Terms of Reference and Operating Procedures

Approved by the Alfred Research Alliance AEC Governance & Policy Committee

Date: November 2019
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1. DEFINITIONS

1.1 Animal Ethics Committee (AEC): a bona fide animal ethics committee, the principal function of which is to determine the ethical standards that are to be applied in the carrying out of scientific procedures as outlined in the ‘Code for the Care and Use of Animals for Scientific Purposes’ under Part 3 of The Prevention of Cruelty to Animals Act 1986 and Regulations 2008. At Alfred Research Alliance, AEC refers to both AEC A and AEC B.

1.2 AEC: The Alfred Research Alliance Animal Ethics Committees in Victoria, Australia. There are two such committees referred to as AEC A and AEC B.

1.3 AEC Governance & Policy Committee (GAP): the governing committee for AEC A and AEC B whose function it is to provide Governance and Policy across both AECs and has representation from all licence holding institutions that utilise the Alfred Research Alliance AECs.

1.4 Institutions: those licence holding institutions listed on the scientific procedures premises licences (SPPLs) and specified animals breeding licence (SABL) that use the Alfred Research Alliance AECs.

1.5 Licence nominee: each nominee on the respective SPPL or SABL.

1.6 Department: the Department of Economic Development, Jobs, Transport and Resources.

1.7 Member: a person appointed to the Alfred Research Alliance AEC by the GAP.

1.8 Proposal: that as defined in The Australian Code ie "a written application to carry out a project for consideration by an AEC”

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


2. FUNCTION OF THE AEC

The primary function of the AEC is to ensure on behalf of the 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 Approve and review 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 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. These should be done preferably annually or at least once every two years. 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 GAP (GAP) committee any measures, including training or supervision, needed to ensure that the standards of *The Australian Code* are maintained

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*, grievances with AEC decisions, including referral to the GAP and the Department as required; (see section 7.8)

2.1.11 Provide advice as appropriate to matters referred by the GAP committee

2.1.12 Report at least annually to the licence nominees and GAP committee on the AEC’s activities.

2.2 The AEC may withdraw or suspend approval for any project where necessary according to the following process:

   2.2.1 Review of written report from any party on non-compliance, breaches or adverse events with regards to animal usage

   2.2.2 Further investigation 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 the Department outlining recommendations and remedial actions as appropriate

   2.2.4 If an approval is suspended, subsequent continuation of the project and/or publishing of the data etc is 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 There may be additional outcomes subject to the advice of the Department and/or licence nominee.

3. RESPONSIBILITY OF ANIMAL ETHICS COMMITTEE MEMBERS

The primary responsibility of members is to ensure that the use of animals for scientific procedures and teaching is ethically justified, provides for the welfare of the animals and incorporates the principles of Replacement, Reduction and Refinement based on collective experience and knowledge. 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 will be maintained. Should external advice be required, this will be sought following de-identification of the project, investigators involved and site of the project.

   3.1.2 A member resigning or retiring from the AEC shall not, without the express written approval of the GAP committee, expose or discuss confidential information
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 chairperson may

3.2.2.1 Refuse the member the right to speak to the business

3.2.2.2 Refuse the member the right to vote on that business

3.2.2.3 Require the member to withdraw from a meeting for the period of discussion and resolution of that business.

4. MEMBERSHIP OF THE AEC AND TERM OF OFFICE

4.1 Term of Office

Appointment of new members will be ratified by the GAP committee. In general, a member will sit on the AEC for a minimum of 1 year and maximum of 3 years. After 3 years, the member may re-apply for a second 3 year term. Members must not be renewed after serving for 2 full terms (i.e. 6 years total).

4.2 Number and Category of Members:

4.2.1 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:

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.

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.

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.

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.

4.2.2 In selecting members, regard for the need for knowledge and experience concerning ethical use of animals in scientific procedures or teaching. In addition to the prescribed Categories A to D, persons with knowledge of the routine care and husbandry of animals involved in projects may be appointed.

4.2.3 Categories C and D must together represent at least one-third of the AEC membership.
4.2.4 The AEC must have a quorum in attendance to conduct meetings. A quorum shall consist of at least one member from each category.

4.2.5 Before appointment, all members of the AEC should acknowledge in writing their acceptance of the terms of reference of the AEC and any requirements for confidentiality required by the GAP committee, including how advice may be sought without breaching confidentiality.

4.3 Varying and Replacing the Members, Absentee Members:

4.3.1 The AEC may recommend to the GAP committee that membership be amended.

4.3.2 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 procedures or teaching. Co-opted members of the AEC cannot exercise voting rights and must adhere to the general principles of confidentiality as per voting members.

