

Animal Experimentation Ethics Committee Operating Procedures

Section 2.2.10 of the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes states that Animal Ethics Committees must establish and document procedures that will enable compliance with the provisions of the Code and where relevant the policies of the institution. It outlines particular areas that such procedures shall cover, and these are included in this document.

Assessment of proposals

1. The AEEC meets every month except December. Proposals that are to be considered at a particular meeting should be submitted in ARIES by the last business day of the preceding month. Amendments to approved proposals are required to be submitted at this time. The Animal Ethics Officer allocates a protocol number to all new proposals
2. Proposals, amendments, annual reviews, along with the agenda, and previous minutes and items of general business are circulated electronically by the Animal Ethics Officer in a "package" to committee members as close as possible to the first day of the month in which the meeting to be held. The contents of the "package" are also available in ARIES.
3. AEEC members read proposals, amendments, annual reviews and any circulated items of general business and direct questions through the AEEC Executive Officer to the primary investigator. Please provide replies to questions by investigators to Pauline.Pilcher@anu.edu.au. Replies are required by COB of the Friday preceding the meeting, although under extenuating circumstances, and at the discretion of the AEEC secretariat, replies may be submitted up to the morning of the meeting.
4. Questions and answers are projected to a screen to facilitate committee consideration during the meeting. The AEEC may wish to speak to an investigator to clarify points and if this is required the investigator is notified in advance of the meeting.
5. The Committee may approve a proposal without conditions, it may approve a proposal with conditions, or it may not approve proposals. When answers to questions are agreed to be satisfactory by all members then the proposal or amendment is approved and signed off by the Chair at the completion of the meeting. If AEEC members are not satisfied with the standard of the proposal, the answers to questions, or if the proposal does not address ethical concerns, a decision may be deferred, or the proposal may be rejected.
6. Annual reviews are considered on a case-by-case basis at the meeting and should be used to determine if a project may continue, be suspended, require modification, or be discontinued.
7. Committee decisions are made on the basis of consensus, with the AEEC's definition of consensus being that all members agree concerning the point under consideration. Should this not be the case then a decision shall be held over to a subsequent meeting with further discussion in an attempt to reach consensus.

Special Meetings

Special meetings may occur if circumstances dictate. Proposals are not normally considered at special meetings. In the past special meetings have been usually called to consider an animal welfare incident.

Quorate AEEC Meetings

For a meeting to be quorate it is a requirement that at least one member of Categories A, B, C, and D be present. It is a requirement of the Code that Categories C plus D should represent not less than one third of those members present. In addition to Category A,B,C, and D members the AEEC will appoint one or more people responsible for the care of animals. Observers may attend an AEEC meeting providing confidentiality requirements are met.

Exceptional Circumstances

In unusually exceptional circumstances where a face-to-face meeting is not possible a meeting may be conducted through the use of video linking or teleconferencing.

Delegation of Authority to Inspect Sites

The AEEC may delegate a sub committee of its members to inspect sites. It may also delegate its Executive Officer to monitor projects at remote sites or where it requires a report concerning a specific project.

Dealing with Non-Compliance with the Code

The ANU AEEC considers activities and facilities that are non-compliant with the Code in considerable detail. Non-compliant activities are often the subject of special meetings. Procedures are discussed with the ANU Legal Office. The Committee interviews the primary investigator, and, where necessary subordinate members of the involved research group. Non compliance issues are discussed with the appropriate ProVice-Chancellor (Research) and the Deputy Vice-Chancellor. Within the terms of the ACT Animal Welfare Act 1992, the AEEC may suspend or cancel authorisations.

1. Reporting concerns regarding the use of animals

Section 2.2.47 of the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes (7th Edition, 2004) (the Code) provides that institutions, AEC's, investigators and teachers have responsibility for compliance with the Code.

Section 2.2.48 requires the institution and the AEC to prepare written procedures, which are agreed to by the institution, (see 2.1.1(v)) to deal with non-compliance and any grievance related to the AEC process (see 2.2.10(v)). The written procedures must clearly define the reporting mechanisms and the responsibility of all parties to ensure fair and effective process.

Section 2.1.1(v) of the Code discusses the responsibility of institutions to implement processes to address concerns raised by the AEC regarding non-compliance with the Code which may include disciplinary action upon advice of the AEC.

Section 2.2.10(v) requires AEC's to establish and document procedures that will deal with non-compliance of the Code to ensure that the processes are fair and effective and that there is appropriate reporting to the institution

Section 2.2.33 states that where inspections detect activities that are non-compliant with the Code, the AEC must ensure that such activities cease immediately and remedial action is initiated.

2. Handling of complaints/concerns

- (i) where disclosures are made to the AEEC, it will endeavour to apply the principles set out in the University's Protected Disclosures Policy to the extent relevant;
- (ii) complaints/concerns will be dealt with confidentially and in accordance with natural justice principles;
- (iii) investigation of a complaint/concern may include:
 - a. interviews with the person raising the complaint/concern, the subject of the complaint/concern and/or witness;
 - b. inspection of the facility or animals the subject of the complaint/concern; and/or
 - c. seeking of advice from experts within or external to the University;
- (iv) concerns or complaints should be confirmed in writing to the Executive Officer of the AEEC, Dr Simon Bain (ext. 50422, email Simon.Bain@anu.edu.au), though they may be made orally in the first instance.

