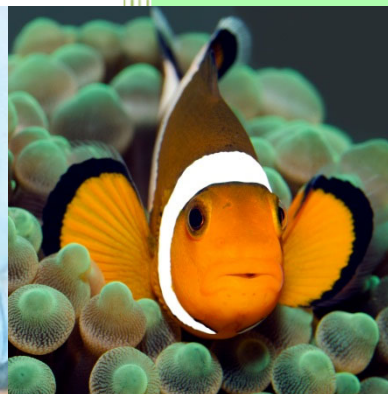
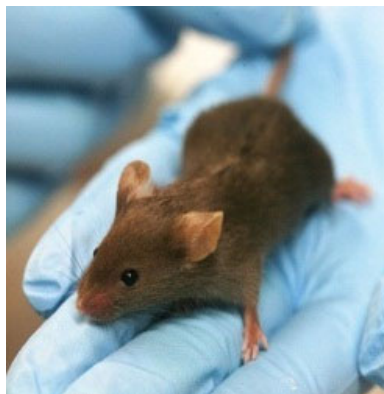




Flinders University Animal Ethics Committee

Operating Procedures



October 2020

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Flinders University Animal Ethics Committee

Operating Procedures

1 OVERVIEW

It is a requirement of the University, the *Australian Code for the Care and Use of Animals for Scientific Purposes, 8th edn 2013* (the Code), and the *South Australian Animal Welfare Act 1985* (the Act) that institutions, Animal Ethics Committees, and people involved in any aspect of the care and use of animals for scientific purposes must be aware of and accept their responsibilities, and act in accordance with the Code.

It is a requirement of the University and the Code that policies and procedures for the fair consideration of animal use proposals, as well as the resolution of disagreements, relating to animal ethics and animal welfare are established and implemented. Responsibility for the implementation of these procedures is shared by Animal Ethics Committees, institutional officers, and senior academic and management personnel. Responsibility for the approval of animal use proposals lies with the Animal Ethics Committee (AEC).

The Flinders University and Southern Adelaide Local Health Network Animal Ethics Committee is entitled the Animal Welfare Committee (AWC).

This document should be read in conjunction with the Flinders University and Southern Adelaide Local Health Network Animal Ethics Committee Terms of Reference.

1.1 Principles that Underpin the Operation of the AEC

- The use of AEC operating procedures will enhance Committee practices that are confidential, fair and reasonable, respectful, and compliant with the Code.
- The risk of disputes relating to applications will be reduced by the use of AEC operating procedures.
- AEC decisions are to be made in a manner that is acceptable to committee members and that is compliant with the Code.
- The AEC evaluates research proposals and communicates with researchers in a manner that is respectful, fair, responsive, transparent, and in which the welfare of animals is given primary consideration.
- Respect for animals must underpin all decisions and actions involving the care and use of animals for scientific purposes. This respect is demonstrated by:
 - (i) Using animals only when it is justified.
 - (ii) Supporting the wellbeing of the animals involved.
 - (iii) Avoiding or minimising harm, including pain and distress, to those animals.
 - (iv) Applying high standards of scientific integrity.
 - (v) Applying Replacement, Reduction, and Refinement (the 3Rs) at all stages of animal care and use:

- a. the Replacement of animals with other methods;
 - b. the Reduction in the number of animals used; and
 - c. the Refinement of techniques used to minimise the adverse impact on animals.
- (vi) Knowing and accepting one's responsibilities.

2 OBJECTIVES AND POWERS OF THE AEC

2.1 AEC Chair

- 2.1.1.** The Chair of the AEC is to be appointed by the DVCR and is responsible to him/her.
- 2.1.2.** The Chair should hold a senior position in the University, with committee leadership experience and relevant expertise. The Chair selection criteria include:
- 2.1.2.1. An ability to communicate well, which includes a capacity to listen to, and appreciate, the views of others, to formulate and express a considered opinion, and a willingness to enter into a process in which differences and conflicting points of view can be explored and resolved;
 - 2.1.2.2. A demonstrated capacity to critically analyse ethical issues as they apply to the use of animals for research or teaching purposes in accordance with legislative and regulatory frameworks and community expectations;
 - 2.1.2.3. Strong commitment to attend meetings, to review research proposals and other relevant documents, and to keep abreast of changes in the animal research ethics environment;
 - 2.1.2.4. Appreciation of community sensitivities associated with the use of animals for research or teaching purposes; and
 - 2.1.2.5. An understanding of the importance of, and a willingness to maintain, confidentiality.
- 2.1.3.** In accordance with the Act and the Code, the Chair is responsible for:
- 2.1.3.1. Impartially guiding the operation of the AEC and ensuring a balanced and transparent approach to the regulation of animal welfare;
 - 2.1.3.2. Ensuring that animal welfare is the primary consideration of the AEC;
 - 2.1.3.3. Ensuring that each application is properly considered and that all issues relevant to the Act and Code are raised and discussed;
 - 2.1.3.4. Ensuring that the Terms of Reference for the AEC are met;
 - 2.1.3.5. Guiding the process of an AEC meeting so that all AEC members have an opportunity to raise issues, resolve conflicts, and reach consensus in decision making in a timely manner;
 - 2.1.3.6. Where differences cannot be resolved within the AEC, conducting a vote, and ensuring that approvals and dissents are recorded in the minutes of the meeting;

