

1. OVERVIEW

It is a requirement of SAHMRI and the *Australian Code for the care and use of animals for scientific purposes (8th Edition 2013) (the Code)* that principles and procedures relating to animal ethics and animal welfare are established and implemented.

The responsibility for the implementation of these procedures is shared by the Animal Ethics Committee (AEC), Chair and Deputy Chair, the AEC Secretariat (Secretary, Veterinary Director and Animal Welfare Officer), animal house staff, SAHMRI researchers and administration.

Principles

The primary responsibility of the AEC is to ensure that all care and use of animals is conducted in compliance with *the Code* and the South Australian Animal Welfare Act 1985 (the Act). The AECs apply a set of principles that govern the ethical conduct of people whose work involves the use of animals for scientific purposes. The role of the AEC is to ensure that the use of animals is justified; provide for the welfare of those animals and incorporate the principles of Replacement, Reduction and Refinement.

This document is associated with the Animal Ethics Committee Terms of Reference (Doc: 0090).

2. MEMBERSHIP

Members shall generally be appointed for a period of two (2) years and are eligible to be reappointed at the end of any 2-year period. All members will be formally appointed in writing.

Prior to appointment, AEC members will acknowledge, in writing, that they will accept:

- the Terms of Reference of the AEC;
- a Confidentiality Agreement.

Members may resign from the AEC at any time by advising the Chair in writing, with a minimum two-month notification period. The Chair will advise the Executive Director of SAHMRI of the resignation.

The Chair has the right to recommend to the Licence Holder, SAHMRI through the Executive Director to request that a member of the Committee stand down or that new members be added to the Committee.

The Chair will monitor the needs of AEC membership in accordance with the Code and Act.

3. RESPONSIBILITIES OF THE CHAIR

The Chair must:

- Ensure that the AEC operates in accordance with the principles and requirements of the Code, legislative requirements, all relevant policies of the institution and the agreed AEC procedures;

- Ensure that an agenda is produced prior to each meeting, and that each agenda item is addressed at the meeting as required to fulfill the responsibilities of the Committee.
- Ensure that applications are considered by the AEC and the outcomes are conveyed to the researchers in a timely fashion;
- Advise the SAHMRI Executive or delegate regarding the appropriate staff and budget resources required by the AEC to perform its function, and of the facilities and staff who provide animal care and research support to animal researchers;
- Represent the AEC in negotiations with the Institute;
- Oversee all requirements of the AEC to report and review its operation as outlined in the Code;
- Ensure AEC records are maintained and made available for review by the institution and authorised external reviewers.

4. OPERATION

Meetings of the Committee

The Committee will meet at least quarterly and more frequently as required. Meeting and submission dates of the Committee will be made readily available.

Minutes are to be maintained recording all decisions and subsequent decisions as well as all other aspects of the Committees operation.

Conflict of interest

Members of the AEC are required to declare at the commencement of the meeting any potential conflict of interest, and any such conflict will be recorded in the Minutes. There is no precise definition of a conflict of interest but broadly it relates to where an external relationship or role could undermine the primary role of the person by influencing their judgment. An external relationship can be personal, religious, political, academic, financial or legal. A common-sense approach will be taken to managing any declared conflicts of interest.

A Conflict of Interest does not necessarily preclude an AEC member from participating in any decision-making process. The Chair will make a decision, with advice from the Committee, on any action to be taken to manage a declared conflict of interest.

When a research proposal is considered by the AEC of which a member is an investigator, the member concerned is required to either absent himself/herself from the meeting during discussion of his/her proposal or absent himself/herself from the discussion and only respond to questions directed to him/her. This member will not participate in voting on the proposal.

Confidentiality

AEC members must treat the information supplied as confidential and undertake to not disclose the specifics or sensitive aspects of application to people outside the AEC. Specifically, no member of the AEC is authorized to make public statements regarding animal research issues, any such statement needs to be made by the Executive Director.

Information can be sought by AEC members from contacts outside the AEC, but they must not identify any individual or divulge information that could identify the project or aspects

which could be regarded as scientifically or commercially sensitive. Members can seek advice from the AEC Chair or AEC Secretariat if they are unsure of how to balance their responsibilities.

