

# Animal Research Ethics Procedure

## Purpose

This procedure sets out the responsibilities and authorities governing animal research and its ethical considerations in accordance to the requirements of the *Australian Code for the Care and Use of Animals for Scientific Purposes* (henceforth referred to as the *Code*) and other relevant codes and legislation.

## Scope

The content of the procedure applies to all staff and research trainees at UNSW and affiliated centres and institutes involved in animal research in Australia and overseas.

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## Introduction

The use of animals in research and teaching is a privilege that brings with it special considerations on whether their use is justified and ethical and whether animal welfare and animal wellbeing are balanced against the potential benefits to humans, other animals or the environment. At UNSW, proposals for the use of live animals are evaluated for their scientific or educational merit justifying the use of animals and assessed on the grounds that animal wellbeing is at the core of all research and teaching involving animals.

## Principles and Objectives

### 1. Regulatory Environment

UNSW is accredited as an Animal Research Establishment under the *Animal Research Act 1985* in New South Wales and holds current Animal suppliers' licences. The Vice-Chancellor, as Head of the Establishment and Holder of the Animal suppliers' licences, has delegated the Deputy Vice-Chancellor

Research & Enterprise and the Pro Vice-Chancellor (Research) to oversee the conduct of animal research at the University. The DVCRE or PVC(R) and other delegated persons and bodies ensure that animal research is conducted in accordance with the Animal Research Ethics Procedure and deal with breaches accordingly.

All animal research at UNSW and its affiliated centres and institutes requires an Animal Research Authority issued by the DVCRE or PVC(R) on recommendation of the Animal Care and Ethics Committees (ACECs). The review process and monitoring as well as training and policy development on animal research ethics at UNSW and its affiliated centres and institutes is supported by Research Ethics & Compliance Support (RECS).

The principle guidance for policy development is provided by the *Code* and State legislation, including the *Animal Research Act 1985 (NSW)* and *Animal Research Regulation 2021 (NSW)*. The DVCRE or PVC(R) ensures that the University's compliance with the *Code* is reviewed annually and complemented by an independent external review at least every four years.

## 2. Principles of Ethical Review at UNSW

The principles of ethical review of proposed research and teaching projects at UNSW are based on the governing principles of the *Code*. The core principle is the respect for animals which underpins all decisions and actions involving the care and use of animals for scientific purposes.

Animal use is only approved when the use of these animals is justified by the potential benefits and where there is strong evidence that the wellbeing of the animals will be supported. Harm, including pain and distress, to the animals must be avoided or minimised. Scientific integrity is evident at a high standard and persons involved in the research know and accept their responsibilities.

The principles of Replacement, Reduction and Refinement (the 3Rs) are considered for all proposed stages of animal care and use, including whether it is possible to replace animals with other methods, whether the proposed numbers of animals can be reduced, and whether techniques can be refined to support and safeguard the wellbeing of the animals.

## 3. University Animal Care and Ethics Committees

### 3.1. ACEC Terms of Reference

The composition, terms of reference, functions and responsibilities and method of operation of the UNSW Animal Care and Ethics Committees (ACECs) have been established to conform to the requirements of the *Animal Research Act 1985 (NSW)*, the *Animal Research Regulations 2021 (NSW)*, and the *NHMRC Australian Code for the Care and Use of Animals for Scientific Purposes*.

The UNSW ACECs shall act in relation to:

- UNSW and its affiliated organisations including those for which Affiliation Agreements are in force with respect to matters related to the care and use of animals for scientific purposes and the role of the UNSW ACECs; and
- all research, teaching or other activity that involves the care and use of live animals as defined under the relevant *Act* and the *Regulations*.

In addition to the responsibilities accorded under the *Act*, the *Regulations*, Guidelines and the Affiliation Agreements, the UNSW ACECs shall provide advice to the Vice Chancellor of UNSW (or delegated officer) in relation to any animal use in the course of, or relevant to, teaching, research or other activities within UNSW or its affiliated organisations.

The UNSW ACECs are accountable to the governing body of the UNSW, the Council, through the DVCRE or PVC(R), and the Vice-Chancellor.

The UNSW ACECs report to the DVCRE or PVC(R) by providing recommendations on reviewed applications. The Presiding Member, as the Senior ACEC Chair, and other ACEC Chairpersons will meet periodically with the DVCRE or PVC(R) and on an annual basis as a minimum. The ACEC Chairpersons, PVC(R), PVC Research Infrastructure and the Conduct & Integrity Office (and other relevant stakeholders), will meet biannually to discuss activities and key trends relating to animal research ethics and facilities.

The primary responsibility of the UNSW ACECs is to ensure, on behalf of the institution for which it acts, that all activities relating to the care and use of animals are conducted in compliance with the *Code*.

