ANIMAL ETHICS PROCEDURES 2022

The Deputy Vice-Chancellor (Research), as delegate of the Senate of the University of Sydney, adopts the following policy.

Dated: 27 January 2022

Last amended: 12 February 2024 (administrative amendments)

Signature:

Position: Deputy Vice-Chancellor (Research)

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1 Purpose and application

These procedures:

(a) give effect to:

(i) the *Research Code of Conduct 2023* ("Research Code");

(ii) the requirements of the *Australian Code for the Responsible Conduct of Research 2018*; and

(iii) the requirements of the *Australian code for the care and use of animals for scientific purposes 8th edition, 2013* ("Animal Code");

(b) support and promote:

(i) the wellbeing of animals used for research or teaching;

(ii) ethical standards when animals are used for research or teaching; and

(iii) compliance with all applicable legislation, regulations, guidelines, policy and other requirements; and

(c) apply to activities which:

(i) are conducted by staff, affiliates or students; and

(ii) involve the care and use of animals for research or teaching purposes.

2 Commencement

These procedures commence on 27 January 2022.

3 Interpretation

Words and phrases used in these procedures and not otherwise defined in this document have the meanings they have in the *Animal Code*.

activity has the meaning given in the *Animal Code*. At the date of these procedures this is:

> means any action or group of actions undertaken that involves the care and use of animals, including acquisition, transport, breeding, housing and husbandry of those animals. An activity may involve one or more procedures. Activities are described in an application to the animal ethics committee.

Note: See also definition of project.

adverse event

has the meaning given in the *Animal Code*. At the date of these procedures this is:

> means any event that has a negative impact on the wellbeing of an animal.

Note: See also definition of "unexpected adverse event".

AEC approval

means approval by an AEC for three years, subject to the submission of *Annual Reports*.

AEC Executive

means a committee of that name which is:

- established by the DVC(R) as provided in subclause 4(5);
- responsible for reviewing specified minor modifications to approved projects; and
- reports to the University AEC.

Note: See section 2.2.23 of the *Animal Code*.

animal

means any:

- live non-human vertebrate (e.g. fish, amphibians, reptiles, birds, mammals, domestic animals, purpose-bred animals, livestock, wildlife);
- cephalopod (e.g. octopus, cuttlefish, squid);
- animal at early stages of development, including:
  - embryonic and foetal forms of mammals;
  - birds and reptiles that have progressed beyond half the gestation or incubation period;
  - fish and amphibia once they can feed independently; and
  - cephalopods at the point when they hatch.

Note: If conducting research or teaching in Victoria, the definition also includes live adult decapod crustaceans (e.g. lobsters, crayfish, crabs).

animal care staff

means individuals responsible for providing general care of an animal. This includes, but is not limited to:

- laboratory animal service staff;
- animal technicians;
- animal attendants;
- technical officers;
- farm managers
- farm hands; and
- veterinary technicians.

Animal Code	means the *Australian code for the care and use of animals for scientific purposes* 8th edition 2013 (updated 2021).
animal ethics committee (AEC)	has the meaning given in the *Animal Code*. At the date of these procedures this is: a committee constituted in accordance with the terms of reference and membership laid down in the Code.
animal facility	means any place where animals are kept or bred.
animal research authority	means an authority issued by the University to any individual to carry out animal research or teaching for a particular project. **Note**: Unless a shorter period is specified, an animal research authority remains in force for 12 months from the date it was issued.
animal tissue	means any biological material obtained from an animal including tissues or fluids. E.g., skin, blood, urine, saliva, hair, bones, tumour and other biopsy specimens.
animal welfare veterinarian	means the University of Sydney Animal Welfare Veterinarians.
category A member	means a person with: • qualifications in veterinary science that are recognised for registration as a veterinary surgeon in Australia; and • experience relevant to the University's activities or the ability to acquire relevant knowledge. **Note**: See section 2.2.4 of the *Animal Code*.
category B member	means a suitably qualified person: • with substantial and recent experience in the use of animals for scientific purposes relevant to the work of the AEC; and • who holds a higher degree in research or equivalent experience. **Note**: If the work of the AEC relates to the use of animals for teaching only, a teacher with substantial and recent experience may be appointed. See section 2.2.4 of the *Animal Code*

category C member	means a person: • with established experience in furthering the welfare of animals; • who is not employed by or associated with the University; and • who is not currently involved in the care and use of animals for scientific purposes. **Note**: See section 2.2.4 of the *Animal Code*.
category D member	means a person: • not employed by or associated with the University; • who has never been involved in the use of animals in scientific or teaching activities, either in their employment or after their undergraduate education; and • must not fit the requirements of any other category. **Note**: See section 2.2.4 of the *Animal Code*.
Chairperson	means the Chairperson of a University AEC.
chief investigator	means the lead University staff or affiliate investigator on a research project. In the case of student projects, the chief investigator is the supervisor of the student.
commercially sponsored research	means research that is sponsored by a for-profit entity external to the University.
complainant	will have the description as provided in the university's Resolution of Complaints Policy
conflict of interests (COI)	has the meaning given in the *Animal Code*. At the date of these procedures this is: means a situation: • in which a person's individual interests or responsibilities have the potential to influence the carrying out of their University role or professional obligations; or • where a University's interests or responsibilities have the potential to influence the carrying out of its obligations.

designated veterinarian	means a veterinarian, independent of the project, who has been designated to examine and treat animals in an AEC approved project. They: • may be the University's Animal Welfare Veterinarian or another veterinarian; and • should be registered as a veterinarian in a state or territory of Australia.
Director	means the University's Director of Research Integrity and Ethics Administration.
DVC (R)	means the Deputy-Vice Chancellor (Research).
ethics item	means an application, modification, report, response or notification submitted to the AEC for review.
Ethics Office	means the office within the DVC(R), Research Integrity and Ethics Administration who support: • investigators to obtain approval for research and teaching involving animals; • the University's Animal Ethics Committees (AEC); and • the University's compliance with animal research codes, legislation and licencing.
high impact procedure	a procedure which has potential to cause significant harm or distress to an animal.
humane endpoint	means the point, defined by one or more clinical criteria, at which an animal is experiencing an adverse event or has developed a degree of pain or distress that requires it to be euthanised, regardless of whether the scientific aim has been met. **Note**: A humane endpoint is chosen with aim of protecting animal wellbeing.
investigator	means any person who uses animals for scientific purposes including: • researchers; • teachers; • students; • product testers; • environmental testers; • producers of biological products; and • wildlife surveys.

