

Definitions

Please refer to the University's Glossary of Terms for policies and procedures. Terms and definitions identified below are specific to these procedures and are critical to its effectiveness:

AEC: the USC Animal Ethics Committee

Animal: any live non-human vertebrates (that is fish, amphibians, reptiles, birds and mammals encompassing domestic animals, purpose-bred animals, livestock, wildlife) and cephalopods. It includes animals at earlier stages of their development i.e. embryonic, foetal and larval forms that have the potential to experience pain or distress based on evidence of neurobiological development.

Animal carer: any person involved in the care of animals that are used for scientific purposes, including during their acquisition, transport, breeding, housing and husbandry.

Animal Ethics Committee (AEC) Executive: a body consisting of the USC AEC Chairperson and at least one other AEC member from category C or D.

Animal welfare: refers to an animal's quality of life, which encompasses the diverse ways an animal may perceive and respond to their circumstances, ranging from a positive state of wellbeing to a negative state of distress.

Animal wellbeing: refers to an animal being in a positive mental state and that can achieve successful biological function, have positive experiences, express innate behaviours, and to respond to and cope with potentially adverse conditions. Animal wellbeing may be assessed by physiological and behavioural measures of an animal's physical and psychological health and of the animal's capacity to cope with stressors and species-specific behaviours in response to social and environmental conditions.

Competent: the consistent application of knowledge and skill to the standard of performance required regarding the care and use of animals. It embodies the ability to transfer and apply knowledge and skill to new situations and environments.

Ethical review: the review of proposed research or teaching activities with regards to its adherence to the Australian Code for the care and use of animals for scientific purposes.

Ethics: a framework in which actions can be considered as good or bad, right or wrong. Ethics is applied in the evaluation of what should or should not be done when animals are proposed for use, or are used, for scientific purposes.

Research: as defined in the Australian Code for the Responsible Conduct of Research.

Scientific purposes: all activities conducted with the aim of acquiring, developing or demonstrating knowledge or techniques in all areas of science, including teaching, field trials, environmental studies, research (including the creation and breeding of a new animal line where the impact on animal wellbeing is unknown or uncertain), diagnosis, product testing and the production of biological products.

Standard Operating Procedure (SOP): a detailed description of a standardised procedure or process.

The Act: the Animal Care and Protection Act (2001) Qld.

The Animal Code: the Australian code for the care and use of animals for scientific purposes

The Code: the Australian Code for the Responsible Conduct of Research

1. Purpose of procedures

This document outlines the procedures associated with ethical review and is to be read in conjunction with the Animal Ethics - Governing Policy and the Animal Code.

APPROVAL AUTHORITY

Deputy Vice-Chancellor (Research and Innovation)

RESPONSIBLE OFFICER

Deputy Vice-Chancellor (Research and Innovation)

DESIGNATED OFFICER

Director, Office of Research

FIRST APPROVED

8 December 2016

LAST AMENDED

28 May 2019

EFFECTIVE START DATE

2 January 2018

REVIEW DATE

8 December 2022

STATUS

Active

RELATED DOCUMENTS

Animal Ethics - Governing Policy
Enterprise Risk Management - Governing Policy
Managing and Investigating Breaches of Responsible Research Conduct - Procedures
Responsible Research Conduct - Governing Policy
Staff Code of Conduct - Governing Policy

RELATED LEGISLATION / STANDARDS

Australian Code for the Responsible Conduct of Research (2018)
Animal Care and Protection Act 2001 (Qld)
Australian Code for the Care and Use of Animals for Scientific Purposes 8th edition (2013)

This procedure applies to all staff and students, visiting academics, volunteers and other personnel who conduct research or teaching activities involving the care and use of animals for scientific purposes under the auspices of USC. It also applies to the USC Animal Ethics Committee (AEC) and all staff involved in the ethical review of animal research and teaching activities and related protocols.

2. Animal Ethics Committee

2.1 The AEC is the prime body within the institution that has overall responsibility for implementing the stated purpose of the Animal Ethics - Governing Policy.

2.2 The AEC terms of reference and operating guidelines have been developed in accordance with the Animal Code.

2.3 The AEC plays a vital role in USC's animal ethics arrangements, but is not solely responsible for the efficient, timely and quality operation of those arrangements, as this is also a key function of the Office of Research.

3. Ethical review pathways

3.1 Animal research or teaching activities must not commence until written ethics approval has been granted. In addition to the need for ethics approval, an activity may be subject to other internal or external approvals before it can commence, for example, a safety specific risk assessment or biosafety approval.

3.2 Ethics approval is required for the collection, housing and use of animals. In determining the duration of approval for individual projects, the AEC will consider 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 funding bodies.

3.3 Generally, chief investigators (CIs) must be USC staff members and not students or external researchers. In cases where an external researcher has been approved as the CI by another AEC and approval by USC is sought via the prior ethical review pathway, the external researcher may remain listed as the chief investigator.

