

ANIMAL ETHICS COMMITTEE (AEC) TERMS OF REFERENCE

Preamble

The Telethon Kids Institute (Institute) is committed to ensuring the ethical, humane, and responsible care and use of animals in research.

The use of animals for scientific purposes and teaching is governed by the *Animal Welfare Act 2002* (WA) (Act) which is administered by the Western Australian Department of Primary Industries and Regional Development, and the National Health and Medical Research Council's (NHMRC) *Australian Code for the Care and Use of Animals for Scientific Purposes 8th Edition 2013* (Code), updated 2021.

The AEC applies a set of principles, outlined in the Code, that govern the ethical conduct of people whose work involves the use of animals for scientific purposes. The role of the AEC is to ensure that the use of animals is justified, provides for the welfare of those animals, and incorporates the principles of Replacement, Reduction and Refinement.

1. Responsibilities

The primary responsibility of the AEC is to ensure that all care and use of animals at Telethon Kids Institute (Institute) is conducted in compliance with the Code. The AEC applies the principles of the Code to govern the ethical conduct of those involved in the use of animals for scientific purposes.

The AEC must:

- i. review applications for projects and approve only those projects that are ethically acceptable and conform to the requirements of the Code;
- ii. review applications for activities associated with the care and management of animals in the Institute 's 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 conform to the requirements of the Code;
- iii. 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 conform to the requirements of the Code;
- v. monitor the care and use of animals, including housing conditions, practices and procedures involved in the care of animals in the Institute's facilities;
- v. take appropriate actions regarding unexpected adverse events;
- vi. take appropriate actions regarding non-compliance;
- vii. approve guidelines for the care and use of animals on behalf of the Institute;
- viii. provide advice and recommendations to the Institute; and
- ix. report on its operations to the Institute.

2. Accountability

The AEC is accountable to the Executive Director of the Institute (Executive Director).

3. The Chair

The Chair is appointed by the Executive Director who should consider an appointment of a person who holds a senior position in the Institute, or a suitable external appointee and who is independent of the care and use of animals for scientific purposes. The Institute must provide the Chair with the necessary support and authority to carry out the role. The Chair may be appointed in addition to Category A to D members¹.

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 the Institute's management.

The AEC may also delegate additional functions to the Chair, such as approval of project extension requests of up to 3 months (with a limit of one such extension request per project); and extension of Standard Operating Procedures (SOPs) timeframes of up to 3 months. Under these circumstances, respective documentation will be submitted to the next available AEC meeting for AEC ratification.

If the Chair is not available, then an acting Chair will be chosen from the AEC members. If the need for an acting Chair is identified between meetings, an acting Chair will be chosen by the Chair or the Executive Director, or by consensus of a majority of the AEC members by email.

4. Composition of the AEC

The AEC comprises:

- Chair
- At least one member of Category A¹
- At least one member of Category B ¹
- At least one member of Category C¹
- At least one member of Category D¹.

The AEC may co-opt people with specific expertise to provide advice as required.

In addition to the members specified above, the following should be in attendance at AEC meetings to provide appropriate support and advice (non-voting members):

- Manager, Research Governance
- Animal Ethics Officer
- Animal Welfare Officer
- Bioresources Manager.

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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 Institute'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 Institute 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 Institute, 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 Institute 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. Support to the AEC

An Animal Ethics Officer (AEO) shall be appointed by the Institute to support the AEC and assist the Chair to manage the regulatory and practical aspects of AEC operations. The AEO (or delegate) will be in attendance at AEC meetings but will not be a voting member of the AEC.

An Animal Welfare Officer (AWO) shall be appointed by the Institute to support the AEC and the Institute by advising and reporting on animal welfare and veterinary matters, providing veterinary care to research animals, and ensuring that activities proceed in compliance with the Code and the decisions of the AEC. The AWO acts as an animal welfare liaison for the AEC and the scientific community of the Institute.

6. AEC Tenure and Appointment

The Executive Director will oversee the appointment, reappointment and retirement of AEC members.

Before appointment, all members of the AEC must acknowledge in writing their acceptance of the terms of reference of the AEC and the Institute's <u>Confidentiality Policy</u> (see also section 8). Appointments are then made on issue of a letter from the Executive Director nominating the member.

The term of office of appointed members is three years with a maximum of two consecutive terms (i.e., six years). In some circumstances the functioning of the AEC will be enhanced by one or more current members having the opportunity to serve more than two terms, should they agree.

A member may resign from the AEC at any time by advising the Chair or the AEO in writing.

Further details can be found in the Institute's <u>Procedures for the appointment, reappointment and</u> retirement of AEC members.

Under the Institute's *Licence to use animals for scientific purposes*, the CEO of the Department of Primary Industries and Regional Development must be notified of all changes to the structure of the AEC within 30 days of the changes being made. Examples of changes to be notified include:

- i. Retirement or resignation of existing members
- ii. Appointment of new members
- iii. Reappointment of an existing member to a different category of membership.

7. AEC Quorum

At least one member from each of Category's A, B, C and D must be present at meetings to establish a quorum. Categories C and D must together represent at least one-third of those members present. If unable to reach a quorum, then the meeting will be rescheduled. If the Chair is a non-voting chair, they are not counted for the purposes of determining whether a quorum is present.

If a meeting is or becomes inquorate during consideration of an item of business due to a member withdrawing because of a conflict of interest, that item can be held over to a later meeting.

To enable quorate meetings video-linking or teleconferencing may be used for individual members unable to be present in person.

