

AgResearch Limited

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

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1. Introduction/Background on the Activities of the Organisation

1.1. Organisational Activities

This Code of Ethical Conduct (CEC) for AgResearch Limited (AgResearch) implements and gives effect to the Animal Welfare Act 1999 (the Act), the Animal Welfare (Records and Statistics) Regulations 1999, and any other relevant legislation. Within this document, the term "animal" refers to any species defined as an animal by the Act and "manipulation" applies to any procedure defined as a manipulation by the Act.

AgResearch is a Crown Research Institute that undertakes research on a range of animal species to enhance the value, productivity and profitability of Aotearoa New Zealand's pastoral, agri-food and agri-technology sectors. AgResearch contributes to the country's economic growth and helps achieve positive animal, environmental and social outcomes. AgResearch employees perform manipulations on animals when undertaking research under the approval and oversight of the AgResearch Animal Ethics Committee (AAEC). AgResearch employees are mainly based on the Invermay, Lincoln, Grasslands and Ruakura campuses. AgResearch closed the AECs at Invermay and Grasslands and began operating a single AAEC based at Ruakura on 21 January 2021.

AgResearch is cognisant that Māori have specific interests in the way their land is used and in the indigenous fauna of New Zealand. This CEC recognises that AgResearch must operate with tiaki (care) and whakautu (respect) when using these resources. AgResearch does not currently undertake specific research on indigenous species, but it acknowledges that, occasionally, research may impinge on these species. Further, this CEC is used by other organisations under parenting arrangements, some of which may wish to work with indigenous species.

The activities undertaken under this CEC do not necessitate Māori representation on the AAEC. However, all applicants must identify and appropriately address Māori perspectives in relation to their research. Questions in the application form require the applicant to specify any area of the proposal that is of particular interest to Māori. Should this be the case, the applicant must discuss these aspects with local iwi or hapu and include evidence that these discussions have taken place and that Māori perspectives are not compromised. If there is any uncertainty, the applicant must approach local Māori representatives for clarification.

1.2. RTT and the Three Rs

AgResearch is committed to the following approaches to RTT:

- To **reduce** the number of animals manipulated.
- To **refine** manipulation techniques so that harm to animals is minimised and benefits to humans, animals, or ecosystems are maximised.
- To **replace** animal models by substituting, where possible, non-sentient or non-animal alternatives.

The philosophy encapsulated in the three bullet points above is implemented by specific questions in the application form and the AAEC and Animal Ethics Office (AEO) activities.

1.3. Responsible Persons

AgResearch is the code holder, and responsibility for the CEC within AgResearch rests with the Director Research Operations or equivalent senior role, who delegates administration and implementation of the CEC and AAEC to the AEO. The AEO comprises the Leader, Coordinator, Animal Welfare Officers (AWO) and Administrator. Research and manipulations are carried out by staff under the approval and oversight of the AAEC. The respective farm

or facility managers are responsible for operations within their farm or facility.

The roles of AgResearch as the code holder organisation include promoting a research culture that aligns with the Three R's and providing management and resources that support best practice implementation of this CEC.

AgResearch promotes a culture of care that fosters integrity and accountability of the actions and decisions of all staff and committee members.

1.4. Persons/Organisations under the CEC

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

The CEC is available on the AgResearch public website and is provided to all organisations before they enter a parenting arrangement with AgResearch.

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

2.1. Functions, duties and powers of the Committee

The AAEC functions independently from AgResearch and parented organisations to give weight to the provisions and intentions of the Act. The AAEC will consider ethical matters on the use of animals in RTT by AgResearch staff and parented organisations. In carrying out its duties, the AAEC has the power to grant or remove approval for the use of animals in RTT, set and vary conditions on how manipulations are carried out, confirm that the Three R's are implemented on all proposals, monitor approved projects and facilities, and determine the suitability of staff to carry out the manipulations and deliver on the outcomes proposed.

The AEO supports the AAEC in carrying out its functions. The Chair of the AAEC leads the AEO; thus, the AEO acts closely with and under the direction and delegation of the AAEC. The AEO provides administrative services and implements the decisions of the AAEC, facilitating connections between the code holder, AgResearch staff, parented organisations and the AAEC.

The AAEC, or persons delegated by the AAEC (see 7.2), can inspect animals, their accommodation, and related experimental records at any time to ensure that approved procedures are carried out as proposed. The AAEC may delegate AWOs, registered veterinarians or other persons with appropriate skills to undertake work as necessary.

