



QIMR Berghofer
Medical Research Institute

ANIMAL ETHICS COMMITTEE

1.0 TERMS OF REFERENCE

1.1 Scope of Responsibilities

1.1.1 The QIMR Berghofer Medical Research Institute Animal Ethics Committee (QIMR Berghofer-AEC) is a committee established by the Council of the Queensland Institute of Medical Research (Council). The primary responsibility of the QIMR Berghofer-AEC is to ensure, on behalf of QIMR Berghofer Medical Research Institute, that all activities relating to the care and use of animals are conducted in compliance with the current *Australian Code for the care and use of animals for scientific purposes* (referred to as the *Code*), 8th edition 2013. QIMR Berghofer-AEC reports to the Council. The Terms of Reference of the QIMR Berghofer-AEC comply with the *Code*, and specifically are in accordance with Clause 2.2.1 of the *Code*.¹

1.1.2 The QIMR Berghofer-AEC is assisted by the Scientific Sub-Committee (SSC). The Animal SSC (ASSC) provides advice on scientific/technical assessment and evaluation of research protocols and compliance with regulatory requirements. The ASSC reports to the QIMR Berghofer-AEC with respect to animal research. Appointments to the ASSC are made by the QIMR Berghofer Director upon recommendations from the AEC and/or ASSC Chair/s.

1.1.3 The QIMR Berghofer-AEC complies with the current *Australian Code for the care and use of animals for scientific purposes, 8th edition, 2013; the Queensland Animal Care and Protection Act 2001; Queensland Animal Care and Protection Regulation 2002; Queensland Biotechnology Code of Ethics* updated 2006; and other relevant regulations.

1.1.4 The QIMR Berghofer-AEC shall:

- (a) Recommend to the Council any measures needed to ensure that the standards required by the *Code*, and of any other relevant extant State, Territory and Commonwealth legislation, are maintained.
- (b) Consider research protocols involving use of animals for scientific purposes:
 - Within the premises of QIMR Berghofer, including both QIMR Berghofer and non-QIMR Berghofer scientific groups;
 - By QIMR Berghofer personnel, whether intra- or extra-mural; and
 - By some organisations for whom QIMR Berghofer has agreed to act.

¹ Re all referred documents: The most recent versions or as amended from time to time will be referred to in the context of this document.

- (c) Review applications for projects and approve only those projects that are ethically acceptable (see Clause 1.3 of the *Code*), for which animals are essential and justified 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 [iii] 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 acquisition, transportation, housing conditions, practices and procedures involved in the care of animals in facilities.
- (g) Take appropriate actions regarding unexpected adverse events.
- (h) Take appropriate actions regarding non-compliance.
- (i) Examine and approve all institutional guidelines, plans and policies for the care and use of animals that are bred, held and used for scientific purposes on behalf of QIMR Berghofer Medical Research Institute.
- (j) Provide advice and recommendations to QIMR Berghofer Medical Research Institute.
- (k) Report on its operations to QIMR Berghofer Medical Research Institute.
- (l) Require that all members declare any conflict of interest before appointment, and deal with situations in which a conflict of interest arises as per Appendix A4.3.
- (m) Ensure that, where a project involves more than one institution, arrangements 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*.
- (n) Maintain a register of all proposals and projects submitted to the QIMR Berghofer-AEC.
- (o) Authorize the emergency treatment or euthanasia of any animal.
- (p) Comply with the reporting requirements of QIMR Berghofer, the *Code*, the National Health & Medical Research Council (NHMRC), and the Queensland government responsible authority.

[Note: Where the conditions of a grant involve compliance with the requirements of any other regulatory agency, particularly an overseas agency, the QIMR Berghofer-AEC will endeavor to meet those requirements. Investigators should notify the QIMR Berghofer-AEC of the requirements before the grant is accepted.]

- (m) Perform all other duties required by the *Code*.

