# Animal Ethics Procedure

# Section 1 - Context

(1) RMIT is committed to promoting a culture of responsible and ethical research consistent with relevant legislation, regulations, and guidelines.

# Section 2 - Authority

(2) Authority for this procedure is established by the Research Policy.

# Section 3 - Scope

(3) This procedure applies to all animal research that is reasonably considered the responsibility of the RMIT Group. It includes all activities utilising animals within RMIT, or by RMIT staff, students or visitors for RMIT research and teaching activities within or outside RMIT, under the Australian code for the care and use of animals for scientific purposes (the Animal Code).

# Section 4 - Procedure

## Animal Ethics Requirements

(4) All research and teaching activities (projects and programs) at RMIT that involve the care and use of animals require prior approval from the RMIT Animal Ethics Committee (AEC), including the acquisition, transport, breeding, housing and husbandry of the animals.

(5) RMIT University will provide professional development, resources, processes and infrastructure that support researchers to know when they require ethics approval, and to gain and conduct research in line with ethical approval and with relevant codes, legislation and RMIT policy.

(6) In Australia, RMIT researchers must remain compliant with the Animal Code at all times, including when at other institutions. While outside Australia, RMIT staff members will remain compliant with the Animal Code provided that such compliance does not breach any relevant local legislation. Research cannot be conducted in other countries as a mechanism of avoiding compliance with the Animal Code.

For advice on this, contact the Research Ethics, Integrity and Governance team (animalethics@rmit.edu.au).

## Gaining Animal Ethics Approval

### Use of Animals in Research or Teaching

(7) All use of animals in research and teaching requires explicit ethics approval from the AEC.

(8) The Principal Investigator will:

a. be a member of RMIT staff, or a person deemed acceptable by the AEC
b. apply using the AEC approved forms available on the Research Ethics Platform (REP)
c. discuss applications with the Animal Welfare Officer and Facility Manager(s) prior to submission, to ensure that RMIT has the capacity and technical expertise to house and care for the animals, as appropriate
d. submit applications online, via REP, to the Research Ethics, Integrity and Governance team (REIG) and AEC in line with the instructions and User's Guide for Researchers provided on the RMIT Researcher Portal.

(9) Submission dates are provided on the Researcher Portal. Applications that fail to meet submission dates or other requirements will be held over to a following meeting.

(10) A project has a maximum approval period of three years from the date of approval.

**Programs for the Breeding of Animals**

(11) The establishment and maintenance of breeding programs (colonies) must be reviewed and approved by the AEC. The process for gaining this approval is provided in clause (8).

(12) For breeding programs involving the creation of new animal lines where the impact on animal well-being is unknown or uncertain, all persons involved in such programs will be regarded as researchers and listed on the application. Once the impact on wellbeing is known and the AEC has accepted the final report, the new animal line will be treated as breeding stock and responsibility for these animals and breeding procedures will be assumed by the relevant Principal Investigator.

(13) All breeding of animals at RMIT must be managed to avoid or minimise the production of excess animals.

**Provisions for Animals at the Conclusion of Their Use**

(14) In keeping with the Animal Code, provisions for animals at the conclusion of their use at RMIT include:

a. rehousing (rehoming)
b. return to normal husbandry conditions or natural habitat
c. humane killing
d. reuse
e. tissue sharing. Please also see provisions for Standard Operating Procedures (SOPs) relating to the care and use of animals.

(15) Researchers must clearly identify the provisions for animals at the conclusion of their use, on the animal ethics application form or via an amendment, and gain AEC approval.

(16) The AEC will review all provisions for animals at the conclusion of their use and approve as appropriate.

(17) Researchers, animal carers and others involved in the care and use of animals at RMIT will ensure that provisions for animals at the conclusion of their use are made promptly and in accordance with the procedures and protocols approved by the AEC.

(18) In considering the reuse of animals, the benefits of reusing animals must be balanced against any adverse effects on the animal's well-being, taking into account the lifetime experience of each animal.

**Animal Research Involving Genetically Modified Organisms (GMOs)**

(19) Researchers must clearly identify where animal research and teaching activities (projects or breeding programs) involve GMOs, either as GM animals or exposure of animals to GMOs, on the animal ethics application form.

(20) Researchers using GMO animals will also apply for and gain approval from the RMIT Institutional Biosafety Committee (IBC) before commencement of the project, in accordance with the Research Involving GMOs Procedure.

**Field Work and Observational Studies**

(21) Researchers who engage in field work will gain any required permissions from other authorities, in addition to AEC approval.

(22) Where required, the researcher will submit a copy of any permits obtained for field work or observational studies to the AEC before starting the work. The AEC will retain a copy of any permits provided.

(23) The AEC, AEC Executive, or authorised delegates, have the authority to inspect field work or observational studies.

