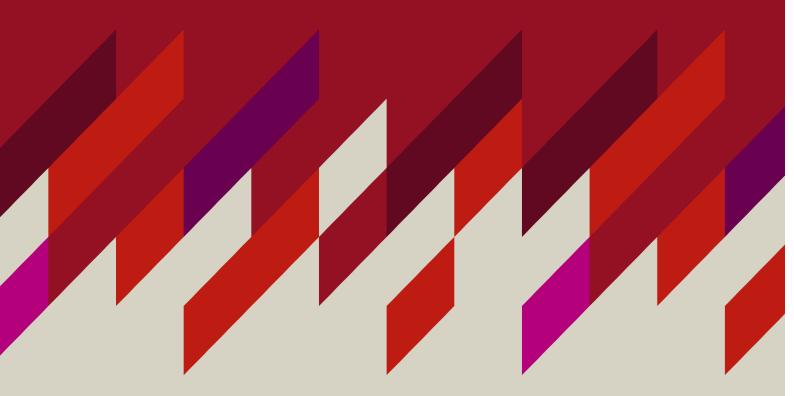
Animal Ethics Terms of Reference and Operating Procedures

This document was developed by Macquarie University Animal Ethics Committee



Signed:

Antzi S

Professor Isak Pretorius, Deputy Vice-Chancellor (Research)

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MACQUARIE University Sydney-Australia

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Historical Notes: Table of Amendments

| Amendment | Date | Short Description |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Establishment of current terms of reference | October 2006 | Developed Dec 2004 to October 2006. Reviewed by AEC October 2006. |
| Revision of full document. | August 2009 | Reviewed by Director, Research Ethics and Animal Welfare Officer. Significant amendments recommended. |
| Minor revision by AWO. | October 2009 | To be reviewed by AEC December 2009. |
| Tabled at AEC meeting. | December 2009 | Accepted by the AEC. |
| Addition of selected points from Code (7 th Ed) Section 2.2.1 as recommended by ARRP (correspondence received 11/01/2010 re renewal of accreditation). Inserted under item 2. Purpose of AEC. | February 2010 | Approved by AEC Feb 2010. |
| Minor revision of Clause 5.2.1. | August 2010 | Approved by AEC Aug 2010. |
| Confidentiality of the minutes of the meetings. 5.5.6. | April 2011 | Approved by AEC April 2011 that non-confidentiality would censor the committee. Thus; confidentiality is a primary component of AEC. |
| Confidentiality of meetings Clause 5.9. | April 2011 | Advised by University Counsel to add a Confidentiality clause. |
| No amendment. Australian Code of Practice for the care and use of animals for Scientific Purposes (8 th Edition) revised. | August 2013 | A copy of the revised 8 th Edition of The Code was presented to all AEC members. |
| Revision of full document. | December 2013 | Reviewed by the AEC, Director Research Ethics and AWO. Pending significant changes. |
| Resubmission of revised Terms of Reference to the AEC version 5. | December 2014 | Approved by AEC December 2014. |
| Biosecurity Queensland - Two registration conditions were applied to Macquarie University's registration (Reg. No. 421). | March 2015 | It was found that the submitted TOR i.e. more specifically clauses 2.2.18 (p21); 2.3.1 (p25) and 2.3.2 (p25 – 26) were not compliant and needed review. Amendments were made; and these were approved by Biosecurity Queensland on 3/3/2015. |
| Revision of AEC TOR v.5 | March 2015 | Approved by AEC/DVCR: Professor Isak Pretorius March 2015. |
| Revision of AEC TOR v.6 | September 2018 | Approved by AEC: September 2018. Approved by the DVCR: Professor Isak Pretorius October 2018 |
| Revision of full document v.7 | December 2021 | Approved by AEC: December 2021. Approved by the DVCR: Professor Isak Pretorius January 2022. |
| Revision of full document v.8 | November 2023 | Reviewed by the AEC, Director Research Ethics, AEC Chair and University Veterinarian (AWO). Significant changes, including: AEC will not usually consider smoke inhalation & forced swim test in rodents AEC notification of collaborative research conducted at other institution(s). Criteria for appointment of AEC members Subcommittees; Frequency of meetings; Chief investigators; Animal Ethics training required for all investigators current within 5 years. |

Animal Ethics Committee

Terms of Reference and Operating Procedures

Table of Contents

| 1. | Context4 | | | | |
|-----|-------------------------------------------|--------------------------------------------|-----|--|--|
| 2. | Establishment of the AEC4 | | | | |
| 3. | Responsibilities of the AEC | | | | |
| | 3.2. | The AEC meets this responsibility by | 5 | | |
| 4. | Membership | | | | |
| | 4.1. | Required and Discretionary | 5 | | |
| | 4.2. | The Chair's Role | 6 | | |
| | 4.3. | The Balance of Membership | 7 | | |
| | 4.4. | Conditions of AEC Members' Appointments | | | |
| | 4.5. | Terms of Membership | 8 | | |
| 5. | Institutional Resources | | | | |
| | 5.2. | Secretary's Role | 9 | | |
| | 5.3. | The Role of the Animal Welfare Officer | .10 | | |
| 6. | Cond | duct of Meetings and Inspections | 11 | | |
| | 6.1. | Frequency | 11 | | |
| | 6.2. | Quorum | 11 | | |
| | 6.3. | Agenda | 11 | | |
| | 6.4. | Minutes | 11 | | |
| | 6.5. | Decision Making | 12 | | |
| | 6.6. | Subcommittees | 9 | | |
| | 6.7. | Delegations | | | |
| | 6.8. | Confidentiality Clause | 13 | | |
| | 6.9. | Inspections | 13 | | |
| 7. | Cons | sideration of Projects | | | |
| | 7.1. | Preliminary Consideration | 13 | | |
| | 7.2. | New or Initial Projects | | | |
| | 7.3. | Pilot Projects | | | |
| | 7.4. | Resubmissions of Projects | | | |
| | 7.5. | Amendments to Projects | | | |
| | 7.6. | Progress Reports | | | |
| | 7.7. | Final Reports and Discontinued Projects | | | |
| | 7.8. | Collaborative Arrangements | | | |
| | 7.9. | Communication of Decisions | | | |
| _ | | Disputes by Researchers on AEC Decisions | | | |
| 8. | | lution of AEC Members' Complaints | | | |
| 9. | | plaints | | | |
| 10. | Non | -compliance with the Code and Legislation | 19 | | |
| | 10.1. | Obligations | 19 | | |
| | 10.2. | Offences of non-compliance | 19 | | |
| | 10.3. | AEC Procedures to deal with non-compliance | 20 | | |
| | | Formal Procedures | | | |
| | | Informal Procedures | | | |
| 11. | Reco | ord Keeping | 22 | | |
| 12. | 2. Reporting of Unexpected Adverse Events | | | | |
| 13. | Repo | orts and Oversights | 23 | | |
| IND | EX | 24 | | | |

1. Context

In NSW, the use of animals for research or teaching purposes is governed by the Animal Research Act 1985 (NSW), Animal Research Regulation 2010 (NSW), and Australian Code for the Care and Use of Animals for Scientific Purposes (8th Edition) (the Code) incorporated by reference into the Animal Research Regulation 2010.