- 2.1.3.7. Ensuring that any matters related to conflicts of interest and confidentiality are attended to;
 - 2.1.3.8. Oversight of the AEC Executive, and ensuring fair and reasonable consideration of approvals;
 - 2.1.3.9. Making decisions about adverse events, non-compliance, or other situations requiring immediate action on behalf of the AEC; and
 - 2.1.3.10. Representing the AEC in any negotiations with University management and other relevant organisations.
- 2.1.4. The DVCR shall appoint a Committee member as Deputy Chair who will also serve as Acting Chair in the absence of the Chair.

2.2 Executive Officer (EO)

- 2.2.1. An Executive Officer (EO) shall be appointed by the University, from Research Development and Support, to assist the Chair in managing the regulatory and practical aspects of AEC operations. The EO (or delegate) will be in attendance at AEC meetings, but will not be a voting member of the AEC. The duties of the EO will be as described in the relevant Position Description.
- 2.2.2. The EO will be provided with adequate resources to carry out their responsibilities in addition to supporting the AEC, as required by the Code (section 2.2.19). Resources should include:
- 2.2.2.1. Staffing and administrative assistance;
 - 2.2.2.2. Financial resources; and
 - 2.2.2.3. Appropriate orientation, education, and training.

2.3 AEC Executive

- 2.3.1. The Committee may appoint an Executive to carry out certain tasks on behalf of the AEC out of session.
- 2.3.2. The Executive must comprise at least two members, being:
- 2.3.2.1. The Chair (or delegate); and
 - 2.3.2.2. One Category C or D member.
- 2.3.3. The Executive will be administered by the EO. The EO will not be a voting member of the Executive.
- 2.3.4. The Executive may approve revised applications that have already received Pending Approval from the AEC, as long as the conditions imposed by that approval have been satisfied.
- 2.3.5. The Executive may approve minor modifications, and a 1 year extensions of time, to currently approved projects.
- 2.3.6. When reviewing revised applications or minor modifications, the Executive may seek advice from the Animal Welfare Officer (AWO) regarding animal impact or welfare considerations.

- 2.3.7.** Should the Executive fail to reach consensus regarding a revised or minor application, the application must be referred back to the full AEC at its next meeting.
- 2.3.8.** The Executive may deal with emergencies, including but not limited to unexpected adverse events, natural disasters, or breaches of approved project protocols.
- 2.3.9.** Any decision made by the Executive must be reviewed and ratified by the AEC at its next meeting.

2.4 Frequency of AEC Meetings

- 2.4.1.** Meetings are scheduled by the EO in consultation with the Chair.
- 2.4.2.** The timetable of meetings for a calendar year should be available before the final meeting of the previous year, and any changes to the dates should be made in consultation with as many members as possible.
- 2.4.3.** The timetable of meetings must include a closing date for submission of applications for each meeting. The closing date must be set to allow adequate time for processing of applications, preparation of meeting documents, and assessment of applications by reviewers prior to the meeting date. Timetables are advertised on the AEC website.

2.5 Quorum

In accordance with the Code, at least six members (as defined below) are required at meetings of the AEC in order to achieve quorum.

- 2.5.1.** The quorum consists of a Chair plus at least one member representative of each Category A to E (refer below); a quorum must be maintained for the duration of each AEC meeting.
- 2.5.2.** Category C plus D members must represent no less than one third of the Category A plus B plus C plus D members present.
- 2.5.3.** If necessary, and preferably prior to the meeting, members from Category A or B can be asked to leave the meeting, so as to maintain the “Category C plus D ‘one third’ rule” whilst maintaining the “one member representative of each Category” rule.
- 2.5.4.** The four categories of membership under the Code are:

Category A - a person with qualifications in veterinary science that are recognised for registration as a veterinary surgeon in Australia.

Category B - a researcher currently employed by the University with substantial and recent experience in the use of animals for scientific purposes.

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 currently involved in the care and use of animals for scientific

purposes.

Category D - a person not employed by or otherwise associated with the institution and who has never been involved in the use of animals in scientific or teaching activities.

