

Monash University Procedure

Procedure Title	Ethical Research and Approvals: Scientific Activities Involving Animals Procedures
Parent Policy	Ethical Research and Approvals Policy
Date Effective	25-November-2009
Review Date	25-November-2012
Procedure Owner	Manager, Research Ethics and Compliance
Category	Academic Quality and Standards
Version Number	1.0
Content Enquiries	Manager Research Ethics
Scope	Applies to all Monash University staff and students, full time, part time, casual or adjunct, from any Monash University campuses, national and international, who host, conduct, participate in or disseminate the results of research involving human or animal subjects. Visitors to the University who participate in research are also covered by this policy.
Purpose	To ensure that research conducted under the auspices of Monash University complies with the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes when using live animals for research.
PROCEDURE STATEMENT	

1. Research Governance

Monash University staff and students who use animals in research activities have a moral obligation to treat the animals with respect and take into consideration all aspects of the animals' welfare when designing and conducting research activities.

Staff and students using animals in research activities must comply with the requirements set out in:

- The Prevention of Cruelty to Animals Act 1986 (Vic);
- The Prevention of Cruelty to Animals Regulation 2008 (Vic);
- Catchment and Land Protection Act 1994 (Vic);
- Catchment and Land Protection Regulations 2002 (Vic);
- The Australian Code of Practice for the Care and Use of Animals for Scientific Purposes 7th Edition 2004;
- The Code of Practice for Housing and Care of Laboratory Mice, Rats, Guinea Pigs and Rabbits;
- The Code of Practice for the Use of Animals from Municipal Pounds in Scientific Procedures 2001;
- The Australian Code for the Responsible Conduct of Research (2007);
- Bureau of Animal Welfare, Department of Primary Industries, Policy, Procedures and Guidelines;
- Monash University Policies, Procedures and Guidelines.

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Staff and students will achieve the above by:

- Familiarising themselves with the content of the above documents;
- Ensuring that all activities involving the use of animals are subject to review and monitoring by an Animal Ethics Committee responsible for reviewing all Monash University research activities using animals;
- Ensuring that no member of staff or student shall use animals for research without the prior written approval of a Monash University AEC.

Responsibility

Monash University staff and students

Non-Monash University persons conducting activities at Monash premises

2. Licences

- The Act requires that all institutes conducting research activities involving the use of animals within Victoria hold a Scientific Procedures Premises Licence (SPPL).
- Applications to obtain or modify a SPPL must be coordinated through the Monash University Animal Ethics Office.
- Licence nominees shall be either the Dean of a Faculty or their nominee but not be obtained without the knowledge of the Dean and the Animal Ethics Office.
- The Act requires that all institutes breeding specified animals for scientific purposes hold a Specified Animals Breeding Licence (SABL). Monash University will hold only one SABL. Only the Director of Monash Animal Services shall be the licence nominee on any SABL held by Monash University.
- Licence nominees must be aware of the research activities to be conducted under the licence. This may be achieved by maintaining an awareness of the research activities considered by the AEC or by nominating a delegate who will maintain such awareness.

Responsibility

Monash University Animal Ethics Office

Director, Monash Animal Services

Deans or nominee

3. Monash University Animal Welfare Committee

- The MUAWC is a subcommittee of the Monash Research Committee and will monitor research activities involving animals conducted by Monash University staff and students or conducted on Monash premises.
- MUAWC will ensure that all AECs reviewing Monash University research activities are operating at the same level and adhering to the requirements of The Code by auditing each AEC and its business.
- MUAWC will, through the Animal Ethics Office, provide training to the Monash research community on matters relating to animal welfare, and legislative requirements applicable to the use of animals in research. Such training will be offered on a biannual basis.

Responsibility

Chair, MUAWC

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4. Animal Ethics Committees

- In accordance with both The Act and The Code each SPPL must nominate or establish an Animal Ethics Committee (AEC) to review all proposed research activities using animals.
 - Composition of the Animal Ethics Committee Members of Monash University AECs are to be appointed by the Licence Nominee. The AEC must comprise at least five persons, including a separate person appointed to each of the following categories A to D:
 - A Chairperson - The Chair shall be appointed by the Licence Nominee;
 - Category A: - A person with qualifications in veterinary science and with experience relevant to the activities of the institution;
 - Category B: - A suitably qualified person with substantial recent experience in the use of animals in scientific or teaching activities;
 - Category C: - A person with demonstrable commitment to, and established experience in, furthering the welfare of animals, who is not employed by or otherwise associated with the institution, and who is not involved in the care and use of animals for scientific purposes;
 - Category D: - A person who is both independent of the institution and who has never been involved in the use of animals in scientific or teaching activities, either in their employment or beyond their graduation.