IRMA	means the Integrated Research Management Application, which is the system used to: • collect and manage information about investigators and research at the University; and • manage the animal ethics submission process.
minor modification	means a change to an approved project where the proposed change is not likely to cause harm to the animals, including pain and distress. **Note**: Examples of a minor modification include: • change in personnel or funding; • time extension up to 12 months time, not exceeding 4 year project approval; • addition of a new research location but using the same project methodology; • additional animals of the same species/strain: <10% of the number originally approved.
modification	means a change to an approved project that still meets the aims and objectives of the original application and does not deviate dramatically from the original species, strains and procedures being performed.
monitoring	means measures to assess, the wellbeing of animals in accordance with the *Animal Code*.
morbidity	means the state or condition of being near death.
project	has the meaning given in the *Animal Code*. At the date of these procedures this is: means an activity or group of activities that form a discrete piece of work that aims to achieve a scientific purpose.
respondent	means the person responsible for responding to a complaint or allegation of a breach.
unexpected adverse event	has the meaning given in the *Animal Code*. At the date of these procedures this: means an event that may have a negative impact on the wellbeing of animals and was not foreshadowed in the approved project or activity.

wellbeing	has the meaning given in the *Animal Code*. At the date of these procedures this is: means an animal is in a positive mental state and is able to: • achieve successful biological function; • have positive experiences; • express innate behaviours; and • respond to and cope with potentially adverse conditions.

PART 1 – ANIMAL ETHICS COMMITTEES

4 Establishment

(1) The DVC (R) must establish one or more AECs, as required.

(2) The DVC (R) must determine the terms of reference for AECs and any AEC Executive, and publish them on the University's website.

(3) An AEC is responsible for requiring activities relating to the care and use of animals for scientific purposes comply with:

(a) the *Animal Research Act 1985 (NSW)*;

(b) the *Animal Code*; and

(c) any other relevant legislation, guidelines and policies.

Note: See Charter of Freedom of Speech and Academic Freedom

(4) AECs must operate consistently with:

(a) the Animal Code;

(b) these procedures; and

(c) their terms of reference.

(5) The DVC (R) may establish an AEC Executive to approve minor modifications to approved projects consistently with the requirements of the *Animal Code*, and determine its terms of reference.

(a) The terms of reference must specify:

(i) the composition of any AEC Executive;

(ii) matters on which it may provide interim approvals for ratification by the AEC; and

(iii) matters on which it may provide guidance.

Note: See the section 2.2.23 of the *Animal Code*.

5 Membership

(1) The composition of the AEC must be consistent with the requirements of the *Animal Code*.

Note: See section 2.2 of the *Animal Code*.

(2) The DVC (R) will appoint the Chairperson of the AEC, and if thought appropriate, a Deputy Chairperson.

(3) The DVC (R) will appoint members to the AEC in consultation with the Chairperson and the Animal Ethics Manager.

(a) The term of appointment is three years.

(b) The Chairperson and the Animal Ethics Manager may recommend that a member be reappointed for further consecutive terms.

(c) Members may only be appointed for a third or further consecutive terms upon recommendation of the Chairperson and the Animal Ethics Manager.

(4) Upon appointing a member to an AEC, the DVC (R) must:

(a) inform the member in writing of:

(i) the commencement and end date for their appointment;

(ii) the responsibilities and confidentiality requirements of the role; and

(b) confirm that they will be indemnified for liabilities arising in the course of bona fide conduct in the role.

(5) Upon being appointed to an AEC a member must provide to the DVC (R) a written undertaking that they will:

(a) keep all matters before the committee confidential; and

(b) disclose and appropriately manage any conflicts of interests that exist or may arise during their membership.

Note: See *External Interests Policy 2010*

(6) The DVC (R) may terminate the appointment of any AEC member by written notice if satisfied that:

(a) it is necessary to do so for the proper and effective functioning of the AEC;

(b) the person is no longer qualified or fit to serve on the AEC; or

(c) the person has failed to carry out their duties as an AEC member.

(7) Members may resign their membership by providing at least two months' written notice to each of the Chairperson and Animal Ethics Manager.

(8) Where a member is appointed to fill a casual vacancy, that appointment will expire at the time the previous member's term would have expired. The casual member will then be eligible for re-appointment.

6 Remuneration of members

(1) Except for the Chairperson and Deputy Chairperson, AEC members who are University staff will not receive additional remuneration for work on the AEC.

(2) Subject to subclause 6(1), the DVC (R) will determine the remuneration for:

(a) Chairpersons and Deputy Chairpersons; and

(b) AEC members who are not University staff.

(3) The Chairperson and Deputy Chairperson may only be remunerated in the following ways.

(a) If the individual is employed by the University:

(i) teaching relief, where money is paid to their faculty or University school to cover some of their teaching responsibilities; or

(ii) research relief, where money is paid to their faculty or University school research account to cover some of their research responsibilities.

(b) If the individual is not employed by the University, through payment of a fee.

7 Agendas

(1) The Ethics Office is responsible for receiving submissions to the AEC and will check them for administrative errors and completeness.

(2) The Ethics Office will prepare and distribute the agenda:

(i) for AEC meetings, at least 9 days before the meeting date; and

(ii) for AEC Executive meetings, at least 4 days before the meeting date.

(3) The Ethics Office will allocate submissions to an AEC for consideration, provided that they are received before the closing date for the next meeting.

(a) Documents received after the closing date may only be included on the agenda or tabled at the meeting by agreement between the relevant Chairperson and Ethics Office.

(4) The DVC (R) will determine the maximum number of matters that may be considered at a single AEC meeting.

(a) If the ethics items submitted for a given meeting exceed the maximum, priority must be given to student projects and grant funded activities.