- 2.5.5.** In addition, Animal Facility Managers, or nominated representatives, must also attend AEC meetings as Daily Care members ("Category E").
- 2.5.6.** In the situation where the proposer of an application is a committee member, and must remove himself/herself from the meeting during consideration of that application due to a conflict of interest (see Section 17), and thereby resulting in the discussion becoming inquorate, the use of teleconference processes with an alternate member can be used to deal with the matter at hand.

2.6 Sub-Committees

- 2.6.1.** The AEC has established two Sub-Committees, the College of Science and Engineering Animal Welfare Sub-Committee (AWS-C), and the College of Medicine and Public Health Animal Ethics Review Sub-Committee (AERSC), which review applications from their respective (and most closely associated) Colleges.
- 2.6.2.** Appointments and re-appointments of members to the AWS-C and the AERSC are approved by the DVCR or delegate/nominee.
- 2.6.3.** The Sub-Committees act as advisory committees to the AEC regarding the scientific validity of the protocols for all AEC applications. They have delegated responsibility for nominating assessors for all projects and reviewing all applications.
- 2.6.4.** The Sub-Committees assess all applications and forward the conclusions of their deliberations to the AEC for consideration. Applications are assessed according to:
 - 2.6.4.1.** The experimental classifications of the Code;
 - 2.6.4.2.** Pain levels set out in the Act; and
 - 2.6.4.3.** Any relevant pain classification systems developed by the AEC.
- 2.6.5.** The AWS-C and AERSC do not approve projects. The Sub-Committees forward all applications, along with their conclusions, to the AEC. The AEC may endorse, reject, or amend the conclusions of the Sub-Committees.
- 2.6.6.** All Sub-Committee members are required to respect confidentiality of documents circulated and business discussed at meetings, and to sign a confidentiality agreement to this effect.

2.7 Communication with Researchers

- 2.7.1.** All communication from the AEC will be sent via the EO or the AEC Chairperson.
- 2.7.2.** All researcher communication to the AEC should be sent via the EO.

2.8 Animal Welfare Officer (AWO)

- 2.8.1. The Animal Welfare Officer (AWO) provides specialist expertise in the management of animal welfare and veterinary treatment related to research and teaching conducted by University staff and students.
- 2.8.2. The AWO should have adequate training/qualifications/skills in training and assessment.
- 2.8.3. The AWO will work closely with the University's AEC and its Sub-Committees, Animal Facility staff, Research Development and Support, and staff involved in research and teaching, to ensure that the use of animals in research and teaching is carried out according to the highest standards of animal welfare, and complies with relevant State legislation and national codes and guidelines.
- 2.8.4. The key responsibilities of the AWO include:
 - 2.8.4.1. Providing veterinary advice to the AEC and its sub-committees, and contributing to the development and review of technical policy and procedure documents related to the care and use of animals for research and teaching.
 - 2.8.4.2. Promoting awareness of, and adherence to, the requirements of the Act and the Code.
 - 2.8.4.3. Implementing action necessary to ensure that the requirements of the Act and the Code are met, and decisions of the AEC are complied with, including on-call availability for situations where urgent attention is required.
 - 2.8.4.4. Inspecting and monitoring all University facilities where animals are housed, to ensure the welfare of animals, and monitoring or liaising with external sites when required.
 - 2.8.4.5. Providing advice to staff and students in the preparation of research proposals involving animals, and for the development and maintenance of required standards of animal welfare.
 - 2.8.4.6. Participating in the ethical review of applications for approval to use animals, and providing advice to the AEC.
 - 2.8.4.7. Assisting in the provision of training to staff and students regarding technical procedures and animal welfare, and providing related advice to members of the AEC.
 - 2.8.4.8. Providing veterinary diagnostic and treatment services and advice to Animal Facility management and personnel.
 - 2.8.4.9. Inspecting and certifying animals for import and export.
 - 2.8.4.10. Liaising with regulatory authorities for drug and biological product purchase and use.
 - 2.8.4.11. Authorising and supervising the purchase and use of prescribed substances regulated by the *Controlled Substances Act (1984)*.
 - 2.8.4.12. Implementing emergency actions to animal ethics projects and

training activities to protect animal welfare, scientific integrity, or disease prevention and control.

2.8.4.13. Other duties as directed by the Director, Research Development and Support.

2.8.5. Where the AWO has implemented action without prior AEC approval in an emergency or unforeseen situation, the AWO must inform the Chair, EO, and Animal Facility Manager as soon as possible, and must inform the AEC at the next AEC meeting via a detailed AWO Report. If the action requires an ongoing change to a project, then the AWO must inform the researcher that a Modification Application must be submitted to the Executive or the next AEC meeting.

3 PROCEDURES FOR THE CONSIDERATION OF ANIMAL USE PROPOSALS

The procedures followed by the Animal Ethics Committee when considering proposals for breeding, holding, and use of animals for scientific purposes must comply with Sections 2.2.15 – 2.2.25 and Section 4 of the Code. Only those scientific, teaching, and husbandry activities that conform to the requirements of all relevant Sections of the Code and legislation may be approved.

