

AEC Terms of Reference

EpiVets Australia Animal Ethics Committee

Governance framework for the ethical review, approval and monitoring of animal care and use for scientific purposes by the EpiVets Australia Animal Ethics Committee.

Document control	Details
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Review date	At least annually, and earlier if the Code, legislation, licence or registration conditions, AEC composition or operating scope changes.
Supersedes	EpiVets Australia Animal Ethics Procedure and Terms of Reference dated 29 August 2024, from the effective date of these Terms of Reference.
Public availability	The current approved Terms of Reference are to be publicly available on the EpiVets Australia website.

Important governance note

These Terms of Reference set out the institutional accountability, scope, membership, decision-making, reporting and core operating requirements of the EpiVets AEC. They are based on the current EpiVets Australia Animal Ethics Procedure and Terms of Reference published on the EpiVets Australia website and the current Australian regulatory framework. Detailed administrative and project-specific procedures may sit in separate controlled documents, but those procedures must remain consistent with these Terms of Reference, the Australian Code and applicable law.

1. Purpose and ethical framework

The EpiVets AEC is established by and accountable to EpiVets Australia Pty Ltd. Its primary responsibility is to ensure, on behalf of EpiVets Australia and any institution for which it lawfully acts, that activities relating to the care and use of animals for scientific purposes are ethically reviewed, approved and monitored in accordance with the Australian code for the care and use of animals for scientific purposes, 8th edition (2013), updated 2021 (the Australian Code).

The AEC must apply the governing principles of the Australian Code, including that:

- Respect for animals must underpin all decisions and actions involving the care and use of animals for scientific purposes;
- Animals may be used only when justified and when the proposed use is ethically acceptable;
- Replacement, Reduction and Refinement must be applied at all stages of animal care and use;
- The potential effects on animal wellbeing must be justified by the potential benefits, and prompt action to alleviate unanticipated pain or distress takes priority over the continuation or completion of a project;
- People involved in animal care and use must have appropriate competence, training and supervision; and
- Activities must be subject to ethical review, approval, ongoing monitoring and appropriate action when adverse events or non-compliance occur.

2. Scope

These Terms apply to projects and activities for which the EpiVets AEC is the responsible or nominated AEC, including research, teaching, testing, field trials, environmental studies, production of biological products, breeding activities that fall within the Australian Code, and associated acquisition, transport, housing, husbandry and procedures involving animals.

The AEC may act only within the scope lawfully available to EpiVets Australia or to another institution or investigator using the EpiVets AEC under a formal arrangement. AEC approval does not replace any licence, registration, accreditation, site approval, wildlife permit, biosecurity approval or other authorisation required by the jurisdiction in which the activity occurs.

Where EpiVets AEC acts as an external or shared AEC, the arrangement must comply with Chapter 2.6 of the Australian Code. A formal agreement must define responsibilities for governance, communication, directions of the AEC, non-compliance and withdrawal from the arrangement.

3. Applicable requirements

The AEC must operate in accordance with the current Australian Code, the Australian Code for the Responsible Conduct of Research 2018 where applicable to research conduct, and the legislation, regulations, licence or registration conditions and regulator directions applying in the

jurisdiction where the activity occurs. The inclusion of a jurisdiction in these Terms does not itself authorise EpiVets Australia or a client to conduct animal work there.

Jurisdiction	Primary framework to be checked and applied
National framework	Australian code for the care and use of animals for scientific purposes, 8th edition (2013), updated 2021; Australian Code for the Responsible Conduct of Research 2018 where applicable.
New South Wales	Animal Research Act 1985 and Animal Research Regulation 2021. The Regulation requires AEC membership to comply with clauses 2.2.2-2.2.8 of the Australian Code.
Queensland	Animal Care and Protection Act 2001. Chapter 4 adopts the Australian Code as the scientific use code. Scientific users must meet registration, AEC approval and reporting requirements.
Victoria	Prevention of Cruelty to Animals Act 1986 and the Victorian scientific procedures licensing framework. Licence holders must nominate a properly constituted and functioning AEC; interstate AEC arrangements may require fieldwork notification.
South Australia	Animal Welfare Act 1985 and Animal Welfare Regulations 2012. Use of animals for research or teaching requires a South Australian licence and AEC approval. Additional wildlife or scientific permits may apply. The Animal Welfare Act 2025 has been enacted but the 1985 Act remains the current operative Act at the date of this draft; commencement must be rechecked before approval.
Tasmania	Animal Welfare Act 1993 and NRE Tas animal research licensing requirements. Animal research may only be conducted by a licensed institution with its own AEC or approved access to an AEC constituted in accordance with the Australian Code. Interstate institutions must satisfy NRE Tas requirements for AEC access, regulator confirmation and project monitoring. Additional wildlife or fisheries permits may apply.