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 the Animal Ethics Committee (AEC).

The Code requires that institutions establish procedures for the effective governance and operation of the AEC that enable the AEC to comply with the Code and relevant institutional policies, and promote competent and timely ethical review of animal care and use.

Macquarie University is committed to the welfare of research animals and respect for their contribution to research and must comply with the Code. The 3R's underpin all of 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.

2. Establishment of the AEC

- **2.1.** Macquarie University, in order to be an *accredited research establishment* enabling research and teaching involving animals, and a *licenced Animal Supplier* under the NSW *Animal Research Act 1985*, has established an Animal Care and Ethics Committee. Macquarie University has elected to call this committee the Animal Ethics Committee to be consistent with the Code.
- **2.2.** The AEC is an independent committee providing advice on matters pertaining to the use of animals for scientific purposes subject to the Code, to the University and its governing body, the University Council, through the office of the Deputy Vice-Chancellor (Research).
- **2.3.** The University has the authority to issue *Animal Research Authorities* to researchers to allow them to conduct research or teaching involving animals. No *Animal Research Authority* can be granted by Macquarie University without the approval and in accordance with the directions of the AEC.
 - The AEC does not issue Animal Research Authorities.
 - However, the Vice-Chancellor representing the University has delegated their power to the Chair of the AEC by instrument of delegation in writing.

3. **Responsibilities of the AEC**

3.1. The AEC is responsible in ensuring that all activities relating to the care and use of animals for research and teaching at Macquarie University or involving Macquarie University staff or students are conducted in compliance with the legislation and the Code.

- 3.2. The AEC meets this responsibility by
 - Making recommendations to the University concerning the granting of Animal Research Authorities by the University, ensuring that only ethically acceptable and Code compliant projects and activities are approved.
 - Reviewing, at least annually, all currently approved projects and activities to ensure that they remain compliant with the Code and ethically acceptable and appropriate.
 - Supervising and monitoring all animal research at or undertaken by the University.
 - Approving and making directions concerning the supply of animals pursuant to any animal supplier's licence.
 - Supervising the breeding and supply of research animals. Monitoring the acquisition, transportation, production, housing, care, use and fate of animals.
 - Inspecting facilities used for research, housing, and teaching involving animals at least annually.
 - Approving guidelines for the care and use of research animals.
 - Taking appropriate action regarding non-compliance and adverse events.
 - Recommending to the institution any measures needed to ensure the standards of the Code are maintained.
 - Authorising the emergency treatment or euthanasia of any animal.
 - Examining and commenting on all institutional plans and policies that may affect the welfare of animals used for scientific purposes.
 - Ensuring reporting as required by the legislation and the Code is both timely and accurate.
 - Performing all other duties required by the legislation and the Code

4. Terms of Membership

4.1. Required and Discretionary

4.1.1. The AEC *must* comprise at least four (4) members: one from each of the following categories:

Category A (Veterinarian)

 a person with qualifications in veterinary science registrable within Australia and preferably with experience relevant to the activities of Macquarie University.

Category B (Researcher)

Category B—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.

Category C (Animal Welfare)

 a person not employed by or otherwise associated with the University and who is not currently involved in scientific research involving animals, with demonstrable commitment to and established experience in animal welfare. (Veterinarians with such specific experience may meet this requirement).

Category D (Independent)

 a person not employed by or otherwise associated with the University, who has never been involved in animal use for scientific research or teaching in either their employment or education, and must not fit the requirements of A, B, or C.

4.1.2. The AEC *may* include:

(a) The Animal Welfare Officer

 The University Veterinarian (AWO) who is the person appointed to assist the AEC in monitoring of animals and compliance with the Code, and promotion of animal welfare.

(b) Additional members

 People with skills and background useful to the AEC, who may be additional to categories A-D.

(c) Attendees

- (i) Facility Managers should be in attendance as required. These are persons appointed to supervise the routine care of animals at Macquarie University.
- (ii) The AEC may invite persons with specific expertise to advise the Committee as required.
- (iii) Should the University have appointed a Secretary to assist the AEC, the Secretary shall attend, and be responsible for the recording and distribution of the Minutes of each AEC meeting, and the provision of administrative assistance to the AEC.

4.1.3. The Chair

The Chair must be one of the members of the AEC.

4.2. The Chair's Role

- **4.2.1.** The Chair *must* preside at AEC meetings.
 - If the Chair is absent, the AEC may elect a member to act as Chair.
 - Alternatively, a person elected as Deputy Chair may preside in the Chair's absence.

4.2.2. The Chair *should*:

- Hold a senior position at the University, or, if an external appointee, be given a commitment by the University of necessary support and authority to carry out their task.
- Be in addition to Categories A-D
- Possess the following attributes:
 - An ability to bring impartiality to the task.
 - The skills to manage the business of the AEC.
 - Good communication, negotiation and conflict resolution skills.
 - An understanding of ethical and animal welfare issues involved in scientific research.

4.2.3. The Chair *must*:

- Impartially guide the operation of the AEC.
- Ensure that the AEC operates in accordance with the principles and requirements of the Code; the relevant policies of Macquarie University, and the agreed AEC procedures.
- Lead discussion of matters within the AEC meeting, especially Executive Committee matters, using neutral wording to avoid influencing AEC member viewpoints.
- Ensure projects to the AEC are considered in a timely manner.
- Ensure that outcomes are conveyed to researchers and teachers in a timely manner.
- Advise the University on resourcing levels necessary for the successful operation of the AEC.

- Given appropriate delegated authority may represent the AEC in any negotiations with management.
- Oversee all reporting requirements required by the Code, including the annual report.
- Oversee all reviewing requirements required by the Code.
- Ensure AEC records are maintained and made available for review by the University and external reviewing authorities.
- **4.2.4.** The Chair's signature on a document authenticates it as a document of the AEC. (An AEC member or Secretary, authorised to do so by the Chair, may also authenticate documents).

4.3. The Balance of Membership

- **4.3.1.** As per point 3.1. the AEC must:
 - Have at least four (4) members.
 - If consisting of more than four (4) members, Categories C and D must comprise at least one third of AEC membership.
 - If an AEC position becomes vacant, the University must appoint a person to fill that vacancy so as to ensure that the balance requirements of the AEC are met.