3.1 Information to Be Supplied to the AEC

- 3.1.1. Applications should be submitted to the AEC through *ResearchNow Ethics and Biosafety*. The application should contain sufficient information to satisfy the AEC that the proposed use of animals is justified and complies with the ethical principles of replacement, reduction, and refinement. There should also be sufficient information to evidence the weighing of scientific or educational merit against the impact to animal welfare, and there should be a justification given for the number of animals requested.
- 3.1.2. Applications should be written in plain English at a level that can be understood by lay people. The predicted impact to animals must be identified in all sections of the application, and the means by which this impact will be minimised should be clearly described.
- 3.1.3. All sections of the application form must be completed in order to comply with the Code. The application form will not be put before the AEC until all sections are complete.
- 3.1.4. Applications should first be reviewed by the relevant AEC Sub-Committee, and the comments of reviewers responded to. The finalised application must be received by the EO by the deadline (as listed on the Animal Ethics website), in order to be included on the agenda of the next AEC meeting.

3.2 AEC Consideration of Animal Use Proposals

- 3.2.1. New proposals and renewal of existing projects must only be considered and approved at quorate meetings of the AEC, as defined in section 2.5.
- 3.2.2. The AEC must be satisfied that the proposed use of animals is justified by weighing the predicted scientific benefits against the potential impact to the welfare of animals.
- 3.2.3. AEC members must treat the information supplied by researchers as confidential, and undertake not to disclose the specifics or the sensitive aspects of the application to people outside the AEC, except where this is needed by a function of the University. Information can be sought by AEC members from contacts outside the AEC, but members must not identify the investigators or divulge information that could identify the project or aspects which could be regarded as scientifically or commercially sensitive. Members will seek advice from the EO or AEC Chair if they are unsure how to balance their responsibilities.

3.3 Outcomes Following AEC Consideration

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

3.3.1. *The Application is Approved Outright*

- 3.3.1.1. Where a project is approved outright at a meeting, the researcher will receive an Approval Notice, which contains the following information:
 - (i) The expiry date of the project – projects are normally approved for a period of 3 years unless a shorter timeframe is requested.
 - (ii) Researchers are expected to comply with reporting requirements for (a) Unexpected Adverse Events, (b) Annual Reports including numbers of animals used, and (c) a Final Report; both types of report are due by 1st February.
 - (iii) Reminder that the researcher is responsible for the animals from the date of issue, and that Clinical Record Sheets are expected to be kept with the animals in the Animal Facility at all times.
 - (iv) At any time the researcher does not comply with these requirements, the AEC has the power to suspend their project and report this suspension to the DVCR as well as the NHMRC/ARC, as appropriate.

3.3.2. *The Application Receives Approval with Conditions*

- 3.3.2.1. Where a project is approved and has been issued with an Approval with Conditions Notice, all those conditions (such as reports, AWO consultation, AWO inspection, video recording, etc) will be specified on the notice of approval issued to the applicant. These may include specific requirements for reporting, consultation with or inspection by the AWO, video recording of approved procedures, or other conditions as may reasonably be required by the AEC.

- 3.3.2.2. A register of conditions imposed for each project concerned will be maintained by the EO, and the AEC will review completed and outstanding conditions in an AEC meeting for compliance.
- 3.3.2.3. Once an approval condition has been completed, it can be approved by the Chair, EO, Executive, or AEC, as advised by the AEC. Where approved by the Chair, EO, or Executive, it must be ratified by the AEC in the next AEC meeting.

3.3.3. *The Application Receives Pending Approval*

- 3.3.3.1. Where a project has received a Pending Approval Notice, the AEC approves the application subject to specified changes being made to the application before the project can commence.
- 3.3.3.2. The researcher must submit a revised application. The AEC will specify whether this application may be subject to final approval by the AEC, or by the Executive (as described in section 4).
- 3.3.3.3. The researcher will then be issued with an Approval Notice, or Approval with Conditions Notice. Where approved by the Executive, the approval of these projects will be recorded on the next AEC meeting agenda for ratification by the committee.

3.3.4. *The Application Receives Deferral/Not Approved*

- 3.3.4.1. Where an application provides insufficient information for a proper assessment to take place, the researcher will receive a Deferral/Not Approved Notice. The AEC may request that it be resubmitted for approval, and specific concerns should be communicated to the researcher, indicating what areas need to be revised before a new application can be submitted.

4 EXECUTIVE APPROVAL

Where a modification has been received for urgent approval, or where a modification has been received with minor changes (such as extensions of time or change of personnel), a process of Executive approval will be invoked. Pending Approval applications may also be examined by the Executive, if specified by the AEC.