All electronic information must be stored securely. Paper documents must be destroyed in an appropriate and timely manner.

Consensus decision-making and voting rights of members

Decisions by the AEC with regard to approval, modification or rejection of a proposal, or withdrawal of approval for a project must comply with Sections 2.3.11 of the *Australian Code for the care and use of animals for scientific purposes* and should be made on the basis of consensus. All decisions must be recorded in the Minutes with the reasons for their decisions.

- When consensus is achieved, then this decision is recorded. If the project is rejected, this rejection should be recorded.
- Where consensus cannot be reached after reasonable effort to resolve differences, the AEC should explore with the applicant(s) ways of modifying the project that may lead to consensus. If consensus is still unachievable, the Chair will decide whether to postpone the decision to allow members further time to consider their position or if voting is required. If a vote is required, a majority decision is to be accepted.

Where a decision is unable to be made on the basis of consensus, a majority vote may be used to resolve the issue. All members have the right to vote, except

- (i) under circumstances as specified under the Conflict of Interest guidelines, or;
- (ii) where an individual is co-opted to the Committee for the purposes of providing expertise on specific issues, and hence takes no part in the proceedings of the Committee other than offering expert advice on the issues concerned. The Secretary of the AEC has no voting rights.

Irreconcilable differences that arise during deliberations by the AEC may be referred to the SAHMRI Executive Director for advice and review of the due process. Procedures for resolving disagreements are detailed below.

Irreconcilable differences between the AEC and an investigator must be referred to the SAHMRI Executive Director for review of the due process (see Section 5.6 of the Code).

The ultimate decision regarding the ethical acceptability of an activity lies with the AEC and must not be overridden.

Emergency Animal Welfare Officer (AWO) / Veterinary Officer (VO) Powers

The AWO or VO may implement emergency actions in projects to protect animal welfare, scientific integrity or implement disease prevention and control.

Where the AWO or VO has implemented action without prior AEC approval, in an emergency or unforeseen situation, to improve animal welfare or maintain scientific integrity, the AWO/VO must inform and obtain the consent of the Director of Bioresources/PIRL, AEC Chair and Facility Manager as soon as possible, and must inform that Committee at the next AEC meeting via an AWO/VO report.

Some cases may require an Amendment application to be completed in retrospect, to be considered by the Executive members and ratified at the next meeting.

5. AEC EXECUTIVE

An Executive of the AEC will be appointed to carry out certain tasks on behalf of the AEC.

The Executive will consist of at least one member from the following categories:

- Chair
- Category A, and
- Category C or D.

The Executive is to review responses to conditions required by the AEC on modifications and applications. It may approve minor modifications to currently approved projects as outlined in the Operating Guidelines. It may approve the additional/deletions of associate investigators and may deal with emergencies. See the Operating Guidelines for the definition of an Amendment.

The AEC Executive will not approve *new proposals*.

The Committee can authorize the Chair to sign approval letters where minor administrative matters require attention.

All decisions by the Executive/Chair are reviewed and ratified by the entire AEC at the next meeting. Decisions by the Executive can be overturned by the full AEC.

6. REPORTING REQUIREMENTS

Report to the Minister

An Annual Report of the AEC will be submitted on behalf of SAHMRI to the Chief Executive DEW in accordance with Regulation 13 of the Animal Welfare Regulations 2012.

Report to the Institution

The AEC must submit a written report on its activities at least annually to the SAHMRI Executive Director. The report should include information on:

- numbers and types of projects assessed and approved or rejected including applicants institution; the physical facilities for the care and use of animals by the institution;
- activities that have supported the educational needs of AEC members, and of personnel involved in the care and use of animals;
- administrative or other difficulties being experienced;
- any matters that may affect the institution's ability to maintain compliance with the Code and if necessary the provision of suitable recommendations; and any other relevant matters.

Report to the NHMRC

The Animal Ethics Committee may be required to report to the NHMRC and will do so when requested.

