PROCEDURES

ANIMAL ETHICS COMMITTEE OPERATING PROCEDURES

PURPOSE

These procedures have been developed in conjunction with the Animal Ethics Committee Operating Policy to ensure compliance with the Australian code of practice for the care and use of animals for scientific purposes 2004, hereafter the Code. The references next to text in these procedures (e.g. [Code 2.2.1]) relate to the relevant Sections of the Code.

PROCEDURE

The Animal Ethics Committee, hereafter the Committee, is required under the Code to establish operating procedures on:

- Conflicts of Interest
- Meeting Frequency
- Reports and Agendas Documentation
- Distribution of Papers Prior to Meetings
- Establishment of Quorum
- Presentation of Proposals
- Timely Consideration and Review of Proposals
- Assessing Proposals
- Methods of Decision Making
- Prompt Notification of Decisions
- Monitoring of Teaching/Research Projects
- Reporting of Adverse Occurrences
- Reporting of Projects
- Reporting to the Institution
- Receiving Complaints
- Advising the Institution to Discontinue a Project
- Projects Involving More Than One Animal Ethics Committee
- Projects Conducted in Other Countries in Association with Australian Institutions
- Non-Compliance with the Code
- Fees
- Confidentiality of the Content of Protocols and Committee Proceedings
- Record Keeping

1 Conflicts of Interest

1.1 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 executive officer 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.

1.2 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.

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Note: A conflict of interest arises where a member of an Animal Ethics Committee has an interest that may be seen to influence the objectivity of a decision [Code 2.2.10 (vi)].

1.3 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 meeting prior to any discussion of the identified item, 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.

2 Meeting Frequency

2.1 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 [Code 2.2.13].

3 Preparation of Reports and Agendas

3.1 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 and its Executive.

3.2 The Secretary will be responsible for final preparation, distribution and record-keeping of all reports, agendas and associated agenda documents.

3.3 Members may request through the Chair or Secretary that an item be placed on the agenda for any meeting.

4 Distribution of Papers Prior to Meetings

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

4.2 Papers for any matter to be considered by the Executive of the Committee shall be despatched by the Secretary to members, to an address nominated by each member, at least five days in advance of any scheduled meeting.

5 Establishment of Quorum

5.1 The Committee shall have a quorum which must include at least one member from each Category A, B, C and D.

5.2 If the Committee has more than four members, Categories C plus D should represent no less than one third of the members.

5.3 If quorum is not achieved at the commencement of the meeting, three options are available:

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- The committee may elect to make contact with non-attending members by telephone to ascertain whether they would be prepared to participate by telephone. If acceptable, then the meeting could proceed to discussion of all business items.
- The inquorate Committee could proceed with discussion of business items such as correspondence, consideration of annual, final or monitoring reports, excluding any new proposals, renewals of proposal or major modifications, and ask the Secretary to re-convene the meeting within five days;
- The Committee could cancel the meeting, and ask the Secretary to re-convene the full meeting at the earliest possible date.

6 Presentation of Proposals

6.1 The Committee shall prepare for use of researchers and students a proforma detailing the format and requirements for presentation of proposals [Code 2.2.15].

7 Timely Consideration and Review of Proposals

7.1 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.

7.2 Decisions must be made as promptly as possible [Code 2.2.21]. The Committee should aim to have completed its consideration of an application by no later than eight weeks after its original consideration at a quorate meeting.

8 Assessing Proposals

8.1 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 2.2.18].

8.2 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 2.2.19].

8.3 New proposals and the renewal of existing projects shall be considered and approved only at quorate meetings of the Committee [Code 2.2.20].

8.4 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 Deeds of Agreement between the institution and the funding bodies [Code 2.2.25].

9 Methods of Decision-Making

9.1 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 for the agenda item during which that application or activity is to be the subject of a decision to be made by the Committee.

9.2 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 unachievable,

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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 2.2.22].