For Executive Approval, the EO will circulate all necessary papers to the AEC Executive (refer section 2.3). This group may also include the AWO, where appropriate.

When responses have been received from all parties and the Chair deems this to constitute approval, the researcher will be issued with an Approval Notice or Approval with Conditions Notice.

5 MUTUAL AGREEMENT DEED

Flinders University has in place a “Deed for Reciprocal Access to Animal Ethics Committees” with most South Australian AECs, and some interstate AECs. This means that where teaching, research, or experimentation will be undertaken by a collaboration of staff from multiple institutions, in most instances only a single AEC approval is required for the activity.

Approval must be obtained from the AEC established by the institution that is responsible for the premises in which the animals will be held. However, if the animals will not be held captive, approval must be obtained from the AEC established by the institution which employs or engages the primary applicant on an Animal Ethics application.

The AEC must comply with the terms of the “Deed for Reciprocal Access to Animal Ethics Committees”.

6 ANNUAL AND FINAL REPORTING

6.1 Annual Reports

An Annual Report is required from researchers. The EO will issue a reminder to all researchers individually by email approximately two months in advance of the due date (1st February). Annual Reports will be accepted up to 1st February in the following year. If not received by that date, the researcher and Animal Facility Manager will be notified that the project is suspended until the submission of a completed Annual Report is received and approved by the AEC. The Dean (Research) of the relevant College, and the DVCR will be notified if it becomes clear there is little likelihood of receiving the report within the required timeframe as this is considered a staff performance issue.

Funding bodies may also be notified.

6.2 Final Reports

A Final Report is required for each project at its expiry date unless an extension of time has been received or approved before the approval expiry on 31st December. The EO will issue a reminder to researchers individually by email approximately two months in advance of the due date (1st February). The Animal Facility Manager will also be notified that the use of animals in this project has now ceased. If a Final Report is not received by 1st February in the following year, the Dean (Research) of College, and DVCR will be notified if it becomes clear there is little likelihood of receiving the report within the required timeframe.

7 MANAGEMENT OF ADVERSE EVENTS

7.1 What is an Unexpected Adverse Event?

An Unexpected Adverse Event is an adverse event that was not foreshadowed in the application approved by the AEC. Unexpected adverse events may be caused by, but are not limited to, the following:

- 7.1.1.** Death of an animal, or group of animals, that was not expected or was prior to planned death (e.g., during surgical procedure, during anaesthesia, following a procedure or treatment).
- 7.1.2.** Adverse effects following a procedure or treatment that were not expected. Examples of clinical signs that may develop include, but are not restricted to, diarrhea, vomiting, respiratory difficulty, collapse, abdominal swelling, and rapid weight loss.
- 7.1.3.** If at any point in the project, the percentage of morbidity or mortality exceeds the stated amount in the application, this constitutes an Unexpected Adverse Event.
- 7.1.4.** A greater level of pain or distress than was predicted during the planning of the project.
- 7.1.5.** Power failures, inclement weather, etc., that impact on the welfare of the animals.

7.2 Legislative Requirements

Clause 2.5.5 of the Code requires investigators, teachers, and Animal Facility Managers to promptly notify the AEC of any unexpected adverse event that may impact on the wellbeing of an animal in their care.

In addition, in the event that an animal dies unexpectedly, or is euthanized due to unforeseen complications, a post-mortem examination must be performed by a person with appropriate qualifications and/or experience, or the AWO, and the AEC must be notified promptly. Requirements of the Code are also embedded in the Act under Part 4 – ‘Teaching and research involving animals’. More generally, all persons involved in the care of animals used for scientific purposes have a duty of care towards those animals to take action to minimise pain and suffering. This means that anyone who notices that an animal is showing signs of distress should report it immediately to the Primary Investigator, as well as the Manager of the Animal Facility or the AWO.

7.3 Reporting an Unexpected Adverse Event

- 7.3.1.** Following an unexpected adverse event, the AWO must be notified as soon as possible, but within 24 hours of the incident, unless other arrangements have been approved by the AEC within the original application. A post-mortem examination must be performed following a mortality deemed to be an unexpected adverse event, preferably following the AEC-approved post-mortem examination guidelines document.
- 7.3.2.** An Unexpected Adverse Event Report should be submitted to the EO as soon as possible, but within 3 working days. The report must include the following information:
 - 7.3.2.1.** Summary of circumstances leading up to the unexpected adverse event;
 - 7.3.2.2.** Actions taken from the time the problem was noticed;
 - 7.3.2.3.** Results of the post-mortem examination, if available, where animals have died;

- 7.3.2.4. Proposed actions to prevent or correct the specific or probable cause of the problem; and
- 7.3.2.5. Attach Clinical Record Sheets, or other monitoring sheets, even if they do not appear to include any useful information.