4.3.3 In the event of a member being obliged or electing to retire or resign during the term of the AEC, a suitable replacement member will be nominated. Details of the eligibility of the nominated member should be provided to the Department before they attend the first AEC meeting. The Department may provide guidance on whether the member meets the criteria of the nominated category.

4.3.4 Where a member fails to attend three consecutive meetings of the AEC without providing an apology or excuse, or is demonstrably unable to maintain an adequate level of participation, the AEC shall recommend to the GAP committee that the member be replaced by a new appointee of the same category.

5. NOMINATIONS AND APPOINTMENT OF THE COMMITTEE

5.1 Nominations of Category A to D members:

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

5.1.1 Existing Victorian AEC members of any category to nominate themselves
5.1.2 Other potential members of any category
5.1.3 Veterinarians with experience specific to the species of animals used by the institution
5.1.4 Category C members

5.2 Appointment of Category A to D members:

Members will be required to sign a letter of undertaking regarding maintaining confidentiality and acceptance of the terms of reference in accordance with item 2.2.11 of The Australian Code.

5.3 Reappointment of the Committee:

Not less than three months prior to the expiry of the term of appointment and subject to the continuance of the AEC, nominations will be called for in accordance with 5.1 for the next term of appointment. With the objective of continuance of effective committee functioning, a staggered re-appointment of AEC members will be attempted.

5.4 Chairpersons:

5.4.1 The GAP committee will appoint a chairperson 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. The chairperson must accept the agreed terms of reference as a condition of appointment.

The chairperson will;

5.4.2 Ensure that the AEC operates in accordance with the principles and requirements of *The Australian Code*, the relevant policies of the GAP committee and the agreed AEC procedures

5.4.3 Ensure that proposals are considered by the AEC and the outcomes conveyed to investigators and teachers in a timely manner

5.4.4 Represent the AEC in any negotiations with management

5.4.5 Oversee all requirements of the AEC to report and review its operations as outlined in *The Australian Code*

5.4.6 Ensure AEC records are maintained and made available for review by the GAP committee and authorised external reviews

5.4.7 Provide a report to the GAP at least annually which details the activities of the AEC

5.4.8 In the absence of the chairperson at any meeting of the AEC, the members present shall appoint one of their members as acting chairperson at that meeting.

6. EXECUTIVE OFFICER

The role of the Executive Officer:

6.1 The Institutions shall provide an executive officer through the Research Office to support the AEC. The executive officer will be the first point of contact for investigators wishing to access the AEC.

6.2 The executive officer will not be a voting member usually but have substantial experience in administration of an AEC and detailed knowledge of related issues.

6.3 The executive officer will ensure that: all relevant documents (minutes, correspondence, proposals, project reports, AEC decisions and AEC procedural documents) as appropriate are distributed to the AEC prior to each meeting, and maintain a filing system for the provision of audit, including a record of reported adverse events.

6.3.1 Documentation related to adverse incidents is to be filed separately.

7. BUSINESS OPERATIONS

7.1 AEC Composition:

7.1.1 The Alfred Research Alliance AEC comprises two separate committees (AEC A and AEC B)

7.1.2 The GAP committee is responsible for maintaining consistency of policies and operating procedures across the two AECs.

7.2 Distribution of Applications:

7.2.1 Applications are distributed for review in order of receipt with an equal division between each AEC. An exception to this may be when the same chief investigator/laboratory submits multiple applications of a similar nature, in which case an effort will be made to group these submissions for review by the same AEC, regardless of the order of receipt.
7.2.2 Once an application has been seen by either AEC A or B, any future correspondence or amendments associated with that project will remain within the same AEC.

7.3 Conduct of Meetings:

Meetings shall be conducted in accordance with the operating procedures established by the AEC under these Terms of Reference. Proposals must be assessed in accordance with the relevant information required in section 2 of *The Australian Code*.

7.4 Correspondence:

7.4.1 Institutional, project or procedural related correspondence from and to the AEC between meetings shall be circulated to all members promptly and a copy filed by the executive officer.

7.4.2 Written correspondence conveying the AEC’s advice to the applicant or the institution, as appropriate, shall be completed as soon as practicable after the relevant meeting.

7.5 Meeting Frequency and Documents:

7.5.1 General meetings:

The time and venue of general meetings of the AEC shall be determined by the AEC but should be at least four times per year.

7.5.2 Special Meetings:

The full AEC, or quorate sub-group of members, may elect to conduct special meetings, if the nature of the required business is urgent or extraordinary.

7.5.3 Meeting Agenda and Relevant Documents:

The chairperson shall ensure that the meeting agenda will consider AEC business as required by AEC’s responsibilities. The executive officer shall circulate not less than 10 days prior to a general meeting or a special meeting, an agenda setting out standing business before the AEC and all relevant proposals and related correspondence.