1.2 Accountability

The QIMR Berghofer-AEC is accountable to the Council. The QIMR Berghofer-AEC, before granting approval to a research study involving animals, must be satisfied that the use of animals is essential and justified and that the protocol conforms to:

- (a) the *Code*;

- (b) *Queensland Animal Care and Protection Act 2001* and *Queensland Animal Care and Protection Regulation 2002*; and
- (c) any requirements of relevant Commonwealth or State/Territory laws; and
- (d) where relevant, overseas regulatory requirements.

1.3 Mechanisms of Reporting

Formal mechanisms of reporting include the following:

- (a) Minutes of all QIMR Berghofer-AEC meetings and occasional reports may be provided to the Director's Consultative Committee (DCC) for noting and are provided to the Council for consideration and endorsement.
- (b) QIMR Berghofer-AEC Annual Report to the Council; annual report and/or occasional reports to the NHMRC-Animal Welfare Committee (NHMRC-AWC) as requested. The annual report details:
 - numbers and types of projects and activities assessed, and approved or rejected;
 - the physical facilities for the care and use of animals by the institution;
 - 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 institution's ability to maintain compliance with the *Code* and, if appropriate, suitable recommendations;
 - Internal reporting; and
 - External Reporting.
- (c) An annual animal ethics review meeting as required by the *Code* (Clause 2.2.37) between the QIMR Berghofer-AEC Chair and the designated representative of the Institute such as the QIMR Berghofer Director, Chair of Council or members of DCC.
- (d) An annual Animal Use Statistics Report to Biosecurity Queensland Department of Agriculture and Fisheries for review of QIMR Berghofer's registration of the QIMR Berghofer-AEC. The report includes:
 - Registrant's details;
 - Activity Details – Project title and number, animal type and numbers used (in one calendar year), primary purpose for the activity and major category of animal use; and
 - Complaints and Grievances
- (e) 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 this Code), submitted by the QIMR Berghofer Director to the Office of Biotechnology & Therapeutic Medicines and Devices, Queensland State Government.

2.0 COMPOSITION AND MEMBERSHIP OF THE QIMR BERGHOFER-AEC

2.1 The QIMR Berghofer-AEC Chair

The Chair of the QIMR Berghofer-AEC is normally a senior member of QIMR Berghofer who is appointed by the QIMR Berghofer Council. In the case of a Chair being an external appointee, QIMR Berghofer will provide the Chair with required support and authority to undertake the role. This facilitates communication between QIMR Berghofer-AEC and the Institute.

2.2 The QIMR Berghofer-AEC Deputy Chair

The Deputy Chair of the QIMR Berghofer-AEC is nominated by the Committee and endorsed by the Council. In the absence of the Chair, the Deputy Chair will perform the duties of the Chair.

2.3 The QIMR Berghofer-AEC Animal Welfare Officer

If an Animal Welfare Officer (AWO) is appointed by QIMR Berghofer, s/he is an employee of QIMR Berghofer staff. The AWO is a qualified veterinarian and as such meets the requirements to be appointed as a Category A member of the QIMR Berghofer-AEC. S/he advises, supports and assists the Chairs of the ASSC and QIMR Berghofer-AEC and Secretary in providing advice to researchers on ethical standards and guidelines with respect to use of animals for scientific purposes.

2.4 The QIMR Berghofer-AEC Secretary

The QIMR Berghofer-AEC Secretary is an employee of QIMR Berghofer. S/he may be able to assist researchers with information requirements of the committees and on the impact of the *Code* guidelines and other documents. The Secretary provides a line of communication and continuity of policy interpretation across committees. The Secretary provides administrative advice on the Institute's research ethics program. The Secretary reports to the Chair of the QIMR Berghofer-AEC in relation to the activities of the committee and to the QIMR Berghofer Regulatory Affairs Manager regarding administrative issues.