4. Institutional accountability and independence

The AEC is established by and directly accountable to the governing body of EpiVets Australia Pty Ltd (i.e. the EpiVets Australia Board). EpiVets Australia remains responsible for ensuring that animal care and use conducted on its behalf complies with the Australian Code. Where the AEC

acts for another institution, responsibilities must be allocated by a formal agreement consistent with Chapter 2.6 of the Australian Code.

The institution must:

- Provide the AEC with the resources, administrative support, education and authority required to carry out its responsibilities;
- Ensure that institutional, commercial, scientific or operational pressures do not compromise the AEC's ethical review and monitoring functions;
- Ensure that activities requiring AEC approval do not commence before written AEC approval and cease if approval is suspended or withdrawn;
- Respond appropriately to AEC reports, recommendations and matters affecting animal wellbeing or compliance;
- Ensure that external AEC, shared AEC and multi-institution arrangements are documented in formal agreements where required by the Australian Code; and
- Ensure that independent external review of institutional compliance is conducted at least every four years, and that the operation of the AEC is reviewed annually, as required by the Australian Code.

5. Functions and authority of the AEC

The EpiVets AEC must perform the functions assigned to an AEC by the Australian Code, including to:

- Review applications for projects and approve only those that are ethically acceptable and conform to the Australian Code;
- Review applications for activities associated with animal care and management and conduct follow-up review of approved projects and activities;
- Monitor the care and use of animals, including animals, housing, facilities, procedures, records and reports;
- Obtain information and, where required, specific expert advice to enable competent, fair and timely review;
- Require modification of a project or activity where needed to maintain ethical acceptability and compliance;
- Take appropriate action in response to unexpected adverse events so that animal wellbeing is protected and activities with the potential to adversely affect animal wellbeing cease immediately (see section 11);
- Suspend or withdraw approval where necessary and determine the requirements for any recommencement;
- Take appropriate action regarding non-compliance and refer matters to EpiVets Australia where necessary (see section 11);
- Consider guidelines for animal care and use referred to it by EpiVets Australia and provide advice and recommendations to the institution; and
- Report on its operations to the EpiVets Australia Board at least annually.

6. Membership

Membership must satisfy the Australian Code. The AEC must include at least one person from each Category A, B, C and D. Categories C and D together must represent at least one-third of the AEC membership. EpiVets Australia may appoint additional members with skills and backgrounds of value to the AEC.

Category	Minimum eligibility
A	A person with qualifications in veterinary science recognised for registration as a veterinary surgeon in Australia, with experience relevant to the institution's activities or the ability to acquire relevant knowledge.
B	A suitably qualified person with substantial and recent experience in the use of animals for scientific purposes relevant to the institution and AEC, including a higher degree in research or equivalent experience.
C	A person with demonstrable commitment to and established experience in furthering animal welfare, who is not employed by or otherwise associated with the institution and is not currently involved in the care and use of animals for scientific purposes.
D	A person not employed by or otherwise associated with the institution who has never been involved in the use of animals in scientific or teaching activities in employment or beyond undergraduate education, and who does not fit another category.

Category C and D independence requirements must be maintained throughout appointment. Category C and D members must not be employed by or otherwise associated with EpiVets Australia and must meet the independence requirements of the Australian Code. A person appointed from EpiVets New Zealand as Chair under section 6.2 is an additional member and is not designated or relied upon as a Category C or D member.