8 PROJECT EXPIRY

A project expires at the date specified as the expiry date. This is normally 31st December of a specific year. All researchers are eligible for one 1-year extension of time until the date of expiry, however, if a researcher does not apply for an extension of time for a project before it expires, then the project will be suspended and they will be required to submit a new application for the project.

9 RESEARCHER NON-COMPLIANCE

9.1 What is Non-Compliance?

Non-compliance is defined as non-compliance with the Code by any party or person involved in the care and use of animals, including investigators, animal carers, the AEC, governance officials, and external parties subject to agreements described in the Code (clauses 2.6.3 and 2.6.6). Non-compliance may involve investigators acting outside of the terms of AEC approval, or where conditions tied to an AEC approval are not fulfilled. Non-compliance may also involve breaches of relevant state or territory legislation.

9.2 Actions Following Non-Compliance

The AEC shall maintain records of breaches of the Code.

For projects discovered to be non-compliant with the Act, Code, or other relevant guidelines, the AEC may:

- 9.2.1. Provide written warning (see section 10).
- 9.2.2. Require a letter of explanation.
- 9.2.3. Require immediate action.
- 9.2.4. Notify the researcher's supervisor, Head of Department, Dean (Research) of College, DVCR, and/or relevant funding bodies.
- 9.2.5. Implement new reporting requirements or conditions of approval.
- 9.2.6. Withdraw project approval.

10 BREACH NOTICES

The AEC may send a written warning in the form of a:

10.1 Minor Breach Notice

A Minor Breach Notice is issued when an unintentional or minor breach has been identified that is deemed by the AEC to be a minor infringement to the conditions of approval. When a Minor Breach Notice is received, the project may continue without interruption provided that all conditions as set out above are strictly adhered to. There is no limit to the number of Minor Breach Notices that one project can receive.

10.2 Major Breach Notice

A Major Breach Notice is issued when an intentional, negligent, or major breach has been identified that is deemed by the AEC to be a significant incident or a major infringement to the conditions of approval. Each project is only allowed to receive a maximum of one Major Breach Notice. Any future incidence of non-compliance (warranting a second Major Breach Notice) can result in immediate suspension of the project, and the DVCR and the regulator being notified as required under the Code.

10.3 Suspension Notice

A Suspension Notice can be issued when it is deemed to be required by the AEC. Suspension Notices can be temporary or permanent. Suspension Notices can be a result of a breach of approval, or following submission of an Unexpected Adverse Event Report, or due to other non-compliance (such as non-compliance with mandatory training requirements, or as a result of Annual/Final Reports not be submitted within the required timeframe). Where appropriate, the DVCR will be notified regarding suspended projects.

11 MEETING PAPERS AND REVIEW PROCESS

11.1 Sub-Committee Review

Applications to the AEC are submitted through one of its two sub-committees, the College of Medicine and Public Health Animal Ethics Review Sub-Committee (AERSC) and the College of Science and Engineering Animal Welfare Sub-Committee (AWS-C). The sub-committees, composed of internal researchers with substantial and recent animal research experience, review the applications to assess scientific merit and claims for justification of animal use. In addition, any minor spelling or editing errors are corrected at this level.

11.2 AEC Review

Once approved by the Sub-Committee, the AEC reviews the application for animal welfare issues and decides whether an application may be approved.

The EO will be responsible for assembling the meeting agenda and uploading papers using a suitable University or web-based file-sharing service, for informed consideration by the AEC. This process will be in consultation with the Chair who may recommend inclusion of additional information, invitation of specific researchers or advisors to the meeting, or other

inclusions necessary to the process of fair and reasonable consideration of applications or correspondence. These meeting papers will be uploaded a minimum of one week in advance of the meeting date. Addendums to the agenda will only be issued if there are matters for urgent consideration by the AEC.

When applications are uploaded, three AEC members will be nominated as reviewers per application. This trio will consist of one veterinary Category A member, one internal researcher Category B member, and an external Category C or D member. Either the Category A or B member will be the primary reviewer and will be called upon by the Chair at the meeting to summarise the application for the committee, identify any administrative issues for the application, and present the issues relevant to animal welfare for discussion. The Chair will convene and direct this discussion to conclusion and committee decision.

12 ANIMAL FACILITIES (AF)

12.1 AF Inspections

Each year the EO will develop a schedule of Animal Facility inspections. The AEC will perform a general inspection of each Animal Facility at least once per year. In addition, where required, the AEC will perform one inspection of each Animal Facility that targets a specific issue (such as Clinical Record Sheets, adverse events, cleanliness and hygiene, labelling of animals and cages, etc).

