1. Purpose

The Walter and Eliza Hall Institute of Medical Research (Institute) has established an Animal Ethics Committee (AEC) to meet its obligations under the Australian code for the care and use of animals for scientific purposes, 8th edition 2013 (Code)\(^1\) and Prevention of Cruelty to Animals Act 1986 (Vic) (Act).

These Terms of Reference are prepared in accordance with section 2.2.18 of the Code to support the proper functioning of the AEC.

These terms of reference should be read in conjunction with the Code. Where inconsistencies exist between these terms of reference and the Code, the Code will prevail.

2. Authority

The AEC has been established by the Institute to assist in ensuring that all activities relating to the care and use of animals for scientific purposes are conducted in compliance with the Code.

The AEC must:

- review applications for projects and approve only those projects that are ethically acceptable and conform to the requirements of the Code
- review applications for activities associated with the care and management of animals in facilities, including procedures applicable to breeding programs integral to the maintenance of an animal line, and approve only those activities that are ethically acceptable and confirm to the requirements of the Code
- conduct follow-up review of approved projects and activities and allow the continuation of approval for only those projects and activities that are ethically acceptable and confirm to the requirements of the Code
- monitor the care and use of animals including housing conditions, practices and procedures involved in the care of animals and facilities.

Governing principles

In undertaking its role, the AEC must consider the Governing Principles contained in section 1 and the governing principles for AECs included in section 2.3 of the Code.

3. Responsibilities of AEC

The AEC will undertake its role consistent with section 2.3 of the Code. This includes:

- ensure, on behalf of the Institute that all activities relating to the care and use of animals are conducted in compliance with the Code (s2.3.1)
- review and approve new and ongoing activities (ss2.3.3 – 2.3.16)

\(^1\) Note that references brackets refer to sections in the Code.
• monitor the care and use of animals (ss2.3.17 – 2.3.23)
• take action regarding unexpected adverse events (s2.3.24)
• take action regarding non-compliance (s2.3.25)
• approve guidelines for the care and use of animals (s2.3.26)
• provide advice and recommendation to the Institute (ss2.3.28-29)

3.1. Ethical review and approval
In conducting an ethical review and considering approval of a project the AEC will act consistently with 2.3.3 to 2.3.16 of the Code.

Term of projects
The AEC will consider the number of years that the project is funded, any milestones or stages outlined in the project and any formal agreements between the Institute and funding bodies determining the period of approval.

Subject to the above the maximum initial period of approval for a project will be three years. Extensions of up to two years may be made in exceptional circumstances where the AEC is satisfied that the project will continue to meet best practice.

3.2. Monitor the care and use of animals
The AEC will monitor the care and use of animals consistent with sections 2.3.17 to 2.3.23 of the Code.

Facility inspections
The AEC will conduct inspections of each facility at least annually. Any facility inspection must include either a category C or D member (s2.3.20 of the Code), though all members are encouraged to attend.

The AEC should promptly report any concerns raised in these inspections to the Institute for immediate action.

Visits of facilities may form part of the AEC meeting agenda which will record the attendees and information outlined in section 2.3.22 of the Code.

3.3. Take action regarding unexpected adverse events
The AEC will take action regarding non-compliance events consistent with section 2.3.24 of the Code.

3.3.1. The AEC will take action regarding non-compliance
The AEC will take action regarding unexpected adverse events consistent with section 2.3.25 of the Code and consistent with Institute policies on handling suspected research misconduct.

3.3.2. The AEC will provide advice and recommendations to the Institution
The AEC must provide advice and recommendations to the Institution regarding the care and use of animals for scientific purposes and strategies required to ensure that the requirements of the Code are maintained and that matters affecting animal wellbeing are addressed.

All correspondence of this nature should be directed to the licence nominee and the Director of the Institute.

4. Membership
The membership of the AEC will be made up of:

• Chairperson (non-voting)
• Category A-D members (voting)

The Institute may also appoint observers to attend meetings to support the Committee. These observers are not members of the Committee and do not have voting rights.

Decisions of the AEC are made by voting members.

4.1. Chairperson
The Institute shall appoint a Chairperson to the AEC consistent with section 2.2.2 and 2.2.3 of the Code.

External appointments
When an external appointment is made to the role of Chairperson the position will be remunerated to reflect the level of responsibility and commitment involved in carrying out the role.
Responsibilities
The Chairperson is responsible for:

- impartially guiding the operation of the AEC
- resolving conflicts of interest related to the business of the AEC
- representing the AEC in negotiations with the Institute’s management.

Voting rights
The Chairperson does not have voting rights in their capacity as Chairperson.

Deputy Chair
The AEC shall appoint a Deputy Chair to act as Chair when the Chairperson is not available. In appointing the Deputy Chair consideration should be given to the requirements of the Code under sections 2.2.2 and 2.2.3.

4.2. Members
The membership of the AEC shall be constituted in accordance with section 2.2.4 of the Code and must include at least one 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.
- **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.

Responsibilities
As a member of the AEC each member is responsible for deciding whether, in their own judgement, an application or other matter under consideration by the AEC is ethically acceptable (refer to section 1.3 of the Code) and meets the requirements of the Code.

To fulfil this responsibility, members should:

- Be familiar with the Code and other policies and guidelines relevant to the business of the AEC.
- Provide opinions on the ethical acceptability of applications and other matters under consideration of the AEC.
- During their appointment to the AEC and before any deliberations of the AEC, members must declare any interest that could influence the objectivity of their decision making.
- Members must maintain confidentiality regarding the content of applications and the deliberations of the AEC.