2.2. Membership of the AEC

The members of the AAEC shall be appointed by the code holder for the period of the CEC in effect.

2.3. Statutory members

- *A senior representative of AgResearch appointed by the code holder with experience in animal welfare or ethics and who is qualified to evaluate applications. This person may or may not be the committee chair;*
- *A veterinarian nominated by the New Zealand Veterinary Association (NZVA) who is not employed by or associated with AgResearch;*
- *A person nominated by the Royal New Zealand Society for the Prevention of Cruelty*

to Animals (RNZSPCA) who is not employed by or associated with AgResearch or involved in the use of animals for research, testing or teaching;

- *A person nominated by a territorial authority or regional council, not employed by, or associated with AgResearch or associated with the scientific community or an animal welfare agency.*

2.4. Organisational members

A minimum of two and up to four additional members may be appointed as requested by the AAEC to assist the functioning of the Committee, such as:

- An AgResearch staff member who is responsible for procuring, producing, or maintaining animals.
- A biometrician.
- A senior member of AgResearch staff who can evaluate applications regarding factors such as the proposer's standing and the research's value.

2.5. External members

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

A reduced reimbursement will be provided to external members who cannot attend a committee meeting but submit apologies in advance and written comments on the agenda items assigned to that meeting.

2.6. Additional members

External persons (supernumerary members) with specific skills may be nominated and appointed to the AAEC by the code holder to assist the activities of the Committee. Supernumerary members shall function and have the same reimbursement as other external members of the AAEC.

The AAEC may request external persons with specific skills to act as Subject Matter Experts (SME) on an *ad hoc* basis. The SME acts in an advisory capacity to the AAEC and may be remunerated on a case-by-case basis.

Animal Welfare Officers (AWO) are not members of the AAEC but attend meetings to provide veterinary, animal welfare and regulatory advice to the AAEC and report on other AWO activities.

2.7. Appointment Procedures

- 2.7.1** Appointments to the AAEC shall be made after consultation between the Committee, the code holder and the relevant nominating agency in the case of statutory external appointments. Consideration of suitability for the role will include skills, experience, time availability and any conflicts of interest.
- 2.7.2** The code holder shall appoint the AAEC chairperson and deputy chairperson for the term of the CEC. If the chairperson is unavailable, the deputy will carry out the chairperson's duties as required.
- 2.7.3** Replacement of an AAEC member during the term of the CEC shall follow the procedure described above for the relevant member category.

2.8. Term of appointment

As a new CEC marks a point when there are new rules for the operation of the AAEC, all AAEC appointments and contracts are for the period of the CEC that is in place at the date

of appointment; therefore, the maximum length of a term is five years. AAEC appointments may be renewed by negotiation between AgResearch, AAEC and the nominating body. There is no limit on the number of terms a person may serve.

2.9. Induction and Training of New Members

New members will be given one-on-one training by AEO staff in the operation of the AAEC and how to access and use ~Te Ara~, the online database used to manage form submissions and reviews. The main functions of ~Te Ara~ are described in section 3.15. Key projects open at the time of the appointment will be discussed. Training will include access to the following resources:

- The current AgResearch CEC.
- NAEAC Induction pack.
- NAEAC Good Practice Guide for Use of Animals in Research, Testing and Teaching.

Continual training and improvement of the knowledge and skills of AAEC members shall be facilitated by distributing appropriate literature, access to AgResearch resources, attendance at conferences, NAEAC workshops, and contact with staff from AgResearch and parented organisations. AAEC members are encouraged to ask for support and training should they be aware of an opportunity they wish to take.

2.10. Vacancies

A vacancy on the AAEC due to resignation during the term of the CEC shall be actioned as soon as the vacancy is known and follow the appointment procedure and for the appointment term described in 2.7. and 2.8. The AgResearch recruitment process will be used to manage staff vacancies in the AEO.

If there is repeated non-attendance at AAEC meetings, defined as a member being absent for more than 25% of scheduled meetings in a calendar year, the nominating body or the code holder will be contacted to determine if a replacement is required and if so, the appointment procedure will be followed.

3 AEC Processes

3.1. AEC meetings

Applications, amendments, project reports, project monitoring reports, adverse events reports, conflicts of interest, complaints, non-compliance reports, SOPs and any other relevant agenda items and documentation are assigned to scheduled meetings, discussed by the AAEC, and responses are agreed to by consensus.