4.4. Conditions of AEC Members' Appointments

- **4.4.1.** Before appointment, all members *must* acknowledge in writing acceptance of the AEC's Terms of Reference, and confidentiality requirements required by the University.
- **4.4.2.** All members are expected to become familiar with the Animal Research Legislation, the Code and relevant University Policy to enable them to contribute effectively to meetings.
- **4.4.3.** All AEC members *must* declare any conflict of interest. A conflict of interest will occur when a member has an interest *that may be seen to influence the objectivity of a decision on its merits.*
 - On declaration of a conflict of interest the relevant member shall absent themselves from the meeting for the duration of the relevant discussion and decision-making.
 - A decision can only be made if the AEC remains quorate in the absence of the member with the conflict of interest.
 - Failure to declare a conflict of interest will result in the relevant decision(s) affected by the conflict of interest being deemed void. Such a decision must be reconsidered at the next AEC meeting.
 - Failure by a member to declare a conflict of interest will result in that conflict of interest being discussed by the AEC as a whole, in that member's presence, in order to ensure that no recurrence of failure to declare will occur.
- **4.4.4.** Members are entitled to:
 - Adequate resourcing and administrative support from the University to fulfil their duties.
 - Orientation and education in respect of their duties under the legislation and the Code.
 - Reimbursement of out-of-pocket expenses and/or payment of an allowance, where appropriate.
 - Information on dispute resolution between AEC members, between the AEC and the University, and between the AEC and researchers/teachers.

 All relevant information concerning University policies, including Freedom of Information and confidentiality requirements, and disease and WH&S hazards relating to animal use and care.

4.5. Terms of Membership

4.5.1. Appointment of AEC Members

AEC members are appointed by Macquarie University (usually by the Deputy Vice-Chancellor (Research) on its behalf) for the terms specified in their instrument of appointment.

- **4.5.1.1.** AEC members may be recruited by direct approach from the Research Services Office. Category B (Researcher) members may be formally nominated by the Faculty Dean.
- **4.5.1.2.** All AEC members remain members unless they resign, their term expires, or they otherwise cease to be a member.
- **4.5.1.3.** A member's term is for three (3) years unless otherwise specified.
- **4.5.1.4.** Members will be appointed for a period of three (3) years with an opportunity to renew at the end of this period. The AEC may suggest that they seek reappointment.
- **4.5.1.5.** Should the member agree, the AEC will recommend to the Deputy Vice-Chancellor (Research) that the member be re-appointed for the term specified in the instrument of appointment.
- **4.5.1.6.** Prospective lay members will be recruited by word of mouth or direct approach. Lay members will be asked to submit a curriculum vitae to Research Service Office before formalising membership. Lay members will be formally appointed by the DVCR.
- **4.5.1.7.** All members, including the Chairperson and Deputy Chairs will receive a letter of appointment. The letter of appointment will include the date of appointment, length of tenure, indemnity and termination. Members will also be provided with an orientation package and will be asked to sign a confidentiality agreement which indicates that all matters of which the member becomes aware during the course of their work on the AEC will be kept confidential and that any conflicts of interest will be declared.
- **4.5.1.8.** Members are expected to participate in education and training as required. Members are expected to be familiar with the Australian code for the care and use of animals for scientific purposes and other guidelines and legislation as required.

4.5.2. Resignation

- AEC members may resign by instrument in writing addressed to the AEC.
- The Chair may resign as Chair by instrument in writing addressed to the AEC.
- An AEC member will cease to be a member if:
 - > They die.
 - They absent themselves from four (4) consecutive meetings of which adequate notice had been given to the member, unless on leave granted by the AEC, or unless within four (4) weeks of the last of the relevant four (4) meetings, the AEC has excused the member from attendance.
 - > They become mentally incapacitated.
 - They commit a criminal offence, punishable by 12 months or more imprisonment.

4.6. Subcommittees

- **4.6.1.** The University may, on the recommendation of the AEC, establish AEC sub-committees to assist it in its work. The AEC may delegate certain functions to the subcommittee(s).
- **4.6.2.** The AEC may recommend to the university the establishment of a subcommittee with specific delegated functions- the AEC **Executive Committee.**
 - The AEC may delegate functions to, and appoint members to the Executive Committee.
 - The Executive Committee must include at least one (1) member from Category C or D and the AEC Chair.
 - The University Veterinarian (AWO) advises the Executive Committee.
 - The Executive Committee shall not approve new projects. New projects must be considered only by a quorate AEC meeting.
 - The Executive may approve minor amendments of existing projects for review at the next AEC meeting.
 - A minor amendment may include a change to an approved project or activity where the proposed change is not likely to cause harm to the animals, including pain and distress; this includes the addition of strain of animal that is consistent to the original project aims and presents no new welfare impacts that require full-Committee consideration.
 - The Executive may approve the addition or removal of personnel.
 - All decisions of the Executive Committee must be submitted to the next AEC meeting for ratification.

5. Institutional Resources

5.1. Macquarie University has an obligation under the Code to provide the AEC with resources adequate for it to meet its statutory responsibilities. Amongst other things, information must be provided to AEC members in a timely manner.

5.2. Secretary's Role

- **5.2.1.** The Secretary is not a member of the AEC.
- **5.2.2.** If the University has appointed a Secretary to the Committee, the duties of the Secretary are:
 - To assist the AEC by the timely provision of information concerning matters relevant to their work.
 - To assist in liaison between AEC members, and between the AEC and the University Veterinarian (AWO), if not a member.
 - To assist the AEC in any necessary or desirable liaison with the relevant Government Departments.
 - To inform the AEC of any meetings on animal welfare organised by the NSW Department of Primary Industries (DPI) and the Animal Research Review Panel or National Health and Medical Research Council or other relevant organisation.
 - To assist in preparing annual reports as required by the legislation and the Code.
 - To assist in preparing and presenting reports for the regulatory bodies (DPI) and the AEC.
 Monitoring animal research authorities and due dates.
 - To assist researchers and members of the public who may have inquiries concerning the work of the AEC.
 - To receive and record all applications for research authorities, progress reports, final reports, and amendments to projects in a register.

