication, and administrative skills, with a thorough understanding of ethical compliance and the operational procedures of the AEC.
   - Responsibilities: The secretary is responsible for managing all secretarial functions related to the AEC, ensuring adherence to ethical and procedural guidelines.
2. Organisation of Meetings:
   - The secretary coordinates the logistics of AEC meetings, including scheduling, venue arrangements (if applicable), and ensuring appropriate technological support for virtual attendance when necessary.
   - They work closely with the AEC Chair to set the agenda, ensuring all necessary items and applications are included and prioritised as required.
3. Agenda Setting:

- The secretary assists the Chair in preparing and distributing the meeting agenda to all members in advance, allowing adequate preparation time and facilitating informed discussions during meetings.

4. Recording and Keeping Minutes:
    - During meetings, the secretary is responsible for accurately recording the minutes, capturing key discussions, decisions, and actions both in writing and as a recorded online meeting. This documentation serves as an official record of the proceedings.
    - Following meetings, the secretary disseminates the minutes to all AEC members and ensures they are securely archived for future reference and compliance purposes.
5. Continuous Improvement: The secretary is encouraged to provide feedback on processes and implement improvements to enhance the efficiency and effectiveness of AEC operations.
6. Other functions: Communicating with applicants and AEC members, maintaining all records, reporting annually to internal and external governing bodies and any other duties as required to support the AEC. The Secretary does not contribute to AEC decision-making.

3.5 Record Keeping Requirements / Ngā Herenga Whakataimau Pūranga

Information Management

1. Documentation Preparation and Storage:
    - The Secretary is responsible for preparing meeting agendas and accurately recording meeting minutes, along with any other documentation related to AEC operations, communications, applications, and reports.
    - All documentation will initially be maintained in electronic formats using standard word processing software and stored securely on a dedicated drive. This includes files related to applications, decisions made, meeting minutes, and other operational records.
2. Access and Security:
    - Access to AEC documentation is restricted and controlled through permission settings on the secure electronic storage system (SharePoint). Only authorised AEC members and essential staff will have access to the documents relevant to their roles and responsibilities.
    - Regular audits of access permissions will be conducted by the Managing Director of EpiVets to ensure that only current AEC members and designated personnel can view or modify documentation.
3. Record Retention:
    - Meeting minutes, decisions, operational records, and applications will be retained for a minimum of ten (10) years.

- Applications and statistical records will specifically be maintained for twenty (20) years, ensuring comprehensive retention of important compliance data.

4. Destruction of Records:
    - Once the retention period has expired, all documentation will be securely destroyed to protect any confidential or sensitive information. Destruction will be carried out through approved methods, such as shredding of physical documents and secure deletion of digital files, in accordance with relevant records management policies and best practices.
5. Backup and Recovery:
    - Regular backups of all electronic documentation will be performed to prevent data loss. Backup systems will ensure that all information can be recovered in the event of a system failure or other unforeseen circumstances.

Animal Use Statistics

Applications must contain all details for the proposed Animal Use Statistics. Within one month of the approval end date, the corresponding information for animals used must be completed and submitted to the AEC. The AEC may revise the impact grade at any time during the project discussion or reports, and the final grading will be recorded upon acceptance of this report.

EpiVets and Parented organisations will provide their animal use statistics directly to MPI unless there is an agreement in place with Tika Ethics to provide their animal use statistics to MPI on their behalf.

4. AEC Technical Processes / Ngā Hātepe Hangarau a te Komiti Matatika Kararehe (AEC)

4.1 Consideration of Applications by the AEC / Tā te Komiti Matatika Kararehe (AEC) Tirotiro i ngā Tono

Criteria for Consideration

Tika Ethics will only consider applications for cattle, sheep, deer, goats, alpacas, Llamas, horses and pigs if provided with the essential information required for compliance with Section 100 of the Animal Welfare Act. All other animals will need to be considered by another ethics committee who have the expertise for such species.

1. Standard Application Form:
    - All applications must be submitted using the Tika Ethics standard application form, which is designed to capture essential information required for compliance with Section 100. This form mandates specific criteria to ensure applicants provide comprehensive information related to their projects.
2. Submission Timeline:

- Applications from staff, students, and external collaborators must be submitted to the Secretary at least two weeks before the scheduled AEC meeting. This lead time allows for detailed preparation and review.

3. Key Criteria for Evaluation:
   - The AEC will carefully consider applications against the requirements of section 100 of the Act in addition to the following criteria:

     a) Necessity of Manipulation: Confirm that the use of animals is essential for educational purposes or scientific research objectives.

     b) Scientific Contribution: Ensure there is a clear rationale that the findings will advance understanding of biological functions, improve health and welfare for humans and animals, enhance productivity, or protect the environment.

     c) Assessment of Alternatives: Applicants must demonstrate that alternative methods such as mathematical models, computer simulations, or in vitro studies cannot achieve the desired results or fulfil the research objectives.

     d) Compassion Fatigue Consideration: Acknowledge the potential for compassion fatigue in personnel caring for animals and detail how this has been considered in the application.

     e) Review of Guidelines: Require evidence that all applicants have read and understood the Tika Ethics Code of Ethical Conduct (CEC) and NAEAC's Good Practice Guide for using animals in research, testing, and teaching.

     f) Ethical Cost vs. Benefit: Consider the ethical implications of animal use versus the potential benefits to be derived from the research.

     g) Duplication of Studies: Evaluate whether duplicating existing experiments is justified, ensuring that any such duplication is necessary and appropriately reasoned.

     h) Animal Welfare and Impact: Assess the potential harm or distress to animals involved and ensure that adequate measures are in place to maintain their health and welfare before, during, and after manipulation.

     i) Multiple Procedures Justification: If an application proposes multiple procedures on a single animal, this must be explicitly justified in the application to confirm that it does not cause unnecessary harm.

     j) Species and Quality of Animals: Confirm that the species and quality of the animals selected for the research are appropriate and fit for the proposed procedures.

