

James Cook University Animal Ethics Committee
Terms of Reference

1. Purpose

The Animal Ethics Committee's purpose is to:

- 1.1. Ensure, on behalf of James Cook University (JCU), that all activities relating to the care and use of animals are conducted in compliance with the *Australian code for the care and use of animals for scientific purposes* (the Code) and the *Act* (the legislation applicable to the state or territory in which the activities will take place).
- 1.2. Oversee all activities using animals for scientific purposes and animal displays must be the subject of oversight and ethical review by the AEC.
- 1.3. Promote ethical conduct and apply ethical standards and the general principles of the Code to all activities involving animals

2. Scope

- 2.1. The AEC will consider proposals for activities and projects involving animals that meet the definitions of animals and scientific purposes in the Code for all staff (including adjuncts), students and agents of JCU and AIMS (Townsville) and any other registered scientific animal users (by agreement), taking place in a jurisdiction in which JCU is registered to operate.
- 2.2. The AEC will consider proposals for animal displays, exhibits and holding on JCU property.
- 2.3. The AEC will consider proposals for activities and projects involving animals that meet the definitions of animals and scientific purposes in the Code for external applicants if their use of the AEC is approved by the Committee and they are registered to operate in Queensland.
- 2.4. The AEC cannot consider proposals for the testing of finished cosmetic products, as defined in the Code, or those that involve the Draize test or LD50-type tests.

3. Functions

The AEC functions to:

- 3.1. Review applications for projects and approve only those projects that are ethically acceptable and conform to the requirements of the Code
- 3.2. 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
- 3.3. Conduct follow-up monitoring of approved projects and activities, and allow the continuation of approval for only those projects and activities that are ethically acceptable and conform to the requirements of the Code.
- 3.4. Monitor the care and use of animals, including housing conditions, practices and procedures involved in the care of animals in facilities and at field sites
- 3.5. Take appropriate actions regarding unexpected adverse events
- 3.6. Take appropriate actions regarding non-compliance
- 3.7. Approve guidelines for the care and use of animal on behalf of the institution
- 3.8. Provide advice and recommendations to the institution
- 3.9. Report on its operations to the institution

- 3.10. Develop documentation to support its function, as outlined in the Code.
- 3.11. Advise the University and Provost on such other matters that are within its duties and responsibilities.
- 3.12. The AEC may suspend or withdraw approval for projects or investigators if it feels it is necessary.
- 3.13. The AEC, Chairperson or Animal Welfare Officer may authorise the emergency treatment or euthanasia of an animal if it is felt it is necessary to prevent pain or distress.
- 3.14. The AEC is able to provide approval, in advance, for the immediate use of animals, if required, for the diagnosis of unexplained and severe disease outbreaks, or morbidity/mortality, in animals or people.
- 3.15. The AEC will perform any other duties as required by the Code.

4. Accountability

- 4.1. The AEC is accountable to the Provost of JCU.
- 4.2. The AEC will provide an annual report to the Provost on its activities and compliance with the Code, and the Chair and Manager, Animal Welfare and Research Ethics will meet to discuss this report and any issues to do with the operation of the AEC.
- 4.3. The AEC will provide an annual report to the regulators in each Australian jurisdiction in which JCU holds registration to operate.
- 4.4. JCU Connect will provide the administrative support and the resources necessary for the compliance and performance of the AEC.

5. AEC Operating Procedures

- 5.1. James Cook University has established procedures for the effective governance and operation of the AEC that enable the AEC to comply with legislation, the Code and relevant institutional policies, and promote competent and timely ethical review of animal care and use.

6. Membership

- 6.1. The AEC Membership will comprise at least four people, one from each of the four categories of membership where:
 - 6.1.1. **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
 - 6.1.2. **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. If the business of the AEC relates to the use of animals for teaching only, a teacher with substantial and recent experience may be appointed.
 - 6.1.3. **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 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 nomination by, such an organisation.

6.1.4. **Category D** – a person not employed 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 under-graduate 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.

