

Contents

<u>1.</u>	<u>Responsibility of the AEC</u>	2
<u>2.</u>	<u>Responsibilities of AEC Members</u>	2
<u>3.</u>	<u>Responsibilities of the Institution</u>	2
<u>4.</u>	<u>AEC Meetings</u>	4
<u>5.</u>	<u>Review of New Applications and Amendments</u>	4
<u>6.</u>	<u>Application Decisions</u>	4
<u>7.</u>	<u>Amendment Decisions</u>	6
<u>8.</u>	<u>Member Appointment</u>	6
<u>9.</u>	<u>Member Replacement</u>	7
<u>10.</u>	<u>Record Keeping</u>	7
<u>11.</u>	<u>Complaints</u>	7
<u>12.</u>	<u>Annual Report and Review of Operations</u>	8
<u>13.</u>	<u>Reporting to Animal Welfare Victoria</u>	9
<u>14.</u>	<u>Death as an Endpoint</u>	9
<u>15.</u>	<u>Revision of the Terms of Reference</u>	10
<u>16.</u>	<u>Related Documents</u>	10

1. Responsibility of the AEC

- i. Must be aware of and accept their responsibility in accordance with the Prevention of Cruelty to Animals Act 1986 (“the Act”), Prevention of Cruelty to Animals Regulations 2019 (“the Regulations”) and the Australian Code for the Care and Use of Animals for Scientific Purposes 8th edition 2013 (“the Code”).
- ii. To make sure that all activities relating to the care and use of animals are conducted in compliance with the Code.
- iii. Review applications for activities associated with the care and management of animals in facilities, including procedures applicable to breeding programs integral to the maintenance of an animal line, and approve only those activities that are ethically acceptable and conform to the requirements of the Code.
- iv. Conduct follow-up review of approved projects and activities (see Clause 2.2.32) and allow the continuation of approval for only those projects and activities that are ethically acceptable and conform to the requirements of the Code.
- v. Monitor the care and use of animals, including housing conditions, practices and procedures involved in the care of animals in facilities. The AEC will inspect animal housing and laboratories on a regular basis and examining records maintained by investigators and the animal facility manager. These inspections will be attended by a minimum of the Chair and a Category C or D.
- vi. Take appropriate actions regarding unexpected adverse events and non-compliances.
- vii. Approve guidelines for the care and use of animals on behalf of the institution.
- viii. Provide advice and recommendations to the institution.
- ix. Report on its operations to the institution.
- x. To perform their role efficiently and act in a timely manner.

2. Responsibilities of AEC Members

- i. The primary responsibility of members is to ensure that the use of animals for scientific purposes or other approved investigative purpose is ethically justified, provides for their welfare and incorporates the principles of Replacement, Reduction and Refinement based on collective experience and knowledge.
- ii. Deciding whether, in their own judgment, an application to undertake a project or any other matter under consideration by the AEC is ethically acceptable and meets the requirements of the Code as per clause 2.2.14.
- iii. Declare Conflicts of interest before any relevant deliberations of the AEC. Members are obliged to declare any interests that could influence the objectivity of their decision making as per the Code 2.2.17. These declarations and their management will be minuted and the person will not partake in the decision making process and may be required to leave the meeting. The remaining members must constitute a quorum with Categories C and D together representing at least one-third of members present as per 2.3.12 of the Code.