9.3 In the event of a vote on a motion/recommendation, assent by three-quarters of the members will decide the matter.

9.4 Where a Committee member is aggrieved by a decision of the Committee he/she should follow the procedures provided in the document, CQUniversity Animal Ethics Committee Grievances Procedures.

10 Prompt Notification of Decisions

10.1 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.

10.2 Projects must not commence until written approval has been received [Code 2.2.23].

11 Monitoring of Teaching/Research Projects

11.1 To ensure compliance with the Code and any relevant legislation, the Committee will determine the regularity and frequency of inspection of records relating to acquisition, breeding, health, care, housing, use and disposal of animals.

11.2 The Secretary shall be responsible for ensuring that the inspection occurs as required and that inspection reports are presented to the Committee.

11.3 The Secretary shall maintain a register of inspection visits and reports.

11.4 Members of the Committee shall inspect animal housing and laboratory areas regularly, record their findings and report to the Committee [Code 2.2.29]. Where possible, a member of the Committee who is external to CQUniversity will participate in inspections [Code 2.2.30].

11.5 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 2.2.32].

11.6 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 2.2.31].

11.7 Where inspections detect activities that are non-compliant with the Code, the Committee shall ensure that such activities cease immediately and remedial action is initiated [Code 2.2.33].

11.8 On each site where animals are used, including the location where fieldwork is undertaken, the Committee shall authorise a person to respond to emergencies, including unexpected adverse outcomes, in the absence of the investigator or teacher [Code 2.2.35]. The Committee Secretary will maintain the contact details for the authorised person.

11.9 In an emergency, before an animal is treated or killed, reasonable steps shall be taken to consult the researcher or student and the Chair of the Committee. Any treatment or euthanasia shall be reported promptly to the responsible Chief Investigator or teacher and the Committee with reasons for the action taken, and confirmed in writing [Code 2.2.36].

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11.10 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 2.2.29].

12 Reporting of Adverse Occurrences

12.1 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.

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 2.2.28]

12.2 A member of a Committee inspection team or the person nominated to respond to emergencies must report any treatment or killing of an animal in an emergency situation, including reasons for any action taken. This must be reported in writing to the Chair of the Committee and the Chief Investigator by no later than the next working day after authorisation of the treatment or killing or response [Code 2.2.36].

12.3 The Chair shall have delegated authority to:

- consult with any other members of the Committee and any other parties to seek advice and assistance in addressing matters arising from any report of adverse occurrence or unforeseen event;
- suspend approval for a research/teaching project and advise the researcher(s) or student(s), the Pro-Vice-Chancellor (Research) and any other formal parties to the project to this effect in writing;
- restore approval for a research/teaching project and advise the researcher(s) or student(s), the Pro-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 adverse occurrence or similar event.

12.4 The Chair shall report on any matters involving adverse occurrences at the next meeting of the Committee and shall seek ratification of any withdrawal of approval or restoration of approval.

12.5 If the Committee agrees on the termination of a project, the Committee will make a recommendation to the Pro-Vice-Chancellor (Research). The Pro-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.

13 Reporting of Projects

13.1 All researchers shall be required to report annually and on the completion of approved projects [Code 2.2.37 & 2.2.39].

13.2 The Committee shall prepare for use of researchers and students a proforma detailing the format and requirements for presentation of reports.

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13.3 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, require modification or be discontinued [Code 2.2.38].

14 Reporting to the Institution

14.1 The Committee shall report annually to the Research Committee of Academic Board and the report shall include:

- numbers and types of projects assessed and approved or rejected;
- the physical facilities for the care and use of animals by the institution;
- activities that have supported the educational needs of Committee members, and of personnel involved in the care and use of animals;
- administrative or other difficulties being experienced; and
- any matters that may affect the institution's ability to maintain compliance with the Code and if necessary the provision of suitable recommendations [Code 2.2.40].

15 Receiving Complaints

15.1 The Committee shall follow the Animal Ethics Committee Grievance Procedures 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.