**Multi-Centre Research (in Australia and Overseas)**

(24) Where RMIT is responsible, in part or in full, for the research and the planned project also involves researchers from other institutions:

a. The ethics applications will formally acknowledge the respective institutions' responsibilities and provide detailed information on the arrangements to protect the welfare of all animals involved.
b. An RMIT researcher will submit any ethics approvals granted by a Committee or other relevant review body for review to the AEC.

(25) Where the research is the sole responsibility of another institution and the planned project also involves researchers from RMIT:

a. The AEC will not review research that is the sole responsibility of another institution (i.e. an external project), provided the research is reviewed by another Committee constituted in line with the Animal Code.
b. RMIT researchers involved in an external project will submit a copy of the application approved by the other institution's Committee via the RMIT Coordinator for AEC acknowledgement, before undertaking any scientific procedures on animals.

## Maintaining Animal Ethics Approval

**Review of Applications**

(26) The AEC reviews all applications and amendments for all research and teaching activities (projects and programs) at RMIT that involve the care and use of animals in line with relevant codes, legislation, policy, and processes.

(27) The AEC will inform the Principal Investigator of the outcome of the review in a timely manner.

**Amendment to an Approved Ethics Application**

(28) Amendments are required where researchers plan to vary any aspect of their approved project or program, including changes to investigators, number or type of animals used, protocols, provisions for animals at conclusion of use, reuse or transfer of animals to other projects or extensions to approval time.

(29) Researchers must gain AEC approval for an amendment prior to implementing the change.

(30) Researchers must seek approval for an amendment to extend ethics approval before the approval period has expired. All activities that require ethics approval will not continue when such approval has expired.

(31) For amendments to projects or programs approved by an AEC:

a. The Principal Investigator will submit an application for an amendment via REP, in line with the instructions, guidance and/or schedule of dates provided on the Researcher Portal. Applications that fail to meet applicable submission dates will be held over to a future meeting.
b. The Principal Investigator may contact the Coordinator or the Chair to request urgent review, where an amendment is time critical. The Chair determines if the Animal Code allows for an out of session review to be carried out prior to the next available committee meeting.

## Reporting

(32) The Principal Investigator will submit an annual report at the end of each calendar year for the life of the project or program (regardless of the duration of animal ethics approval), via REP, in line with the instructions, guidance and/or schedule of dates provided on the Researcher Portal.

(33) The annual report will detail the project progress over the past 12 months. For projects, this will include:

a. the animals used so far in the project
b. what progress has been made towards the objectives of the study
c. any adverse incidents or animal welfare concerns observed over the reporting period (including details regarding the nature of the animal welfare concern and the frequency if it is repeated).

(34) The annual report for breeding programs will include:

a. the animals bred so far in the project
b. what use has been made of the animals (including details of any excess animals)
c. the health status of the animals
d. any adverse incidents or animal welfare concerns observed over the reporting period (including details regarding the nature of the animal welfare concern and the frequency if it is repeated).

(35) The Animal Facility Manager will provide regular (monthly and annual) reports on breeding programs to the AEC including details of animals bred, their usage and any excess animals.

(36) Ongoing approval of a project or program is conditional upon the submission of annual reports.

(37) In the final year of a project or program, the Principal Investigator will submit a final report within six months of the end of the approval period, via REP, in line with the instructions, guidance and/or schedule of dates provided on the Researcher Portal.

(38) For projects, the final report will include:

a. the total number(s) of animals used in the project
b. the progress made towards the objectives of the study
c. any adverse incidents or animal welfare concerns observed over the reporting period (including the number and types)
d. a conclusion statement detailing the outcomes of the project and outline any publications (either submitted or in progress) resulting from the project.

(39) For breeding programs, the final report will include:

a. the total number(s) of animals bred
b. what use of the animals has been made over the life of the program (including details of all excess animals)
c. any adverse incidents or animal welfare concerns observed over the life of the program (including the number

and types)

d. a conclusion statement detailing the performance of the breeding colony or program.

(40) Annual and final reporting will be undertaken using the AEC approved forms, via REP, in line with the instructions, guidance and/or schedule of dates provided on the Researcher Portal.

(41) Reports are still required even where an approved project has not commenced or has been abandoned.

(42) The AEC may decide not to review new applications from a Principal Investigator whilst annual and final reports for previous projects or programs remain outstanding.

## Non-Compliance

(43) Any party or person involved in the care and use of animals for scientific purposes will comply with the Animal Code and related RMIT policy.

(44) Where non-compliance is identified it will be reported promptly to the AEC in writing. When an investigator detects non-compliance with the Animal Code, the Principal Investigator, or, in their absence, the acting Principal Investigator nominated on the approved application will make this report.

(45) Where there is any uncertainty as to whether non-compliance has occurred, researchers must consult REIG for advice. REIG will determine whether an instance of non-compliance has occurred, in consultation with the AEC and other relevant parties.