3. Responsibilities of the Institution

- i. Ensure that the AEC membership will allow the committee to meet its responsibilities. Membership must comprise at least four people, one from each of four categories of membership.
- ii. Ensure that the AEC has terms of reference that are publicly available.
- iii. Provide the AEC with the resources required to carry out its responsibilities, and to maintain the AEC.
- iv. Establish procedures for the effective governance and operation of the AEC that will enable the AEC to meet its responsibilities under the Code and relevant institutional policies and promote competent and timely ethical review of animal care and use.
- v. Conduct an annual review of the operation of the AEC.
- vi. Ensure that membership of the AEC comprises at least one person from each of four categories of membership as per section 2.2.2-2.2.7 of the Code:
 - **Chairperson:** a person who either holds a senior position in the institution, or if an external appointee, be given a commitment by the institution to provide the necessary support and authority to carry out the role. The Chairperson may be an additional appointment to Categories A to D members and will impartially guide the operation of the AEC. They can also help to resolve conflicts that relate to the AEC and will represent the AEC in negotiations with the institution's management.
 - **A Deputy or Acting Chairperson** may be appointed from the AEC membership, to act for the Chairperson in their absence.
 - **Category A member(s):** a person with qualifications in veterinary science that are recognised for registration as a veterinary surgeon in Australia, and with experience relevant to the activities of the institution or the ability to acquire relevant knowledge.
 - **Category B member(s):** a suitably qualified person with substantial and recent experience in the use of animals in scientific purposes relevant to the institution. This must include possession of a higher degree in research or equivalent experience.
 - **Category C member(s):** a person with demonstrable commitment to, and established experience in, furthering the welfare of animals, who is not employed by or otherwise associated with the institution, and who is not involved with the care and use of animals for scientific purposes. Veterinarians with specific animal welfare interest and experience may meet the requirements of this category. While not representing an animal welfare organisation, the person should, where possible, be selected on the basis of active membership of, and endorsement by, such an organisation.
 - **Category D member(s):** a person employed or otherwise associated with the institution and who has never been involved in the use of animals in scientific or teaching activities, either in their employment or beyond their under-graduate education. Category D members should be viewed by the wider community as bringing a completely independent view to the AEC, and must not fit the requirements of any other Category.
 - **Animal Facility Manager/representative (ex officio):** a person responsible for the routine care of animals from within the institution.
 - **Animal Welfare Officer (ex officio)**

- Other members appointed / co-opted by the Committee
 - Member from the Office for Research
- vii. At least one member from each of the membership categories A, B, C and D must be present at meetings to establish quorum for the conduct of a meeting and must be present throughout the meeting. Categories C and D together must represent at least one-third of those members present as per section 2.2.8 of the Code.

4. AEC Meetings

- i. AEC meetings will be held a minimum once per month from February to December or as needed. Meeting dates, and closing dates for the receipt of applications, will be advertised on the AEC website.
- ii. Attendance of meetings may be facilitated by video linking or teleconferencing of some members in circumstances, where face-to-face attendance is not possible.
- iii. If consensus is unable to be achieved, the AEC should only proceed to a majority decision after members have been allowed time to review their positions, followed by further discussion. In this instance the decision will be considered to be carried by a majority vote of two-thirds of members who examined the proposal, providing the majority includes at least one Category C and/or one Category D member. Minority views will be recorded in the minutes.
- iv. A fee will be charged to review applications and major amendments by the AEC. The fee will be set by the Office for Research and is subject to change.
- v. Investigators will receive the outcome of their submission 5 business days from the meeting.

5. Review of New Applications and Amendments

- i. Activities for scientific purposes involving the use of animals must not start before written AEC approval is given as per the governing principles of the Code clause 2.3. proceed with work beyond the three-year initial approval they will need to submit an amendment requesting additional time to the AEC for review. A maximum extension period of 12-months may be granted.
- ii. When needed an AEC Executive will be established to discuss minor amendments or activities for ratification at the next quorate AEC meeting. The Executive will contain at a minimum the Chair and a Category C or D. Other members may be added to the Executive at the discretion of the Chair or Office for Research team.
- iii. New applications will only be reviewed at a scheduled AEC meeting.
- iv. The AEC may request the applicant to supply further information in relation to an application to clarify issues that may arise during review. This may involve an applicant attending a meeting with the AEC or the AEC Executive to facilitate review of a research protocol.
- v. The AEC will endeavour to approve applications within 30 business days, if the application is complete and ready for review, and adheres to relevant legislation and guidelines. The clock starts from closing date of the AEC meeting, it stops when the outcome letter is received. It is a cumulative clock that starts each time a response is received from researcher (on the closing date) and will stop once approval is issued. The clock does not include days the application is with the investigators.