7. PROCEDURES FOR CONSIDERATION OF APPLICATIONS TO THE AEC

When considering proposals for breeding, holding and the use of animals for scientific purposes, the procedures followed by the AEC must comply with Sections 2.3.3, 2.1.5 – 2.2.25 and Section 4 of the Code. Only those scientific, teaching and husbandry activities that conform to the requirements of the Code and legislation may be approved.

Information to be supplied to the AEC

- a) Proposals must provide sufficient information to satisfy the AEC that the proposed use of animals is justified and complies with the principles of Replacement, Reduction and Refinement. The justification requires weighing the predicted scientific benefit or educational value against the potential impact on the welfare of the animals and the number of animals requested.
- b) Proposals should be presented in a form that allows the AEC to easily assess the information provided. They should be written in a manner that can be understood by all members of the AEC (i.e. lay language) and must identify the impact of the proposed research on the animals and the means by which the impact will be minimised. Advice on these matters can be obtained from the AEC Secretariat.
- c) SAHMRI's AEC requires all proposals to be made using the SAHMRI application form. The form seeks information from applicants in order to meet the requirements of the Australian Code for the care and use of animals for scientific purposes (refer to Sections 2.3.3-2.3.16). Applicants must supply the required information by completing all sections of the application form, and by addressing specific queries raised by the AEC during its deliberations.
- d) Applications should be received by the Secretary of the SAHMRI AEC by the deadline date on SAHMRI's website in order to be included on the Agenda for the subsequent AEC meeting. Late applications will only be accepted under special circumstances.

Consideration of Proposals

- a) New proposals considered in full by the AEC, and amendment applications that are not considered as minor by the Chair and/or Deputy Chair (i.e. where there are no animal welfare issues), must be considered and approved only at quorate meetings of the AEC.
- b) The AEC must be satisfied that the proposed use of animals is justified by weighing the predicted scientific benefit or educational value of the proposal against the potential impact on the welfare of the animals. An essential component of this assessment by the AEC involves consideration of the steps taken by the applicant to comply with the principles of Replacement, Reduction and Refinement specified in the Australian Code for the care and use of animals for scientific purposes (refer to Section 1 and Section 2.7.4 of the Code).
- c) Decisions should be made in a manner that is fair to applicants, acceptable to all AEC members and in accordance with the procedures detailed above.
- d) AEC decisions must be made as promptly as possible and researchers must be informed of the AEC decision in writing in a timely manner. Scientific research activities involving the use of animals must not start before written approval is received.

- e) SAHMRI's AEC Secretary will maintain a register of all proposals made to the AEC, including the outcomes of the Committee's deliberations.

8. OUTCOMES FOLLOWING AEC DELIBERATIONS

The consideration of an application by the AEC will normally result in one of the following outcomes:

Full Approval

The Chief Investigator will be informed in writing. Notification of approval will include: approval number, start date, expiry date, species and total number of animals approved.

Interim Approval

Approval may be given for a particular number of animals so as to address some specific issues relating to the welfare. This may occur when:

- The project is a pilot study;
- The project is staged and reviewed at each stage before the next can proceed.

On occasions Pilot Studies are recommended to an applicant if experience with a particular procedure or animal seems to be insufficient so as to fully predict the animal related outcomes or if it is anticipated that the pilot study data will inform the calculation of appropriate animal numbers, and/or animal welfare issues.

For staged projects, a report to the Committee or the Executive on the first few animals will be requested, and depending upon the positive outcome, this may then allow the project to proceed as originally requested by the applicant.

Pilot studies, where proposed by the applicant or suggested or required by the AEC, should be regarded as integral to the overall project, essentially to enable assessment of the feasibility of the project and the potential for enhancement of the principles of Refinement and Reduction. Pilot Studies should be assessed by the AEC according to the usual criteria applied to project approval.

Pilot Studies may be stand-alone, or described as a 'Phase 1', depending upon the experience of the research group with the proposed model or the scientific question being asked.

The Chief Investigator is required to forward to the AEC a report on the result of a Pilot Study before approval is given to commence animal work on the full protocol.