12.2 AF Reports

Each Animal Facility must provide an Animal Health Monitoring Report to every AEC meeting, covering the period between each report. The Animal Health Monitoring Reports must be considered and approved by the AEC.

12.3 AF Standard Operating Procedures (SOP) and Safe Work Method Statements (SWMS)

Animal Facility Standard Operating Procedures (SOPs) and Safe Work Method Statements (SWMS) must be approved by the AEC, after which they will be publically available on the AEC website. The SOPs may be divided under broad headings such as the College of Medicine and Public Health, and the College of Science and Engineering. Researchers are encouraged to use the available SOPs/SWMSs when referring to techniques and procedures within applications.

Any researcher-created SOP must use the Animal Facility template and must first receive Animal Facility Manager and/or AWO approval, before being sent to the AEC for approval and addition to the AEC website. Revisions to approved SOPs/SWMSs can be approved by the Executive.

13 REGISTER OF PROJECTS CONSIDERED NOT TO REQUIRE AEC APPROVAL

The EO will maintain a Register of the use of animals in projects which are defined as being outside of the requirements for an AEC approval, but which have implications for Flinders University and research integrity. These projects would normally include situations where animal tissue will be scavenged from dead animals. In the case of scavenged tissue, the researcher will be required to complete a coversheet with information regarding the source of the tissue, the use of the tissue, the place where the tissue will be used and how it will be disposed of. The AEC is acutely aware of the need to monitor this with regard to biosafety issues. All applications nominated for the Register must be approved by the Chair before they can be added to the Register. The EO will maintain a “Register of Projects Deemed Not to Require Animal Ethics Approval” guidelines document that is to be made publically available on the AEC website.

14 ANIMAL WELFARE TRAINING FOR RESEARCHERS

14.1 Animal Ethics Online Training (AEOT)

In order to work with animals at Flinders University, all staff and students (both internal and external) must complete Flinders University’s Animal Ethics Online Training (AEOT) before they can apply for an Animal Ethics Application. In addition, all staff or students who are new to animal research must also attend the next available Animal Ethics Group Workshop (AEGW). New staff who have significant previous experience may be granted an exemption by the AEC upon application.

This training will provide researchers with the knowledge and skills to promote the ethical, humane, and responsible care and use of animals for scientific and teaching purposes. It consists of short readings, followed by a multiple choice quiz.

Animal Ethics Online Training replaces the formally held Animal Welfare Day (AWD).

14.2 Animal Ethics Group Workshop (AEGW)

All staff and students (both internal and external) must attend one AEGW in order to work with animals. New staff who have significant previous experience may be granted an exemption by the EO upon application.

The AEGW is a 2 hour small group workshop that focuses on various topics, such as ethics application forms, Clinical Record Sheets, animal scoring, and problem solving situations. The workshops will be staggered throughout the year.

14.3 Animal Researcher Information Session (ARIS)

A 1 hour seminar will be conducted at least once a year for all researchers to refresh their knowledge and understanding of current thinking in animal welfare, the regulation of the use of animals in research and teaching, and current best practice. This will be followed by a panel discussion of issues raised by the participants. It is mandatory that all researchers either complete Animal Welfare Refresher Training (AWRT) or attend Animal Researcher

Information Session (ARIS) at a minimum of every 3 years.

14.4 Animal Welfare Refresher Training (AWRT)

Animal Welfare Refresher Training (AWRT) is an animal ethics refresher training course that provide researchers with the knowledge and skills to promote the ethical, humane, and responsible care and use of animals for scientific and teaching purposes. It consists of short readings, followed by a multiple choice quiz. It is mandatory that all researchers either complete Animal Welfare Refresher Training (AWRT) or attend an Animal Researcher Information Session (ARIS) at a minimum of every 3 years.

14.5 Animal Facility Induction and Skills Training

The Animal Facility Manager will conduct an induction program for new Animal Facility users and offer training in specific techniques for both new and senior researchers. Researchers will be supervised until considered competent and then their names will be entered on a skills register.

Researchers are responsible for ensuring that all animal procedures and interventions are performed in accordance with the AEC approval and/or any conditions that pertain to that approval, by people competent for the procedures with adequate training, or are performed under the direct supervision of a person competent to perform the procedures. The Chief Investigator of a project is responsible for ensuring provisions are made for the education, training, and supervision of all staff and students listed on their project.

14.6 ANZCCART Scholarships

Research Development and Support will offer financial support for up to two researchers (1 from each of the two relevant Colleges) to attend the annual Australian and New Zealand Council for the Care of Animals in Research and Teaching (ANZCCART) conference each year, where feasible.

14.7 Volunteer Animal Ethics Test

The Volunteer Animal Ethics Test is only to be used by field work volunteers who are working on a project on a limited/once-off basis, and will not handle the animals. The inclusion of volunteers must be foreshadowed in the approved animal ethics application prior to commencement.

