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 and Regulations ("the Act and Regulations") and the National Health and Medical Research Council (NHMRC) Australian Code of Practice for the Care and Use of Animals for Scientific Purposes 8th edition ("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 Austin Health 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 appointment, reappointment and retirement of members of 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 Ludwig Institute and the Melbourne Brain Centre 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, 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. It is recommended that the Chairperson is an additional appointment to Categories A to D members except in the exceptional circumstance that a category member is a late apology.

(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. Veterinarians who lack this experience must familiarise themselves with the biology and clinical characteristics of the species of animals used.

(3) Category B member(s): a suitably qualified person with substantial recent experience in the use of animals in scientific or teaching activities. This will usually entail 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 who is both independent of 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 undergraduate 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) 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 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 Manager/representative are to give a report at each meeting.
3. APPOINTMENT AND RETIREMENT OF MEMBERS

(1) The Austin Health Scientific Procedures Premises License Nominee is responsible for appointing the Chairperson and Membership of the AEC. Austin Health recommends that the Chairperson interview proposed new AEC members to ensure their suitability to serve on 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) Prospective members must declare interests and procedures to manage any conflicts of interest in making appointments agreed by the License Nominee, the Chair and new member.

(3) 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.

(4) The new member will be sent a letter of appointment from the AEC.

(5) External persons are covered by Austin Health Professional Indemnity policy for the Committee work they perform for Austin Health.

(6) 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 every two months (February, April, June, August, October and December), to allow interaction of AEC members and to enable the AEC to fulfil its terms of reference (Code Section 2.2.26).

(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) Sections 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 should represent not less than one third of the members present.

(3) Section 2.2.26 (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
(4) If there is a last minute cancellation by a category and an alternate cannot be arranged then the AEC must decide if it is appropriate for the chair to act in another category capacity provided he/she meets the requirements of that category of membership and has approval from the Bureau of Animal Welfare to act in that category.

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 minor amendments to projects and deal with emergencies. Any decisions by the Executive must be reviewed and ratified by the AEC at its next meeting (Code Section 2.2.23).

(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, then 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 to 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 a member is an investigator is considered by the AEC, the minutes of meeting should clearly record and reflect that:

(1) Where Chairperson is an Investigator
   a) The Chairperson vacates the Chair,
   b) The meeting is then chaired by the Deputy/Acting Chairperson at that point, and
   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
   d) The Chairperson assumes the Chair at the conclusion of consideration of that proposal.

(2) In the case where a 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 Chief 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 and renewal of existing projects 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 should 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. SUSPENSIONS 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 ceased immediately and remedial action is initiated (section 2.3.25 of the code).

(2) The AEC may suspend approval of a project at their discretion. Investigators will be advised of this suspension in writing within 7 days of such a decision. The principal investigator will be advised of reasons why suspension has occurred and will be provided with steps to reinstate ethical approval for their project.

(3) The AEC may withdraw approval of a project at their discretion. Investigators will be advised of this suspension in writing within 7 days of such a decision. The investigator will be advised of reasons why withdrawal of ethical approval has occurred. Further remedial action may be initiated. The institution, the animal facility manager and the license nominee will also be advised of the withdrawal of ethical approval.

12. EMERGENCY TREATMENT OR EUTHANASIA OF AN ANIMAL

(1) In compliance with 2.3.23 of “the code” the AEC authorise the BRF staff to respond to emergencies including unexpected adverse outcomes. In case of emergencies, before the animal is treated or euthanased, all steps should be taken to contact the principal investigator or their representative (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 may also be required to be submitted to the AEC.

13. REPORTING

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

14. OPERATING PROCEDURES

(1) A cut off submission date is advertised on the AEC website for all AEC meeting dates.

(2) All studies submitted by the advertised cut off date will be placed on the agenda for the advertised meeting.

(3) After each AEC meeting the minutes will be completed and sent to the chairman for final review. Upon final review, letters will be drafted and authorised by the AEC chairman or his 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.

(5) The AEC will determine at their meeting the course of action to take for each item including approving the item with no changes, approving the item with changes or requesting a re-submission of the project with the option of inviting the investigator to attend the meeting.

(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.

(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

If a member of an 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 license nominee or the Director of Research of Austin Health.

Animal Welfare Concerns Reported to the AEC

(1) If animal facility, academic or other staff or students have any enquiries or concerns about 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, or to the Animal Welfare Officer.

(2) All complaints, concerns or enquiries will be treated confidentially and sympathetically. All personnel and students may voice concerns without jeopardising their employment, careers or coursework.

(3) If the complaint is of a serious nature, or if the matter cannot be resolved, then the Director of Research of Austin Health should be notified in a timely manner.

16. INSPECTION OF ANIMAL FACILITIES AND LABORATORIES

(1) Animal facilities and laboratories are monitored continually by 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. MINOR AMENDMENTS / MODIFICATIONS

Examples of minor amendments / modifications include:

- Addition of new staff
- A small change in procedure
- A change in animal numbers
- 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, minor amendments are only allowed, generally speaking, when there is no substantial change in the overall nature or direction of the project.

NOTE:

Change in animal numbers: change of 10% or less for proposals with more than 250+ animals is generally acceptable. Exceptions to this guideline are left to the discretion of the AEC and the request needs to be fully justified.

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.

18. BUREAU OF ANIMAL WELFARE

Refer to Appendix 7 for Bureau of Animal Welfare (BAW) Licenses explanation.

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 submit it to the Bureau of Animal Welfare by the specified deadline. The Bureau supplies a form designed for the purpose.

Alterations to the SPPL or SABL

The Bureau needs to be notified promptly of:

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

A form designed for the purpose is supplied by the BAW. Changes should be notified within 2 weeks of the alteration.

Fieldwork notification
The Bureau 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 Australian Code of Practice 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). '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 the BAW.

**Auditing of SPPL, SABL and AEC’s**

The Department BAW conducts triennial audits of licenses 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 the BAW webpage.

**Training for AEC members**

The BAW provides complimentary half-day training for new and pre-existing AEC members. The BAW and the Animal Welfare Advisory Committee hold an annual Scientific Procedures Seminar at the end of the year for AECs, Animal Facility Staff and Researchers.