4. Review and Assessment Process:
   - Applications will undergo a thorough evaluation by the AEC, with each criterion carefully scrutinised to ascertain compliance with ethical and legislative requirements. This includes a review of the competence of

personnel conducting the research and the suitability of the facilities being used.

5. Decision-Making Process:
    - Decisions will be made by consensus among AEC members, utilising the comprehensive criteria established in Section 100 as the guiding framework. All discussions, rationales, and decisions will be meticulously documented in the meeting minutes for accountability and transparency.

Impact Grading

The AEC will grade applications according to ethical cost as set out in the MPI Animal Use Statistics Guidance Document.

Outcomes after Consideration

1. Approval Outcomes:
    - a) Approved: The application may be approved, allowing the project to proceed as per the planned start dates.
    - b) Approved with minor modifications required: Approval may be granted for the project to start on the planned start date, contingent upon the applicant making specified minor corrections or administrative modifications, which must then be submitted to the Secretary before the start date.
    - e) Conditional Approval Subject to Further Details: The AEC may approve the application to start on the planned start date on the condition that the applicant provides specified details that are deemed acceptable by the Chair and relevant members of the committee before the planned start date.
2. Deferment and Rejection Outcomes:
    - g) Revision required: If additional information is needed before making a decision, the AEC may defer the application and request specific details from the applicant for further consideration.
    - h) Rejection: If the application does not meet the necessary criteria or ethical standards, it may be rejected.
3. Communication of Decisions:
    - All outcomes and decisions made by the AEC will be communicated to the applicant as swiftly as possible, typically via email, following the committee's deliberation.
    - Approved projects cannot commence until the applicant has received written notification from the AEC. This communication will specify the approval status and details, including any conditions that must be met before work commences.
4. Revision and Resubmission:

- If the AEC identifies the need for revisions, the applicant will be notified and must address the specified points before resubmitting the application. No work described in the application may begin while revisions are being processed.
- Once revisions have been submitted, they will be reviewed at the subsequent AEC meeting, or if conditions are met satisfactorily at the discretion of the Chair, quicker approval may be granted.

5. Documentation:
    - All decisions, including notes from discussions and outcomes, will be documented in meeting minutes and securely stored to ensure transparency and compliance with regulatory requirements.

Conditions of Approval

Approval of an application includes the approved start and end dates, reporting dates, monitoring requirements or other conditions as the AEC decides. When an application is approved, conditions may be stipulated, e.g. that approval holders must report outcomes to the AEC, or that monitoring of the manipulations is required.

Maximum Approval Period

The maximum approval period for any application is 3 calendar years. Applications for ongoing research, testing or teaching procedures must be submitted for consideration at least every three (3) years.

Power to Suspend, Revoke and Vary Approvals

1. Ethical Concerns: The AEC may direct that any approved procedures be stopped or modified on ethical grounds if there are concerns about the treatment or welfare of the animals involved. This may include situations where the manipulation poses unforeseen risks to animal welfare.
2. Non-Compliance: If the chief approval holder fails to comply with reasonable requests from the AEC in a timely or satisfactory manner, the committee reserves the right to suspend or revoke the approval. Compliance expectations are outlined within the approval documentation, and failure to adhere to these may necessitate such actions.
3. Monitoring and Welfare Concerns: The AEC, or individuals delegated by the committee, has the authority to access any ongoing project for monitoring purposes at any time deemed necessary. If monitoring reveals issues concerning the welfare of the animals, the AEC may suspend or revoke approved protocols, requiring the immediate cessation of all manipulations related to the project.
4. Safeguarding Animal Welfare: In instances where there is a perceived or actual threat to the welfare of the animals under study, the AEC may implement immediate actions to ensure their safety, which may include euthanasia or ensuring proper care.
5. Notification and Ratification: Should the Chair (or, where appropriate, the Deputy Chair) exercise the power to suspend or revoke an approval between meetings, the

AEC will be notified immediately, and such decisions will be ratified at the next scheduled AEC meeting to ensure transparency and accountability.

Modifications to Approved Applications

All proposed alterations must be formally requested and categorised as either minor or major modifications.

1. Definitions:
    - Minor Modifications: These are changes that do not adversely affect animal welfare, increase the number of animals involved, or reduce the validity of the study or educational benefits. Examples include adjustments to operational details such as minor personnel changes, minor date adjustments, or minor logistical changes in housing or transport. There are, however, instances where suspension of the study may need to occur if these modifications are not clearly defined before animal manipulation.
    - Major Modifications: These modifications may potentially impact animal welfare negatively, such as increasing the manipulation grading, requiring a greater number of animals, or substantially altering the methodological approach. Examples include changes to the experimental design, the introduction of different drugs or chemicals, or any modification that might reduce the expected benefits of the research or teaching. Major changes in personnel or location may be considered as a major modification as well if the PI changes or there is a significant study relocation.
2. Process for Managing Modifications:

Minor Modifications:

- Applicants must submit a request using the 'Amendment Request Form. ' The Chair has the authority to approve minor amendments in advance.
- Following approval, these minor modifications will be ratified at the next scheduled AEC meeting to ensure transparency in the decision-making process.

  While awaiting formal notification of approval, the approval holders do not need to suspend all related research, testing, or teaching (RTT) activities

Major Modifications:

- For major modifications, applicants must submit a formal request that outlines the proposed changes, detailed on the same 'Amendment Request Form.' Such requests must be made known to the AEC during a scheduled meeting or via email for more urgent matters.
- Major modifications will be thoroughly evaluated during the AEC meeting, and if the modifications involve applications graded as 'C,' 'D,' or 'E,' the approval holder must submit a modified version of the original application for detailed consideration at the next scheduled meeting.