Minor Modifications or Clarification Required

Where the AEC has queries or concerns, and requires clarification or alterations to the application, the Chief Investigator is notified and will be asked for a response to the points raised by the AEC. The response is either considered by the full committee at its next meeting, out-of-session by the full committee, by the AEC Executive or by the Chair and Deputy Chair. The decision about which mechanism is appropriate is decided at the time of the initial consideration and depends upon the inadequacies of the initial application. At the next formal meeting of the AEC, there will be a discussion of the "out-of-session" decisions, and the course of action must be ratified or rejected at that meeting.

Resubmission

Where the application is not approved due to major concerns by the AEC, the AEC will request a resubmission of the entire application. The Chief Investigator will be notified and will be asked to resubmit the application to address the points of concern raised by the AEC. The applicant may contact the AEC's delegated contact to discuss the Committee's concerns and obtain assistance in responding if necessary. The resubmission is then considered by the full AEC at the meeting following its receipt.

Rejection

This occurs where the AEC considers the work proposed contravenes existing legislation or the Code or that the welfare impact on the animals exceeds the scientific merit of the work.

9. APPROVAL PERIOD AND CONDITIONS

Applications are normally approved for 3 years, but under some circumstances approval can be for 5 years (e.g.. Breeding applications or long-term grants).

All approvals are subject to:

- Adherence to all provisions of the Code and the Act; and
- Submission of a satisfactory AEC Annual and/or Final Report for each calendar year, due by the end of January of the following year; and
- Adverse occurrences relating to animal use have been reported to the AEC and have been addressed to the satisfaction of the AEC.

10. APPLICATION TO AMEND AN APPROVED PROJECT

An amendment form must be completed and can be managed by the AEC Executive, the full Committee out-of-session, or at a formal meeting of the AEC. This decision is at the discretion of the Chair.

Additional Number of Animals Requested

- Where the increase is generally 1/3 or less of the original number, the request can be considered by the Executive. If, after consideration, the Executive decides the application requires review by the full committee, it will be submitted to the upcoming meeting for discussion and the researchers will be notified.
- Where the increase is more than 1/3 of the original number, the amendment must be considered by the full Committee.
- In circumstances where the above rules prove impracticable, (e.g. projects using a limited number of animals) the request can be dealt with at the discretion of the Chair and/or the Deputy Chair.

Extension of Time

Extensions to existing approvals may be given for a maximum of 24 months beyond the original expiry date. Extension requests can be considered by the Executive out-of-session.

Expired Projects

In exceptional circumstances the AEC may reinstate an expired project for a maximum of 12 months to satisfy a scientific imperative.

Change of Strain or Species

It is recognized that at times a change in strain of animal, or even species of animal, may be required. Its scientific justification needs to be presented to the AEC.

Animal Welfare Issues

Any change of protocol that involves animal welfare issues considered by the Chair to be minor can be dealt with by the Executive. Otherwise, such amendments should be dealt with by the full AEC.

Limit to number of Amendments

Generally, no more than three procedural amendments are to be applied for, except under exceptional circumstances as agreed to by the AEC.

In cases where more than 1/3 of the original number of animals are requested ie. If an amendment requests more than 1/3 of the original number of animals and approval was given at a meeting, any subsequent requests for additional animals must go to the full committee.

Where additional animals (more than 1/3 of the original number) have been approved by the full AEC any further amendment requests for additional animals, less than 1/3 of the **new total** can be considered by the AEC Executive. See Example 1.

| Example 1 | | | |
|-------------------------|---------------------------------|---|----------------------------|
| 1. Original Application | 100 animals approved | | |
| 2. Amendment 1 | 75 additional | Approved by full AEC | Total approved 175 animals |
| 3. Amendment 2 | 20 additional animals requested | Can be considered by the AEC Executive | |

Several amendments requesting additional animals can be considered by the AEC Executive if the number of animals requested is less than 1/3 of the original number. Any further amendments requesting additional animals must be considered by the full AEC. See Example 2.

| Example 2 | | | |
|-------------------------|---------------------------------|---------------------------------------|----------------------------|
| 1. Original Application | 100 animals approved | | |
| 2. Amendment 1 | 10 additional animals requested | Approved by AEC Executive | Total approved 110 animals |
| 3. Amendment 2 | 10 additional animals requested | Approved by AEC Executive | Total approved 120 animals |
| 4. Amendment 3 | 10 additional animals requested | Approved by AEC Executive | Total approved 130 animals |
| 5. Amendment 4 | 10 additional animals requested | Must be considered by full AEC | |

In cases where multiple amendments have been submitted, the Chair and Secretariat could determine if the amendments complied with the Guidelines and if not, a new project application would need to be submitted.

