

AUSTIN HEALTH ANIMAL ETHICS COMMITTEE

TERMS OF REFERENCE

Approved 2010
Revised August 2014
Revised March 2017
Revised August 2020
Revised March 2021

PREAMBLE

The provision of a high standard of animal welfare is necessary to sustain excellence in research.

The use of animals for scientific purposes and teaching is governed by Victorian Legislation, the Prevention of Cruelty to Animals Act 1986, the Prevention of Cruelty to Animals Regulations 2019 ("the Act and Regulations") and the National Health and Medical Research Council's (NHMRC) *Australian Code for the Care and Use of Animals for Scientific Purposes* 8th edition 2013 ("the Code").

For the purposes of the *Code* and the Act, the Animal Ethics Committee (AEC) at Austin Health is the legally constituted animal ethics committee. The AEC's membership, responsibilities, terms of reference and procedures must comply with the requirements of the 8th edition of the *Code*, the Act and Regulations.

The primary responsibility of the AEC is to ensure, on behalf of Austin Health, that all care and use of animals is conducted in compliance with the *Code*, the Act and Regulations, and with Austin Health's policies, procedures and guidelines. The role of the AEC is to ensure that the use of animals is justified, provides for the welfare of those animals and incorporates the principles of Replacement, Reduction and Refinement.

The primary role of the Austin Health Animal Ethics Committee is to ensure a uniform and high standard of animal welfare and ethics in animal experimentation throughout Austin Health.

To this end, the following terms of reference have been prepared to ensure uniformity and a clear understanding of the method of operation of the Austin Health AEC.

Austin Health recommends that these Guidelines be followed by the AEC.

1. TERMS OF REFERENCE

The Terms of Reference of the Animal Ethics Committee includes the following provisions:

1. To approve guidelines for the care of animals that are bred, held and used for scientific purposes at Austin Health on behalf of Austin Health;
2. To monitor the acquisition, transport, production, housing, care, use and fate of animals;
3. To recommend to Austin Health any measures needed to ensure that the standards of the *Code* are maintained;
4. To observe the procedures authorised by Austin Health for the appointment, reappointment and retirement of members of the Animal Ethics Committee;
5. To require all members to declare any conflict of interest;
6. To observe the procedures authorised by Austin Health to deal with situations in which a conflict of interest arises;
7. To examine and approve, approve subject to modification, or reject written proposals relevant to the use of animals for scientific purposes;
8. To approve only those studies for which animals are essential and justified and which conform to the requirements of the *Code*. This should take into consideration factors including ethics, the impact on the animal or animals and the anticipated scientific, environmental or educational value;
9. To withdraw approval for any project that is conducted in a manner not compliant with the *Code*, Act and Regulations;
10. To authorise the emergency treatment of any animal, with reference to Section 2.3.24 of the *Code*;
11. To examine and comment on all Austin Health plans and policies that may affect the welfare of animals used for scientific purposes;
12. To maintain a record of proposals and projects, including the outcomes of the AEC deliberations;
13. To comply with the reporting requirements of Austin Health, the Act and Regulations, and the *Code*;
14. To perform all other duties required by the *Code*, Act and Regulations;
15. In association with Austin Health, The University of Melbourne, the Olivia Newton-John Cancer Research Institute and any third party ensure that staff and students (particularly post-graduate students) are adequately educated and trained in the care and use of animals for scientific purposes;
16. To perform all other duties required by Austin Health, including compliance with policies, monitoring of approved projects, regulations and guidelines, annual

audit and inspection of animal facilities and laboratories, and submission of annual and other reports; and

17. To have these terms of reference publicly available.

2. AEC MEMBERSHIP

The membership of the AEC must enable it to fulfil its terms of reference and be compliant with Sections 2.2.2 – 2.2.12 of the Code. It must comprise at least five persons, including a separate person appointed to each of the following categories.