- In cases where the modifications could impact the welfare of the animals or the scientist's educational benefit, approval holders must not commence related activities until the AEC has provided written approval of the modifications.

3. Personnel Changes:
    - Any changes in personnel related to an approved application, including replacing the original approval holder, require a written amendment to be submitted to the AEC for consideration.
    - New co-applicants added post-approval must read the original application and sign a copy of the 'Applicant Declaration Form,' which must then be forwarded to the Secretary along with a request for their inclusion.

4.2 Standard Operating Procedures considered by the AEC / Ngā Tukanga Whakahaere Whānui e whakaarohia ana e te Komiti Matatika Kararehe (AEC)

Standard Operating Procedures (SOPs) describing procedures for research-related manipulations must be submitted to the AEC for approval. The SOPs will become available for all Parented organisations, and they may use these or write their own SOPs.

It is the responsibility of the chief approval holder to ensure that all personnel performing procedures covered by the SOP have access to and follow the SOP. All SOPs will be made available to applicants and approval holders via the Animal Ethics SharePoint site.

SOPs must be reviewed by the AEC every three years, where their use is ongoing.

4.3 Amend, Suspend or Revoke the CEC / Ka Whakarerekē, Ka Whakatārewa, Ka Whakakore rānei i te Tikanga Mahi Matatika

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

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

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

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

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

Tika to parented organisations:

Following approval, all amendments to the CEC will be immediately notified in writing to the approval holders of all approved protocols and parented organisations. The amended CEC will be published on the Tika Ethics' website.

5. Monitoring by the AEC / Tā te Komiti Matatika Kararehe (AEC) Aroturuki

(Section 99 of the Animal Welfare Act 1999)

The Animal Ethics Committee (AEC) possesses the authority to inspect animals, their housing, and related health and experimental records at any time to ensure that all procedures are being conducted appropriately. This authority is delegated to the Chair (or, when applicable, the Deputy Chair) or their designated representative between meetings. Additionally, any AEC member may request access to animals or facilities at any time, contingent upon approval from the Chair or Deputy Chair.

5.1 Monitoring during the Approval Period / Te Aroturuki i te Wā Tuku Whakaae

The AEC implements a structured approach to monitoring that includes both scheduled and unscheduled visits.

1. Monitoring Frequency and Responsibility:
    - Approved applications will be subject to ongoing monitoring. The AEC member carrying out the monitoring will depend on the location of the study.
    - During these monitoring visits, the welfare of the animals and the adherence to approved protocols will be assessed.
2. Documentation and Reporting:
    - Each monitoring visit will be documented in a written report, which will detail the findings and any observations made regarding animal welfare and compliance with the approved application.
    - Following each visit, the report will be discussed during an AEC meeting. Any requirements or actions resulting from these discussions will be recorded in the meeting minutes.
    - The chief applicant will receive written communication outlining any specific requirements or issues identified during the monitoring visit.
3. Involvement of AEC Members:
    - While monitoring visits may be scheduled, the AEC may also conduct unscheduled visits to ensure compliance at any time. For scheduled visits, the Chair will notify AEC members in advance, allowing them the opportunity to attend if their schedules permit.

- Encouraging member participation in monitoring visits enhances transparency and fosters a collaborative approach to maintaining ethical standards.

4. Specific Monitoring Protocols:
    - The application form requires applicants to specify how animal welfare will be monitored throughout the project, including the parameters to be monitored, methodologies, and frequency of monitoring. This information must be detailed within the application and is mandatory for submission.

5.2 Monitoring by Proxy / Te Aroturuki mā te Tangata ka Tohua

At Tika Ethics, when direct monitoring by AEC members is not feasible due to timing or geographical constraints, monitoring may be delegated to qualified individuals nominated by the AEC. This process ensures that animal welfare standards are maintained while also accommodating practical considerations.

1. Selection of Nominated Individuals:
    - Nominated individuals may include external experts, such as veterinarians or other external experts who possess the necessary experience and qualifications to conduct thorough monitoring. The selection process will be based on the individual's expertise, familiarity with animal welfare standards, and understanding of the specific research protocols being monitored.
    - In cases where external monitoring is required, the nominated individuals must be confirmed at a scheduled AEC meeting, ensuring transparency in the selection process.
2. Monitoring Process:
    - Once nominated, these individuals are tasked with conducting monitoring visits to assess compliance with approved protocols and the welfare of the animals involved. They will have the authority equivalent to that of AEC members during the monitoring process.
    - If the designated individuals are unable to perform the monitoring due to timing or location constraints, the AEC may choose to contract an independent veterinarian or an appropriate professional to carry out the monitoring visit.
3. Documentation of Monitoring Visits:
    - The monitoring individual will be provided with the relevant application documents and access to all necessary information to facilitate a comprehensive evaluation during the visit.
    - Monitoring visits will be documented in a report that details the findings, observations, and any compliance issues related to animal welfare. This report will include any photographic or videographic evidence if deemed necessary for clarification.
4. Reporting Back to the AEC:

- Completed monitoring reports will be submitted for review at the next scheduled AEC meeting. The reports will be systematically evaluated, and any required actions or follow-ups will be documented in the meeting minutes.
- The AEC will communicate findings from the monitoring visits, along with any recommendations or requirements for the chief applicant, ensuring all parties are informed and any necessary adjustments are made promptly.

5.3 Monitoring across Impact Grades / Te Aroturuki i te whānuitanga o ngā Paearu Whai Pānga

Projects graded C, D or E will be monitored annually if longer than a year, or if less than a year, will be monitored during the approval period. 10% of projects graded A and B need to be monitored each year.

5.4 Monitoring Specific Manipulations / Te Aroturuki i ngā Rāpoi Whāiti

Manipulations not previously monitored, those performed by new personnel, those given conditional approval and projects using unfamiliar experimental models are more likely to be selected for monitoring.

