

THE FLOREY ANIMAL ETHICS COMMITTEE
Terms of Reference and Procedural Guidelines

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1. Governing Legislation

- 1.1. The primary responsibility of The Florey Institute for Neuroscience and Mental Health Animal Ethics Committee is to ensure, on behalf of The Florey and any associated organisations, that all activities relating to the care and use of animals for scientific purposes is conducted in compliance with the following:
- The Victorian *Prevention of Cruelty to Animals Act 1986* (POCTA)
 - The *Prevention of Cruelty to Animals Regulations 2019*
 - The National Health and Medical Research Council *Australian Code for the Care and Use of Animals for Scientific Purposes*, 8th Edition 2013;
 - The *Code of Practice for the Housing and Care of Laboratory Mice, Rats, Guinea Pigs and Rabbits*;
 - Florey Institute of Neuroscience and Mental Health policies, procedures and guidelines.

2. Terminology

- 2.1. The Florey Animal Ethics Committees, hereafter referred to as the “AEC”.
- 2.2. The Florey Institute of Neuroscience and Mental Health and any associated organisations, hereafter referred to as the “The Florey”.
- 2.3. The Kenneth Myer Building in Parkville, hereafter referred to as the “KMB”.
- 2.4. The Howard Florey Laboratories, hereafter referred to as “HFL”.
- 2.5. The Australian Code for the Care and Use of Animals for Scientific Purposes, 8th edition 2013, hereafter referred to as “The Code”.
- 2.6. The Victorian Prevention of Cruelty to Animals Act 1986 (POCTA) and the Prevention of Cruelty to Animal Regulations 2019, hereafter referred to as “The Act”.
- 2.7. The Code of Practice for the Housing and Care of Laboratory Mice, Rats, Guinea Pigs and Rabbits, hereafter referred to as the “Laboratory Animal Housing Code”.
- 2.8. The Victorian Government regulator, Animal Welfare Victoria, hereafter referred to as “AWV”.
- 2.9. The nominated natural person on a Licence granted according to Section 3 of the Act, for which the Florey AEC is nominated, hereafter referred to as the “Licence Nominee”.

- 2.10. The online platform for animal ethics and animal husbandry, tick@lab, hereafter referred to as TAL.

3. Licence Designations

- 3.1. The Florey AEC shall be the designated AEC for any Scientific Procedure Premises Licence, Scientific Procedures Field work Licence, or Specified Animals Breeding Licence held by The Florey under Section 3 of the Act.
- 3.2. The Florey AEC may agree to be the designated AEC for any other Licence held by another Institution under Section 3 of the Act.
- 3.2.1. Any such Institution must agree to these terms of reference.

4. Scope of AEC Responsibilities

Approve activities

- 4.1. Review and approve new and ongoing activities. (Code 2.3.3-2.3.16) Rigorously examine and review the following types of submissions:
- Project applications and amendments relating to the use of animals in breeding or scientific experimentation;
 - Standard Operating Procedures (SOPs), with each SOP to be reviewed triennially;
 - Phenotype reports for genetically modified animals that may have specific welfare needs;
 - Project progress reports and closure reports;
 - Delegation of responsibility requests from other universities and research institutions.
 - Activities associated with the care and management of animals in facilities, including procedures applicable to breeding programs integral to the maintenance of an animal line. (Code 2.3.2 (ii))
- 4.1.1. In considering these, the committee will decide whether each item is either approved (with or without conditions), deferred subject to modification, or not approved.
- 4.1.2. The AEC will Approve only those applications that are ethically acceptable and conform to the requirements of the Code. (Code 2.3.2 (i)) This should include consideration of factors such as:
- the anticipated scientific or educational value;
 - the impact or burden on the animal/s;
 - the principles of Replacement, Reduction, Refinement;
 - the use of plain English and whether the application is easily understood by a lay member with little or no scientific background.
- 4.2. Approve guidelines for the care and use of animals. Approve Florey animal welfare guidelines and comment on Florey plans and policies that may impact on animal welfare including, but not limited to, renovations, development and building of new facilities. (Code Section 2.3.2 vii; 2.3.26)