(46) Where non-compliance involves or may involve an unexpected adverse event, researchers must also follow the process set out in the procedures for management of unexpected adverse events.

(47) The AEC will review the written notification of non-compliance and any subsequent actions at its next scheduled meeting.

(48) The AEC may require researchers or others to provide further information, to modify the project or activity, to complete additional education or training, and/or to carry out further actions as appropriate. The AEC may also suspend or withdraw ethics approval as per procedures for suspension or withdrawal of ethics approval. Where appropriate and/or as required, the AEC will notify the line manager, licence holder, the Department and/or any other relevant bodies.

(49) Where projects involve more than one institution, REIG will report the non-compliance to the other institutions involved, as appropriate or required.

(50) REIG will maintain records of reports of non-compliance and any breaches of the Animal Code.

## Adverse and Unexpected Adverse Events

### Management of Adverse Events

(51) The Animal Code requires rapid detection, investigation and reporting of adverse events. Researchers must be aware of and accept their responsibilities under the Animal Code. These include:

a. providing appropriate and sufficient detail about expected adverse events in ethics applications
b. developing, implementing and reviewing strategies to detect, to avoid and to minimise any pain and distress in animals, including humane endpoints as defined in the Animal Code
c. ensuring that animals are monitored and assessed at all stages of the project or program for signs of pain and distress, including deviations from normal behaviour (at a frequency and level commensurate with the

projected welfare impacts of the program or project)

d. prompt notification of any unexpected adverse event (see procedures for management of unexpected adverse events).

**Management of Unexpected Adverse Events**

(52) An unexpected adverse event occurs when animal welfare is or may be negatively impacted, and which is not identified or foreshadowed in the approved project or program. Unexpected adverse incidents that must be reported include:

a. death of an animal under anaesthesia
b. death of an animal during or after surgery
c. death of animal during or after a procedure or treatment e.g. oral gavage, intraperitoneal injection
d. other unexpected events detrimental to animal wellbeing (including death) before or after a procedure or treatment
e. when there is a greater level of pain or distress than predicted in the original project
f. when adverse events occur in a larger number of animals than predicted in the original project, or
g. an emergency situation such as a power failure, inclement weather or other factors external to a project or activity that negatively impact on the welfare of animals.

(53) Where an unexpected adverse event occurs researchers must notify this event to the AWO for information and advice.

(54) Where there is any uncertainty or ambiguity as to whether an unexpected adverse event has occurred, the AWO will determine whether the adverse event constitutes an unexpected adverse event, in consultation with relevant parties.

(55) Prompt action will be undertaken to alleviate pain and distress that were not anticipated in an approved project or activity, or that occur as a result of an emergency. This action takes precedence over the project or activity and may include immediate humane killing. Where the AWO is unavailable and prompt action is required, the Animal Facility Manager can use their technical expertise and judgement.

(56) Investigators will report all unexpected adverse events and emergencies promptly (within 48 hours and noting, reports should be made as soon as possible once the unexpected event or emergency is identified) to the AEC, via REP, in line with the instructions and guidance provided on the Researcher Portal.

a. This form will be completed and submitted by the Principal Investigator or, in their absence, the acting Principal Investigator nominated on the approved application.
b. The AWO will review all Adverse Event Reports for accuracy and completeness before submission of the Adverse Event Report form to the AEC.

(57) REIG will add discussion of an Adverse Event Report to the agenda for the next scheduled meeting of the AEC, following receipt of a complete Adverse Event Report form. At this meeting, this incident and any subsequent actions will be reviewed by the AEC. The AEC may require researchers to provide further information and/or carry out further actions. Where appropriate and/or as required, the AEC will notify the Principal Investigator's line manager, RMIT licence nominee, and/or the Department.

## Animal Deaths

(58) When an animal dies unexpectedly or is humanely killed due to unforeseen complications, a post-mortem (necropsy) should be performed.

(59) The necropsy will be performed by a person competent in post-mortem procedures; at RMIT this will normally be the AWO. In the event that the AWO is absent or unavailable, contact the Animal Facility Manager who will make alternative arrangements.

(60) Where there is any uncertainty if an animal death should be reported as an unexpected adverse event, researchers must consult the AWO procedures for management of unexpected adverse events).

## Monitoring Approval

(61) The AEC will monitor all approved activities (projects and programs) that involve the care and use of animals at RMIT.

(62) The AEC will monitor the care and use of animals through inspection of animals, animal housing and the conduct of scientific procedures, and/or reviewing of records and reports (including annual and final reports, review of Adverse Incident Report forms), with assistance and advice from the AWO and Facility Manager(s).

