

ANIMAL RESOURCES CENTRE (ARC)

Animal Ethics Committee (AEC)

Terms of Reference and Mode of Operation

Background

The Western Australian *Animal Welfare Act 2002* (the Act) requires the holder of a licence for the use of animals for scientific purposes to comply with the *Australian Code for the Care and Use of Animals for Scientific Purposes* (8th Edition 2013), referred to as the Code.

The Western Australian Department of Agriculture and Food administers the Act. Under the Act, the Department has issued two licences to the Animal Resources Authority, one being a licence to use animals for scientific purposes, and the other a licence to supply animals to other scientific establishments for use for scientific purposes. The licensee is the Chief Executive Officer (CEO) of the ARC.

The purpose of the Code is to promote the ethical, humane and responsible care and use of animals for scientific purposes. The Code applies to the care of all live non-human vertebrates and cephalopods.

The Code requires that the use of animals for scientific purposes must have scientific or educational merit, must aim to benefit humans, animals or the environment, and must be conducted with integrity. All involved in the care and use of animals for scientific purposes must be aware of the relevant Commonwealth, state and territory legislation.

Governing principles

The governing principles for the care and use of animals for scientific purposes, as set out in the Code, will apply to all animals for which the ARC has responsibility, namely that:

1. Respect for animals will underpin all decisions and actions involving the care and use of animals for scientific purposes, demonstrated by:
 - (i) using animals only when justified;
 - (ii) supporting the wellbeing of animals involved;
 - (iii) avoiding or minimising harm, including pain or distress, to those animals;
 - (iv) applying high standards of scientific integrity;
 - (v) applying Replacement, Reduction and Refinement (the 3R's) principles at all stages of animal care and use;
 - (vi) knowing and accepting one's responsibilities to animals themselves and under relevant legislation and the Code.

2. The care and use of animals for scientific purposes will be subject to ethical review by the AEC.
3. A judgement as to whether a proposed use of animals is ethically acceptable will be based on information that demonstrates that the principles given in clause 1 of these principles, and will balance whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits.
4. The obligation to respect animals, and the responsibilities associated with this obligation, apply throughout the animal's lifetime, including acquisition, transport, breeding, housing, husbandry, use of the animal in a project, and provisions for the animal at the conclusion of their use.

All ARC activities subject to the AEC

All activities that involve the care and use of animals for scientific purposes will:

- (i) be subject to ethical review, approval and monitoring by the AEC;
- (ii) commence only after the AEC has granted approval;
- (iii) be conducted in accordance with the AEC approval;
- (iv) cease if the AEC approval is suspended or withdrawn.

Terms of Reference of the AEC

The AEC will:

1. approve guidelines for the care of animals that are bred, held and used for scientific purposes on behalf of the ARC. Such guidelines will usually take the form of standard operating procedures and/or other instructions.
2. monitor the acquisition, transport, production, housing, husbandry, care, use and disposal of animals used for scientific purposes through inspections, review of standard operating procedures and production reporting to the AEC.
3. recommend to the ARC any measures needed to ensure that the standards of the Code are maintained.
4. require anyone with a real or potential conflict of interest to declare that conflict.
5. deal with each situation in which a real or potential conflict of interest is identified.
6. examine and approve, approve subject to modification, or reject written proposals for activities involving use of animals for scientific purposes.
7. approve only those activities which conform with the requirements of the Code.
8. oversee activities approved by the AEC.
9. require the suspension of activities where the AEC detects that activities are non-compliant with the Code, and require or approve remedial action which may include intervention and/or withdrawal of AEC approval for that project.
10. authorise or require, if appropriate, the emergency treatment or humane euthanasia of any animal.
11. examine and comment on all ARC plans and policies that may affect the welfare of animals used for scientific purposes.
12. maintain a register of all proposals submitted to the AEC, including the outcomes of the AEC's deliberations.
13. report to the ARC as required by the ARC, the responsible government Department, or the Code and by other voluntary compliance including ISO 9000.
14. carry out all regulatory duties and institutional AEC policies and guidelines, as required by the Code.

Mode of Operation

Role of the Animal Resources Centre Animal Ethics Committee

The ARC supports a properly constituted AEC, which functions to ensure regulatory compliance, and the ethical and humane care and use of animals for scientific purposes. The AEC facilitates the ARC in fulfilling its primary business of producing and supplying genetically-defined, specific pathogen free (SPF) research rats and mice to support the biomedical research industry in Australia and the Asia-Pacific region.

