

November 2023

# Terms of Reference & Operating Procedures

## DRNSW Animal Ethics Committees

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### BACKGROUND

In NSW, the use of animals for research or teaching purposes is governed by the *Animal Research Act 1985* (**the Act**), the *Animal Research Regulation 2021* (**the Regulation**), and the *Australian code for the care and use of animals for scientific purposes (8th Edition)* (**the Code**), incorporated by reference into the Regulation.

The Code promotes the ethical, humane, and responsible care and use of all live non-human vertebrates and cephalopods (collectively referred to as animals) for scientific purposes, providing governing principles and an ethical framework to guide the decisions and actions of those involved in the care and use of animals for scientific purposes.

The Code details the responsibilities of everyone involved in the care and use of animals for scientific purposes, including institutions, investigators, animal carers, and Animal Ethics Committees (AECs).

The NSW Department of Primary Industries (DPI) and the Department of Regional NSW (DRNSW; the Institution) are committed to animal welfare and aim to ensure that thorough ethical consideration is given to how and why animals are used for the Department's research, teaching and extension activities, and that animals are treated humanely. The 3R's underpin all its animal research activities:

- The Replacement of animals with other methods.
- The Reduction in the number of animals used.
- The Refinement of techniques used to reduce the adverse impact on animals.

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### 1. ESTABLISHMENT OF DRNSW AECs<sup>1</sup>

- 1.1 The DRNSW, an Accredited Research Establishment (ARE) and a licensed Animal Supplier under the Act, operates three internal AECs and has elected to call the committees by the

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<sup>1</sup> For the purposes of this document and to create consistency across Terms of Reference and Operating Procedures, the DRNSW internal AECs and the public-facing Secretary's ACEC will all be referred to as DRNSW AECs as they are administered by the same Team within the NSW DPI. Any clauses in this document not relevant to a particular AEC will be nominated.

below names to remain consistent with the Code:

- Fisheries Animal Care and Ethics Committee (ACEC)
- Elizabeth Macarthur Agricultural Institute (EMAI) AEC
- Orange AEC

- 1.2 The DRNSW AECs are independent committees providing advice to the Institution on matters pertaining to the use of animals for scientific purposes subject to the Code.
- 1.3 The Head of the Institution (or their delegate) issues Animal Research Authorities (ARAs) to researchers to allow them to conduct research or teaching activities involving animals only on the advice of the AECs. No ARA can be granted by the Institution without the approval of, and in accordance with, the directions of the relevant AEC.
- 1.4 The DPI within DRNSW also hold legal delegations to administer the Secretary's ACEC, a public facing committee established to give effect to section 25A of the Act. The Secretary (or their delegate) of DRNSW may issue an ARA to an individual and relevant powers under the Act are delegated via a legal instrument of delegation. This committee is not for use by employees of DRNSW as an ARE, who must use one of the above internal AECs.

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## 2. MEMBERSHIP

### 2.1 Composition (*the Code, Section 2.2*)

2.1.1 The composition of the DRNSW AECs is in accordance with the Code.

2.1.2 The Secretary, the Institution, or their delegates, will appoint eight or more persons to each AEC, with at least two in each of the following categories to ensure a quorum is established to meet requirements under points 2.3.1 and 5.3.2:

- **Category A (Veterinarian)** - A person with qualifications in veterinary science that are recognised for registration as a veterinary surgeon in Australia, and with experience relevant to the institution's activities or the ability to acquire relevant knowledge.
- **Category B (Researcher)** - A suitably qualified person with substantial and recent experience in the use of animals for scientific purposes relevant to the institution and the business of the AEC. This must include possession of a higher degree in research or equivalent experience. If the business of the AEC relates to the use of animals for teaching only, a teacher with substantial and recent experience may be appointed.
- **Category C (Animal Welfare)** - A person with demonstrable commitment to, and established experience in, furthering the welfare of animals, who is not employed by or otherwise associated with the institution, and who is not currently involved in the care and use of animals for scientific purposes. Veterinarians with specific animal welfare interest and experience may meet the requirements of this

category. While not representing an animal welfare organisation, the person should, where possible, be selected on the basis of active membership of, and endorsement by, such an organisation.

- **Category D (*Community Member/Independent*)** - A person not employed by or otherwise associated with the institution and who has never been involved in the use of animals in scientific or teaching activities, either in their employment or beyond their undergraduate education. Category D members should be viewed by the wider community as bringing a completely independent view to the AEC and must not fit the requirements of any other category.

