

Welcome Information Pack

Welcome to Tika Ethics! We are so excited to have you join us!

Origins and ownership of Tika Ethics

Tika Ethics is a wholly owned subsidiary of EpiVets Ltd. It is an ethics committee that is designed to oversee research applications involving cattle, sheep, goats, alpacas, Llamas, pigs and horses.

We set this up as we wanted to create a process that still adhered to high ethical standards, but was simple, practical and easier for others to use.

Our people

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

The Chair (Dr Ali Cullum) is a contracted staff member, appointed by the Managing Director of EpiVets to work on behalf of Tika Ethics. Ali is highly experienced in this space as a veterinarian and member of the Waikato University Ethics Committee.

Nicola, our secretary has worked in the agricultural industry for more than 17 years, organising TB testing programmes and M Bovis testing programmes amongst many other roles. She will be your main point of contact and is there to help you as much as possible.

Statutory members

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

Stephen Hopkinson – Large animal veterinarian, CEO of Taranaki Vets

and/or Lucy Cameron - Large animal veterinarian at The Veterinary Centre Waimate

 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

Alison Vaughan - Alison is currently a scientific officer for SPCA. She grew up in Scotland on a horse farm with an uncle who ran a sheep farm.

 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

Mark Hurst-



· A senior member of EpiVets

Helene Baigent - Veterinarian and regulatory specialist

What parenting means

In the context of ethical governance, "parenting" refers to the guidance and oversight provided by an ethics committee to another organisation to ensure compliance with the established code of ethical conduct. This relationship is characterised by a collaborative effort where the ethics committee imparts its expertise and principles, facilitating the adoption and implementation of ethical standards within the organisation it oversees.

The primary objective of this "parenting" role is to cultivate an organisational culture rooted in integrity, transparency, and accountability. The ethics committee serves as a steward, offering strategic direction, resources, and best practices to align the organisation's operations with the overarching ethical framework. This includes regular evaluations, feedback, and adjustments to ethical practices to foster continuous improvement and uphold the highest standards of ethical behaviour.

Code of Ethical Conduct

A code of ethical conduct serves as a foundational framework that guides the behaviour and decision-making processes within an organisation. It articulates the core values and principles that uphold the integrity, accountability, and transparency of the organisation's operations. By establishing clear ethical standards, the code provides employees and stakeholders with a definitive guide to expected conduct, ensuring that all actions taken are aligned with the organisation's mission and the broader societal norms.

For companies that are parented under this ethical framework, adherence to the code of ethical conduct is key. As a parented company, it is essential to integrate these ethical guidelines into every aspect of your operations. Please read and become familiar with this code.

Non-disclosure and confidentiality

We acknowledge and respect the confidentiality concerns associated with your research submissions. While all members of our committee are bound by a contract with Tika Ethics that specifies confidentiality terms, we understand that some entities may desire additional assurances. Consequently, we offer a non-disclosure agreement that you may choose to execute with the Tika Ethics Committee prior to submitting your applications.

We also recognise any potential concerns regarding the relationship between Tika Ethics and EpiVets. This matter is addressed with utmost seriousness. One member of the EpiVets regulatory division serves on the Tika Ethics Committee as part of our compliance with establishing our Code of Ethical Conduct. This individual is entirely separate from the clinical research division's daily operations and upholds strict confidentiality standards akin to all other committee members.

Your application and related documentation will be securely stored on the Tika Ethics SharePoint site, accessible solely to authorised Tika Ethics personnel. Other EpiVets employees



cannot access the Tika Ethics SharePoint, unless explicit permission is granted by you. Access control and oversight are vigorously managed by Nicola Aitken, the secretary of Tika Ethics.

What is different about Tika Ethics?

At Tika, you are a valued **customer** and will be treated as such. Wherever we can help you navigate the process, we will. What does this mean?

