

Australian Nuclear Science and Technology Organisation (ANSTO)

Australian Synchrotron, ANSTO Animal Ethics Committee

TERMS OF REFERENCE

AND

OPERATING PROCEDURES

As at February
Version 2.0

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Abbreviations

AEC	Animal Ethics Committee
ANSTO	Australian Nuclear Science and Technology Organisation
AWO	Animal Welfare Officer
MARP	Monash Animal Research Platform
MAEO	Monash Animal Ethics Office
The Act	Prevention of Cruelty to Animals Act 1986 (Vic)
The Regulation	Prevention of Cruelty to Animals Regulations 2008 (Vic)
The Code	Australian Code for the Care and Use of Animals for Scientific Purposes, 8th Edition, 2013

1. Preamble

- 1.1. Australian Nuclear Science and Technology Organisation (ANSTO) is licenced under the *Prevention of Cruelty to Animals Act 1986 (Vic) (The Act)* and *Prevention of Cruelty to Animals Regulations 2008 (Vic) (The Regulations)* to use of animals in research or teaching (defined as 'scientific procedures'). In order to be an accredited research establishment enabling research and teaching involving animals, ANSTO must establish an Animal Ethics Committee (AEC) under the *Australian Code for the Care and Use of Animals for Scientific Purposes, 8th Edition, 2013 (The Code)*.
- 1.2. The Director, Australian Synchrotron, ANSTO is responsible for all matters affecting the care and use of animals involving the Australian Synchrotron, ANSTO and/or its external registrants. The Director, Australian Synchrotron, ANSTO shall monitor research and teaching activities involving animals conducted by internal and external staff and students or conducted on the Australian Synchrotron, ANSTO premises.
- 1.3. In this document, unless a contrary intention appears, the Terms of Reference and the Operating Procedures shall apply to the Australian Synchrotron, ANSTO AEC and under the auspices of ANSTO.
- 1.4. AEC has Terms of Reference that shall be publicly available.

2. Responsibilities of AEC

- 2.1. The primary responsibility of an AEC is to ensure, on behalf of ANSTO, for which it acts, that all activities relating to the care and use of animals are conducted in compliance with *The Act, The Regulations and The Code*.

- 2.2. The AEC must have a membership to enable its Terms of Reference and fulfil ANSTO's duty of care which demands a genuine commitment to the welfare of animals. The AEC is responsible for ensuring, on behalf of Australian Synchrotron, ANSTO, that all care and use of animals complies with *The Code*, the use of animals is justified and the principles of Reduction, Replacement and Refinement are implemented.
 - 2.2.1. The replacement of animals with other methods.
 - 2.2.2. The reduction in the number of animals used.
 - 2.2.3. The refinement of techniques used to reduce the adverse impact on animals.
- 2.3. The AEC must:
 - 2.3.1. Review applications for projects and approve only those projects that are ethically acceptable and conform to the requirements of *The Act, The Regulations and The Code*.
 - 2.3.2. Review applications for activities associated with the care and management of animals in facilities and approve only those activities that are ethically acceptable and conform to the requirements of *The Act, The Regulations and The Code*.
 - 2.3.3. Monitor the acquisition, transportation, housing, care and use of animals including housing conditions, practices, procedures and fate of animals in facilities.
 - 2.3.4. Take appropriate actions regarding unexpected adverse events.
 - 2.3.5. Take appropriate actions regarding non-compliance.
 - 2.3.6. Approve guidelines for the care of animals that are held and used for scientific purposes on behalf of Australian Synchrotron, ANSTO.
 - 2.3.7. Provide advice and recommendations to the Australian Synchrotron, ANSTO.
 - 2.3.8. Report on its operations to the Australian Synchrotron, ANSTO.
- 2.4. The AEC shall:
 - 2.4.1. Review and approve new and ongoing activities
 - Proposed amendments to an approved project or activity
 - Review of progress of an ongoing project or activity after each beam round at least annually
 - 2.4.2. Inspect facilities used for research and teaching involving animals at least annually.
 - 2.4.3. Examine and comment on all institutional plans and policies that may affect the welfare of animals used for scientific purposes.
 - 2.4.4. Authorise the emergency treatment or euthanasia of any animal.
 - 2.4.5. Recommend to the Australian Synchrotron, ANSTO any measures needed to ensure the standards of *The Code* are maintained.
 - 2.4.6. Perform all other duties required by *The Code*.

3. Composition of the Animal Ethics Committee

3.1. Chairperson

- 3.1.1. The Chairperson shall be appointed by the Licence Nominee or his/her delegate.
- 3.1.2. The Chairperson may hold a senior position at ANSTO, or be an external appointee. ANSTO shall provide the chairperson with the necessary support and authority to carry out the role.
- 3.1.3. The Chairperson may be appointed in addition to Category A to D members.
- 3.1.4. The Licence Nominee may appoint a Chairperson who is independent of the care and use of animals for scientific purposes.
- 3.1.5. A Deputy Chairperson(s) or Acting Chairperson shall be appointed when a scheduled or unexpected absence of the Chairperson occurs. Deputy Chairperson(s) or an Acting Chairperson must be a committee member nominated by the Chairperson in discussion with the AEC Secretariat so that a regular meeting is not abandoned.
- 3.1.6. In the absence of both Chairperson and the Deputy Chairperson(s), the AEC must determine who shall act as Chairperson and assume the delegated authority of the Chairperson.