#### 2.1.3 The AEC may include:

- 2.1.3.1 An animal welfare officer who is the person appointed to assist the AEC in monitoring of animals and compliance with the Code, and promotion of animal welfare;
- 2.1.3.2 Members with skills, expertise and background useful to the AEC, who may be additional to categories A – D (known as *Category Other*);
- 2.1.3.3 A person responsible for the routine care of animals within the institution; and/or
- 2.1.3.4 Attendees, who are not formal members, but who may be invited to attend an AEC meeting due to specific skills or knowledge.

2.1.4 An Executive Officer will be appointed to provide administrative and technical support to the AEC. The Executive Officer shall attend and be responsible for the recording and distribution of the Minutes of each AEC meeting.

2.1.5 The AEC will have an appointed Chair. The Chair must be one of the members of the AEC.

### 2.2 The Chair (*the Code, Section 2.2*)

2.2.1 The Chair is responsible for impartially guiding the operation of the AEC, resolving conflicts of interest related to the business of the AEC, and representing the AEC in any negotiations with the Institution's management.

2.2.2 The Chair must preside at AEC meetings.

2.2.2.1 If the Chair is absent, the AEC may elect a member to act as Chair.

2.2.2.2 Alternatively, a person elected as Deputy Chair may preside in the Chair's absence.

2.2.3 The Chair:

2.2.3.1 Should hold a senior position within the Institution, or, if an external appointee, be given a commitment by the Institution of necessary support and authority to carry out their task.

2.2.3.2 May be in addition to Categories A-D.

2.2.4 The Chair must:

2.2.4.1 Impartially guide the operation of the AEC.

- 2.2.4.2 Ensure that the AEC operates in accordance with the principles and requirements of the Code; the relevant policies of the Institution and the agreed AEC procedures.
- 2.2.4.3 Lead discussion of matters within the AEC meeting, especially Executive Committee matters, using neutral wording to avoid influencing AEC member viewpoints.
- 2.2.4.4 Ensure submissions to the AEC are considered in a timely manner.
- 2.2.4.5 Ensure that outcomes are conveyed to researchers and teachers in a timely manner.
- 2.2.4.6 Given appropriate delegated authority, represent the AEC in any negotiations with management.
- 2.2.4.7 Oversee all reviewing requirements required by the Code.

### 2.3 The Balance of Membership (*the Code, Section 2.2.25*)

- 2.3.1 Further to point 2.1. the AEC must:
  - 2.3.1.1 Have at least four (4) members.
  - 2.3.1.2 If consisting of more than four (4) members, Categories C and D combined must comprise at least one third of AEC membership.
  - 2.3.1.3 If an AEC position becomes vacant, the Institution must appoint a person to fill that vacancy to ensure AEC balance requirements are met.

### 2.4 Appointment

- 2.4.1 AEC members are recruited by direct approach, nomination or by advertisement through an open and transparent process.
- 2.4.2 Prospective members may be invited to observe one or more meetings of the AEC prior to formal appointment.
- 2.4.3 New members are appointed by the Head of the Institution (or their delegate). The letter of appointment includes the date of appointment, length of tenure, and indemnity. Appointment is completed upon formal ratification by the Animal Research Review Panel.
- 2.4.4 Upon appointment, members are provided with an orientation package and asked to sign a Confidentiality Agreement.
- 2.4.5 Members are appointed for a period of up to 3 years; subsequent reappointments of up to 3 years may be approved by the Head of the Institution (or their delegate). A probationary period may be implemented in consultation with the Chair.
- 2.4.6 Where there is a need for business continuity or specialist knowledge/skills, the Chair and any other member may serve longer terms with the approval of the Head of the Institution (or their delegate). Members are advised when their term has expired.
- 2.4.7 New and renewed appointments allow for a combination of continuity, development of expertise within the AEC, and regular input of fresh ideas and

approaches.