In compliance with Sections 13 and 80 of the Act, the ARC must ensure that all AEC approved activities are undertaken in compliance with the conditions of approval and the Code, and that no activities involving the use of animals for scientific purposes are undertaken unless AEC approval is granted.

The mode of operation outlined in this document provides guidance to the AEC to perform its function as an AEC of standing within the institution in order to assess all proposed use of animals for scientific purposes. The AEC primarily assesses animal use proposals submitted by researchers with Custom Strains lines housed and maintained at the ARC. The AEC also assesses the ARC's proposal for the production and supply of mice and rats for sale and the training proposal required for training ARC staff on routine animal husbandry procedures. This is in addition to an annual review of all standard operating procedures and work instructions relating to animal care and use.

This document should be read in conjunction with the Act, the Code and the licences to use and supply animals for scientific purposes.

AEC Membership

The AEC consists of members appointed by the ARC in accordance with the requirements defined in the Act and Code. The AEC is chaired by the Scientific Officer and is comprised of an ARC staff member for Category A and independent external members for Category B, C and D. A minimum of one staff member involved in the day to day care of animals is also on the AEC.

- (i) Chairperson: A person who holds a senior management position at the ARC and who is independent of the ARC's care and use of animals for scientific purposes.
- (ii) Category A: A person with qualifications in veterinary science that are recognised for registration as a veterinary surgeon in Australia, and with experience relevant to the ARC's activities or the ability to acquire relevant knowledge.
- (iii) Category B: A suitably qualified person with substantial and recent experience in the use of animals for scientific purposes relevant to the ARC and the business of the AEC. This must include possession of a higher degree in research or equivalent experience. If the business of the AEC relates to the use

of animals for teaching only, a teacher with substantial and recent experience may be appointed.

- (iv) Category C: A person with demonstrable commitment to, and established experience in, the welfare of animals; and is not involved in the care or use of animals for scientific purposes, and not associated with the ARC.
- (v) Category D: A person not fitting the requirements of any other Category who is independent of the ARC, and has never been involved in the use of animals for scientific purposes either in their employment or beyond their undergraduate education, and who can be seen by the wider community as bringing a completely independent view to the AEC.

Responsibilities of the AEC Chairperson

The Chairperson of the AEC will:

- maintain a sound understanding of the Act, Code, relevant ARC policies and procedures;
- ensure the AEC and the Executive of the AEC operate in accordance with the Act, Code and AEC Terms of Reference;
- ensure animal use proposals are considered by the AEC and decisions conveyed to Chief Investigators in a timely manner;
- ensure the AEC's decisions and directives are enacted prior to the use of animals for scientific purposes;
- oversee all requirements of the AEC to report and review its operations as outlined in the Code;
- ensure records related to AEC business are maintained;
- communicate with the Licence holder of the ARC as to the resource needs of the AEC; and
- represent the AEC in any negotiations with ARC staff and/or management.

Responsibilities of AEC Members

Each member of the AEC is responsible for:

- deciding whether, in their own judgment, an application or other matter under consideration by the AEC is ethically acceptable and meets the requirements of the Code;
- being familiar with the code and other policies and guidelines relevant to the business of the AEC;
- providing opinions on the ethical acceptability of applications and other matters under consideration by the AEC;
- declaring any conflict of interests that may influence the objectivity of their decision making; and

- maintaining confidentiality regarding the content of applications to the AEC and the deliberations of the AEC.

Alternate Members

The ARC shall appoint an alternate Category member(s), deputy, in the event that an AEC member is anticipated to be absent from an AEC meeting or where a conflict of interest requires an AEC member to withdraw from a matter being considered by the AEC.

The person appointed as deputy shall have the same qualifications required by the member for whom the deputy is appointed and when deputising for the member, they shall be deemed to be a member and will be bound by the same responsibilities as the AEC members.

AEC Executive

In accordance with the Code, the AEC has an Executive consisting of the Chairperson, the Category D member, and when required the Category A member.