6.1.5. Categories C and D must together represent one-third of the AEC membership.

Chair:

- 6.2. A Chair will be appointed by the Provost, in addition to Category A to D members and they will not be a member of the AEC.
- 6.3. The Chair should hold a senior position in the institution or may be an external appointee, and where possible will be someone who is independent of the care and use of animals for scientific purposes.
- 6.4. If the Chair is an external appointee they will be provided with the necessary support and authority to carry out the role.
- 6.5. The role of the Chair will be to impartially guide the operation of the AEC, resolving conflicts of interest related to the business of the AEC.
- 6.6. The Chair will facilitate the AEC's decision making but will have no role in the decision-making process.

Acting Chair

- 6.7. At times when the Chairperson is unable to attend, or when the Chair has declared a conflict of interest, an Acting Chair will be appointed to manage AEC business.

Other Attendees

- 6.8. The AEC or its Chair may invite applicants who have submitted animal ethics applications to attend the AEC, as required for the purposes of the AEC.
- 6.9. Managers of animal facilities may be invited to attend meetings as observers to advise the AEC on matters relevant to their facilities, but will not take part in the final decision-making.
- 6.10. To meet regulatory requirements for South Australia, a person involved in the day-to-day care of animals used for scientific purposes will be involved in the review of projects taking place in that jurisdiction.
- 6.11. The AEC may request other personnel to attend meetings if they feel their attendance would be of value.

Notification of a Change to Membership

- 6.12. Regulators in all jurisdictions must be notified of any changes to AEC membership within 28 days.

Terms of Appointment and Meeting Attendance

- 6.13. All members, other than the Chairperson, are appointed for a term of three years. At the end of a member's first term, they may reapply for a second appointment, but if reappointed can only serve one more three year term such that no member can serve more than two consecutive terms at a time. It is acceptable for members to subsequently be re-appointed to the AEC after a period of absence.
- 6.14. Where a replacement member is not able to commence appointment at the end of a current member's term, the current member may be asked to remain on the AEC until the replacement member has been appointed and inducted.
- 6.15. Members who do not attend three consecutive meetings or at least half of the meetings in any calendar year, without approved leave of absence, may be asked to reconsider their membership.

Recruitment, Appointment and Retirement of Members

- 6.16. Recruitment and appointment of new AEC members will be conducted as outlined in the AEC Operating Procedures.
- 6.17. All new AEC members will be provided with an induction as outlined in the Training and Assessment of Competency Procedure.

Acceptance of the Terms of Reference

- 6.18. Prior to commencement, AEC members and the Chairperson will acknowledge their acceptance of these Terms of Reference in writing.

Professional Development

- 6.19. The AEC members will be offered ongoing professional development and support to undertake training in relation to their roles on the AEC wherever possible.

7. Officers of the AEC

Animal Ethics Officer

- 7.1. The Animal Ethics Officer will provide administrative support to the AEC.

Animal Welfare Officer

- 7.2. An Animal Welfare Officer (AWO) will be appointed and will be a registered veterinarian with experience in animal research, welfare and ethics.
- 7.3. The AWO will oversee the university's Program of Veterinary Care and provide advice to the AEC on matters of veterinary, animal welfare, ethics and compliance but will not be a member of the AEC.
- 7.4. The AWO will not be a member of the AEC.
- 7.5. The AEC will delegate to the AWO the power to order the urgent treatment or euthanasia of an animal or its removal from a protocol if it is required.
- 7.6. The AWO will be the point of contact for complaints and animal welfare concerns and will conduct investigations of non-compliance.

8. Animal Ethics Monitors

- 8.1. Animal ethics monitors will be appointed by nomination from their college or approach from the AEC officers.
- 8.2. Animal Ethics Monitors will provide a scientific peer pre-review of AEC applications and be a point of contact within the colleges on matters related to animal ethics and the scientific use of animals.

9. Conduct of Business

Operating Procedures

- 9.1. The HREC shall establish, implement, document its working procedures concerning:
 - Frequency of meetings
 - Attendance at meetings (including non-members and researchers)
 - Conduct and structure of meetings and deliberations
 - Preparation of agendas and minutes
 - Timely distribution of papers prior to meetings
 - Presentation of applications for ethical review
 - Timely consideration and review of applications
 - Identification, declaration and management of any conflicts of interest
 - Prompt notification of decisions to researchers
 - Record keeping
 - Reporting and handling of adverse occurrences
 - Receipt and handling of complaints
 - Advising external institution(s) or organisation(s) of decisions to withdraw ethical approval of a research project
 - Handling of complaints
- 9.2. The AEC Operating Procedures will be reviewed at least every three years, or more often as required.
- 9.3. The HREC's Terms of Reference and Operating Procedures will be made public on its website.