3.2. Legally Required Members

- 3.2.1. Membership of the AEC must comprise at least one person from each of four categories of membership:
- **Category A:** A person with qualifications in veterinary science that are recognised for registration as a veterinary surgeon in Victoria, and with experience relevant to Australian Synchrotron, ANSTO's activities or the ability to acquire relevant knowledge.
 - **Category B:** A suitably qualified person with substantial and recent experience in the use of animals for scientific purposes relevant to the Australian Synchrotron, ANSTO and the business of the AEC. This must include possession of a higher degree in research or equivalent experience.
 - **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 ANSTO, and who is not currently involved in the care and use of animals for scientific purposes. Veterinarians with specific animal welfare interest and experience may meet the requirements of this category. While not representing an animal welfare organisation, the person should, where possible, be selected on the basis of active membership of and endorsement by, such an organisation.
 - **Category D:** A person not employed by or otherwise associated with ANSTO and who has never been involved in the use of animals in scientific or teaching activities, either in their employment or beyond their undergraduate education. Category D members should be viewed by the wider community as bringing a completely independent view to the AEC, and must not fit the requirements of any other category.
- 3.2.2. Categories C and D must comprise at least one third of AEC membership both on the AEC membership list and members present at the meetings.

3.3. Discretionary Members to Assist the AEC :

- *Animal Welfare Officer (AWO):* A person who assists the AEC in the monitoring of animals and authorised by ANSTO to ensure that activities proceed in compliance with *The Act, The Regulations and The Code* and the decisions of the AEC.
- *Animal Ethics Committee Secretariat:* A person who provides administrative support and is responsible for the recording and the distribution of the minutes and agendas of each AEC meeting, provides advice to the AEC and research community to ensure that activities proceed in compliance with *The Act, The Regulations and The Code* and the decisions of the AEC.
- *Animal Facility Manager/Representative:* A person who is responsible for the routine care of animals within the Australian Synchrotron, ANSTO.
- *Expert:* A person with specific expertise to provide advice, as required and invitations must be made through the Chairperson and/or AEC secretariat.
- *Representative of ANSTO:* To assist the Committee to function effectively, ANSTO may appoint members with skills and background of value to the Committee. These members may be additional to the members required by Categories A to D.
- Discretionary Members are non-voting members unless specified otherwise.

3.4. Responsibilities of the Chairperson

- 3.4.1. The Chairperson must preside at AEC meetings
- If the chairperson is absent, a person appointed as a Deputy Chairperson(s) or an Acting Chairperson may preside in the Chairperson's absence.
 - If both Chairperson and Deputy Chairperson(s) are absent, the AEC may elect a member to act as a Chairperson.
- 3.4.2. The Chairperson is responsible for impartially guiding the operation of the AEC, resolving conflicts of interest related to the business of the AEC, and representing the AEC in negotiations with ANSTO management.
- 3.4.3. The Chairperson has delegated authority to authenticate the documents of the AEC. The AEC secretariat are authorised by the Chairperson to authenticate the documents on behalf of the Chairperson.

3.5. Responsibilities of Members

- 3.5.1. Each member is responsible for deciding whether, in their own judgement, an application or other matter under consideration by the AEC is ethically acceptable and meets the requirements of *The Code*.

- 3.5.2. Members must maintain confidentiality regarding the content of applications and the deliberations of the AEC, in accordance with ANSTO's requirements.
- 3.5.3. During their appointment to the AEC, and before any deliberations of the AEC, members must declare any interest that could influence the objectivity of their decision making.
- 3.5.4. To fulfil this responsibility, members should:
 - be familiar with the Legislations, Regulations, *The Code* and other policies and guidelines relevant to the business of the AEC;
 - Provide opinions on the ethical acceptability of applications and other matters under consideration by the AEC.

3.6. Conditions of AEC Members' Appointments

- 3.6.1. Before appointment, all members *must* acknowledge in writing acceptance of the AEC's Terms of Reference, and confidentiality requirements of ANSTO.
- 3.6.2. All AEC members must declare any conflict of interest. A conflict of interest shall occur when a member's individual interests or responsibilities have the potential to influence the carrying out of his or her institutional role or professional obligations, or where an institution's interests or responsibilities have the potential to influence the carrying out of its obligations
- 3.6.3. On declaration of a conflict of interest the relevant member shall absent themselves from the meeting for the duration of the relevant discussion and decision-making.
- 3.6.4. Failure to declare a conflict of interest shall result in the relevant decision(s) affected by the conflict of interest being deemed void. Such a decision must be reconsidered at the next AEC meeting.
- 3.6.5. Failure by a member to declare a conflict of interest shall result in that conflict of interest being discussed by the AEC as a whole, in that member's presence, in order to ensure that no recurrence of failure to declare shall occur.