6. Application Decisions

The AEC will examine applications for approval with the following decisions as per Animal Welfare Victoria Guidelines for the conduct of AECs:

- i. **Approved:** The AEC is satisfied that the application is ethically acceptable and complies with the Australian code. The application is approved by the AEC, as submitted, with no changes required.
- ii. **Approved with condition(s):** The AEC is satisfied that the application will be ethically acceptable and comply with the Australian code, subject to a specific correction or defined alteration. Alternatively, where outcomes or effects of procedures are not well known, the AEC may wish to receive reports at specified time points to ensure the project remains ethically acceptable. The agreed and exact condition(s) are recorded in the AEC meeting minutes as a decision of the AEC. There are two options to formalise the decision:
 - The investigator is required to revise the original application in accordance with the instruction from the AEC and may resubmit to a person authorised by the AEC, for example the Office for Research or AEC chair, to administratively confirm that the instruction of the AEC has been followed exactly. The resubmission must not contain any new information or require a decision, simply reconciliation with instructions. The approval date of the application must not be before the date of confirmation. The revised application then becomes the application approved by the AEC.
 - The investigator is made aware that exact conformity with specified alterations is a condition of approval. The condition(s) of approval must be defined in the letter of approval. For example, the AEC may require six monthly progress reports, direct veterinary oversight of novel procedures, or report of completion of a pilot study to the satisfaction of the AEC prior to commencing the next phase of a project.
- iii. **Subject to changes to the satisfaction of the AEC:** The AEC is satisfied that the application has in-principle justification but requires additional information and the required modifications meet the AEC's criteria for a minor amendment. In that instance the revised application may be considered out of session and the approval is delegated to an executive of the AEC.
 - If the AEC executive is satisfied with the resubmitted application, the executive may approve the revised application; subject to ratification by the AEC at the subsequent quorate meeting of the AEC. The approval date is the date approved by the executive of the AEC.
 - If the AEC executive determines that the resubmitted application contains modification(s) outside of the criteria for a minor amendment it must refer the applicant to a quorate meeting of the AEC.
- iv. **Deferred:** The AEC is satisfied that the application has in-principle justification, but requires additional information, clarification or changes to make a decision that is outside of the scope of a minor amendment. In that instance the resubmitted application must return to the full AEC for appraisal at a quorate meeting. Modifications that have potentially high animal welfare impact (for example justification for inducing pain in the absence of analgesia, single housing for social

species, queries as to why valid alternatives are not used) must be considered by a quorate meeting of the AEC.

- v. **Not approved, may be re-submitted to a quorate meeting of the AEC:** The AEC generally understands the proposed animal use, and is satisfied the proposal has merit. However, the application lacks sufficient information for the AEC to fully consider the application and it does not comply with the Australian code. The AEC may elect to provide general advice to the applicant in an educational capacity with the aim of improving the quality of a resubmitted application. In this circumstance it is recommended that the AEC carefully communicate the reasons for requiring resubmission of the application to assist the applicant to be successful in the following submission. The AEC may find it beneficial to inform the applicant that upon receipt of all required information further modification may be necessary for the AEC to fully consider the application.
- vi. **Not approved:** This situation will arise where, in the judgment of the AEC, the potential effects on the wellbeing of the animals involved is not justified by the potential benefits of the project. In this circumstance the AEC should clearly communicate its decision and require the applicant to withdraw the application.

7. Amendment Decisions

- i. An investigator may apply for an amendment to an approved project as long as the proposed changes do not alter the substantive procedures or processes to such a degree that a new project application is warranted.
- ii. The AEC will determine if a new application is required.
- iii. The AEC must approve in writing any proposed amendments to an approved project before the change is implemented.
- iv. Although there is no limitation as to how many amendments / modifications are allowed within the approved duration of the research project, minor amendments are only allowed, generally speaking, when there is no substantial change in the overall nature or direction of the project, particularly in regard to animal welfare.

8. Member Appointment

- i. All applicants that are deemed appointable (except for the Chair) will be interviewed at a minimum by the Manager of the Office for Research, the Chair of the AEC and any other stakeholders as deemed appropriate.
- ii. Applicants for Chair will be interviewed by the Manager of the Office for Research and/or Austin Health Licence Nominee (or their delegate).
- iii. Before appointment, all members of the AEC must acknowledge in writing their acceptance of the terms of reference of the AEC and be approved by Animal Welfare Victoria.
- iv. The institution will ensure that the AEC members undergo appropriate induction and have access to appropriate education programs and resources.
- v. New AEC members (but not reappointed) are required to complete an approved training course in their obligations and responsibilities under the 'Code' prior to or within 6 months of their appointment as per the 'The Regulations'.

