



Terms of Reference

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

1. INTRODUCTION

The use of animals for scientific purposes and teaching is governed by Victorian Legislation, the Prevention of Cruelty to Animals Act (POCTA) 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 an AEC is to ensure, on behalf of MCRI and its Campus partners, that all activities relating to the care and use of animals are conducted in compliance with the Code.

The primary role of the MCRI Animal Ethics Committee is to ensure a uniform and high standard of animal welfare and ethics in the use of animals for scientific purposes throughout the Royal Children's Hospital Campus, including MCRI, The Royal Children's Hospital and historically The University of Melbourne Department of Paediatrics (the Campus). The provision of a high standard of animal welfare is essential to sustained excellence in research.

The terms of reference are provided to both support the AEC and to ensure uniformity and a clear understanding of the method of operation of the MCRI AEC.

MCRI recommends that these Guidelines be followed by the AEC.

2. AEC MEMBERSHIP

As defined in section 2.2.4 of the Code, membership of the AEC comprises at least one person from each of the following four categories of membership. Where there are more than four members categories C and D together must represent at least one-third of the membership.

Chair: *a person who either holds a senior position with MCRI, or if an external appointee, is supported by MCRI with the necessary authority to carry out the role. The Chair may also have a co-appointment as one of Categories A to D.*



Category A member(s): *a person with qualifications that are recognised for registration as a veterinary surgeon in Australia, and with experience relevant to the MCRI'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 MCRI 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 MCRI, 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.*

Category D member(s): *a person not employed by or otherwise associated with MCRI 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.*

Additional members:

Members with additional skills and background of value to the AEC -

- **Animal Facility Manager(s)/representative(s):** *a person responsible for the routine care of animals from within MCRI.*
- **Animal Welfare Officer/Health Manager:** *a person (Vet) responsible for the oversight of welfare requirements of animals from within MCRI.*
- **AEC Executive Officer:** *a person responsible for the taking of minutes and the daily management of AEC function*

The chair is responsible for impartially guiding the operation of the AEC, resolving conflicts of interest related to the business of the AEC, and representing the AEC in any negotiations with MCRI. In the absence of the Chair at any meeting of the AEC, the members present shall appoint one of their members as acting Chair at that meeting

The MCRI Chief Operating Officer (COO), as License Nominee, and co-opted staff shall be *ex officio* members of the AEC; these are non-voting roles.

Animal Facility manager(s) or their representatives are to provide a report to the AEC at least x3 times per annum.

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 COO is responsible for appointing the Chair and Members of the AEC.
- ii. The MCRI COO or their representative are to interview proposed new AEC members to ensure the applicant's suitability to serve on the AEC and to reveal any biases which could be detrimental to the workings of the committee.
- iii. External members will be given a volunteer appointment at MCRI
- iv. It is recommended that new members commit to the role for an initial period of two years.
- v. External committee members are covered by the MCRI Professional Indemnity policy
- vi. Member's appointments should be reviewed annually, confirming their commitment to the role or intention to retire.
- vii. In the interests of good governance consideration will be given to retiring members with extended terms of service, i.e. 10 – 15 years.
- viii. Appointment of a Member may be terminated at any time by the MCRI COO by sending a letter of termination.

4. MEETINGS

- i. Meetings must be held no less than every two months (February to November) of the calendar year.
- 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

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

6. EXECUTIVE

- i. The AEC Chair may establish an Executive, which must include the Chair 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.
- v. Any decisions by the Executive must be reviewed and ratified by the AEC at its next meeting.
- vi. Members may not take part in an executive where they have a conflict of interest.

7. CONFIDENTIALITY & SECURITY

- i. Members and attendees of the AEC must comply with any confidentiality policies from MCRI.
- ii. It is recommended that all hardcopy documents be collected by the AEC executive officer and shredded at the end of each meeting.
- 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.

8. CONFLICT OF INTEREST

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

- i. The conflicted member stepped out of the meeting during deliberations and the decision making process.
- ii. If the conflicted member is the Chair, then the remaining members will deputise an acting Chair until the conclusion of that proposal consideration.
- iii. The conflicted member may respond to queries, but they cannot participate in voting on the matter.

9. CONSENSUS DECISION-MAKING AND VOTING RIGHTS OF MEMBERS

- i. Each member is responsible for deciding, whether, in their own judgement, a matter under consideration by the AEC is ethically acceptable and meets the requirements of the code
- ii. Decisions by the AEC should be made on the basis of consensus.
- iii. When consensus is achieved, then the decision is recorded. If the project is rejected, this should be recorded in the Minutes with the reasons for the rejection.
- iv. 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.



10. PROCEDURES FOR REVIEW OF SUBMISSIONS

Note 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 fits within the governing principles and ethical framework of the code:
 - a. Uses animals only when justified,
 - b. supports the wellbeing of animals,
 - c. avoids or minimises harm, pain & distress to animals,
 - d. applies high standards of scientific integrity,
 - e. applies the 3R's at all stages i.e., replacement, reduction and refinement.
- 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 Section 9.
- iv. Investigators must be informed of decisions in writing via email and/or AMS
- 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. Activities involving the use of animals must not commence before written approval is given.

