



Animal Experimentation Ethics Committee Terms of Reference

INTENT	<p>This document sets out the Terms of Reference (TOR) for the Peter MacCallum Cancer Centre Animal Experimentation Ethics Committee (Peter Mac AEEC). It ensures uniformity and a clear understanding of the method of operation of the AEEC and how it operates to assist Peter Mac researchers in the care and use of animals in research activities consistent with the Australian Code for the Care and Use of Animals for Scientific Purposes 8th edition, 2013, legislative requirements, current best practice and Peter Mac policies and procedures. The TOR provide an outline of the resources and infrastructure at Peter Mac, and the mechanisms for reporting between Peter Mac, the AEEC and, as necessary, the Licensing and Audit division of Animal Welfare Victoria, to promote ethical and responsible animal research and teaching practices at the institution.</p> <p>AEEC processes for managing unexpected adverse events, complaints and non-compliance that have been developed in accordance with Victorian legislation, the Australian Code and Peter Mac procedures are also described.</p>
SCOPE	Applicable to all Peter Mac staff, students, visiting researchers, honorary appointees and non-Peter Mac organisations who conduct or participate in animal research at Peter Mac.
EXCLUSIONS	Research not reasonably considered to be the responsibility of Peter Mac.
<p>1. Relevant Legislation and Guidelines</p> <p>In Victoria, the use of animals (live non-human vertebrates and cephalopods) for research and teaching is governed by Part 3 of the Prevention of Cruelty to Animals Act 1986 (the Act), Part 5 of the Prevention of Cruelty to Animals Regulations 2019 (the Regulations), and the Australian Code for the Care and Use of Animals for Scientific Purposes, 8th edition, 2013 (the Australian Code).</p> <p>Animal Welfare Victoria (AWV) regulates the use of animals in research and teaching and audits the operation of animal ethics committees, animal facilities and the use of animals in approved projects.</p>	
<p>2. Animal Ethics at Peter Mac</p> <p>Peter Mac is committed to providing a research culture that reflects the core values of excellence, innovation and compassion. Researchers are expected to maintain high standards of responsible research conduct and to foster a research environment distinguished by intellectual honesty and</p>	

Prepared by: Manager Animal Ethics

Approved by:  AEEC Chair

integrity, scholarship, scientific rigour and best research practice that is consistent with all relevant codes and legislation.

All research involving the use of animals at Peter Mac must be reviewed and approved by the Peter Mac AEEC. The AEEC is a legally constituted animal ethics committee that complies with the Act and Regulations, the Australian Code and Peter Mac policies, procedures and guidelines. The primary role of the AEEC is to ensure that all activities relating to the care and use of animals are conducted in compliance with the Australian Code, incorporate the principles of Replacement, Reduction and Refinement, that a high standard of animal welfare is observed and that animal facilities are maintained to an excellent standard. Integral to an environment that promotes high quality research and best research practices is a rigorous and robust process for the ethical review and approval of projects, in addition to a framework of education, policies and procedures, and resources for research. In this way, researchers can meet their responsibilities and deviance from acceptable research practices is minimised.

3. Responsibilities

AEEC Coordinator: person responsible for providing administrative support to the AEEC.

Animal Experimentation Ethics Committee (AEEC): a committee constituted in accordance with the Peter Mac AEEC Terms of Reference and membership as prescribed by the Australian Code. It ensures, on behalf of Peter Mac, that all activities relating to the care and use of animals are conducted in compliance with the Australian Code. The Peter Mac AEEC achieves this by conducting rigorous ethical review, approval and monitoring of animal care and use in accordance with the Australian Code, and by providing advice and recommendations to the institution on any aspect of animal experimentation and animal welfare. Through training programs, the AEEC promotes the welfare of animals in research and teaching at Peter Mac.