8 Preparation for meetings

(1) Prior to distributing the agenda the Ethics Office will:

(a) for each application and modification on the agenda:

(i) assign an AEC member as primary reviewer; and

(ii) assign another AEC member as secondary reviewer.

(b) for all other ethics items requiring discussion on the agenda:

(i) assign an AEC member as primary reviewer.

(2) The primary reviewer must:

(a) read and consider the agenda item;

(b) if necessary, contact the relevant chief investigator to gather further information; and

(c) lodge a written review of the item in IRMA at least two days before the meeting.

(3) The secondary reviewer must provide a written review of the assigned item in IRMA at least five days prior to the meeting, for the primary reviewer to consider.

(4) All AEC members must read and consider each meeting agenda item for any meetings that they attend.

(5) The Ethics Office and the Chairperson must consider whether an investigator should be invited to the AEC meeting to assist in informed decision making and timely resolution of queries.

(a) Such invitations should be issued with sufficient time to permit the investigator to prepare for the meeting.

9 Meetings

(1) Quorum for an AEC meeting is achieved when:

(a) a Chairperson is present;

(b) at least one member from each category is present; and

(c) at least one-third of the members present are categories C and D members.

Note: See 2.2.25 of the *Animal Code*.

(2) Quorum must be maintained for the duration of a meeting.

(3) With permission of the Chairperson, non-members may attend meetings to assist the AEC to function effectively.

(4) AEC meetings may be held:

(a) in person at a single venue; or

(b) at two or more venues simultaneously, using any technology that gives members a reasonable opportunity to participate.

(5) In exceptional circumstances, the Chairperson, Deputy Chairperson or AEC Executive may approve consideration and approval of urgent matters by circulation.

(a) The AEC must review and ratify any decisions made by circulation at the next meeting.

(6) The Chairperson may cancel a meeting, but should reschedule it to occur within 10 working days.

(7) AECs should meet approximately 12 times per year, at monthly intervals.

(a) Additional meetings may be scheduled if necessary.

(b) The Ethics Office will publish meeting dates and agenda item submission closing dates on the University's animal ethics website.

(8) Meetings, and discussion at meetings, will be confidential.

(9) Visitors other than investigators must agree to maintain confidentiality before entering the meeting room.

(a) The identity of the visitor and their agreement to maintain confidentiality must be recorded in the minutes.

(b) Visitors who do not agree to maintain confidentiality must not be permitted to observe or take part in a meeting.

(10) The AEC may consult or seek advice from experts to assist in the review of an application, subject to such experts agreeing to maintain confidentiality of the material.

(a) Experts must declare, and appropriately manage, any conflicts of interests, as specified in clause 11.

(11) As far as possible the AEC should reach decisions on the basis of consensus.

(a) Where consensus cannot be reached after reasonable effort to resolve differences, the AEC should explore ways of modifying the project or activity with the investigator that may lead to consensus.

(b) If consensus is still not achieved, the AEC should only proceed to a majority decision after members have been allowed time to review their positions, followed by further discussion.

(c) If a vote is required, the vote including numbers for and against (and, where applicable, numbers of members abstaining from voting) must be noted in the minutes.

Note: See section 2.3.11 of the *Animal Code*.

10 Outcomes of meetings

(1) The AEC must make one of the following decisions in relation to each ethics item.

(a) Approve the ethics item as ethically acceptable, with or without conditions;

(b) Approve the ethics item in principle, subject to modifications or clarifications, which may then be reviewed for final approval by:

(i) the AEC;

(ii) the Chairperson;

(iii) the AEC Executive; or

(iv) the Ethics Office.

(c) Defer a decision pending clarification or further information;

(d) Decline the ethics item; or

(e) Note the ethics item.

Note: An investigator whose application is declined may choose to rewrite the proposal and resubmit.

(2) Subject to subclause 17(3), the Ethics Office must notify the chief investigator and co-investigators in writing of the AEC decision within 10 working days of the meeting.

(3) If ethical approval is granted to an application or annual report, the Ethics Office will issue an Animal Research Authority (ARA) to the chief investigator and co-investigators. The ARA must include:

(a) the title of the project;

(b) a unique AEC identification number;

(c) a plain language summary of the project;

(d) the name of the chief investigator;

(e) names of authorised personnel;

(f) the date of the start and expiry of the AEC approval;

(g) the date of the start and expiry of the ARA approval;

(h) approved animal use;

(i) designated land on which the project will be conducted;

(j) confirmation that all documents have been reviewed and approved by the AEC;

(k) any conditions of the AEC approval.

(4) Unless a shorter period is specified, an ARA remains in force for 12 months from the date on which it was issued.

Note: Conducting research without a current ARA is an offence under the *Animal Research Act 1985* which is punishable by a penalty or imprisonment.

(5) If applicants are required to provide further information in support of their ethics item, the notification must:

(a) specify the information required;

(b) state the reasons for the request; and

(c) where appropriate, refer to the *Animal code* or other relevant legislation and guidelines.

(6) If an ethics item is declined, the notification must invite the chief investigator to contact the Chairperson to discuss the outcome.

11 Conflicts of interests

(1) All AEC members must comply with the *External Interests Policy 2010*.

(2) AEC members must declare any conflicts of interests verbally, or in writing to the Ethics Office:

(a) at the time of their appointment; and

(b) at any time they become aware of a further conflict of interests during their tenure.

(3) The Chairperson must call for declarations of conflicts of interest relating to any matters on the agenda at the beginning of every meeting and record them in the minutes.

(4) The Chairperson is responsible for determining, in consultation with other members of the AEC, the appropriate manner of managing any declared conflicts.

(a) If the Chairperson makes a declaration, the Deputy Chairperson is responsible for this process.

(5) Where possible, the Ethics Office will avoid known conflicts of interests when assigning ethics items for review.

(6) Subject to subclause 11(7), a member with a conflict of interests must not participate in either of the discussion of, or decision about, the relevant agenda item.

(7) In appropriate circumstances the AEC may permit a member with a conflict of interests to remain in the meeting room during the initial discussions to answer questions. Such circumstances include situations where the conflict of interests is minor.