3.4 Applications must be accompanied by other relevant documents, such as permits and licences, data collection tools, SOPs and record monitoring sheets.

3.5 Applications requiring full ethical review must be submitted at least three weeks prior to the next AEC meeting. Applications eligible for review via another pathway can be reviewed and approved at any time and will be noted or ratified by the AEC at the next meeting.

3.6 The use of animals in other countries must have USC ethics approval prior to commencement of the overseas activity as outlined in Animal Ethics - Governing Policy.

3.7 Research and teaching activities that only involve the observation of animals that does not impact on the animal's habitat or wellbeing, or the use of animal tissue and biological material that does not alter any aspect of an animal's life or death are subject to review and approval via the exemption pathway.

3.8 All animal research and teaching proposals, including activities outlined in 3.7 above, must be submitted to the Office of Research for review via one of the below pathways.

Exemption - for activities as outlined in 3.7 above. Applications are submitted via the Animal Ethics Exemption request form for approval by the Office of Research.

Prior ethical review (PR) - for activities that have already been granted ethics approval by another AEC. Applications are submitted via the Animal Ethics Prior ethical review cover sheet, along with all documentation considered by the other AEC and evidence of their approval, for approval by the Office of Research.

Full ethical review (FR) - for activities that do not qualify for either of the above pathways, or where the Animal Code specifies that the research or teaching activity must be reviewed by an AEC. Applications are submitted via the Animal Ethics Application to use animals for scientific purposes form, along with relevant documentation (as per 3.4 above) for review by the AEC.

4. Amendments to approved projects

4.1 Amendments to approved projects require ethics approval before the amended protocol can commence. Requests for amendments must be submitted to the Office of Research using the relevant form.

4.2 In accordance with the Animal Code, amendments are classified as major or minor and will be assessed on a case-by-case basis depending on the details of the amendment.

4.3 In accordance with the Animal Code, minor amendments are not likely to cause harm to the animals, including pain and distress. Examples of minor amendments may be:

- change in personnel with evidence of relevant experience or relevant training and supervision
- change of location of research that does not change animal welfare or has a lesser impact on animal welfare
- change of source of animals
- refinement in techniques that are beneficial to animal welfare having a lesser impact than the original protocol
- refinement in husbandry and animal housing that is beneficial to the animal.

4.4 Approvals for minor amendments can be granted by the AEC Executive and ratified by the AEC at its next meeting. If the AEC Executive deem the amendment to be major, it will be referred to the AEC for review at the next meeting.

4.5 Major amendments must be approved by the AEC with requests submitted at least three weeks prior to the next AEC meeting.

4.6 If an amendment has already been granted ethics approval by another AEC, the amendment may be reviewed by the Office of Research via the prior review pathway described in 3.8 above. Applicants must submit an Amendment request cover sheet, along with the application documentation considered by the lead ethical review body and evidence of their ethics approval.

5. Projects involving more than one institution or AEC

5.1 Where USC is involved in collaborative research or teaching activities that involve more than one institution and/or AEC, ethics approval must be granted via one of the ethical review pathways listed in section four above prior to the commencement of the activity in which USC is involved.

5.2 If the research or teaching activity has been reviewed and approved by another AEC, USC ethics approval may be granted via the prior ethical review pathway. However, if the ethical review was not in line with the requirements of the Animal Code, or the ethical review body that previously granted approval will no longer be involved in monitoring the project, USC ethics approval will need to be granted via one of the other ethical review pathways outlined in section four above.

5.3 USC staff must disclose all interactions with other institutions and/or AECs relevant to their projects when applying for USC animal ethics approval.

5.4 For activities that involve more than one AEC, the USC AEC will establish an agreement that articulates the monitoring responsibilities of each AEC.

6. Monitoring animal welfare

6.1 Researchers and teachers are responsible for all matters relating to the wellbeing of animals including their housing, husbandry and care throughout the period of use approved by the AEC.

6.2 The CI or teacher in charge has ultimate responsibility to ensure all persons involved in a project understand and accept their responsibilities for the care and use of animals in the project.

6.3 Procedures for monitoring and assessing the wellbeing of the animals must be developed by the investigators and approved by the AEC.

6.4 Monitoring should be carried out by competent people who are knowledgeable about the normal behaviour and signs of pain and distress of the animals being used. Persons responsible for monitoring and emergencies are specifically nominated on the relevant application form.

6.5 Researchers and teachers must ensure that the frequency of monitoring is sufficient to ensure sick, injured or distressed animals are promptly detected and appropriate action is taken.

6.6 Animals held outdoors must be protected from adverse environmental conditions and predation, and provided with access to adequate shelter, food and water.

