

QIMR BERGHOFER ANIMAL ETHICS COMMITTEE

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1 TERMS OF REFERENCE

The purpose of this document is to outline the terms of reference, including the role, responsibilities, composition and operating guidelines of the QIMR Berghofer Medical Research Institute (the Institute) Animal Ethics Committee (the AEC).

The Terms of Reference of the QIMR Berghofer Animal Ethics Committee comply with the current *Australian Code for the care and use of animals for scientific purposes, 8th edition 2013*, and specifically are in accordance with Clause 2.2.1 of the Code.

2 PURPOSE

- 2.1 The AEC is a committee established by the Council of the Queensland Institute of Medical Research (the Council), to ensure that all activities relating to the care and use of animals at the Institute are conducted in compliance with the current *Australian Code for the care and use of animals for scientific purposes, 8th edition 2013* (the Code).
- 2.2 The AEC and these Terms of Reference are intended to comply with the requirements of the Code and the *Animal Care and Protection Act 2001* and other relevant laws and regulations.

3 AUTHORITY

- 3.1 The AEC is accountable to, and reports to, the Council.
- 3.2 The AEC is assisted by the Animal Scientific Subcommittee (ASSC). The ASSC provides advice on scientific/technical assessment and evaluation of research protocols and compliance with regulatory requirements. Appointments to the ASSC are made by the AEC and the Director and CEO of the Institute.
- 3.3 The ASSC reports to the AEC with respect to animal research.

4 ROLES AND RESPONSIBILITIES

4.1 Role of the AEC

The functions of the AEC are to:

- a) Recommend to the Council any necessary measures to ensure that the standards required by the Code, and of any other relevant State, Territory and Commonwealth legislation, are maintained.
- b) Consider research protocols involving use of animals for scientific purposes:
 - i. Within the premises of the Institute, including both Institute and non-Institute scientific groups;
 - ii. By Institute personnel, whether intra- or extra-mural; and
 - iii. By other organisations for whom the Institute has agreed to act.
- c) Review applications for projects and approve only those projects that are ethically acceptable (see Clause 1.3 of the Code) and conform to the requirements of the Code.

- d) 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 conform to the requirements of the Code.
 - e) Conduct follow-up review of approved projects and activities (see Clause 2.2.32 [ii] of the Code), and allow the continuation of approval for only those projects and activities that are ethically acceptable and conform to the requirements of the Code.
 - f) Monitor the care and use of animals, including housing conditions, practices and procedures involved in the care of animals in facilities.
 - g) Take appropriate actions regarding unexpected adverse events (such as but not limited to suspending work in the interest of animal welfare).
 - h) Take appropriate actions regarding non-compliance (such as but not limited to suspending work pending an investigation on compliance).
 - i) Approve guidelines for the care and use of animals on behalf of the Institute.
 - j) Provide advice and recommendations to the Institute.
 - k) Report on its operations to the Institute.
 - l) Ensure that, where a project involves more than one institution, formal procedures exist by which the project has met ethical approval from the responsible AEC and complies with Clauses 2.6.4 - 2.6.7 of the Code.
 - m) Maintain a register of all proposals and projects submitted to the AEC.
 - n) Comply with the reporting requirements of the Institute, the Code, the National Health and Medical Research Council (NHMRC), and the Queensland Government responsible authority.
 - o) Perform all other duties required by the Code.
- 4.2 Before granting approval to a research study involving animals, the AEC must be satisfied that the use of animals is essential and justified and that the protocol conforms to:
- a) The Code;
 - b) *Animal Care and Protection Act 2001* and *Animal Care and Protection Regulation 2002*;
 - c) Any requirements of relevant Commonwealth, State or Territory laws; and
 - d) Where relevant, overseas regulatory requirements.
- 4.3 In carrying out their duties, Committee members must consider the Code's Governing principles:
- a) Respect for animals must underpin all decisions and actions involving the care and use of animals for scientific purposes. This respect is demonstrated by:
 - i. Using animals only when it is justified;
 - ii. Supporting the wellbeing of the animals involved;
 - iii. Avoiding or minimising harm, including pain and distress to those animals;
 - iv. Applying high standards of scientific integrity; and
 - v. Considering the following options at all stages of animal care and use:
 - the Replacement of animals with other methods;
 - the Reduction in the number of animals used; and
 - the Refinement of techniques used to minimise the adverse impact on animals;
 - vi. Knowing and accepting one's responsibilities
 - b) The care and use of animals for scientific purposes must be subject to ethical review by the AEC.