3. Concerns regarding treatment of animals

- (i) Where a person (including an AEEC member) is concerned about the treatment of animals in a facility for which the University is responsible, they should raise that concern with the AEEC via its Executive Officer.
- (ii) Any concern raised will be considered by the AEEC at its next ordinary monthly meeting, at a special meeting called to discuss the matter, or by AEEC members by electronic communication, depending on the seriousness and urgency of the concern. In urgent cases, the AEEC may take action to ensure that the behaviour/situation giving rise to the concern is immediately suspended pending a decision of the AEEC.

- (iii) The AEEC will investigate the concern and will determine:
 - a. whether the Code has not been complied with;
 - b. any necessary remedial action to be undertaken;
 - c. whether the research protocol/investigators/activities giving rise to the concern are to be suspended for a period of time or discontinued.
- (iv) The AEEC's decision will be communicated to the person raising the concerns, the relevant Investigators and the University's Deputy Vice-Chancellor (Research).
- (v) If the person raising the concern/an Investigator is dissatisfied with the decision of the AEEC or the procedures followed by it, he/she may direct his/her complaint to the Deputy Vice-Chancellor (Research). The Deputy Vice-Chancellor (Research)'s decision on the matter will be final.

4. Concerns regarding decisions made by the AEEC

- (i) Where an Investigator considers that the AEEC has not complied with its responsibilities under the Animal Welfare Act 1992 (ACT), the Animal Welfare Regulation 2001 (ACT) or the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes (7th Edition, 2004), the Investigator should make a complaint to the AEEC via its Executive Officer within one month of being notified of a decision of the AEEC. The complaint should outline the evidence upon which the complaint is based.
- (ii) Any complaint received will be considered by the AEEC at its next ordinary monthly meeting, at a special meeting called to discuss the matter, or by AEEC members by electronic communication, depending on the seriousness and urgency of the complaint.
- (iii) The AEEC will review the matters giving rise to the complaint and will determine:
 - a. to uphold its decision; or
 - b. to vary its decision.
- (iv) The AEEC's decision will be communicated to the complainant and the University's Deputy Vice-Chancellor (Research).
- (v) If the Investigator is dissatisfied with the decision of the AEEC or the procedures followed by it, he/she may direct his/her complaint to the Deputy Vice-Chancellor (Research). The Deputy Vice-Chancellor (Research)'s decision on the matter will be final.

Investigators who are ANU staff, students or visitors should be aware that the AEEC's procedures for investigating breaches of the Code are separate from those of the University for investigating misconduct in research. Findings reported to the Deputy Vice-Chancellor (Research) under these Non-Compliance and Grievance Procedures may found misconduct action by the University under its Responsible Practice of Research Policy, Responding to Allegations of Scientific Misconduct that involve United States Public Health Service Research Grants or Applications for Funds or Enterprise Agreement.

Resolution of Conflicts of Interest

The AEEC requires members to declare conflicts of interest. Conflicts of interest may occur when proposals in which AEEC members are involved are considered by the Committee and it is normal for the member to declare the conflict of interest at that time. The system of questions directed to specific proposals prior to the meeting usually circumvents potential problems. In particularly sensitive issues involving conflicts of interest the member with the conflict would be expected to absent themselves from the meeting while the issue was considered.

Immediate use of Animals

The AEEC may give approval in advance, for the immediate use of animals, should they be required for the diagnosis of unexplained and severe disease outbreaks, or morbidity/mortality, in animals or people.

Wherever possible there should be communication between AEEC members re the relevant circumstances that warrant the immediate use. For this purpose approval in advance is interpreted as approval in advance of animal proposal application.

Veterinary Involvement in Post-mortems

Users of the larger animals such as rabbits, pigs, and guinea pigs are aware of the need for involvement of a veterinarian in performing post-mortems on animals where unforeseen deaths occur. In studies involving mice and rats where death is unforeseen, clinical complications occur as a result of experimental regimes or where euthanasia is necessary due to animal deterioration not identifiable with experimental design, it may be more difficult to determine at what stage a veterinarian should be involved. Performing a post-mortem or series of PM's is important both to identify factors that compromise, or have the potential to compromise science, as well as maintain appropriate animal ethics standards.

The recently released 7th edition of the Australian Code for the Care and Use of Animals for Scientific Purposes (Section 3.3.24) states that when an animal dies unexpectedly, or is euthanased due to unforeseen complications, an autopsy should be performed by a person with appropriate qualifications and/or experience. The AEEC should be notified promptly.

The AEEC has considered this section of the Code, and feel that, while it is appropriate for the investigator or someone appropriately trained to perform the autopsy on a single animal, a veterinarian should be involved in the situation of a larger number of rodents dying of unforeseen complications. Please ring 50422 or 53721 should you wish to request this service.