

Murdoch Children's Research Institute (MCRI) Animal Ethics Committee

PREAMBLE

The provision of a high standard of animal welfare is essential to sustained 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 2013 ("the Code").

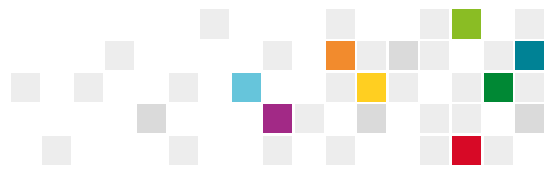
For the purposes of the Code and the Act, the Animal Ethics Committee (AEC) at Murdoch Children's Research Institute (MCRI) is the legally constituted animal ethics committee. The AEC's membership, responsibilities, terms of reference and procedures must comply with the requirements of the 8th edition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

The primary responsibility of the AEC is to ensure, on behalf of MCRI and its Campus partners, that all care and use of animals is conducted in compliance with the Code, the Act and Regulations, and MCRI 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 MCRI Animal Ethics Committee is to ensure a uniform and high standard of animal welfare and ethics in animal experimentation throughout The Campus, which incorporates MCRI, The Royal Children's Hospital & The University of Melbourne Department of Paediatrics.

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 MCRI AEC.

MCRI Executive 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:

- i. To approve guidelines for the care of animals that are bred, held and used for scientific purposes at The Campus Animal Facilities on behalf of MCRI
- ii. To monitor the acquisition, transport, production, housing, care, use and fate of animals
- iii. To recommend to MCRI Executive any measures needed to ensure that the standards of the Code are maintained
- iv. To observe the procedures authorised by MCRI Executive for appointment, reappointment and retirement of members of Animal Ethics Committee
- v. To require all members to declare any conflict of interest
- vi. To observe the procedures authorised by MCRI Executive to deal with situations in which a conflict of interest arises
- vii. To examine and approve, approve subject to modification, or reject written proposals relevant to the use of animals for scientific purposes
- viii. 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
- ix. To withdraw approval for any project that is conducted in a manner not compliant with the Code, Act and Regulations
- x. To authorise the emergency treatment of any animal, with reference to Section 2.5.6 of the Code
- xi. To examine and comment on all MCRI Executive plans and policies that may affect the welfare of animals used for scientific purposes
- xii. To maintain a record of proposals and projects, including the outcomes of the AEC deliberations
- xiii. To comply with the reporting requirements of MCRI Executive, the Act and Regulations, and the Code
- xiv. To perform all other duties required by the Code, Act and Regulations
- xv. In association with The Campus Partners, ensure that staff and students are adequately educated and trained in the care and use of animals for scientific purposes
- xvi. To perform all other duties required by MCRI Executive, including compliance with policies, regulations and guidelines, audit and inspection of animal facilities and laboratories, and submission of annual and other reports
- xvii. 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 – 2.2.8 of the Code. It must comprise at least five persons, including a separate person appointed to each of the following categories.

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.*

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 institution's activities or the ability to acquire relevant knowledge.*

Category B member(s): *a suitably qualified person with substantial recent experience in the use of animals in scientific purposes relevant to the institution and the business of the AEC. This must entail 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 nomination by, such an organisation.*

Category D member(s): *a person not employed by 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.*

Other members appointed / co-opted by the Committee

Animal Facility Manager/representative (ex officio): *a person responsible for the routine care of animals from within the institution.*

Animal Welfare Officer/Health Manager: *a person (Vet) responsible for the oversight of welfare requirements of animals from within the institution.*



AEC Executive Officer: *a person responsible for the taking of minutes and the daily management of AEC function*

The role of the Chairperson is to represent the AEC in negotiations with the MCRI Executive and to ensure that the AEC operates in accord with the Code, the Act and Regulations, and MCRI 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 MCRI Chief Operating Officer, as License Nominee, and the other co-opted staff shall be ex officio members of the AEC and may attend meetings. If in attendance, the Animal Facility Managers/representatives are to give a quarterly report at minimum.

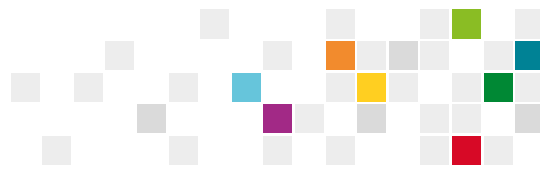
The License Nominee and AEC Chair shall meet at least twice yearly to discuss the operations of the AEC.