3.2. Frequency of Meetings

Scheduled face-to-face meetings (in-person or via video conference) shall be held at least twenty times per year, generally on a fortnightly basis. If required, additional meetings may be scheduled. The regularity of meetings means that members know the meeting schedule for the following year before the end of each year.

The time and place of the next meeting are provided on each agenda and confirmed with AAEC members at each meeting.

3.3. Timing for Circulation of Agenda Items

The AEO organises meetings and sets and distributes the agenda. All meeting documents, including agendas, minutes, applications, amendments and reports, and AEO communications, are available to AAEC members in ~Te Ara~ or in an alternate secure online

location to facilitate document sharing and editing. Members are notified of the agenda at least five days before a meeting but can access meeting documents before this as soon as they are assigned to that meeting. Documents may be assigned up to four weeks before a meeting.

The AEO communicates between the AAEC and applicants in *~Te Ara~*, and decisions are recorded in the minutes.

3.4. Quorum

A quorum for scheduled meetings shall consist of at least 50% plus one of the current members of the AAEC, at least two of whom must be statutory external members, and one must be the chairperson or deputy chairperson. The provision of notes by a member does not count towards a quorum.

3.5. Decision Process

Decisions of the AAEC are made by consensus only; if consensus cannot be reached, a project will not be approved. In this case, the application may be returned to the applicant for revision or rejected.

3.6. Effective Input of Committee Members

All committee members have access to all agenda items and shall have equal opportunity to contribute to the business of the meeting. The chairperson will ensure that all members, particularly statutory external representatives, can contribute and are satisfied with the discussion before making any decisions.

Research staff will be made available at the request of any AAEC member to obtain additional information and answer questions regarding the applications made to the AAEC.

3.7. Establishment and Membership of Subcommittees

Sub-committees are not used.

3.8. Conflict of Interest

AAEC members must declare any potential conflict of interest at the start of the meeting. Conflicts of interest can be declared and recorded on *~Te Ara~*, and the conflicted member can no longer review that item. The AAEC shall establish the protocol to manage other potential conflicts on a case-by-case basis, which will be recorded in the minutes.

Where a member of the AAEC is the principal investigator or has a significant role in a project being considered, the member may provide information if asked but must retire from the deliberation on the approval or other decisions on the project. If the member of the AAEC with a conflict is the chairperson, the deputy chairperson will run the meeting while the item with the conflict is considered.

A member of the AAEC named on a proposal acting in a largely advisory or supply capacity must declare their role on the project to the meeting, but it shall not be deemed a conflict of interest.

3.9. Confidentiality

To ensure the confidentiality of sensitive information, all AAEC members, internal and external, shall sign a confidentiality agreement, a breach of which may give rise to personal liability in civil law.

All documents, including forms and correspondence, are maintained in *~Te Ara~* or an alternate secure online location to which the AEO controls access. Should members make a copy of any documents, they must be kept in a safe place, returned, or deleted when no

longer required and securely destroyed. Email communication to AAEC members must also be deleted by the AAEC members when no longer needed.

No documentation shall be released to external parties unless approved by the chairperson.

3.10. Use of Tele/Video Conferencing

All meetings shall be face-to-face (in person or by video conference) for the quorum of AAEC members as defined in 3.4. Written notes may be used to enable contributions by AAEC members if they cannot attend face-to-face.

3.11. Consideration between Meetings

The AAEC will not consider applications between meetings.

Applications submitted under urgency may be prioritised through the preview process and considered at the next in-person AAEC meeting. Urgent applications are those submitted within one month of the proposed start date and must include valid reasons for urgency in the application.

Requests for urgent consideration of major amendments (section 4.7) to an approved application may be considered between meetings, providing there is a valid reason for urgency, and the requested change is to an application with an impact grade of A, B or C and the amendment does not increase the impact grading of the application. AAEC members will be notified of an urgent amendment to review by email. Decisions between meetings are made by consensus of a quorum of members as defined in 3.4.

Decisions made between meetings are recorded in ~Te Ara~ and ratified in the minutes of the subsequent AAEC meeting.

3.12. Public Presence at Meetings

AgResearch is a Crown Research Institute and, therefore, not subject to the Local Government Official Information and Meetings Act 1987. Consequently, AAEC meetings are not open to public attendance.

Information about AAEC meetings is official information under the terms of the Official Information Act 1982, and requests by members of the public for its release are to be treated as requests under this Act.

