

Terms of Reference & Operating Procedures

Document:	Alfred Research Alliance (ARA) Animal Ethics Committee (AEC) Terms of Reference (TOR)
Approved By:	Governance & Policy (GAP) Committee
Date Effective:	15 September 2021
Review Date:	2024
Version:	5.1
Document Number:	AEC-TOR-10-2021-v5.1
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2021



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Definitions

Activity: Any action or group of actions undertaken that involves the care and use of animals, including acquisition, transport, breeding, housing and husbandry of those animals. An activity may involve one or more procedures. Activities are described in an application to the Animal Ethics Committee (AEC).

AEC Governance & Policy (GAP) Committee: The governing Committee for AEC A and AEC B whose function it is to provide governance and policies across both AECs with representation from all Licence Holders that use the Alfred Research Alliance (ARA) AECs.

Alfred Research Alliance (ARA) or The Alliance: A collaborative partnership between like-minded organisations focused on biomedical research. This includes:

- Burnet Institute
- Baker Heart and Diabetes Institute
- Monash University Central Clinical School
- Alfred Health
- AMREP Animal Services Pty Ltd
- Other approved organisations that use ARA AEC

Animal Ethics Committee (AEC): A Committee constituted in accordance with the Terms of Reference (TOR) and membership laid down in the Australian Code. At the Alfred Research Alliance, AEC refers to both AEC A and AEC B.

Animal Welfare Victoria (AWV): The external regulator of the use of animals for scientific purposes.

External Member: A member of the AEC who is not employed by the Licence Holders. All Category C and D members are external. A Category A member may also be external.

Institutions: Those licence-holding institutions listed on the scientific procedures premises licences (SPPLs), specified animals breeding licence (SABL) or scientific procedures fieldwork licence (SPFL) that use the Alfred Research Alliance AECs.

Licence Holder Nominee: The individual nominated by the Licence Holder to be responsible for procedures under each respective SPPL, SABL or SPFL.

Member: A person appointed to the Alfred Research Alliance AEC by the GAP Committee. They may be voting or non-voting.

Non-Voting AEC Member: A member appointed to the AEC that does not have voting rights therefore does not count towards the quorum and balance of the Committee. A non-voting member attends the meetings and receives all the meeting material that voting members do.

POCTA Act: The Prevention of Cruelty to Animals Act 1986 and Regulations 2019 as located at www.dpi.vic.gov.au/animalwelfare/

Proposal: That as defined in The Australian Code i.e. “a written application to carry out a project for consideration by an AEC”.

Project: That as defined in The Australian Code i.e. a ‘scientific activity’ or ‘activities’ that form a discrete piece of work. A project cannot commence until it has been approved by the AEC.

Scientific Premises Procedure Licence (SPPL): Authorises the use of facilities for scientific procedures. Any facility being used to hold animals or conduct research must be listed on an SPPL.



Scientific Procedures: Defined in Part 3 of the Prevention of Cruelty to Animals Act 1986.

Scientific Procedures Fieldwork Licence (SPFL): Authorises the use of premises or locations that are not normally used by the licence holder for scientific procedures.

Specified Animals Breeding Licence (SABL): Authorises the Licence Holder to breed specified animals within Victoria for supply for use in scientific procedures.

The Australian Code: The current edition of The Australian Code for the Care and Use of Animals for Scientific Purposes, mandatory under Part 3 of The Prevention of Cruelty to Animals Act 1986 and Regulations 2008.

Voting AEC Member: A member appointed to the AEC that has voting rights. Their attendance at an AEC meeting needs to be managed with the other voting members to ensure that the meeting(s) are balanced and quorate.

Introduction

In Victoria, the use of animals for research and teaching is regulated by Part 3 of the Prevention of Cruelty to Animals (POCTA) Act 1986 and Part 5 of the POCTA Regulations 2019. Under the POCTA legislation, organisations or individuals wanting to conduct scientific procedures with animals or breed specified animals for supply in Victoria must hold an authorising licence issued by Animal Welfare Victoria.

The Alfred Research Alliance partners hold authorising licences to use animals for scientific procedures and to breed specified animals for supply to other institutions or for use under other licences. Each licence nominates a properly constituted and functioning Animal Ethics Committee to oversee animal care and use on the licence.

The Australian Code for the Care and Use of Animals for Scientific Purposes (the Australian Code), 8th edition (2013), requires that AECs have Terms of Reference that include the following provisions:

- a) the scope of its responsibilities for ethical review, approval and monitoring of animal care and use
- b) its institutional accountability
- c) its mechanisms of reporting
- d) the way in which it meets the requirements for categories of minimum membership

These Terms of Reference fulfil that requirement.

These Terms of Reference shall be made available to the public upon request.

Related Documents

The following are policies and/or procedures related to the Terms of Reference. They can be accessed via the Animal Ethics Website on the policies page (amrepaec.baker.edu.au/home/policies).

Note: You will need a log-in to this website. This should have been provided to you when you joined the ARA AEC.