3. APPOINTMENT AND RETIREMENT OF MEMBERS

- i. The MCRI Executive is responsible for appointing the Chairperson and Membership of the AEC.
- ii. The MCRI Executive recommends that the Chairperson and/or License Nominee interview 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
- iii. The AEC executive officer will organise all external AEC members to be given a volunteer appointment at MCRI. The new member is to be sent a letter of appointment from MCRI
- iv. External persons are covered by MCRI Professional Indemnity policy for the Committee work they perform for MCRI
- v. Agriculture Victoria are to be notified of new appointments prior to the commencement of a members duties
- vi. Appointment of a Member may be terminated by the MCRI Executive by sending a letter of termination

4. MEETINGS

- i. Meetings should be held at minimum every two months (February to November), to allow interaction of AEC members and to enable the AEC to fulfil its obligations under the code.
- ii. The operating procedures of the AEC must comply with Sections 2.2.20 – 2.2.37 of the Code



- iii. Minutes must be maintained that record decisions, inspections and other aspects of the AEC's operation

5. QUORUM

Section 2.2.25 of the Code defines a quorate meeting:

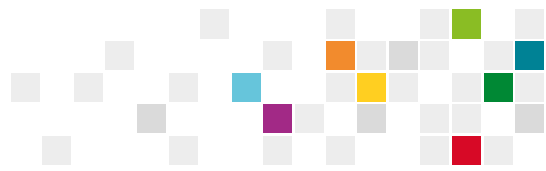
At least one member from each of the membership categories A, B, C and D must be present at meetings to establish a quorum for the conduct of a meeting, and must be present throughout the meeting. Categories C and D together must represent at least one-third of those members present.

6. EXECUTIVE

- i. The AEC Chairperson may establish an Executive, which must include the Chairperson and at least one member from Category C or Category D.
- ii. Additional members of the AEC may also be appointed to the Executive
- iii. 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
- iv. The Executive may review responses 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)
- v. 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

- i. 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.
- ii. 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.
- iii. 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.
- iv. The MCRI License Nominee, the Executive Officer, and the Animal Facility & Welfare members have no voting rights.



8. CONFIDENTIALITY & SECURITY

- i. Members and attendees of the AEC must comply with any confidentiality policies of MCRI
- ii. In the interests of confidentiality and security it is recommended that all hardcopy documents be collected by the AEC executive officer and shredded at the end of each AEC meeting. In special circumstances and with agreement of the AEC executive officer and/or chairperson, committee members may be allowed to keep copies of applications
- iii. PDF documents provided to the committee may be stored on a secure device, such documents are to be deleted by the member once no longer required and at the end of tenure.

9. CONFLICT OF INTEREST

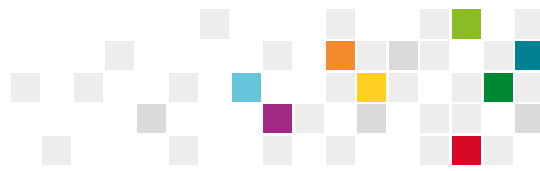
When a research proposal of which the chairperson or a member is an investigator is considered by the AEC, the minutes of meeting should clearly record and reflect that:

- i. Where the investigator conflict involves the Chairperson, the Chairperson vacates the Chair for the consideration of that proposal, the meeting is then chaired by the Deputy/Acting Chairperson until the conclusion of that proposal consideration.
- ii. The Chairperson or member concerned is required to absent himself from the meeting during discussion of his proposal and only respond to questions directed to him upon returning to the room. The Chairperson or member will not participate in voting on the proposal

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 – 2.3.16 and Section 3 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.

- i. New proposals and renewal of existing projects must be considered and approved only at quorate meetings of the AEC.
- ii. 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
- iii. 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.
- iv. Investigators must be informed of decisions in writing



- v. A register of all proposals to the AEC, including the outcomes of the Committee's deliberations, must be maintained
- vi. Decisions must be made as promptly as possible
- vii. Scientific or teaching activities involving the use of animals must not start before written approval is given

11. MODIFICATIONS

Examples of Modifications Include:

- Change of investigator
- A minor variation in procedure (*should not complicate experimental design*)
- A change in animal numbers
- An extension of duration of the project

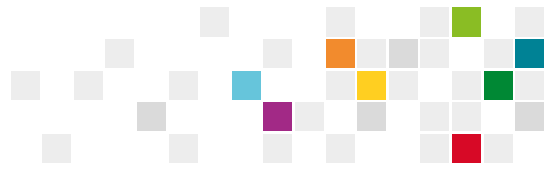
Although there is no limitation as to how many modifications are allowed within the approved duration of the research project, minor amendments are only allowed, generally speaking, when there is no substantial change in the overall nature or direction of the project.

NOTE:

No single project may run longer than four years in total (including extensions).