6.1 Appointment, tenure and cessation

- EpiVets Australia must maintain procedures for appointment, reappointment and retirement of AEC members. The term of each appointment is to be specified in writing.
- Before appointment, prospective members must declare interests relevant to the appointment. Appointed members must acknowledge in writing their acceptance of the AEC Terms of Reference and EpiVets Australia confidentiality requirements.
- Members must declare any interest that could influence the objectivity of their decision-making before AEC deliberations and must maintain confidentiality regarding applications and AEC deliberations in accordance with institutional requirements.

- Consistent with the existing published EpiVets Australia Terms of Reference, members are to be informed of the commencement and end date of appointment, their responsibilities and confidentiality requirements, and that EpiVets Australia will indemnify them for liabilities arising during bona fide conduct in the AEC role. Resignation, retirement or termination must be managed so that the AEC remains properly constituted.

6.2 Chair, Deputy Chair and secretariat

EpiVets Australia must appoint a Chair. The Australian Code permits the Chair to be an external appointee and to be appointed in addition to Category A-D members. Under these Terms, EpiVets Australia may appoint a suitably qualified person from EpiVets New Zealand as an additional AEC member and as Chair, subject to applicable jurisdictional requirements. This structure satisfies the New South Wales requirement that the Chairperson be a member of the ethics committee. The Chair is non-voting under these Terms and is not relied on to satisfy any Category A-D membership requirement. For any one-third Category C and D membership-proportion requirement, the Chair is included in the total AEC membership (the denominator) but is not counted as a Category C or D member (the numerator). EpiVets Australia must provide an external Chair with the support and authority necessary to carry out the role.

The Chair is responsible for impartially guiding AEC operations, managing conflicts of interest related to AEC business and representing the AEC in negotiations with EpiVets Australia management. The Chair may participate fully in discussion and deliberation but has no deliberative or casting vote under the general EpiVets AEC model. The Chair must declare and appropriately manage any actual, potential or perceived conflict arising from employment, governance or other relationships, including an association with EpiVets New Zealand. A Deputy Chair or acting chair may preside when required.

6.3 Training and performance

EpiVets Australia should ensure that AEC members and the Chair receive appropriate induction and have access to education programs and resources relevant to their responsibilities. Training and support must be sufficient for the AEC to function effectively and comply with applicable jurisdictional requirements.

7. Meetings and decision-making

The AEC must meet often enough to function effectively. Meetings may be conducted in person or, where face-to-face attendance is not possible, by videoconference or web-conference, or in special circumstances by teleconference, provided the meeting remains quorate and members can participate effectively. This permits a Chair based in New Zealand to preside remotely where the meeting otherwise complies with these Terms and the Australian Code.

7.1 Quorum

Quorum is determined in accordance with clause 2.2.25 of the Australian Code: at least one member from each Category A, B, C and D must be present throughout the meeting, and

Categories C and D together must represent at least one-third of the AEC members present. The non-voting Chair cannot be used to satisfy a Category A-D requirement. For the one-third quorum calculation, the Chair is included in the total number of AEC members present (the denominator) but is not counted as a Category C or D member (the numerator). The Chair must preside; if the Chair is absent, an eligible AEC member may act as Chair in accordance with applicable law and these Terms.

7.2 Papers and participation

Meeting papers must be distributed in sufficient time to allow members to be fully informed. Decisions must be based on a thorough, fair and inclusive discussion, and only people present throughout the relevant discussion may participate in the decision. Applicants and advisers may be invited to provide information but do not participate in the AEC decision.

7.3 Decisions

AEC decisions should be made by consensus. If consensus cannot be reached after reasonable efforts, the AEC should explore modifications with the applicant that may lead to consensus. A majority decision should occur only after members have been allowed time to review their positions and further discussion has occurred. Under the general EpiVets AEC model, only appointed voting members vote and the non-voting Chair has no deliberative or casting vote.

The AEC may approve an application with or without conditions, defer it subject to modification or further information, or not approve it. Following review of an annual report, the AEC may continue, suspend, modify or discontinue approval. The AEC may also suspend or withdraw an approval where required.