Conflict of interest

The AEC will require that all members declare any conflict of interest:

- Prior to their appointment by must, in writing, declare any interest that could influence the objectivity of their decision making.
 - As matters arise by making a declaration to the Chairperson or Animal Ethics Officer.
 - At each meeting in relation to items to be discussed at the meeting, by making a declaration of conflict of interest at the beginning under the item Conflicts of Interest.
- 9.4. All people with a conflict of interest must remove themselves from the decision-making process on matters related to that conflict of interest.
 - 9.5. All conflicts and the measures taken in response will be recorded in the meeting's minutes.

Confidentiality

- 9.6. AEC members and the Chairperson and all other meetings attendees must sign the AEC's confidentiality agreement before being provided with AEC documents or attend a meeting.

Meetings

- 9.7. The AEC shall meet once a month (subject to the number of animal ethics applications received) excluding January.
- 9.8. Animal Ethics applications and agenda items will be submitted and the agenda prepared according to the Operating Procedures and instructions posted on the Animal Ethics Webpage.
- 9.9. The Secretariat shall forward applications and agenda at least one week before the meeting to all members of the AEC.
- 9.10. For the purposes of accountability and meeting efficiency, all meetings shall be run according to a pre-determined agenda with items presented under an item coversheet that clearly identifies the recommended action.

Quorum

- 9.11. A quorum consists of one of each Category of Membership, i.e. Category A, B, C and D with categories C and D together representing at least one-third of members present at a meeting.

Conduct of Meeting

- 9.12. The Chair shall preside at all meetings of the AEC.
- 9.13. Meetings will be face-to-face (all AEC members in the same room) and via video conferencing between the Cairns and Townsville campuses, with members given the option to join by videoconference or attend in person.
- 9.14. The conferencing feature must be utilised so that all participating members can see and/or hear each other during discussions and decision-making.

10. Commercial-in-Confidence

- 10.1. The AEC operates under strict confidentiality. In order to fulfil its role and comply with the Code, the AEC must be provided all the information relevant to a particular project. For this reason, the AEC cannot approve applications where necessary information is not provided and does not accept commercial-in-confidence as a reason for withholding necessary information.
- 10.2. The AEC also requires that wherever possible all research involving animals must be published or disseminated to the scientific community.

AEC Decisions

- 10.3. Respect for animals must underpin all decisions and actions involving the care and use of animals for scientific purposes. The respect is demonstrated by:
 - 10.3.1. Using animals only when justified
 - 10.3.2. Supporting the wellbeing of the animals involved
 - 10.3.3. Avoiding or minimising harm, including pain and distress, to those animals
 - 10.3.4. Applying high standards of scientific integrity
 - 10.3.5. Applying Replacement, Reduction and Refinement (the 3Rs) at all stages of animal care and use:
 - The Replacement of animals with other methods
 - The Reduction in the number of animals used

- The Refinement of techniques used to minimise the adverse impact on animals
- 10.4. Knowing and accepting one's responsibilities.
- 10.5. 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.
- 10.6. Each AEC member is responsible for deciding whether, in their own judgement, an application or other matter under consideration by the AEC is ethically acceptable and meets the requirements of the Code. AEC members should be familiar with the requirements of the Code and other policies and guidelines relevant to the business of the AEC.
- 10.7. Decisions will be made on the basis of consensus. Where consensus cannot be reached after reasonable effort to resolve differences, the AEC should explore ways of modifying the project or activity that may lead to consensus. If consensus is still not achieved, the AEC should only proceed to a majority decision after members have been allowed a period of time to review their positions, followed by further discussion.

Records and Documentation

The AEO will maintain all AEC records in line with the Code and JCU policies, including:

- 10.7.1. A register of all applications to the AEC, including the outcomes of deliberations
 - 10.7.2. Minutes that record decisions and other aspects of the AEC's operation
 - 10.7.3. Records of inspections conducted by the AEC
- 10.8. Animal carers will have access to records of those approved projects and activities that relate to the facilities they work in.