3.13. Applicant Presence at Meetings

Application personnel may be invited to attend AAEC meetings under the following circumstances:

- An application is in a new area or is unfamiliar to the AAEC. This attendance will be before the application is submitted and considered.
- The AAEC wishes to hear a presentation on the results of a project.
- Committee discussions can be facilitated by specific questions directly to the applicant.
- Other requests for attendance that the AAEC deems necessary.

In all situations above, application personnel must not be present in any capacity during AAEC deliberations on the application. All attendance at meetings is recorded in the meeting agenda and minutes.

3.14. Secretarial Support

Secretarial support is managed by the AEO, which maintains a team of staff with appropriate skills to provide full support to the AAEC.

3.15. Record Keeping and Information Management

All records and documentation associated with the operation of the AAEC are stored securely in electronic form in ~Te Ara~ or an alternate secure location to which the AEO controls access for not less than ten years. These are accessible by AEO staff only. When deleted, this will be done securely.

The database used for managing the animal ethics process and storing information is named ~Te Ara~. This database is a commercial product designed for human and animal ethics management that has been extensively customised and is a bespoke system for AgResearch requirements. The underlying database software is updated by the commercial provider and AgResearch at intervals to improve the system's operation, but this does not interfere with the use and security of the database.

Use of ~Te Ara~ by registered users, the AEO and the AAEC underpins the application, review and reporting process by using a system of customised forms and communication between reviewers and application personnel. All interactions with ~Te Ara~ are recorded with the time and user, and all versions of forms are archived for retrieval if required.

The AEO controls access to information in ~Te Ara~. Application personnel can only see information relevant to them that they have created or shared with them by the owner of the information, such as the applicant. AAEC members can only see documents when required to undertake their role.

When submitted for review, forms are locked against further editing and can only be unlocked by the AEO. All decisions, status changes, and correspondence are dated, time and person stamped and recorded in ~Te Ara~. Automated tracking of changes and archives of all versions provide a record of all editorial changes.

3.16. Reporting of Animal Use Statistics to MPI

Applications must contain all details for 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 AAEC in an Animal Welfare and Use report. The AAEC may revise the impact grade at any time during the project discussion or reports, and the final grading will be recorded with acceptance of this report. This information will be stored as detailed in 3.15.

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

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

3.17. Protection of AEC Members

No member of the AAEC is personally liable for any act done or omitted by the member or the Committee in good faith during the operations of the Committee.

3.18. Process to amend the CEC

If the AAEC determines that this CEC should be amended at any time, a recommendation will be made to the code holder by the AEO. Should amendments be required due to any such request from the AAEC, the AEO will notify MPI and submit the proposed changes.

4 Consideration of Applications by the AEC

4.1. Criteria for Consideration

Criteria that the AAEC must consider in evaluating applications are set out in Section 100 of the Act and are included in the application form in a way that makes an answer compulsory. All applications must be completed online in ~ Te Ara ~. Criteria for consideration include, but are not confined to, the following:

- Personnel and their competency to undertake named procedures.
- Facilities and locations of animals.
- Implementation of the Three R's.
- Science quality, justification, and outputs.
- Materials and methods, including drugs and compounds administered.
- Animal use, treatments and groups.
- Impact grade.
- Biometric evaluation.
- Monitoring, endpoints, handling of contingencies and adverse events.
- Any other matters the Committee deems relevant.

All applications and reports must be previewed before being assigned to a meeting. Previews are carried out by the AEO and a senior member of AgResearch science staff, who is also an AAEC member. During the preview process, a form may be returned to the applicant for revision as often as required until the preview team considers it ready to be assigned to an AAEC meeting. Once assigned, proposals are available for review, and comments can be recorded directly against the relevant section of a proposal in ~Te Ara~ by AAEC members before a meeting. The approval status is decided by consensus at the meeting using the criteria for approval above.

The AAEC will not consider an application that includes the Porsolt Swim Test.

4.2. Impact Grading

The applicant assigns an impact grading for animal manipulations proposed in an application. The MPI Animal Use Statistics guide is available to the applicants in ~Te Ara~ for reference. The AAEC may adjust the grading at the time of approval, after the work has started, or when the actual impact on the animals has been evaluated via the monitoring program, an Adverse Event or Animal Welfare and Use forms. The AAEC will use the MPI Animal Use Statistics guide for reference in assigning an impact grading.