- (1) 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.*
 - (2) 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.*
 - (3) 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.*
 - (4) 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.*
 - (5) 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.*
 - (6) Animal Facility Manager/representative (*ex officio*): *a person responsible for the routine care of animals from within the institution.*
 - (7) Animal Welfare Officer (*ex officio*)
 - (8) Other members appointed / co-opted by the Committee
 - (9) AEC Secretary
- The role of the Chairperson is to represent the AEC in negotiations with Austin Health Management and to ensure that the AEC operates in accord with the Code, the Act and Regulations, and Austin Health's policies, procedures and guidelines. The responsibilities of the Chairperson are detailed in Section 2.2.13 of the Code.
 - A Deputy or Acting Chairperson may be appointed from the AEC membership, to act for the Chairperson in their absence.

- The Animal Welfare Officer and the Animal Facility Manager/representative shall be *ex officio* members of the AEC and attend meetings. If in attendance, the Animal Welfare Officer and the Animal Facility (the BioResources Facility (BRF)) Manager/representative are to give a report at each meeting.

3. APPOINTMENT AND RETIREMENT OF MEMBERS

- (1) Austin Health is responsible for appointing the Chairperson and Membership of the AEC. Austin Health interviews proposed new AEC members to ensure their suitability to serve on the AEC, and that the person fills the criteria for their Category and to reveal any biases which could be detrimental to the workings of the committee.
- (2) Austin Health will adopt open and transparent processes including advertising for applications for membership and making appointments of members.
- (3) Members will be appointed for a term of three years and eligible for re-appointment for a second term but no member may serve more than two successive terms, except with the express approval of the License Nominee of Austin Health.
- (4) Prospective members must declare interests and procedures to manage any conflicts of interest in making appointments agreed by Austin Health and new member.
- (5) Before appointment, all members of the AEC must acknowledge in writing their acceptance of the terms of reference of the AEC and any requirements for confidentiality required by Austin Health.
- (6) The new member will be officially appointed on Austin Health's AEC by notification to Animal Welfare Victoria. Animal Welfare Victoria will be notified prior to the member participating in AEC meetings, discussions and decisions.
- (7) The new member will be sent a letter of appointment from the AEC.
- (8) External persons are covered by Austin Health's Professional Indemnity policy for the Committee work they perform for Austin Health.
- (9) Appointment of a Member may be terminated by the Scientific Procedures Premises License Nominee of Austin Health sending a letter of termination.

4. MEETINGS

- (1) Meetings should be held monthly (or at least every two months), to allow interaction of AEC members and to enable the AEC to fulfil its terms of reference (Section 2.2.26 of the *Code*).
- (2) The operating procedures of the AEC must comply with Sections 2.2.25 – 2.2.26 and 2.3.3 – 2.3.16 of the *Code*.
- (3) Minutes must be maintained that record decisions, inspections and other aspects of the AEC's operation.

5. QUORUM

- (1) Section 2.2.25 of the *Code* define a quorate meeting to be:
 - The presence at meetings of at least one member from each of Categories A, B, C and D.
- (2) If more than four AEC members are present, Category C and D members must together represent at least than one third of the members present.
- (3) Section 2.2.26 of the *Code* (ii) allows for the conduct of quorate AEC meetings in circumstances where a face-to-face meeting is not possible, through the use of videoconferencing and web-conferencing or, in special circumstances, teleconferencing.

6. EXECUTIVE

- (1) The AEC Chairperson may establish an Executive, which must include the Chairperson and at least one member from Category C or Category D. Other members of the AEC may also be appointed to the Executive.
- (2) The Executive may not have a permanent membership but may consist of a different representative group of the AEC depending on the item being reviewed.
- (3) The Executive may review reply to queries raised by the AEC, approve amendments to projects (see section 17), and deal with emergencies and non-compliance issues. Any decisions by the Executive must be reviewed and ratified by the AEC at its next meeting (Section 2.2.23 of the *Code*).
- (4) Executive members are required to declare if they have a conflict of interest with an item and another member must be appointed for consideration of the item.