- 2.4.8 Members seeking to resign or take a leave of absence for an extended period from the AEC are asked to give notice to their Executive Officer who will then advise the Head of the Institution (or their delegate). Steps are taken to fill the vacancy.
  - 2.4.9 The appointment of any member of the AEC may be terminated if the Head of the Institution (or their delegate) is of the opinion that:
    - 2.4.9.1 It is necessary for the proper and effective functioning of the AEC;
    - 2.4.9.2 The person is not a fit and proper person to serve on an AEC; or
    - 2.4.9.3 The person has failed to carry out their duties as an AEC member.
  - 2.4.10 Members can volunteer to participate in relevant specialised working groups as required.
  - 2.4.11 DRNSW provides indemnity for members of the AEC for liabilities that arise as a result of the member exercising their duties in good faith.
- 2.5 Orientation and training for AEC members
- 2.5.1 New AEC members are provided with orientation/training as determined to be appropriate by the Institution.
  - 2.5.2 Orientation involves some or all of the following:
    - 2.5.2.1 Introduction to other AEC members;
    - 2.5.2.2 Provision of a training and induction package, including online interstate requirements;
    - 2.5.2.3 Processes and procedures, and use of the Research Ethics Online (REO) system if relevant;
    - 2.5.2.4 ‘Partnering’ with another AEC member to provide new member support; and
    - 2.5.2.5 Priority given to participate in training sessions.
  - 2.5.3 Each member is:
    - 2.5.3.1 expected to become familiar with the Code, the Act and Regulations; and
    - 2.5.3.2 expected to become familiar with the use of the REO system<sup>2</sup>.

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### 3. ACCOUNTABILITY

- 3.1 Through the Internal Assignment of Functions, the internal DRNSW AECs are directly accountable to the Head of the Institution (or their delegate).
- 3.2 Through the Animal Research Instrument of Delegation, the Secretary’s ACEC is directly

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<sup>2</sup> Noting this is currently only relevant for the DRNSW internal AECs, as the Secretary’s ACEC is yet to be transitioned to this online system. Once this occurs, this clause will then apply to the Secretary’s ACEC.

accountable to the Secretary (or their delegate).

- 3.3 The AECs provide an annual report to the relevant delegate at the end of each calendar year. This reporting is used as a mechanism to monitor and evaluate its performance.
- 3.4 The AECs bring to the attention of the relevant delegate issues of significant concern.

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## 4. SCOPE OF RESPONSIBILITY

- 4.1 AECs are responsible for ensuring that all activities relating to the care and use of animals are conducted in compliance with the Act, the Regulation, and the Code. The internal DRNSW AECs consider applications for animal ARAs from staff of NSW DPI and any other accredited research establishment with which a current formal Sharing Agreement exists. The Secretary's ACEC considers applications for ARAs from users according to established and documented Use Criteria for that committee.
- 4.2 DRNSW AECs will (*the Code, Section 2.3.2*):
  - 4.2.1 review applications for projects and approve only those projects that are ethically acceptable and conform to the requirements of the Code;
  - 4.2.2 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 approve only those activities that are ethically acceptable and conform to the requirements of the Code;
  - 4.2.3 conduct follow-up review of approved projects and activities and allow the continuation of approval for only those projects and activities that are ethically acceptable and conform to the requirements of the Code;
  - 4.2.4 monitor the care and use of animals, including housing conditions, practices and procedures involved in the care of animals in facilities;
  - 4.2.5 take appropriate actions regarding unexpected adverse events;
  - 4.2.6 take appropriate actions regarding non-compliance;
  - 4.2.7 approve guidelines for the care and use of animals; and
  - 4.2.8 provide advice and recommendations to the Institution or the Secretary (or their relevant delegates).

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## 5. CONDUCT OF BUSINESS

- 5.1 Procedures
  - 5.1.1 The AECs conduct their business in accordance with these Terms of Reference, which are aligned to the Code (*Sections 2.2, 2.3 and 2.6*).

## 5.2 Online Review<sup>3</sup>

- 5.2.1 The AECs conduct online initial review of submissions using the Research Ethics Online (REO) system.
- 5.2.2 AEC members are expected to read submissions and add written comment following system procedures for AEC members.
- 5.2.3 All online submissions and review comments are discussed at formal AEC quorate meetings.