The Volunteer Animal Ethics Test is composed of two documents. The first document is entitled the "Volunteer Information Manual", which includes information that provides volunteers with the knowledge and skills to promote the ethical, humane, and responsible care and use of animals for scientific and teaching purposes. The second document is entitled the "Volunteer Question Booklet", which contains several questions based off the "Volunteer Information Manual" that must be answered by the volunteer. Supervisors must then go through the completed and signed "Volunteer Question Booklet" with volunteers and discuss the answers.

15 AEC MEMBER TRAINING

15.1 Induction of New AEC Members

- 15.1.1. Where possible, prospective new members, subject to signing a confidentiality agreement, will be offered an opportunity to attend an AEC meeting prior to being formally invited to become a member.
- 15.1.2. Newly-appointed AEC members will be provided with an “AWC Members Induction Pack”, and copies of the Code and the Act.
- 15.1.3. New members will be asked to attend an Induction with the EO, which will include an overview of the Act and the Code, an introduction to the application forms and how to review them, a synopsis of the Committee process, and a discussion of the roles of the Category A to E members.
- 15.1.4. All members will be added to the ANZCCART mailing list.

15.2 Ongoing Training of AEC Members

AEC members will receive ongoing training in the form of:

15.2.1. ANZCCART

AEC members will be encouraged to attend the ANZCCART conference, and two members, in addition to the Chair, AWO, and EO, will be supported by Research Development and Support to attend each year, where feasible.

15.2.2. Investigator Seminars

Various researchers will be invited to attend and present at after-AEC meeting “Investigator Seminars” (10 – 60 minutes) to increase AEC members’ understanding of research projects, research issues, or animal ethics issues. These will be planned to not coincide with Animal Facility inspections, where possible.

16 COMPETENCY SKILLS REGISTER

The Competency Skills Register is maintained through *ResearchNow Ethics & Biosafety* as of November 2020.

All current researchers should aim to have their competency acknowledged on the Competency Skills Register.

A separate AWC approved (internal only) document entitled “Competency Training and Assessment Guidelines” has been created to outline the basic guidelines of the Competency Skills Register.

17 RETENTION OF RECORDS

17.1 Record Management

- 17.1.1.** Full documentation of AEC business will be maintained by Research Development and Support, and managed by the EO.
- 17.1.2.** All records pertaining to research projects or protocols must be retained in accordance with the Government of South Australia General Disposal Schedule 24, as follows:
 - 17.1.2.1.** Research or teaching program protocol applications for animal ethics approval and related correspondence may be destroyed 7 years after the last action is completed;
 - 17.1.2.2.** Records relating to breaches of ethical practice and complaints in relation to research or teaching must be retained as per Sections 8.2.1 or 8.2.2, whichever is relevant; and
 - 17.1.2.3.** Records relating to the monitoring of ethical practices, including individual project monitoring, annual review of activities, internal reports to governing bodies, summary reports, and compliance reports to external bodies, must be retained as per Sections 8.2.1 or 8.2.2, whichever is relevant.
- 17.1.3.** If a record is reactivated after a retention period has commenced, the time is recalculated from the date of the subsequent last action. The reactivation of a record is triggered by such events as:
 - 17.1.3.1.** Record retrieved to meet a Freedom of Information (FOI) request.
 - 17.1.3.2.** Record retrieved to meet a subpoena.
 - 17.1.3.3.** Record accessed for research.
 - 17.1.3.4.** Record identified as being of significant risk management status.
 - 17.1.3.5.** Record identified as being required for possible legal proceedings.

18 MEDIA AND COMMUNICATION WITH THE PUBLIC

All external media issues and requests are to be directed to the DVCR.

All internal media issues and requests are to be directed to the Chair, in the first instance.

All Freedom of Information applications will be directed to the Policy and Secretariat Administrative Officer, Governance Unit.

19 CONFLICT OF INTEREST

19.1 AEC Member Conflict of Interest

- 19.1.1.** The Agenda for each AEC meeting should state that members are required to

declare a conflict of interest, and must refrain from voting on, and remove themselves from the discussion of, an item of business in which they have a pecuniary, personal or other conflict of interest.

- 19.1.2.** When a member of the AEC is an applicant on a project, or has another declared conflict of interest, the member must leave the room during the discussion of the project and during the decision-making process. Whilst a member may be given the opportunity to clarify aspects of the project with which he or she is involved, this must not be a greater opportunity than is afforded to other applicants.
- 19.1.3.** The Minutes of the meeting should clearly record whether a member with a conflict of interest has:
 - 19.1.3.1.** Absented himself / herself from the meeting during discussion of an application or business item; or
 - 19.1.3.2.** Absented himself / herself from the room during the decision-making process, and only responded to questions directed to him / her by the Committee.