7. CONSENSUS DECISION-MAKING AND VOTING RIGHTS OF MEMBERS

- (1) Decisions by the AEC with regard to approval, modification or rejection of a project proposal, or withdrawal of approval for a project must comply with Sections 2.3.3 – 2.3.16 of the *Code*, and should be made on the basis of consensus.
- (2) When consensus is achieved, this decision is recorded. If the project is rejected, this should be recorded in the Minutes with the reasons for the rejection.
- (3) Where consensus cannot be reached after reasonable effort to resolve differences, the AEC should explore with the applicant(s) ways of modifying the project that may lead to consensus. If necessary, investigators can attend the next meeting.
- (4) If consensus is still not achieved, the AEC should only proceed to a majority decision after members have been allowed a period of time to review their positions, followed by further discussion. The Secretary of the AEC, the animal welfare officer and the animal facility manager have no voting rights.

8. CONFIDENTIALITY & SECURITY

- (1) Members and attendees of the AEC must comply with any confidentiality policies of Austin Health.
- (2) In the interests of confidentiality and security, all meeting documents circulated electronically are password protected and deleted post-meeting. Also it is recommended that at all approved applications and confidential paper documents be collected by the AEC Secretary and shredded at the end of each AEC meeting. In special circumstances and with agreement of the AEC secretary and/or Chairperson, committee members may be allowed to keep copies of applications.

9. CONFLICT OF INTEREST

When a research proposal of which the chairperson or any other member of the AEC is an investigator is considered by the AEC, the minutes of the meeting should clearly record and reflect that:

(1) Where the Chairperson is an Investigator:

- a) The Chairperson vacates the Chair;
- b) The meeting is then chaired by the Deputy/Acting Chairperson at that point;
- c) The Chairperson is required to absent himself/herself from the meeting during discussion of his/her proposal and only respond to questions directed to him/her upon returning to the room. The Chairperson will not participate in voting on the proposal; and
- d) The Chairperson assumes the Chair at the commencement of consideration of the next item.

(2) In the case where another AEC member is an Investigator:

- a) The member concerned is required to absent himself/herself from the meeting during discussion of his/her proposal and only respond to questions directed to him/her upon returning to the room. This member will not participate in voting on the proposal.
- (3) An Investigator is a researcher who is involved in the conduct of the experiments. The "Person to act in Principal Investigator's absence", as named in the research proposal application form, is generally considered **not** a researcher unless he/she is actively involved in the research project.
- (4) If an AEC member is not an investigator on a project being conducted by their department, they should declare that they do not have a conflict of interest. This declaration will be recorded in the minutes.

10. PROCEDURES FOR APPROVING ANIMAL USE PROPOSALS

The procedures followed by the AEC when considering proposals for breeding, holding and use of animals for scientific purposes must comply with Sections 2.3.3 – 2.3.13 and Section 4 of the *Code*. Only those scientific, teaching and husbandry activities that conform to the requirements of all relevant sections of the *Code* and legislation may be approved.

- (1) New proposals must be considered and approved only at quorate meetings of the AEC.
- (2) The AEC must be satisfied that the proposed use of animals is justified by weighing the predicted scientific or educational value of the proposal against the potential impact on the welfare of the animals. An essential component of this assessment by the AEC involves consideration of the steps taken by the applicant to comply with the principles of Replacement, Reduction and Refinement specified in the *Code*.
- (3) Decisions must be made in a manner that is fair to applicants, acceptable to all members and in accordance with the procedure detailed above at point 7.
- (4) Investigators must be informed of decisions in writing.
- (5) A register of all proposals to the AEC, including the outcomes of the Committee's deliberations, must be maintained.
- (6) Decisions must be made as promptly as possible.
- (7) Scientific or teaching activities involving the use of animals must not start before written approval is given.

11. SUSPENSION AND WITHDRAWAL OF APPROVAL

- (1) If an inspection detects activities that are non-compliant with the *Code*, the AEC will ensure that such activities are subject to investigation and processing as per the current approved AEC non-compliance procedure (Section 2.3.25 of the *Code*).
- (2) This non-compliance procedure may include the AEC suspending or withdrawing the approval of a project. This will occur as per the Austin Health AEC Procedure for non-compliant events.

12. EMERGENCY TREATMENT OR EUTHANASIA OF AN ANIMAL

- (1) In compliance with 2.3.23 of the *Code*, the AEC authorises the BRF staff to respond to emergencies including unexpected adverse outcomes. The AEC encourages the separation of animals in regards to health concerns and/or injury. The AEC authorises the BRF staff to respond in this situation and to act accordingly. In case of emergencies, before the animal is treated or euthanased, all steps should be taken to contact the principal investigator or their representative (Section 2.5.6 of the *Code*). If emergency treatment or euthanasia is instigated, the principal investigator and AEC should be notified promptly. An adverse event report written by the principal investigator will also be required to be submitted to the AEC.