The principle being that repeated amendments become unreasonable because at some point a decision needs to be made when the scientific direction of the proposal is becoming unclear requiring a new application.

11. APPLICATION TO ESTABLISH AND MAINTAIN AN ANIMAL BREEDING COLONY

Any animal breeding programme conducted to supply animals for scientific research and teaching that is carried out on SAHMRI premises or by personnel employed by SAHMRI requires formal approval by the AEC.

Where it is proposed that a new strain or breed of genetically modified animal be bred an Application to Establish and Maintain an Animal Breeding Colony form must be submitted and approved.

Applications need to demonstrate compliance with the NHMRC Guidelines for the generation, breeding, care and use of genetically modified and cloned animals for scientific purposes.

The applicant must be the person who is responsible for the animal breeding procedures and animal care. The applicant may delegate this responsibility to an animal facility supervisor provided that the consent of that supervisor is obtained and evidenced in writing.

Cross-breeding can result in new and sometimes deleterious phenotypes. A final phenotype report should be completed for new hybrid strains. If the breeding results in a new phenotype, the report should be forwarded to the AEC and approved before the new strain can be regarded as breeding stock.

12. UNEXPECTED ADVERSE EVENT

An unexpected adverse event is an event as defined by the Code that is not anticipated and which impacts negatively on the wellbeing of animal(s). If there is an adverse event, animals must be appropriately assessed and treated, and veterinary advice sought, and a report provided to the AEC via the Chair/Secretariat. The AEC will take appropriate action in response to adverse events to ensure that animal wellbeing is not compromised, and for the issue to be addressed promptly and steps are taken to avoid future reoccurrence. The report process is a key part of continuous improvement whereby corrective actions are put in place to reduce or manage adverse events.

13. RESOLUTION OF DISAGREEMENTS WITHIN THE COMMITTEE

The risk of disputes relating to applications will be minimised by the use of AEC operating procedures in a manner that is confidential, fair to applicants, acceptable to AEC members, and compliant with the Code.

Operating procedures as outlined in the SAHMRI Workplace and Grievances Policy (POL 0016/2) will be followed for the resolution of any disputes, concerns or grievances that may arise between AEC members, the AEC and animal house staff, or between the AEC and researchers will be followed.

Decisions by the AEC with regard to approval, modification or rejection of a proposal, or withdrawal of approval for a project, should be made according to Section 8 of this document.

Members may request that their abstention/dissension be recorded in the Minutes.

14. PROCEDURES FOR HANDLING CONCERNS AND GRIEVANCES INVOLVING THE APPLICATION OF AEC RULINGS

If a researcher has a grievance about the operation or ruling of the committee, they should discuss it, in confidence, with the Chair of the AEC in the first instance. The Chair, after consultation with others deemed appropriate, will decide whether the matter is best referred back to the AEC or referred directly to the CEO, SAHMRI.

15. MANAGEMENT OF NON-COMPLIANCE

Reports of non-compliance with matters under the auspices of the SAHMRI AEC must be considered by the AEC. Concerns may be received from anyone and should be directed to the Chair. The procedures will ensure that persons may raise concerns without jeopardising their employment, careers or coursework.

The Chair is to use the principles outlined in Appendices 1 and 2 when managing complaints against the Committee or against the management of a particular project.

The remedies available to the AEC where non-compliances are considered to have occurred include:

- Stopping part or all of the animal research of one or more investigators;
- Suspension of a specific activity;
- Suspension of a specific project;
- Termination of a specific project;
- Specific action to be taken by the Chief Investigator and/or organisation;
- Preventing further animals being released;
- Notifying other AECs where applicable; As per the Deed for Reciprocal Access to Animal Ethics Committees;
- And/or referring the matter further to the institution.

