ANIMAL ETHICS COMMITTEE OPERATING POLICY AND PROCEDURE



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1 PURPOSE

1.1. Operating procedures are required under Section 2.2.20 of the <u>Australian code for the care and use of animals for scientific purposes 8th edition 2013, hereafter the Code, and consequently also for continued registration with the Queensland, New South Wales and Western Australian State Governments as a scientific user of animals.</u>

2 SCOPE

2.1 This policy and procedure applies to staff and students conducting research and teaching using animals and to Animal Ethics Committee members

3 POLICY STATEMENT

4.1. This policy and procedure has been created to ensure compliance with the <u>Australian code for the care and</u> use of animals for scientific purposes 8th edition 2013.

4 PROCEDURE

4.1. The Institution is required under the Code 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 ethical review of animal care and use. These procedures should include declarations and management of conflicts of interest, confidentiality, appointment of and delegation of functions to an AEC Executive, administrative processes, meeting procedures, communication, complaints and non-compliance, records and documentation.

Conflicts of Interest

- 4.2 The Committee will require that all members declare any conflict of interest:
 - Prior to their appointment by making a signed declaration of all real or potential conflicts of interest as part of the member application process.
 - As matters arise by declaring all real or potential conflicts of interest and the nature of that interest to
 either the chair or secretary of the Committee as soon as is reasonable after they become aware of the
 conflict.
 - At each meeting by declaring as an early item of the meeting agenda all real or potential conflicts of
 interest and the nature of that interest. This must include all real or potential conflicts with any items on
 the meeting agenda or any other matter relating to membership of the Committee.
- 4.3 All declarations of real or potential conflicts of interest (as part of the appointment process, between or at meetings) are to be recorded in the relevant meeting minutes.
- 4.4 The Committee will deal with situations in which a conflict of interest arises, including any situation where a member of an Animal Ethics Committee has an interest that may be seen to influence the objectivity of a decision by:
 - requiring a member whose objectivity may be influenced by an interest (including consideration of a
 proposal submitted by that member) to leave the room prior to any discussion of the identified item,
 returning only at the invitation of the remaining members to provide clarification on issues raised (after
 which the member will again be requested to leave), or returning only when a decision has been finalised;
 - recording the method of dealing with any conflict in the relevant meeting minutes (e.g. recording that the member left and returned to the room);
 - considering and responding to any concern or claim raised by an activity leader or other party that a
 Committee member has a conflict of interest that may have influenced the objectivity of a Committee
 decision;
 - advising complainants, in writing, of the Committee's response to any concern or claim relating to a
 conflict of interest. If the complainant is not satisfied with the Committee's response, a grievance may be
 lodged.

Meeting Frequency

4.5 The Committee will meet at least quarterly each year and will advise the University community of the meeting dates, including closing dates for applications to be considered at each meeting.

Preparation of Reports and Agendas

- 4.6 The University will appoint a Secretary of the Committee who will consult with the Chair in the preparation of reports and agenda for the Committee..
- 4.7 The Secretary will be responsible for final preparation, distribution and record-keeping of all reports, agendas and associated agenda documents.
- 4.8 Members may request through the Chair or Secretary that an item be placed on the agenda for any meeting.

Distribution of Papers Prior to Meetings

4.9 Papers for meetings of the Committee shall be dispatched by the Secretary to members, to an address nominated by each member, at least seven calendar days in advance of any scheduled meeting.

Establishment of Quorum

- 4.10 The Committee shall have a quorum which must include at least one member from each Category A, B, C and D.
- 4.11 If the Committee has more than four members, Categories C plus D should represent no less than one third of the members.
- 4.12 If quorum is not achieved at the commencement of the meeting, two options are available:
 - The committee may elect to make contact with non-attending members by telephone to ascertain whether
 they would be prepared to participate by videoconference (if possible) or by telephone. If acceptable,
 then the meeting could proceed to discussion of all business items.
 - The Committee could cancel the meeting, and ask the Secretary to re-convene the full committee at the earliest possible date.

Presentation of Proposals

4.13 The Committee shall prepare for use of researchers and students a proforma detailing the format and requirements for presentation of proposals [Code 2.7.1].

Timely Consideration and Review of Proposals

- 4.14 Where practicable, meetings of the Committee will be scheduled to enable timely consideration of proposals in relation to dates for applications for research grants from the:
 - Australian Research Council
 - National Health and Medical Research Council
 - Various Internal Research Grants Schemes.
- 4.15 Decisions must be made as promptly as possible [Code 2.2.27]. The Committee should aim to have completed its consideration of an application by no later than six weeks after its original consideration at a quorate meeting.