- To record the Minutes of and draft the Agenda for each meeting in consultation with the Chair.
 - To circulate the Minutes prior to the next meeting.
 - To circulate the draft Agenda and any supporting information at least one (1) week prior to the next meeting.
 - To draft research authorities and letters to researchers as directed by the Committee.
 - Only the Chair or an AEC member with appropriate delegated authority may sign research authorities.
- To assist the Executive Committee by:
 - Distributing information relevant to Executive Committee decision-making in a timely manner.
 - Coordinating Executive Committee responses.
 - Communicating to relevant parties the Executive Committee's decisions in consultation with the Chair.
 - Drafting the appropriate correspondence or authorities to be sent as soon as possible after finalisation of Executive consideration.
- Since the Secretary is not a member of the AEC, and cannot receive any delegated authority from the AEC, the Secretary has no authority to sign Executive communications or research authorities, nor can such authority be delegated to the Secretary.
- Only the Chair or an AEC member with the appropriate delegated authority may sign communications of Executive decisions, since the Executive only has such authority as may be delegated by the AEC itself, in accordance with the University's approval.
- To communicate the outcome of applications to researchers and teachers as promptly as possible.
- To report to the AEC at its next meeting in writing on Executive Committee decisions, so that the AEC may ratify the Executive decisions.
- To assist any subcommittees in addition to the Executive Committee.
- To assist University Veterinarian (AWO) in their role as functional arm of the AEC.

5.3. The Role of the University Veterinarian (Animal Welfare Officer)

- **5.3.1.** The University Veterinarian (AWO) is employed by the University. The University Veterinarian (AWO) is authorised by the Committee to ensure compliance with the legislation and with the decisions of the Committee. The University Veterinarian (AWO) effectively acts as the functional arm of the AEC on a day-to-day basis by:
 - Overseeing all animals and their use within the responsibility of the University.
 - Monitoring of all procedures and techniques used in both research and teaching, and inspecting all animal holding facilities associated with the University's activities involving animals.
 - Coordinating records of all animals used in the University's research and teaching activities.
 - Advising the AEC of the numbers and types of animals used for research and teaching purposes within the University, and providing professional advice to the Committee on the acceptability of procedures and techniques used in those activities.
 - Assisting in the development of courses for researchers and teachers in animal research ethics and animal care and handling.
 - Taking all steps necessary to ensure that all persons using animal services do so in compliance with University policy.
 - Liaising with any veterinary experts as appropriate; and coordinating the veterinary requirements of animal users as required.
 - Organising AEC inspections of University animal facilities as required.

- Informing animal users of AEC decisions and liaising with animal users concerning AEC requirements.
- Providing advice on animal welfare issues.
- Liaising with the Chair of the AEC, where appropriate.
- Performing such other functions as might be required by the University from time to time.
- Periodically inspecting animal facilities, databases and log books.
- Reporting on animal welfare issues.
- Reviewing projects before submissions and assisting researchers in the formation of the projects.
- Assisting the Director, Research Ethics with documentation where appropriate.
- Liaising between animal researchers who have submitted projects for consideration and members of the Committee.
- Assisting the Secretary in preparing and presenting reports for the regulatory bodies (DPI), the University and the AEC.
- Assisting the Secretary in preparing annual reports as required by legislation and the Code.
- Overseeing the supply of animals, and any re-homing or relocation of animals.
- Liaising with Animal Facility Managers and Head Animal Facilities on issues affecting animal welfare.

6. Conduct of Meetings and Inspections

6.1. Frequency

- The Macquarie University AEC meets at least 11 times a year.
- Meetings commence at 12:00 pm unless otherwise specified.

6.2. Quorum

- **6.2.1.** The AEC shall require the presence of at least one member from Categories A-D to establish a quorum. If more than four (4) members are present, Categories C plus D should constitute not less than one third of the members present.
 - In exceptional circumstances, a quorum may be established through teleconferencing or video-links.
 - Only a quorate meeting of the AEC shall consider and approve new projects, or consider and approve renewal of existing projects.

6.3. Agenda

- **6.3.1.** The Secretary shall 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.
 - The Secretary shall consult with the Chair on the items on the Agenda.
 - The draft agenda must be sent to AEC members and regular attendees, together with any new projects for consideration, and any supporting material at least one (1) week prior to the next meeting.

6.4. Minutes

6.4.1. Information must be provided to AEC members in a timely manner.

6.4.2. Minutes of the meeting must be maintained, recording the decisions and business of the AEC.

The Secretary is responsible for the taking, writing-up and distribution of the Minutes to AEC members, regular attendees and the University Veterinarian (AWO).

The Minutes must:

- > Be full and accurate.
- > State the reasons for any decision on a research project.
- > Be confirmed at the next meeting and formally signed by the Chair.
- > Be kept for seven (7) years after the Minutes are ratified by the Committee.
- **6.4.3.** 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.
- **6.4.4.** The Secretary shall consult with the Chair before distribution of the draft Minutes.
- **6.4.5.** The Minutes of an AEC meeting must be finalised and circulated to members, regular attendees and the University Veterinarian (AWO) at least one (1) week prior to the next meeting.
- **6.4.6.** Per Section 2.2.22 of the Code confidentiality must be maintained regarding the content of applications and the deliberations of the AEC, including how members may seek advice without breaching confidentiality. As per the policy of Macquarie University, the minutes of the meeting are confidential to the members of the AEC.

6.5. Decision Making

- 6.5.1. All members of the AEC have equal status.
- **6.5.2.** All members are entitled to put forward their views and 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.
- 6.5.3. A member may request that their views be specifically recorded in the Minutes.
- **6.5.4.** 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

6.6. Delegations

- **6.6.1.** The Vice-Chancellor, by instrument in writing, may delegate their authority to issue animal research authorities to the Chair of the AEC.
- **6.6.2.** The University, on the recommendation of the AEC, may establish subcommittees to assist the AEC in its work.
- **6.6.3.** The AEC may delegate any of its functions to subcommittees **other than** the following with respect to research projects:
 - Considering the project.
 - Approving or refusing to approve the project.
 - Revoking a previous approval.
- **6.6.4.** The AEC may elect a Deputy Chair to assist the AEC in the absence of a Chair, and may delegate to the Deputy Chair the authority of the Chair in the Chair's absence.

- If neither the Chair nor the Deputy Chair is present at a quorate AEC meeting, the AEC may elect a member to act as Chair, and delegate to that person the authority of the Chair.
- **6.6.5.** AEC authority and functions in accordance with the above may be delegated *only* to members of the AEC.
 - The AEC may however delegate authority to an agent to inspect and monitor remote sites.

6.7. Confidentiality Clause

The deliberations, discussions, notices, Agendas and Minutes of all AEC meetings are confidential to members of the AEC and the AEC Secretariat.