UNSW ACECs operate according to the following terms of reference to:

- review applications for projects and recommend for approval to the DVCRE or PVC(R) only those projects and proposed amendments to projects that are ethically acceptable and conform to the requirements of the *Code*, the *Animal Research Act 1985 (NSW)*, and the *Animal Research*

*Regulation 2021 (NSW)*; 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

- recommend for approval to the DVCRE or PVC(R) only those activities that are ethically acceptable and conform to the requirements of the *Code*, the *Animal Research Act 1985 (NSW)*, and the *Animal Research Regulation 2021 (NSW)*;
- approve guidelines for the care and use of animals on behalf of the institution;
- conduct follow-up review of approved projects and activities, and recommend to the DVCRE or PVC(R) suspension, withdrawal or termination of projects and activities that are not deemed ethically acceptable and do not conform to the requirements of the *Code*, the *Animal Research Act 1985 (NSW)*, and the *Animal Research Regulation 2021 (NSW)*;
- monitor the care and use of animals, including housing conditions, practices and procedures involved in the care of animals in facilities;
- take appropriate actions regarding adverse events, including the authorisation of emergency treatment or humane killing of animals;
- take appropriate actions regarding non-compliance including informing the Conduct & Integrity Office of breaches of the *UNSW Research Code of Conduct* and where deemed appropriate, recommend to the DVCRE or PVC(R) withdrawal, suspension or termination of approval for any project on identification of deviation from the approved protocol or adverse events;
- provide advice to the DVCRE or PVC(R) on draft and existing institutional animal care and ethics policies and procedures and on the implementation for the University of new and revised codes and legislation updates affecting the conduct of animal research;
- provide advice to the University on the building or modification of animal facilities or areas adjacent to animal facilities in relation to animal welfare;
- contribute to the professional development of researchers, research trainees and the induction of new committee members;
- fulfil all agreed obligations to any other accredited institution for which they are providing ACEC purview; and
- report on their operations annually to the DVCRE or PVC(R) and the Council.

### 3.2. ACEC Membership and Appointment

UNSW ACECs have a membership that allows them to fulfil its terms of reference, with at least one third of the members external to the University and including separate persons appointed to each of the following categories:

- Chairperson, with suitable experience, whose other responsibilities will not impair the ACEC's capacity to carry out its obligations under the *Code*;
- 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 UNSW's activities or the ability to acquire relevant knowledge;
- Category B: a suitably qualified person with substantial and recent experience in the use of animals for scientific purposes relevant to UNSW and the business of the ACEC. 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 UNSW, 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; and
- Category D: a person not employed by or otherwise associated with UNSW 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 ACEC, and must not fit the requirements of any other category. Members of the Animal Care Team may attend ACEC

meetings in an *ex-officio* advisory capacity. UNSW animal facility management, or facility representatives from Affiliated Institutes responsible for the routine care of animals within the institution, may also attend ACEC meetings.

All ACEC members are formally appointed by the DVCRE or PVC(R). The term of membership is normally for three years, with the possibility to renew membership for additional terms as decided by the DVCRE or PVC(R). As part of the nomination process potential members are requested to declare real and potential conflicts of interest and facts that may preclude them from the nominated category. External candidates are interviewed and background and referee checks obtained as required.

Memberships may be terminated by the DVCRE or PVC(R) at any time by providing not less than 24-hour notice in writing. Members may voluntarily retire during their appointment by providing not less than 24-hour notice in writing to the DVCRE or PVC(R). Members that are staff of UNSW may need to seek approval from their Head of School or Dean prior to submitting a notice of retirement.

The University offers reimbursement and professional development for ACEC members as determined by the DVCRE or PVC(R) to allow members to fulfil their duties according to the *Code* and UNSW policies and procedures. ACEC members are indemnified under UNSW's general insurance program.

### 3.3. ACEC meetings and decision-making

ACECs meet as required, normally monthly from February to December, to make decisions about animal research ethics proposals at quorate meetings, with at least one member in each category present and Category C and D members representing at least one third of the members present. ACECs should strive to reach decisions by general agreement; this need not involve unanimity.

Any ACEC member who has an interest, through research collaboration or otherwise, in a proposal or other agenda item considered by the ACEC, should as soon as practicable declare such interest and withdraw from the meeting until the consideration of the matter has been completed.

Urgent considerations of new proposals or requests for major amendments to approved projects may only be considered in exceptional circumstances at quorate extra-ordinary meetings at the discretion of the ACEC Presiding Member.

Only minor amendments to approved projects that are not likely to cause harm to the animals may be considered by the ACEC Executive in non-quorate meetings and discussions. The ACEC Executive includes the Chairperson, at least one Category C or D member, and, where possible, the spokesperson who originally led the review of the approved project.

Recommendations by the ACECs, their Executive or the Chairperson are submitted to the DVCRE or PVC(R) for approval and added to the agenda of the next ACEC meeting for ratification. All meetings of the ACECs are minuted and records of all decisions maintained.