3.7. Entitlements of Members

- 3.7.1. Adequate resourcing and administrative support from ANSTO to fulfil their duties.
- 3.7.2. Orientation and education in respect of their duties under the legislation and *The Code*.
- 3.7.3. Reimbursement of out-of-pocket expenses and/or payment of an allowance, where appropriate.
- 3.7.4. Information on dispute resolution between AEC members, between the AEC and ANSTO, and between the AEC and researchers.
- 3.7.5. All relevant information concerning ANSTO policies, including Freedom of Information and confidentiality requirements and Occupational Health and Safety hazards relating to animal use and care.

3.8. Appointment, Re-Appointment and Retirement of Members

- 3.8.1. AEC secretariat shall monitor the membership requirements of each AEC in consultation with the AEC Chairperson.
- 3.8.2. If a new member is required, AEC secretariat may use whatever means available and considered appropriate to call for "expressions of interest" internally and/or externally to ANSTO. Unsolicited applications lodged periodically by internal and/or external persons with an interest in serving on an AEC may also be considered.
- 3.8.3. AEC secretariat shall notify the Government of Victoria on prospective members. The Government of Victoria is to assess member's suitability for the proposed membership Category in accordance with *The Code*.
- 3.8.4. When the Government of Victoria approves the proposed member, the AEC secretariat will discuss the role of the AEC with the prospective member to ensure the person has a clear understanding of the type of work undertaken at the Australian Synchrotron, ANSTO prior to letter of offer being sent by the AEC secretariat.
- 3.8.5. Where the person is external to ANSTO, the AEC secretariat requests ANSTO Human Resources to appoint the prospective member as Honorary Member to the ANSTO.
- 3.8.6. A letter of appointment shall be provided to the prospective member from the AEC secretariat.
- 3.8.7. External Members are appointed to ANSTO as an Honorary member for two years, appointments are either renewed or re-appointed as appropriate until either members resign or are retired by the Director of the Australian Synchrotron, ANSTO.

- 3.8.8. Members may resign from the Australian Synchrotron, ANSTO AEC at any time by advising the AEC secretariat in writing. The AEC secretariat shall then advise the AEC.
- 3.8.9. The Chairperson may ask a member to resign from the AEC if it is deemed to be in the best interests of the functioning of the AEC. This shall follow consultation with the AEC Chairperson and MAEO. If the member does not accede to the Chairperson's request, the Chairperson in conjunction with the MAEO may initiate action through the Director, Australian Synchrotron, ANSTO to retire the member.
- 3.8.10. The Government of Victoria may retire members at any time by providing not less than 24 hours notice in writing.
- 3.8.11. Changes in the membership of the AEC shall be noted at the next AEC meeting and recorded in the minutes.

3.9. Indemnity of Members and Confidentiality

- 3.9.1. ANSTO shall provide indemnification to the members during their appointment to the AEC.
- 3.9.2. AEC members shall be Indemnified from and against any loss, damage, claims, actions, demands, proceedings, costs, expenses and liability (including legal costs assessed on a solicitor and own client basis) suffered or incurred by, or made against, those Indemnified, arising out of or in connection with the AEC including any matter, conduct, approval or advice relating to animal research activities.
- 3.9.3. This indemnification shall cover officially approved activities undertaken with the knowledge of ANSTO, or under the direction or control of, or at the request of the Australian Synchrotron, ANSTO, or which are activities relevant to that person's position with the ANSTO.
- 3.9.4. The names and personal information of AEC members shall be treated as confidential for their personal security and shall not be made publicly available or published on the ANSTO website.

3.10. Financial Arrangements

- 3.10.1. Sitting Fees
- Appointed external members shall be paid meetings fees as determined by ANSTO
- 3.10.2. Travelling Expenses
- Private motor vehicle usage reimbursement rates, as determined from time to time by ANSTO, shall be paid to all appointed members attending meetings.
 - Costs of travel by train, bus, tram, or taxi to attend meetings of the Committee shall be reimbursed.
- 3.10.3. Out of pocket expenses
- Where appropriate, ANSTO shall reimburse the actual and necessary out of pocket expenditure incurred by the members.

4. Institutional Resources

4.1. Monash Animal Ethics Office (MAEO)

- 4.1.1. MAEO provides administrative support to the operations of the Australian Synchrotron, ANSTO AEC and ensures that all activities relating to the care and use of animals at the Australian Synchrotron, ANSTO is conducted in compliance with relevant Legislations, Regulations and Codes.
- 4.1.2. The MAEO coordinates the annual report to institute and annual animal use returns to the Government of Victoria.

4.2. Animal Welfare Officer (AWO)

- 4.2.1. The AWO is employed by Monash University and is authorised by ANSTO to ensure compliance with the legislation and with the decisions of the AEC.
- 4.2.2. Advise ANSTO on resourcing levels necessary for the successful operation of the AEC.
- 4.2.3. AWO is responsible for ensuring that animal use at the Australian Synchrotron, ANSTO proceeds in compliance with The Act, The Regulations and The Code and the decisions of the AEC and provides advice for the welfare of animals.
- 4.2.4. The Animal Welfare Officer shall have the right at any time, and without notice, to inspect the animal housing facilities and experimental laboratories where Monash Animal Research Platform, Monash University is responsible from day-to-day activities.