AEEC Executive: a sub-committee of the AEEC. At a minimum, the AEEC Executive includes the Chairperson and at least one member from Category C or D (as per the Australian Code), however, it will ordinarily comprise the Chairperson, a Category A member, a Category B member and a Category C member.

Animal Facility Manager: the person responsible for the overall management of the facilities used for the breeding and holding of animals. This person provides advice to the AEEC on the capabilities of the various animal facilities, in terms of the type and availability of animals required, requirements to support the wellbeing of the animals, technical expertise and space availability.

Chief Executive: the senior executive at Peter Mac who has final responsibility for receiving reports of the outcomes of assessment or investigation of potential or found breaches of the Australian Code for the Responsible Conduct of Research, and deciding on the actions to be taken.

Designated Officer: the Designated Officer (DO) determines whether a complaint relates to a potential breach of the Australian Code for the Responsible Conduct of Research, 2018. The DO oversees the

Prepared by: Manager Animal Ethics

Approved by: AEEC Chair

conduct of a preliminary assessment if this is the case, indicates whether an investigation is required and oversees an investigation if it takes place. The DO for Peter Mac is the Executive Director Cancer Research. If the Executive Director Cancer Research has a perceived conflict of interest or is unavailable, then another member of the Research Executive or the Laboratory Research Executive will act as the DO.

Executive Director Cancer Research (EDCR): the person responsible for overall institutional governance with respect to the care and use of animals.

Institute Veterinarian: a qualified veterinarian who provides high-level technical advice to the AEEC and support to research staff, students and animal technicians during the routine care and use of animals. The Institute Veterinarian’s primary role is to ensure that high standards of animal welfare, as prescribed by Peter Mac, are maintained in all research and teaching activities, and to provide oversight of the program of veterinary care. Consistent with the powers granted under section 24D of the Act, a veterinarian may act without specific instruction from the AEEC, if required, to take emergency actions to relieve an animal’s pain or distress.

Licence Holder: this is Peter Mac. As detailed under section 26 (2) of the Act, the licence holder nominates a natural person(s) to be responsible for any procedures carried out on Peter Mac premises.

Licence Nominee: the person nominated by the Licence holder (Peter Mac) for each Scientific Procedures Premises Licence (SPPL). As the Licence Nominee, they are ultimately responsible for ensuring scientific procedures are conducted in accordance with the conditions of the licence.

Principal Investigator: the person who is responsible for the overall management and conduct of an individual project, and for ensuring that clear lines of responsibility, communication and accountability regarding the care and use of animals in the project are identified. They must be a member of Peter Mac staff or honorary staff.

Researchers: staff of Peter Mac who are engaged in the conduct or administration of research or teaching practices involving animals (investigators). They have a responsibility to understand and apply the relevant policies and procedures and any other relevant regulations and/or legislation that may apply to their work or research. Researchers must submit an application to the AEEC, and obtain written approval from the AEEC, prior to the commencement of any research or teaching involving animals. Further, as a condition of AEEC approval, researchers are required to submit an annual report to the AEEC on the yearly anniversary of approval, and a final report within two months of completion of the project.

4. Functions of the Peter Mac AEEC

The AEEC’s role is to approve justified animal use on behalf of the SPPL holder (Peter Mac). The use of all animals in research and teaching is reviewed (and must be approved) by the AEEC.

The Peter Mac AEEC shall:

1. Provide general oversight of all matters pertaining to the care and use of animals for scientific purposes within Peter Mac, including the approval of policies, procedures and guidelines for the care and use of animals for scientific purposes.