The Committee shall have the power to co-opt members subject to the approval of the Licence Nominee.

- All AEC Chairs should familiarise themselves with Section 2.2 of The Code: Responsibilities and operation of AECs.

Responsibility

Licence Nominees
Chair, AEC
Monash University Animal Ethics Office

5. Animals to be covered by these procedures

- The Code and therefore this procedure covers:
 - All mammals, including marine mammals, but excluding human beings;
 - All birds;
 - All other vertebrate animals, including reptiles, amphibians, and fish;
 - Any octopus, squid, crab, or crayfish, including freshwater crayfish, cuttlefish and nautilus;
 - Any animal of a species that is declared by the Minister of Agriculture, by notice in the Gazette, to be a species of animal for the purposes of The Prevention of Cruelty to Animals Act 1986 (Vic) and The Code.
- The above species include any mammalian fetus, or any avian or reptilian pre-hatched young, that is in the last half of its period of gestation or development, including marsupial pouch young but not including human beings or other prenatal, pre-hatched, larval, or other such developmental stages of species other than mammals, birds, and reptiles.

Responsibility

N/A

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6. Animal use and ethical review

- Written approval must be sought for all research projects, breeding programs, teaching units or training courses involving animals regardless of where the animals are located, where the animals may be housed or used, or of the source of funding when such activities:
 - Are sponsored by Monash University;
 - Are conducted by or under the direction of any employee, student, or agent of Monash University in connection with his or her individual Monash University responsibilities;
 - Are conducted by or under the direction of any employee, student, or agent of Monash University involving the use of any Monash University property or facility; or
 - Involve any collaborating, sub-granting, or sub-contracting individual or institution working with Monash University.

Note: When considering an application for the use of animals in teaching coursework the reviewing AEC must consider the requirements of the Monash University [“Use of Animals in Coursework Programs Policy and Procedures”](#).

- All animals must be monitored at least daily by the investigator or nominee. Applications must clearly indicate who has the primary responsibility for monitoring animals – both during weekdays and after hours.
- Notification to the AEC is required prior to obtaining or using biological material discarded following the practice of veterinary procedures by a veterinarian, or found in the animal’s environment.
 - For tissues and/or organs scavenged from Veterinary Clinics, written consent of the owner of the animal must be obtained.
 - For tissues and/or organs collected from dead native wildlife (including road kills) a wildlife permit from the Victorian Department of Sustainability and Environment must be obtained.
 - For tissues and/or organs that are imported from overseas, written approval from Australian Quarantine and Inspection Service and/or Convention on International Trade in Endangered Species must be obtained.
- Scavenging, which is the use of an entire animal or organ or tissue from an animal already killed for another purpose, or animals that are killed as part of another AEC-approved project, does not require approval in addition to the original written approval for the original use.

Note: The killing of animals for the specific purpose of obtaining these materials is considered a scientific procedure and requires prior written approval from the AEC.

- Activities involving non-Monash facilities and/or non-Monash staff
- When activities are to be conducted at a location within Victoria not under the jurisdiction of any AEC in Victoria, Monash staff and students must:
 - Submit an animal ethics application and obtain written approval from a Monash University AEC before field activities begin;
 - Notify the Monash University Animal Ethics Office who will notify the Bureau of Animal Welfare via a BAW Field Work Notification Form;
 - Inform themselves of any other approvals and/or permits from other authorities that may be required.
- When activities are to be conducted at a location within Victoria under the auspices of another institution’s AEC, Monash University may or may not assess projects depending on the host institution’s policy on external researchers conducting experiments on its premises, however Monash University staff must:

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- Advise Monash University via the AEC of their involvement by submitting Field Work Notification if approval is obtained from the host institution;
- Provide full details in writing of the activity and location. The minimum details are those required by the Monash AEC Field Work Notification Form;
- Provide confirmation of written approval of the project by the AEC of the host institution if the approval is obtained from the host institution;
- Terminate their involvement in the activity if the responsible investigator fails to respond to Monash AEC concerns regarding the welfare of the animals. Such termination must be confirmed in writing to the person responsible for the project and a copy sent to the Secretary of the Monash AEC.
- Non-Monash staff or students wishing to house animals and/or conduct research at Monash University premises must ensure the following:
 - Investigators from institutions with a legally constituted AEC that are based in Victoria;
 - Non-Monash staff and students are required to obtain approval from their home institution;
 - Responsibilities of the home AEC are to be delegated to a Monash AEC with formal inter-institutional agreement for the duration of the animal housing/scientific procedures taking place at Monash University.
 - Investigators from institutions with a legally constituted AEC that are not based in Victoria;
 - Non-Monash staff and students are required to obtain approval from their home institution;
 - Non-Monash staff and students are required to obtain a Scientific Procedures Fieldwork Licence from BAW and provide a copy of that licence to Monash University;
 - A Monash AEC is to be nominated with formal inter-institutional agreement for the duration of animal housing/scientific procedures taking place at Monash University premises in the Scientific Procedure Field Licence or Scientific Premises Procedures Licence.
 - Investigators from institutions without a legally constituted AEC that are based or not based in Victoria;
 - Non-Monash staff and students are required to obtain approval from a Monash AEC;
 - Non-Monash staff and students are to obtain a Scientific Procedures Fieldwork Licence from BAW and provide a copy of that licence to Monash University;
 - A Monash AEC is to be nominated with formal inter-institutional agreement for the duration of animal housing/scientific procedures taking place at Monash University premises in the Scientific Procedure Field Licence or Scientific Premises Procedures Licence.
 - Confirmation must be provided that written approval of the project by the AEC of the host institution has been granted.
 - An application to the AEC responsible for the animal facility will be made and permission to allow animal housing and/or the conduct of research at Monash premises shall be given by that Monash AEC on a case-by-case basis. In the event that a proposal is not submitted in accordance with and containing the information specified in The Code, Monash AEC may in their absolute discretion, decline to act

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as the delegated and/or nominated AEC in relation to particular research activities on Monash University premises.

- If a research project, breeding program, teaching unit or training course involves the use of animals interstate or overseas, special licensing arrangements must be made by Monash University and ethical review from an ethics committee constituted in the other state may be required. Researchers should refer to the Animal Ethics Office for advice before commencing any activities involving animals outside of Victoria. Staff and students must comply with these requirements.

Responsibility

Monash University staff and students and non-Monash University persons undertaking activities at Monash premises

7. Research proposals and subsequent amendments involving the use of animals for ethical review

- New applications and subsequent amendments to approved protocols must be submitted to the relevant AEC on the current application and amendment forms as per the [guidelines](#) found on the Animal Ethics Office website.
- Complete proposals will be receipted by the AEC secretariat and assigned to the next available meeting of the AEC.
- Incomplete proposals will be returned to the researcher for their attention and will not be considered as having been submitted to the AEC secretariat.
- Closing dates for AEC meetings are available from the [Animal Ethics Office website](#).
- The AEC may require inspection of the facilities, procedures and personnel before giving written approval.
- Researchers are notified of the review outcome in writing following the meeting. Any issues to be addressed are itemised in a letter from the Committee. Proposals with no issues will receive written notification of approval. Proposals that have issues to be addressed will be approved once the issues have been addressed to the satisfaction of the Committee.
- AEC 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 longer duration by the external funding agency.
- Any subsequent modifications to the protocol, changes in personnel or time extensions must be subject to written approval from the AEC.

Responsibility

Monash University staff

8. Reports

- Annual/Completed Project Reports to AEC
All researchers receiving written approval from the AEC for research projects, breeding programs, teaching units or training courses must submit annual progress reports and a completed project report within six months of completion of the project, including those discontinued, not commenced or completed. The AEC reserves the right not to approve new applications in the event of non-compliance in relation to reporting requirements on past approved applications.
- Annual Animal Use Return to BAW

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Chief Investigators are required to submit annual animal use reports on the Animal Use Return Form provided by BAW as stipulated under The Act. Researchers will be notified via the AEC when returns are due and provided with the latest forms for completion. Complete forms must be returned to the AEC by the specified due date.