- 4.2.5. If non-compliance is detected and/or welfare of animals is compromised, the AWO is authorised by the AEC to suspend the approval and/or procedures pending further investigation by the AEC.
- 4.2.6. The AWO may direct or perform euthanasia of animals to alleviate any animal suffering or distress if deemed necessary.

4.3. AEC secretariat

- 4.3.1. The AEC secretariat are employed by Monash University, and provides administrative support and responsible for the recording and the distribution of the minutes and agendas of each Australian Synchrotron, ANSTO AEC meeting.
- 4.3.2. Receives and records all applications for research activities, progress reports, completed reports, and amendments to protocols in a register.
- 4.3.3. Distributes information relevant to Executive Committee decision-making in a timely manner and coordinates Executive Committee responses.
- 4.3.4. Ensure AEC records are maintained and made available for review by ANSTO and external reviewing authorities.
- 4.3.5. Provide advice to AECs and research community to ensure that activities proceed in compliance with *The Act*, *The Regulations and The Code* and the decisions of the AEC.
- 4.3.6. AEC secretariat authenticate documents as authorised by the Chairperson.

4.4. Monash Animal Research Platform (MARP)

- 4.4.1. MARP animal care technicians are responsible for the daily care, husbandry and agistment of animals at the Australian Synchrotron, ANSTO Animal Holding facilities.
- 4.4.2. Where appropriate, animal carers shall have access to records of approved projects and activities.

4.5. Monash Animal Research Platform (MARP) Clinical Veterinarians

- 4.5.1. Provide veterinary care and support for all animals held within the Australian Synchrotron, ANSTO Animal Holding facilities, including diagnosing medical conditions and prescribing treatments.
- 4.5.2. Have the right at any time and without notice to enter the facilities in which the animals are housed and/or the laboratories in which experimental work occurs, to inspect the procedures used and the condition of the animals.
- 4.5.3. Advise on surgical/non-surgical techniques relevant to their own expertise and to provide support in the collection and analysis of materials.
- 4.5.4. Provide advice to the AEC and investigators on matters concerning welfare of animals.
- 4.5.5. MARP Clinical Veterinarians may direct or perform euthanasia of animals to alleviate any animal suffering or distress if deemed necessary.

5. Conduct of Meetings

5.1. Frequency

- 5.1.1. The AEC meets as required to allow for effective functioning of the AEC.

5.2. Quorum

- 5.2.1. At least one member from each of the membership categories A, B, C and D must be present at meetings to establish a quorum for the conduct of a meeting, and must be present throughout the meeting.
- 5.2.2. If consisting of more than four (4) members, Categories C and D must together represent at least one-third of the AEC membership and Categories C and D together must represent at least one-third of those members present at the meeting.
- 5.2.3. In circumstances of failure to achieve or loss of quorum, members from other categories shall be asked to refrain from voting in order to achieve quorum.
- 5.2.4. In exceptional circumstances, a quorum may be established through teleconferencing or web conferencing.
- 5.2.5. Only a quorate meeting of the AEC shall consider and approve new protocols, minor amendments or consider and approve renewal of existing protocols.
- 5.2.6. If an AEC position becomes vacant, ANSTO must appoint a person to fill that vacancy so as to ensure that the balance requirements of the AEC are met.

5.3. Agenda

- 5.3.1. The AEC secretariat shall develop an Agenda for each meeting, taking into account decisions reached at the preceding meeting, any pending business and any new developments.
- 5.3.2. The agenda must be sent to AEC members and regular attendees 14 days prior to meeting unless there are extenuating circumstance(s), together with any new protocols for consideration, and any supporting material prior to the scheduled meeting.

5.4. Minutes

- 5.4.1. The AEC secretariat are responsible for the taking, writing and distribution of the Minutes to AEC members.
- 5.4.2. Minutes of the meeting must be maintained that record decisions and all other aspects of the AEC's operations.
- 5.4.3. The minutes must;
 - Register all applications to the AEC, including the outcomes of deliberations
 - Record decisions and other aspects of the AEC's operation.
 - State the reasons for any decision on a research protocol.
 - Records inspections conducted by the AEC
 - Be confirmed formally at the next meeting of the AEC
- 5.4.4. Decisions of the AEC must be communicated to researchers as promptly as possible and a researcher must not commence research under a protocol until advised in writing of approval.

5.5. Inspections

- 5.5.1. Inspections of animal housing/holding facilities and/or laboratories where experimental work occurs may be announced or unannounced.
- 5.5.2. AEC members should inspect all animal facilities and laboratories at least annually.
- 5.5.3. Where possible, a Category C or D member of the AEC should participate in animal facility inspections.
- 5.5.4. Records of inspections that include the names of attendees, observations, any identified problems, recommended actions, ongoing or outstanding issues, and outcomes must be recorded in the minutes.
- 5.5.5. Where inspections identify a breach of *The Code*, the AEC must ensure that such activities cease immediately, and remedial action is instituted.