(8) If an expert adviser declares a conflict of interests the Chairperson will determine the appropriate manner of managing the declared conflict.

(a) If an expert adviser's conflict of interests is declared or identified after a report is received, the Chairperson must determine if the matter declared renders the report unacceptable.

Note: See sections 2.2.13 and 21 of the *Animal Code*.

12 Training for members

The Ethics Office is responsible for arranging:

(a) induction training for newly appointed AEC members; and

(b) opportunities for AEC members to attend training relevant to their AEC tenure.

13 Records and reporting

(1) The Ethics Office is responsible for preparing and retaining written records of AEC activities, including:

(a) agendas and meeting minutes;

(b) correspondence; and

(c) membership details.

Note: See *Privacy Policy 2017*; *Privacy Procedures 2023*; *Recordkeeping Policy 2017*; *Recordkeeping Manual*.

(2) The Chairperson must review minutes of all meetings.

(3) The minutes are ratified at the next AEC meeting.

Note: See *Privacy Policy 2018*; *Privacy Procedures 2023*; *Recordkeeping Policy 2017*; *Recordkeeping Manual*.

(4) The Ethics Office must establish and maintain in IRMA a confidential record of each application received and reviewed, including:

(a) project number;

(b) date entered;

(c) requested start and end dates;

(d) requested animal types, animal numbers and procedures;

(e) project title;

(f) outcome of review;

(g) names of investigators;

(h) documents submitted for review;

(i) conditions of ethics approval of the activity; and

(5) The AEC must provide:

(a) an annual compliance report to the NSW Department of Primary Industries and other State and Territory Governments as required; and

Note: See the NSW Department of Primary Industries approved form.

(b) an annual report on the AEC operations to the DVC (R).

PART 2 –REVIEWS AND APPROVALS

14 When an AEC review is required

(1) An AEC must review an activity involving animals when:

(a) animals are to be used for teaching or research purposes; or

(b) the activity is associated with the care and management of animals in facilities, except where:

(i) the facility is a University farm; and

(ii) the activity is part of standard animal husbandry for the farm.

(2) An AEC must review an activity involving only animal tissues when:

(a) animal tissues are to be used for teaching or research purposes; and

(b) animals were alive when the tissues were removed.

(i) Where the tissue was removed as part of routine animal care, not related to research or teaching, this review can be a notification of tissue sample use submitted through IRMA.

(3) An AEC does not need to review an activity involving only animal tissues or cadavers where:

(a) the tissues were collected from animals which were already dead; and

(b) the animals were not killed for the purposes of teaching or research; or

(c) the animals were killed:

(i) for a teaching or research purpose already approved by an AEC; and

(ii) in a manner approved by the AEC.

(4) Where there is difficulty in determining whether an activity requires AEC review, the staff member or affiliate involved in, or responsible for supervising the activity should contact the University's Ethics Office for advice.

(5) For activities that require AEC review, the chief investigator or most senior staff member or affiliate supervising the activity must:

(a) determine the appropriate AEC to review the application. This may be the University's AEC or another institution's AEC; and

(b) obtain approval from this AEC before commencing the activity.

Note: Investigators should contact the Ethics Office to clarify from which AEC they should seek approval. Further information is also provided on the animal ethics website.

(6) An investigator named on a project approved by an external AEC must promptly advise the University's AEC of:

(a) the approval, by submitting a notification of external AEC approval form online on IRMA attaching;

(i) the approved external AEC application form;

(ii) the external AEC approval letter; and

(b) any misconduct or breaches of the *Animal Research Act 1985* (NSW) that occur in relation to this approved project.

(7) Where there is no requirement to seek approval from an external AEC, investigators are only required to seek approval from a University AEC.

15 University AEC review

(1) Applications for review by the University AEC must be submitted online, in IRMA:

(a) by the chief investigator; or

(b) with the chief investigator's permission, by any University staff member, affiliate or student involved in a research project.

(2) No matter who submits the application, the chief investigator remains responsible for the project and the submission.

(3) Each application must name:

(a) a single staff member or affiliate as chief investigator; and

(b) all investigators involved in the project.

(4) The following people must endorse the application:

(a) staff, students and affiliates listed on the application, through IRMA;

(b) investigators external to the University, by signing and submitting an *External Investigator Declaration* form.

(c) the:

(i) Dean or Head of School and Dean of the chief investigator's faculty or University school; or

(ii) a relevant Associate Dean or Head of School nominated by the Dean or Head of School and Dean, through IRMA; and

(d) the Facility Manager of the animal facility where the investigators propose to hold or use animals, through IRMA.

(5) The application must contain sufficient detail of all activities relating to the care and use of animals including, but not limited to, animal:

(a) acquisition;

(b) transport;

(c) breeding;

(d) housing; and

(e) husbandry.

(6) Where animals need to be transported from one institution to another, or a long distance within one institution during the project, details must be provided to the AEC in:

(a) the project application; or

(b) a modification request.

16 Modifications to an existing project

(1) No modification to an existing project may be implemented without a further AEC approval.

(2) Subject to subsection 16(3), the original applicant and the relevant facility supervisor must each endorse the modification form before it is submitted in IRMA.

(3) The chief investigator may authorise a University staff member, affiliate or student who is involved in the research to submit a modification request online in IRMA, using the *Modification to an existing approved application* form.

(4) If the modification involves a change of personnel or funding only, this must be lodged using the *Change in personnel and funding only* form.

17 Fees

(1) For projects that are considered to be commercially sponsored research or the chief investigator is external to the University, The DVC (R) will set an administration fee for review of ethics applications which relate to this research.

(a) The Ethics Office will publish the fee on the animal ethics website.

(2) Fees:

(a) are payable on submission of the application; and

(b) are non-refundable, even if an application is withdrawn before being considered.

(3) Notice of the outcome of the application will not be provided until the fee is paid.