2.5 Membership of the QIMR Berghofer-AEC

The QIMR Berghofer-AEC membership conforms to the *Code*. Currently, the QIMR Berghofer-AEC includes the following:

(a) At least one member from each of the following four 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. (**NB.** The QIMR Berghofer Animal Welfare Officer also acts as the Category A member, where appropriate).

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.

[* Category C and D members represent no less than one third of the Committee members.]

(b) Nominated positions

These may be persons already in specific Categories or alternatively, act in a non-voting position to the QIMR Berghofer-AEC.

- The Chair
- The Deputy Chair
- The Animal Welfare Officer
- The QIMR Berghofer-AEC Secretary – non-voting
- A person responsible for the routine care of animals from within the institution –non-voting

(c) The AEC may invite people with specific expertise to provide advice as required (Clause 2.2.7 of the Code)

2.6 The QIMR Berghofer-AEC Executive

According to the Code (Clause 2.2.23) the AEC Executive committee must include the AEC chairperson and a 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.

3.0 APPOINTMENT OF MEMBERS

3.0.1 QIMR Berghofer-AEC members, Categories A-D are appointed by the Council. Prior to appointment all individuals nominated for membership must be accepted for nomination by Biosecurity Queensland Department of Agriculture and Fisheries. All changes to the QIMR Berghofer-AEC membership are communicated to the QIMR Berghofer Council, NHMRC-AWC, DAFF and other regulatory agencies, as required.

3.0.2 Vacancies of Categories A, C and D will be advertised via publications such as QIMR Berghofer's LifeLab, network notices, Queensland Health's Health matters, or UQ's University News. Upon submission of Curriculum Vitae and approval by the Chair, 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 assess their commitment to the Committee and familiarise themselves with committee procedures. Subsequent to agreement from all parties (prospective member, Chair and AEC members), the Chair will recommend the candidate's appointment to Council.

3.1 Period of Appointment

QIMR Berghofer-AEC voting members are normally appointed for a three-year term. A retiring member may be reappointed. Appointments to fill casual vacancies are for the balance of the original appointee's term.

3.2 Terms and Conditions of Appointment

- (a) Members are appointed for their expertise and diversity of the categories and not in a representative capacity.
- (b) Before appointment, members acknowledge in writing their acceptance of the terms of reference of the QIMR Berghofer-AEC and any requirements for confidentiality required by QIMR Berghofer. Actual and potential conflicts of interest should be declared. All members must acknowledge that conflicts of interest that arise during the appointment will be declared as the situation arises.
- (c) Members receive a formal notice of appointment and assurances that the Institute will provide legal protection in respect of liabilities that may arise in the course of *bona fide* conduct of their duties as Committee members.
- (d) A member absent for three (3) consecutive meetings without tendering an apology may be deemed to have forfeited his/her membership on the Committee.
- (e) The appointment may be terminated by the member or the Council at any time, with written notice of four (4) weeks.

3.3 Remuneration

QIMR Berghofer-AEC voting members provide their services on a voluntary basis. Parking will be provided at Herston for members while on QIMR Berghofer-AEC business. All essential and necessary expenses incurred by members in carrying out their QIMR Berghofer-AEC duties will be reimbursed by QIMR Berghofer, on production of original receipts.

4.0 WRITTEN PROPOSALS

- 4.0.1** The QIMR Berghofer-AEC requires electronic submissions via the QIMR Berghofer Electronic Forms (E-Forms) system in a standard format for animal ethical approvals.
- 4.0.2** The formulation of the QIMR Berghofer-AEC animal ethics application is guided by the *Code*. Proposals for use of animals for scientific purposes must conform to required information as defined in Clauses 2.4.6-2.4.9 of the *Code*.
- 4.0.3** A copy of the full protocol and associated documents for each project is recorded and kept in the QIMR Berghofer E-Forms system.

5.0 WORKING PROCEDURES

The working procedures for the QIMR Berghofer-AEC are described in Appendix A.