Monitor Activities

- 4.3. Monitor the care and use of animals. Approve and monitor the acquisition, transportation, breeding, housing, and husbandry of all animals used in scientific experimentation. (Code 2.3.17-2.3.23)
- 4.4. Inspect activities. Monitor care and use of animals on a regular and ongoing basis to ensure projects are proceeding in compliance with the Code and AEC decisions. This may occur through direct inspection of animals or procedures, and/or review of records and reports. Monitoring of activities likely to cause pain and distress should occur at an early phase of the

project. The AEC may delegate authority to conduct such inspections to suitably qualified people, including but not limited to Florey veterinarians, and external AECs or their delegated officers. (Code 2.3.17-23)

- 4.5. Inspect facilities. Inspect and approve the facilities of the Florey HFL, KMB and any other sites used in animal experimentation and husbandry and maintain records of inspections. Inspections must be conducted at least annually, and should involve at least one Category C or D member, while encouraging other categories of AEC members to participate. (Code 2.3.2 (iv), 2.3.20)
- 4.6. Provide advice and recommendations to the institution. Ensure that all teaching and scientific use of animals performed under the authority of Florey POCTA Licences complies with the Act, The Code and the Laboratory Animal Housing Code. Provide advice and recommendations to The Florey on measures required to ensure all standards of the Code and relevant State legislation are maintained. (Code 2.3.2 (viii); 2.3.27)
- 4.7. Report annually to The Florey on its operations. This will include:
 - numbers and types of projects and activities assessed, and approved or rejected;
 - the physical facilities for the care and use of animals by the institution;
 - actions that have supported the educational and training needs of AEC members and people involved in the care and use of animals;
 - administrative or other difficulties experienced;
 - any matters that may affect the institution's ability to maintain compliance with the Code and, if appropriate, suitable recommendations.

Delegate Authority

- 4.8. Delegate to the AEC Executive the responsibility for approving out-of-session applications for minor amendments to already-approved applications. The definition of minor amendment is described in the AEC Guideline on minor amendments. The AEC Executive Committee shall not approve any new pilot projects or applications or amendments that do not fit the minor amendment criteria.
- 4.9. Delegate to the AEC Executive, Chairperson, or Secretary the responsibility to review modifications requested by the AEC, where such modification requests fall within the scope described in AEC Guideline on minor amendments.
- 4.10. Delegate to the AEC Chairperson the authority to suspend an AEC application, in whole or part, when the welfare of animals is a concern.
- 4.11. All decisions made by the AEC Executive out-of-session will be reviewed and ratified by the entire AEC at the next quorate meeting.

Respond to Complaints, Unexpected Adverse Events & Non-compliances

- 4.12. The AEC will review complaints, on a confidential basis, from animal house staff, researchers or others on conduct relating to the use of animals.
 - 4.12.1. The AEC shall ensure that a robust enquiry/review is conducted in the event of an unexpected adverse event. See the Guidelines for Reporting Animal Incidents and Unexpected Adverse Events for details.
- 4.13. The AEC will take appropriate actions regarding unexpected adverse events and non-compliance.
 - 4.13.1. The AEC may require corrective actions on the part of investigators to reduce the chance of recurrence or return to compliance.
 - 4.13.2. Where deemed necessary, approval may be withdrawn for any project or activity, thus

causing cessation of all experimentation. Refer to the Procedures for Animal Related Non-Compliance for details.

- 4.14. If deemed necessary, the AEC may escalate complaints or non-compliances to the Licence Nominee for disciplinary procedures as outlined in institutional procedures.
- 4.15. A summary of unexpected adverse events, non-compliance and complaints will be sent to the Licence Nominee on a regular basis.