If you do not have a log in, or cannot remember your log-in details, please contact the Animal Ethics Office (AECSecretary@baker.edu.au)

- ➔ Distribution of Business to Alfred Research Alliance Animal Ethics Committees
- ➔ Code of Conduct for Scientific Procedures Using Animals under Alfred Research Alliance Licences
- ➔ Policy on the Review of AEC Member Performance
- ➔ Policy on the Use of Standard Operating Procedures (SOPs) in relation to AEC applications
- ➔ Policy and Procedures for reporting Adverse Events
- ➔ Policy on Minor Amendments that can be considered by an AEC Executive

Terms of Reference

1. Scope

This Terms of Reference applies equally to the following Alfred Research Alliance AECs:

- a) AEC A
- b) AEC B

These AECs are nominated for use under more than one authorising licence at the ARA site.

Projects are allocated to an AEC according to the *Policy for the Distribution of Business to Alfred Research Alliance Animal Ethics Committees*.

2. Function of the AEC

- 2.1. The primary function of the AEC is to ensure, on behalf of the ARA institutions, that all use and care of animals is conducted in compliance with the current Australian Code and Prevention of Cruelty to Animals Act. The AECs will report to the institutions via the licence nominees.

The AEC(s) must:

- 2.1.1. Review and approve Standard Operating Procedures (SOPs), policies and guidelines for the care of animals that are bred, held and used for scientific or teaching purposes on behalf of the institutions.
- 2.1.2. Examine and approve, approve subject to modification, or reject written proposals as submitted on the agreed institutions' application form. Approval will be for 3 years in the first instance, or a period determined by the AEC, subject to annual reporting of approved projects.
- 2.1.3. Review annual and final reports of projects, according to The Australian Code.
- 2.1.4. Monitor the acquisition, transportation, production, housing, care, use and fate of animals involved in an approved project. Establish provisions for monitoring that include the maintenance of appropriate records of animal care and use by investigators and reporting of unexpected or adverse effects that impact on the welfare of the animals to the AEC.
- 2.1.5. Conduct inspections of relevant sites and monitor project activities approved by the AEC. All sites must be inspected at least once every two years, however the frequency of inspection of specific areas on the ARA licences under the POCTA Act may vary. The AEC may delegate this authority to a subset of members that must include at least one Category C or D member.
- 2.1.6. Recommend to the AEC Governance & Policy (GAP) Committee any measures, including training or supervision of investigators or teachers needed to ensure that the standards required by The Australian Code are met.
- 2.1.7. Facilitate on-going education of AEC members.
- 2.1.8. Facilitate the establishment of protocols to authorise the emergency treatment or euthanasia of any animal.
- 2.1.9. Maintain a record of proposals and projects for seven years.

- 2.1.10. Deal with alleged non-compliance with The Australian Code, including by referral to the GAP Committee and Animal Welfare Victoria as required.
 - 2.1.11. Deal with grievances with AEC decisions, including by referral to the GAP Committee and Animal Welfare Victoria as required.
 - 2.1.12. Provide advice as appropriate to matters referred by the GAP Committee.
 - 2.1.13. Report at least annually to the licence nominees and GAP Committee on the AEC's activities in the form of an Annual Report to the Institution.
 - 2.1.14. Review and approve modification to, or works associated with, the animal facilities.
 - 2.1.15. Review and approve new equipment being installed and used within the licenced premises.
- 2.2. The AEC may withdraw or suspend approval for any project where necessary according to the following process:
- 2.2.1. Review of a written report from any party on non-compliance, breaches, or unexpected adverse events with regards to animal usage.
 - 2.2.2. Investigations of any non-compliances as warranted, which may include interviewing all stakeholders.
 - 2.2.3. Any decision to continue, suspend or withdraw an approval will be made in writing to the investigator(s) and the relevant licence nominee. A report may be made to Animal Welfare Victoria outlining recommendations and remedial actions as appropriate.
 - 2.2.4. If an approval is withdrawn or suspended, continuation of the project and/or publishing of the data will be subject to additional AEC approval which will be based on confirmation that the issues have been addressed to the satisfaction of the AEC.
 - 2.2.5. The completion of any additional steps based on advice from Animal Welfare Victoria and/or the respective licence nominee.

3. Responsibilities and Expectations of Animal Ethics Committee Members

The primary responsibility of AEC members is to ensure that the use of animals for scientific purposes is compliant with the Australian Code.

A member must not represent any particular interest group.

3.1. Confidentiality:

- 3.1.1. Full confidentiality of all matters discussed in any context pertaining to the AEC must be maintained. Should external advice be required, it will be sought following de-identification of the project, the investigators involved and location at which the project will be conducted.
- 3.1.2. A member resigning or retiring from the AEC shall not, without the express written approval of the GAP Committee, divulge or discuss confidential information.
- 3.1.3. Before attending their first meeting, members will be required to sign a Confidential Information Declaration form that will apply for the duration of their time on the AEC.