6.0 AMENDMENT HISTORY

Endorsed by MEC – 8 October 2002

Amendments Endorsed by MEC – 22 February 2005

Endorsed by Council – 15 October 2002

Amendments Endorsed by Council – 15 March 2005; 21 March 2006; 19 May 2009; 16 June 2009

Endorsed by Council – 5 November 2013

Amendments Endorsed by AEC – 30 April 2015

Amendments Endorsed by Council – 26 May 2015

REFERENCES

- [Australian Code for the care and use of animals for scientific purposes, 8th Edition, 2013](http://www.nhmrc.gov.au/files_nhmrc/publications/attachments/ea28_code_care_use_animals_130728.pdf)
http://www.nhmrc.gov.au/files_nhmrc/publications/attachments/ea28_code_care_use_animals_130728.pdf
- [Queensland Animal Care and Protection Act 2001](#) – Current as at 1 November 2013 - Web site:
- [Queensland Animal Care and Protection Regulation 2002](#) – Current as at 7 February 2014
- [Registration of persons using animals for scientific purposes and teaching \(Queensland Primary Industries & Fisheries\)](#)
- [International Guiding Principles for Biomedical Research Involving Animals](#)
- Other Queensland Government codes, guidelines, legislation, where applicable, e.g.:
 - (1) [Fisheries Act 1994](#)
 - (2) [Queensland Biotechnology Code of Ethics updated 2006](#)
- [Wildlife Protection \(Regulation of Exports and Imports\) Act 1982 No.149 of 1982 – SECT 4](#)
- Office of the Gene Technology Regulator, Department of Health and Ageing, Australian Government
Please refer to <http://www.ogtr.gov.au/>
for the following amended legislation:
 - [The Gene Technology Act 2000 \(compilation incorporating amendments up to Act No. 99 of 2007\)](#)
 - [Gene Technology Amendment Act 2011](#) (commencement 1 July 2007)
 - [The Gene Technology Regulations 2001 \(compilation incorporating amendments up to SLI 2011 No. 73\) \(commencement 1 September 2001\)](#). These are the complete regulations in force from 1 September 2011.
- [Australian Quarantine Act 1908](#) (commencement 12 March 2014)
- [The International Air Transport Association \(IATA\) Live Animal Regulations](#)
- [Environment Protection and Biodiversity Conservation Act 1999](#)

APPENDIX A

Working Procedures

A1.0 Frequency of Meetings

Meetings are held bimonthly. If necessary, additional meetings may be held. The ASSC meets approximately three weeks prior to the QIMR Berghofer-AEC meeting. A timetable for meetings for the year will be announced by November of the preceding year.

A2.0 Preparation of Agenda

Deadlines for submission of ethics applications to the QIMR Berghofer-AEC are advertised widely. The deadlines allow time for an initial administrative consideration of proposals and for review by the ASSC, enabling applicants to modify their applications prior to the QIMR Berghofer-AEC meeting.

A3.0 Distribution of Materials Prior to Meetings

The Secretary distributes research ethics applications and relevant papers to all QIMR Berghofer-AEC members prior to the meeting, allowing sufficient time for reading.

A4.0 Meetings and Methods of Decision Making

A4.1 The quorum for a QIMR Berghofer-AEC meeting must include at least one member from each Category A, B, C and D, and C plus D members must comprise at least one third of the total. Occasional participation by teleconferencing is permissible, provided the member has received all relevant material and can participate freely with other members.

A4.2 Members who are unable to attend a meeting are encouraged to contribute prior to the meeting via electronic, written or oral submissions to the Secretary or Chair. Members are especially encouraged to post their comments on the research ethics submissions into the "Commentary" section of the Animal E-forms.