The Executive of the AEC:

- may approve minor modifications to AEC approved projects, for ratification by the full AEC at its next meeting;
- may not approve new or repeat proposals;
- must ensure that all AEC Executive decisions are documented; and
- must ensure that all AEC Executive decisions are reviewed and endorsed by the full AEC at its next meeting.

The AEC will provide guidance on the type of activity that constitutes a minor amendment, which 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.

Selection, Appointment and Obligations of AEC Members

Appointments to the AEC shall be made by the CEO of the ARC.

Persons may be selected for appointment either by invitation or by application.

The ARC may appoint a person as an AEC member if the person meets the requirements of the relevant category position.

The appointment of all AEC members will be in writing and before carrying out any role as an AEC member, a person appointed as a member must acknowledge in writing their acceptance of the AEC's Terms of Reference and any issue of confidentiality required by the ARC.

All members of the AEC are covered by the ARC's insurance and are appropriately indemnified while engaged in AEC business.

Where relevant and appropriate, the ARC will cover the cost of education programs, resources and where appropriate, the reimbursement of out-of-pocket expenses and/or payment of an allowance to AEC members.

Term(s) of Membership, Termination and Retirement of AEC Members

External AEC members will be appointed for a three year term with a provision for reappointment for a further 4 terms. Appointments to the AEC will be verified by a written offer of appointment and acceptance.

The ARC may, after due enquiry, terminate at any time, by notice in writing, the membership of an AEC member who, in the ARC's opinion, has failed to:

- i. comply with the AEC's Terms of Reference; and
- ii. maintain the confidentiality required by the AEC or the ARC in relation to proposals and business of the AEC.

An AEC member may request to retire from the AEC, provided four weeks written notice is given to the Chairperson of the AEC.

Meetings and Operating Mechanisms

Meetings

The AEC will meet a minimum of four times each calendar year with a quorum consisting of:

- At least one member from each of the membership categories A, B, C and D with all members present for the duration of the meeting.
- Category C and D members together representing at least one-third of members present.

Agenda papers will be emailed to all AEC members at least 7 business days prior to the AEC meeting.

In exceptional circumstances and at the discretion of the AEC Chairperson, AEC members may be permitted to participate in meetings via conference call or other electronic formats which enable all members to actively participate in the discussions and deliberations of the AEC.

AEC members are required to declare any real or potential conflict(s) of interest. Declaring conflicts of interest is a standing agenda item at AEC meetings. Where conflict of interest arises, the member(s) with a conflict of interest may contribute to discussions but must withdraw from the meeting during the decision making process. Once such members have withdrawn, the remaining members must constitute a quorum. The Chairperson, with a PhD and research experience, is an alternate Category B member. The Category B member, as a Veterinarian (BVMS), is an alternate Category A member. If no quorum, the agenda item is postponed until the next AEC meeting, during which time a suitable alternate member is sought. With quorum, a decision is reached with actions taken recorded in the minutes of that meeting.

Operating Mechanisms

In order to carry out its role, the AEC will:

- operate in a manner consistent with the Act, Code, and voluntary accreditation standards;
- assess proposals in a manner that is fair to applicants and acceptable to AEC members, including providing information to AEC members in a timely manner;
- ensure that no animal use projects/activities commence without written AEC approval;
- resolve any real or potential conflict(s) of interest any member may have in any matter;
- appoint and delegate functions of the AEC to an Executive of the AEC;
- maintain a record of AEC meetings, decisions and all other aspects of the AEC's operation;
- approve and maintain a registry of standard operating procedures and work instructions;
- provide an annual written report on its activities to the CEO of the ARC;
- make decisions and provide appropriate direction and guidance to ARC staff in regard to the approval, management, monitoring, evaluation and reporting of individual activities involving the use of animals for scientific purposes; and
- make decisions and provide appropriate direction and guidance to ARC staff on occupational/environmental health and safety matters pertaining to laboratory animals.

Review, Assessment and Approval Process for New Animal Use Proposals using Live Animals

The AEC is required to review, approve or withhold approval on all proposals involving ARC staff, facilities and animals, when used for scientific purposes at the ARC, as defined in the Code. Animals supplied by the ARC for use for scientific purposes at other scientific establishments are subject to ethical review and approval of their use for scientific purposes by the AEC of the scientific establishment prior to dispatch from the ARC.