18 Suspension or withdrawal of approval

(1) If an activity or animal facility is deemed in breach of the approved project, *Animal Code*, *Animal Research Act 1985 (NSW)*, any other relevant legislation and policies, or animal wellbeing is compromised beyond that described in the approved project, the following individuals may immediately suspend the activity and refer the matter to the AEC:

(a) Animal Ethics Manager,

(b) Animal Welfare Veterinarian,

(c) Associate Director of Laboratory Animal Services; or

(d) Director, Research Integrity and Ethics Administration.

(2) If an AEC believes that an activity or animal facility may be in breach of the approved project, *Animal Code*, *Animal Research Act 1985 (NSW)*, or any other relevant legislation and policies, the AEC must:

(a) take action to protect animal wellbeing;

(b) direct that any activity that may adversely affect animal wellbeing cease immediately;

(c) promptly address the issues in consultation with the investigators or facility managers;

(d) if necessary:

(i) suspend or withdraw the relevant AEC approval; and or

(ii) refer the issue to another appropriate person or authority for action, such as referring the matter to the Research Integrity Office or the Director, Research Integrity and Ethics Administration;

Note: See *Research Code of Conduct 2023*.

(e) implement appropriate follow up action, which may include:

(i) increased monitoring;

(ii) modification of the activity or animal facility; or

(iii) further training of investigators involved in procedures or animal care staff.

(3) If an approval is suspended or withdrawn:

(a) the Animal Ethics Manager, the Animal Welfare Veterinarian or the Director of Research Integrity and Ethics Administration must inform the chief investigator or facility manager; and

(b) the chief investigator or facility manager must promptly:

(i) suspend all relevant activities; and

(ii) make arrangements to meet the needs of the animals.

(4) If AEC approval is withdrawn, the activity may only recommence after a fresh application is submitted and further approval given.

(5) If AEC approval or animal facility approval is suspended, the activity must not resume until:

(a) the activity or facility has been modified to provide sufficient protection of animal wellbeing; and

(b) the AEC has reviewed and approved the modification.

(6) The Animal Ethics Manager or the Director of Research Integrity and Ethics Administration will inform the chief investigator or facility manager in writing of:

(a) any decision to suspend or withdraw approval;

(b) any decision to approve a modified project and thereby remove a suspension.

PART 3 – MONITORING, ADVERSE EVENTS, COMPLAINTS AND NON-COMPLIANCE

19 AEC monitoring

(1) The AEC is responsible for monitoring the care and use of animals used in teaching and research.

(2) Monitoring may be undertaken by any or all of the following:

(a) inspecting animals;

(b) inspecting animal facilities;

(c) reviewing procedures;

(d) monitoring records; and

(e) reviewing annual and completion reports.

20 AEC inspections

(1) The AEC will determine the frequency and timing of inspections.

(2) Inspections may be announced or unannounced.

(3) The Ethics Office must advise AEC members of inspection locations, dates and times in a timely manner.

(4) The Animal Welfare Veterinarian or the Animal Ethics Manager may inspect facilities.

Note: See *Privacy Policy 2017*; *Privacy Procedures 2023*; *Recordkeeping Policy 2017*; *Recordkeeping Manual*.

(a) Where possible, a category C or D member should also participate in animal facility inspections.

(b) Inspections of remote sites, or where access is difficult, may be performed by a person nominated by the AEC and can be facilitated or corroborated with photographic or video imaging.

(5) An AEC inspection should include, but is not limited to, reviewing:

(a) that the chief investigator has maintained required documents in the animal facility or when undertaking fieldwork, including:

(i) a copy of the ARA;

(ii) emergency contact details in case of an animal emergency;

(iii) monitoring sheets;

Note: See Schedule One.

(b) species specific condition and suitability of animal enclosures (e.g. pens, cages and containers), and that they are correctly labelled with the:

(i) chief investigator's name;

(ii) number of animals;

(iii) dates of birth, if provided;

(iv) arrival date of each animal in the enclosure;

(v) sex; and

(vi) strain,

(c) animal facility maintenance, including:

(i) security;

(ii) physical state of repair; and

(iii) adequate space for the work being performed,

(d) appropriate environmental factors for species, that are checked and recorded daily; and

(e) animal welfare, environmental enrichment, care and husbandry.

(6) The AEC may inspect the conduct of procedures in AEC approved projects.

(a) Such an inspection must be undertaken by the Animal Welfare Veterinarian or another suitably qualified person..

(7) During an inspection, the AEC or its nominee may direct the immediate suspension of a project or use of an animal facility, until further review by the AEC.

Note: see also clause 18.

(8) The Ethics Office must retain records of inspections. Records must include:

(a) the names of those in attendance;

(b) observations;

(c) identified problems;

(d) recommendations; and

(e) outcomes.

Note: See *Privacy Policy 2017*; *Privacy Procedures 2023*; *Recordkeeping Policy 2017*; *Recordkeeping Manual*.

(9) The AEC must review all reports of facility inspections and procedures inspections and resolve to:

(a) adopt the report, with no further action required;

(b) require further clarification, additional information or modification, which must be addressed to the satisfaction of the AEC;

(c) direct that animals are moved to an alternate site until rectifications are made; or

(d) perform a follow-up inspection of the facility or procedure.

21 Annual and completion reports

(1) The chief investigator or student, staff member or affiliate involved in a project must submit on IRMA:

(a) annual reports at least 4 weeks prior to the ARA expiring; and

(b) a completion report at the completion of a project.

(2) The AEC will review all annual reports and completion reports, and will resolve to:

(a) adopt the report, with no further action required;

(b) request further clarification, additional information or modification to the ethics project, which must be addressed to the satisfaction of the AEC; or

(c) identify any immediate harm or risk of harm to animals. In this instance the AEC may:

(i) suspend or withdraw ethics approval for the project; or

(ii) escalate the matter to the Research Integrity Office or Director, Research Integrity and Ethics Administration to manage under the Research Code.

Note: See *Research Code of Conduct 2023*.

(3) The Ethics Office will notify the person submitting the report in writing of the AEC's decision within 10 working days of the meeting.

22 Animal wellbeing monitoring plans

(1) All investigators involved in an approved project must monitor the wellbeing of animals involved.