## 5.3 Meetings

- 5.3.1 AECs maintain scheduled meetings.
- 5.3.2 A quorum of members is required to attend and contribute to meetings. The quorum for meetings is at least one member from each of the core categories (section 2.1.2 above) with the appropriate member ratio (section 2.3.1 above)
- 5.3.3 The Executive Officer will develop an agenda for each meeting, taking into account decisions reached at the preceding meeting, any pending business (including action items from previous meetings) and inspections, and any new developments.
- 5.3.4 The Executive Officer shall consult with the Chair on the items on the agenda.
- 5.3.5 The agenda must be sent to AEC members and other attendees, together with any new projects for consideration and any supporting material, at least one (1) week prior to the next meeting.
- 5.3.6 Minutes of the meeting will be maintained, recording the decisions and business of the AEC.
  - 5.3.6.1 The Executive Officer is responsible for the taking, writing-up and distribution of the minutes to AEC members and other attendees.
  - 5.3.6.2 The minutes must:
    - 5.3.6.2.1 Be full and accurate.
    - 5.3.6.2.2 State the reasons for any decision on a research project.
    - 5.3.6.2.3 Be confirmed at the next meeting and formally signed by the Chair.
    - 5.3.6.2.4 Be kept for seven (7) years after the minutes are ratified by the Committee.

## 5.4 Declaration of interest

- 5.4.1 An AEC member must declare to the AEC any conflicts of interest they have in relation to an application for ethical and scientific review or any other matter for consideration at the meeting. Conflicts of interest include financial interests, personal, professional or institutional benefits or advantages that depend

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<sup>3</sup> This is currently only relevant for the DRNSW internal AECs, as the Secretary's ACEC is yet to be transitioned to this online system. Once this occurs, this clause will then apply to the Secretary's ACEC also. Secretary's ACEC will review electronic agenda papers and discuss comments at meetings.



significantly on the research outcomes and/or the decision of the AEC.

- 5.4.2 The minutes record declaration of interest and the decision of the AEC on the procedures to be followed.

## 5.5 Confidentiality

- 5.5.1 The deliberations, discussions, notices, agendas, and minutes of all AEC meetings are confidential to members of the AEC and the AEC Secretariat.

## 5.6 Decision making

- 5.6.1 The AEC endeavours to reach a decision concerning the ethical and scientific acceptability of an application by consensus agreement.
- 5.6.2 Where a consensus decision is not reached, the Chair will facilitate the expression of opinion from all members, identify points of agreement and of disagreements and judge when a sufficient degree of general agreement has been reached.
- 5.6.3 All members of the AEC have equal status and all members are entitled to put forward their views.
- 5.6.4 Each member is responsible for deciding whether, in their own judgement, any matter under consideration by the AEC is ethically acceptable and consistent with the requirements of the Code.
- 5.6.5 A member may request that their views be specifically recorded in the minutes.
- 5.6.6 Decisions of the AEC must be communicated to researchers as promptly as possible, and a researcher must not commence research under a project until advised in writing of approval.

## 5.7 Records

- 5.7.1 Online records associated with REO are maintained within the online system.
- 5.7.2 Written records of any meetings of the AEC are maintained (including agendas and minutes, and electronic submissions to Secretary's ACEC) within CM9.
- 5.7.3 Files are kept securely and confidentially in accordance with the requirements of the State Records Act 1998.
- 5.7.4 The AEC maintains a register of all the applications received and reviewed in accordance with the Code and legislation.

## 5.8 Monitoring research projects

- 5.8.1 The AEC monitors approved research projects to ensure compliance with the conditions of approval and to protect the rights, safety, and welfare of animal participants. This includes inspections of research sites, procedures, paperwork and animals, review of annual progress reports and final reports, adverse event reports and reports of project violations or modifications.
- 5.8.2 The AEC has the discretion to adopt other appropriate mechanisms for monitoring depending on the complexity, design and risk perceived, including:
  - 5.8.2.1 Discussion of relevant aspects of the project with investigators, at any



time;

5.8.2.2 Random inspection of research sites, data, or consent documentation;

5.8.2.3 Interviews with research participants or other forms of feedback from them such as additional reporting

5.8.3 The AEC also has the discretion to recommend in the letter of approval that the research team co-ordinates onsite monitoring at recommended intervals or randomly throughout the project.

## 5.9 Discontinuation or suspension of research

5.9.1 Researchers must advise the AEC if the research project is to be discontinued before the expected date of completion, and why. This is done within the REO system<sup>4</sup> by way of a Final Report.

5.9.2 Where the AEC finds reason to believe that continuance of a research project will compromise animal welfare, it should immediately seek to establish whether ethical approval for the project should be withdrawn. This process should ensure that researchers and others involved in the project are treated fairly and with respect. Documentation related to discussions will be maintained in the REO<sup>5</sup> project. If a project is to be closed, this will be done by a formal letter from the Chair.