6.8. Inspections

- **6.8.1.** Inspections of facilities used for research, housing and teaching involving animals are carried out by a delegated AEC subcommittee.
 - Macquarie University's AEC delegates conduct two inspections annually of each facility, at least one announced.
 - Inspections are held on the morning of the relevant AEC meeting or on another day by arrangement.
 - Members will be advised of inspection dates and times in a timely manner.
 - Where possible, inspections will be attended by at least a Category C or D member of the AEC
 - Inspections of remote sites may be delegated to an agent.
 - Records of inspections are kept, recording any observations, identified problems, follow up and outcomes and names of those in attendance.
 - Where possible, a member of the AEC who is external to the University should participate in inspections.
 - Where inspections identify a breach of the Code, the AEC must ensure that such activities cease immediately, and remedial action is instituted.
- **6.8.2.** Inspections of fieldwork conducted at extremely remote sites or where access is difficult may be performed by a delegate or agent and can be facilitated or corroborated with photographic or video imaging.

7. Consideration of Projects

7.1. Preliminary Consideration

- **7.2.1.** A pilot study to enable assessment of the feasibility of the project must be considered by the AEC in the overall context of the project, and is subject to the same criteria as initial projects. They are to be considered only by a quorate AEC.
- **7.2.2.** All projects for consideration by the AEC must be submitted approximately three (3) weeks in advance of the AEC meeting to the Research Office.
- **7.2.3.** To facilitate timely consideration of projects at the meeting, AEC members will receive the Agenda and all appropriate documentation approximately two (2) weeks prior to the meeting.

- **7.2.4.** Each AEC member has the opportunity to raise any problems that they have with the projects with the Secretary approximately one (1) week prior to the meeting, to allow the Secretary or the University Veterinarian (AWO) time to consult with the researcher to clarify matters.
 - The Secretary or the University Veterinarian (AWO) will seek clarification from the researcher in writing.
 - The Secretary or the University Veterinarian (AWO) will circulate the questions and the responses to AEC members.
 - Both the requests for clarification and the researchers' responses will form part of the original documentation of the whole project.

7.2. New or Initial Projects

- **7.2.1.** New projects or renewal of existing projects *must* be considered only by a quorate AEC.
- 7.2.2. In considering projects:
 - The AEC *must* balance the predicted scientific/educational value of the project against the potential impact on the welfare of the animals.
 - Projects can proceed only if the AEC has decided they are justified as a result of this balance.
 - An essential element in this assessment is AEC consideration of the applicant's response to the questions regarding:
 - **Replacement**, wholly or partially, of animals by use of techniques not involving animals.
 - Use of only the minimum number of animals, and reduction in the number of animals used, if this can be achieved without greater suffering to individual animals or nonessential repetitious use of animals.
 - Refinement of experimentation to adapt to individual species' requirement, biological characteristics, and general health, using best available scientific and educational techniques to avoid or minimise pain and distress in animals.
 - The AEC *must* consider whether there will be adequate monitoring of the animals' wellbeing, and the progress of the experiment together with appropriate record-keeping.
 - The AEC *must* consider any risks to other animals or humans arising from the project.
 - The AEC must be satisfied that all personnel with a specific role in the animal component(s) of the project are listed on the application, this includes but is not limited to the planning and supervision of the project.
 - The AEC must be satisfied that the person with ultimate responsibility for the conduct of the project, including the planning thereof, is identified as the Chief Investigator.
 - The AEC or delegate *must* sight agreement of all research personnel on a project to be accountable for the welfare of animals involved in the project to the declarations.
 - The AEC *must* sight certification of appropriate education, training and assessment of competence in Animal Ethics and Welfare training for all research personnel on a project. This training should be current within 5 years of the application.
 - The AEC *must* be satisfied that all and any Licences or other approvals required by law by any other organisation have been obtained.

- The AEC *must* act fairly in considering projects. Researchers may be required to attend the meeting to respond to questions personally (this may be done in person or by phone).
 - Any such questions or discussion will form part of the record with respect to that researcher's project.
- Any AEC member with a conflict of interest *must* declare it, and shall not attend discussion of the relevant matter.
- The AEC *must*, while taking into account its obligations under the legislation and the Code, strive for consensus on a decision whilst considering projects.
- AEC approval will not usually be considered for the Forced Swim Test or smoke inhalation procedures in rodents, as per the NSW DPI guidelines issued in 2022.
- The AEC has authority to:
 - Approve the project.
 - Reject the project.
 - Modify the project (e.g. by suggesting a pilot project).
 - Subject the project to conditions.
 - Suggest withdrawal of the project.
- **7.2.3.** An animal research authority issued pursuant to these operating procedures may be cancelled at any time by the University.
- **7.2.4.** An animal research authority issued by the University in accordance with the AEC's recommendation remains in force for 12 months only, or for such shorter period as is specified in the authority.
- **7.2.5.** A researcher must submit a yearly progress report, at the meeting prior to the expiry of the current animal research authority to enable the AEC to assess whether the authority should be renewed for up to a further 12 months.

7.3. Pilot Projects

7.3.1. A pilot study to enable assessment of the feasibility of the project must be considered by the AEC in the overall context of the project, and is subject to the same criteria as initial projects. They are to be considered only by a quorate AEC.

7.4. Resubmissions of Projects

- 7.4.1. Projects which are resubmitted *must* be considered only by a quorate AEC.
- **7.4.2.** Such projects are subject to the same criteria as initial projects in accordance with the Code and legislation.

7.5. Amendments to Projects

- **7.5.1.** Amendments to projects must be submitted to the AEC.
- **7.5.2.** The Executive Committee of the AEC has authority *to approve* **minor amendments** to existing approved projects at their discretion, subject to review and ratification by the AEC as a whole.

- 7.5.3. The Executive Committee shall not consider any amendments which amount to:
 - Re-consideration of the project.
 - Substantial changes to the project, such as those that address different or additional project aims from the original project, which effectively make it a new project.
- **7.5.4.** Any amendment which is more than a minor amendment to an existing approved research project, or which amounts to any of the instances mentioned in the preceding paragraph, shall not be considered by the Executive, and must be considered by the AEC.
- **7.5.5.** Where a request for minor amendment to an existing approved project is made, it shall be made on the appropriate form to the AEC through its Secretary, who shall
 - Record receipt of the requested amendment.
 - > Add the amendment request to the agenda for the next meeting.
 - If the request for amendment is urgent, at the discretion of the Secretary and the University Veterinarian (AWO), they will forward the matter to the Executive for consideration.
 - If there is no consensus, the Secretary shall contact the Chair to seek an appropriate means of proceeding.
 - In such an instance, the most appropriate response of the Chair would be to refer the matter to the next meeting of the AEC.
 - If the matter is urgent, the Chair shall consult personally with Executive Members.
 - The outcome of the Executive Committee decision shall be communicated by the Chair or delegate to the researcher in a timely fashion.
 - Copies of all relevant papers and the outcome of the Executive Committee's consideration in writing shall be submitted by the Secretary to the AEC for review and ratification.
 - Should the quorate AEC not accept the Executive Committee's decision, the researcher must be notified as a matter of urgency, and the research on the basis of the amendment as agreed to by the Executive must cease immediately.
 - Should the AEC ratify the Executive Committee's decision, those papers submitted to the AEC become part of the documentation of the researcher's approved project.