Prepared by: Manager Animal Ethics

Approved by: AEEC Chair



2. Monitor the care and use of animals, including housing conditions, practices and procedures involved in the care of animals in facilities, and the numbers of animals used.
3. Review applications for projects and approve only those projects that are ethically acceptable and conform to the requirements of the Australian Code (Clause 1.3).
4. 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 Australian Code.
5. Conduct follow-up review of approved projects and activities (Clause 2.2.32) and allow the continuation of approval for only those that are ethically acceptable and conform to the requirements of the Australian Code.
6. Oversee compliance with the principles of Replacement, Reduction and Refinement as described in the Australian Code.
7. Provide advice and recommendations to the Executive Director Cancer Research, the Peter Mac Research Committee and the Chief Executive on any aspect of animal experimentation and animal welfare within Peter Mac.
8. Ensure that investigators are aware of their responsibilities under the Australian Code and the Act, and have received adequate training in animal ethics, handling and experimentation.
9. Conduct an annual inspection of the animal facilities at Peter Mac.
10. Meet at regular intervals, and not less than six times a year.
11. Take appropriate actions regarding unexpected adverse events and non-compliance.
12. Receive complaints on a confidential basis and institute corrective measures and disciplinary procedures in accordance with Peter Mac procedures.
13. Make available to Peter Mac and the larger community, the procedures and guidelines adopted by the AEEC in discharging its responsibilities.

The AEEC Coordinator is responsible for maintaining complete records of all correspondence and matters relating to these procedures.

AEEC contact details

Email: aeec.com@petermac.org

Telephone: 03 8559 5956

5. Review of AEEC Terms of Reference

The Peter Mac AEEC has been formed in line with the requirements of the Australian Code and the POCTA Act and its Terms of Reference based upon the requirements of the Australian Code. Where

Prepared by: Manager Animal Ethics

Approved by: AEEC Chair

there is an omission, the relevant section of the Australian Code shall apply. Terms of Reference are reviewed and approved for use by the AEEC annually.

The effectiveness of the AEEC is reviewed annually by the Executive Director Cancer Research, Peter Mac Research Committee and Chief Executive in consultation with the AEEC Chair and Animal Ethics Manager. The Executive Director Cancer Research shall notify the AEEC Chair and Animal Ethics Manager of the outcome of the report.

6. AEEC Membership

The AEEC comprises membership as defined under the Australian Code (clauses 2.2.4 -2.2.8). The Chairperson of the AEEC will hold a senior position in the institution, and be appointed by the Executive Director Cancer Research. If the Chairperson is an external appointee, they will be given the necessary support and authority to carry out the role. The Chairperson is a voting member and is appointed in addition to Category A to D members (all of which are voting members). A Category B member of the AEEC is appointed as Deputy Chairperson and has the authority to act for the Chairperson in their absence.

Appointments to the various categories are made by the Executive Director Cancer Research. In addition to the categories of members defined in the Australian Code, additional members may be appointed, including the Animal Facility Manager, a Senior Animal Technician and the Institute Veterinarian. These are non-voting members. From time to time, the AEEC may invite people with specific expertise to provide advice, as required. Members of the Peter Mac AEEC will be appointed for a term of two years. At the end of their term, members may be invited to re-apply for a further two years.

The Peter Mac AEEC Executive may approve minor amendments to approved projects (refer to Section 8 below) and deal with emergencies. The AEEC Executive must not approve new proposals (i.e. proposals that have not previously been reviewed by the AEEC) and decisions by the Executive must be ratified by the AEEC at its next meeting (wherever possible and depending upon submission deadlines). The AEEC Executive may defer items submitted for approval to the full AEEC when they believe further discussion of the proposal is warranted.

In order to maintain the integrity of the AEEC, all members shall receive a copy of the agenda regardless of whether they are required to attend the meeting or not. Distribution of meeting agendas to AEEC members will be not less than 7 working days prior to the day of the meeting.

In accordance with the Australian Code, during their appointment to the AEEC members must acknowledge in writing their acceptance of the Terms of Reference of the AEEC and any requirements for confidentiality required by Peter Mac. Notwithstanding the above, individual members have the

Prepared by: Manager Animal Ethics

Approved by: AEEC Chair



freedom, whenever necessary, to discuss aspects of protocols with colleagues and co-workers. This must be done in a generic manner without discussing or disclosing confidential details that compromise potential patents or the reputation of Peter Mac.