A4.3 When a proposal before the QIMR Berghofer-AEC involves a Committee member, s/he is required to declare her/his conflict of interest, real or potential, and it is recorded in the minutes. S/he may be required to leave the meeting before a final decision is taken by the Committee, to avoid any conflict of interest. As a QIMR Berghofer staff member, s/he is required to abide by QIMR Berghofer *Policy on [Conflict of Interest](#)*, document posted on QIMR Berghofer intranet. http://intranet.qimr.edu.au/intranet/corporate/policy/2.5_ConflictOfInterest.pdf

A4.4 Investigators can request to attend the AEC meeting, or request a phone call from the meeting, to discuss their application, should they wish. The AEC also may invite investigators to a meeting, or telephone them during a meeting, to discuss their proposal.

A4.5 In general, decisions by QIMR Berghofer-AEC are reached by general agreement rather than by majority vote. Where one or more committee members have serious concerns about a project, that concern must be addressed before approval is given. Where a vote is taken, approval requires a majority of the Committee and a majority of the external members who are present. An abstention is taken to be a vote against the proposal.

A5.0 Expedited Review of Proposal Between QIMR Berghofer-AEC Meetings

A5.1 The QIMR Berghofer-AEC Executive may not approve new proposals. New proposals must first be submitted to the ASSC for scientific review and must be submitted to the AEC for consideration at a quorate meeting, for approval.

A5.2 The QIMR Berghofer-AEC recognises that on occasion animal protocols require modification more rapidly than the bimonthly AEC meetings allow. The *Code* allows the institute to establish procedures for the effective governance and operation of the AEC that enable the AEC to comply with the *Code* and relevant institutional policies, and promote competent and timely review of animal care and use. In this instant the AEC is able to establish procedures including the appointment and delegation of functions to an AEC Executive. The AEC Executive can review and approve minor changes requested by the AEC and minor modifications to approved projects or activities between meetings, for ratification at the next AEC Meeting, where the proposed change is not likely to cause harm to the animals, including pain and distress.

A5.3 The AEC Executive reviews minor modifications twice a month via virtual meetings. The schedule of Executive review is advertised to staff via “Working with Animals at QIMR Berghofer” web page. The Executive aims to provide comment to investigators within 5-7 working days from the fortnightly deadline. The Executive may:

- Decide that approval can be given subject to ratification at the next full committee meeting;
- Require amendment of the proposal;
- Require the modification to be reviewed by the full committee at the next AEC meeting; or
- Refuse to give approval.

A5.4 All decisions given between meetings are subject to ratification by the full Committee at its next meeting. These decisions can be modified, suspended and/or withdrawn by the QIMR Berghofer-AEC if it deems necessary to do so.

A6.0 Preparation of Minutes and Recording of Decisions

A6.1 To encourage free and open discussion and to emphasise the collegiate character of QIMR Berghofer-AEC deliberations, particular views of individual members are not recorded in the minutes unless specifically requested.

A6.2 The minutes are produced as soon as practicable following the relevant meeting and checked by the Chair as a true and correct record. The draft is then circulated to members for approval and confirmation between meetings. Once the minutes are confirmed by members, AEC comments on the protocols are then disseminated to investigators via the E-forms system; the confirmed minutes are then provided to Council. In instances where the production of minutes is delayed the secretariat can disseminate AEC comments to investigators before final approval of the minutes by members if approved by the AEC Chairperson. Copies of the confirmed minutes are again sent to QIMR Berghofer-AEC members at least 7 days prior to the next meeting, as part of the meeting Agenda for noting.

A7.0 Prompt Notification of Decisions

The Secretary is responsible for notifying researchers of the QIMR Berghofer-AEC decisions as soon as practicable following the Committee meeting at which their research proposals have been discussed.

A8.0 Researcher Compliance with Decisions

Researchers are expected to comply with decisions reached by the QIMR Berghofer-AEC and any other recommendations/conditions as required by collaborating (AEC/s). Chief investigators must notify the QIMR Berghofer-AEC: (1) if collaborating AEC/s place any provisos or reservations with respect to their approvals on the project, and/or (2) if the project has been rejected by another AEC. Where there were disagreement/s between AEC/s, QIMR Berghofer-AEC will work collaboratively with Chief Investigators and collaborating AEC/s to resolve matters.