7.6. **Progress Reports**

- **7.6.1.** The code requires that researchers submit annual progress reports. These reports must be submitted to the AEC prior to expiry of the current approval. If the AEC does not receive the progress report prior to the expiry of the current approval, the animal research authority will lapse. No work can proceed under this project until the progress report is submitted, approved by the AEC and a new animal research authority of issued.
- **7.6.2.** On consideration of the annual progress report, the AEC may determine that the project:
 - Continue.
 - Be suspended.
 - Continue subject to modification.
 - Be discontinued.

7.7. Final Reports and Discontinued Projects

- **7.7.1.** The Code requires that researchers submit a final report when the research under the approved research authority is completed or discontinued.
- **7.7.2.** This report must be submitted to the AEC within one (1) month after the completion or discontinuance of the project, or expiry of the animal research authority, whichever occurs first.

7.8. Collaborative Arrangements

- **7.8.1.** Where a project is to be conducted at more than one research institution, a **formal agreement** should be entered into between the institutions. This is to facilitate the respective institutions' understanding of their responsibilities, which *must* include the establishment of procedures to ensure that:
 - Animals are well cared for in all project phases.
 - The responsible AECs are in a position to inspect the animals during all phases of the project.
 - Each AEC approves or delegates approval of the scientific or teaching activities being conducted by members of its institution **before** any work commences.
 - Clear lines of communication are established between all involved AECs and researchers/teachers.
 - The Code suggests that where parts of a project occur at different institutions, the relevant AECs may choose to approve and monitor only that part of the research occurring at their institution.
 - But each AEC must be cognisant of the project as a whole.
 - Any such arrangement should be part of the formal agreement.
 - Animal research projects conducted in other countries by, or on behalf of, Macquarie University researchers must comply with the Australian Code.
 - The requirement for a formal agreement must be considered where collaborative research involving a researcher from Macquarie University and any other institution(s) involves the use of animals in research activities and is expected to continue or recur into the foreseeable future, as per the Research Third Party Arrangements Policy and supporting documents.
 - Formal agreements must include quality assurance and reporting mechanisms as well as renewal or termination arrangements, as per the Research Third Party Arrangements Policy and supporting documents.
 - The Animal Ethics secretariat may be consulted during the establishment of formal agreements for co-institutional projects involving the use of animals to ensure due diligence around AEC and relevant legislation.
 - Where a researcher from one such institution conducts the research wholly at another institution, the researcher's home institution is nevertheless equally responsible for any liability arising from derelictions by that researcher under the Australian Code and legislation.
 - All researchers collaborating on research involving the use of animals are required to complete due diligence with regards to appropriate ethics approvals.
- **7.8.2.** Any researcher undertaking collaborative research involving another institution, or a researcher from another institution, is required to notify the AEC in advance in writing in circumstances including, but not limited to, the following:

- The researcher is involved in the handling of animals for the research, either directly or via the supervision of students or other persons;
- (ii) The researcher will be designing, leading, managing or coordinating the research;
- (iii) Resources or funding for the research activity is contributed to, or administered by, Macquarie University;
- (iv) The research activity does not already have oversight by an Australian AEC;
- (v) The research activity involves the use of primates, dogs, cats, endangered or iconic species.
- **7.8.3.** Relevant correspondence including adequately detailed description of the research project and documentation of approval must be provided, along with translations if required into plain English
- **7.8.4.** Researchers must notify the AEC of collaborative research activities, as described above, at the earliest possible time point. This should be either before the project has commenced, or before researchers begin involvement in a research project if such involvement began after project commencement.
- **7.8.5.** If, based on the information provided in the notification, the AEC considers that the 3Rs and the governing principles of the Australian Code do not underpin the animal research activities or the AEC have concerns for the welfare of animals, these must be conveyed to the researchers with recommendations for improvement. Researchers must consider this advice when determining their involvement in the collaborative research with consideration to their responsibilities outlined in the Code and the AEC Terms of Reference document.
- **7.8.6.** If the AEC have concerns about lack of compliance with the Australian Code, then they must notify the Director, Research Ethics and Integrity or the DVCR.
- **7.8.7.** Failure of a researcher to comply with the notification procedures and due diligence requirements could constitute a potential breach of the Macquarie Code for the Responsible Conduct of Research and may be referred as a complaint to the Director, Research Ethics and Integrity or the DVCR, as per the AEC Complaints and non-compliance procedures.

7.9. Communication of Decisions

- **7.9.1.** AEC decisions are required to be communicated to applicants in writing as soon as practicable.
 - No research can be undertaken until an Animal Research Authority is received by the researcher.
- **7.9.2.** The Chair has delegated authority to sign animal research authorities. In the Chair's absence, the Deputy Chair has authority. In the absence of both, the AEC must determine who will act as Chair, and that person will assume the delegated authority of the Chair.
- **7.9.3.** The Secretary to the AEC must maintain a register of all applications to the AEC and of the outcomes.

7.10. Disputes by Researchers on AEC Decisions

7.10.1. A researcher may request reconsideration of an adverse decision by the AEC within 10 working days of the notification of the decision, by following the procedure outlined in Section 3 of the Complaints and non-compliance Procedures.

8. Resolution of AEC Members' Complaints

8.1. A member of the AEC may lodge a complaint about the AEC, or another member by following the procedure outlined in Section 4 of the Complaints and non-compliance Procedures.

9. Complaints

- **9.1.** A person may make a complaint in writing to the Chair of the AEC, if the person has good reason to believe that there has been an infraction of the Animal Research legislation or Code. In such an instance, the formal procedures outlined in the "AEC Complaints and non-compliance Procedures" will be followed.
- **9.2.** Where a complaint is received that does not relate to an infraction of the Animal Research legislation or Code, but does relate a possible breach or research misconduct under The Macquarie Code for the Responsible Conduct of Research, the matter will be referred to the Director, Research Ethics and Integrity and the complainant notified of this action.
- **9.3.** Where a complaint is received that does not relate to an infraction of the Animal Research legislation or Code or the Macquarie Code for the Responsible Conduct of Research, it will be referred to the appropriate department or office and the complainant will be notified of these actions

10. Non-compliance with the Code and Legislation

10.1. Obligations

10.1.1. The University, the AEC, researchers and teachers all have an obligation to comply with the Animal Research Legislation and the Code.