Before any deliberations of the AEEC during meetings, members and experts whose advice is sought by the AEEC must declare any interest that could influence the objectivity of their decision making and leave the meeting during discussion of matters that relate to the conflict of interest. Where the AEEC Chairperson/member is an investigator on a research proposal being considered by the AEEC, they are required to leave the meeting whilst the project is discussed. They may respond to questions directed to them upon their return to the meeting but must not participate in voting on the proposal. The Chairperson must vacate the chair in favour of the Deputy Chairperson in this situation. The agenda for each meeting must include the following statement: *“Members are required to refrain from voting and withdraw from the meeting during discussion of an item of business in which they have a pecuniary or conflict of interest.”*

7. Application Process

The AEEC must make a judgement on whether the proposed use, or continued use, of animals is ethically acceptable. This judgement must be based on information provided by the applicant that demonstrates the application of the Governing Principles outlined in the Australian Code and must balance whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits.

1. Applications to use animals in research and teaching will use the Peter Mac AEEC-approved forms, and be submitted as per the instructions provided on the Animal Ethics intranet page.
2. The Principal Investigator must be a member of Peter Mac staff or honorary staff member.
3. Applications should be completed in consultation with the Institute Veterinarian and Animal Facility Manager, to ensure that Peter Mac has the capacity and technical expertise to house and care for the animals being applied for, where appropriate.
4. Applications are to be submitted according to the schedule of dates provided on the Animal Ethics intranet page to the AEEC Coordinator. Incomplete proposals will be returned to the investigator for their attention and will not be considered as having been submitted to the AEEC Coordinator.
5. AEEC approvals are generally issued for periods of up to three years, however approvals may be issued for longer periods if the research project is funded for a longer duration by the external funding agency.
6. An application for a time extension (maximum 12 months) must be submitted before the end date of the current approval and can be submitted only once. Approval for a further 1 year

Prepared by: Manager Animal Ethics

Approved by: AEEC Chair



extension is conditional on the researcher submitting the replacing protocol no later than 6 months from the date of the approval for extension.

7. Amendments to existing projects, including changes to investigators, animals, the protocol or extensions to the approval period, must be submitted using the AEEC-approved forms, and as per the instructions provided on the Animal Ethics intranet page.
8. Investigators will be notified of the review outcome in writing within 10 working days of the meeting at which their submission was reviewed. Investigators are to respond to AEEC feedback within 30 days, providing the AEEC with the information requested.
9. The AEEC may decide that:
 - (i) An application to commence a project or activity, or amend an approved project or activity, is approved with or without conditions, deferred subject to modification to the satisfaction of the AEEC Executive, or not approved;
 - (ii) Following review of the annual report for an approved project or activity and possible consultation with the applicant, the approval for the project or activity is continued, suspended, modified or discontinued;
 - (iii) An approval is suspended or withdrawn.

Animal research involving Genetically Modified Organisms (GMOs):

1. Where animal research involves GMOs, this must be clearly identified on the AEEC application form.
2. All animal research involving GMOs must also be reviewed and approved by the Peter Mac Institutional Biosafety Committee (IBC) before commencing.

8. Minor Amendments

A minor amendment is defined as one in which the proposed change is not likely to cause harm to the animals (including pain and distress) and is expected to have little or no impact on their well-being.

Examples include:

1. Addition of suitably experienced personnel, or personnel under the supervision of an experienced and competent trainer.
2. Additional numbers of mice.
3. Additional strains with known phenotypes.
4. Changes to routes of administration where the impact to the animals is the same or less than originally approved.
5. Minor changes to a monitoring regimen (more frequent or additional monitoring criteria).
6. Minor changes to a non-surgical procedure (e.g. less frequent or less invasive than currently approved).