(2) The chief investigator has ultimate responsibility for the project and must:

(a) develop a project-specific monitoring plan that meets the requirements of the *Animal Code* and expectations of the AEC;

(b) include the monitoring plan in the application to the AEC; and

(c) distribute the monitoring plan to all investigators involved in the project.

(3) The requirements that must be included in the monitoring plan are specified in Schedule One.

(4) The chief investigator must record the monitoring plan in accordance with the requirements specified in Schedule One.

23 Animal care guidelines

(1) At the time a facility is approved, the facility manager must:

(a) develop species-specific animal care and emergency guidelines that include:

(i) basic animal care;

(ii) arrangements for providing food, water and enrichment; and

(iii) environmental monitoring;

(b) submit the guidelines for, and obtain, AEC approval;

(c) confirm that animal care staff are trained and competent in following the guidelines; and

(d) promptly notify the AEC, investigators and other users of any problems with the facility that may have a negative impact on animal wellbeing.

(2) The facility manager must review and update the guidelines at least every three years.

(3) Animal care staff must:

(a) monitor and assess the animals for which they are responsible according to the relevant guidelines, including:

(i) basic animal care (provision of food, water and enrichment); and

(ii) daily environmental monitoring; and

Note: This obligation is in addition to the obligation of investigators to monitor animals.

(b) promptly report to their supervisors and relevant investigators any concerns about:

(i) the facility; or

(ii) changes in animal wellbeing.

(4) If animals are taken to a room on the Camperdown/Darlington Campus, outside of an animal facility:

(a) species-specific animal care and emergency guidelines must be followed; and

(b) dispensation must be sought from the AEC, in consultation with the faculty, LAS and Safety, Health and Wellbeing through completing the *Dispensation Request Form*.

23 Humane endpoints

(1) An animal's involvement in an activity must end when any of the following occur:

(a) a scientific endpoint has been reached;

(b) a humane endpoint has been reached;

(c) there is no way the scientific outcome can be met;

(d) the animal develops severe pain or discomfort that does not respond to analgesia, unless prior approval has been obtained from the AEC for an exemption from this requirement in relation to a particular approved project; or

(e) the animal develops a morbidity that:

(i) is unexpected;

(ii) is not part of the project; and

(iii) cannot be treated without interfering with the scientific outcome.

(2) The chief investigator must specify humane endpoints in the ethics application for AEC review. These must address:

(a) expected adverse events; and

(b) any unplanned or unexpected adverse events that may cause pain or distress.

(3) If death is a likely outcome from the use of animals in an activity, then a pre-terminal humane endpoint must always be chosen in place of death or morbidity.

(4) The following humane endpoints should not be exceeded unless strong justification is provided in an ethics application and approval is granted:

(a) weight loss of 15% from baseline weight;

(b) ulceration of the skin, including the skin over tumours;

(c) tumours that reach a size greater than $1cm^3$ in rodent tumour induction studies; or

(d) an inability to move, such that the animal cannot eat or drink.

24 Adverse events

(1) Where an adverse event occurs, an investigator must:

(a) take timely and appropriate action; and

(b) report it immediately to the chief investigator.

(2) In the case of expected adverse events, investigators must follow the strategies and procedures specified in their approved project to avoid or minimise harm, including pain and distress.

(3) In the case of unexpected adverse events, investigators must:

(a) take prompt action to alleviate pain and distress and remove any obvious hazards;

(b) If necessary, animals must be humanely killed without delay;

(c) If necessary, immediately contact the designated veterinarian or the animal welfare veterinarian. Prompt veterinary treatment, autopsies, testing or risk minimisation strategies may be required;

(d) notify:

(i) the chief investigator;

(ii) animal care staff, to confirm that the care and housing of the animal is appropriate; and

(iii) the AEC as specified in subclass 24(5)

(4) Investigators must prioritise animal wellbeing and act as specified in subclause 25(3) over:

(a) reaching the scientific endpoint; or

(b) the continuation or completion of the project.

(5) If an adverse event is not listed in the approved project, or the attrition rate for the adverse event is exceeded, the chief investigator or an investigator listed in the approved project must submit an *Adverse Event Report* in IRMA:

(a) no later than 48 hours after the incident; or

(b) no later than 24 hours after the incident, where an adverse event is serious.

(c) This includes cases where the investigation or treatment remains ongoing at the time of submission of the *Adverse Event Report*.

Note: See clause 25.

(d) If the report cannot be submitted within 48 hours, the investigator must notify the Animal Welfare Veterinarian by email and provide details of the incident and the potential cause.

(6) If an unexpected adverse event is due to an issue with the facility, such as a power failure, the facility manager must submit an *Adverse Event Report* to the AEC.

(a) The report may be submitted using email outside of IRMA, as this report may cover multiple projects in a facility.

(7) The Ethics Office will assign the report for review by the relevant AEC.

(8) After reviewing an *Adverse Event Report,* the AEC must make one of the following decisions.

(a) That the actions taken and subsequent management of the event are satisfactory and no further action will be required.

(b) To require further clarification, additional information or modification to the projects which must be addressed to the satisfaction of the AEC.

(i) This may include requesting additional monitoring by the investigators or the Animal Welfare Veterinarian.

(c) That the actions taken were inappropriate or insufficient to adequately alleviate immediate harm or risk to animals. That is, a breach of ethics approval or the *Animal Code*, *Animal Research Act 1985 (NSW)*, or any other relevant legislation and policies has occurred. In this instance the AEC may do either or both of:

(i) suspend or withdraw ethics approval for the research; or

(ii) escalate the matter to the Research Integrity Office or Director, Research Integrity and Ethics Administration to manage under the Research Code.

Note: See *Research Code of Conduct 2023*; *Charter of Freedom of Speech and Academic Freedom*

(9) The Ethics Office must notify the chief investigator or facility manager in writing of the AEC decision within 10 working days of the meeting.

(10) If the adverse event relates to an emergency with risk to humans as well as animals, the wellbeing of people takes priority over animals. The University's emergency procedures must be followed.

Note: See *Work, Health and Safety Policy 2016*, *Risk Management Policy 2017*.