10.2. Offences of non-compliance

- **10.2.1.** Carrying out research involving animals without a current animal research authority under the University's and the AEC's authority is a breach of the Code.
 - This is a serious offence.
 - May be subject to prosecution and a fine of 20 penalty units or a maximum of 12 months imprisonment or both.
- **10.2.2.** No person at Macquarie University shall carry out research involving animals except:
 - In accordance with the terms of the research authority.
 - With the approval and in accordance with Macquarie University's AEC.
 - Failure to comply with these conditions is an offence, subject to prosecution and punishable by a fine of 30 penalty units or a maximum of 12 months imprisonment or both.
- **10.2.3.** Supplying animals for animal research without an animal supplier's licence is an offence.
 - Subject to prosecution and punishable by a fine of 160 penalty units in the case of a corporation, and 30 penalty units or a maximum of 12 months imprisonment, or both in the case of an individual.
- **10.2.4.** The holder of an animal supplier's licence shall supply animals only on the terms specified in the licence.

 Failure to comply with these conditions is an offence, subject to prosecution and punishable by a fine of 160 penalty units in the case of a corporation, and 30 penalty units or a maximum of 12 months imprisonment, or both in the case of an individual.

10.3. AEC Procedures to deal with non-compliance

- **10.3.1.** The AEC is obliged to have procedures which deal with non-compliance with the Code, which are fair and effective, and which include appropriate reporting to the University.
- **10.3.2.** The AEC procedures are documented in the MQ procedure document "AEC Complaints and non-compliance Procedures".

10.4. Formal Procedures

- 10.4.1. Should the AEC during an inspection, and/or on the basis of a written and signed complaint, or on the basis of its own inquiries, and/or on the basis of an investigator's notification become aware of a breach (or possible breach) of the Code as set out above, the following steps must be taken.
 - The Chair and the University Veterinarian (AWO) must be informed immediately.
 - Suspected breaches of the Code should be referred to the Director Research Ethics and Integrity for initial investigation.
 - The Chair must notify all AEC members and the Deputy Vice-Chancellor (Research) of the breach or alleged breach.
 - If in the opinion of the Chair, the circumstances require urgent action, the Chair may take such action as deemed necessary, which may include suspending the approval for any projects or procedures pending further investigation.
 - The Chair must notify the researcher of the breach or alleged breach of the Code.
 - The Chair and the University Veterinarian (AWO) must speak with the researcher concerning the breach or alleged breach, and ascertain all relevant facts, and put them in writing. The researcher must be invited to put their position in writing.
 - These documents must be forwarded to all AEC members and to the Deputy Vice-Chancellor (Research).
 - The Chair and the researcher must take immediate and appropriate steps to ameliorate the breach, if possible.
 - There shall be NO retrospective ratification of illegal research.
 - Depending on the circumstances of the breach or alleged breach, the Chair may determine whether the matter should be investigated by the Chair assisted by the University Veterinarian (AWO), or by a subcommittee of the AEC.
 - Any such subcommittee must consist of at least one member of each category, the Chair and the University Veterinarian (AWO), and any nominated person whose expertise may be deemed necessary for investigation of the complaint (such person(s) need not be members of the AEC).

- The Chair and the University Veterinarian (AWO), or the subcommittee, must conduct any investigation on the basis of natural justice.
 - Before beginning any investigation, the person against whom the complaint has been made, or who has been said to have been in non-compliance with the Code, shall be informed of the complaint or the allegation, and of the procedures for investigation to be followed.
 - Any other relevant person, such as the Manager of the relevant facility; a supervisor; or a Head of Division and the Deputy Vice-Chancellor (Research) shall be informed of the complaint/allegation and the investigation.
 - Resolution between the complainant and the researcher, if the matter is based upon a complaint, must be attempted.
- If the matter cannot be resolved, the investigating body shall make their own inquiries and inspections and consult all relevant records and may interview any persons relevant to the matter and prepare a written report for the AEC.
 - If the matter is based upon AEC inspection, or AEC concerns, the researcher must be invited to give their position and given the opportunity to answer any points the investigating body makes.
 - The report must make recommendations with respect to the complaint or breach or alleged breach; such recommendations may include the following:
 - > The explanation by the relevant person is satisfactory and no further action is required.
 - > The project or procedure is modified.
 - > Conditions be placed upon the relevant research authority or approval.
 - > Approval for the project be suspended.
 - The matter is referred to the Director, Research Ethics and Integrity as a possible breach of the Macquarie Code for the Responsible Conduct of Research, or possible research misconduct.
 - Code 5.5. (ii) where activities are not conducted in accordance with AEC approval, the matter is referred back to the University for action.
 - Before any written report is to be submitted to the AEC, the person who is the subject of the complaint or allegations of non-compliance with the Code shall be given an opportunity, not normally more than 10 working days; to examine, comment upon and seek amendments to the report.
 - The report may be modified by agreement between the investigating body and the relevant person, or the report may stand and be accompanied by any written rebuttal or observations the relevant person may wish to make.
 - The AEC shall consider the report, its recommendations and any accompanying statements from the relevant person; the AEC may seek to discuss the matter with the relevant person if it wishes any information additional to that which the person has already provided; the AEC may then make recommendations on the report's recommendations which may:
 - > Accept them.
 - > Modify them.
 - Reject them.

- The AEC shall convey the report and any accompanying statement and its findings on those recommendations in writing to the Deputy Vice-Chancellor (Research). A copy of this report will be provided to the Director, Research Ethics and Integrity.
- The Deputy Vice-Chancellor (Research) shall carefully consider the recommendations of the AEC and shall act upon them in accordance with established University processes.
- The Deputy Vice-chancellor (Research) shall inform the relevant person of the receipt of the AEC's report and of the nature of its recommendations and shall invite the relevant person to make any observations orally and in writing before the Deputy Vice-Chancellor (Research) proceeds to decide on the course of action relating to the AEC's recommendations.

10.5. Informal Procedures

- **10.5.1.** Informal procedures are for use where there is an oral complaint, or an anonymous complaint made either orally or in writing, alleging a breach of the Code (Signed written complaints are to be dealt with under the formal procedures above).
- **10.5.2.** Anonymous and third party complaints (hearsay) shall be pursued only to the extent reasonably available to the complaint recipient and may, or may not, be recorded in bare detail, as seems appropriate to the recipient.
- **10.5.3.** The person receiving an informal complaint, using their best judgement as to the bona fides of the complaint, shall take such steps to make such inquiries as would normally be within their role to ascertain whether there are any grounds for concern.
 - > If there are no apparent grounds for concern, the matter should rest.
 - If grounds for concern appear to exist, the complaint recipient must take the matter up with the person(s) alleged to have acted in breach of the Code.
 - If it appears as a result of these discussions, that there has been no breach of the Code, but that perhaps some additional effort or recording needs to be done, this should be brought to the attention of the AEC and the University Veterinarian (AWO).
 - If there appears to be no cause for concern, nevertheless the matter and this conclusion should also be brought to the attention of the University Veterinarian (AWO) and the AEC so as to avoid any future misunderstanding.
 - Details of informal investigation outcomes that reveal no grounds for concern are to be recorded only in the Minutes of the AEC at the time of AEC notification.