3.2. Conflict of Interest:

- 3.2.1. Where a member has any direct or indirect interest in any matter of business before the AEC, that may be construed as having pecuniary or other gain, that interest shall be declared to the AEC.
- 3.2.2. Where a member declares a conflict of interest, the Chair, in consultation with the AEC, will.
 - 3.2.2.1. Determine the validity of the declaration.
 - 3.2.2.2. In the event of a conflict of interest, require that the member withdraw from the meeting for the period of discussion and resolution of that business.
 - 3.2.2.3. Assist the AEC by asking the member questions related to the agenda item but ensuring that they are not present for the final deliberation and decision.
 - 3.2.2.4. In the absence of the conflict member, the remaining members must constitute a quorum as defined in Clause 2.2.25 of the Australian Code – that is, one member from each of the membership categories A, B, C and D and with Categories C and D together representing at least one-third of members present.

3.3. Level of participation:

- 3.3.1. Members are expected to attend at least 80% of regularly scheduled meetings unless otherwise agreed to by the AEC Chair.
- 3.3.2. Members are expected to attend any AEC training days run by the ARA Animal Ethics (AE) Office. Any member unable to attend such training days must discuss the matter with the AE Office Manager.
- 3.3.3. Members are expected to have read all the AEC meeting materials in advance and to be prepared to discuss their views.
- 3.3.4. In the event of a virtual meeting, members are expected to have their video on at all times.

If the member is having difficulty with their internet connection, they must notify the AE Administrator and can turn their video off so they can still participate in the meeting.

This should not be the default option for members, as it makes it difficult for the AE Administrator to manage the balance of members in attendance at the meeting and ensure that the minutes accurately capture who was present for discussions.

- 3.3.5. Members are expected to complete (by whatever means are available, whether on-line course, webinar or face-to-face workshop) Animal Welfare Victoria's legislated training of AEC members within 6 months of their appointment to the AEC.

3.4. Behavioural standards:

- 3.4.1. Members must conduct themselves in a manner that supports and strengthens the community's trust and confidence in the integrity of the ARA AECs.
- 3.4.2. Members must be respectful to all those with whom they interact while undertaking their AEC duties.
- 3.4.3. Members are expected to be punctual in their attendance at scheduled meetings.

- 3.4.4. Members should, when possible, avoid leaving an AEC meeting while business is under discussion to avoid disruption and to facilitate maintenance of the quorum.
- 3.4.5. Members must not initiate private conversations during meetings.
- 3.4.6. Members must not use offensive or slanderous language, or engage in any form of bullying and harassment, physical or verbal, which a reasonable person would deem to be unwelcome, offensive, humiliating, or intimidating. This includes making derogatory or discriminatory comments about any person or group of persons.
- 3.4.7. Members must remain impartial when reviewing meeting material. Each application should be considered on its own merits and members must not be swayed by past history with the lab/research group.
- 3.4.8. Members must declare any potential conflicts.

4. Responsibilities and Expectations of ARA Researchers

- 4.1. Researchers must adhere to the *Code of Conduct for Scientific Procedures using Animals under Alfred Research Alliance Licences*.

5. Membership of the Animal Ethics Committee and Term of Office

5.1. Term of Office.

- 5.1.1. Appointment of new members will be ratified by the GAP Committee.
- 5.1.2. All members will be given an appointment terms of 3 years, but this is subject to a performance review every 12-18 months.
- 5.1.3. At the end of the 3-year appointment, the members will be invited to express their interest in continuing their membership.
- 5.1.4. Any expressions of interest will be discussed with the AEC Chair and the applicants subject to a performance review.
- 5.1.5. Re-appointment of members will be ratified by the GAP Committee.

5.2. Number and Category of Members:

- 5.2.1. The membership of the AEC shall comprise members who have a genuine interest and commitment to the ethical use of animals for scientific procedures or teaching. The AEC must comprise and meet with at least one appointed person from each of the following categories:

Category A. 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. A suitably qualified person with substantial and recent experience in the use of animals for scientific purposes relevant to the institution and the business of the AEC. This must include possession of a higher degree in research or equivalent experience. If the business of the AEC relates to the use of animals for teaching only, a teacher with substantial and recent experience may be appointed.

Category C. 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 currently involved in 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.

Category D. 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 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.

- 5.2.2. The selection of members will be informed by the need for knowledge and experience concerning ethical use of animals for scientific purposes. In addition to the prescribed Categories A to D, persons with knowledge of the routine care and husbandry of animals used at the site may be appointed.
- 5.2.3. Categories C and D must together represent at least one-third of the AEC membership, at all times when decisions are being made.
- 5.2.4. The AEC must have a quorum in attendance to conduct meetings. A quorum shall consist of at least one member from each category and must be maintained at all times when decisions are being made.
- 5.2.5. Before appointment, all members of the AEC should acknowledge in writing their acceptance of these Terms of Reference and any confidentiality requirements of the GAP Committee, including how advice may be sought without breaching confidentiality.