The AEC will not:

- consider proposals for approval outside of a properly convened AEC meeting;
- approve an animal use proposal where it lacks confidence in the Chief Investigator having due respect for the welfare of animals; or
- approve an animal use proposal that lacks sufficient scientific merit given the animal welfare concerns.

The AEC will:

- Only accept proposals for consideration, which:
 - Are submitted on an AEC approved application form and by the specified submission date.
 - Are signed with the hand written or electronic signature of the nominated Chief Investigator and all investigators on the animal use proposal.
 - Contain the level, type and clarity of information the AEC might reasonably expect in order to make informed decisions.
 - Are endorsed by the Chairperson of the AEC as meeting the standard acceptable for submission to and consideration by the AEC. The AEC Chairperson consults and liaises with the Chief Investigator, in concert with liaising with ARC veterinarians if required, to ensure standards are met.
 - Are endorsed by the Chairperson of the AEC as being within the scope and operational structure of the ARC. Prior to submission of the proposal to the AEC, and during consultation with the Chief Investigator, the AEC Chairperson liaises with ARC staff to ensure the proposed animal use activities can be conducted at the ARC. This process includes consultation with veterinarians at the ARC on animal welfare, monitoring, endpoints (established limits beyond which animals will be removed from the procedure/study) and appropriate remedial action.
 - Have procedures that comply with published NHMRC guidelines relating to the use of animals for scientific purposes, where appropriate. If these standards are not met within the experimental design then the Chief Investigator must provide scientific justification, quoting appropriate literature, for the use of this procedure. In these cases the Chief Investigator should discuss with the Chairperson of the AEC whether attendance at the AEC meeting would be appropriate.
 - The Chief Investigator assures the AEC that the proposal avoids unnecessary duplication of animal experimentation.
 - The animal model selected is appropriate for the research paradigm.
 - Alternatives have been explored for those procedures that cause more than momentary pain or distress.
- Only approve proposals which clearly demonstrate that:
 - The use of live animals is necessary and warranted.
 - The Chief Investigator has appropriately applied the '3R' principles of replacement, reduction and refinement.
 - The proposed care and management arrangements, including minimising pain or distress, are consistent with the intent and requirements of the Code.

- Personnel listed on the animal use proposal are competent in the procedures they are listed to perform.

The AEC may invite outside consultants to assist in the review of issues arising out of AEC review of proposed activities. Consultants will not approve or withhold approval of an activity and will not vote on the proposal unless they are also members of the AEC.

When assessing animal use proposals the AEC should aim to reach decisions by consensus, with decisions falling into one of the following three categories:

- Approved – approved without modification
- Conditionally approved – approved subject to AEC directed modifications
- Not approved – not approved but subject to AEC directed modifications for resubmission

Where a consensus decision cannot be reached after reasonable effort to resolve differences, the AEC will explore with the Chief Investigator of the proposal ways of modifying the project or activity that may lead to consensus. This may include an invitation to the Chief Investigator to attend an AEC meeting to explain the project if the project is considered to contain contentious or difficult issues. If consensus is still not achieved, the AEC should only proceed to a majority decision after members have been allowed a period of time to review their positions, followed by further discussion. AEC members who have a minority view will be given an opportunity to detail in writing the reasons for their minority view, which will be forwarded to the CEO of the ARC. AEC approval of animal use proposals is for a default period of three years at which time a project completion form (WIF 55) must be submitted to the AEC Chairperson. Chief Investigators seeking to continue a project beyond this time must submit a new animal use proposal.

Notification of Committee Decisions

Upon a decision being made, the Chairperson of the AEC will:

- Inform the Chief Investigator of the decision in writing within five business days of the AEC meeting.
- In the case of animal use proposals approved without modification, assign an AEC reference number and provide the Chief Investigator with a signed copy of the approved animal use proposal. The Chief Investigator must not commence projects or order animals without receiving the AEC approved copy of the animal use proposal.
- In the case of ‘conditionally approved’ or ‘not approved’ proposals, provide the Chief Investigator with a clear, written report detailing the AEC’s instructions and modifications required in order for the proposal to be approved.
- In the case of ‘conditionally approved’ proposals, inform the Chief Investigator that the project cannot commence until all conditions specified by the AEC have been met, documented and submitted within two weeks of notification of conditional approval. The AEC Chairperson is responsible for ensuring that all conditions are met prior to final approval being granted by the AEC Executive.