16. REVIEW AND APPROVAL OF SOPs

Research Support Standard Operating Procedures (SOPs) are to be reviewed and approved by the AEC. SOPs that have been reviewed and approved or in the approval process will be uploaded on to the AEC Sharepoint site. Approved SOPs will then be put onto the appropriate data platform.

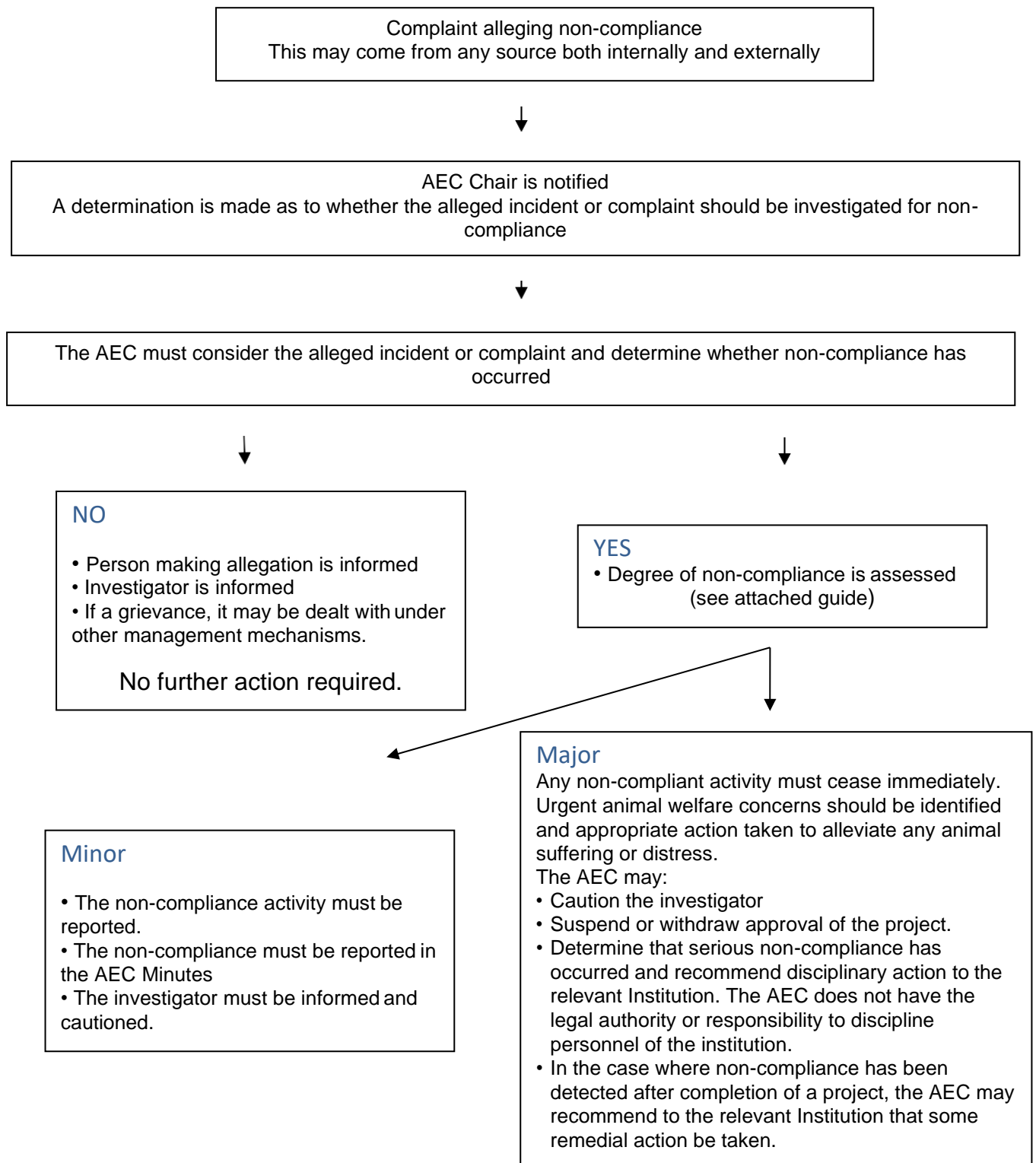
Project specific SOPs are attached to project applications and are approved as part of the experimental protocol. Any changes to the SOPs will require an Amendment Application to be submitted.