5.3. Varying and Replacing the Members, Absentee Members:

- 5.3.1. The AE Office shall make recommendations to the GAP Committee on how membership should be amended, and a member replaced by a new appointee of the same membership category, if the member:
 - 5.3.1.1. Fails to attend two consecutive meetings of the AEC without providing an apology or excuse in advance.
 - 5.3.1.2. Is demonstrably unable to maintain an adequate level of participation (as outlined in 3.3).
 - 5.3.1.3. Repeatedly (more than three times) fails to declare conflicts of interest.
 - 5.3.1.4. Does not comply with these Terms of Reference.
- 5.3.2. The AEC may co-opt other persons with relevant experience or expertise as required, including persons with experience in the routine care of animals for scientific purposes. Co-opted members of the AEC cannot exercise voting rights and must adhere to the general principles of confidentiality as per voting members.
- 5.3.3. In the event of a member resigning or retiring prematurely during their appointed term on the AEC, they should notify the AE Office in writing and provide at least 4 weeks' notice, where possible.

Once notice of resignation or retirement is received, the AE Office will begin looking for a suitable replacement member. Details of the eligibility of potential members should be provided to Animal Welfare Victoria before they attend the first AEC meeting. Animal

Welfare Victoria may provide guidance on whether the member meets the criteria of the nominated category.

- 5.3.4. If the Chair feels that a member is not performing in their role on the AEC (i.e. demonstrates a lack of engagement, does not appear to have reviewed meeting material etc.) then they will raise the matter with the GAP Committee and may recommend that the member be terminated.

If a member is terminated, they can appeal the decision by submission to the AE Office. The matter will then be discussed by the GAP Committee Chair and AEC Chair and a final decision made on the termination of membership.

- 5.3.5. Where a member is repeatedly overdue in completing AEC Executive review (as outlined in 9.11.2) the Chair shall recommend to the GAP Committee that the member be replaced by a new appointee of the same category.

5.4. Assessment of individual member performance:

- 5.4.1. The conduct and performance of AEC members will be reviewed every 12-18 months by the AE Office. This review will be conducted in accordance with the *Policy for Review of AEC Member Performance*.

5.5. Training of new members:

5.5.1. Training and induction of new members:

5.5.1.1. Members must undertake mandatory AEC training in accordance with the POCTA Regulations 2019.

5.5.1.2. Members will receive a Human Resources (HR) and Occupational Health and Safety (OHS) induction at the Baker Institute.

5.5.1.3. Members will receive an induction into the Precinct Animal Centre (PAC).

5.5.1.4. Members will receive an induction into the ARA AE Office which includes training on how to use the Conduit database and where to access key AE documents.

5.5.2. Training of existing members:

5.5.2.1. Members will be provided with training on how to use the Conduit database and where to access key AE documents.

5.5.2.2. Members will be provided details of all external training opportunities that the AE Office is aware of.

5.5.3. Requests for additional training should be directed to the AE Office.

6. Nomination of Members and their Appointment to the AEC

6.1. Nomination and appointment of members to an AEC will be managed by the AE Office.

6.2. Nominations of Category A to D members:

On behalf of the GAP Committee, the AE Office shall invite, recruit, or accept self-nomination from:

- 6.2.1. Existing Victorian AEC members of any category to nominate themselves.

- 6.2.2. Other potential members of any category.
- 6.2.3. Veterinarians with experience specific to the species of animals used by the institution.
- 6.2.4. Category C members.
- 6.3. Appointment of AEC members:
 - 6.3.1. Potential AEC Members will be invited to a meet-and-greet with the Chair of the AEC in need of additional members and the AE Office Manager.
 - 6.3.2. Following the meet-and-greet, if the potential member is still keen to join an AEC, they will be invited to observe an AEC meeting for the relevant AEC.
 - 6.3.3. Following the meeting observation, the relevant Chair will be consulted, and the potential member will be followed up to see if they would be a good fit for the AEC.
 - 6.3.4. Upon agreeing to join an ARA AEC, members will be sent a Letter of Offer and Welcome Pack from the HR department of the Baker Institute. This pack will include documents that must be signed and returned to HR for processing of the appointment, the addition of new appointees to the Baker Information Technology (IT) system and the allocation of a Baker email address. Members will also be required to attend the relevant inductions (OHS and HR).
 - 6.3.5. On completion of the steps listed above, the AE Office will provide the member with the relevant documentation, organise an induction to PAC and any training required to get started.
- 6.4. Reappointment of the AEC members:
 - 6.4.1. Reappointment of AEC members, at the end of their 3-year term, is subject to:
 - 6.4.1.1. Members nominating for their position for another term on the AEC.
 - 6.4.1.2. Discussion of the nominations with the AEC Chair.
 - 6.4.1.3. Performance review of members.
- 6.5. AEC Chair:
 - 6.5.1. The GAP Committee, subject to Licence Holder Nominee approval, will appoint an AEC Chair who possesses the relevant attributes to bring impartiality to the consideration of applications submitted to the AEC, skills to manage the business of an AEC, to communicate, negotiate and resolve conflict with an understanding of the relevant ethical and animal welfare issues.
 - 6.5.2. The Chair may hold a senior position within the ARA or can be an external appointee.
 - 6.5.3. The Chair must accept the Terms of Reference as a condition of appointment.
 - 6.5.4. In relation to the AEC, the Chair will;
 - 6.5.4.1. Be considered a voting member of the AEC and their attendance at meetings needs to be considered when determining if a meeting is balanced.