- c) A judgement as to whether a proposed use of animals is ethically acceptable must be based on information that demonstrates the principles in Clause 1.1 of the Code and must balance whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits.
- d) The obligation to respect animals, and the responsibilities associated with this obligation, apply throughout the animal's lifetime, including acquisition, transport, breeding, housing, husbandry, use of the animal in a project, and provisions for the animal at the conclusion of their use.

4.4 Mechanisms of Reporting

Formal mechanisms of reporting include the following:

- a) Minutes of all AEC meetings and occasional reports are provided to the Director's Executive Committee (DEC) for noting and are provided to the Council for consideration and endorsement.
- b) The AEC will provide a report to the Council after the end of each calendar year (the Annual Report) detailing:
 - **Urgent matters requiring the Institute's immediate action and/or attention with request for a response to the AEC**
 - Numbers and types of projects and activities assessed, and approved or rejected; Turn-over data overtime.
 - The physical facilities for the care and use of animals by the Institute;
 - Actions that have supported the educational and training needs of AEC members and people involved in the care and use of animals;
 - Administrative or other difficulties experienced;
 - Any matters that may affect the Institute's ability to maintain compliance with the Code and, if appropriate, suitable recommendations;
 - Summary reports of AEC Internal reviews reports; and
 - Reports of independent external reviews conducted every four years.
- c) The AEC Annual Report and/or occasional reports are provided to the NHMRC Animal Welfare Committee (NHMRC-AWC) as requested.
- d) An annual animal ethics review meeting is held as required by the Code (Clause 2.2.37) between the AEC Chair and the designated representative of the Institute such as the Director and CEO, Council Chair or members of the Director's Executive Committee.
- e) An annual animal use statistics report is provided to the Queensland Department of Agriculture and Fisheries (DAF) for a review of the AEC. The report includes:
 - QIMR Berghofer details;
 - Activity Details – project title and number, animal type and numbers used (in one calendar year), primary purpose for the activity, major category of animal use; and
 - Complaints and Grievances relating to the AEC or the use of animals for scientific purposes.
- f) An annual report on compliance with the Queensland Biotechnology Code of Ethics, which includes a statement on the care and protection of animals (Clause 13 of the Code), is submitted to the Office of Biotechnology & Therapeutic Medicines and Devices, Queensland State Government by the Director and CEO of the Institute.

4.5 Monitoring of the Institute's Conformity to the Code

To ensure the Institute's conformity to the Code, the operation of the AEC and its relationship, administrative and actual operation is to be reviewed by an independent external panel every four years (Clause 6.1 of the Code).

An annual internal review is also to be conducted by a QIMR Berghofer senior scientific staff member to ensure efficient operation of the AEC.

5 MEMBERSHIP AND MEETINGS

5.1 Chair and Deputy Chair

- The Chair of the AEC is appointed by the Council. 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.
- In recruiting a Chair, Council will prioritise the appointment of an external person and will provide the Chair with the required support and authority to undertake their role and facilitate communication between the AEC and the Institute.
- If the Chair is an employee of the Institute, Council will ensure that the Chair holds a senior position in the Institute and is independent of the care and use of animals for scientific purposes.
- The Deputy Chair of the AEC is nominated by the AEC and endorsed by the Council.
- In the absence of the Chair, the Deputy Chair will perform the duties of the Chair.

5.2 The QIMR Berghofer-AEC Animal Welfare Officer

If an Animal Welfare Officer (AWO) is appointed by the Institute, the AWO is required to be a qualified veterinarian, registered with the Australian Veterinary Surgeons Board or equivalent and may be appointed as a Category A member of the AEC. The AWO's role on the AEC is to advise, support and assist the Chairs and Secretary of the ASSC and the AEC in providing advice to researchers on ethical standards and guidelines with respect to the use of animals for scientific purposes.