13. REPORTING

- (1) The AEC Chairperson will submit a written report to the institution on its activities at least annually.

14. OPERATING PROCEDURES

- (1) A cut-off submission date is listed on the AEC website for all AEC meeting dates.
- (2) All submissions submitted by the cut-off date will be placed on the agenda for the AEC meeting, unless otherwise indicated by current AEC meeting protocol.
- (3) After each AEC meeting, the minutes will be completed and sent to the Chairperson for final review. Upon final review, letters will be drafted and authorised by the AEC Chairperson or the authorised delegate. The principal investigator will be sent a signed copy of the letter via email.
- (4) Investigators have a 3-month period to reply to queries. If the requested information is not received within this time frame, the project will be withdrawn and must be resubmitted.
- (5) The AEC will determine at their meeting the course of action to take for each item including approving the item with a condition(s), deferring the decision, subject to modification to the satisfaction of the AEC, not approving the project but the project may be resubmitted to a quorate meeting of the AEC with the option of inviting the investigator to attend the meeting, or not approving the project.
- (6) If an item is approved out-of-session, the investigator will be provided with a signed copy of the certificate of approval. A copy should be returned to the Office for Research for the project file after the investigator signs the acknowledgement of approval conditions. Any decisions by the Executive must be reviewed and ratified by the AEC at the next meeting (Section 2.2.23 of the *Code*).
- (7) The animal facility manager will be advised of all approved projects within one week of approval.

15. PROCEDURES FOR HANDLING ANIMAL ETHICS CONCERNS AND GRIEVANCES

Grievances concerning AEC Operation and Processes

If a member of the AEC or a researcher has any grievance about the operation of that committee, they should discuss this, in confidence, with the Chairperson of that AEC. If the grievance cannot be resolved, they should then take their concerns to the Austin Health licence nominee or the Manager of the Office for Research at Austin Health.

Grievances concerning non-compliance with the *Code* and Animal Welfare issues

- (1) If the animal facility, academic or other staff or students have any enquiries or concerns about a non-compliant event or the well-being of animals held at Austin Health for use in breeding, research or teaching, these concerns should be reported to the Chairperson of the AEC, the BRF Manager and/or to the Animal Welfare Officer.
- (2) The appropriate action will be undertaken to ensure any animal welfare issues have been addressed. The animal may be euthanised, administered analgesic, or the appropriate enrichment will be provided to alleviate any welfare issues which may arise. Researchers may also be re-trained to ensure the current best practice is used or to ensure their technique is accurate.
- (3) Conscientious objection - If a staff member or student wishes to conscientiously object to participate in an activity within the BRF, this should be received in writing to the relevant supervisor/institution with both the AEC and the BRF informed.
- (4) All complaints, concerns or enquiries will be treated confidentially and sympathetically. Complaints must be addressed in writing to the AEC. All personnel and students may voice concerns without jeopardising their employment, careers or coursework.
- (5) If the complaint is of a serious nature, or if the matter cannot be resolved, then the Manager of the Office for Research at Austin Health should be notified in a timely manner.

Grievances concerning the AEC and the Institution

If there is a grievance between the AEC and the Institution, the complaint shall be submitted in writing by the AEC to the Institution.

- All attempts to resolve this with discussion between the parties should occur.
- If the grievance cannot be resolved in this manner, the matter shall be referred to the regulatory Department.

Grievances concerning the AEC and an Independent External Review

If there is a grievance between the AEC and the Independent External Review, the complaint shall be submitted in writing by the AEC to the review body.

- 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 Chief Veterinary Officer and the Minister of the Department.