Once approval is granted, the Chief Investigator will receive a signed copy of the approved animal use proposal.

- In the case of proposals ‘not approved’, inform the Chief Investigator that the project cannot commence unless the proposal is:
 - i. amended so as to address all written concerns raised by the AEC;
 - ii. re-signed by all participants as if a new proposal; and
 - iii. re-submitted to the AEC for assessment and pending approval.

Requests for Collection of Dead Animals or Dead Animal Tissues from the ARC for Scientific Purposes

It is a policy of the AEC that customers can request to harvest tissues from freshly culled animals post-euthanasia or request freshly culled animals without an AEC number given the following conditions:

- the animals requested are genuinely surplus to the operations of the ARC,
- the number, age, strain and gender of the requested animals is not specified, and
- the animals are culled according to ARC operating procedures, including euthanasia method and day of cull.

All such requests are to be made via completion of a ‘dead tissue request’ form (WIF 50) to the AEC Executive who will then either approve or not approve the request. Any approved requests are communicated to the AEC at the next meeting.

Proposals Involving non-ARC Staff and/or Facilities

The ARC AEC will not approve animal use proposals to be conducted at other scientific establishments, even those involving ARC staff, unless special permission is gained from the AEC Chairperson. ARC staff working on projects at other scientific establishments must ensure that the approved project proposal is submitted to the ARC AEC for its information. ARC staff involved must also ensure that an Inter-Institutional Agreement exists between the ARC and the other scientific establishment where the project or activity is being carried out.

All scientific use of animals at facilities of other scientific establishments must be submitted to the AEC of the host scientific establishment for assessment and approval.

All scientific use of animals carried out on or using ARC facilities by non-ARC staff must be submitted to the ARC AEC for approval.

Staff Training and Competency

The ARC is committed to ensuring that staff members who are involved in the care and use of animals for scientific purposes are appropriately trained in the required skills to perform their duties.

- Animal technicians at the ARC are trained in basic animal handling, restraint and husbandry procedures.
- For training and to assess competence, staff may undertake an AEC approved animal use activity under the direct supervision of competent personnel or qualified trainers.
- Competencies of ARC animal technicians is formalised and documented through the ARC's registered training program.
- Only staff at the ARC deemed competent may undertake procedures as part of a project/activity.
- In addition to the provision of basic animal husbandry, many standard animal management procedures and research projects require the use of more invasive techniques with potential animal welfare implications. To be deemed competent, evidence of relevant training and/or experience must be documented and endorsed by the ARC's veterinarians and qualified trainers.
- Surgical procedures at the ARC classified as minor, major or multiple surgical procedures, due to animal welfare implications if conducted incorrectly, will only be approved by the AEC, if conducted by, or under the direct supervision of the ARC veterinarians, or by competent ARC staff approved by ARC veterinarians.
- Where appropriate and at the discretion of the AEC, with endorsement from the CEO of the ARC, external researchers listed on AEC animal use proposals may be trained by the ARC veterinarians.

Standard Operating Procedures and Work Instructions

The ARC's standard operating procedures and work instructions relating to the care and use of animals at the ARC are to be approved and periodically reviewed by the AEC.

Standard operating procedures and work instructions must:

- have current approval from the AEC;
- include in its title the date of approval or last review by the AEC; and
- be noted for review by the AEC if any major variations to the standard operating procedures or work instructions could impact animal welfare.

New standard operating procedures and work instructions must not be used until approved by the AEC.

All approved standard operating procedures and work instructions must be reviewed by the AEC every three years.

Modification and Annual Review of Approved Projects

No element of an AEC approved project may be amended from that detailed in the approved proposal without the amendment first being formally endorsed by either the AEC or, at the AEC Chairperson's discretion, the AEC Executive.

It is the Chief Investigator's responsibility to ensure that a project involving the use of animals is conducted in accordance with the conditions and requirements of AEC approval, except as formally amended by written agreement with the AEC.

The AEC Chairperson will provide appropriate guidance to Chief Investigators, following consultation with ARC veterinarians if required, on the development and submission of amendment requests to the AEC.