Payment to members
Members will receive a stipend to cover expenses associated with their appointment consistent with any guidelines provided by Animal Welfare Victoria.

Voting rights
Members of the AEC who hold a position under Category A-D are voting members of the committee.
Balance of membership
Categories C and D must together represent at least one-third of the AEC membership (s2.2.8).

4.3. Access to expertise (s2.2.7)
The AEC may invite people with specific expertise to attend the meeting and provide advice as required.

4.4. Recruitment, appointment, reappointment and retirement of voting members (s2.2.9)

Appointment of voting members and Chairperson
The institute makes all appointments of voting members and the Chairperson to the AEC. All appointments must be in writing and provide confirmation of the period of the appointment.

Prior to the confirmation of appointment of prospective voting members must:
- declare any interests that may impact on their ability to undertake their role. Where a conflict is shown to exist it will be managed in accordance with the Code and Institute policies and procedures.
- acknowledge their acceptance of these terms of reference
- complete the Institute’s confidentiality agreement
- agree to complete the Institute’s induction program for AEC members and participate in ongoing training.

(ss 2.2.10 to 2.2.12)
The AEC Convenor is responsible for maintaining records related to the appointment of members including the Chairperson.

Term
Voting members of the AEC may be appointed for terms of up to three years.

Reappointment
Members may be reappointed to a position for up to three terms or a maximum of nine years.

Previous members who have met the nine-year term limit may seek reappointment after a period of five years when their term will re-commence.

Retirement and resignation
Members may resign from the AEC by written notice to the Chairperson and copied to the AEC Convenor.

Given the nature of the AEC, members are requested to provide at least two-months’ notice of their resignation.

Observers
The Institute may appoint observers to attend meetings and support the AEC in their role. Observers will usually be staff of the Institute with areas of responsibility or expertise of benefit to the AEC.

The Institute will appoint at least one observer to attend AEC meeting who has expertise in the routine care of animals in the Institute. This person will generally be the head of one of the Institute's animal facilities.

The term and nominations for these roles will be at the discretion of the Institute.

5. Meetings

5.1. Distribution of papers – (s2.2.26 (i))
AEC meeting papers will be distributed at a minimum seven days prior to each meeting.

Late papers may only be distributed if they relate to minor amendments such as the addition of strains or the addition or removal of staff.
5.2. Attendance at meeting

Video or web conferencing – (s2.2.26 (ii))
The Chair may approve for members to attend an AEC meeting using videoconferencing or web conferencing. Teleconferencing may only be used in special circumstance.

Apologies
AEC members must notify the AEC Convenor as soon as possible if they are unable to attend a meeting.

5.3. Quorum – (s2.2.26 (ii))
At any meeting of the AEC at least one representative of each Category A, B, C, D where category C and D members represent at least one-third of the voting members present shall form a quorum.

The AEC can only make decisions relating to the approval of applications, new projects and activities and the ongoing approval of existing projects and activities where a quorum is present (2.3.6).

5.4. Decision making
When assessing applications and reports the AEC will do so in a manner that is fair to applicants and acceptable to all members. (s2.3.7)

Decisions of the AEC are to be made consistent with sections 2.3.10 to 11 of the Code. Note that decisions can only be made by those present during the discussion.

Decisions of the AEC must be made as promptly as possible (s2.3.12). Requests from the AEC to provide additional information should be addressed in a timely manner.

5.5. Conflicts of interest
Conflicts of interest must be declared at the commencement of each meeting.

A person with a perceived or actual conflict of interest in relation to a matter being considered by the AEC must withdraw from the meeting and not participate in discussions. (s2.2.21)

Minutes
All conflicts of interest should be recorded in the minutes of the meeting.

5.6. Frequency – (s2.2.26 (v))
A minimum of nine AEC meetings will be conducted each year.

6. AEC Executive
The Institute has established an AEC Executive.

Membership
The AEC Executive consists of:

- the Chairperson
- At least one member from category C or D

Authority
The AEC Executive has authority to approve minor amendments to approved projects or activities

Minor amendments may include a change to an approved project or activity where the proposed change is not likely to cause harm to the animals, including pain and distress. Examples of minor amendments include:

- addition of suitable experienced personnel
- minor changes to procedures, where minor is defined as any change that has little or not impact on the well-being of the animals involved in the project; for example, verifying dose rates for drugs, needle sizes, routes of administration where the impact to the animals is the same or less than originally approved.
- opportunistic diagnostic or veterinary activities intended to benefit the animals
- reactivation of paused projects.²

² Refer to Animal Welfare Victoria, Guidelines for Conduct of AECs, page 4
The Walter and Eliza Hall Institute will also consider the following as minor amendments:

- removal of personnel
- administrative amendment to approved Standard Operating Procedures where the proposed change is not likely to cause harm to animals, including pain and distress.

The AEC Executive may not approve new applications.

**Ratification**

All decisions of the AEC Executive must be presented for ratification at the next AEC meeting.

### 7. Advice and reporting

**Licence holder**

The Chair of the AEC will meet at least monthly with the licence nominee to proactively address ethical compliance issues.

**Director**

The Chair of the AEC will meet with the Director of the Institute as required, but at least once a year.

**Reports to board**

The AEC will provide a written report to the Board of the Institute at least annually addressing the points outlined in section 2.3.29 of the Code.

See also 3.3.2 of these terms of reference.

**Related Documents**

*Australian code for the care and use of animals for scientific purposes, 8th edition 2013*

*Animal Welfare Victoria - Guidelines for the conduct of animal ethics committees*

**Review cycle**

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**Version History**

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