16. INSPECTION OF ANIMAL FACILITIES AND LABORATORIES

- (1) Animal facilities and laboratories are monitored continually by the BRF staff.
- (2) AEC members also perform an annual inspection of the facilities/laboratories (or as often as required). Inspections should be conducted in accordance with the Act and Regulations, the *Code* (Sections 2.3.17 – 2.3.23 and Section 4). Authority for inspection of facilities and projects at remote sites may be delegated to an agent or another AEC; the inspection report is considered at a meeting of the AEC.
- (3) Inspection parties should consist of at least one AEC member who is external to the Institution.
- (4) A report of the inspection should be written and include the names of those who attended, observations, any identified problems, follow-up and outcomes. The inspection report should be an agenda item for consideration by the Committee.

17. **AMENDMENTS / MODIFICATIONS**

An amendment may include a change to an approved project or activity where the proposed change is not likely to cause harm to the animals, including pain and distress.

Examples of amendments / modifications include:

- Addition or removal of staff
- A small change in procedure
- A change in animal numbers or strains
- An extension of duration of the project

Although there is no limitation as to how many amendments / modifications are allowed within the approved duration of the research project, 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.

NOTE:

Extension of duration of the project: generally no longer than one year, except that a request for a longer extension may be granted upon request and justification.

A **major amendment** may include a change to an approved project or activity where the proposed change **is likely** to cause harm to the animals, including pain and distress.

Examples of major amendments / modifications include:

- Addition of a new aim (Note: this may require submission of a new project);
- Addition of a new technique/procedure not previously approved in this protocol, etc.

18. ANIMAL WELFARE VICTORIA

Annual Return

All holders of Scientific Procedures Premises Licences (SPPL) and Specified Animals Breeding Licences (SABL) are required by the legislation to complete an Annual Return of Animal Usage each calendar year and to submit it to Animal Welfare Victoria by the specified deadline. Animal Welfare Victoria supplies a form designed for this purpose.

Alterations to the SPPL or SABL

Animal Welfare Victoria needs to be notified promptly of:

- Alterations to AEC membership
- Additions / deletions of animal facilities or laboratories to Licences
- Change to the nominated person or their contact details

A form designed for this purpose is supplied by Animal Welfare Victoria. Changes should be communicated before alterations take place.

Fieldwork notification

Animal Welfare Victoria needs to be notified (prior to commencement) of Austin Health projects conducted at sites other than those listed on the Scientific Procedures Premises Licence. These sites are termed “Field Work”. The use of any animal at Austin Health for research purposes must be reviewed and approved by the Austin Health AEC.

Death as an endpoint

“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 2019).

“Death as an end point” procedures must be approved by the Minister for Agriculture. An application for ministerial approval to conduct these procedures must be sent to Animal Welfare Victoria.

Auditing of SPPL, SABL and AECs

Animal Welfare Victoria conducts audits of licences and AECs to assess compliance with the relevant legislation and Codes of Practice. Audit panel members are suitably qualified veterinarians and/or animal welfare officers.

The audit protocol is found on Animal Welfare Victoria’s webpage.

Training for AEC members

Animal Welfare Victoria provides complimentary training for new and pre-existing AEC members.

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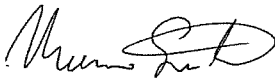

Animal Welfare Victoria and the Animal Welfare Advisory Committee hold a periodic Scientific Procedures Seminar at the end of the year for AECs, Animal Facility Staff and Researchers.

19. RELATED DOCUMENTS

- Australian code for the care and use of animals for scientific purposes 8th edition (2013).
- AUSTIN HEALTH AEC (2017) Guideline for use of animals in disease outbreak
- AUSTIN HEALTH AEC (2018) Guideline for Pain and Distress Management in Rodents
- AUSTIN HEALTH AEC (2019) Guideline for management of adverse events
- AUSTIN HEALTH AEC (2020) Procedure for non-compliant events
- AUSTIN HEALTH AEC (2020) Guideline training and competency
- AUSTIN HEALTH AEC (2021) Guideline for animal monitoring and assessment

Revision date

This Terms of Reference shall be reviewed every three years.

Signed as an accurate record:		
Name (please print)	Signature	Date
Prof Mauro Sandrin, AEC Chairperson		05 March 2021
Dr Mark Lubliner Chief Medical Officer Acting Chief Medical Officer Austin Health		14 March 2021

Dr Mary O'Reilly