4.3. Outcomes after Consideration

Following consideration of an application using the criteria outlined in 4.1., the AAEC may approve the project. Should minor information be required that is unknown at the submission date (e.g., farm locations), an application may be approved with explicit directions to provide that information.

If consensus cannot be reached, or the Committee decides that additional conditions,

information, or changes must be made before an application is approved, the applicant will be asked to address the points and revise and resubmit the application. The applicant must not start any work described in the application while the revision process is underway. Once the applicant has submitted the changes required, the application will be previewed and either reconsidered at either the next AAEC meeting or if the chairperson is satisfied that the conditions have been met and has been given delegation to do so for this specific application by the AAEC, the application may be approved.

All formal correspondence, including committee decisions, between AEO, AAEC, the applicant and the research team is done directly via ~Te Ara ~ or if needed, entered in ~Te Ara ~ by the AEO.

If the AAEC rejects an application, the applicant must not start any work described in the application.

4.4. Conditions of Approval

Approval of an application includes the approved start and end dates, reporting dates, monitoring requirements or other conditions as the AAEC decides. During the approval period, the AAEC may set, vary or revoke conditions of approval as deemed necessary and communicate this to the applicant.

4.5. Maximum Approval Period

Application approval will be for no more than one year unless a specific request is made and justified for longer. Interim reports are required at least annually for applications approved for over one year. No approval for an application will be for more than three years.

An applicant may request to extend the approval period using a form in ~ Te Ara ~, providing that the total period of approval does not exceed three years. Requests to extend an approval period must be made to permit decisions before the original approval expires, or a new application would be required.

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

4.6. Power to Suspend, Revoke and Vary Approvals

The AAEC can suspend, revoke and vary approvals when deemed necessary. If approval is suspended or revoked, all manipulations must cease, and arrangements must be made to safeguard the welfare of the animals. If the concerns of the Committee are resolved, the project may be approved to continue. Otherwise, the approval is ended permanently.

If there are concerns regarding the welfare of animals on a project, the AAEC or persons delegated by the AAEC have the power to immediately access a project for monitoring purposes at any time deemed necessary. Manipulations can be stopped anytime, and animals managed to safeguard their welfare, and approval revoked.

4.7. Changes to Approved Applications

An applicant may request to make amendments to an approved application using a specific sub-form of their project in ~ Te Ara ~.

Once the request is accepted, the application is unlocked in ~Te Ara ~, and the applicant can make amendments. These are all recorded in ~ Te Ara ~ and visible as track changes.

The amended application must follow the same preview process as applications.

The AAEC categorises amendments as either Minor (e.g. staff, date, location, transport or housing/caging changes) or Major (e.g. methodology, manipulations, drugs or chemicals, or

grading changes). The AAEC has delegated review and approval of minor amendments to the AEO. Major amendments must follow the same procedure as outlined in 4.3. or if urgent, as in 3.11.

All amendments must be ratified by the AAEC at the next in-person meeting.

5 Responsibilities under AEC Approved Applications

5.1 Compliance

5.1.1 Project Reporting

Applicants must meet all reporting requirements associated with their project.

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

Applicants must submit a report on the animal welfare outcomes, and animal use statistics one month after the approval end date.

Final reports covering the project's scientific outcomes must be submitted within six months of the end of the approval period.

5.1.2 Compliance Reporting

If, while carrying out its duties, the AEO or AAEC becomes aware that a project has not been carried out within the conditions of approval or CEC, it may add conditions, suspend or stop projects, and a formal non-compliance notice will be issued to the applicant. Non-compliance notices are recorded and stored in ~Te Ara ~. Minor non-compliances may be self-reported by the applicant and accepted by the AAEC with a plan to prevent re-occurrence.

When the AAEC determines that a non-compliance is concerning to the extent that it requires disciplinary action, this will be referred to AgResearch management and follow AgResearch employment policy. In the case of external personnel, it will be directed to the management of the organisation concerned.

If the AAEC deems there has been a serious non-compliance with the Act, the project will be stopped immediately, and the situation will be referred to the appropriate regulatory body such as MPI, SPCA or Police.

5.2. Appropriate Qualifications

All personnel who undertake animal manipulations must be trained in an approved Standard Operating Procedure (SOP). The trainer is either an AWO or another suitably qualified person who is approved as a trainer by an AWO. Training is specific to the species and manipulation and has an expiry date (usually three years) determined by an AWO.