- 6.5.4.2. Ensure that the AEC operates in accordance with the principles and requirements of The Australian Code and relevant legislation, the relevant policies of the GAP Committee and the agreed AEC procedures.
 - 6.5.4.3. Confirm that each meeting is quorate and balanced before decisions are made.
 - 6.5.4.4. Work with the relevant AE Administrator to ensure that proposals are considered by the AEC and the outcomes conveyed to investigators and teachers in a timely manner.
 - 6.5.4.5. Represent the AEC in any negotiations with licence nominees.
 - 6.5.4.6. Oversee all requirements of the AEC to report and review its operations as outlined in The Australian Code.
 - 6.5.4.7. Provide a report to the GAP at least annually which details the activities of the AEC. This will be done by providing a copy of the Annual Report to the Institutions that is completed by the AEC and provided to the Licence Holder nominees.
 - 6.5.4.8. Advise the AE Office as soon as possible of any intended absences.
 - 6.5.4.9. Prior to taking any period of unavailability, nominate a member to be acting Chair in their absence and delegate their responsibilities to an acting Chair and ensure that they know exactly what is expected of them.
 - 6.5.4.10. In the unexpected 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.
- 6.5.5. Other responsibilities of the Chair include:
- 6.5.5.1. Being a member of the Licence Holder Nominee Committee and attending the scheduled meetings.
 - 6.5.5.2. Meeting with the individual Licence Holders once a year to review the function of the AEC and discuss the Annual Report to the Institution.
 - 6.5.5.3. Being a member of the GAP Committee and attending the scheduled meetings.

7. Animal Ethics Administrator

- 7.1. The institutions shall provide AE Administrators(s) to support the AEC(s). The AE Administrator will be the first point of contact for investigators wishing to access the AEC.
- 7.2. The AE Administrator will not be a voting member of the AEC but will have substantial experience in administration of an AEC and detailed knowledge of related issues.
- 7.3. The AE Administrator will:
 - 7.3.1. Report directly to the AE Office Manager.
 - 7.3.2. Be allocated as AE Administrator to one of the two ARA AECs and be responsible for all business relating to that Committee.
 - 7.3.3. Distribute all relevant documents (minutes, correspondence, proposals, project reports, AEC decisions and AEC procedural documents etc.) in a timely manner, usually allowing two weekends before each the respective AEC meetings.

- 7.3.4. Maintain a filing system for the provision of audit, including a record of reported adverse events.

8. Animal Ethics Office Manager

- 8.1. An AE Office Manager will be appointed to oversee the functioning of the AE Office.
- 8.2. The AE Office Manager will:
 - 8.2.1. Manage the overall business of the AE Office.
 - 8.2.2. Manage the AE Administrators, allocating them to an ARA AEC(s).
 - 8.2.3. Provide advice and guidance to the AE Administrators to aid them in completing their roles.
 - 8.2.4. Will be available to attend AEC meetings as required but will not attend all AEC meetings.
 - 8.2.5. Ensure the development of standard processes within the AE Office and produce detailed manuals to assist with this.
 - 8.2.6. Handle grievances that come through the AE Office.

9. Business Operations

- 9.1. AE-related Committees:
 - 9.1.1. The Alfred Research Alliance has two separate AECs – AEC A and AEC B.
 - 9.1.2. The GAP Committee is responsible for maintaining consistency of policies and operating procedures across the two AECs.
- 9.2. Distribution of Business:
 - 9.2.1. Applications are distributed in accordance with the *Policy on the Distribution of business to Alfred Research Alliance Animal Ethics Committees*.
- 9.3. Conduct of Meetings:
 - 9.3.1. Meetings shall be conducted in accordance with the operating procedures established by the AEC under these Terms of Reference.
 - 9.3.2. All business before an AEC must be assessed on the basis of the information provided, as set out in section 2 of The Australian Code.
- 9.4. Correspondence:
 - 9.4.1. Written correspondence conveying the AEC's advice to the applicant or the Institution, as appropriate, shall be completed as soon as practicable within 1 week (5 working days) of the relevant meeting.
 - 9.4.2. AEC members are to use their Baker emails as their primary source of communication.
 - 9.4.3. Generally, all communication to investigators should come through the AE Office. If communication is not sent from the AE Office, then the AE Office must be Cc'd in the communication.