5.5 Monitoring Animal Facilities / Te Aroturuki i ngā Pā Kararehe

1. Routine Inspections:
    - Typically, most animal facilities are commercial farms, and these are not considered research facilities. These would therefore not be considered a facility to regularly monitor. If there is a "research farm" where the farm is used regularly for multiple trials and has an SOP of operation and approval by the AEC, this facility will be inspected at least once annually by the AEC. The inspections will typically be conducted by the Chair. Additional AEC members are encouraged to participate in these inspections whenever possible, ensuring maximum oversight and perspective during the evaluation process.
2. Non-Scheduled Visits:
    - The AEC retains the right to conduct non-scheduled monitoring visits to animal facilities as necessary. These visits may occur in response to specific concerns raised regarding animal welfare or compliance with approved protocols, allowing for immediate action if issues are identified.
3. Delegation of Monitoring:
    - For facilities associated with parented organisations, monitoring will be performed by AEC representatives or other qualified delegates. This will ensure a consistent and thorough approach to monitoring across all facilities under the jurisdiction of Tika Ethics.
4. Documentation of Inspections:

- Following each facility inspection, a written report will be prepared detailing the findings, observations, and any recommendations for improvements. This report will be submitted to the AEC for review and discussion at the next scheduled meeting.

5. Communication of Findings:
    - The outcomes of facility inspections will be communicated to the relevant facility management and chief applicants. Any concerns identified during the monitoring process will include an action plan for addressing those issues, ensuring that all parties are informed and accountable for maintaining high standards of animal care and ethical research practices.

6. Responsibilities of organisations/individuals with AEC Approved Applications / Ngā takohanga a ngā whakahaere / tāngata takitahi kua whai Tono Kua Whakaaetia e te Komiti Matatika Kararehe (AEC)

6.1 Reporting to the AEC / Te Tuku Pūrongo ki te Komiti Matatika Kararehe (AEC)

Project Reports

All approved applicants are required to adhere to the following guidelines regarding interim and final reports:

1. Interim Reports:
    - Submission Requirements: Interim reports may be submitted at any time, but they are also required as a condition of approval for certain projects or as specifically requested by the AEC.
    - Content: Interim reports should include information on animal welfare outcomes, any deviations from approved protocols, and updates on the project's progress.

2. Animal use reports:

A report on the animal use numbers, species and grading will be completed within one month of the study completion.

3. Final Reports:
    - Submission Timeline: Final reports must be submitted using the 'End of Project Report Form.' Final reports are due within six months of the project's conclusion, as indicated in the original application.
    - Content: Final reports must cover both the scientific outcomes of the project and provide a summary of animal welfare outcomes and animal use statistics, including any issues encountered during the project and how they were addressed.

4. Feedback and Compliance:
    - The AEC may provide feedback on interim reports, and any follow-up actions or requirements will be communicated in writing to the chief applicant.
    - Compliance with reporting requirements is essential, and failure to submit reports on time may result in further action from the AEC, which could include the suspension of the project's approval.

End of Approval Grading & Animal Use Statistics

The 'Animal use form' includes a section on statistics relating to final grading of manipulations, numbers of animals used, and other details required to be submitted to MPI as required under the Animal Welfare (Records and Statistics) Regulations 1999.

This will be completed within one month of the trial completion date.

Adverse Events

1. Definition of Adverse Events:
    - Adverse events are unanticipated or atypical incidents that occur to an animal as a result of:

▪ experimental manipulation; and/or

▪ animal husbandry failures; and/or

▪ disease

    - Adverse events are also unanticipated or atypical incidents that negatively affect the proposed benefits of the approved research, testing or teaching project (e.g. data or sample compromise)

2. Reporting Requirements:
    - Approval holders must report any adverse events to the AEC within 48 hours via email and report within 5 days, using the Adverse Event Report Form available on the Tika Ethics intranet.
    - Detailed documentation of the actions taken in response to the adverse event must be included in the report. This includes any treatments or management practices implemented to address the situation, as well as outcomes of any necropsies performed.

3. Monitoring and Contingency Plans:
    - Applicants must outline their monitoring methods, endpoints, and contingency plans for handling adverse events in their original application. These plans should specify procedures for emergency euthanasia if necessary.
    - The adverse event report should also include recommendations for reducing the likelihood of recurrence and whether modifications to the experimental protocol or standard operating procedures (SOPs) are warranted in response to the event.

4. Investigation and Documentation:
    - Following the reporting of an adverse event, an investigation will be conducted. The responsible individuals (applicant, facility manager, program manager, or veterinarian) will collaborate to determine appropriate corrective actions.
    - All adverse event notifications and their outcomes will be documented in the AEC meeting minutes, ensuring transparency and accountability in the management process.
5. Necropsy Requirements:
    - Animals that die unexpectedly or are euthanised before the completion of the study, or that have an unexplained death, require necropsy. These will be conducted by a qualified veterinary pathologist or veterinarian. If the applicant conducts a necropsy, it is recommended that independent expertise be sought to avoid potential conflicts of interest.
    - No necropsy is required when animals die or are euthanised as part of normal animal management practices. As these losses are considered 'normal', they must be stated in the animal ethics application. Where it has not been indicated that losses are expected, or losses exceed expectations, necropsy examination may be required.
    - Findings from necropsies must be reported to the AEC, especially when unexpected mortality occurs or where losses exceed normal mortality expectations.
6. Feedback Mechanism:
    - The AEC may provide written or in-person feedback regarding notifications of adverse events or investigations conducted as a result. This feedback will assist the approval holder in understanding the implications of the event and improving future practices.
7. Continuous Improvement:
    - The AEC will review adverse event reports at scheduled meetings, and any necessary amendments to protocols will be discussed and documented. This ensures that lessons learned from adverse events contribute to ongoing improvements in animal welfare practices within Tika Ethics.

