

Terms of Reference

Animal Ethics Committee (AEC)

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1. Role and responsibilities of the AEC

The Federation University Animal Ethics Committee (AEC) is appointed by the Pro Vice-Chancellor (Research and Innovation). As per requirements of the National Health and Medical Research Council (NHMRC), the Committee reviews proposals for research and teaching involving animals and monitors progress of approved proposals in accordance with the *Australian Code for the Care and Use of Animals for Scientific Purposes 2013* (the Code) and the *Australian Code for the Responsible Conduct of Research 2018*.

The AEC ensures research and teaching that involves animals conducted by Federation University academics is designed in accordance with the following governing principles:

- using animals only when it is justified
- supporting the wellbeing of the animals involved
- avoiding or minimising harm, including pain and distress, to those animals
- applying high standards of scientific integrity
- 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
- knowing and accepting one's responsibilities.

The role of the AEC is to:

- Ensure that Federation University (the institution) has in place appropriate policies and practices for the administration of research and teaching involving animals, and to oversee these practices.
- Ensure that research and teaching projects involving animals that fall within the jurisdiction of Federation University are not conducted without the appropriate approval of the Committee.
- Review the ethical acceptability of research and teaching proposed by Federation University researchers involving animals as per the Code.
- Approve only those proposals deemed to satisfy requirements of ethical standards as described in the Code.
- Monitor approved projects to completion and allow the continuation of approval for only those projects that are ethically acceptable and conform to the requirements of the Code.
- Where appropriate, advise the institution on appropriate action regarding non-compliance.
- Annually report on operations to the Federation University Research Committee.

2. Committee membership

2.1 Membership categories

2.1.1 In accordance with the minimum requirements for membership of an AEC as specified by the Code, the University will appoint at least four members, including:

- **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.
- **Category B**
A suitably qualified person with substantial and recent experience in the in 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.

- 2.1.2 The PVC (Research and Innovation) shall appoint a Committee Chairperson with relevant experience and expertise. This may be a senior Federation University researcher.
- 2.1.3 A Deputy Chairperson shall be elected by the Committee from its Category A-D members.

2.2 Executive of the Committee

- 2.2.1 An Executive shall be appointed by the Committee, comprising the Chairperson and at least one member from Categories C or D, to make decisions on minor amendments of approved and provisionally approved projects. A quorum shall be two members.
- 2.2.2 These decisions will be ratified at subsequent Committee meetings.

2.3 Recruitment of Committee members

- 2.3.1 Federation University may recruit new AEC members by calling for expressions of interest.
- 2.3.2 Expressions of interest should include a current curriculum vitae, short statement of interest and, if applicable (for Federation University staff members), line manager approval.
- 2.3.3 Applicants (excluding Chair and Deputy Chair) will be interviewed by the Manager, Research Ethics and the current AEC Chair.
- 2.3.4 Applicants for the Chair and Deputy Chair positions will be interviewed by the PVC (Research and Innovation) and the Director Research Services and/or Manager, Research Ethics.
- 2.3.5 AEC members will be appointed in writing by the PVC (Research and Innovation) with the approval of the Department of Energy, Environment and Climate Action (DEECA), for a four year term, renewable with the agreement of both parties. Members are re-appointed on the Chairperson's recommendation to the PVC (Research and Innovation).
- 2.3.6 AEC members will not receive payment for their membership of the AEC or attendance at meetings. However, non-Federation University staff members will be reimbursed for expenses associated with Committee membership via the Research Compliance Committees External Members Allowance, set and managed by Research Services and payable at the completion of each meeting.
- 2.3.7 Committee members may resign at any time by notifying the Manager, Research Ethics in writing of their intention to leave the Committee.

2.4 Requirements of Committee members

- 2.4.1 New Committee members must acknowledge in writing their acceptance of the terms of reference of the AEC and sign a Membership Agreement, which includes confidentiality requirements.
- 2.4.2 New members are required to complete the mandatory Animal Ethics Committee member training provided by Animal Welfare Victoria, as well as any other relevant training, as advised by the Manager, Research Ethics.
- 2.4.3 New members will be invited to observe one Committee meeting prior to commencing their role on the Committee.

- 2.4.4 Committee members are required to provide the Ethics Team, Research Services, with current contact details including telephone number, email address and, if appropriate, postal address.
- 2.4.5 Federation University retains the right to terminate Committee membership for reasons including:
- Inability to maintain adequate level of participation in Committee proceedings;
 - Inability to meet the responsibilities of the Committee or terms of appointment, as per letter of appointment and Membership Agreement; and/or
 - Proper and effective functioning of the relevant Committee.
- 2.4.6 Committee members are advised to undertake regular professional development related to the work of the Committee and notify the Ethics Team. This may include, but is not limited to, in-meeting presentations organised by the Ethics Team or Committee.

2.5 Indemnity

- 2.5.1 Federation University will provide professional indemnity for members of the AEC in respect of liabilities that may arise during the conduct of their duties.

2.6 Conflicts of Interest

- 2.6.1 A member of the Committee who is aware of having a direct or indirect interest, pecuniary or otherwise, in a matter being considered must disclose the nature of the interest immediately.

3. Meetings

3.1 Meeting dates

- 3.1.1 Meetings of the AEC will be scheduled every second month from February to December on dates and times determined by the Research Services Ethics Team, in consultation with the Committee Chair. At least two meetings must be held each year.
- 3.1.2 Meetings may be cancelled with the agreement of the Committee Chair due to lack of business.
- 3.1.3 Committee meeting dates and application deadlines will be published on the Federation University website by the end of each calendar year for the following 12 months. Minor adjustments may be made to these dates as necessary to account for public holidays or other unforeseen interruptions to the normal schedule.
- 3.1.4 The Committee may elect to conduct special meetings, if circumstances or the nature of business is urgent or extraordinary.