9.5. Meeting Frequency and Documents:

9.5.1. General meetings:

9.5.1.1. The time and venue of general meetings of the AEC shall be determined by the AE Office in November-December of the previous year to prepare for the New Year. The meeting dates will be circulated to all relevant AEC members to ensure they suit the majority of members.

9.5.1.2. There will be 11 to 12 general meetings a year per AEC.

9.5.2. Annual Report Meetings:

9.5.2.1. There will be one annual report meeting each year, in March-May, to review all the annual reports (progress and final) that have been submitted for the previous year.

9.5.2.2. Any annual reports not submitted at the time of the meeting will be discussed by the AEC and appropriate action will be determined. This may include escalation to the Licence Holder Nominees or suspension of the project etc.

9.5.2.3. This meeting may be in addition to the general meetings and will be scheduled around the regular meeting dates for the year.

9.5.2.4. No new business (i.e. new experimental application) will be reviewed at this meeting.

9.5.2.5. SOPs and guidelines may be reviewed at this meeting.

9.5.2.6. Adverse event reports and modification applications may be allocated to this meeting if the AEC Chair determines that they cannot wait until the next, general AEC meeting.

9.5.3. Special Meetings:

9.5.3.1. The AEC may decide to conduct special meetings if the business to be dealt with is urgent or extraordinary. Such meetings will be organised by the AE Office as needed and will be conducted in the same manner as the general meetings (i.e. the relevant AE Administrator will create and circulate an agenda as soon as possible prior to the meeting and minutes will be taken)

9.5.4. Meeting Agenda and Relevant Documents:

9.5.4.1. The agenda pages are to be the running sheet for a meeting and the AE Office will use them to advise the AEC why items are on the agenda and any background information that members may need.

9.5.4.2. For standard meetings, the AE Administrator shall circulate no less than 2 weekends (12 days) prior to a general meeting, an agenda setting out the business before the AEC and all relevant proposals and related correspondence.

9.5.4.3. For special meetings, the AE Administrator shall circulate as soon as possible prior to the special meeting an agenda setting out standing business before the AEC and all relevant proposals and related correspondence.

9.5.5. Meeting Minutes:

- 9.5.5.1. The AE Administrator will prepare the minutes from an AEC meeting and send them to the Chair for acceptance no more than 15 days after a meeting.
- 9.5.5.2. The minutes are to specify each item of business discussed, summarise essential items of discussion, and record the decisions and actions to be taken.
- 9.5.5.3. Once the AEC Chair has accepted the meeting minutes, they will be confirmed at the next meeting of the AEC.

9.6. Attendance of meetings:

- 9.6.1. 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.
- 9.6.2. Categories C and D together must represent at least one-third of the voting members present at the meeting.
- 9.6.3. Unless a quorum is in attendance the AEC may discuss proposals but must not approve or reject proposals.
- 9.6.4. The achievement of a quorum at meetings may be facilitated by video-linking or teleconferencing of some members in circumstances, where face-to-face attendance is not possible. Such remote members may authorise the AE Administrator or Chair to record their support of any proposals or other decision outcomes.
- 9.6.5. Any duly convened meeting at which a quorum is in attendance shall be competent to consider and resolve any business of the AEC and shall have and may exercise all the functions of the AEC.
- 9.6.6. There may be times where face-to-face meetings are unable to proceed. In this instance, all attendees will be expected to attend a meeting via video-linking.

9.7. Review of experimental, tissue and breeding applications (including modification applications).

The review outcome of these items will be communicated to researchers within 1 week (5 business days) of the meeting date.

- 9.7.1. Only those experiment protocols which conform to the requirements of all relevant sections of The Australian Code and legislation may be approved.
- 9.7.2. The AEC has the authority to accept or reject proposals based on ethical, welfare, scientific and/or educational merit.
- 9.7.3. If the AEC deems that the information provided in the application is inadequate, inconsistent, or incomplete, the proposal must be sent back to the researcher to be rewritten.
- 9.7.4. The AEC has the authority to impose conditions as part of the approval process.
- 9.7.5. Proposals must be considered and approved only at scheduled or special meetings of AEC. Minor modifications to existing proposals can be approved at any time by the AEC Executive as outlined in 9.11.
- 9.7.6. The AEC must provide approval to researchers in writing. This is done via the online database, Conduit.

9.7.7. If relevant, SOPs must be referenced in all applications as outlined in the *Policy on the Use of Standard Operating Procedures (SOPs) in relation to AEC Applications*. Failure to do this will result in the application being sent back to be amended.

9.8. Review of SOPs, annual reports and unexpected adverse event reports:

The outcome of the review of these items will be communicated to researchers within 1 week (5 business days) of the meeting date.