Assessing Proposals

- 4.16 Only those scientific and teaching activities that conform to the requirements of all relevant sections of the Code and of legislation shall be approved [Code 2.3.2 (i)].
- 4.17 Pilot studies, where proposed, should be regarded as integral to the overall project, especially to enable assessment of the feasibility of the project, and the potential for Refinement and Reduction will be assessed according to the usual criteria applied to project approval [Code 2.3.14].
- 4.18 New proposals and the renewal of existing projects shall be considered and approved only at quorate meetings of the Committee [Code 2.3.6].

4.19 In determining the duration of approval for individual projects, the Committee shall take into account the number of years for which the project is funded, any milestones or stages outlined in the project, and any formal agreements between the institution and the funding bodies [Code 2.3.16].

Approve guidelines for the care and use of animals

4.20 The AEC must consider approval of guidelines for the care and use of animals that are referred to it by the institution (see clause 2.1.5 (v)) (Code 2.3.26)

Methods of Decision-Making

- 4.21 The Committee shall request the Chief Investigator for any animal ethics application or approved activity to be available at the time of the meeting of the Committee during which that application or activity is to be the subject of a decision to be made by the Committee.
- 4.22 The Committee shall strive to reach decisions by general agreement or consensus. Where consensus cannot be reached after reasonable effort to resolve differences, the Committee shall explore with the applicant(s) ways of modifying the project that may lead to consensus. If consensus is still not achieved, the Committee shall only proceed to a majority decision after members have been allowed a period of time to review their positions, followed by further discussion [Code 2.3.11].
- 4.23 For decision making members with a conflict of interest must withdraw from the meeting. Once such members have withdrawn, the remaining members must constitute a quorum as defined in Clause 2.2.25 that is one member from each of the membership categories A, B, C and D, with categories C and D together representing at least one-third of members present. (Code 2.3.12)
- 4.24 In the event of a vote on a motion/recommendation, assent by a majority of members will decide the matter.
- 4.25 Where a Committee member is aggrieved by a decision of the Committee, he/she should follow the procedures provided in the document, CQUniversity <u>Animal Ethics Committee Complaints and Grievances</u> Policy and Procedure.

Prompt Notification of Decisions

- 4.26 As far as practicable, within ten working days of any decision on a proposal, the Secretary will advise the proposer(s) in writing of the Committee's decision.
- 4.27 Projects must not commence until written approval has been received [Code 2.4.4 (iii)].

Monitoring of Teaching/Research Projects

- 4.28 The AEC must monitor all activities relating to the care and use of animals (including the acquisition, transport, breeding, housing and husbandry of animals) on a regular and ongoing basis to assess compliance with the Code and decisions of the AEC. The AEC must ensure that identified problems and issues receive appropriate follow-up and if necessary refer suspected breaches of the Code to the institution (Code 2.3.18).
- 4.29 The Secretary shall be responsible for ensuring that the inspection occurs as required and that inspection reports are presented to the Committee.
- 4.30 The Secretary shall maintain a register of inspection visits and reports.
- 4.31 A category C or D member of the AEC should participate in animal facility inspections [Code 2.3.20].
- 4.32 The frequency and timing of inspections will be determined by factors such as the number and accessibility of sites, the amount, type and variety of scientific and teaching activities, and whether inspections can be combined with scheduled Committee meetings. As a guide, the Committee will routinely inspect animal holding areas at least annually and preferably more frequently. In addition, certain projects may necessitate more frequent inspections of animals and animal use [Code 2.3.21].

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- 4.33 Any projects likely to cause pain or distress, such as the study of pain, responses to stressors, certain animal models of human diseases or attempts to change behaviour by physical or chemical means, shall be subject to early inspection by the Committee as a condition of approval [Code 2.3.19].
- 4.34 Inspections of fieldwork conducted at extremely remote sites, or where access is difficult, may be performed by a delegate and can be facilitated or corroborated with photographic or video imaging [Code 2.3.23].