6.2 Records Management / Te Whakahaere i ngā Pūranga Kōrero

The AEC and the approval holder must keep records of:

- the research protocol and data obtained from the experiment;
- the AEC approval, amendments, non-compliances and adverse events;
- the animals used and whether they have previously been used for other RTT work;
- the manipulations performed and actual impact grading as determined and approved by the AEC;

- any veterinary treatment or medicines administered;
- the fate of the animals at the conclusion of the project;
- Personnel training records (as relevant).

These records must be kept by the approval holder for a minimum of five years and by the AEC for 20 years after the provision of the end of approval reports.

6.3 Appropriate Qualifications / Ngā Tohu Mātauranga e Hāngai Ana

1. Competency of Personnel:
    - Applicants are required to provide details regarding their qualifications and those of all co-applicants and animal technicians within the application form. This includes evidence of competency to conduct RTT and manage animal welfare effectively.
    - The Animal Ethics Committee (AEC) may request additional information or documentation regarding the qualifications and experience of personnel before the approval of a project. In some instances, applicants may be asked to attend a meeting to demonstrate their competence and understanding of ethical animal care practices.
2. Supervision and Oversight:
    - The AEC encourages the participation of qualified personnel in all stages of RTT, including daily husbandry, to provide guidance and support to less experienced team members.

6.4 Sick and Injured Animals / Ngā Kararehe e Māuiui ana, e Whara ana

Animals that are sick or injured must receive appropriate veterinary attention without delay or be euthanised based on the circumstances. In cases where animals experience severe or chronic pain, distress, discomfort, or disability that cannot be alleviated, euthanasia should be carried out immediately. This protocol applies to animals involved in studies on farms involved in research managed by EpiVets or parented organisations.

Illness or injury that is considered to be an adverse event, along with their subsequent outcomes, must be reported to the Animal Ethics Committee (AEC) within 48 hours and reported within five working days and documented in the minutes of the following AEC meeting.

6.5 Standard Operating Procedures developed by the Code Holder / Ngā Tukanga Whakahaere Whānui ka whakaritea e te Kaipupuri i te Tikanga

SOPs describing teaching and research-related manipulations or AEC procedures may be developed by the CEC Holder. SOPs may be obtained from other organisations or prepared by a subcommittee with contributing personnel with expertise in the area.

6.6 Management of Animal Facilities / Te Whakahaere i ngā Pā Kararehe

Policies & Procedures

1. Facility Design and Maintenance:

- Applicants and approval holders must ensure that all animal facilities are appropriately designed, constructed, equipped, staffed, and maintained to safeguard the health and welfare of animals and their handlers. Facilities must meet the requirements specified in the application while reflecting established good practices and current scientific knowledge.
- Standard Operating Procedures (SOPs) must be developed for each facility, encompassing procedures for emergency management, animal maintenance, transportation, and housing.

2. Compliance with Codes of Welfare:
    - Animal housing must adhere to the guidelines outlined in the National Animal Ethics Advisory Committee (NAEAC) publication, "Good Practice Guide for the Use of Animals in Research, Testing and Teaching." This includes ensuring that animals' general health is protected and that undue stress is avoided.
    - Each animal must be provided with sufficient space tailored to its species and needs, and environmental conditions, including temperature, humidity, appropriate diet, ventilation, lighting, and social interaction, must be appropriately managed.
3. Notification of Farm Locations:
    - For animals maintained within a commercial farming environment, care must align with good farming practices that comply with relevant codes of welfare specific to the species. *Emergency Management*

Emergency management

1. Emergency Situations:
    - Emergencies may encompass a variety of scenarios such as fire, natural disasters (e.g., earthquakes, floods), pandemics, and other large-scale events that could jeopardise the health and management of animals.
2. Facility Managers' Responsibilities:
    - Facility managers are tasked with developing emergency plans as part of their facility manual or Standard Operating Procedures (SOPs). These plans must specifically address the needs of the animals and outline the necessary steps for protecting their welfare during crises.
3. Risk Identification:
    - All farms, including those operated by parented organisations, are required to identify potential large-scale threats that could adversely affect animal health or management. Such risks include pandemics, natural disasters, and infrastructure failures, such as loss of water supply or power outages.
4. Contingency Plans:
    - Contingency plans must be established to ensure that animal care and management can continue effectively during emergencies.

- Preparations must be made in advance of any potential emergency, detailing how animals will be managed and cared for under various scenarios.

5. Awareness:
    - All personnel involved in conducting research, testing, and teaching (RTT) must be aware of the contingency plans.
6. Documentation and Communication:
    - Emergency response procedures and contingency plans must be documented in the farm manual, and all staff must have access to this information.

Housing of Animals

The following procedures are implemented, referencing the Animal Welfare Act 1999 (AWA 1999) as well as relevant codes of welfare and regulations.

1. Space and Housing Requirements:
    - Animals must be housed in environments that adequately safeguard their general health and welfare. Sufficient space must be allocated according to the specific needs of each species to allow for natural behaviour and movement.
2. Environmental Needs:
    - The housing conditions must meet the species' environmental requirements, including appropriate temperature, humidity, ventilation, lighting, enrichment, and opportunities for social interaction. These conditions are essential to prevent undue stress and promote the well-being of the animals.
3. Nutritional Standards:
    - Animals must be provided with food that is appropriate to their species-specific requirements in terms of quality and quantity to maintain health. They should have continuous access to fresh water unless the research specifically involves studying the effects of nutritional variation, in which case, the variations must be approved by the AEC.
4. Reference to Codes of Welfare:
    - The management of animal facilities and practices—including design, hygiene, and overall management—must align with good practice as outlined in the "Good Practice Guide for the Use of Animals in Research, Testing and Teaching" published by NAEAC, along with the relevant Codes of Welfare established by the Ministry for Primary Industries (MPI).
5. Standard Operating Procedures (SOPs):
    - Approved SOPs may also be in place to address specific housing and care situations, ensuring that established best practices are followed consistently.
6. Monitoring and Oversight:

- Animals from a small number of farms involved in studies from parented organisations with approved and current projects will have their animal health and welfare monitored by the Animal Ethics Committee (AEC), or their delegate, at least once annually to ensure compliance with these standards.
- Non-scheduled monitoring visits may occur at the discretion of the AEC, allowing for prompt assessments and interventions if issues are identified.