9.8.1. SOPs

- 9.8.1.1. SOPs associated with applications must be approved by the AEC and must have been reviewed within the previous three years.
- 9.8.1.2. Early in the year of expiration, the author(s) of any SOPs will be notified that their documents need renewal. They will be provided a word version of the document and asked to submit the updated document for review by the AEC. The author will be given a date of submission, which will usually be in the first half of the year (prior to 30 June).
- 9.8.1.3. If they fail to submit an SOP for review by the specified submission date, a reminder will be sent to the researcher to prompt them to submit the updated document.
- 9.8.1.4. After the 30th June, any non-renewed SOPs will be included in the AE Office report to the Animal Users Group and it is up to them to manage any SOPs, suggesting that they be renewed under a different author.
- 9.8.1.5. At the same time that the Animal Users Group is being notified of expiring SOPs, the AE Office may send an email to all researchers advising of an SOPs expiration and asking if anyone wants to take over the responsibility for it.
- 9.8.1.6. At the end of the year, a researcher communication will be sent to investigators across the ARA site advising them of SOPs that have expired and are no longer active.
- 9.8.1.7. If an SOP expires, it cannot be quoted in new applications. The last reviewed version of the SOP can still be used on active (previously approved) projects.

9.8.2. Annual Reports

- 9.8.2.1. Annual reports are to be submitted in February-March each year on a date to be determined by the AE Office.
- 9.8.2.2. Any project that was approved/active in the previous calendar year must submit a report.
- 9.8.2.3. Any annual reports that are not submitted by the specified deadline will be followed up by the AE Administrator. If the report is still not submitted the matter will be escalated to the AEC for discussion where the AEC will consider suspending the project(s) for which annual reports have not been submitted by the deadline.
- 9.8.2.4. Annual reports will be reviewed at a specific meeting early in the year, usually around March or April.

9.8.3. Unexpected Adverse Event (UAE) Reports

- 9.8.3.1. UAE reports should be submitted in accordance with the *Policy and Procedures for Reporting Adverse Events*.
- 9.8.3.2. When they are submitted, UAEs will be assigned to the next available meeting. If the relevant agenda has been finalised at the time of submission of the report, the AE Administrator will consult with the Chair to decide if the report should be tabled at the upcoming meeting.
- 9.8.3.3. Any UAE reports that are not submitted within 1-2 weeks of the preliminary report will be followed up by the AE Administrator. If the report is still not submitted the matter will be escalated to the AEC for discussion where the AEC will consider suspending the project.

9.9. Review of incoming delegations (projects being conducted on the ARA site but approved by another AEC).

The review outcome of these items will be communicated to researchers within 1 week (5 business days) of the meeting date.

- 9.9.1.1. The ARA AECs must only accept responsibility for delegated projects that clearly state who is responsible for all activities related to the use of animals.

9.10. Facility inspections

- 9.10.1. All facilities listed on any of the licences held by the ARA AE Office will be inspected annually, unless in exceptional circumstances, by an Executive of the AEC.
- 9.10.2. The AE Office will prepare a report of the inspection for inclusion on the agenda of the next AEC meeting. The report will include the names of AEC members who attended the inspection, and a list of areas visited and the findings.

9.11. AEC Executives and out-of-session review:

- 9.11.1. The AEC may establish an executive at any time from the available members and must include the Chair and at least one member from category C or D. The executive may:
 - 9.11.1.1. Approve minor modifications (that fit the criteria outlined in the *Policy on Minor Amendments that can be Considered by an AEC Executive*) to projects for review with the decision to be ratified at the next meeting of the AEC
 - 9.11.1.2. Review specific urgent action required in response to reports of adverse events or emergencies.
 - 9.11.1.3. Inspect new rooms to be added to a Licence.
 - 9.11.1.4. Be authorised, by the AEC, to lift a suspension when specific corrective actions are completed between AEC meetings. This would then be ratified at the next AEC meeting.
- 9.11.2. Review by an AEC Executive:
 - 9.11.2.1. Review should be completed within 5 business days, and absolutely no more than 10 business days, of AEC Executive members receiving a notification that the item has been assigned to them. The AE Administrator will send email reminders on the day the review is due and then follow up with text message reminders the day after.

- 9.11.2.2. AEC Executive review items will revert to review at the next AEC meeting if the Executive has not completed its review within the specified timeframe(s). Members will be sent the additional agenda items by email on the Friday before a meeting to allow them 5 days to review the additional items.
- 9.11.2.3. If new or significant actions are raised by the Executive, the AEC Chair and AE Administrator should withdraw the application from out-of-session review and re-agenda it for review by the AEC at the next available meeting.
- 9.11.2.4. The investigator may be invited to be interviewed by the full AEC if their application has been withdrawn from out-of-session review and re-agended by the full AEC at the next available meeting to discuss any new or significant actions raised by the Executive.

9.12. Chair and out-of-session review:

9.12.1. The Chair may authorise specific urgent actions required in response to reports of adverse events or emergencies.

9.12.2. Chair review out-of-session

- 9.12.2.1. Out-of-session reviews should be completed within 1 week of receiving a notification that the item has been assigned for review by the Chair. The AE Administrator will send email reminders on the day the review is due and then follow up with text message reminders the day after.