7.5.4 Meeting Minutes:

The executive officer will maintain and circulate to members as soon as practicable minutes of the meeting specifying each item of business discussed, summarising essential items of discussion, and recording the decisions reached or advice resolved and actions to be taken. The minutes will be confirmed at the subsequent meeting of the AEC.

7.6 Attendance of meetings:

7.6.1 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. Categories C and D together must represent at least one-third of those members present.

7.6.2 Unless a quorum is in attendance the AEC may discuss proposals but must not approve or reject proposals.

7.6.3 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 Executive Officer or chairperson to record their support of any proposals or other decision outcomes.
7.6.4 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.

7.7 Submission and approval of proposals:

7.7.1 Only those experiments which conform to the requirements of all relevant sections of The Australian Code and legislation may be approved.

7.7.2 The AEC has the authority to accept or reject proposals based on ethical, welfare, scientific and/or educational merit.

7.7.2.1 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.

7.7.2.2 If modifications are made which meet the requirements of the AEC, then the chairperson or an executive may approve the proposal out of session and the project may proceed.

7.7.2.3 The AEC has the authority to impose conditions as part of the approval process.

7.7.3 The AEC is only required to consider completed and signed protocols submitted by the responsible investigator(s) or teacher(s). The organisation may also elect to have proposals signed off by other relevant people such as student supervisor, animal facility manager, the scientific premises licence nominee or field work licence holder.

7.7.4 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 executive (see executive; point 7.8).

7.7.5 The AEC must provide approval to researchers in writing.

7.7.6 Standard Operating Procedures (SOPs) associated with applications must be approved by the AEC and reviewed every three years. AEC members should have access to a copy of the SOPs.

7.8 Executive:

The AEC may establish an executive at any time from the available members and must include the Chairperson and at least one member from category C or D. The executive may only:

7.8.1 Approve minor modifications to projects for review and endorsed at the next meeting of the AEC;

7.8.2 Specify urgent action required in response to reports of adverse events or emergencies.

7.9 Executive review out of session:

7.9.1 If a member of the AEC Executive receives an item for out of session review but is unable to complete their review within 5 business days and/or if new or significant actions are raised by the Executive, the AEC Chair and Secretary should withdraw the application from out of session review and re-agendaed it for review by the full Committee at the next available meeting.

7.9.2 The researcher must be invited to be interviewed by the full Committee if their application has been withdrawn from out of session review and re-agendaed by the full Committee at the next available meeting to discuss any new or significant actions raised by the Executive.
7.10 Voting:

7.10.1 Decisions at a meeting of the AEC shall be determined by consensus as defined by *The Australian Code*. Where consensus cannot be reached after reasonable effort to resolve differences, the AEC should explore with the applicant(s) ways of modifying the project that may lead to consensus. If consensus is still unachievable, the AEC should only proceed to a majority decision after members have been allowed a period of time to review their positions, followed by further discussion.

7.10.2 No person at a meeting, other than an appointed member, may have the right to vote.

7.11 Grievance Procedures:
The following grievance procedures will be adopted if there is dissent:

7.11.1 In the case of dissension with a committee decision the chairperson, on behalf of the AEC, may:

7.11.1.1 Attempt to resolve the matter with the dissenting person(s)
7.11.1.2 Seek an opinion from the licence nominee or nominated responsible person either at the AEC meeting or as soon as possible afterwards
7.11.1.3 Place the matter before the licence nominee or nominated responsible person at a formal meeting for resolution. This meeting will be attended by the chairperson, executive officer, dissenting person(s) and other nominated AEC member(s)
7.11.1.4 Refer the decision and discussions back to the AEC.
7.11.1.5 Should there be continued dissension, the matter shall be referred to the GAP committee

7.11.2 Where there are concerns that the requirements of the Code, relevant Guidelines or policies are not being met:

7.11.2.1 The AEC will investigate and seek a written explanation of the incident from the applicant or other relevant persons
7.11.2.2 The written explanation is distributed to all AEC members for comment and if necessary an extraordinary AEC meeting may be convened for further discussion
7.11.2.3 The chairperson will report the incident and the AEC’s findings to the licence nominee for information and may provide recommendations for further action

7.11.3 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 licence nominee and may report their dissent to the Department.

8. **FINANCIAL ARRANGEMENTS**

8.1 Sitting Fees for Members:

   Appointed members not employed by the licence nominees may be paid a meeting fee. The fee is to cover all expenses including travel and home office.

9. **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.
10. 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 policy or concerns expressed by members of the AEC.

I, _________________________________________

agree to comply with the Terms of Reference detailed above.

Signed: ________________________________ Date: _______________