Maintain records

- 4.16. Maintain records of staff competencies in procedures and ensure that procedures involving animals are only carried out by competent personnel, or under the supervision of competent personnel.
- 4.17. Maintain minutes of meetings. Minutes of every AEC meeting will be prepared by the AEC Administrative Officer and approved at the next AEC meeting. The approved Minutes will be maintained as a record, and copies provided to the Licence Nominee on request.
- 4.18. Maintain accurate records of all projects, amendments, unexpected adverse events, non-compliances, SOPs, approved personnel and personnel changes.
- 4.19. Maintain records of staff completion of the online Animal Ethics Induction.
 - 4.19.1. All staff must complete the induction course before beginning work with animals.
 - 4.19.2. This training must be refreshed every 3 years, or more frequently if required by the AEC.

5. Number of Committees and the Florey AEC Executive

- 5.1. The Florey may appoint as many Animal Ethics Committees (AECs) as determined by the Florey Director upon the advice of the Chairpersons of the AECs and the Licence Nominee.
- 5.2. Before appointing a new AEC, the Florey must first formally notify the government regulator (Animal Welfare Victoria) of the proposal.
- 5.3. An AEC Executive for the purpose of reviewing minor amendments as described in the Guideline on Minor Amendments will be established either by:
 - The AEC, from among members present, for items considered during a quorate meeting, or
 - The AEC Secretary, from among all listed members, for items to be considered out-of-session.
- 5.4. As a minimum, an Executive shall consist of the AEC Chairperson and a Category C or Category D member. Other member(s) may be appointed as required by the AEC. Other members of the AEC may ask to be included in the Executive for the purpose of reviewing specific applications if desired.
- 5.5. The AEC Secretary shall ensure that the number of executive reviews assigned to each external member is approximately even over time.
- 5.6. Within Tick@lab, review by the AEC executive is referred to as Designated Member Review, or DMR.

6. Membership

Membership Categories Required for Quorum (Code 2.2.2-12)

6.1. Any AEC must include at least one separate person for each of the categories A, B, C & D. The Chairperson may also be designated as a Category A, B, C, or D member.

Category A A person with qualifications in veterinary science that are recognized for registration as a veterinary surgeon in Australia, and with experience relevant to the activities of the Florey. Veterinarians who lack this experience must familiarise themselves with the biology and clinical characteristics of the species of animals used.

Category B A suitably qualified person with substantial and recent experience in the use of animals in scientific and/or teaching activities. This will usually entail possession of a higher degree in research.

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 Florey, and who is not 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 organization, the person should, where possible, be selected on the basis of active membership of, and endorsement by, such an organization.

Category D A person who is both independent of the Florey 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.

Chairperson The Florey must appoint a Chairperson of the AEC. (Code 2.2.2). The Chairperson must be a member of the Florey AEC. The Chair may hold a senior position in the Institute, or be an external appointee with the necessary Institutional support and authority to carry out the role of Chair. The Chairperson is responsible for impartially guiding the operation of the AEC, resolving conflicts of interest relating to the business of the AEC, and representing the AEC in any negotiations with the Florey management. (Code 2.2.13)

6.2. Categories C & D must together represent at least one-third of the AEC membership, and one third of members present for any decision making during a meeting. (Code 2.2.8)

Assignment of Additional Members

6.3. To assist the AEC to function effectively, The Florey will assign additional people with skills and background of value to the AEC. These additional people may be members of the AEC, and may perform more than one role. Their presence is not required for quorum.

6.4. The Florey will assign to the AEC:

- One or more Deputy Chairpersons, drawn from the AEC membership.
- An AEC Secretary to provide administrative support to the AEC. This individual need not be an AEC member.

Deputy Chairperson/s – A Deputy Chairperson shall assume the role of Chair if the Chair is absent.

Acting Chairperson – In the event that both the Chairperson and Deputy Chairpersons are unavailable, the AEC will appoint one of its members to assume the role of Acting Chairperson until the Chairperson or Deputy Chairperson can resume their role.