Responsibility

Monash University staff

9. Responsibilities of chief investigators

The Chief Investigator is the nominated officer to liaise with the AEC and is responsible for ensuring the following:

- The Chief Investigator (CI) and any named co-investigators are familiar with Section 3 of The Code;
- The CI must accept primary responsibility for work undertaken including the selection of an appropriate animal species, the choice of the number of animals, the nature of the procedures and all matters related to the monitoring and continuing welfare of the animals and their ultimate disposal, according to the principles outlined in this procedure. The AEC will only liaise with the CI and not with other co-workers or students working under the CI's supervision. In the absence of the CI, the AEC will liaise with the nominated co-worker who acts on behalf of the CI;
- It is the responsibility of the CI to obtain written approval from the Monash AEC before beginning a program of research projects, breeding programs, teaching units or training courses that uses any animal (as defined in Section 5 of The Code);
- The CI must ensure that adequate records of animal use, procedures and monitoring are kept and that such records are kept when students/staff leave and for seven years after the completion date;
- The CI must continually reconsider the value of specific animal procedures to the overall aim of the study before carrying out each series of tests or procedures on animals. In the event of an audit the CI will be required to demonstrate evidence that such a review has been conducted;
- If a suitable alternative to animal experimentation becomes available, the CI must consider the alternative procedure in view of the requirement to minimise the number of animals used;
- It is the responsibility of the CI to notify the AEC in advance before modifying a research program. Major changes may require written approval from the AEC at one of its scheduled meetings; therefore projects should be planned well before the actual starting date;
- The CI must ensure that all students, technicians, and collaborators are named on the application and properly trained to carry out specific animal procedures. It is acceptable for the CI to train staff in specific techniques. It is expected that the CI will provide close personal supervision until such time that complete competence has been attained in activities;
- The CI must report to the AEC any adverse events associated with an approved protocol as soon as possible after the incident using the [Monash Adverse Event Report Form](#).

Responsibility

Monash University staff

10. Training

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- The Code requires that Monash University ensures that investigators and teachers are aware of their responsibilities under The Code through the provision of educational programs, continuing training and workshops. Therefore Monash University requires that:
 - All new Monash research staff and students complete the information session “Regulatory Issues, Animal Care and Use in Research and Teaching at Monash University (Full Day)” run by the Animal Ethics Office at the first available session;
 - Researchers who have recently joined Monash University from other universities or research institutes, who have undergone training in this area and may be eligible for “recognised prior learning”, complete the information session “Understanding your Legal Responsibilities and Animal Use in Research and Teaching at Monash University”;
 - Researchers must have successfully completed the relevant training to be named on an animal ethics application.

Responsibility

Monash University staff

11. Compliance

- The University Animal Welfare Officer, the AEC or its appointed representative shall have the right at any time, and without notice, to inspect the facilities in which the animals are housed and/or inspect the laboratories in which experimental work occurs, the procedures used and the condition of the animals. Where there is concern they shall be required to investigate and to take appropriate action. All members of the University or other persons may bring to the attention of the AEC any concern regarding compliance with The Act, Regulations and The Code.
- The AEC shall be responsible for ensuring compliance with The Act, Regulations, Code and is authorised to require a University member to either modify (as directed by the Committee) or to stop their teaching or research program involving live animal usage.

Responsibility

Monash University staff and students
Animal Welfare Officer
AEC members

12. Appeals

- A Chief Investigator wishing to appeal an AEC decision must do so in writing to the AEC Chairperson within 14 days after being advised of the AEC decision.
- The AEC Chairperson is responsible for adding the appeal to the agenda of the next scheduled AEC meeting where the AEC will review the appeal.
- The AEC Chairperson will inform the Chief Investigator in writing of the outcome of the AEC review of the appeal within 14 days from the AEC meeting.
- If an investigator or teacher finds the outcome unsatisfactory the complaint must be referred in writing to MUAWC within 28 days of the AEC decision for review of the due process.
- MUAWC will advise the AEC, the researcher and the SPPL Nominee of the outcome of the review of due process.
- If MUAWC finds fault with the process for an AEC decision, the Chair of MUAWC may initiate discussions with the AEC and request that the AEC re-review the application in light of any finding and with due process.