The AEC will:

- only consider amendments to approved animal use projects when requested through submission of an Amendment Form (WIF 53), and which contain the level, type and clarity of information the AEC might reasonably expect in order to make informed decisions;
- seek to approve minor amendments in a timely manner by the AEC Executive at the discretion of the AEC Chairperson;
- accept only a maximum of three major amendments to an approved animal use project; and
- require resubmission of an animal use proposal where more than three major amendments have been requested by the Chief Investigator.

All AEC approved animal use projects, regardless of the duration of AEC approval for the project, are subject to annual review by the AEC. In this regard, the AEC will:

- consider the annual report and annual animal usage for all projects seeking to continue into a new calendar year at an AEC meeting held early in that calendar year; and
- determine, for each animal use project, whether the project is continued, suspended, modified or discontinued.
- determine for each animal use project if there are any significant or minor deficiencies that need to be addressed and subsequently rectified through submission of an amendment request.

The AEC Chairperson will:

- provide appropriate guidance, following consultation with ARC veterinarians if required, to Chief Investigators on the development and submission of project annual reports to the AEC;
- ensure annual reports are considered by the AEC at an AEC meeting held early each calendar year;
- notify the Chief Investigator in a timely manner of the outcome of the AEC's review of annual reports; and
- pursue the submission of a final report within four weeks of the termination of an animal use project.

Grievances and Appeals

If a Chief Investigator is aggrieved by a decision of the AEC, then the AEC will offer the investigator an opportunity to submit the grievance in writing to the AEC Chairperson for consideration by the AEC at its next meeting. The final decision in all cases rests with the AEC.

Reporting of Activities and Animal Welfare Monitoring

Once an animal is assigned to a project, the animal is deemed to be being used for a scientific purpose, and it is the responsibility of the Chief Investigator to ensure the wellbeing of an animal throughout its period of use in the approved project.

In this regard the AEC will:

- through review of project annual reports, monitor all activities relating to the care and use of animals to assess compliance with the Code and decisions of the AEC;
- ensure Chief Investigators are aware of their obligation to provide prompt and appropriate notification of any unplanned deaths, emergency euthanasia and unexpected adverse event(s) that impacted the wellbeing of an animal assigned to a project;
- consider any issue or report that may represent a critical risk to the ethical or humane treatment of animals at the next scheduled meeting;
- consider any reports on unexpected adverse event(s), and remedial actions taken, at the next scheduled meeting and assess compliance; and
- in the case of suspected or confirmed non-compliance with the Code, communicate in writing as soon as practicable with the Chief Investigator and pending the outcome of an investigation by the AEC, the Chairperson of the AEC will subsequently communicate the suspected or confirmed breach with the CEO of the ARC.
- provide appropriate notifications in the event that an animal use project is suspended.

The AEC is required to conduct post-approval monitoring on activities and procedures for the care and use of animals at the ARC and ensure adequate monitoring of all approved animal use projects.

In this regard, the AEC will:

- monitor all activities and procedures at the ARC relating to the care and use of animals, including the acquisition, transport, breeding, housing and husbandry; and
- consider, review and approve written standard operating procedures and work instructions, including procedures on general management of the facility and all routine husbandry procedures.
- provide methods for anonymously communicating animal welfare concerns.

Annual Inspection

The AEC is required to conduct an annual inspection of the ARC and monitor housing conditions, practices and procedures involved in the care and use of animals in breeding and holding facilities.

In this regard, the AEC will:

- as a quorate Committee, conduct an annual inspection of the ARC, including structural and environmental conditions, housing, biosecurity measures and animal handling arrangements for the care and use of animals at the ARC; and
- record their findings of the annual inspection in the meeting's minutes, during which the inspection was conducted, including the names of those who attended the inspection, observations, any identified problems, follow-up and outcomes;

Annual Reports and External Reviews

The AEC is required to provide an annual report to the governing body of the ARC and is subject to an external review of its operations.

In this regard, the AEC Chairperson will:

- in consultation with relevant ARC staff, ensure an annual report is prepared and submitted to the Department of Agriculture and Food.
- in consultation with the AEC, ensure an annual report on the AEC's operation is prepared and submitted to the CEO of the ARC, which will include recommendations and records of minority views.
- ensure an external review is conducted, at least every four years, to assess the AEC's activities and to ensure performance is in accordance with provisions stipulated in the Code and any relevant licence conditions.