Prepared by: Manager Animal Ethics

Approved by: AEEC Chair

7. Opportunistic diagnostic or veterinary activities intended to benefit the animals.
8. Re-activation of paused projects that are within their original approval period.
9. An extension to the duration of the project.

9. Monitoring and Withdrawal of Approval

The AEEC will monitor the conduct of approved projects at scheduled times (e.g. when reviewing annual and final progress reports), and when circumstances trigger additional follow-up review, including when reviewing a proposed amendment to an approved project or an unexpected adverse event.

As a condition of approval for all projects, researchers must submit an annual report on the yearly anniversary of approval for the life of the project. This includes those discontinued, not commenced or completed. This will be replaced by a final report for the final year in which the project is undertaken. Reports will detail any amendments made to the project, the number of animals used so far, updated phenotype observations, what progress has been made towards the objectives of the study, any adverse incidents observed over the reporting period, whether any reductions, refinements or replacements have been found and details of any publications. In addition, the final report will provide a conclusion statement detailing the overall findings of the work and whether the project was ultimately successful.

The AEEC may withdraw approval for any project, and may do so if:

1. During inspection it is identified that the welfare of animals has been compromised through practice that is inconsistent with the approved project. In this instance the AEEC Chairperson, Deputy Chairperson, or the Institute Veterinarian may require that the activities (either the specific activity in question or the full project) cease immediately.
2. The AEEC becomes aware that an animal is being used in a manner inconsistent with the approved protocol.
3. It becomes apparent that the approved protocol has a greater impact on animal welfare than originally understood.
4. The Principal Investigator does not fulfil their annual reporting requirements.
5. Any other instance of non-compliance with the Australian Code, which the AEEC deems of sufficient nature to warrant withdrawal of approval for a project.

Where the AEEC has withdrawn approval for a project, the AEEC Chairperson will notify the Principal investigator and Licence Nominee, and may also notify AWV if appropriate. In reviewing cases of non-compliance or situations in which animal welfare has been compromised, the AEEC may, as appropriate, refer the matter to the institution via the Designated Officer at Peter Mac for investigation as per the

Prepared by: Manager Animal Ethics

Approved by: AEEC Chair

Peter Mac [Management of potential breaches of the Code](#) (the Australian Code for the Responsible Conduct of Research 2018) procedure, and/or to AWV.

10. Projects Involving Multiple Institutions and/or Animal Ethics Committees

Investigators must notify the Peter Mac AEEC in writing if they are involved in collaborative studies using animals at another institution, or if they are named in an application to the animal ethics committee (AEC) of another institution.

Approval of and responsibility for experimentation involving animals conducted on the premises of another institution may be delegated to either the AEC of that institution (provided that both institutions involved agree to delegate the responsibility for decision making to, and support the necessary actions of, that AEC), or the Peter Mac AEEC. A formal inter-institutional agreement will be in place for the duration of animal housing/scientific procedures across institutions and must include details of processes for complaints and non-compliance.

The responsible AEC must be aware of all aspects of the proposed use of animals, consider the cumulative effects on the wellbeing of the animals involved, and monitor the animals to ensure that they receive appropriate care in all phases of the project, including during any transportation.

Clear communication channels must be established between each institution. A project must not commence before each AEC approves, or the delegate AEC approves, activities to be conducted by members of its institution. Each AEC is responsible for approval and monitoring of animal care and use that occurs at the institution for which it acts. If the research being conducted involves Peter Mac investigators who will work with animals under the sole responsibility of another institution, and that work is reviewed by another AEC constituted in accordance with the Australian Code, this research will not be subject to additional review by the Peter Mac AEC. A copy of the application approved by the other institution's AEC must be submitted to the AEEC Coordinator prior to any staff member working on an external project.