A9.0 Advice to QIMR Berghofer or Collaborating Research Institutes Regarding Discontinuation of Research Projects

In cases of non-compliance and/or where circumstances warrant that a research project should be discontinued, the QIMR Berghofer-AEC will withdraw approval, notify the researcher/s, the QIMR Berghofer Director and QIMR Berghofer Management and recommend to the collaborating research Institute/s that the research project be discontinued or suspended.

A10.0 Reporting of Changes to Proposals

All researchers are required to report anything that might warrant review of ethical approval of the proposal, including:

- Deviations from the proposal;
- New information and/or unforeseen events that might affect continued ethical acceptability of the project; and
- Allegation or suspicion of scientific fraud.

A11.0 Reporting of Adverse and Beneficial Events

All researchers are required to promptly notify the AEC through the Animal Facility Manager about anything that might impact on the wellbeing of the animal or warrant review of ethical approval of the protocol, including:

- Unexpected adverse effects on animals and/or personnel; and
- Any information that would indicate an increase risk to animals and/or personnel.
- Findings that could be beneficial to the welfare of animals

Researchers are required to submit an adverse events report via E-forms. The guidelines for the reporting of adverse events can be found on the intranet under the ["Working with Animals at QIMR Berghofer"](#) page.

A12.0 Appropriate Monitoring

The QIMR Berghofer-AEC requires:

- Adequate records to be kept and maintained on animal experimentation proposals;
- Regular inspections of all animal housing and laboratory areas by Committee members;
- Annual reports from Chief investigators;
- Immediate reports in the event of unexpected adverse effects on the well being of animals and/or personnel involved in the project;
- Proposed changes in the proposal to be submitted for approval before implementation;
- Safety approval granted before any work on projects/modifications begin;
- Immediate reports about any unforeseen events that might affect continued ethical acceptability of the project;
- Reports from researchers if the research project is discontinued before the expected date of completion, giving reasons;
- Access to interview researchers, as necessary;
- Reports from other staff or personnel in QIMR Berghofer, as necessary;
- Expert reports/reviews on matters from external sources, if required by the QIMR Berghofer-AEC; and
- Notification of published results/research publications.

If considered necessary, the QIMR Berghofer-AEC may take action to ensure that a project is complying with the terms of an approval including, but not limited to, requiring a report from the Chief Investigator, interviewing the researcher/s or research subjects, inspecting the laboratory and commissioning an external review of the project.

A13.0 Complaints or Grievances, Receiving and Handling

A13.1 Complaints (from QIMR Berghofer staff, members of the public, animal ethics applicants or members of the AEC) on the scientific use of animals at QIMR Berghofer or on the process, conduct or decisions of the QIMR Berghofer-AEC should be made in writing to the QIMR Berghofer-AEC via the Secretary, to the Chair of the QIMR Berghofer-AEC.

A13.2 The Chair or Secretary will acknowledge the receipt of the complaint to the complainant within seven working days.

A13.3 The Chair will consider the complaint and will determine a course of action, which may necessitate an out-of-session meeting of the QIMR Berghofer-AEC.

A13.4 The complainant will be notified of the decision of the QIMR Berghofer-AEC within 30 days of receipt of the complaint.

A13.5 If the complainant does not accept the decision conveyed by the QIMR Berghofer-AEC Chair, then further consideration may be obtained by addressing the complaint to the QIMR Berghofer Council.

A13.6 The ultimate decision of the AEC, after the above procedure, must not be over-ridden unless there was an error in due process.

A14.0 Fees and Charges

QIMR Berghofer may levy fees and charges on ethical review of commercial sponsored research.