5.6. AEC Subcommittees

- 5.6.1. ANSTO may, on the recommendation of the AEC, establish AEC sub-committees to assist AEC. The AEC may delegate certain functions to the subcommittee(s).
- 5.6.2. The Executive Committee of the AEC has authority to approve minor amendments that have no or minimal impacts on animal welfare to existing approved protocols at their discretion and deal with emergencies between AEC meetings, subject to review and endorsement by the AEC.
- 5.6.3. Approval by the Executive Committee is only exercised when there is a strong argument for urgency and the case for urgency must be provided in writing to support the request.
- 5.6.4. The Executive Committee;
 - Must include the Chairperson and at least one member from Category C or D;
 - Decisions and recommendations of the Executive Committee must be endorsed by the next quorate meeting of the AEC and recorded in the minutes.
- 5.6.5. The executive committee must not;
 - Approve new applications;
 - Approve resubmitted applications;
 - Consider amendments that amount to substantial changes to the approved application and/or changing the main aims, scientific question or model;
 - Suspend or withdraw a previous approval.

6. Consideration of Applications

6.1. Submission of Applications

- 6.1.1. All applications and subsequent amendments to approved protocols must be submitted to the Australian Synchrotron, ANSTO AEC.
- 6.1.2. All submission to be receipted by the by the secretariat within five working days and assigned to the next available meeting of the AEC unless there are extenuating circumstance(s).
- 6.1.3. Incomplete proposals shall be returned to the investigator for their attention and shall not be considered as having been submitted to the AEC secretariat.
- 6.1.4. Submission of an application before the submission deadline does not guarantee that the application is reviewed by the AEC at the next available meeting; applications may be reviewed at subsequent AEC meetings.
- 6.1.5. AEC meeting dates may be changed without notice to applicants.

6.2. Review of New Applications

- 6.2.1. The AEC must consider and approve applications for new projects and activities, and the ongoing approval for existing projects and activities, only at quorate meetings of the AEC.
- 6.2.2. The AEC may approve only those projects and activities that are ethically acceptable and conform to the requirements of *The Code*.
- 6.2.3. The AEC must make a judgement on whether the proposed use, or continued use, of animals is ethically acceptable. This judgement must be;
 - Based on information provided by the applicant.
 - Evidence to support a case to use animals must demonstrate that:
 - the project has scientific or educational merit, and has potential benefit for humans, animals or the environment
 - the use of animals is essential to achieve the stated aims, and suitable alternatives to replace the use of animals to achieve the stated aims are not available
 - the project involves the minimum number of animals required to obtain valid data
 - the project involves the minimum adverse impact on the wellbeing of the animals involved.
 - Projects must only be undertaken:
 - to obtain and establish significant information relevant to the understanding of humans and/or animals, or
 - to maintain and improve human and/or animal health and welfare, or
 - to improve animal management or production, or
 - to obtain and establish significant information relevant to the understanding, maintenance or improvement of the natural environment, or
 - to achieve educational outcomes in science, as specified in the relevant curriculum or competency requirements.
 - when the potential effects on the wellbeing of the animals involved is justified by the potential benefits.
- 6.2.4. Investigators may be required to attend the meeting to respond to questions in person or be contacted by phone.
- 6.2.5. AEC may seek advice or clarification on aspects of proposals from experts outside of the AEC. The AEC must reach an agreement on how advice or clarification can be sought from outside experts without breaching confidentiality. This advice will be circulated to all AEC members and shall be sought under conditions of strictest confidence. Person consulted who are not Committee members shall be asked to sign a confidentiality agreement.
- 6.2.6. Members who feel they need to consult a person who has more specialised knowledge should raise their questions or concerns with the AEC Chairperson who may grant limited permission for the member to seek advice outside the Committee. The member must identify who they wish to consult, their reasons for consulting that person and the issues and questions they wish to discuss. Confidentiality must be rigorously maintained and persons outside the Committee who are consulted on AEC matters shall be asked to sign a confidentiality agreement.
- 6.2.7. If the application propose the reuse of animals, the AEC must take into account:

- the pain and distress, and any potential long-term or cumulative effects, caused by previous activities and conditions;
- the time allowed for recovery of the animals between activities;
- whether an animal has fully recovered from the previous activities;
- the pain and distress likely to be caused by the next and subsequent activities;
- the total time over which an animal will be used.

6.2.8. The AEC may require inspection of the facilities, procedures and personnel before giving written approval..

6.3. Review of Pilot Studies

6.3.1. A pilot study to enable assessment of the feasibility of a project must be considered by the AEC in the overall context of the protocol and is subject to the same criteria as a new application.

6.3.2. Pilot studies are to be considered only by a quorate AEC and must be assessed according to the criteria applied to new applications.

6.3.3. The AEC may delegate person(s) to monitor activities that are likely to cause pain or distress at an early phase during the conduct of pilot study. This requirement may be a condition of approval for the pilot study.