7.4 Out-of-session and urgent matters

New projects and activities, and ongoing approval of existing projects and activities, must be considered and approved only at quorate AEC meetings. If an AEC Executive is established, it must be appointed by the AEC at a quorate meeting, with its membership and delegated authority recorded in the minutes. The Executive must include the Chair and at least one Category C or D member and may be delegated to approve minor amendments to approved projects or activities for ratification at the next AEC meeting. An AEC Executive must not approve new applications.

8. Ethical review requirements

The AEC may approve a project or activity only when satisfied that it is ethically acceptable and conforms to the Australian Code. Review must consider information sufficient to determine whether the proposed use of animals is justified and whether the potential effects on animal wellbeing are justified by the potential benefits, including:

- The aims, scientific or educational justification, and whether the proposed methods are scientifically valid and feasible;
- Replacement alternatives and why animals are necessary;

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- Reduction, including justification of animal numbers and avoidance of unnecessary duplication;
 - Refinement of animal care, handling and procedures to avoid or minimise harm, pain and distress;
 - The likely impact on animal wellbeing, including cumulative effects over the animal's lifetime involvement;
 - Species, source, health status and suitability of the animals for the proposed use;
 - The competence, training and supervision of investigators and animal carers;
 - Monitoring arrangements, intervention points and humane endpoints appropriate to the species and project;
 - Arrangements for veterinary care and prompt action in response to pain, distress, emergencies and unexpected adverse events;
 - Provisions for animals at the conclusion of their use, including rehoming, return to normal husbandry, reuse or humane killing where applicable;
 - Housing, husbandry, transport and site or facility conditions relevant to animal wellbeing;
 - Responsibilities of owners or custodians where privately owned animals are involved, where applicable under the Australian Code;
 - Recordkeeping, reporting and any additional information needed for the AEC to assess ethical acceptability; and
 - Confirmation that all other legal and regulatory authorisations required for the activity will be obtained before commencement.

8.1 Approval period and conditions

The AEC must determine the duration of each project approval having regard to the project funding period, milestones or stages and relevant formal agreements. Investigators must provide an annual report for an approved project regardless of the duration of AEC approval. Any separate jurisdiction-specific authority, licence or certificate must be managed in accordance with the applicable law and must not be treated as a substitute for AEC approval.

8.2 Modifications

A modification to an approved project or activity that may affect animals, animal welfare, approved procedures, animal numbers, study sites or other material aspects of the work must not proceed without prior AEC approval.

Minor amendments may be considered by an AEC Executive only where authority has been formally delegated in accordance with clause 2.2.23 of the Australian Code and the amendment meets documented EpiVets AEC criteria for a minor amendment. The composition and limits of the AEC Executive are set out in section 7.4. Decisions made under delegated authority must be documented and ratified by the full AEC at its next meeting.

Urgent action required to protect animal welfare must not be delayed while awaiting approval. Any resulting departure from the approved project must be promptly documented, reported to the AEC and reviewed in accordance with EpiVets Australia procedures.

8.3 Complaints and review of process

EpiVets Australia must maintain procedures for complaints, non-compliance, complaints about the AEC review process and irreconcilable differences between the AEC and an investigator. Where a process complaint cannot be resolved directly with the AEC, the complainant must have access to review of the process by a person or agency external to the AEC. The ultimate decision about ethical acceptability remains with the AEC and must not be overridden.

9. Monitoring and inspections

The AEC must monitor all activities relating to the care and use of animals on a regular and ongoing basis to assess compliance with the Australian Code and AEC decisions. Monitoring may include inspection of animals and housing, observation of procedures, and review of records and reports.

- Inspections may be announced or unannounced, and the AEC should determine their frequency and timing having regard to the number and accessibility of sites, the number and types of projects and activities, and the level of animal welfare risk.
- Activities likely to cause pain or distress should be monitored at an early phase during the activity, and the AEC may require more frequent monitoring for particular projects or activities.
- A Category C or D member should participate in animal facility inspections. The AEC may delegate monitoring of remote sites to suitably qualified people, provided reports are supplied to the AEC and may include still or video images.
- Inspection records must include the names of attendees, observations, identified problems, recommended actions, ongoing or outstanding issues and outcomes.
- The AEC remains responsible for oversight of monitoring and must ensure that identified problems receive appropriate follow-up, including referral of suspected breaches to EpiVets Australia where necessary.