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- If the matter is not resolved, a written request for intervention may be made to the Deputy Vice Chancellor (Research) by either the complainant or the Chair of MUAWC within 28 days of the AEC's final decision. The written request must include the basis on which the request for intervention is being made.
- The DVC(R) must review the complainant's application and then attempt to resolve the complaint through further negotiation or mediation, or may advise the complainant in writing that the complaint is considered to be lacking in substance, or frivolous and/or vexatious, and that no further consideration or intervention is to be conducted.
- A complaint case will be considered closed upon receipt by the DVC(R) of a written withdrawal of the complaint by the complainant, or when the DVC(R) determines that there is nothing further that can be done in order to settle the complaint.
- Decisions of the DVC(R) may be appealed by the complainant in writing to the Vice-Chancellor. An appeal must be made within 28 days of receipt of the decision of the DVC(R). An appeal must be in writing and include the grounds for the appeal. It will not be sufficient for a complainant to ask for a re-consideration of the original complaint. The complainant must provide some reasons why they consider the decision to be incorrect or unfair.
- The decision of the Vice-Chancellor is considered to be final

Responsibility

Chair, AEC
Animal Ethics Office
Chair, MUAWC
Head, Academic Unit
Deputy Vice Chancellor (Research)
Deputy Vice Chancellor (Education)
Vice-Chancellor

13. Misconduct

- Where University employees fail to obtain written ethical approval when such approval is required or where they act contrary to the decision of an AEC, the matter may amount to misconduct and be dealt with under the University's Procedures for Investigating Complaints of Research Misconduct. Where a student has engaged in an unethical activity, the matter should be dealt with by the student's examiner or supervisor, and where necessary, referred to the head of the school.

Responsibility

Senior Deputy Vice-Chancellor and Deputy Vice-Chancellor (Research)
Monash Research Committee (MRC)
Monash University Animal Welfare Committee (MUAWC)
Monash Research Office
Heads of academic/administrative units
Research supervisors and managers
Monash University staff and students

Responsibility for implementation	Deputy Vice Chancellor (Research) Campus Research Committee (Sunway) Deputy Pro Vice-Chancellor Research (South Africa)
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	<p>Monash Research Committee (MRC)</p> <p>Monash University Human Research Ethics Committee (MUHREC)</p> <p>Monash University Animal Welfare Committee (MUAWC)</p> <p>Departmental/School Animal Ethics Committees</p> <p>Monash Research Office</p> <p>Heads of academic/administrative units and controlled entities</p> <p>Research supervisors and managers</p> <p>Research staff</p> <p>All Students</p>
Status	New
Approval Body	<p>Name: Academic Board</p> <p>Meeting: 06/2009</p> <p>Date: 25-November-2009</p> <p>Agenda item: 17.1.1</p>
Definitions	<p>AEC: Animal Ethics Committee</p> <p>The Act : Prevention of Cruelty to Animals Act 1986 No 46 (Vic)</p> <p>The Regulations: Prevention of Cruelty to Animals Regulations 2008 No. 162(Vic)</p> <p>The Amendment: Animals Legislation Amendment (Animal Care) Bill 2007 No 65 (Vic)</p> <p>The Code: Australian Code of Practice for the Care and Use of Animals for Scientific Purposes, 7th Edition 2004</p> <p>BAW: Bureau of Animal Welfare</p> <p>DPI: Department of Primary Industries</p> <p>SPPL: Scientific Procedures Premises Licence</p> <p>SABL: Specified Animals Breeding Licence</p> <p>MUAWC: Monash University Animal Welfare Committee</p> <p>DVC (R): Deputy Vice-Chancellor (Research)</p> <p>DVC (E): Deputy Vice-Chancellor (Education)</p>
Legislation Mandating Compliance	<p>Queries may be addressed to Risk and Compliance at: riskandcompliance@monash.edu.</p>
Related Policies	
Related Documents	<ul style="list-style-type: none"> • Use of Animals in Coursework Programs Policy and Procedures • Monash Adverse Event Report Form