7. Adverse Event Reporting:
    - Any adverse events related to facility management practices or animal welfare must be reported as specified in section 6.1, ensuring that all incidents are documented and reviewed for corrective actions.

Transportation of Animals

Animal transport that occurs as part of an RTT procedure must be included in the original application and considered as part of the AEC deliberations.

Animals must be transported following relevant legislation and meet all applicable regulatory requirements.

6.7 Euthanasia for Tissue Collection / Te Whakamate kia Kohia te Pūtautau

1. AEC Approval Requirements:
    - Approval from the Animal Ethics Committee (AEC) is mandatory for the euthanasia of animals primarily intended for dissection or tissue collection.
    - If animals are euthanised for other purposes but later used for tissue collection, AEC approval is necessary if the method of euthanasia or animal management significantly deviates from what the animal would typically experience, particularly if these methods are not covered under an approved animal manipulation protocol, an approved Standard Operating Procedure (SOP), or the Code of Welfare: Commercial Slaughter. Retroactive approval cannot be provided in these circumstances. If there is any uncertainty about future use, this needs to be consulted with the AEC.
2. Determining Euthanasia Methods:
    - The determination of appropriate euthanasia methods will be made by veterinarians, ensuring the methods align with best practices and current scientific knowledge. Resources, including the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals, will be referenced to identify humane methods of killing.
3. Veterinary Insight:
    - In cases involving the euthanasia of animals for tissue collection, veterinary guidance is integral to ensure that the procedures adhere to humane standards and minimise distress to the animals.
4. Tissue Sharing Opportunities:

- The AEC may also consider and recommend tissue sharing with other organisations as part of research, testing, and teaching (RTT) applications. This collaboration can enhance the use of collected tissues while reducing the impact on animal populations.

5. Documentation and Reporting:
    - Detailed documentation must be maintained for all euthanasia procedures conducted for the purposes of tissue collection. This includes justifications for the actions taken, methodologies utilised, and any compliance with the AEC's approval conditions.
    - Findings from any tissue collection and insights regarding the euthanasia process will be reported back to the AEC during scheduled meetings for review and discussion.

6.8 Rehoming / Te Tuku ki Kāinga Kē

1. Assessment for Rehoming:
    - Animals may be made available for rehoming when it is determined that they are likely to adapt to a new home environment and can enjoy a good quality of life. The decision to rehome will be based on an assessment of each animal's health, behaviour, and temperament.
2. Exclusions from Rehoming:
    - Animals that are deemed to pose an increased risk of harm to people, the environment, or other animals, or those that require biosecurity containment, are not eligible for rehoming.
    - Only individuals or families equipped to provide suitable care and a high quality of life for the animals will be considered as potential adopters.
3. Disclosure of Health and Behavioural Issues:
    - Before seeking agreements for rehoming, any known health issues or behavioural problems associated with the animal must be fully disclosed to potential adopters. Transparency is key in ensuring that new owners can appropriately manage the animals' needs.
4. Support and Consultation:
    - The Animal Ethics Committee (AEC) Chair should be contacted for guidance or assistance when needed in the rehoming process, ensuring that all procedures are followed correctly.

7. Compliance Breaches & Complaints Procedures / Ngā Tukanga mō te Takahanga Tikanga me ngā Amuamu

(Section 103 of the Animal Welfare Act 1999)

7.1 Compliance Breaches / Ngā Takahanga Tikanga

Non-Compliance with an AEC Approval

1. Legal Framework:
    - The Animal Welfare Act 1999 and the codes of welfare and regulations state that individuals who contravene or fail to comply with provisions of the regulations may face summary conviction, fines, or imprisonment. The maximum penalties for both individual and corporate offences are detailed within the relevant legislation.
2. Compliance Requirements:
    - All participants in RTT must comply with all applicable Acts, regulations, and bylaws governing the obtaining, holding, possession, care, and treatment of animals. Adherence to all conditions specified in approved applications is also mandatory.
3. Disciplinary Actions:
    - If the AEC determines that non-compliance is severe enough to warrant disciplinary action, the matter will be referred to EpiVets management or the EpiVets board of Directors. For external personnel, issues will be directed to the management of the respective organisation.
    - In cases of serious non-compliance, the AEC may suspend the project immediately and report the situation to appropriate regulatory bodies, such as the Ministry for Primary Industries (MPI), the Society for the Prevention of Cruelty to Animals (SPCA), or law enforcement agencies.