The frequency and method of day-to-day animal monitoring must be appropriate to the species, project, procedures, and foreseeable risks. The Australian Code does not establish a universal twice-weekly monitoring rule; monitoring must be sufficient to identify and respond promptly to changes in animal wellbeing.

10. Animal wellbeing, endpoints and veterinary care

Applications and approved activities must contain monitoring and intervention arrangements sufficient to safeguard animal wellbeing. Responsibilities for monitoring, assessment criteria, records, intervention points, humane endpoints and emergency actions must be clear to the people responsible for the animals.

Where pain or distress is predicted or unavoidable, intervention points and humane endpoints must be established using validated criteria appropriate to the species and the nature and time course of the predicted effects. They must be applied as early as feasible. Death as an endpoint must be avoided unless essential to the project and specifically justified and approved in accordance with the Australian Code and any additional jurisdictional requirement.

Prompt action must be taken in response to unexpected adverse events and emergencies, including alleviation of pain and distress and, where necessary, humane killing without delay. Alleviating unanticipated pain or distress takes precedence over an animal reaching the planned endpoint or the continuation or completion of a project.

11. Adverse events, non-compliance and suspension

Investigators must promptly notify the AEC of unexpected adverse events in accordance with AEC and institutional procedures. The AEC must take appropriate action so that animal wellbeing is not compromised, the issue is addressed promptly and activities with the potential to adversely affect animal wellbeing cease immediately.

When non-compliance with the Australian Code is detected, the AEC must ensure that animal wellbeing is protected, the issue is addressed with the people involved, matters are referred to EpiVets Australia when necessary, and appropriate follow-up occurs. Actions may include modification, increased monitoring, suspension or withdrawal of approval.

If approval is suspended or withdrawn, the affected activity must cease and arrangements must be made to meet the immediate and ongoing needs of the animals. Any resumption of the activity requires the approval or other authorisation specified by the AEC and applicable law.

12. Records, confidentiality and transparency

EpiVets Australia must ensure that records of AEC business are maintained, including a register of applications and outcomes, minutes recording decisions and other aspects of AEC operations, and records of inspections. Project and activity records must be retained as required by the Australian Code and applicable law.

Minutes must accurately record attendance, quorum, conflicts of interest and their management, decisions, reasons and conditions, and any majority vote or abstention. Meeting records must distinguish voting members, the non-voting Chair, advisers and visitors where relevant.

AEC members must maintain confidentiality regarding applications and AEC deliberations in accordance with EpiVets Australia requirements. Experts and other people invited to assist the AEC must also be subject to appropriate confidentiality and conflict-of-interest controls.

EpiVets Australia must ensure that the current approved AEC Terms of Reference are publicly available. The Terms must state the AEC's scope of responsibilities, institutional accountability, reporting mechanisms and how minimum membership requirements are met.

13. Reporting

13.1 Annual report to the institution

At least annually, the AEC must submit a written report on its operations to the EpiVets Australia Board. The report should address the numbers and types of projects and activities assessed and their outcomes, facilities for animal care and use, education and training, administrative or resource difficulties, and matters affecting EpiVets Australia's ability to maintain compliance with the Australian Code.

13.2 Regulatory reporting

EpiVets Australia and any institution or investigator using the EpiVets AEC must meet the reporting, registration, licence and notification requirements that apply in the relevant jurisdiction. In New South Wales and Queensland, reporting must be consistent with the Animal Research Act 1985 and Animal Research Regulation 2021, and the Animal Care and Protection Act 2001 and associated scientific-use requirements, respectively. In South Australia, the Animal Welfare Act 1985 and Animal Welfare Regulations 2012 require the applicable research and teaching licence, use of the AEC identified or approved for that licence, and annual AEC reporting within the prescribed timeframe. In Tasmania, animal research must be conducted under an Animal Research Licence, interstate AEC access and monitoring arrangements must meet NRE Tas requirements, and the licensed institution must submit annual animal-research reports in accordance with the Act, licence conditions and current NRE Tas reporting instructions.