9.13. Voting and decision making:

9.13.1. All members of the AEC have equal status and are entitled to put forward their views.

9.13.2. Decisions at a meeting of the AEC shall be determined by consensus as defined by The Australian Code. Consensus decision-making is a group decision-making process in which group members develop and agree to support a decision in the best interests of the whole group or common goal.

9.13.3. 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. This may be by conversation during the meeting. If consensus is still not achievable, the AEC should allow members time to review their positions, such as calling a recess or deferring the matter to a later meeting, and then allow time for further discussion. The matter should then proceed to a majority decision (over 50% of the votes) with the members present. Voting may be by any means deemed appropriate by the Chair, including a show of hands or secret ballot.

9.13.3.1. The total of each response will be recorded in the minutes i.e. number for and number against.

9.13.3.2. If a member(s) votes no, they will have the option for their name to be recorded in the minutes.

9.13.4. No person at a meeting, other than an appointed member, may have the right to vote (i.e. a proxy cannot be nominated).

9.14. Seeking external expert advice

By an AEC

- 9.14.1. An AEC may seek advice or clarification on aspects of proposals from external experts.
- 9.14.2. The AEC must reach an agreement on how advice or clarification can be sought from external experts without breaching confidentiality. Any person consulted who is not an ARA AEC member must sign a confidentiality agreement prior to consultation. The advice received must be circulated to all AEC members in writing.

By an individual member

- 9.14.3. Individual members who feel they need to consult a person who has more specialised knowledge should raise their questions or concerns with the AEC Chair who may grant limited permission for the member to seek external advice. The member must identify who they wish to consult, their reasons for consulting that person and the issues and questions they wish to discuss. Confidentiality must be maintained, and any person consulted on AEC matters must sign a confidentiality agreement prior to consultation. The information acquired by the member must be circulated to all AEC members in writing.

9.15. Grievance with Administration:

The following grievance procedures will be adopted:

- 9.15.1. In the case of dissension with an AEC decision, the Chair, on behalf of the AEC, may:
 - 9.15.1.1. Attempt to resolve the matter with the dissenting person(s)
 - 9.15.1.2. Seek an opinion from the Licence Holder Nominee or nominated responsible person either at the AEC meeting or as soon as possible afterwards.
 - 9.15.1.3. Place the matter before the Licence Holder Nominee or nominated responsible person at a formal meeting for resolution. This meeting will be attended by the Chair, AE Administrator, dissenting person(s) and other nominated AEC member(s)
 - 9.15.1.4. Refer the decision and discussions back to the AEC.
 - 9.15.1.5. Should there be continued dissension, the matter shall be referred to the GAP Committee.
- 9.15.2. Where there are concerns that the requirements of the Australian Code, relevant Guidelines or policies are not being met:
 - 9.15.2.1. The AEC will investigate and seek a written explanation of the incident from the applicant or other relevant persons.
 - 9.15.2.2. The written explanation will be distributed to all AEC members for comment and if necessary, an extraordinary AEC meeting may be convened for further discussion.
 - 9.15.2.3. The Chair will report the incident and the AEC's findings to the respective licence nominee for information and may provide recommendations for further action.
- 9.15.3. Should an AEC member, after the above procedures have been exhausted, still be unsatisfied that appropriate action has or will be taken to safeguard animal welfare, then that member should advise the GAP Committee and the respective licence nominee and may report their dissent to Animal Welfare Victoria.

10. Financial Arrangements

10.1. Sitting Fees for Members

Appointed external members will be paid a sitting fee for each of the scheduled meetings throughout a year. The fee is to cover all expenses including travel and home office.

A sitting fee would also be received for attendance at the annual facility inspection day(s).

- 10.2. Sitting fees will not be paid for attendance of AEC members at an extraordinary meeting of the AEC (i.e. those outside the standard scheduled meetings) or ad hoc facility inspections.

11. Insurance of Members

Under 14 (3) of the Accident Compensation Act 1985, an appointed member of the AEC is deemed to be an employee of the Crown while attending meetings or while undertaking any directed or approved activity on behalf of the AEC. Cover is provided by WorkCover.

12. Revision of Terms of Reference and Operating Procedures

These Terms of Reference and operating procedures will be reviewed annually or as necessary in response to changes in the legislation, GAP Committee policies and/or concerns expressed by members of the AEC.

Any changes to the TOR will be reviewed and approved by GAP Committee.

Record of Version

Version	Version Reason	Author(s)	Date
1.0	New		Feb 2011
2.0	Revision		Nov 2015
3.0	Revision		Sep 2017
4.0	Revision		Nov 2019
5.0	Revision	D. Ramsey, A. Mitchell & J. Nash	Sep 2021
5.1	Minor changes in response to review by AE Compliance Officer. The following sections were updated: 3.2.2.4, 5.2.3.3, 5.2.4, 6.5.4.3, 9.13.3.1 & 9.13.3.1	J. Nash & D. Kaiserman	Oct 2021