3.2 Requirements for quorum

- 3.2.1 The AEC must have a quorum of members in attendance to conduct meetings. Such quorum must comprise at least one member from each category. Categories C and D together must represent at least one-third of those members present.
- 3.2.2 Attendance of quorate meetings may be facilitated by submission of written comments, video linking or teleconferencing of some members.

3.3 Conflicts of interest

- 3.3.1 Any member of the AEC who has a conflict of interest associated with a proposal or other related matter being considered by the AEC should declare such an interest at the earliest opportunity. The member shall remove themselves from the Committee's decision making on matters related to the conflict. The Committee may request that a person with a conflict of interest leave the meeting during discussion of the relevant project, to return once the AEC has considered the matter and a decision has been reached. All declarations of interest and their management and absences of members will be minuted. Where there are no declarations of interest, this will also be minuted.

3.3.2 No Committee member may participate in review or discussion on research in which that member has any conflict of interest, including any personal involvement or participation in the research, any financial interest in the outcome or any involvement in competing research.

3.4 Committee decisions

3.4.1 The AEC will examine applications for approval with the following decisions:

- **Approved**
The AEC is satisfied that the application is ethically acceptable and complies with the Code. The application is approved by the AEC, as submitted, with no changes required.
- **Approved with comment**
The AEC is satisfied that the application will be ethically acceptable and comply with the Code, subject to a specific correction or defined alteration. Alternatively, where outcomes or effects of procedures are not well known, the AEC may wish to receive reports at specified time points to ensure the project remains ethically acceptable. The agreed and exact condition(s) are recorded in AEC meeting minutes as a decision of the committee. The investigator is made aware that exact conformity with specified alterations is a condition of approval. The condition(s) of approval must be defined in the letter of approval. For example, the AEC may require six monthly progress reports or require completion of one stage of the research before approving for the next stage to commence.
- **Provisional approval**
The AEC is satisfied that the application has in-principle approval but requires additional information and the required modifications meet the committee's criteria for minor changes. The AEC will communicate the reasons for their decision to researchers via the Research Services Ethics Team. In that instance the revised application may be considered out of session and the approval is delegated to the Executive of the Committee. The approval date is the date approved by the Executive. Approval is ratified by the AEC at its next meeting.
- **Approval withheld**
The AEC is satisfied that the application has in-principle justification, but requires additional information, clarification or changes to make a decision that are outside of the scope of a minor amendment. The AEC will communicate the reasons for their decision, based on the criteria outlined in the Code, to researchers via the Research Services Ethics Team. In that instance the resubmitted application must be resubmitted for review at a quorate meeting.
- **Not approved**
This situation will arise where, in the judgment of the AEC, the potential effects on the wellbeing of animals involved is not justified by the potential benefits of the project. In this circumstance the AEC should clearly communicate the reasons for its decision, quoting relevant sections of the Code as appropriate. A research proposal that has been rejected on ethical grounds cannot be resubmitted.

3.5 Consensus

3.5.1 The AEC will endeavour to reach a unanimous consensus decision concerning the ethical acceptability of a research protocol. Where a unanimous decision is not reached, the Committee may explore with the applicant(s) 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.

3.5.2 Meetings will be conducted in such a way to encourage discussion, debate and the exchange of ideas.

3.6 Confidentiality

3.6.1 All matters relating to research proposals and Committee proceedings are confidential.

4. Reporting

The AEC will report annually to the Research Committee via the Manager Research Ethics. The AEC will also report via the Chairperson/Manager Research Ethics to the PVC (Research and Innovation) relevant matters, including:

- 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.

5. Project monitoring and compliance

- 5.1 The AEC will monitor approved projects in accordance with the Code to verify that the conduct of the research conforms to the approved proposal.
- 5.2 Mechanisms for monitoring include, but are not limited to:
 - a. Review of annual project progress reports;
 - b. Review of incident and adverse event reports, as applicable;
 - c. Review of amendment requests, as applicable;
 - d. Risk based monitoring and /or auditing of research;
 - e. Site inspections carried out by a Category C or D member (at minimum); and
 - f. Other forms of monitoring in accordance with the Code.
- 5.3 The AEC requires that annual progress reports are submitted for all approved projects. Reports are due annually in January until project completion or approval expiry.
- 5.4 More frequent progress reports may be required if the AEC deem appropriate. In such cases, researchers shall be notified in writing at the time of approval.
- 5.5 The AEC requires that final progress reports are submitted for all approved projects. Final reports are due on the earlier date of either expiry of approval or within one month of project completion.
- 5.6 Submission of a final report results in the project being closed off. Closed projects cannot be reopened except via submission of a new application.
- 5.7 The Committee may be asked to consult on any event that may warrant review of ethical approval.
- 5.8 The Committee may withdraw approval for any project due to researchers failing to report on project progress or to submit amendment requests as required.
- 5.9 The Committee may temporarily suspend, or withdraw approval for a project, due to failure to conduct research as approved.
- 5.10 If it is deemed that animal welfare may be jeopardised by continuation of a project, the Committee may temporarily suspend or withdraw ethics approval pending an investigation/decision regarding next steps.
- 5.11 Complaints considered to raise the possibility of research misconduct, as outlined in the Code, will be referred immediately to the Research Integrity Office, as per relevant institutional policies and procedures.