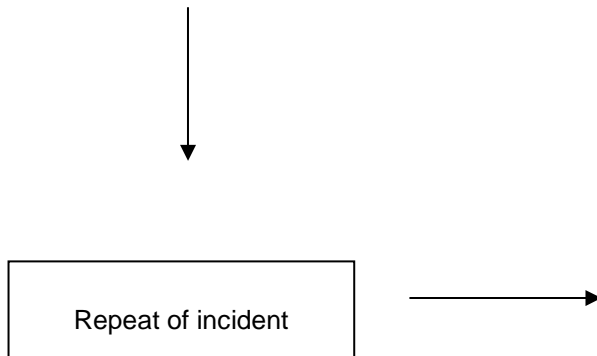
17. DEED FOR RECIPROCAL ACCESS TO AECs

A formal agreement between Institutions can be reached whereby applicants can apply to the AEC which has jurisdiction over the facility where the animals are housed. There are reporting responsibilities outlined in the Deed for Reciprocal Access to AECs.

Appendix 1

NON-COMPLIANCE





- The Chair report the outcomes of the AEC decision to the Executive Director
- The investigator is informed and has the right of appeal
- The Executive Director of the institution may report to the statutory authority
- In cases of major non-compliance, NHMRC must be notified and funding may be withdrawn

* See Code

Appendix 2

DEGREES OF NON-COMPLIANCE

| Level of Severity | Incident | Admin/Procedural/ Animal Impact |
|--------------------------|---|--|
| 5* | <ul style="list-style-type: none"> • AEC not quorate and project approved by non-quorate meeting, then it commences (invalid decision, animal use without approval) • Unauthorised animal use: <ul style="list-style-type: none"> - animal use for a project or use of an animal procedure without submission of an application to the AEC - animal procedure performed that is specifically not allowed by the AEC or legislation - animal use continues after approval has been withdrawn or suspended • Failure to submit annual or progress report | <p>Procedural</p> <p>Animal impact</p> <p>Administrative</p> |
| 4 | <ul style="list-style-type: none"> • Unauthorised animal use: <ul style="list-style-type: none"> - animal use for a project commences prior to written approval - failure to perform a procedure, eg regular monitoring, euthanasia, analgesia resulting in likely animal suffering | Animal impact |
| 3 | <ul style="list-style-type: none"> • Failure to report adverse outcomes to AEC • Unauthorised animal use: <ul style="list-style-type: none"> - animal use continues on a project where the period of approval has expired | <p>Animal impact</p> <p>Animal impact</p> |

| | | |
|---|---|--|
| | <ul style="list-style-type: none"> - overuse of animals detected by AEC or another party - change of procedure without AEC approval - overuse of animals reported by investigator - change of animal species or strain without submission of modification to AEC | |
| 2 | <ul style="list-style-type: none"> • - Failure to submit an annual or final report on time • - Failure to keep satisfactory records of animal use • - Animals held and not used • - Unauthorised investigator: Animal procedures performed by an investigator not included on project application | <p>Administrative</p> <p>Administrative</p> <p>Procedural</p> <p>Animal impact</p> |
| 1 | <ul style="list-style-type: none"> • Incomplete paperwork e.g. no signatures • Failure to submit a satisfactory annual or final report | <p>Administrative</p> <p>Administrative</p> |

* Considered to be major and should be dealt with by Executive Director

Please note that:

1. This document is for guidance only and each breach should be determined on a case-by-case basis keeping in mind the number of incidents, length of response time and whether the non-compliance was deliberate, a mistake or supplier error etc.
2. Communication between the AEC and animal facility staff is important to help compliance. For example, when filling out annual reports or when special conditions have been imposed.