Reporting of Adverse Occurrences or Disease Outbreaks

- 4.35 In accordance with clause 2.1.5 (e) of the Code, on notification of an instance of unexplained and severe disease outbreaks, or morbidity/mortality in animals or people, the Chair of the Animal Ethics Committee in consultation with the Animal Welfare Officer, are authorised to approve the immediate use of animals to undertake diagnosis, by appropriated qualified personnel. This approval will be based on guidance from the Department of Agriculture and Fisheries.
- 4.36 The Committee shall ensure that the following condition of approval for any teaching/research proposal is included in any formal advice to the proposer of an approved research protocol:

"It is a condition of approval of this proposal that you report immediately anything which may warrant review of ethical approval of the project, including:

- serious or unexpected adverse effects on animal(s);
- proposed changes in the protocol and/or project; and
- unforeseen events that might affect continued ethical acceptability of the project.
- 4.37 A written report detailing the adverse occurrence or unforeseen event must be submitted to the Committee Chair within one working day after the event." [Code 2.4.18 (ix)]
- 4.38 If an emergency welfare intervention is considered necessary for an animal allocated to a project (eg treatment or humane killing of an animal), animal carers must take reasonable steps to first contact the responsible investigator. However the welfare of the animal must be the priority at all times and may necessitate immediate intervention. Animal carers must promptly advise the responsible investigator of actions taken and the reasons for emergency interventions. Reporting of the event to the AEC and responsibility of such reporting must be in accordance with institutional and AEC policies and procedures (Code 2.5 6, and 2.1.5 (v) (d))
- 4.39 The AEC must take appropriate action in response to unexpected adverse events to ensure that animal wellbeing is not compromised, the issue is addressed promptly, and activities that have the potential to adversely affect animal wellbeing cease immediately (see Clause 2.1.5 [v] [d]). The following steps will be taken:
 - the Chair will contact the chief investigator to address the issues;
 - details of the adverse event, and any resulting actions will be circulated to the full committee via email;
 - where members agree that appropriate actions have been taken, details are placed onto the next available agenda for formal noting;
 - where members are not satisfied that appropriate actions have been taken, an emergency meeting of the committee will be convened to consider the adverse event.
- 4.40 If the Committee considers that the project should not continue, the Committee will make a recommendation to the Deputy Vice-Chancellor (Research). The Deputy Vice-Chancellor (Research) will review the recommendation and relevant documentation and notify the researcher or student and supervisor and the Committee of his/her decision.

Reporting of Projects

- 4.41 All researchers shall be required to report annually and on the completion of approved projects [Code 2.4.34 (i) and(iii)].
- 4.42 The Committee shall prepare for use of researchers and students a proforma detailing the format and requirements for presentation of reports.

4.43 The Committee shall review the annual report and may determine on the basis of the report and further consultation with the investigator, that the project may continue, be suspended or require modification. Where necessary, the committee may make a recommendation to the Deputy Vice-Chancellor (Research) that the project be discontinued [Code 2.3.9].

Providing advice to, and reporting to the Institution

- 4.44 The AEC must provide advice and recommendations to the institution regarding the care and use of animals for scientific purposes conducted on behalf of the institution, and strategies required to ensure that the requirements of the Code are maintained and that matters affecting animal wellbeing are addressed (Code 2.3.27).
- 4.45 The Committee shall report annually to the Research Committee of Academic Board and the report shall include:
 - 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; and
 - Any matters that may affect the institution's ability to maintain compliance with the Code and if appropriate, suitable recommendations [Code 2.3.29].
- 4.46 The Institution must conduct an annual review of the operation of the AEC to ensure that it is effective and consistent with the Code and institutional policies. This must include an assessment of the AECs annual report (see clauses 2.1.9 and 2.3.28-39) and a meeting with the AEC Chairperson

Receiving Complaints

The Committee shall follow the Animal Ethics Committee Grievance Policy and Procedure to receive and attempt to resolve complaints or concerns about the conduct of an approved project from persons who are participants in the project, teachers/researchers, or other interested persons. (Code section 5)

Advising of the Discontinuation of an Approved Project

- 4.48 Animal Ethics Committee advising the Researcher:
 - In the event that the Committee has determined that a project is not being conducted or cannot be conducted in accordance with the approved protocol and that the welfare of animal(s) is not or will not be protected, the following steps will be taken.
 - Committee shall formally advise the researcher (s) or student of specified steps to be taken to allow the project to continue; or
 - Suspend the project until the committee is satisfied that the welfare of the animal(s) is/are protected and that the approved protocols will be followed; or
 - Recommend to the Deputy Vice-Chancellor (Research) that the project be suspended or discontinued
- 4.49 Researcher advising the Animal Ethics Committee:
 - As a condition of approval the researcher has the responsibility to report the project discontinuation within five working days to the Committee.