A register of SOPs, trained personnel, training details and their competency is kept in ~ Te Ara ~. Information on who is trained in an SOP is available to all users when creating an application, and all users trained in an SOP have access to that SOP.

5.3. Sick and Injured Animals

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

The AAEC delegates oversight over sick and injured animals to the AWOs, who have a fixed agenda item at scheduled meetings to report back activities to the AAEC. They preview and

can contribute to all adverse event reports before consideration by the AAEC.

5.4. Standard Operating Procedures

SOPs are created and submitted in ~Te Ara~. The SOPs are reviewed and approved with an expiry date by the AWOs as delegated by the AAEC. Training of staff to an SOP is undertaken by AWOs or persons delegated by the AWOs who have achieved the required competency level to train others. Training records that contain details of the training, competency achieved, and expiry date are stored as a sub-form of the SOP in ~Te Ara~. SOPs and training details are accessible to the AAEC and must be referenced, along with staff trained in the SOP or request training, in an application proposing to use an SOP. The AAEC considers the use of the SOP by the named persons when the application is discussed.

5.5. Adverse Events

Adverse events may occur during a project due to causes as diverse as extreme weather events, unpredicted side effects of a treatment or manipulation or if approved animal welfare thresholds are exceeded. All adverse events must be reported to the AEO within 24 hours of the event. An adverse event report must also be completed by the appropriate person (applicant, facility manager, program manager or veterinarian) and submitted within 30 days, allowing time for an appropriate investigation. The person(s) responsible for the animals (in consultation with a veterinarian if necessary) must take appropriate action, including treatments, management practices, or post-mortem.

The applicant must describe their monitoring methods, endpoints, contingency plans for adverse events, and animal welfare thresholds in the application. A contingency plan must include the action to be taken and the procedure for emergency euthanasia. Furthermore, the adverse event form requires the applicant to consider how the risk of the same or similar event can be reduced and to determine if the experimental protocol and SOP need to be modified considering the adverse event. The adverse event report and actions taken or proposed are previewed by the AWOs and accepted by the AAEC at a meeting. The applicant must make any required change to protocols detailed in the adverse event form through an amendment to the application. The AEO is delegated to ensure this occurs and that amendments are previewed and considered by the AAEC. The AWOs ensure that SOPs are updated and training undertaken as necessary.

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

5.6. Record Keeping

The following essential records (among others) are stored electronically in ~Te Ara~ or an alternate secure storage location for at least ten years. All records may be deleted or destroyed securely after this period.

- The CEC and any amendments.
- Policies and procedures of the AAEC.
- Agendas and minutes of meetings.
- Appointments of members.
- All forms, including applications, amendment requests, SOPs, training records, non-compliances, and complaints.
- Communication and correspondence with applicants, including applications, AAEC decisions and amendments.

- All reports, including project and facility monitoring and visits, adverse events, interim reports, training, post-approval reporting facility and drug store audits.

5.7. Killing of animals for tissue collection/dissection

Killing animals for the purpose of tissue collection/dissection requires a complete application to the AAEC documenting the justification and method of killing. The AWOs will determine appropriate methods of killing using resources, including The American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals as a reference.

5.8. Rehoming

The AEO will assess protocols for the potential to rehome animals at the end of studies, and this is denoted in the application and approved by the AAEC. The AWOs assess potential locations and conditions for rehoming on a case-by-case basis. AgResearch has an internal Animal Rehoming Policy and a checklist to support successful rehoming.

6 Animal Facilities

6.1. Management of Animal Facilities

6.1.1 Policies & Procedures

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

Facility standards shall be maintained by providing in-house training and access to external training for animal care staff. The AAEC monitors facilities and records kept in ~Te Ara ~.

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

The relevant facility managers must review and sign off all applications using that facility. Farm managers must follow the same processes as facility managers. Applications will not be approved until all relevant facility managers have signed.

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

6.1.2 Emergency Management

The facility must have an approved manual that includes managing animals in emergencies appropriate for the class and condition of the animals. Emergencies include fire, natural disasters and pandemics.

The facility managers create emergency plans as part of the facility manual or SOP (see section 6.2).

6.2. Development of SOPs for Facility Management

Facilities shall have associated manuals created by facility managers and reviewed by the AWOs. Parented organisations may use their template or the AgResearch template. All manuals must be reviewed and approved by an AWO delegated by the AAEC.