11. MODIFICATIONS

- i. A modification may be requested to an approved project via the submission of a revision to the AEC.
- ii. A modification should fall within the parameters of the original project; it should still fit with the Title of the approved project and within the Aims of the original project.
- iii. A modification is to be submitted to the full committee in the same manner as an application; in all instances where there is an increase in welfare impact on an animal the amendment must be submitted for a quorate review.
- iv. A minor amendment may be submitted to an executive only if urgent circumstances dictate a request for out of session review, a minor amendment cannot increase the welfare burden on an animal.
- v. Although there is no limitation as to how many modifications are allowed within the approved duration of the research project, amendments are allowed, generally speaking, only when there is no substantial change in the overall nature or direction of the project. A request for amendment that falls outside these guidelines should be submitted as a new application.
- vi. No single project may run longer than four years in total (including extensions).



Minor Amendments include but are not limited to the following examples:

- Change of investigator.
- An extension of duration of the project.
- Additional animal strain.
- Vary the age of an animal.
- Procedural changes that do not increase the welfare burden on an animal.
- A change in timeline without increasing the welfare burden on an animal.
- Agent dosage variations where it does not increase the welfare burden on an animal.

12. OPERATING PROCEDURES

- i. A cut-off date is advertised on the MCRI AEC intranet for all AEC meeting dates.
- ii. All submissions received by the advertised cut-off date will be placed on the agenda for the scheduled meeting and documents distributed to the committee.
- iii. 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.
- iv. If actions are required of the investigator they will be summarised by the Chair.
- v. After each AEC meeting the minutes will be sent to the Chair for final review.
- vi. Once approved the responses are issued by the AEC executive officer as authorised delegate of the AEC.
- vii. The AEC must clearly communicate its decisions, the reasons for its decisions and any conditions attached to an approval to investigators in writing (email or AMS) as promptly as possible.
- viii. Investigators must receive a response from the AEC within 7 calendar days of the meeting date (or as soon as practicable for items considered 'out of session').
- ix. Investigators have a 3-month period to reply to queries or the submission will be considered lapsed.
- x. The animal facility manager(s) will have access to, or be advised of, all approved projects within one week of approval.

13. INSPECTION OF LICENSED FACILITIES

- i. MCRI recommends that licensed facilities be inspected by the AEC at least annually.
- ii. A Category C or D member of the AEC should participate in facility inspections.
- iii. A report of the inspection must be written and should include attendees, observations, 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. The AEC may suspend or withdraw approval of a project at its discretion.
- ii. Investigators will be advised of this suspension or withdrawal in writing within 7 calendar days of such a decision.
- iii. The principal investigator will be advised of reasons why suspension or withdrawal has occurred and if applicable will be provided with remedial actions required to reinstate ethical approval.
- iv. 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 members of the AEC upon primary notification of an event.

16. REPORTING

The AEC will submit a written report to the MCRI Executive on its activities at least annually. A copy of the report will 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 Chair of the AEC. If the complainant cannot do so in full confidence or the grievance cannot be resolved they should then take their concerns to the MCRI License Nominee or their representative.

Animal Welfare Concerns Reported to the AEC

- i. If any person (animal facility, academic, other staff or students) has 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 Chair 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 License Nominee 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 the 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 License Nominee should be notified.
- iv. A register of notable non-compliance items is to be maintained.

18. ANIMAL WELFARE VICTORIA (AWV)

Refer to the Animal Welfare Victoria ('the Department') website for an explanation of Licenses and an overview of their role in managing Animals Used in Research and Teaching (<https://agriculture.vic.gov.au/livestock-and-animals/animal-welfare-victoria/animals-used-in-research-and-teaching>)

Annual Returns

Holders of Scientific Procedures Premises Licences (SPPL) and Specified Animals Breeding Licences (SABL) are required by the regulations to complete an Annual Return of Animal Usage each calendar year and submit it to AWV by the specified deadline, March 30th. The Department supplies a form designed for the purpose.

Alterations to the Licence

Forms are supplied by AWV for changes to the license, changes must be notified prior to commencement.

The Department needs to be notified of:

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



Fieldwork notification

This form must be submitted prior to fieldwork commencing under a Scientific Procedures Fieldwork Licence (SPFL) that utilises an interstate Animal Ethics Committee.

Death as an endpoint

Death as an endpoint (DAEP) scientific procedures are rare, very high-impact animal procedures where death of the subject animal is a deliberate measure and where there will be no intervention to kill the animal humanely. Such procedures are prohibited in Victoria unless the objective cannot be achieved by any other means, these procedures require ministerial approval and are only made available in prescribed circumstances.

Auditing of SPPL, SABL and AEC's

Institutions must ensure that an independent external review is conducted at least every four years to assess MCRI's compliance with the Code, and to ensure the continued suitability, adequacy and effectiveness of its procedures to meet its obligations under the Code.

Training for AEC members

Animal Welfare Victoria offers a compulsory introductory training for all new AEC members. MCRI encourages the mentoring of new members by those more experienced and supports additional training as can be sourced from Peak Bodies and key stakeholders from within the relevant field.