## 4. Oversight of animal care

At UNSW the Director of Animal Care and Animal Welfare Officers ensure the humane, responsible, and scientifically sound use of animals in accordance with the *Code* and approved research protocols. They conduct regular monitoring of animal care and use programs and facilities, review the health status of experimental and breeding animals, investigate issues related to animal welfare, and perform or arrange for necropsies, including access to diagnostic services, on animals which died or had to be euthanized as part of an unexpected adverse event. They are also the first point of contact for researchers, students and animal facility staff on veterinary clinical care and advice, development and refinement of specialised animal-based research procedures, and other animal welfare advice.

The Director of Animal Care and Animal Welfare Officers lead the provision of training programs and professional development for research staff and students involved in animal-based research and teaching at UNSW and affiliated institutes. This includes establishing registers and assessment for competency in understanding the requirements of the *Code* and institutional requirements as well as in experimental and animal handling techniques.

## 5. External and multi-centre animal research

UNSW researchers do not need to seek ethical review by UNSW ACECs if the research is conducted elsewhere and an external ACEC registered with the appropriate Australian State authority provides the ethical review, approval and monitoring of the research according to the requirements of the *Code*. However, evidence of the external review and approval must be provided by the lead UNSW researcher to UNSW prior to the commencement of the research or participation in an external project as requested on the UNSW Animal Research Ethics website. Projects involving the care and use of animals at more than one institution need to be approved and monitored by the responsible ACECs, where each ACEC is responsible for approving and monitoring animal care and use at its institution. Participating ACECs need to be aware of all aspects of the proposed use of animals and consider the cumulative effects on the wellbeing of animals involved.

The University reserves the right to place conditions on involvement or refuse involvement in external projects by its researchers should approved proposals not conform to the requirements of the *Code*, other relevant legislation or potentially expose the University to undue risk.

## 6. Schedule 4D, 8 and 9 Drug Usage and Compliance

The use of Schedule 4D, Schedule 8 (Drugs of Addictions, S8) and 9 (Prohibited Substances, S9) substances for animal research at UNSW, including their storage and security arrangements, reflects the requirements of the *Poisons and Therapeutic Goods Regulation 2008 (NSW)*. Researchers intending to use S8 or S9 drugs apply for the authority to possess the substances after ACEC approval is obtained. NSW Health may then issue approval for the term of the ACEC approval. Authorised persons as issued by NSW Health are responsible for the storage, dispensing and use, monitoring and security of the substances and may delegate some of the tasks to drug custodians. S4D, S8 and S9 drugs may only be destroyed and/or disposed of by or under the direct personal supervision of a police officer, organised by the RECS Office. Inventories of all S8 and S9 drugs under their authority are prepared twice a year and forwarded to RECS. The DVCRE or PVC(R) will be immediately notified of any non-compliance identified during the preparation of the inventories or any other times where possible non-compliance is noticed. RECS will monitor the NSW Poisons List published by NSW Health and update University procedures as required.

## 7. Research Conducted Overseas

Where a research project involving animals is to be conducted overseas and the Investigator is a UNSW researcher or employee of an affiliated centre or institute, UNSW ACEC review is required. In addition, approval may be required from an overseas ethics committee or equivalent body where appropriate or available. At a minimum it is expected that the governing principles of the *Code* are met when conducting research overseas, taking into account compliance with local requirements.

Where UNSW or affiliated centre and institute researchers and research trainees intend to participate in animal research approved overseas, they need to provide evidence of the external review and approval as requested on the UNSW Animal Research Ethics website. The University reserves the right to request that the requirements of the *Code* and local compliance are met and that any differences with overseas legal or other processes are resolved as set out in the *Code*.

## 8. Monitoring of Research and Adverse Events

Animal research approved by UNSW is monitored by the University and its delegated bodies through mechanisms described in the *Code*, including annual progress and final reports for each approved project, internal and external audits of compliance with the approved protocol, and site visits and interviews with investigators and animal care staff. The University may suspend or withdraw approval for animal research where it is reasonable to believe that continuation of the research project may compromise animal welfare.

Chief investigators are required to monitor animal wellbeing and report unexpected adverse events to the ACECs and the Director of Animal Care as soon as possible in accordance with the UNSW Animal Research Adverse Event Standard Operating Procedure. The Committees and the Director of Animal Care may request additional monitoring and other actions as deemed appropriate.

Issues identified during monitoring or unexpected adverse event reporting which may possibly involve breaches of the [UNSW Code of Conduct and Values](#), the *Australian Code for the Responsible Conduct of Research* or the

[Australian code for the care and use of animals for scientific purposes](#) are handled in accordance with the [Complaints Management and Investigations Policy and Procedure](#). Where necessary, the ACECs should provide advice to the DVCRE or PVC(R) who may withdraw, suspend or terminate project approval.