Approved facility manuals are stored in ~Te Ara~ and are available to the AAEC. All facility manuals have expiry dates when they must be reviewed and updated as required.

Facilities are monitored by AWOs at least once per year, and reports of these visits are stored in ~Te Ara~. The AAEC considers and accepts facility monitor reports.

6.3. Transportation of Animals

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

6.4. Housing of Animals

Animal facilities and practices (design, hygiene and management) shall be managed following good practice and scientific knowledge (as recommended by NAEAC in its "Good Practice Guide for the Use of Animals in Research, Testing and Teaching" and to the relevant "Codes of Welfare" issued under section 75 of the Animal Welfare Act 1999). In addition, there may be approved SOPs in place regarding specific situations of housing and care.

Facilities of parented organisations with an approved, current project will be monitored by AWOs, AAEC or its delegate (see 7.2) at least once yearly. Non-scheduled monitor visits to facilities may be carried out at the discretion of the AAEC.

7 Monitoring

The AAEC, its members, and AWOs have the authority to inspect animals, their accommodation, or experimental records at any time to ensure that procedures are consistent with the approval and that facilities meet requirements. While the applicant is usually notified of such visits in advance, this is not a requirement.

7.1 Monitoring during the Approval Period

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

7.2 Monitoring by Proxy

Where the timing or geographic location makes monitoring by the AAEC difficult, AWOs are delegated by the AAEC as the preferred person(s) to undertake monitoring. If the AWOs cannot monitor a required project because of timing or location, the AAEC may contract an independent veterinarian to perform the monitoring visit. The veterinarian is confirmed at an AAEC meeting and must have the required skills to complete the monitor visit. As delegates of the AAEC, contracted personnel have the same authority as AAEC members.

The monitoring veterinarian will be supplied with the relevant application, other documentation, and access to complete the monitoring report online. Alternatively, they may provide it to the AEO for entry into ~Te Ara~ and submit it for AAEC review. Monitor reports

are reviewed and accepted at an AAEC meeting (see 3.1).

7.3 Frequency of Monitoring

Monitoring visits are decided at an AAEC meeting before approval of a project. When any monitoring visit is made, a report is attached to the related application in ~Te Ara~. This report may be made by the AAEC members or the AEO. All monitor reports will be considered agenda items at an AAEC meeting.

In addition to formal monitoring visits, AWOs visit projects during their daily duties and verbally report these at AAEC meetings.

Upon receipt of a monitor report or any other additional information, the AAEC may suspend, revoke, or vary its approval for a project or specific parts of a project. The AAEC may place additional conditions on a project, require corrective actions or make recommendations to the applicant. The applicant may be requested to attend a Committee meeting to explain the situation in more detail and answer questions.

7.4 Monitoring of Manipulations Grade A & B

The AAEC will monitor 10% of all projects with an impact grade of A or B.

7.5 Monitoring of Manipulations Grade C-E

The AAEC will monitor all projects with an impact grade of C, D or E.

7.6 Specific Manipulations

Specific monitoring of any project outside the impact grade requirements will be determined by the AAEC, considering factors such as the novelty of the manipulation or facilities, researcher or perceived risks.

7.7 End of Approval Reporting

Every application must include two post-approval reports to fulfil monitoring obligations under the Act and assess animal use justification. The first report is about animal welfare, implementation of the Three R's, expected and actual impact grades and animal use (statistics) and is due one month after the approval end date. The final report details the main results and scientific outcomes of every project in relation to those proposed. The AAEC must formally accept both reports before a project is closed. These reports are detailed in 5.1.1.

7.8 End of Approval Grading

Within one month of the completion of a project, the applicant completes an Animal Welfare and Use report, which contains an assessment of the impact grading of the project. The AAEC considers this report alongside any monitoring and adverse event reports completed during the project.

7.9 Compliance Breaches

7.9.1 Non-compliance with an AEC approval

All staff of AgResearch and all organisations parented to the AgResearch CEC are responsible for familiarising themselves with this CEC and all other policies and procedures that apply to using animals for research testing and teaching. By signing the parenting agreement, organisations agree to follow this CEC.

Non-compliance with conditions of approval is dealt with and recorded as described in 5.1.2.

7.9.2 Non-compliance with legislation or regulations (*including non-compliance with this CEC*).

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

treatment of animals are to be complied with. AAEC approval does not override individuals' obligations under legislation or regulation other than the Animal Welfare Act. Animal ethics approval is limited to approving the use of animals in Research, Testing and Teaching under the Animal Welfare Act 1999 (Part 6).