6.7 The living conditions in indoor facilities in which animals are bred, held and used must be checked daily.

6.8 Appropriate monitoring records must be maintained and accessible by all people involved in the care of the animals. These records must be made available for audit by the institution, the AEC and authorised external reviewers.

6.9 The AEC determines the frequency of inspections of animal holding facilities and animal records. Inspections are normally announced, but if appropriate (for example, where there is an immediate concern about animal welfare) they may be unannounced.

7. Monitoring research and teaching activities

7.1 Researchers and teachers must submit annual and final reports using the Annual/final report form unless the project was approved via the exemption pathway.

7.2 For projects approved via the prior review pathway, applicants may submit a copy of the report submitted to the lead AEC and evidence of their approval for the report instead of the USC Annual/final report form.

7.3 Annual reports are required for each calendar year that ethics approval is active.

7.4 Final reports are due as soon as the use of animals is complete, ethics approval has expired, or the project has been discontinued.

7.5 Reports for projects originally approved via the full review pathway will be reviewed by the AEC.

7.6 Reports for projects originally approved via the prior review pathway may be reviewed by the Office of Research, unless departure from the approved protocol, an adverse event resulting from the activity, or non-compliance with the conditions of approval, in which case the AEC must review the report.

7.7 Compliance may also be monitored by any other means deemed necessary or appropriate, such as random audits.

7.8 The AEC may appoint an agent or delegate to conduct the monitoring and inspection of overseas activities on its behalf.

8. Standard operating procedures

- 8.1 Standard operating procedures (SOPs) for processes likely to be relevant to more than one ethics application must be documented and submitted to the AEC for approval.
- 8.2 New SOPs and amendments to approved SOPs must be approved by the AEC before implementation.
- 8.3 Once approved, SOPs may be referenced in an animal ethics application. The use of an AEC-approved SOP does not negate the need for animal ethics approval.
- 8.4 The AEC may grant a maximum three-year approval for a SOP to be used in animal research or teaching activities. The AEC will only approve the use of a SOP in a research project when it is satisfied that each researcher, teacher or other person who implements all or part of a proposed SOP has the necessary expertise and competency to do so.
- 8.5 A register of approved SOPs will be maintained by the Office of Research and made available to researchers and teachers.
- 8.6 No change may be made to an approved SOP without the approval of the AEC.

9. Emergencies and adverse events

- 9.1 Researchers and teachers must take prompt action in response to adverse events to alleviate pain and distress of animals affected, and if necessary animals should be humanely killed without delay.
- 9.2 Researchers and teachers must report unexpected adverse events within twenty-four hours of the event occurring using the Unexpected adverse event report form to the Office of Research.
- 9.3 In cases where it is not possible to complete the relevant form within one day of the adverse event occurring, the event should be reported to the Office of Research by another means, such as email or phone, until such time the relevant form can be completed.

10. Complaints and non-compliance

- 10.1 Complaints and non-compliance are managed in accordance with the Code, the Animal Code and where appropriate the Responsible Research Conduct - Governing Policy and related procedures.
- 10.2 Where complaints relate to activities that have the potential to adversely affect animal wellbeing, activities must cease immediately and ethics approval may be withdrawn or suspended.
- 10.3 Complaints regarding:
- activities that would normally require ethics approval
 - non-compliance with ethics approval or AEC decisions, and/or
 - the AEC's review of an application, amendment or report
- should be submitted to the Office of Research. Where possible, such complaints should be in writing and include supporting evidence.
- 10.4 The Director, Office of Research or delegate will review the complaint and reach a resolution or refer it to the AEC Chairperson, the AEC or the Deputy Vice-Chancellor (Research and Innovation) as appropriate.
- 10.5 Where such complaints are referred to the AEC or AEC Chairperson and cannot be resolved by communication with the complainant, the matter will be referred back to the Director, Office of Research or delegate for further review, seeking advice internally and/or externally as appropriate, and the matter may be referred to the Deputy Vice-Chancellor (Research and Innovation) for review.
- 10.6 Where deemed appropriate, the Director, Office of Research or delegate or Deputy Vice-Chancellor (Research and Innovation) may request that the AEC review its process in reaching its decision on an application, amendment or report and consider re-evaluating its original decision. However, the ultimate decision regarding the ethical acceptability of an activity lies with the AEC and cannot be overridden.
- 10.7 Where complaints raise the possibility of breaches of responsible research conduct, the complaint will be handled in accordance with the Responsible Research Conduct - Governing Policy and Managing and Investigating Breaches of Responsible Research Conduct - Procedures.
- 10.8 All staff who are involved in handling complaints or non-compliance activities will respect the privacy and confidentiality of the complainant and the respondent and only engage other parties on a need-to-know basis.
- 10.9 Researchers and teachers can be assured that submitting complaints will be a confidential process and will not affect future ethics applications.

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