- vi. Members will be appointed for a period of three years with an opportunity to renew at the end of this period for a maximum second term, unless at the discretion of Manager of the Office for Research. The Office for Research will notify the member in writing prior to any lapse in membership.
- vii. All members including the Chair and Deputy Chairs will receive a letter of appointment. The letter of appointment will include the date of appointment, length of tenure, and termination.
- viii. If a member who resides out of Victoria is appointed, they will be expected to make travel arrangements to be able to participate in meetings/inspections face to face. If face to face meetings are unsafe due to extraordinary circumstances, the interstate member may join meetings/inspections via videoconferencing/ web-conferencing or in special circumstances teleconferencing.
- ix. External members will be paid a monthly sitting fee based on their attendance and to cover nominal expenses associated with performance of their duties as outlined in their appointment letter.

9. Member Replacement

The Institution on the advice of the Office for Research team may elect to vary membership or replace a member at any time if they believe:

- i. It is necessary for the proper and effective functioning of the AEC
- ii. The person is not fit and proper to serve on an AEC
- iii. The person has failed to carry out their duties
- iv. Where a member fails to attend three consecutive meetings of the AEC without providing an apology or reasonable reason or has demonstrated an inability to maintain an adequate level of participation or meet the responsibilities of AEC membership, the AEC shall recommend to the Institution via the Office for Research that the member be replaced by a new appointee of the same category.

10. Record Keeping

- i. The Office for Research will prepare and maintain an official file for each application received. This may be electronic, and will include a copy of the application, any relevant correspondence including that between the applicant and the AEC or AEC Executive in accordance with the Public Records Act 1973 (Vic). Meeting minutes will be retained in a Minutes file in accordance with the Public Records Act 1973 (Vic).
- ii. The AEC will monitor approved projects in accordance with the Code 2.3.2 to verify that the conduct of the research conforms to the approved proposal and to ensure that any harm, including pain and distress, is promptly detected and managed (the Code 2.1.5 (v) (c)).

11. Complaints

- i. The Office for Research may receive complaints about the care and use of animals for scientific purposes or AEC operation that may be raised by any person or group, including investigators, animal carers, AEC members, students, employees and

- members of the public. All complaints will be dealt with confidentially and acted on in a timely fashion.
- ii. Complaints that do not relate to the care and use of animals for scientific purposes or AEC operation will be directed to the relevant areas.
 - iii. If a member of the AEC or a researcher has any grievance about the operation of that committee or about the care and use of animals for scientific purposes, they should discuss this, in confidence, with the Office for Research Manager.

Resolution of Complaints will be handled in the following manner:

- i. If the complaint is of a serious nature, or if the matter cannot be resolved, then the Office for Research Manager should be notified in a timely manner by the person who received the complaint or directly by the complainant.
- ii. Under these circumstances the Office for Research Manager will commence an initial assessment into the complaint to determine the severity and validity of the complaint, obtain in writing the grounds of the concern or complaint and where possible categorise it. The Office for Research Manager may on-refer the complainant to the Office for Research Director, or the Executive or institutional Licence Nominee depending on the nature and seriousness of the complaint.
- iii. A letter of acknowledgement to the complainant and a letter of notification to the principal investigator (where relevant) will be sent, outlining the complaint and the mechanism for investigating the complaint.
- iv. The complainant will be informed of the outcome of the investigation. If the complainant is not satisfied with the outcome of the investigation, then they can refer the complaint to the Director of the Office for Research, or Licence Nominee, or request the Office for Research Manager or AEC Chairperson to do so.
- v. Where complaints relate to activities that would normally require AEC approval, the complaints are referred to the Manager of the Office for Research (or delegate) who will work with the AEC to investigate whether such activities were conducted in accordance with AEC approval.
- vi. Complaints considered to raise the possibility of research misconduct, as outlined in Australian Code for the Responsible Conduct of Research 2018, will be referred immediately to the appropriate person as per relevant institutional policies and procedures.
- vii. During monitoring of facility or investigation of adverse events, the AEC may uncover potential matters of concern to animal welfare, or misconduct or research misconduct. These will be investigated and be handled as stated above.
- viii. The Office for Research will maintain a record of all complaints received regarding the activities of the Committee. This record will include the complaint, the outcome of the complaint, and any related investigations. A record of complaints received regarding AEC approved research will also be maintained. This will include the complaint, the outcome of the complaint and any related investigations.
- ix. All attempts should be made to resolve the matter between the parties, but if this is unsuccessful then the matter shall be referred to an external independent mediator. If appropriate, the regulatory Department will also be informed. If the