6.4. Review of Resubmitted Applications

6.4.1 Resubmitted applications must be considered only by a quorate meeting of the AEC.

6.4.2 Resubmitted applications must be assessed according to the criteria applied to new applications.

6.5. Review of Amendments to Approved Applications

6.5.1. Request for a minor amendment to an existing approved protocol must be submitted to secretariat of AEC using the minor amendment form.

- AEC secretariat shall record the receipt of the requested amendment
- Amendment request shall be added to the agenda for the next meeting.

6.5.2. Minor Amendments must be reviewed at quorate AEC meetings.

6.5.3. Any modifications to the protocol such as changes to the number of animals, species/strains/breeds of animals, procedures, location of research/housing, source, addition/removal of personnel or time extensions must be subject to written approval from the AEC.

6.5.4. Application for a time extension (maximum for 12 months) must be submitted before the end date of approval and can be submitted only once unless there are extenuating circumstance(s).

6.5.5. If the request for amendment is urgent, at the discretion of the AEC secretariat or the Chairperson, the amendment shall be forwarded to an Executive Committee for consideration

- Date of receipt and forwarding, name(s) of Executive Committee shall be recorded
- Responses from Executive Committee shall be recorded
- Executive Committee shall be notified on consensus
 - If there is no consensus, the AEC secretariat shall contact the Chairperson to seek an appropriate means of proceeding.
 - Chairperson shall refer the matter to the next quorate meeting of the AEC.
 - If the matter is urgent, the Chairperson shall consult personally with the Executive Members and Investigators to explore ways of modifying the amendment or activity that may lead to consensus.
- The outcome of the Executive Committee decision shall be communicated to the Executive Committee members and the investigator
- Copies of all relevant papers and the outcome of the Executive Committee's decision in writing shall be included in the agenda for the next quorate AEC meeting for review and endorsement.
 - Should the AEC not accept the Executive Committee's decision on the amendment, the investigator must be notified as a matter of urgency, and the research on the basis of the amendment as agreed to by the Executive must cease immediately.
 - Should the AEC endorse the Executive Committee's decision, all relevant documents submitted to the AEC become part of the documentation of the investigator's researcher's approved project.

6.6. Reports

6.6.1. Annual and Completed Reports to the AEC

- Investigators must provide an Animal Experiment Report for research I, teaching units or training courses conducted under each beam proposal, regardless of the duration of AEC approval for the project.
- Following review of the Animal Experiment Report for an approved project or activity, the AEC may determine the approval for the project or activity is;
 - Continued
 - Suspended
 - Continued subject to modification
 - Discontinued

6.6.2. Annual Animal Use Returns to the State of Victoria

- Investigators must complete the Animal Use Return Form provided by the State of Victoria as stipulated under the State Legislation(s) before the due date.

6.6.3. The AEC may suspend, withdraw the approval of an application or not accept new applications from the investigator if the reports are not submitted to the AEC before the specified due date.

6.7. Projects involving more than one institution and/or animal ethics committee

6.7.1. Where a project is to be conducted at more than one accredited research institution, or projects involving investigators from more than one institution, or the care and use of animals at more than one institution, projects are approved and monitored by the responsible AEC.

6.7.2. Investigators from institutions with a legally constituted AEC

- Investigators from institutions with a legally constituted AEC that are based in Victoria, South Australia, New South Wales Queensland, ACT and Tasmania must obtain an approval from their home institution. Investigators from institutions with a legally constituted AEC that are based in Western Australia and Northern Territory must obtain approval from the Australian Synchrotron, ANSTO AEC.
- Investigators from institutions without a legally constituted AEC or investigators from overseas must submit an application to the Australian Synchrotron, ANSTO AEC for review and should contact the User Office for guidance for submission of an application.

6.8. Decision Process and Voting

6.8.1. The AEC must base its decisions on the information it receives from the applicant in the documentation and in any direct discussions with the applicant, and may use information in addition to that obtained from the applicant.

6.8.2. Decisions should be based on a thorough, fair and inclusive process of discussion and deliberation by AEC members, and should be made only by those present throughout the discussion.

6.8.3. All members of the AEC have equal status and are entitled put forward their views.

6.8.4. Any AEC member with a conflict of interest must declare the conflict and shall not participate in the discussion of the relevant matter nor vote on the matter.

6.8.5. For decision making, members with a conflict of interest must withdraw from the meeting. Once such members have withdrawn, the remaining members must constitute a quorum that is at least one member from each of the membership categories A, B, C and D, with Categories C and D together representing at least one-third of members present.

6.8.6. Decisions should be made on the basis of consensus.

- Where consensus cannot be reached after reasonable effort to resolve differences, the AEC should explore with the applicant(s) ways of modifying the project or activity that may lead to consensus.
- If consensus is still not achievable, the AEC should allow members time to review their positions, allow time for further discussion and then should proceed to a majority vote.
- If the member(s) vote no or abstained from voting, the reason objection or abstaining from voting is recorded in the minutes.

6.9. Communications

6.9.1. The AEC must clearly communicate its decisions, the reasons for its decisions and any conditions attached to an approval to investigators in writing as soon as practicable.