12. OPERATING PROCEDURES

- i. A cut-off date is advertised on the MCRI AEC intranet for all AEC meeting dates
- ii. All studies submitted by the advertised cut-off date will be placed on the agenda for the advertised meeting
- iii. After each AEC meeting the minutes will be completed and sent to the chairman for final review. Upon final review, responses will be drafted, and signed by the AEC chairman or authorised delegate. The principal investigator will be notified via email and/or online animal management systems.
- iv. Investigators have a 3-month period to reply to queries.
- v. 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 resubmission of the project with the option of inviting the investigator to attend the meeting.
- vi. If an item is approved out of session the investigator will be provided with notification of the approval via email or online systems.
- vii. The animal facility manager will have access to, or be advised of, all approved projects within one week of approval.



13. INSPECTION OF ANIMAL FACILITIES AND LABORATORIES

- i. MCRI recommends that The Campus Animal Facilities and laboratories be monitored by the AEC at least annually.
- ii. Inspection parties should consist of at least one AEC member who is external to the institution
- iii. A report of the inspection should be written and include the names of those who attended, observations, any identified problems, follow-up and outcomes.
- iv. The inspection report should be an agenda item for consideration by the Committee

14. SUSPENSIONS AND WITHDRAWAL OF APPROVAL

- i. 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)
- ii. 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
- iii. 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

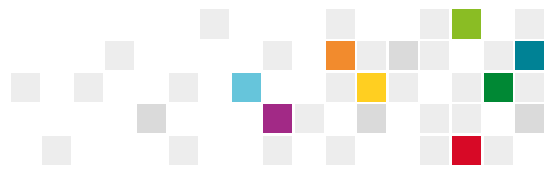
15. EMERGENCY TREATMENT OR EUTHANASIA OF AN ANIMAL

The AEC is authorised to approve remedial actions by Investigators, Animal Facility or Animal Welfare staff as required by the code in the case of an emergency or unexpected adverse event as is set out in the AEC Policy & Procedural documents.

The AEC is required to investigate adverse events as reported. This may be 'out of session' or as a scheduled agenda item as deemed appropriate by the AEC.

16. REPORTING

The AEC will submit a written report to the MCRI Executive on its activities at least annually. A copy of the report is to be provided to all license holders on whose behalf the committee acts.



17. PROCEDURES FOR HANDLING AEC CONCERNS, GRIEVANCES & NON-COMPLIANCE

Grievances concerning AEC Operation

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 the AEC. If the grievance cannot be resolved they should then take their concerns to the MCRI Executive/delegate.

Animal Welfare Concerns Reported to the AEC

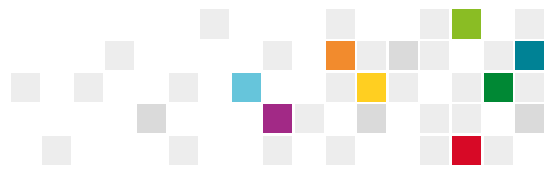
- i. If the animal facility, academic or other staff or students have any enquiries or concerns about the well-being of animals held at MCRI for use in breeding, research or teaching, these concerns should be reported to the Chairperson or Executive Officer of the AEC, or to the MCRI License Nominee.
- ii. 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.
- iii. If the complaint is of a serious nature, or if the matter cannot be resolved, then the MCRI Executive should be notified in a timely manner.

Non-compliance

- i. The AEC is authorised to investigate instances of non-compliance and make such recommendations and institute actions as is necessary to safeguard animals, investigators and MCRI.
- ii. The welfare of any animals is of primary concern, once addressed, any remedial action required to bring the project and institution back into a state of compliance is as set out in the AEC Policy & Procedural documents.
- iii. If the matter is of a serious nature or cannot be resolved, then the MCRI Executive should be notified.
- iv. A register of notable non-compliance items is to be maintained.

18. Dept. Economic Development, Jobs, Transport and Resources (DEDJTR)

Refer to the DEDJTR – Agriculture Victoria ('the Department') website for an explanation of Licences (<http://agriculture.vic.gov.au/agriculture/animal-health-and-welfare/animals-used-in-research-and-teaching/licensing/types-of-licences>)



Annual Returns

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 Agriculture Victoria by the specified deadline. The Department supplies a form designed for the purpose.

Alterations to the Licence

The Department 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 Department, changes are to be notified prior to commencement.

Fieldwork notification

The Department needs to be notified, prior to commencement, of projects approved by the MCRI AEC to be conducted at sites other than those listed on the Scientific Procedures Premises Licence. These sites are termed "Field Work".

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 Act 2015). '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 Department.

Auditing of SPPL, SABL and AEC's

Agriculture Victoria conducts four-yearly audits of licenses and AEC's 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 Departmental webpage.

Training for AEC members

Agriculture Victoria offers introductory and advanced training for new and pre-existing AEC members. The Department 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. The MCRI Executive recommends introductory and advanced training from the Department for all AEC members.