Guidelines and Standard Operating Procedures (SOP)

- 10.9. Guidelines for animal care and use must be developed in consultation with the AEC, approved by the AEC, and implemented and promoted within the institution.
- 10.10. New SOPs must not be implemented into practice until they have been included in an application for consideration by the AEC and approved by the AEC.
- 10.11. An SOP can only be referenced in an application under the following conditions:
- the SOP must have current approval from the AEC
 - the SOP must include in its title the date of approval or last review by the AEC
 - investigators named in the application must be competent to implement the SOP
 - any variation to an SOP must be described in the application and should be considered as a prompt for review of the SOP.

11. Executive Committee

- 11.1. The Executive Committee membership will consist of the Chairperson and at least one member of the Categories C or D.
- 11.2. The Executive Committee may be delegated to review minor amendments to approved projects or activities. The AEC will provide guidance on the type of activity that would be considered a minor amendment where the proposed change is not likely to cause harm to the animals, including pain and distress. This guidance will be outlined in the AEC's Operating Procedures.

- 11.3. Decisions made by the EC must be ratified at the next AEC meeting.
- 11.4. The AEC must not approve new application.

12. Complaints and Grievances

JCU will ensure that:

- 12.1. Where complaints relate to activities that have the potential to adversely affect animal wellbeing, the activities must cease immediately and immediate actions will be to ensure animal welfare.
- 12.2. Where complaints relate to activities that would normally require AEC approval, the complaints are referred to the AEC to investigate whether such activities are conducted in accordance with AEC approval
- 12.3. Where complaints raise the possibility of 'research misconduct', as described in the *Australian code for the responsible conduct of research*, the complaint is handled in accordance with procedures specified in that document
- 12.4. Where complaints allege misconduct that falls outside the range of 'research misconduct', as described in the *Australian code for the responsible conduct of research*, the complaint is handled in accordance with institutional processes for dealing with other forms of misconduct.
- 12.5. Procedures for handling complaints, investigations and actions related to non-compliance are outlined in the AEC's Operating Procedures.
- 12.6. Complaints related to the policies, actions, decisions or operation of the AEC will be handled as outlined in the AEC's Operating Procedures.
- 12.7. A summary of all complaints and incidences of non-compliance will be provided in the AEC's Annual Report.

13. Conscientious Objection to Animal Activities

- 13.1. JCU will develop procedures that allow staff and students the right to abstain from activities that involve animals if they have a genuine conscientious objection.

14. Freedom of Information

- 14.1. In line with the *Right to Information Act* and *Information Privacy Act*, members of the public may apply to have access to AEC documents or information that aren't made readily available through other means.

15. Monitoring the Care and Use of Animals

The AEC will monitor the care and use of animals at JCU by:

- 15.1. Conducting follow-up reviews of approved projects and activities through annual and final reporting and allowing the continuation of approval for only those projects and activities that are ethically acceptable and conform to the Code.
- 15.2. Conducting an annual inspection of permanent animal holding facilities
- 15.3. Conducting other announced and unannounced inspections of facilities and research locations
- 15.4. Authorising a delegate to carry out an inspection
- 15.5. Reviewing video or photographic material for fieldwork or overseas work
- 15.6. Reviewing Unexpected Adverse Events (UAE) Reports, annual progress and final reports
- 15.7. UAEs will be handled in line with the UAE Policy and Procedure

16. Training and Assessment of Competency

- 16.1. All people working with animals at JCU must be trained in the legislation, the Code and JCU AEC's policies and procedures.
- 16.2. People who care for and use animals must be competent in the procedure they perform or be under the direct supervision of a person who is competent to perform the procedure.
- 16.3. All people who care and use animals must participate in the AEC's Training and Competency Program, which is outlined in the Training and Assessment of Competency Policy and Procedures with the competencies documented in their training record.

17. Independent External Review of the Operation of Institutions

- 17.1. An independent external review of the animal-related operations of JCU will take place at least every four years.
- 17.2. The external review will be conducted as outlined Section 6 of the Code.

18. Annual Review of the Terms of Reference

- 18.1. The Terms of Reference of the AEC will be reviewed after the AEC's annual review of operations if required and following any changes to the legislation or the Code, in conjunction with the external review of the University, as per section 6 of the Code or as required to ensure effective compliant operation of the AECs.
- 18.2. Following any changes, the Terms of Reference will be reviewed by the AEC, and if acceptable a recommendation will be made to the Provost for approval. The approved document will then sent to the Queensland Regulator for approval.