The Institute may nominate suitably qualified Category A members to serve as Category B members on request to assist with achieving a quorum during all or part of a meeting (See *Operating Procedures of Telethon Kids Institute AEC*, for more detail).

8. Confidentiality

AEC members will sign the Institute's Confidentiality Policy prior to appointment to the committee.

Members and attendees must maintain confidentiality regarding the content of applications and the deliberations of the AEC.

The Institute recognises that in some instances, members will be required to seek advice and guidance from external contacts in order to fulfil their role and responsibilities including matters pertaining to ethics and animal welfare in research. Advice can be obtained relating to procedural techniques, procedural burden, pain management, experimental endpoints, monitoring, animal husbandry and accommodation from a range of reputable sources, without breaching confidentiality.

In such instances, only information required to obtain the advice is permitted to be disclosed, and no other information which could be regarded as socially, scientifically, or commercially sensitive may be divulged.

The external contacts from whom the advice is sought must also be informed of the sensitive nature of such an enquiry and the corresponding confidentiality restrictions, and be asked to be mindful of such, to exercise absolute discretion and not to discuss the nature of any conversations or information gained with other persons except in conjunction with AEC business or purposes. It is up to members to seek advice from the Chair if they are unsure of how to balance their responsibilities with regard to confidentiality and security.

9. Financial arrangements

The Institute offers members a token honorarium payment per meeting to recognise the members' valued input to the AEC. This is in addition to parking compensation at QEII facilities. The honorarium process is managed by the Animal Ethics Office (AEO) who will provide the members with the Institute Honorariums Payment Form for completion and signature each quarter.

10. AEC Executive²

In accordance with the Code, an Executive of the AEC may be established. The membership of the AEC Executive is detailed in the AEC Executive Terms of Reference, and comprises the AEC Chair and at least one AEC member from Category A or B, and one member from Category C or D.

The AEC Executive may approve minor amendments to existing projects or activities for ratification at the next AEC meeting. The AEC will provide guidance on the type of activity that would be considered a minor amendment. The AEC Executive must not approve new applications.

The AEC Executive has the discretion to require that a minor amendment be referred to a full AEC meeting for consideration. Should the AEC Executive fail to reach consensus regarding a minor amendment, the application must be referred to the full AEC at its next meeting.

11. Pre-submission Review³

The Institute may adopt a pre-submission review process to provide scientific, animal welfare and or statistical advice to the applicant about project applications prior to ethics review. The pre-submission review process does not preclude the AEC from discussions of scientific, animal welfare or statistical merit.

² See also separate statement AEC Executive Terms of Reference

³ See also separate statement AEC Operating Procedures

12. Reporting

12.1 Reporting of projects

Investigators must provide the following to the AEC:

- i. An annual report for an approved project, regardless of the duration of AEC approval for the project
- ii. Prompt notification of any unexpected adverse events
- iii. A final report on outcomes as soon as practicable after completion or discontinuation of a project
- iv. Reports on the creation and maintenance of genetically modified animals
- v. Any other reports as required by the AEC.

12.2 Institutional Reporting

The AEC will report annually on its operations to the Risk and Compliance sub-committee of the Board and will advise on:

- i. numbers and types of projects and activities assessed, and approved or rejected.
- ii. any matters that may affect the Institute's ability to maintain compliance with the Code and, if appropriate, suitable recommendations.
- iii. Adverse events
- iv. Overview of the most recent Independent External Review.

13. Revision Requirements

The Terms of Reference and AEC Operating Procedures will be reviewed every three years or as necessary in response to changes in the legislation, Institute policy or concerns expressed by AEC members.

Changes and amendments to the Terms of Reference will require the endorsement of the AEC and approval of the AEC Chair.

14. Version History

Version	Approval Date	Review Date	Approved By	Endorsed By	Sections Modified
1.0	2007	-	AEC	-	-
2.0	March 2009	-	AEC Chair	-	-
3.0	22/09/2010	-	AEC Chair	-	-
4.0	14/05/2014	-	AEC	-	-
5.0	9/12/2015	-	AEC	-	Addition of AEC dispute resolution process
6.0	25/02/2016	-	AEC Chair	-	Update of position title
7.0	19/06/2017	19/06/2018	AEC Chair	Institute Executive Director	All sections reviewed
8.0	18/06/2018	18/06/2019	AEC	Institute Executive Director	Addition of Manager Res Gov to in attendance
9.0	19/08/2019	19/08/2022	AEC	Executive Director	All sections reviewed
10.0	16/09/2019	16/09/2022	AEC	Executive Director	Section 4 (Quorum), addition of the possibility of having a appointed AEC member with the capacity of Category A and B to resolve a quorum.
10.1	25/05/2020	16/09/2022	AEC	Executive Director	Section 5 (The Chair), addition of Chair functions delegated by AEC.
10.2	19/07/2021	31/07/2023	AEC	Executive Director	Section 3 update of AEC non-voting membership due to recent Institute re-structuring.
					Section 6: addition of link to the Institute's Procedures for the appointment, reappointment and retirement of AEC members procedure.
					Section 9.2: update to the institutional reporting processes

Version	Approval Date	Review Date	Approved By	Endorsed By	Sections Modified
11.0	19/07/2023	31/07/2026	AEC Chair	AEC	All sections reviewed. Inclusion of provisions for AEC members to seek external input and/or advice on applications without breaching confidentiality, and guidance on sitting fees.