Well, for starters, here are a few things our ethics committee will be doing:

- We have gone a bit "old school" and are using Word documents. The reason for this is
 its more intuitive for most and suggested changes are written on the document itself for
 easier review.
- You will be communicating with a **person** our secretary, Nicola Aitken. She is here to help you in this process, and when you have little changes to make, she will happily pop in and make those changes for you, as we realise you are busy enough!
- You will have access to ALL EpiVets SOPs. You can choose to use these or use your own.
- You can keep track of your training for SOPs, or EpiVets staff are happy to come out and train you as a separate service offering. You are welcome to utilise EpiVets training documentation that they use to keep track of their own staff training, or you can keep your own. As long as you have evidence, that is all we need.
- We need to know the staff that are involved in the study and evidence (via the training records) that they are suitable, but do not need all of them to sign the form. This will just be signed by the applicant.
- We will keep track of all your animal usage statistics for you. So, when it is time to submit them, they will be all ready for you.
- It's hard to remember when all the reports are due! We will send you friendly reminders just in case you forget as well as create an easy spreadsheet with every task and when it is due in your client folder.
- We will peer review your applications before they are submitted to the committee to make sure the process with the committee is as efficient as possible.
- If you have fistulates, yes, this will be considered under our committee and will fall under a "facility" approval.

What if you need help?

It is entirely optional, but if you would like help from EpiVets Ltd to navigate trial design, regulatory approvals, sample sizes, statistical methods or just help working through the process, you can let us know and we will get you in touch with the right people.

What if you have suggestions?

Please let us know!! We want to create the best process for you to follow so your ideas will be so valuable to help us get this service right!

Process

1. We will set you up as a parented company under Tika Ethics. Agreements and NDA's will be signed.



- 2. We will set you up to be connected to your own SharePoint folder. This is where all your applications will live. You will also be able to access a joint folder where the CEC, SOPs, timetable of ethics committee meetings and templates will live.
- 3. When you are ready, you can fill in your ethics application. You will submit this to the Tika Ethics secretary. It will then get peer reviewed and sent back with tracked changes and questions/comments on the document.
- 4. When you are ready to resubmit, send it again to the Tika Ethics secretary and this will be ready for the next ethics meeting. This application needs to be in one week before the ethics committee meeting, so the committee members have time to read it before the meeting.
- 5. From here you will get communication from the secretary.

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 prior to the start date.
- c. 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.

Deferment and Rejection Outcomes:

- d. 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.
- e. **Rejection**: If the application does not meet the necessary criteria or ethical standards, it may be rejected.

Communication of Decisions:

- f. All outcomes and decisions made by the AEC will be communicated to you as swiftly as possible, typically via email from Nicola, following the committee's deliberation.
- g. Approved projects cannot commence until you have 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.

Revision and Resubmission:

h. If the AEC identifies the need for revisions, you 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.

Documentation:

- j. 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.
- 6. Following approval, either before or during the trial period you may need to submit:
 - a. Adverse events
 - b. Interim reports
 - c. Major or minor modifications
 - d. Correspondence
 - e. Complaints
 - f. Questions
- 7. Other things you will submit are:
 - a. Animal use numbers
 - b. Final report (optional, but useful to the committee)

All of these will be submitted to the Tika Ethics secretary. She will remind you of the time frames that you need to submit these documents by.

Want more information?

Great!! If you read the Code of Ethical Conduct, this will have all the information you need about the process.

Feel free to contact us at info@tikaethics.co.nz

Pricing

Item	Charge (Excl. GST)
Annual parenting fee	\$495
Ethics application	\$3000
Urgent application (requiring an extra meeting)	\$4000
Facility application (E.g. fistulate cattle)	\$3000
Major amendment (requiring a meeting)	\$500
Minor amendment	\$0
Annual facility visit, trial visits	\$200/hour + travel costs

Invoicing will be in the same month that you have submitted your application and will be due on the 20th of the following month.

Sadly, you will still be charged the application fee, if your application is denied, as we still have to spend the same time reviewing the application and processing it through the committee who are paid for their time \mathfrak{S} .