Projects Involving More Than One Animal Ethics Committee

4.50 Institutions must ensure that projects involving investigators from more than one institution, or the care and use of animals at more than one institution, are approved and monitored by the responsible AECs. Procedures must be developed and implemented to ensure that: (Code 2.6.4 to 2.6.7)

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- All parties involved are aware of, and can meet, their respective responsibilities under the requirements of the Code
- A project does not commence before each AEC approves or the delegate AEC approves (see clause 2.6.5) activities to be conducted by members of its institution. Each AEC should be responsible for approval and monitoring of animal care and use that occurs at the institution for which it acts
- The responsible AECs are aware of all aspects of the proposed use of animals, and consider the cumulative effects on the wellbeing of the animals involved
- The responsible AECs can inspect the animals so that all phases of the projects are monitored including any animals transported between sites
- Animals will receive appropriate care in all phases of the project, including any animal transport between sites
- Clear communication channels are established between all AECs and all investigators
- Institutions may agree to one AEC (the delegate AEC) approving the entire project, provided that all
 institutions involved agree to delegate the responsibility for decision making to and support the necessary
 actions of that AEC.
- Arrangements between institutions should be as a formal agreement. Institutions should avoid unnecessary duplication of processes
- Arrangements should include mechanisms of reporting non-compliant activities between institutions and AECs

Projects Conducted in Other Countries in Association with Australian institutions

- 4.51 When considering approval for a project to be conducted in another country, the AEC may accept approval granted by a local AEC or its equivalent if it is satisfied that outcomes would be equivalent to those expected through application of the Code (Code 2.6.11)
- 4.52 The AEC must ensure that animal use and care in the other country is adequately monitored. The AEC may appoint an agent or delegate to conduct the monitoring and inspection on its behalf. (Code 2.6.12)

Non-Compliance with the Code

- 4.53 When projects or activities that are in breach of the Code are detected, the AEC must ensure that actions are taken to ensure that animal wellbeing is not compromised, the issue is addressed promptly, and activities that have the potential to adversely affect animal wellbeing cease immediately (see clauses 5.2 (i) and 5.4 (i)). Actions may include suspending or withdrawing approval for the project or activity. The following steps will be taken:
 - The Chair will contact the chief investigator to address the issues:
 - details of the non-compliance will be circulated to the full committee via email, ahead of a meeting of the full committee being convened to consider the non-compliance;
 - where the non-compliance can be rectified without compromising animal wellbeing, the researcher will be advised that the project may proceed following confirmation of rectification being effected;
 - when considered necessary, recommend to the Deputy Vice-Chancellor (Research) that a project/activity be suspended, discontinued or that other necessary steps be taken;
 - restore approval for a research project/teaching activity and advise the researcher(s) or student(s), the Deputy Vice-Chancellor (Research) and any other formal parties to the project to this effect in writing, if satisfied that appropriate action has been taken to ensure no further non-compliance occurs.

Investigators who do not have direct access to an institutional animal ethics committee and use an animal ethics committee established by an institution

4.54 When an investigator who does not have direct access to an institutional AEC uses an AEC established by an institution, such use must be based on a formal agreement that has been developed in consultation with the AEC. The agreement must include:

- · procedures for communication between the AEC and the investigator
- an undertaking by the investigator that they will abide by the directions of the AEC
- the circumstances under which either party may withdraw from the agreement.

Confidentiality of the Content of Protocols and Committee Proceedings

- 4.55 Research protocols submitted for approval will remain confidential to the Committee, any persons from whom expert advice is sought by the Committee, and it's Secretary.
- 4.56 Each file for each research protocol with associated documents will be accorded high security status and be accessible only by Committee members and the Committee's Secretary.
- 4.57 Reports, agenda and papers of the Committee will remain confidential to the Committee and the Committee's Secretary except as required by law and where specified extracts from minutes or documents are authorised by the Committee to be conveyed to:
 - an applicant seeking ethics approval
 - a research funding body
 - an expert adviser to the Animal Ethics Committee
 - the Deputy Vice-Chancellor (Research) in the event of a complaint concerning a research project or a grievance or an irreconcilable difference with the Committee.