Non-compliance with Legislation or Regulations (including the CEC)

1. Reporting Timeline:
    - All instances of non-compliance, including breaches of the CEC, animal welfare regulations, or deviations from approved applications, must be reported as soon as possible to the AEC by the applicant. This should occur within one working day of becoming aware of the issue to ensure timely intervention.
2. Types of Non-Compliance:
    - Minor Non-Compliances: These can be self-reported by the applicant to the AEC chair and may involve less severe deviations that may not impact animal welfare or animals at all. The AEC will assess these reports and may accept them with an accompanying plan to prevent recurrence.
    - Major Non-Compliances: Serious breaches that could affect animal welfare or ethical standards (e.g. reporting) must be reported immediately to the AEC chair. These instances will likely require a more detailed investigation and response.
3. Response to Non-Compliance:

o Reporting Non-Compliance: Any individual, including staff members, researchers, or external parties, can report instances of non-compliance. Reports can be made confidentially and will be taken seriously by the Animal Ethics Committee (AEC).

o Initial Evaluation Timeline: Upon receiving a report of non-compliance, the AEC will acknowledge the complaint and initiate an evaluation within 7 days. The AEC will assess the details and severity of the non-compliance and determine the necessary course of action.

o Responses to Findings:

For major non-compliance, defined as a significant deviation from approved protocols that poses a serious risk to animal welfare, the AEC will suspend the project immediately. A formal notice of suspension will be provided to the applicant, outlining the reasons for the suspension and any corrective actions required to address the issues.

For minor non-compliance, the AEC may impose additional conditions on the project and provide a formal notice to the applicant detailing the nature of the violation and corrective actions needed.

o Corrective Action Requirements: All corrective actions required as a result of non-compliance will be clearly specified in the formal notice. The AEC will monitor compliance with these actions to ensure that animal welfare is prioritised and maintained.

o Review Process: In accordance with the MPI Good Practice Guide, the AEC will review and assess any critical non-compliance issues closely. Depending on the situation, it may involve consultation with external experts to ensure appropriate measures are implemented to safeguard animal welfare.

Critical non-compliance

Immediate Action: Upon identification of critical non-compliance (a severe deviation from specifications or standards with direct and adverse effects), the project must be immediately suspended. A formal written notification of the suspension should be issued to the applicant.

Formal Notification: The formal notice to the applicant will detail the nature of the critical non-compliance, the reasons for suspension, and the specific corrective actions required to rectify the situation and ensure animal welfare is prioritised.

MPI Involvement: For critical non-compliance, the AEC will promptly report the issue to the MPI within 72 hours.

Thorough Investigation: The AEC will conduct a thorough investigation to ascertain the root cause of the non-compliance. This may involve consultation with external experts, reviewing existing SOPs, or other relevant measures.

Corrective Actions and Monitoring: The AEC will oversee the implementation of the corrective actions outlined in the notification. They will also monitor the situation closely to confirm that appropriate measures have been taken. Ongoing monitoring is required to prevent a recurrence.

Review Process: A full review of the project will be conducted by the AEC. They may decide to impose stricter conditions on the project, modify the project's operations, or revoke the approval completely.

Documentation: Meticulous record-keeping of all steps involved in the process is crucial. This documentation is reviewed as part of the regular AEC processes and audits. This needs to be thoroughly done.

4. Documentation and Record Keeping:
    - All non-compliance incidents and actions taken will be documented and stored in SharePoint.
5. Disciplinary Actions:
    - If the AEC determines that non-compliance warrants further disciplinary action, this matter will be escalated to EpiVets management for appropriate handling. If this non-compliance relates to the Managing Director of EpiVets, then a representative on the Board of Directors of EpiVets will be chosen. In cases involving external personnel or organisations, the relevant management will also be notified.
    - Serious non-compliance situations that violate the Animal Welfare Act will lead to immediate cessation of the project and referral to the appropriate regulatory body (e.g., MPI, SPCA, or law enforcement), depending on the severity of the violation.

7.2 Animal Welfare Complaints / Ngā Amuamu mō te Hauora Kararehe

The Animal Ethics Committee (AEC) will investigate complaints specifically related to concerns about animal welfare and the procedures and processes associated with research, testing, and teaching (RTT). All complaints will be documented in the AEC meeting records and brought to the committee's attention to raise awareness of the issues at hand.

Each complaint will be evaluated and investigated promptly, with the potential for escalation to EpiVets management or the board of directors if necessary. Additionally, individuals may lodge animal welfare complaints directly with external bodies such as the Ministry for Primary Industries (MPI), the Society for the Prevention of Cruelty to Animals (SPCA), or the Police.

The investigation of complaints will be conducted by the Chair of the AEC along with EpiVets management. However, in cases where the complaint involves EpiVets management, the investigation will be carried out by the board of directors to ensure impartiality.

Outcomes from the investigations will be recorded in the AEC meeting documents. If the complainant’s identity is known, the AEC will inform them of the outcome, either verbally or in writing.

Any suspected offence against the Animal Welfare Act can be reported in writing to the Secretary or Chair. Alternatively, the public can communicate their complaints directly to an animal welfare agency or the MPI.

By the Public

1. Reporting Suspected Offences:
    - Individuals suspecting an offence against the Animal Welfare Act may report their concerns in writing to the Secretary or Chair of the Animal Ethics Committee (AEC).
    - Alternatively, members of the public can communicate their complaints directly to relevant animal welfare agencies, such as the Ministry for Primary Industries (MPI) or the Society for the Prevention of Cruelty to Animals (SPCA).
2. Response to Complaints:
    - Complaints made by members of the public shall be initially reported to the AEC chairperson. The chairperson may correspond directly with the complainant to inform them of Tika Ethics' position on the matter and provide clarity on how the complaint will be handled.
    - Complainants will be advised that for further correspondence, they may choose to contact MPI or appropriate animal welfare agencies directly.
3. Documentation and Investigation:
    - All complaints will be recorded, and the AEC will evaluate each case to determine the necessary investigation process. Investigations will be conducted as soon as practicable to address any immediate concerns.
    - Outcomes of the investigations will be documented and discussed in AEC meetings, ensuring transparency and accountability in the management of complaints.