16 Advising of the Discontinuation of an Approved Project

16.1 *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 Committee shall withdraw its approval.
- The Committee shall formally advise the researcher(s) or student(s), Pro-Vice-Chancellor (Research) and Secretary of any withdrawal of approval and recommend to the Pro-Vice-Chancellor (Research) that the research/teaching project be discontinued, suspended or that specified steps be taken to allow the project to continue.

16.2 *Researcher advising the Animal Ethics Committee:*

- As a condition of approval [Code 3.1.12] the researcher has the responsibility to report the project discontinuation within five working days to the Committee.

17 Projects Involving More Than One Animal Ethics Committee

17.1 Where projects are to be conducted at more than one institution, the Committee will request a copy of the approval certificate from the other institution [Code 2.2.41].

17.2 Where parts of a project take place at different institutions, the Committee may choose to approve and monitor only those parts that take place at its institution. Notwithstanding this arrangement, it is essential that each Animal Ethics Committee is cognisant of all aspects of the project and ensures that any cumulative impact of procedures on animals is considered. Such arrangements will be part of a formal agreement between the institutions involved.

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18 Projects Conducted in Other Countries in Association with Australian institutions

18.1 The welfare of animals used for scientific purposes in countries not subject to the Code or Australian law shall be considered by the Committee on a case-by-case basis [Code 2.2.45].

18.2 In the case where an Australian institution operates facilities that use animals for scientific purposes in another country, projects at those facilities should be compliant with the Australian Code [Code 2.2.46].

19 Non-Compliance with the Code

19.1 In the event that an activity in breach of the Code or any relevant legislation is identified, the Committee will ensure that the activity ceases immediately and that appropriate action is taken. The Committee shall follow sections 11-15 of the Code of Conduct for Research to resolve any breach of Codes [Code 2.2.48].

20 Fees

20.1 The Committee shall consider only projects and protocols from persons affiliated with CQUniversity and will charge no fees for its considerations.

21 Confidentiality of the Content of Protocols and Committee Proceedings

21.1 Research protocols submitted for approval will remain confidential to the Committee, any persons from whom expert advice is sought by the Committee, and its Secretary.

21.2 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.

21.3 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 Pro-Vice-Chancellor (Research) in the event of a complaint concerning a research project or a grievance or an irreconcilable difference with the Committee.

22 Record Keeping

22.1 The Secretary will maintain a record of agendas, reports and other aspects of the Committee's operation [Code 2.2.12 & 2.2.24].

22.2 The application proposal shall contain the following information [Code 2.2.16]:

- 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;

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- Potential benefits of the project;
- Overview of the project;
- Reduction;
- Replacement;
- Refinement;
- Monitoring of animals;
- Justification;
- Practical considerations to assist Animal Ethics Committees and animal carers;
- Declaration.

22.3 The Secretary shall maintain a register for all proposals and shall keep the following records for each teaching or research proposal submitted for ethics approval:

- Commencement and completion dates for project;
- Name of the Chief Investigator;
- Names of all other researchers;
- Names of any supervisors;
- Title of project;
- Ethics approval or non-approval with date;
- Approval or non-approval of any changes to the protocol;
- Details of the animals, including species and numbers;
- Terms and conditions if any of approval of any protocol;
- Whether the opinion of another Animal Ethics Committee was considered;
- Action taken by the Committee to monitor the conduct of the research;
- Any adverse occurrences and actions taken in consequence .

22.4 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.

22.5 The Secretary shall keep on file a copy of all reports to governing bodies and the institution.

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.

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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.

RESPONSIBILITIES

The Animal Ethics Committee is responsible for ensuring these procedures are followed.

RECORDS

All records relevant to these procedures are to be maintained in a recognised University record keeping system.

DOCUMENTATION

Animal Ethics Committee Operating Policy
Australian code of practice for the care and use of animals for scientific purposes 2004
Animal Care and Protection Act 2001

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