CONTEXT

The use of animals for research and teaching is governed in Victoria by Part 3 of the Prevention of Cruelty to Animals Act 1986 (the Act), Part 4 of the Prevention of Cruelty to Animals Regulations 2008 (the 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 ed) (the Code).

All research involving the use of animals at Peter Mac must be reviewed and approved by the Animal Experimentation Ethics Committee (AEEC). The AEEC is a legally constituted animal ethics committee that complies with the Act and Regulations, the Code and Peter Mac policies, procedures and guidelines.

This document sets out the Terms of Reference for the AEEC and has been developed to ensure uniformity and a clear understanding of the method of operation of the AEEC. Terms of Reference are in accordance with section 2.2.18 of the Code.

PURPOSE

The primary role of the AEEC is to ensure that all activities relating to the care and use of animals are conducted in compliance with the Code, a high standard of animal welfare is observed, and that animal facilities are maintained to the highest standard and incorporate the principles of Replacement, Reduction and Refinement.

FUNCTIONS

The Committee shall:

(a) Provide general oversight of all matters pertaining to the care and use of animals for scientific purposes within Peter Mac, including the formulation of policy, procedures and guidelines for the care and use of animals for scientific purposes.

(b) Approve guidelines for the care of animals that are bred, held and used for scientific purposes on behalf of the institution.

(c) Monitor the acquisition, transport, production, housing, care, use and disposal of animals, and ensure that adequate records are maintained.

(d) Review and approve, approve subject to modification, or reject written proposals associated with the use of animals in experiments (including procedures applicable to breeding programs integral to the maintenance of an animal line), and approve only those activities that conform to the requirements of the Code and the Act and Regulations, taking into consideration whether potential effects on wellbeing are justified by the potential benefits.

(e) Conduct follow-up review of approved projects and activities and allow continuation of approval for only those that are ethically acceptable and conform to the requirements of the Code.

(f) Provide advice and recommendations to the Executive Director Cancer Research, the Chief Executive and the Peter Mac Research Committee on any aspect of animal experimentation and animal welfare within Peter Mac.

(g) Ensure that experimenters are aware of their responsibilities under the Code and the Act, and have received adequate training in animal handling and experimentation.

(h) Conduct an annual inspection of the animal facilities at Peter Mac. Committee members may access the animal facilities at any reasonable time; however such access must be arranged through the Chair of the Committee.

(i) Meet at regular intervals, and not less than six times a year.

(j) Take appropriate actions regarding adverse events and/or non-compliance: the AEEC may withdraw or suspend approval for any project, or authorise the treatment or humane killing of any animal where such action is deemed necessary in accordance with the Code and the Act and Regulations.
an allegation of research misconduct is received the Committee will advise the Research Integrity Co-ordinator, and the matter will be considered under the Research Misconduct Procedure.

(k) Receive complaints on a confidential basis, from animal facility staff, research workers or others on the conduct of projects, and institute corrective measures and disciplinary procedures in accordance with Peter Mac procedures.

(l) Observe the procedures for appointment, reappointment and retirement of members of the AEEC.

(m) Maintain confidentiality of material contained in proposals (see below).

(n) Declare all actual or potential conflicts of interest as soon as they become apparent (see below).

(o) Make available, via the Chair, to Peter Mac and larger community, the procedures and guidelines adopted by the Committee in discharging its responsibilities.

(p) Provide an annual report of the Committee’s activities to the Executive Director Cancer Research, the Chief Executive and the Peter Mac Research Committee.

(q) A draft version of the annual report shall be circulated to the Committee to provide members with the opportunity for input. In particular, comments from Category C and D members shall be given due regard.

Guidelines regarding the operation of the AEEC are included as Appendix 1.

REVIEW

Terms of reference are to be reviewed and approved for use by the AEEC annually.

The effectiveness of the AEEC is reviewed annually by the Executive Director Cancer Research in consultation with the AEEC Chair and AEEC Co-ordinator. The Executive Director Cancer Research shall notify the AEEC Chair and AEEC Co-ordinator of the outcome of the report.

MEMBERSHIP

The AEEC must have a membership that allows it to fulfil these terms of reference. The AEEC is comprised of:

(a) A Chair: The Chair of the Committee is a senior researcher (Laboratory Head) within the Research Division of Peter Mac. The Chair is appointed on the recommendation of the Executive Director Cancer Research. The Chair is a voting member of the Committee.

Delegate of the Chair
- To ensure the AEEC operates in accordance with the principles and requirements of the Code and the Act and Regulations, Peter Mac Policies and AEEC procedures.
- To ensure that proposals are considered by the AEEC and the outcomes are conveyed to investigators in a timely manner.
- To advise the Executive Director Cancer Research of any resource requirements of the AEEC.

(b) A Co-ordinator: The Co-ordinator is appointed from the operations staff of the Research Division. The Co-ordinator is not a voting member of the Committee.

Delegate of the Co-ordinator
- Maintain a register of approved research proposals in accordance with the requirements of the Code of Practice and the Act and Regulations.
- Maintain a register of the minutes of all meetings and committee decisions, including a record of all correspondence related to the functioning of the Committee.
- Ensure AEEC records are maintained and made available for review by the institution and authorised external reviewers.
  - The Co-ordinator may sign/authorise all AEEC related documents that are approved by the Executive and the Committee.
(c) **Category A** members: At least two persons with qualifications in veterinary science and experience relevant to the activities of Peter Mac. In those situations where veterinarians lack this experience, they are required to familiarise themselves with the biology and clinical characteristics of the species of animals used within Peter Mac (i.e. mice). The number of Category A members who can be in attendance at a meeting at any one time is limited by the rules stated under ‘Quorum’, below. Category A members are voting members of the Committee.