25 Investigating an adverse event

(1) The chief investigator must investigate any event which:

(a) has the capacity to affect the wellbeing of:

(i) a significant number of animals remaining on the project or in a facility;

(ii) the animal facility; or

(iii) the environment;

(b) occurs as a result of intentional cruelty, reckless behaviour, persistent negligence or misconduct;

(c) may be considered a breach of legislation; or

(d) has the capacity to negatively affect the reputation of the University.

(2) The chief investigator must inform the Animal Welfare Veterinarian of any such event within 24 hours of first becoming aware of it.

(3) The investigation should:

(a) determine the cause of the event;

(b) determine the necessary strategies and treatments to alleviate pain and distress of affected animals;

(c) assess the likelihood of recurrence;

(d) determine its relatedness to the project;

(e) determine whether the project or facility must be modified to prevent future recurrence; and

(f) assess the response and actions taken.

(4) In cases of unexpected death or euthanasia, the investigation should include a necropsy.

(a) This should be performed by an appropriately experienced person.

(b) If there is not a suitably experienced person to perform a necropsy, within the project, the chief investigator should contact the Animal Welfare Veterinarian for advice on how to proceed.

26 Complaints

(1) Complaints about animal welfare should be made to the Animal Welfare Veterinarian

(2) Other complaints about the conduct of a research or teaching activity involving animals or an animal facility should be made to the Animal Ethics Manager.

(3) In most circumstances, complainants will need to provide their name.

Note: See the *Resolution of Complaints Policy 2015*; *Charter of Freedom of Speech and Academic Freedom*.

(4) Upon receipt of a complaint, the Animal Ethics Manager or Animal Welfare Veterinarian must:

(a) record the details in writing;

(b) unless the complainant is anonymous, acknowledge the complaint in writing within three working days of receipt; and

(c) if necessary, inspect the relevant animals or facilities.

(5) The Animal Ethics Manager or Animal Welfare Veterinarian must assess whether to manage the complaint under these procedures or to refer it to another appropriate person or authority.

(a) Referral is required if:

(i) the matter is not related to animal research or teaching activity;

(ii) the matter is more appropriately addressed by a body outside the ethics approval process; or

(iii) the matter is more appropriately addressed as an integrity matter under the Research Code.

Note: See *Research Code of Conduct 2023;* the *Charter of Freedom of Speech and Academic Freedom,*

(6) If the complaint is not referred, the Animal Ethics Manager or Animal Welfare Veterinarian must:

(a) inform the complainant how the complaint will be managed, and when to expect an outcome;

(b) collate all relevant information, which may include:

(i) the original record of the complaint;

(ii) a formal submission from the respondent addressing the concerns raised;

(iii) advice from the Office of General Counsel, or other relevant internal advice;

(iv) advice from a relevant external expert or agency; or

(v) relevant documents such as ethics applications, research tools, information statements and correspondence; and

(c) present the collated information to the AEC.

(7) If the AEC is satisfied that the complaint is substantiated, it may make any of the following decisions:

(a) direct the investigators to modify the activity or facility;

(b) increase the AEC's monitoring;

(c) suspend ethical approval or investigators;

(d) withdraw ethical approval;

(e) refer the matter to the relevant faculty or University school with recommendations for disciplinary action;

(f) refer the matter to the Research Integrity Office or Director, Research Integrity and Ethics Administration to manage under the Research Code.

Note: See *Research Code of Conduct 2023*.

(8) The Animal Ethics Manager or Animal Welfare Veterinarian will inform the respondent and the complainant in writing of the outcome.

(9) If no resolution is possible, or the complainant is dissatisfied with the resolution, either the Animal Ethics Manager or the complainant may refer the matter to the Director, Research Integrity and Ethics Administration.

PART 4 – DISPUTE RESOLUTION

27 Disputes among AEC members

(1) An AEC member who is concerned about a decision, or the operation, of an AEC should firstly attempt to resolve the matter by discussion with the Chairperson, Deputy Chairperson or Animal Ethics Manager.

(2) If the matter is unable to be resolved, the member may refer the matter to the Director, Research Integrity and Ethics Administration.

28 Disputes about AEC decisions

(1) Applicants may request clarification of an AEC decision about an application for approval from the:

(a) Ethics Office;

(b) Chairperson; or

(c) Deputy Chairperson of the AEC.

(2) If, after clarification, a dispute remains the Ethics Office, Chairperson or Deputy Chairperson of the AEC should attempt to resolve the matter by informal means.

(3) If it is not possible to resolve the dispute informally, the aggrieved party should lodge the matter as a complaint, to be dealt with as provided in clause 27, and if necessary clause 30.

29 Referral to the Director, Research Integrity and Ethics Administration

(1) Upon receipt of a referral under clause 27, the Director, Research Integrity and Ethics Administration will obtain all relevant information from the Animal Ethics Manager or Animal Welfare Veterinarian, including:

(a) full details of the dispute;

(b) materials reviewed by the AEC;

(c) outcomes of the AEC review; and

(d) any other relevant documents.

(2) If the Director, Research Integrity and Ethics Administration has a conflict of interests in relation to a referred matter, they must refer the matter to another appropriate University staff member, of an equivalent level of seniority.

(3) The Director, Research Integrity and Ethics Administration will consider the material and determine whether further investigation is warranted.

(4) If the Director, Research Integrity and Ethics Administration determines that no further investigation is warranted, they will:

(a) confirm the relevant decision; and

(b) inform the complainant and the AEC of this decision;

(5) If the Director, Research Integrity and Ethics Administration determines that further investigation is warranted, they will appoint a suitably qualified staff member independent of the complainant and the relevant activity or facility to consider it

(6) In considering the complaint, the independent person:

(a) must give the Chairperson of the AEC and the complainant the opportunity to make submissions;

(b) may access any documentation relating to the relevant activity or facility;

(c) may interview other parties as they consider appropriate; and

(d) may obtain internal and or external advice as necessary.

(7) The independent person will determine and report the outcome of their consideration of the complaint in writing to the Director, Research Integrity and Ethics Administration.