Record Keeping

- 4.58 The Secretary will maintain a record of agendas, reports and other aspects of the Committee's operation [Code 2.2.30].
- 4.59 The application form to commence a project must allow the applicant to provide the following information, as appropriate for the circumstances [Code 2.7.4]:
 - Using animals only when it is justified (see clauses 1.1 9i) and 1.5 1.7)
 - Applying high standards for scientific integrity (see clauses 1.1 (iv) and 1.15 1.17_
 - Applying replacement, reduction and refinement (the 3 Rs) (see clauses 1.1 (v) and 1.18 1.30)
 - Supporting the wellbeing of animals (see clauses 1.1 (ii) and 1.8 1.9)
 - Avoiding or minimising harm, including pain and distress, to animals (see clauses 1,1 (iii), and 1.109 to 1.14)
 - Knowing and accepting responsibilities (see clauses 1.1 (vi) and 1.31 to 1.32)
- 4.60 The application form must also contain the following:
 - Name of the institution if different from governing institution
 - Title of the project
 - Commencement and completion dates for project
 - Names of all personnel involved with the project, their role and details of the experience and training that qualifies them to perform specific procedures using animals
 - Source of animals and any permits required, details of where the animals will be housed and where procedures will be performed
 - Potential benefits of the project
 - Overview of the project
 - Details of experimental protocols
 - Monitoring of animals

- · Justification and
- Declaration.
- 4.61 The Secretary shall maintain records of AEC business, including:
 - a register of all applications to the AEC, including the outcomes of deliberations
 - Minutes that record decisions and other aspects of the AEC's operation
 - Records of inspections conducted by the AEC (see clause 2.3.22)
- 4.62 The Secretary shall keep on file a copy of each project/protocol and application submitted for approval by the Committee, including any permits, licences or other relevant documentation or correspondence in the form in which they are approved.
- 4.63 The Secretary shall keep on file a copy of all reports to governing bodies and the institution.

5 RESPONSIBILITIES

5.1. The Animal Ethics Committee, supported by the Research Division, is responsible for ensuring that this policy and its corresponding procedures are implemented.

Compliance, Monitoring and Review

- 5.2. The Senior Ethics Officer will be responsible for ensuring that this policy is followed.
- 5.3. Evidence of compliance is demonstrated by Animal Ethics Committee Annual reports to Queensland Government Department of Agriculture and Fisheries, New South Wales Department of Primary Industries, Western Australian Department of Agriculture and Food and to Research Committee of Academic Board.

Reporting

5.4 No additional reporting is required.

Records Management

5.3 Staff must maintain all records relevant to administering this policy and procedure in a recognised University recordkeeping system.

6 DEFINITIONS

6.1 Terms not defined in this document may be in the University's glossary.

Terms and Definitions

Animal: Any live non-human vertebrate, that is, fish, amphibians, reptiles, birds and mammals, encompassing domestic animals, purpose-bred animals, livestock, wildlife, and also cephalopods such as octopus and squid.

Animal Ethics Committee (AEC): a committee constituted in accordance with the terms of reference and membership laid down in the Code.

Animal Housing or Facilities: places where animals are kept, including yards, paddocks, tanks, ponds and buildings.

Animal welfare: an animal's quality of life based on an assessment of an animal's physical and psychological state as an indicator of how the animal is coping with the ongoing situation as well as a judgement about how the animal feels.

Animal well-being: an animal's present state with regard to its relationship with all aspects of its environment, both internal and external. It implies a positive mental state, successful biological function, positive experience and freedom from adverse conditions.

Euthanasia: the humane killing of an animal, in the interests of its own welfare, to alleviate pain and distress.

Replacement: the replacement of animals with other methods.

Refinement: the refinement of techniques used to reduce the adverse impact on animals.

Reduction: the reduction in the number of animals used.

7 RELATED LEGISLATION AND DOCUMENTS

Animal Care and Protection Act 2001

Animal Research Act 1985

Animal Welfare Act 2002

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

Animal Ethics Committee Terms of Reference

8 FEEDBACK

University staff and students may provide feedback about this document by emailing the policy office at policy@cqu.edu.au.

9 APPROVAL AND REVIEW DETAILS

Approval and Review	Details
Approval Authority	Academic Board
Advisory Committee to Approval Authority	Research Committee of Academic Board
Administrator	Deputy Vice-Chancellor (Research)
Next Review Date	16/11/2019

Approval and Amendment History	Details
Original Approval Authority and Date	Academic Board 30/03/2005
Amendment Authority and Date	Academic Board 1/06/2011; Academic Board 13/11/2013; Academic Board 16/11/2016.
Notes	This document consolidates and replaces Animal Ethics Committee Operating Policy and related Animal Ethics Committee Operating Procedure.

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