5.3 Secretary

- The AEC Secretary is an employee of the Institute.
- The Secretary, in consultation with the Chair, will prepare and send notices of meetings and agendas and accurately record all decisions of the Committee.
- The Secretary will table all correspondence, reports, submission and other information relevant to the Committee.
- The Secretary assists the Chairs of the AEC and the ASSC and undertakes administrative tasks of the AEC and ASSC under the guidance of the Manager Research Ethics and Clinical Trials.
- The Secretary acts as a liaison between the AEC, its Subcommittees and the researchers.
- The Secretary provides administrative advice to the researchers on the Institute's research ethics processes.

5.4 Membership

In accordance with the Code, the AEC membership comprises at least one person from each of four categories of membership:

- a) **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. (The QIMR Berghofer Animal Welfare Officer also acts as the Category A member, where appropriate).

- b) **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.
- c) **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.
- d) **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.
- e) [* Category C and D members must represent no less than one third of the Committee members.]
- f) Institutions should appoint to the AEC a person responsible for the routine care of animals within the institution.
- g) The AEC may invite people with specific expertise to provide advice as required (Clause 2.2.7 of the Code).

5.5 The AEC Executive

- a) According to the Code (Clause 2.2.23) the AEC Executive must include the AEC Chair and at least one other member from Category C or D. The Executive may approve minor modifications to approved projects or activities, for ratification at the next AEC meeting. It must not approve new projects.

5.6 Appointment of Members

- a) Vacancies in Categories A, C and D may be advertised via network notices, newsletters and publications of the Institute and stakeholders such as Queensland Health, The University of Queensland, SEEK, etc.
- b) Upon submission of a Curriculum Vitae and approval by the Chair, (which will include an interview) the prospective member will be invited to attend the next AEC meeting as an Observer. During this meeting, the prospective member will have an opportunity to become familiar with committee procedures and workings. Subsequent to agreement from all parties (prospective member, Chair and AEC members), the Chair will recommend the nomination to Council.
- c) AEC members in Categories A-D are appointed by the Council. Prior to appointment all individuals nominated for membership must be accepted for nomination by the Queensland Department of Agriculture and Fisheries (DAF). All changes to the AEC membership are communicated to the Council, the NHMRC-AWC, DAF and other regulatory agencies, as required.

5.7 Period of Appointment

- a) A Committee member is normally appointed for a three-year term. A retiring member may be reappointed, with a maximum total term of six years. This period of appointment does not apply to the members appointed for the following Nominated Positions:
 - The Animal Welfare Officer;
 - The AEC Secretary; or
 - A person responsible for the routine care of animals from within the Institute.
- b) The Chair is appointed for a three-year term. A retiring Chair may be reappointed for one additional term, unless otherwise approved by the Council in writing.
- c) A Committee member who is subsequently appointed as Chair of the Committee may serve for a maximum total term of nine years.
- d) Notwithstanding anything to the contrary in these Terms of Reference, the Chair of Council may, in their sole discretion, consent to the extension of an appointment beyond the applicable maximum term.
- e) Appointments to fill casual vacancies are for the balance of the original appointee's term.
- f) Appointments may be terminated by either party after two months' notice given in writing.

5.8 Conditions of Appointment

- a) Members are appointed as individuals for their knowledge, qualities, expertise and relevant experience, not as representatives of any organisation, group or opinion.
- b) Before appointment, members acknowledge in writing their acceptance of the Terms of Reference of the AEC and any requirements for confidentiality required by the Institute.
- c) Members must not disclose to any person, make known in any manner or use the Confidential Information for any purpose other than as required to meet their responsibilities as Members of the AEC or for executing their roles as Institute employees. Confidential Information means any documents, information, discussions, data or any other information related to the AEC's deliberations including animal research ethics applications, research data, expert reports, commissioned reports and information about animal use within the Institute. Any breach of these confidentiality requirements could result in immediate termination of appointment from the AEC.
- d) Members receive a formal notice of appointment and assurances that the Institute will provide legal protection in respect to liabilities that may arise in the course of bona fide conduct of their duties as Committee members.
- e) A member who is absent for three consecutive meetings without tendering an apology may be deemed to have forfeited his/her membership on the Committee.
- f) The appointment may be terminated by the member or the Council at any time, with written notice of four weeks.

5.9 Remuneration

- a) Council in its absolute discretion may elect to remunerate the Chair in recognition of the workload associated with meeting the responsibilities of the role, including preparation and follow-up actions for meetings. The Council will determine and approve the quantum of such payment in line with the *Remuneration Procedures for Part-Time Chairs and Members of Queensland Government Bodies* or any other applicable government requirements.
- b) Other AEC members provide their services on a voluntary basis.
- c) All essential and necessary expenses incurred by members in carrying out their AEC duties will be reimbursed by the Institute, on production of original receipts.