- 6.9.2. The AEC may consider face-to-face meetings with applicants to resolve issues
- 6.9.3. The AEC may require inspection of the facilities, procedures and personnel before giving written approval.
- 6.9.4. AEC research and teaching approvals are issued for three calendar years; however approvals may be issued for longer periods if the research project is funded for a longer duration by an external funding agency.
- 6.9.5. The AEC may;
 - Approve the application or minor amendment with or without conditions
 - Approve the application or minor amendment subject to clarification by the investigator which can be approved out of session by the Chairperson/delegated members with or without conditions
 - Not approve the application or minor amendment, defer subject to major modification which must be resubmitted to a subsequent quorate AEC meeting
 - Not approve
- 6.9.6. The AECs are authorised to suspend, or withdraw approval any time.

6.10. Appeals to AEC Decision

- 6.10.1. A Chief Investigator wishing to appeal an AEC decision must do so in writing to the AEC Chairperson within 14 days after being advised of the AEC decision.
- 6.10.2. The AEC Chairperson is responsible for adding the appeal to the agenda of the next scheduled AEC meeting where the AEC shall review the appeal.
- 6.10.3. The AEC Chairperson shall inform the Chief Investigator in writing of the outcome of the AEC review of the appeal within 14 days from the AEC meeting. The AEC may
 - Uphold its decision
 - Vary its decision
 - Invite investigators to present their case in person
- 6.10.4. If an investigator finds the outcome unsatisfactory the complaint must be referred in writing to the Head of Science at the Australian Synchrotron, ANSTO (Head of Science) within 28 days of the AEC decision for review of the due process.
- 6.10.5. The Head of Science shall advise the AEC, the investigator and the Scientific Procedures Premises Licence Nominee of the outcome of the review of due process.
- 6.10.6. If the Head of Science finds fault with the process for an AEC decision, the AEC may be requested to re-review the decision in light of any finding and with due process.
- 6.10.7. If the matter is not resolved, a written request for intervention may be made to the Director of the Australian Synchrotron, ANSTO, by either the complainant or the Head of Science within 28 days of the AEC's final decision. The written request must include the basis on which the request for intervention is being made.
- 6.10.8. The Director of the Australian Synchrotron, ANSTO must review the complainant's application and then attempt to resolve the complaint through further negotiation or mediation, or may advise the complainant in writing that the complaint is considered to be lacking in substance, or frivolous and/or vexatious, and that no further consideration or intervention is to be conducted.
- 6.10.9. A complaint case shall be considered closed upon receipt by the Director of the Australian Synchrotron, ANSTO of a written withdrawal of the complaint by the complainant, or when the Director of the Australian Synchrotron, ANSTO determines that there is nothing further that can be done in order to settle the complaint.
- 6.10.10. The decision of the Director of the Australian Synchrotron, ANSTO is considered to be final.

6.11. Complaints

- 6.11.1. Complaints may be raised by any person or group, including investigators, animal carers, animal ethics committees (AECs), AEC members, students, and employees of the institution and members of the public. Complaints may relate to the activities of any party or person involved in the care and use of animals, including investigators, animal carers, the AEC and governance officials.
- 6.11.2. Complaints concerning AEC operation
 - If an AEC member has a complaint about the operation of the AEC or another member of the AEC, the member should discuss his/her concerns with the Chairperson of the AEC in confidence.

- If the grievance cannot be resolved, the complaint should be forwarded to Head of Science in writing.
- If the matter is not resolved, the member can make a complaint to the Director of the Australian Synchrotron, ANSTO and/or Government of Victoria.

6.11.3. Complaints concerning animal welfare

- All complaints and concerns will be dealt with confidentially and in accordance with rules of natural justice and procedural fairness.
- If animal facility, academic or other staff or students have any enquiries or concerns about the well-being of animals held at the Australian Synchrotron, ANSTO for use in research or teaching, these concerns should be reported to the Chairperson of the AEC, AEC Secretariat or AWO.
- If the complaint is of a serious nature, or if the matter cannot be resolved, the Australian Synchrotron, ANSTO AEC Secretariat, AWO, Head of Science or Director of the Australian Synchrotron, ANSTO must be notified immediately.

6.12. Unexpected Adverse Events

6.12.1. The AEC and/or its representatives (AWO or Chairperson) must take appropriate action in response to unexpected adverse events to ensure that animal wellbeing is not compromised, the issue is addressed promptly, and activities that have the potential to adversely affect animal wellbeing cease immediately. Actions may include;

- Consulting with relevant people
- Suspending the approval for the project or activity
- Withdrawing approval for the project or activity

6.13. Non-Compliance

6.13.1. Governing principles

- All activities, including projects, that involve the care and use of animals for scientific purposes must:
 - be subject to ethical review, approval and monitoring by the AEC
 - commence only after written approval has been granted by the AEC
 - be conducted in accordance with AEC approval
 - cease if approval from the AEC is suspended or withdrawn

6.13.2. Non-compliance occurs where there is a specific action or omission that constitutes a breach of *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. Non-compliance may also involve breaches of relevant state or territory legislation(s).