### Suspension and/or Withdrawal of Approval

(63) The AEC may suspend or withdraw approval for any project when:

a. the welfare of animals has been compromised through practice that is inconsistent with the approved project. In this instance, the Chair, the Deputy Chair, and/or the AWO may require that the activities (either the specific activity in question or the full project) cease immediately,
b. an animal is being used in a manner inconsistent with the approved protocol,
c. the approved protocol has a greater impact on animal welfare than originally anticipated or understood,
d. the researchers do not fulfil their reporting requirements, or
e. any other instance of non-compliance with the Animal Code, which the AEC deems of a sufficiently serious nature to warrant suspension or withdrawal of approval for a project.

(64) Where the AEC has suspended or withdrawn approval for a project, the Chair will notify the line manager of the Principal Investigator and RMIT licence nominee and may also notify the Department and other parties as appropriate or required. The status of the project will be updated accordingly in REP.

(65) In reviewing cases of non-compliance or situations in which animal welfare has been compromised, the AEC will refer the matter to the institution (the Designated Officer at RMIT), or the Department as appropriate for consideration. Where required, the AEC will refer a matter to the institution (the Research Integrity Office) for consideration in line with the Management of Breaches of Research Integrity Procedure.

## Standard Operating Procedures

(66) As set out in the Animal Code, the AEC can establish approved Standard Operating Procedures (SOPs) relating to the care and use of animals.

(67) The AEC will regularly review SOPs, at least every three years, or as required to keep pace with changes to best practice, as advised by the Animal Facility Manager, AWO and other stakeholders.

(68) Researchers are encouraged to reference approved SOPs in ethics approval applications to help standardise the application. SOPs should only be used where appropriate.

(69) Copies of all approved SOPs are available online in the Researcher Portal for all RMIT researchers and committee members.

## Facilities

(70) The AEC will inspect and approve all animal facilities used for research and teaching purposes at RMIT at least annually, to ensure compliance with the relevant regulatory requirements. The Department will also inspect these animal facilities, as required.

(71) The licence holder will register any RMIT facilities in Victoria with the Department.

(72) Should additional facilities be required for use in animal research, researchers must contact the Secretary who will provide advice and liaise with the Department to register these facilities for use.

## Complaints

### Complaints Concerning Animal Research

(73) Staff, students, members of the public, or any other concerned persons may make a complaint concerning care and use of animals in research or teaching at RMIT.

(74) These complaints will be forwarded to REIG who will respond as appropriate.

### Complaints Concerning the Care and Use of Animals at an RMIT Facility

(75) Staff, students, members of the public, or any other concerned persons may make these complaints.

(76) Where there are apparent ongoing animal welfare impacts that extend beyond those described in the application, RMIT may require that researchers cease activities and the AEC may suspend or withdraw approval.

(77) These complaints will be forwarded to the Coordinator who will notify REIG, the AWO and the Chair. REIG will acknowledge receipt of the complaint and take one or more of the following steps:

a. where the complaint relates to activities that would normally require AEC ethics approval, refer the complaint to the AEC to investigate in accordance with the Animal Code
b. where the complaint raises the possibility of research misconduct or a breach that is not related to ethics approval, refer the complaint to the Designated Person who will handle the complaint in line with the Management of Breaches of Research Integrity Procedure
c. where the complaint alleges misconduct that is not research-related, refer to the appropriate institutional process or procedure
d. dismiss the complaint and provide reasons for the dismissal.

(78) REIG will update the complainant and other relevant parties, including the Department, as appropriate and in a timely manner.

### Complaints Regarding Ethical Decisions Made by the AEC

(79) The AEC is the ultimate decision-making authority regarding the ethical acceptability of an activity, in line with the Animal Code. Therefore, any decisions regarding the ethics of animal research made by the AEC cannot be overridden.

### Complaints Regarding the Operation of the AEC

(80) Staff, students, members of the public, or any other concerned persons may make these complaints.

(81) Complaints should be made in writing to the Director, Research Services, who will notify the AEC and REIG.

(82) Where communication between the AEC and the complainant cannot resolve the complaint, the AEC will form a subcommittee to investigate the facts of the complaint, formulate a response and produce a report including any findings and recommendations.

(83) Where the subcommittee cannot resolve the complaint:

a. a person external to the AEC (the RMIT Designated Officer or nominee) will review the operational process followed by the AEC, and report findings and recommendations to the complainant and to the AEC.
b. the AEC will consider the findings and recommendations of this review, in line with the Animal Code.

## Status and Details

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| **Status** | Future |
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| **Policy Owner** | Calum Drummond<br>Deputy Vice-Chancellor Research and Innovation |
| **Policy Author** | Jane Holt<br>Executive Director, Research Strategy and Services |
| **Enquiries Contact** | Research Services |

## Glossary Terms and Definitions

**"RMIT Group"** - The University, its controlled entities and strategic investment vehicles (known as the RMIT Group).