(d) **Category B** members: At least two persons with substantial and recent experience in the use of animals for scientific or teaching purposes. These individuals are in possession of a higher degree in research. The number of Category B members who can be in attendance at a meeting at any one time is limited by the rules stated under ‘Quorum’, below. Category B members are voting members of the AEEC.

(e) **Category C** members: Two persons with a demonstrable commitment to, and established experience in, furthering the welfare of animals, who are not employed by or otherwise associated with Peter Mac, and who are not involved in the care and use of animals for scientific purposes. These persons are selected on the basis of membership of an animal welfare organisation. Category C members are voting members of the AEEC.

(f) **Category D** members: Two independent community representatives who are not employed by or otherwise associated with Peter Mac, and who have never been involved in the use of animals in scientific or teaching activities. Category D members are voting members of the AEEC.

(g) **Category E** members: At least one person responsible for the routine care of animals from within the institution.

Members of the Committee will be appointed for a term of two years. At the end of their term, members may be invited to re-apply for a further two years.

The Committee must appoint from amongst its members, a Deputy Chair who will have the authority to act for the Chair in the Chair's absence.

The Committee shall establish an Executive comprising a minimum of 2 people, including the Chair and one other member of the AEEC not employed by the Institute, one of whom is appointed under Category C or D of the Code of Practice. The Executive may approve minor amendments to approved projects (defined as minor by the Chair) and deal with emergencies. The Executive must not approve new proposals (i.e. proposals that have not previously been reviewed by the AEEC). Decisions by the Executive must be reviewed by the AEEC at its next meeting. The Executive may defer items submitted for approval to the full Committee when they believe further discussion of the proposal is warranted.

In order to maintain the integrity of the Committee, all committee members shall receive a copy of the agenda regardless of whether they are required to attend the meeting or not.

**CONVENER**

AECC Co-ordinator.

**MEETING FREQUENCY**

At least every 2 months (or more as required).

**QUORUM**

One member from each membership category (e.g. A, B, C, D) is required to establish a quorum. Where four or more AECC members are present, Categories C plus D must represent not less than one third of those members present.

**REPORTS TO**
The Committee shall be responsible to the Executive Director Research of the Peter Mac in accordance with the requirements of the Code of Practice and the Act and Regulations, as amended from time to time.
Appendix 1: Guidelines for the operation of the AEEC.

Experimentation by members of Peter Mac undertaken at other institutions

Approval of and responsibility for experimentation involving animals conducted on the premises of another institution will be delegated (on a case by case basis) to either the animal ethics committee (or other appropriate governing body) of that institution, or the Peter MacCallum AEEC. Peter Mac researchers may undertake animal experimentation as members of staff of another institution provided that written approval has been obtained from the duly authorised officer of the other institution. Evidence of approval must be provided upon request to the Peter Mac AEEC.

Experimentation involving non-human primates requires the approval of the Peter Mac AEEC as well as approval by the animal ethics committee (or other appropriate governing body) of the institution in which the project will be carried out. All such projects are required to comply with the NHMRC Policy on the use of non-human primates in medical research in addition to the Code of Practice and the Act, and any other conditions laid down by the AEEC.

Confidentiality and security

In accordance with item 2.2.11 of the Code, before appointment, all AEEC members must acknowledge in writing their acceptance of the Terms of Reference of the AEEC and any requirements for confidentiality required by Peter Mac. In the interests of confidentiality and security, it is recommended that where Committee members require disposal of AEEC documents, these are given back to the AEEC Secretary for shredding and destruction.

Notwithstanding the above, individual members have the freedom, whenever necessary, to discuss aspects of protocols with colleagues and co-workers. This must be done in a generic manner without discussing or disclosing confidential details that compromise potential patents or Peter Mac's reputation.

All AEEC applications and amendment documents must be kept by the AEEC Co-ordinator in a locked filing cabinet or cupboard.

Conflicts of interest

The agenda for each meeting must include the following statement:

“Members are required to refrain from voting and absent themselves from the discussion of an item of business in which they have a pecuniary or conflict of interest.”

Where the Chair/member is an investigator on a research proposal being considered by the AEEC, they are required to absent themselves from the meeting or discussion whilst the project is discussed, and only respond when questions are directed to them. The Chair/member must not participate in voting on the proposal. The Chair must vacate the chair in favour of the Deputy Chair in this situation.

Grievance procedures

The following grievance procedures will be adopted if there is dissent over approval of a project:

(a) In those situations where consensus is not achieved, the Committee must resolve issues in dispute by exploring, with the applicant(s), modifications to the project that may achieve consensus. Where consensus can not be reached, the Committee will proceed to a majority decision only after members have been allowed a period of time to review their positions, followed by further discussion.

(b) Irreconcilable differences between the AEEC and an investigator will be referred to the Executive Director Research for review of the due process. The ultimate decision of the AEEC after such review must not be over-ridden.
Where AEEC requirements are not being met

(a) The Chair and Co-ordinator will investigate the report and seek a written explanation of the incident from the researcher/staff member.

(b) The Chair and Co-ordinator will report the incident/alleged incident either prior to, or at, a regular meeting of the Committee where the matter will be discussed.

(c) The Chair will report the incident and the Committee’s view(s) to the Director of Research for information and/or action.

(d) Should an AEEC member be dissatisfied that appropriate action has or will be taken to safeguard animal welfare, then that member should advise the Executive Director Research and pursue the issue as a personal matter through the Bureau of Animal Welfare.