In Australia, Peter Mac staff members will remain compliant with the Australian Code at all times, including when at other institutions. While outside Australia, Peter Mac staff members will remain compliant with the Australian Code at all times where possible. Where Peter Mac researchers conduct research in locations interstate, at other institutions, they should be aware they may be subject to different legislation, codes and regulations and may need to seek ethical approval from another AEC. Any project conducted on behalf of Peter Mac in another country must, at a minimum, comply with the governing principles of the Australian Code, provided that such compliance does not breach relevant

Prepared by: Manager Animal Ethics

Approved by: AEEC Chair

local legislation. When considering approval for a project to be conducted in another country, the AEEC may accept approval granted by a local AEC or its equivalent in that country if it is satisfied that outcomes would be equivalent to those expected through application of the Australian Code.

11. Reporting

The AEEC shall be responsible to the Executive Director Cancer Research, in accordance with the requirements of the Australian Code, the Act and the Regulations, as amended from time to time.

The AEEC will provide an annual report of the AEEC's activities to the Executive Director Cancer Research, the Peter Mac Research Committee and the Chief Executive. A copy of the report shall be circulated to the AEEC to provide members with the opportunity for input. In particular, comments from Category C and D members shall be given due regard.

The AEEC has a responsibility to report to regulatory authorities and does so in accordance with those requirements. Such reports will be made available to the institution as appropriate.

12. Standard Operating Procedures

As prescribed by *the* Australian Code, the AEEC has established Standard Operating Procedures (SOPs) relating to the care and use of animals. SOPs may be referenced in applications to standardise the application process. New SOPs must not be used until approved by the AEEC, and SOPs must be reviewed every three years.

Approved SOPs are made available to all researchers and AEEC members. SOPs should only be used where appropriate.

13. Unexpected Adverse events, Complaints & Non-compliance

Any unexpected adverse event, in which animal welfare has been impacted beyond what has been identified in the approved project, must be immediately reported to the AEEC (AEanimalsafetyreporting@petermac.org).

Complaints may be raised by any person or group, including investigators, animal carers, the AEEC or an AEEC member, students and employees of Peter Mac, and members of the public. Complaints may relate to the care and use of animals or pertain to the AEEC process of review. Peter Mac is committed to the highest standards of integrity and conduct and the provision of an environment in which people feel able to raise legitimate issues relating to Peter Mac's operations. People who report improper conduct (whistleblowers) can do so in the knowledge that they will be protected under the Public Interest Disclosures Act 2012 (Vic).

Prepared by: Manager Animal Ethics

Approved by: AEEC Chair



It is the responsibility of anyone working with animals at Peter Mac under AEEC approval to report non-compliant events to the AEEC (aeec.com@petermac.org). Immediate action is required to alleviate any animal suffering or distress.

Where Peter Mac researchers fail to obtain written ethical approval when such approval is required, or where they act contrary to the decision of the AEEC, these actions may constitute breaches of the Code and the AEEC will refer the matter to the Designated Officer and the processes outlined in the Management of potential breaches of the Code procedure will be followed. For a detailed description of Peter Mac processes regarding unexpected adverse events, complaints and non-compliance, refer to Peter Mac AEEC Procedures for Unexpected Adverse Events, Complaints and Non-Compliance.

14. Facilities

All animal facilities used for research and teaching purposes at Peter Mac will be inspected and approved by the AEEC and registered with AWV. Both the AEEC and AWV inspect these animal facilities to ensure compliance with the relevant regulatory requirements.

<p>Supporting Instructions or Documents</p>	<p>Australian Code for the Care and Use of Animals for Scientific Purposes Prevention of Cruelty to Animals Act (1986) & Regulations (2019) Australian Code for the Responsible Conduct of Research, 2018 Guide to managing and investigating potential breaches of the Australian Code for the Responsible Conduct of Research, 2018</p>
<p>Related Documents:</p>	<p>Peter Mac AEEC Procedures for Unexpected Adverse Events, Complaints and Non-Compliance Peter Mac Responsible Conduct of Research policy Peter Mac Management of potential breaches of the Code procedure Peter Mac Complaints About Unacceptable Workplace Behaviour procedure Peter Mac Adverse Incident Report Form Peter Mac Guidelines for Submitting an Application for a Minor Amendment</p>
<p>Definitions and acronyms</p>	<p>Activity: 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 AEEC. See also ‘Project’.</p> <p>Adverse event: any event that has a negative impact on the wellbeing of an animal. See also ‘Unexpected adverse event’.</p> <p>Animal: any live non-human vertebrate (that is, fish, amphibians, reptiles, birds and mammals, encompassing domestic animals, purpose-bred animals, livestock, wildlife) and cephalopods. This includes embryos, foetuses and larval</p>