14. External AEC services and multi-institution projects

Before the EpiVets AEC acts for another institution or an investigator without direct access to an institutional AEC, the arrangement must be based on a formal agreement developed in consultation with the AEC. The agreement must include, as applicable:

- The parties and the scope of the animal care and use covered by the arrangement;
- Procedures that allow each institution to meet its responsibilities for AEC governance and operation;
- Communication, governance and reporting arrangements between the AEC and the other institution or investigator;
- An undertaking that investigators and other relevant personnel will comply with AEC directions;
- An undertaking to comply with AEC policies and procedures relating to non-compliance;
- Arrangements for access, monitoring, inspection, records and communication necessary for the AEC to discharge its responsibilities;
- The circumstances in which either party may withdraw from or terminate the arrangement; and

- Any additional responsibilities required by applicable state or territory law, licence or registration conditions.

For projects involving more than one institution and/or AEC, the institutions and AECs must ensure that responsibilities are clear, relevant AEC approvals are in place before activities commence, animal care and use can be adequately monitored across all sites, and effective communication channels are maintained. Formal arrangements should avoid unnecessary duplication while preserving accountability under the Australian Code.

15. Review of these Terms of Reference

EpiVets Australia must review the operation of the AEC annually and should review these Terms of Reference at least annually and whenever a material change affects the Australian Code, legislation, licensing or registration, AEC composition, the Chair arrangement, institutional structure or the jurisdictions in which the AEC acts. This includes commencement of the Animal Welfare Act 2025 (SA), replacement South Australian regulations or any material change to South Australian research and teaching licence or AEC requirements. Any change requiring regulator notification or approval must be completed before the amended arrangement is relied upon.

16. Definitions

Term	Definition
Activity	Any action or group of actions involving the care and use of animals, including acquisition, transport, breeding, housing and husbandry, as described in an application to an AEC.
Adverse event	Any event that has a negative impact on the wellbeing of an animal.
Animal	Any live non-human vertebrate and cephalopod within the meaning of the Australian Code, subject to any broader definition applying under relevant state or territory law.
Animal wellbeing	An animal is in a positive mental state and is able to achieve successful biological function, have positive experiences, express innate behaviours and respond to and cope with potentially adverse conditions.
Conflict of interest	An interest that could influence the objectivity of a person involved in AEC decision-making. People with a relevant conflict must remove themselves from the AEC decision on the matter.

Term	Definition
Humane endpoint	The point at which an animal should be humanely killed, regardless of whether the aims of the study have been achieved, based on criteria appropriate to the species and the project.
Institution	EpiVets Australia Pty Ltd or, where the EpiVets AEC is formally appointed, nominated or otherwise authorised to act for another organisation, that organisation as applicable to the particular responsibility described in these Terms of Reference.
Project	An activity or group of activities that form a discrete piece of work intended to achieve a scientific purpose.
Unexpected adverse event	An event that may have a negative impact on animal wellbeing and was not foreshadowed in the approved project or activity.

17. References

- EpiVets Australia, Animal Ethics Procedure and Terms of Reference, public version valid from 29 August 2024 to 29 August 2026, published at epivets.com.au.
- National Health and Medical Research Council, Australian code for the care and use of animals for scientific purposes, 8th edition (2013), updated 2021.
- National Health and Medical Research Council, Australian Research Council and Universities Australia, Australian Code for the Responsible Conduct of Research 2018.
- New South Wales, Animal Research Act 1985 and Animal Research Regulation 2021, current versions published on the NSW legislation website.
- Queensland, Animal Care and Protection Act 2001 and official Business Queensland guidance on animal ethics committees and the scientific use of animals; and Agriculture Victoria official guidance on Animal Ethics Committees and scientific procedures licensing where Victorian activities are undertaken.
- South Australia, Animal Welfare Act 1985 (current authorised version), Animal Welfare Regulations 2012, and Department for Environment and Water guidance on animal welfare research and teaching licences and animal ethics committees.
- Tasmania, Animal Welfare Act 1993, Department of Natural Resources and Environment Tasmania Animal Research guidance, and the NRE Tas Animal Research Licence Application.