(8) Outcomes may include, but are not limited to:

(a) dismissing the complaint; or

(b) having the Director, Research Integrity and Ethics Administration to take further action, such as referring the matter back to the AEC for further consideration.

(9) A complainant who is not satisfied with the outcome may, by written notice, require the Director, Research Integrity and Ethics Administration to refer the complaint to an external reviewer.

(10) The external reviewer must be:

(a) an appropriately qualified individual or an organisation external to the University;

(b) engaged on a confidential basis;

(c) provided with terms of reference for the review; and

(d) required to provide a written recommendation to the Director, Research Integrity and Ethics Administration.

(11) The Director, Research Integrity and Ethics Administration will provide the external reviewer with all relevant materials necessary to address the terms of reference, including:

(a) full details of the dispute;

(b) materials reviewed by the AEC;

(c) outcomes of the AEC review; and

(d) any other relevant documents.

(12) Following this review, the AEC may:

(a) review its process in reaching the decision that is the subject of the report; and

(b) make a fresh decision re-evaluate its decision in light of the reviewed process.

(13) Regardless of any recommendations made, the AEC must remain the decision maker in relation to the ethical acceptability of an activity or facility.

Note: See *Charter of Freedom of Speech and Academic Freedom*.

NOTES

Animal Ethics Procedures 2022

Date adopted: 27 January 2022

Date commenced: 1 February 2022

Date amended: 12 February 2024 (administrative amendments)

Administrator: Director, Research Integrity and Ethics Administration

Review date: 1 February 2025

Related documents:

Animal Research Act 1985

Animal Research Act Regulation 2010

Australian Code for the Responsible Conduct of Research 2018

Australian Code for the Care and Use of Animals for Scientific Purposes 8th Edition

Charter of Freedom of Speech and Academic Freedom

Privacy Policy 2017

Research Code of Conduct 2023

Recordkeeping Policy 2017

Privacy Procedures 2023

Recordkeeping Manual

External Interests Policy 2010

AMENDMENT HISTORY

Provision	Amendment	Commencing
1(a)(i)	'Research Code of Conduct 2019' replaced with 'Research Code of Conduct 2023'	12 February 2024

Provision	Amendment	Commencing
13(1)(c) note; 13(3) note; 20(4) note; 20(8) note; Schedule 1: 5(e)(iii) note	‘Privacy Policy 2013’ replaced with ‘Privacy Policy 2017’ ‘Privacy Management Plan’ replaced with ‘Privacy Procedures 2023’ ‘University Recordkeeping Policy’ replaced with ‘Recordkeeping Policy 2017’	12 February 2024
18(2)(d) note; 21(2)(c)(ii) note; 24(8)(c)(ii) note; 26(5)(a)(iii) note; 26(7)(f) note	‘Research Code of Conduct 2019’ replaced with ‘Research Code of Conduct 2023’	12 February 2024
Related documents	‘Privacy Policy 2013’ replaced with ‘Privacy Policy 2017’ ‘Privacy Management Plan’ replaced with ‘Privacy Procedures 2023’ ‘University Recordkeeping Policy’ replaced with ‘Recordkeeping Policy 2017’ ‘Research Code of Conduct 2019’ replaced with ‘Research Code of Conduct 2023’	12 February 2024

SCHEDULE ONE

Monitoring plans

(1) Animals must be monitored at least twice weekly, and records maintained.

(2) General environmental monitoring and food and water provisions must be monitored daily, and records maintained.

(3) In developing a monitoring plan for a project, the chief investigator must consider:

(a) animal specific details such as:

(i) species;

(ii) strain;

(iii) phenotype;

(iv) sex; and

(v) age;

(b) project specific details such as:

(i) types of procedures;

(ii) level of impact at each stage;

(iii) housing type; and

(iv) stocking rate or density;

(c) availability of resources such as:

(i) remote monitoring systems and telemetry;

(ii) anaesthetic monitors; and

(iii) handling equipment;

(d) the levels and frequency of monitoring required and whether different monitoring schedules are required at different stages or procedures. For example:

(i) acclimation period, which is the date of arrival at a facility to the date the research or teaching commences. For smaller animals (e.g. rodents, fish) this period is one week and for larger animals (e.g. pigs, sheep) this period is two weeks;

(ii) pre-research;

(iii) post-surgical monitoring;

(iv) anaesthetic monitoring; and

(v) monitoring of new strains of genetically modified animals

(e) scientific endpoints; and

(f) humane endpoints;

Note: See clause 23.

(g) behaviour, including:

(i) response to stimuli;

(ii) their interaction with other animals; and

(iii) food, water, defaecation and urination abnormalities;

(h) body weight and an assessment of body condition;

(i) physical appearance;

(j) physiological or clinical parameters.

(4) Each animal must be:

(a) closely and individually monitored to detect clinical signs and behavioural changes that may indicate of pain or distress;

(b) physically examined during and after high impact procedures;

(c) monitored continuously after surgery until they can walk or move independently without falling (regain their righting reflex);

(d) monitored for the duration of their stay in the facility;

(e) monitored with a mix of objective (quantitative) and subjective (qualitative) criteria; and

(f) monitored no less than twice a week.

(i) The Animal Welfare Veterinarian or the designated veterinarian will decide the frequency of monitoring for animals that have experienced an adverse event or are under treatment.

(5) The chief investigator is responsible for:

(a) certifying that investigators working on the project are competent to perform their duties; and

(b) providing adequate training to investigators;

(c) if required, developing specific monitoring sheets and procedures for monitoring animals during anaesthesia;

(i) For animals undergoing major surgery with recovery, an acute experiment and anaesthetic monitoring sheet for each animal must be developed.

(d) keeping appropriate records that:

(i) are accessible where the relevant animals are being housed;

(ii) indicate that all the necessary criteria have been assessed at each of the monitoring time points;

Note: A single monitoring record sheet may be used to monitor multiple animals.

(e) if required, making these records available to:

(i) the AEC;

(ii) external auditors; or

(iii) a relevant state or territory regulatory body

Note: See *Privacy Policy 2017*; *Privacy Procedures 2023*; *Recordkeeping Policy 2017*; *Recordkeeping Manual*.