6.5. The Florey may also assign to the AEC:

- Additional administrative officer/s.
- A “Category E” person responsible for the routine care of animals from within The Florey.
- Other members, as determined by the AEC Secretary, Chairpersons of the Animal Ethics Committees, or the Licence Nominee.

Appointment, Reappointment and Retirement of Members

- 6.6. The AEC Secretary will advise the Licence Nominee regarding the appointment, reappointment, retirement, or resignation of AEC members.
- 6.7. If there is to be a change in the membership of an AEC, the Licence Nominee must notify Animal Welfare Victoria of the proposed change before the change is made. In cases of resignation, the Licence Nominee must notify AWV within 7 business days.
- 6.8. All newly appointed AEC members must complete a training course approved by the Minister for Agriculture prior to, or within 6 months of, their appointment.

Terms of Appointment

- 6.9. Each appointment shall normally be for a term of three years with a probation of 6 months. It is recognised that in some circumstances the non-availability of suitably qualified potential members will require some members to serve for longer periods. In such cases and prior to the expiry of the current term of office, a member might be invited in writing to serve an additional term of office. On written acceptance, the member will be deemed to have been re-appointed. Where a member declines this invitation, a vacancy will be declared.

Appointment of new members

- 6.10. On declaration of a vacancy, an advertisement will be posted through the Director’s office inviting expressions of interest from persons who meet the eligibility criteria for the vacancy. All applicants will need to provide a Curriculum Vitae, a declaration of interests and potential conflicts of interest, and any other details required by The Florey or Animal Welfare Victoria. People with qualifications deemed to be a desirable addition to the AEC may be approached by the AEC Secretary and invited to apply for the vacancy.
- 6.11. Expressions of interest will be assessed by the Licence Nominee, AEC Chairpersons and AEC Secretary. Interviews of eligible candidates will be conducted where required. Final appointment requires approval of candidates by Animal Welfare Victoria.
- 6.12. New and reappointed members will undergo appropriate induction and mandatory training, familiarize themselves with the Code and other relevant policies and guidelines, and have access to appropriate education programs and resources relevant to animal welfare and the business of the AEC. (Code 2.2.12, 2.2.15) Mandatory training will address obligations and responsibilities of Members of AECs under the Code.

Resignation or retirement of members

- 6.13. Members shall be retired in one of three ways:
- by written self-nomination;
 - at the end of their term;
 - as requested in writing by the Director, on the advice of the Chair, where a breach of the Code of Conduct has been established.
- 6.14. When a member retires or resigns, the AEC Secretary will notify AWV within 7 business days.

Equality

- 6.15. As far as possible, the Committee will strive for gender equality as outlined in the Florey

Equality in Science guidelines.

Confidentiality

- 6.16. Before their appointment, all AEC members shall acknowledge in writing their acceptance of The Florey AEC Terms of Reference and any requirements for confidentiality required by The Florey.
- 6.17. Members must maintain confidentiality regarding the content of applications and the deliberations of the AEC. (Code 2.2.17)

7. AEC GOVERNANCE

Evaluation and Review of the AEC

- 7.1. The Licence Nominee will oversee the functions of all Florey Animal Ethics Committees.
 - All administrative or procedural disputes will be forwarded to the Licence Nominee for resolution.
 - Minutes of all AEC meetings will be forwarded to the Licence Nominee.

Terms of Reference

- 7.2. These Terms of Reference must be reviewed at least every three years, or more frequently if required, in conjunction with the AEC.
- 7.3. The AEC Terms of Reference must be made publicly available. (Code 2.2.18)

Institutional Annual Review (Code 2.2.37)

- 7.4. In accordance with The Code, The Florey must conduct an annual review of the AEC to ensure that it is effective and consistent with The Code and Florey policies. This must include:
 - Consideration of the annual report from the AEC of its' operations.
 - Conducting an annual review of the effectiveness of AEC processes regarding complaints and non-compliance.
- 7.5. The Annual Review of the Operations of the AEC must include an assessment of the AEC Annual Report, and one or more meetings between the Licence Nominee and the AEC Chairperson/s.