Prepared by: Manager Animal Ethics

Approved by: AEEC Chair



forms that have progressed beyond half the gestation or incubation period of the relevant species, or that have become capable of independent feeding.

Animal Facility Manager: person responsible for the overall management of the Peter Mac Animal Facility, used for the breeding and holding of animals.

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

Animal Welfare Victoria (AWV): the Victorian state government agency responsible for enforcing compliance with the Australian Code (part of the Department of Jobs, Precincts and Regions).

Australian Code: the Australian code for the care and use of animals for scientific purposes, 8th Edition 2013.

Animal Experimentation Ethics Committee (AEEC): a committee constituted in accordance with the Peter Mac AEEC terms of reference and membership as prescribed by the Australian Code, the Act and the Regulations.

Committee: the Peter Mac AEEC.

Complaint: a statement that something is unsatisfactory or unacceptable. This may relate to the activities of any party or person involved in the care and use of animals, including investigators, animal carers, the AEEC and governance officials.

Facility: any place where animals are kept.

Investigator: any person who uses animals for scientific purposes. Includes researchers, teachers, and undergraduate and postgraduate students involved in research projects.

Monitoring: measures undertaken to assess, or to ensure the assessment of, the wellbeing of animals in accordance with the Australian Code. Monitoring occurs at different levels (including those of investigators, animal carers and the AEEC).

Non-compliance: failure to act in accordance with relevant legislation, or with projects and standard operating procedures approved by the AEEC.

Principal Investigator: person who is responsible for the overall management and conduct of an individual project, and for ensuring that clear lines of responsibility, communication and accountability regarding the care and use of animals in the project are identified.

Project: an activity or group of activities that form a discrete piece of work that aims to achieve a scientific purpose. A project cannot commence until it has been approved by the AEEC.

Prepared by: Manager Animal Ethics

Approved by: AEEC Chair

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

Scientific procedure: definition in accordance with the definition within the Act.

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

SPPL: Scientific Procedures Premises Licence.

The Act: Prevention of Cruelty to Animals Act 1986.

The Australian Code: the current edition of The Australian Code for the Care and Use of Animals in Scientific Purposes, mandatory under Part 3 of the Act and Part 5 of the Regulations.

The Regulations: *Prevention of Cruelty to Animals Regulations 2019*.

Unexpected adverse event: an event that may have a negative impact on the wellbeing of animals and was not predicted in the approved project or activity. An unexpected adverse event may result from different causes, including but not limited to:

- Death of an animal, or group of animals, that was not expected (e.g. during surgery or anaesthesia, or after a procedure or treatment, or during or after capture and restraint);
- Adverse effects following a procedure or treatment or capture that were not expected;
- Adverse effects in a larger number of animals than predicted during the planning of the project or activity, based on the number of animals actually used, not the number approved for the study;
- A greater level of pain or distress than was predicted during the planning of the project or activity;
- Power failures, inclement weather, emergency situations or other factors external to the project or activity that have a negative impact on the welfare of the animals.

An unexpected adverse event must be reported as soon as it is discovered (AEanimalsafetyreporting@petermac.org). These events are reviewed by the AEEC to assist in determining the cause of the event, and to consider mitigations that reduce the likelihood of a recurrence.

Prepared by: Manager Animal Ethics

Approved by: AEEC Chair