5.9.3 If the Institution or the AEC considers that urgent suspension of research is necessary before the process described in paragraphs 5.9.1 and 5.9.2 is undertaken, the instruction to stop should come via the Head of the Institution (or their delegate).

## 5.10 Monitoring of research sites

5.10.1 Inspections of investigators and projects being conducted within fixed facilities will be undertaken on a regular basis. Inspections of projects being conducted remotely will be undertaken where possible.

5.10.2 Records of inspections should include the names of those who attended, observations, any identified problems, follow-up, and outcomes.

5.10.3 Inspections of remote sites and monitoring of projects at those sites may be carried out by appropriately experienced delegates on behalf of the committee.

5.10.4 Where an inspection detects an activity non-compliant with the Code, the AEC must ensure that the activity ceases immediately, and remedial action is initiated.

## 5.11 AEC Reporting

5.11.1 The AEC must report annually to the Head of the Institution (or their delegate). The report should include information on (*the Code, Section 2.3.29*)

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<sup>5</sup> As above.

- 5.11.1.1 numbers and types of projects and activities assessed, and approved or rejected;
- 5.11.1.2 the physical facilities for the care and use of animals by the Institution;
- 5.11.1.3 actions that have supported the educational and training needs of AEC members and people involved in the care and use of animals;
- 5.11.1.4 administrative or other difficulties experienced; and
- 5.11.1.5 any matters that may affect the Institution's ability to maintain compliance with the Code and, if appropriate, suitable recommendations.

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## 6. PROJECTS INVOLVING AN EXTERNAL AEC

- 6.1 Where projects are to be conducted at or involving more than one institution, procedures must be in place to ensure that (*the Code, Section 2.6*):
  - 6.1.1 animals will be well cared for in all phases of the project;
  - 6.1.2 the responsible AECs are in a position to inspect the animals during all phases of the work;
  - 6.1.3 before any work commences, each AEC approves, or delegates approval of, scientific and teaching activities being conducted by members of its institution;
  - 6.1.4 clear communication channels are established between all involved AECs and investigators and teachers; and
  - 6.1.5 such arrangements should be as a formal agreement that ensures that all parties are aware of and can meet their respective responsibilities under the requirements of the Code and relevant legislation.
- 6.2 Where parts of a project take place at different institutions, each AEC may choose to approve and monitor only those parts that take place at their institution. However, it is essential that each AEC is cognisant of all aspects of the project and ensures that any cumulative impact of procedures on animals is considered. Such arrangements should be part of a formal agreement.

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## 7. APPEALS AND COMPLAINTS

- 7.1 Appeals regarding AEC rejection or suspension:
  - 7.1.1 Where the AEC has rejected an application, the investigator has the discretion to:
    - 7.1.1.1 submit a new application to the AEC, taking due account of the AEC's concerns; or
    - 7.1.1.2 lodge an appeal with the AEC Chair, specifying the grounds of the appeal in writing.

## 7.2 Appeals regarding AEC approval

7.2.1 Where the AEC has given a favourable decision on an application and

7.2.1.1 an ethical or scientific issue is subsequently identified by any party; or

7.2.1.2 it has become apparent that the decision was based on inconsistent application of policy and guidelines

a written appeal is lodged with the Chair in the first instance.

## 7.3 Appeals to the Head of the Institution (or their delegate)

7.3.1 If the applicant considers that the AEC has failed to follow due process after making an appeal in line with 7.1 and 7.2 and remains unsatisfied with the outcome, they have the discretion to lodge an appeal with the Head of the Institution (or their delegate) or request that the Chair do so (*National Statement 5.6.1 (a) and (b)*).

## 7.4 Complaints about the conduct of AEC members

7.4.1 Complaints about the conduct of an AEC member are managed by the Head of the Institution (or their delegate), who informs the Chair of the complaint.

## 7.5 Complaints about the conduct of an approved research project.

7.5.1 Complaints about the conduct of an authorised research project, including allegations of research misconduct, are managed in accordance with the NSW DPI Guideline for the Responsible Conduct of Research and are provided to the Head of the Institution (or their delegate).

## 7.6 The Institution will maintain Grievances Procedures and make these available.

These Terms of Reference will be made publicly available on the DPI website and such other placements as the Department may decide.

Approved by the head of the accredited research establishment or their delegate:

Date: 29 November 2023

Signature: 

Title: NSW DPI Chief Scientist