Applicants and personnel are responsible for compliance with all other legislation and regulations. Specific questions in the application are asked to ensure compliance requirements outside the Animal Welfare Act have been met. These questions are included so the AAEC can be confident that any other potential compliance issues have been addressed and where compliance with other legislation may influence any details required in the animal ethics application.

7.10 End of Approval Statistics

When preparing an application form, the applicant must complete the 'Proposed' section of a copy of the MPI Animal Use Statistics form in ~ Te Ara ~. Within one month of the end of the approval period, the applicant must complete the 'Used' section of the MPI Animal Use Statistics within an Animal Welfare and Use form. This form is reviewed, assigned to a meeting and, if no revisions are required, accepted by the AAEC.

8 Arrangements for External Parties to Use the CEC and AEC

8.1 Arrangements are Permitted

Parenting arrangements with outside organisations shall be entered into on a case-by-case basis. Parenting arrangements will be entered into only if the AAEC has the appropriate expertise to review applications and monitor the approvals that will be submitted by the parent company.

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

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

External applicants must complete all the same application, amendment, and reporting requirements as AgResearch employees. Parent companies must provide their animal use statistics directly to MPI unless there is an agreement in place with AgResearch to provide their animal use statistics to MPI on their behalf.

9 Complaints Procedures

Note: Maximum penalties for individual and corporate offences against the Animal Welfare Act 1999, the Animal Welfare (Records and Statistics) Regulations 1999 and other legislation and regulations that apply to the use of animals for research, testing and teaching are included in the text of each Act and Regulation.

9.1 Animal Welfare Complaints

9.1.1 Complaints by the Public

Complaints made by members of the public shall be reported to the AAEC chairperson, who may correspond directly with those concerned to inform them of AgResearch's position and

advise them that further correspondence may be addressed to the Ministry of Primary Industries.

9.1.2 Complaints by employees

Any person employed by AgResearch or a parented organisation can bring to the notice of the AAEC any instance where they believe that the welfare of animals (whether or not they are being managed under a current AAEC approval) is compromised. This communication can be made directly to the chairperson or AEO or by submitting a specific complaint form in *~Te Ara~*. Submission of a complaint form automatically notifies the chairperson and AEO that a complaint has been lodged.

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

All complaints will be formally reviewed by the AAEC, recorded in *~Te Ara~* and action will be taken in line with the severity of the issue. If the complaint leads to non-compliance, it will be dealt with as outlined in 5.1.2.

9.1.3 Complaints by AEC Members

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

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

9.1.4 Breaches of the Act

When investigated, serious complaints relating to a breach of the Animal Welfare Act (e.g., cases of animal cruelty) will be referred to the appropriate regulatory body and the code holder or appropriate person in a parented organisation.

9.2 Procedural Complaints

9.2.1 Complaints by Applicants

If an applicant wishes to make a procedural complaint, the complaint will be directed to the Director Research Operations or AAEC Chairperson, who will decide if a formal investigation or other action is required. If the Director Research Operations is notified directly, the AAEC Chairperson must receive a copy of the complaint. If the complaint is made directly to the AAEC chairperson, the Director of Research Operations will receive a copy of the complaint and record of any action taken.

An AgResearch staff member who makes such a report in good faith shall not be liable to any disciplinary or civil proceedings because of having made that complaint.

9.2.2 Complaints by AEC Members

The AAEC chairperson and other members of the AAEC will initially investigate procedural complaints from any member of the AAEC and inform the Director of Research Operations. If the complaint is substantiated, then the Director of Research Operations shall be notified, a formal investigation will be initiated and appropriate action taken.

9.2.3 Complaints against the Chair

If a complaint from any person concerns the chairperson of the AAEC, it can be made directly to the Director Research Operations for investigation and appropriate action to be taken.

10 Process to Amend, Suspend or Revoke the CEC

The AAEC may recommend changes (amendment, suspension, or revocation) in the CEC to the code holder AgResearch via the delegated representative of the code holder (see 1.3). The code holder will determine the nature and extent of the proposed changes.

The Director-General of the Ministry of Primary Industries will be notified in writing of any minor amendments to the CEC (minor amendments are those that would not materially affect the purposes of the code) before the changes are implemented, and staff and external organisations are notified. Where significant changes to the CEC are required, the Director-General of the Ministry of Primary Industries will be contacted for advice and approval.

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