- d) Parking will be provided at Herston for members who are not QIMR Berghofer employees while attending to AEC business.

5.10 Meetings and attendance

- The AEC will meet at least nine times per year.
- A quorum will consist of at least one member from each of the membership categories A, B, C and D. Categories C and D together must represent at least one-third of those members present.

5.11 Ethical practices

Members are required to declare any interests that could constitute a real, potential or apparent conflict of interest with respect to participation on the Committee. The declaration must be made on appointment to the Committee and in relation to specific agenda items at the outset of each Committee meeting, and be updated as necessary.

6 COMMITTEE OPERATION

6.1 Written Proposals

- a) The AEC reviews project applications submitted via the QIMR Berghofer Electronic Forms (E-Forms) system, or other such system as adopted by the Institute from time to time.
- b) The design of the AEC animal ethics application is guided by the Code. Proposals for use of animals for scientific purposes must include the required information as defined in Clauses 2.7.4-2.7.6 of the Code.
- c) A copy of the full protocol and associated documents for each project is recorded in the QIMR Berghofer E-Forms system, or other such system as adopted by the Institute from time to time.

6.2 Working Procedures

The working procedures for the AEC are described in the Animal Ethics Committee Working Procedures accessible on the QIMR Berghofer intranet.

7 EVALUATION OF COMMITTEE ACTIVITIES

The Committee shall review and assess its performance annually and report the results to the Council.

[A survey of members may/will include:

- Effectiveness of the induction /package for new members
- Consistency of committee business with terms of reference
- Efficiency and effectiveness of discussions and consideration of significant matters
- Skills, experience and fit of the membership
- Preparedness of members
- Clarity, sufficiency, accuracy and timeliness of agendas, papers and minutes
- Efficiency of chairing
- Ability of members to contribute and participate
- Atmosphere of meetings conducive to open and productive debate

- Conduct of members aligns with Institute values, is courteous and professional]

[A survey tool can be developed for consistent use across the Institute]

8 REVIEW OF TERMS OF REFERENCE

The Committee shall review and assess the adequacy of these terms of reference every three years and, if appropriate, recommend changes to the terms of reference to the Council.

Approval of the Terms of Reference is by the Council.

9 REFERENCES

1. Australian Code for the care and use of animals for scientific purposes, 8th Edition, 2013
<https://nhmrc.gov.au/about-us/publications/australian-code-care-and-use-animals-scientific-purposes>
2. [Animal Care and Protection Act 2001](#) – current as at 1 July 2016:
3. [Animal Care and Protection Regulation 2012](#) – current as at 1 January 2022.
4. [Biotechnology Code of Ethics](#) updated 2006
5. [Using animals for scientific purposes](#) (Queensland Government)
6. [International Guiding Principles for Biomedical Research Involving Animals](#)
7. Other Queensland Government codes, guidelines, legislation
8. [Wildlife Protection \(Regulation of Exports and Imports\) Act 1982 No.149 of 1982 – SECT 4](#)
9. [Gene Technology Act 2000 and Gene Technology \(Queensland\) Act 2016](#)
10. [Biosecurity Act 2015](#)
11. [The International Air Transport Association \(IATA\) Live Animal Regulations](#)
12. [Environment Protection and Biodiversity Conservation Act 1999](#)
13. Animal Ethics Committee Working Procedures

10 AMENDMENT HISTORY

| Approved by | Date | Scope of change |
|---------------------|------------------|----------------------------------|
| Endorsed by Council | 15 October 2002 | Endorsed by MEC |
| Endorsed by Council | 15 March 2005 | Amendments Endorsed by MEC |
| Endorsed by Council | 21 March 2006 | |
| Endorsed by Council | 19 May 2009 | |
| Endorsed by Council | 16 June 2009 | |
| Endorsed by Council | 5 November 2013 | |
| Endorsed by Council | 26 May 2015 | Amendments endorsed by AEC |
| Endorsed by Council | 21 May 2019 | Amendments endorsed by AEC |
| | 31 March 2020 | Amendments to Working Procedures |
| Endorsed by Council | 22 February 2022 | |