By Employees

1. Protected Disclosures:
    - Employees may refer to the organisation's Protected Disclosures Policy to understand the protections afforded to them under the Protected Disclosures (Protection of Whistleblowers) Act 2022. This policy ensures that individuals can report concerns without fear of reprisals.
2. Submission of Complaints:
    - Any staff member can bring to the AEC's attention any situation where they believe animal welfare is being compromised, regardless of whether the animals are managed under a current AEC approval. This can be communicated directly to the AEC chairperson or the Animal Ethics Officer (AEO).
    - Alternatively, employees can submit a specific complaint form, which will automatically notify the chairperson and AEO of the lodged complaint.
3. Investigation of Complaints:

- All complaints will be formally reviewed by the AEC. The committee has the authority to direct that any procedure, whether or not it has received prior approval, be halted or modified on ethical grounds.
- Additionally, the AEC can mandate that animals be provided with appropriate care or euthanised should the situation require it.

4. Documentation and Accountability:
    - Complaints and their outcomes will be documented, and appropriate actions will be taken based on the severity of the issue. This ensures transparency and accountability in addressing animal welfare concerns.
5. Follow-Up Actions:
    - If a complaint results in findings of non-compliance, the necessary actions will be taken in accordance with established policies as outlined in the appropriate guidelines.

By AEC Members

1. Right to Report:
    - AEC members have the right to report any concerns regarding animal welfare or compliance with the Code of Ethical Conduct (CEC). The obligation to maintain confidentiality regarding information in applications does not prevent members from making complaints.
2. Reporting Procedures:
    - Procedures for addressing complaints from AEC members will mirror those established for employees. Members are encouraged to raise concerns directly with the Chair of the AEC or management of EpiVets Ltd.
    - Complaints can also be directed to the Ministry for Primary Industries (MPI) if AEC members feel that their concerns are not being adequately addressed.
3. Reporting Non-Compliance:
    - If any AEC member believes that the committee or Tika Ethics is materially failing to comply with the CEC, they may report this non-compliance to the Director-General of MPI.
    - AEC members who are employed by Tika Ethics—and who report such non-compliance in good faith—will not face disciplinary action or civil proceedings as a result of making that report.
4. Investigation and Documentation:
    - All complaints submitted by AEC members will be formally reviewed by the AEC. The outcomes of these investigations will be documented to ensure clarity and accountability.
    - The AEC will take appropriate actions based on the severity of the issues raised to rectify any identified concerns.

5. Transparency and Feedback:
    - Investigations into complaints and their outcomes will be communicated to the AEC members involved, fostering transparency within the committee.
    - Feedback from the investigation process can lead to improvements in practices and protocols to enhance animal welfare standards.

7.3 Procedural Complaints / Ngā Amuamu ā-Tukanga

(Section 103 of the Animal Welfare Act 1999)

By Applicants

Procedural complaints by applicants or approval holders of EpiVets or other parented organisations of any nature about the activities of the AEC or its decisions shall be notified to the Chair or the CEC Holder or their nominee as appropriate to the circumstances.

Applicants and approval holders may also make a complaint directly to NAEAC via MPI.

By AEC Members

Procedural complaints by members of the AEC should, in the first instance, be raised with the Chair or Deputy Chair, who will investigate the nature of the complaint and seek a resolution as appropriate to the circumstances. The complaints may also be provided to EpiVets management.

AEC members may also make a complaint directly to NAEAC via MPI.

Against the Chair/Deputy Chair/Administrator

Complaints against the Chair should be made to EpiVets managing Director (the CEC Holder) or the Deputy Chair.

Complaints against the Deputy Chair or Secretary should be made to the Chair.

8. Arrangements for External Parties to Use the CEC and AEC / Ngā Whakaritenga kia Whakamahi ai te Whakahaere Rāwaho i te Tikanga Mahi Matatika (CEC) me te Komiti Matatika Kararehe (AEC)

(Section 84 of the Animal Welfare Act 1999)

Tika Ethics permits external organisations to use the CEC and AEC under structured arrangements, ensuring compliance with established protocols and standards. The following procedures are implemented:

1. Proposal Submission:
    - External organisations wishing to establish a parenting agreement must initially submit a formal written proposal to the Secretary of the AEC. This proposal should outline the nature of the organisation's research, testing,

and teaching (RTT) activities, as well as the expected maximum number of applications anticipated for submission in a calendar year.

2. Review and Approval Process:
    - The proposal for a parenting agreement will be reviewed by the AEC at its next scheduled meeting. Consideration will be given to the potential increase in the AEC's workload and whether the members have the relevant expertise to evaluate the proposed RTT activities adequately.

3. In-person meeting:
    - A meeting between the Chair of the AEC and the parented organisation will be undertaken to be able to talk through the requirements of Tika Ethics and how it all works. This will enable the parented organisation to be shown through the documents, and the meeting schedule and be clear on all requirements.

4. Formal Written Agreement:
    - If the AEC grants approval for the parenting agreement, a formal written contract will be drawn up and signed between the AEC Chair (representing the CEC holder) and the Chief Executive Officer (or their nominee) of the external organisation. This agreement will outline the obligations and expectations of both parties.

5. Notification to MPI:
    - Upon the establishment of a parenting agreement, Tika Ethics will notify the Ministry for Primary Industries (MPI) in writing. This notification must occur before the external organisation can submit any applications to the AEC.

6. Responsibilities of Parented Organisations:
    - Organisations participating in parenting arrangements are responsible for submitting animal use statistics directly to MPI, ensuring compliance with monitoring and reporting requirements.
    - They must also submit their Standard Operating Procedures (SOPs) to the AEC for review, as specified in Section 6.5 of the relevant guidelines.

7. Compliance with the CEC:
    - All organisations with an approved parenting arrangement must adhere to the policies and procedures outlined in the CEC, ensuring that their work aligns with ethical standards set by Tika Ethics.

8. Monitoring and Review:
    - Tika Ethics reserves the right to review and monitor the operations and compliance of parented organisations, ensuring that they maintain a commitment to animal welfare and ethical practices throughout their RTT activities.