Independent External Review

- 7.6. The Florey must ensure that an independent external review of the Institution's compliance with the Code is conducted at least every four years. (Code 6.1)
- 7.7. The inspection and audit reviews conducted by an independent contractor shall fulfill the requirements of an independent external review.
- 7.8. A summary of the independent external review report may be made publicly available.

8. AEC OPERATION and PROCEDURES

Frequency of AEC Meetings

- 8.1. The AEC shall meet at least quarterly, or as often as required to fulfil its functions effectively.

Institutional Support for the AEC

- 8.2. The Florey will provide the AEC with appropriate administrative assistance and resources. Such administrative assistance may be provided by an AEC Administrative Officer.

Preparation for Meetings

- 8.3. The AEC shall have, at its discretion, unlimited access to experimental personnel to discuss and investigate issues of protocols, efficacy and animal welfare.
- 8.4. Committee members are required to fully prepare for each meeting and read the documentation in advance.
- 8.5. Members must maintain confidentiality regarding the content of applications and the deliberations of the AEC. If they believe that they require additional advice, members should consult the Chairperson as to how this might be achieved without breaching confidentiality. (Code 2.2.22)
- 8.6. 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. Before any deliberations of the AEC, members must declare any interest that could influence the objectivity of their decision-making. (Code 2.2.14 & 2.2.16)

Observers In Attendance at meetings

- 8.7. At the discretion of the AEC Chair or Secretary, observer status may be offered to individuals to attend an AEC meeting. Those who are not Florey or University of Melbourne staff or students will be required to sign a Confidentiality Agreement before attending any AEC Meeting.

Interview of Applicants

- 8.8. Applicants will be interviewed at the discretion of the AEC. (Code 2.2.28) Applicants must be available for interview at those meetings when their application will be discussed by the AEC. The AEC Administrative Officer and the AEC Secretary will communicate with Applicants about these matters.

Interview Regarding Adverse Incident Reports (AIRs) and Non-compliances

- 8.9. Personnel submitting AIRs or non-compliance reports may be interviewed at the discretion of the AEC. The PI, or a person with authority to act in the PI's absence, should be available for interview at those meetings when their AIR will be discussed by the AEC. The AEC Administrative Officer or AEC Secretary will communicate with the relevant personnel about these matters.

9. Administrative Processes

New Applications

- 9.1. AEC applications must be made via the online platform TAL (tick@lab) and submitted to the Florey AEC for consideration and approval.
- 9.2. Applications for experimentation that involve the creation and breeding of new animal lines where the impact on animal wellbeing is unknown shall be required to submit a phenotype report at the appropriate time, as determined by the AEC. The AEC shall assess the impact of the genetic alteration on animal wellbeing and decide whether to give ongoing approval for the generation or breeding of the new animal line.

Amendments to Applications

- 9.3. An amendment may include:
 - Addition/removal of personnel to/from an approved project and/or a change in role for a named investigator;
 - Extension of the project approval period;
 - A change of animal numbers for an existing species/strain;

- A change of animal species, strain or breed;
- Addition of a test substance;
- A change or addition of experimental procedure, including euthanasia methods;
- A change in housing requirements, transportation requirements, hazards, locations.

9.4. The AEC will determine whether the scope of requested amendments is acceptable or requires submission as a New Application.

9.5. Minor amendments may be assessed and approved by an executive of the AEC. The definition of what constitutes a minor amendment is contained in the Guideline on Minor Amendments.

Standard Operating Procedures (SOPs) (Code 2.2.34-36)

9.6. SOP applications at The Florey HFL and KMB must be made on Florey SOP application forms and submitted to the Florey AEC for consideration and approval.

9.7. Approved SOPs must be made available to all relevant people, including AEC members. They will be accessible via the Florey Intranet- “Nucleus” and TAL.

9.8. SOPs may be approved for a period of up to 3 years. In order to provide continuity of approval, they must be reviewed and re-approved by the AEC within the approval period.