## 9. Complaints and Grievances

UNSW has established a complaints and grievances mechanism for UNSW personnel, students and persons external to the University. This process allows the voicing of concerns regarding animal research and the ethical review process.

Complaints about the conduct of research involving animals by UNSW staff and research trainees should be directed to the Director of Research Ethics and Compliance Support (RECS) ([animalethics@unsw.edu.au](mailto:animalethics@unsw.edu.au)). Conduct & Integrity Office ([research.integrity@unsw.edu.au](mailto:research.integrity@unsw.edu.au)) are informed of allegations involving possible breaches of the *Australian Code for the Responsible Conduct of Research* to be reviewed in accordance with the [UNSW Code of Conduct and Values](#). Grievances about ethics review and processes by UNSW staff and students should be addressed to the Director of RECS ([animalethics@unsw.edu.au](mailto:animalethics@unsw.edu.au)).

## 10. Additional Operating Guidelines

Operating guidelines in support of this Procedure are approved by the Committees and displayed in their most current form on the Research Ethics and Compliance Support website.

**Version:** 3.2

**Effective:** 6 August 2024

**Responsible:** Director, Research Ethics & Compliance Support

**Lead:** Manager, Research Ethics & Compliance Support

## Appendix

### Legislative compliance

1. This procedure supports the University's compliance with the following legislation:
  - 1.1. Australian Code for the Responsible Conduct of Research 2007
  - 1.2. Australian Code for the Care and Use of Animals for Scientific Purposes 2013
  - 1.3. Animal Research Act 1985 (NSW)
  - 1.4. Animal Research Regulation 2021 (NSW)
  - 1.5. Poisons and Therapeutic Goods Act 1966 (NSW)
  - 1.6. Poisons and Therapeutic Goods Regulation 2008 (NSW)
  - 1.7. Drug Misuse and Trafficking Act 1985 (NSW)

### Related Documents

- UNSW Animal Research Adverse Event Reporting Standard Operating Procedure
- Complaints Management and Investigations Policy and Procedure

Definitions and Acronyms	
<b>Animal</b>	Any non-human vertebrate (including fish, amphibians, reptiles, birds and mammals and encompassing domestic animals, purpose-bred animals, livestock and wildlife) and cephalopods. This includes animals at early stages in their development.
<b>Animal Care and Ethics Committees (ACECs)</b>	Animal Care and Ethics Committees constituted according to the terms of reference and membership determined in the <i>Australian Code for the Care and Use of Animals for Scientific Purposes (2013)</i> .
<b>Animal Research Authority</b>	Issued by the UNSW ACECs for each research project prior to commencement and following project approval by the Deputy Vice-Chancellor Research & Enterprise or Pro-Vice Chancellor (Research). In accordance with the Animal Research Act, authorities can only be issued for a 12-month period and will need to be renewed annually during the life of any approved project that runs for more than 12 months. At UNSW, renewal of the authority is conditional upon submission of a satisfactory annual report to the ACECs.
<b>Animal Research Establishment</b>	A corporation which uses animals in research and teaching in NSW and is accredited as an animal research establishment under the <i>Animal Research Act 1985</i> .
<b>Animal Research Review Panel (ARRP)</b>	A statutory body created by the <i>Animal Research Act 1985 (NSW)</i> to participate in monitoring the self-regulatory process that was established within institutions by the <i>Act</i> .
<b>Chief investigator</b>	The person who takes responsibility for the conduct of the animal research according to the protocol issued by the UNSW Animal Research Authority in the role of 'person with ultimate responsibility' as defined in the <i>Code</i> .
<b>The Code</b>	National Health & Medical Research Council (2013) Australian Code for the Care and Use of Animals for Scientific Purposes, 8th edition. Canberra: National Health & Medical Research Council.
<b>Unexpected Adverse Event</b>	An event that may have a negative impact on the wellbeing of animals and was not foreshadowed in the approved project or activity.

### Version history

- **Version 1.0** approved by Vice-President & Deputy Vice-Chancellor (Research) on 24 February 2015 effective 24 February 2015. New document.
- **Version 2.0** approved by Deputy Vice-Chancellor (Research) on 9 February 2018 effective 9 February 2018. Full review leading to minor amendments.

- **Version 3.0** approved by Deputy Vice-Chancellor Research & Enterprise on 23 March 2021 effective 23 March 2021. Full review leading to minor change.
- **Version 3.1** approved by Deputy Vice-Chancellor Research & Enterprise on 2 April 2024 effective 2 April 2024. Minor changes including updated date of Regulation. Minor wording updates to reflect current processes.
- **Version 3.2** approved by Director of Governance on 1 August 2024 effective 6 August 2024. Administrative updates to remove outdated titles and references to policy.