Independent External Review has been undertaken by the regulatory Department and the matter cannot be resolved between the parties then it shall be submitted in writing to the Victorian Department of Jobs, Precincts and Regions and the Minister of the Department.

- x. If deemed necessary after investigation, the AEC may withdraw or suspend the approval of a project. This may also involve the suspension of a specific researcher or group if their conduct is considered to not be in line with the Code.

12. Annual Report and Review of Operations

- i. The AEC will produce an annual report of its operations for submission to the Licence Nominees, any regulatory agency and eligible institutions. By no later than April each year, Austin Health will receive an annual institutional report outlining activities from the previous calendar year.
- ii. **The annual Austin Health Institutional report should advise on:**
 - numbers and types of projects and activities assessed and approved or not approved.
 - the physical facilities for the care and use of animals by eligible institutions
 - actions that have supported the educational and training needs of AEC members and people involved in the care and use of animals
 - administrative or other difficulties experienced in AEC operations
 - any matters that may affect the eligible institution's ability to maintain compliance with the Australian code
 - any matters that may affect the AEC's ability to maintain compliance with the Australian code
 - appropriate recommendations to address matters of non-compliance and measures for effective, remedial change.
- iii. The AEC chair and/or Office for Research Manager will make themselves available to meet with the relevant regulatory agency and/or the institution to discuss the annual report.

13. Reporting to Animal Welfare Victoria

- i. All holders of Scientific Procedures Premises Licences and Specified Animals Breeding Licences are required by the legislation to complete an Annual Return of Animal Usage each calendar year and submit it to Animal Welfare Victoria by the specified deadline. Animal Welfare Victoria supplies a form designed for the purpose. Changes should be notified within 2 weeks of the alteration.
- ii. Animal Welfare Victoria needs to be notified promptly of alterations to Scientific Procedures Premises Licence or Specified Animals Breeding Licences:
 - Alterations to AEC membership
 - Additions / deletions of animal facilities or laboratories to Licenses.
 - Change to the nominated person or their contact details.

- iii. Animal Welfare Victoria conducts audits of licenses and AECs to assess compliance with the relevant legislation and Codes of Practice. The audit protocol is found on Animal Welfare Victoria webpage.

14. Death as an Endpoint

- i. 'Death as an end-point' refers to those rare procedures where death is the deliberate measure for evaluating biological or chemical processes, responses or effects (see the Code page 4). These procedures may only be carried out for the achievement of prescribed outcomes, and only where the objective cannot be achieved by any other scientific means (Prevention of Cruelty to Animals Regulations 1997).
- ii. Persons who seek approval to conduct scientific procedures, or a series of scientific procedures involving death as an endpoint must apply for Ministerial approval to conduct such procedures. The proposal must be given preliminary assessment by the AEC and a copy of the application to the AEC and relevant comments from the AEC must accompany the application for Ministerial approval.
- iii. Animal Welfare Victoria will assess this application and make recommendations to the Minister as to whether the application should be approved. It is the responsibility of the investigator making this application to provide enough information as per the application below which will be held in confidence by Animal Welfare Victoria.

15. Revision of the Terms of Reference

- i. These Terms of Reference will be reviewed as necessary in response to changes in legislation, policies or upon the request of the AEC, or every three years, whichever occurs first.

16. Related Documents

- i. [Australian Code for the Responsible Conduct of Research 2018](#)
- ii. [Australian Code for the Care and Use of Animals for Scientific Purposes](#)
- iii. [Guidelines for the conduct of AECs](#)
- iv. [Guidance note: AEC Decisions](#)
- v. [Prevention of Cruelty to Animals Act](#)
- vi. [Prevention of Cruelty to Animals Regulations](#)