6.13.3. Responsibilities

- Investigators must report any adverse event and non-compliance associated with the approved protocol to the AEC as soon as possible.
- The AWO, the AEC or its appointed representative shall have the right at any time, and without notice, to inspect the facilities in which the animals are housed and/or inspect the laboratories in which experimental work occurs, the procedures used and the condition of the animals. Where there is concern they shall be required to investigate and to take appropriate action.

6.13.4. Procedures

- Reports of incidents and complaints alleging a possibility of non-compliance including inadvertent non-compliance may come from an internal or external source. Complaints can be made verbally or in writing (preferred). Written complaints should be submitted AEC secretariat and the complainant can remain anonymous.
- The concern should be reported to the AWO, the Chairperson of the AEC or directly to AEC secretariat. In the event of the AWO or the Chairperson are not being available, complaints can be reported to or the Deputy AEC Chairperson, Head of Science or Director of the Australian Synchrotron, ANSTO.
- Members of the AEC may identify potential instances of non-compliance during the routine inspection of Animal Housing/Holding Facilities and Laboratories where research involving animals is conducted.

- The AWO and/or Chairperson are responsible for determining whether the alleged incident or complaint is to be investigated for non-compliance based on a preliminary review of the facts and it may include inspections of the facility or animals the subject of the complaint/non-compliance, communication with the person raising the complaint/non-compliance, Chief Investigator and/or partner investigator who is the subject of the complaint/non-compliance and/or witnesses.
 - If the AWO and/or Chairperson determines that non-compliance has not occurred, the AEC Secretariat will advise;
 - The person raising the complaint/non-compliance
 - Chief Investigator and/or partner investigator who is the subject of the complaint/non-compliance
 - The AEC at the next quorate meeting
 - Incident/complaint will be recorded in AEC minutes and register
 - If the AWO and/or Chairperson determine that non-compliance has occurred, the degree of non-compliance is assessed. Non-compliance varies in nature, severity and frequency. Depending on the severity of the alleged non-compliance as determined by the AEC the following will occur:
 - In all instances of Minor non-compliance,:
 - Chief investigator is requested to submit an incident/non-compliance report by the AEC secretariat.
 - Any non-compliant activity must cease immediately.
 - Incident/non-compliance report shall be considered by the AEC at its next quorate meeting.
 - The Chief Investigator, Head of Science and Director of the Australian Synchrotron, ANSTO are informed in writing of the AEC decision.
 - The allegation, assessment and recommended actions are reported in the AEC minutes and register.
 - If there is a repeat of the same incident, depending of the severity of the non-compliance, it may be dealt with as a major non-compliance.
 - In all instances of Major non-compliance:
 - Non-compliant research or teaching activity must cease immediately until the incidence/non-compliance is investigated by the AEC.
 - If non-compliance has the potential to adversely affect animal wellbeing, the AWO and/or Chairperson are authorised by the AEC to suspend all activities, or certain activities or new activities pending the AEC investigation.
 - The AWO and/or MARP Clinical Veterinarians are responsible for determining whether immediate action is required to alleviate any animal suffering or distress. AWO and/or MARP Clinical Veterinarians may direct or perform the immediate action and the action may include euthanasia of animals if deemed necessary by the AWO and/or MARP Clinical Veterinarians.
 - AWO and/or AEC secretariat informs;
 - Chief Investigator and/or partner investigator
 - Head of Science
 - Director of the Australian Synchrotron, ANSTO
 - The AEC shall investigate the non-compliance and investigation may include;
 - Interviews with the person raising the complaint/non-compliance, the subject of the complaint/concern and/or witness; Chief Investigator and/or partner investigator who is the subject of the complaint/non-compliance
 - Inspections of the facility or animals that are the subject of the complaint/non-compliance,
 - Seeking of advice from experts within or external to ANSTO
 - Depending on the degree of non-compliance, the AEC may;

- Caution the Chief Investigator and/or /partner investigator
- Suspend research protocol/investigator(s)/activities giving rise to the non-compliance for a period of time within the project.
- Withdraw approval for research protocol/investigator(s)/activities giving rise to the non-compliance.
- Investigate other projects involving the staff member or Chief Investigator
- The AEC does not have the legal authority or responsibility to discipline personnel but may recommend disciplinary action to the Director of the Australian Synchrotron, ANSTO and/or to the institute where investigator(s) are employed.

6.14. Governance

- 6.14.1. The Director of the Australian Synchrotron, ANSTO will monitor research and teaching activities involving animals conducted at the Australian Synchrotron, ANSTO premises
- 6.14.2. The AEC is required to report annually on its activities to ANSTO
 - Annual Report to the institute is prepared by the AEC Secretariat.
 - Following approval by the AEC at a quorate meeting, the Annual Report to ANSTO shall be forwarded to the Director of the Australian Synchrotron, ANSTO.
- 6.14.3. Annual review of the operation of the AEC shall be conducted by the assessment of the AEC's annual report to ANSTO and an annual meeting with the AEC chairperson and Licence Nominee or his/her delegate and/or Head of Science