11. Record Keeping

- **11.1.** The AEC or delegate must maintain a record of all submitted projects.
- **11.2.** A database will be kept recording for each project:
 - Project number and date of submission.
 - Outcome of AEC deliberation.
 - Date of outcome.
 - Number of animals approved.
 - Number of animals used.
 - Chief Investigator.
 - Due dates of progress reports.
 - Due dates of final report.
 - Any amendments.
 - Dates of approval of any amendment.

12. Reporting of Unexpected Adverse Events

- **12.1.** Researchers are advised within the Unexpected Adverse Events Protocols Document that Unexpected Adverse Events are to be reported to University Veterinarian (AWO) within 24 hours of occurrence.
- **12.2.** Researchers are to submit an online report regarding the Unexpected Adverse Event within 72 hr, hours of occurrence.
- **12.3.** AEC members will read details of all Unexpected Adverse Events within the online system and indicate any concerns requiring follow up.
- **12.4.** The University Veterinarian (AWO) will summarise Unexpected Adverse Events at the monthly AEC meeting,

13. Reports and Oversights

- **13.1.** The AEC is required to report annually on its activities to the University. This must take the form of a written report and should include details about:
 - the numbers and types of projects submitted for review, and approved or rejected
 - the University's facilities provided for the care and use of animals
 - training and education for AEC members and others involved in the care and use of animals
 - administrative and other difficulties encountered
 - matters which may affect the University's ability to comply with the Code, and suitable recommendations for mitigation where appropriate.
- **13.2.** The AEC is subject to annual review by the University as part of this review the DCVR is required to meet with the AEC Chair.
- **13.3.** The University and the AEC's performance are subject to triennial external review (conducted by NSW Department of Primary Industries' Animal Research Review Panel [ARRP]).
- **13.4.** The AEC is required to report annually to the NSW Department of Primary Industries on research involving animals for the previous calendar year.
 - The AEC Chair is required to sign parts B and C of this report (Form L).
 - The University is required to meet with the Chair of the AEC annually.
- **13.5.** The AEC is required to report annually to government departments in other jurisdictions where this is a requirement for the maintenance of licencing for scientific animal use within that jurisdiction.

INDEX

absent, 6, 7 accredited research establishment, 4 accredited research institution, 14 Additional members, 5 Adequate resourcing, 7 adverse impact, 4 AEC Procedures, 17 AEC's performance, 20 Agenda, 8, 9, 11 agreed AEC procedures, 6 alleged breach, 17, 18 allowance, 7 amendments, 18 Amendments to Projects, 13 animal holding facilities, 8 animal research, 4, 8, 9, 10, 12, 13, 14, 16 animal supplier's licence, 5, 16 animal welfare issues, 6, 9 Animal Welfare Officer, 2, 5, 8 annual reports, 8 anonymous complaint, 19 Attendees, 5 breach, 11, 16, 17, 18, 19 breach of the Code, 11, 17, 19 Category A, 5 Category B, 5 Category C, 5, 10 Category D, 5 Chair, 4, 5, 6, 7, 8, 9, 10, 11, 13, 15, 16, 17, 20 circulate, 8, 12 clarification. 11. 12 Collaborative Arrangements, 14 collaborative research, 14 Communication of Decisions, 14 complaint, 15, 16, 17, 18, 19 Complaints, 16 completion, 14 compliance, 5, 8, 9, 16, 17, 18 confidentiality, 2, 6, 7 conflict of interest, 6, 7, 12 consensus, 12, 13 decision-making, 6, 8 Decisions, 14 delegate, 10, 11, 12, 13 delegated authority, 8, 15 delegation, 4, 10 Deputy Chair, 6, 11, 15 **Director Research Ethics**, 9 Discontinued Project, 14 dispute resolution, 7 Disputes, 15 duties of the Secretary, 7 ethical, 6 evidence, 15 **Executive Committee**, 8, 10, 13, 14 expiry of the current approval, 14 external appointee, 6 Facility Managers, 5, 9 fieldwork, 11 Final Report, 8, 14

formal agreement, 14 Formal Procedures, 17 Head of Division, 17 Informal Procedures, 18 inspection dates, 11 inspections, 9, 11, 18 Licences, 12 Meetings, 9 member's term, 7 Members' Complaints, 15 minor amendments, 13 Minutes, 5, 8, 9, 10, 11 Non-compliance with the Code, 16 offence, 7, 16 Offences, 16 oral complaint, 19 Orientation, 7 outcome of applications, 8 out-of-pocket expenses, 7 Pilot Projects, 13 pilot study, 11, 13 Primary Industries, 20 procedures, 8, 12, 14, 15, 16, 17, 19 professional advice, 8 progress report, 8, 14, 19 **Proposals**, 11, 12 quorate, 9, 10, 11, 12, 13 ratification, 10, 13, 17 reappointment, 7 reduction, 4, 12 Refinement. 12 refinement of techniques, 4 Reimbursement, 7 relevant information, 7 Replacement, 12 replacement of animals, 4 report, 6, 8, 14, 18, 19, 20 Reports, 19 research authorities, 4, 8, 15 research authority, 4, 12, 13, 14, 16, 18 researchers, 4, 6, 7, 8, 9, 10, 12, 14, 16 resign, 7 Resolution, 15, 18 Resubmissions of Projects, 13 Role, 7, 8 Secretary, 5, 7, 8, 9, 10, 13, 15 specific expertise, 5 sub-committees, 10 supply of animals, 5, 9 Supplying animals, 16 term, 7 **Terms**, 3, 6 terms of the research authority, 16 the relevant person, 18 triennial external review, 20 veterinary experts, 9 veterinary inspections, 9 Voting, 9, 10 welfare, 4, 5, 8, 9, 12



ANIMAL ETHICS

Research Services Ground Floor, 16 Wally's Walk, Macquarie University, NSW 2109, Australia

T: +61 2 9850 7758 E: animal.ethics@mq.edu.au https://www.mq.edu.au/research/ethics-integrity-and-policies/ethics/animal-ethics