9.9. SOPs with lapsed or expired approval cannot be referenced on new applications. (Code 2.2.35)

Meeting Procedures

9.10. An Agenda shall be prepared by the Administrative Officer in consultation with the AEC Chairperson and/or AEC Secretary and the link to the electronic documents forwarded to all AEC members at least 12 days prior to the scheduled meeting.

9.11. All items for the meeting agenda should be submitted to the Administrative Officer via TAL no less than 16 days prior to a scheduled meeting of the AEC. All necessary meeting documents shall be made accessible electronically or via TAL to each AEC member 12 days prior to the date of the meeting. Under extenuating circumstances, additional items may be provided via TAL at least 48 hours prior to the meeting.

9.12. Items of clarification or of minor correction may be sent to AEC members via e-mail and link to the electronic documents.

9.13. Unless there are circumstances deemed extenuating by the AEC Chairperson, applications submitted late shall not be considered at the forthcoming meeting; they will be held in abeyance until the subsequent meeting of the AEC.

9.14. The AEC must only make decisions when it is balanced and quorate, including after the withdrawal of any members with a conflict of interest.

9.14.1. Quorum requires at least one member from each of the Categories A to D.

9.14.2. Balance requires Categories C and D to represent no less than one third of the combined Category A, B, C and D members.

9.15. When a face-to-face meeting is not possible, and the meeting does not reach a quorum, the use of videoconference facilities may be used to establish a quorum. The videoconference must remain in place for the duration of the meeting.

9.16. All AEC members are required to declare, at the beginning of any relevant discussions, any conflict of interest. Members with a conflict of interest must not be present during AEC discussions or decisions, but may be interviewed by the AEC as any other applicant. (Code 2.2.16)

9.17. Approval, modification, or rejection of all applications, amendments and addenda shall be by 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. (Code 2.3.11)

- 9.18. If consensus cannot be achieved, the AEC should only proceed to a majority decision after members have been allowed a period of time to review their positions, followed by further discussion. If requested by at least two (2) members of the AEC a vote by “show of hands or by ballot” may be conducted. In such instances, only those members listed on the applicable Licence as voting members shall participate in the vote.
- 9.19. The AEC may decide that an application to commence a project, or amend an approved project, is:
 - Approved without conditions;
 - Approved with conditions;
 - Conditions may include modification of the Application to the satisfaction of the AEC executive, Chairperson, or Secretary as described in the AEC Guideline on Minor Amendments;
 - Not approved, but may be revised and resubmitted to the AEC;
 - Not approved.
- 9.20. Where modifications are required for approval, the AEC’s comments will be sent to the applicant(s) in a timely manner by the Administrative Officer via TAL. It is the applicant’s responsibility to check TAL for status updates on their application(s) and to respond to the AEC’s comments accordingly.
- 9.21. All required signatures must be captured in TAL before approval can be given to an application, amendment, or Report.
- 9.22. A notification of approval sent via TAL must be received by the applicant before experiments can start. This approval notice must include any conditions of approval imposed by the AEC.
- 9.23. The AEC may decide that following review of the annual report for an approved project, the approval is continued, suspended, modified, or discontinued.

Complaints Concerning AEC Process

- 9.24. Investigators that wish to query an AEC decision should first raise their concerns with the AEC Secretary or Chairperson for further explanation. If they are unsatisfied with the response, they may escalate their grievance to the Licence Nominee.
- 9.25. The Licence Nominee may investigate the decision-making processes of the AEC. If they find that the correct process was not followed, they may send the item back to the AEC for re-consideration.
- 9.26. Any investigation into AEC decisions is limited to a determination of whether the correct process was followed. The decisions of the AEC may not be overturned, except by the AEC itself.

Facility Inspections

- 9.27. The frequency and timing of inspections is determined by the AEC, but inspection of animal facilities must occur at least annually.
- 9.28. The inspection team should include at least one Category C or D member, while encouraging other categories of AEC members to participate.
- 9.29. The AEC shall have ready access to animal housing facilities at any reasonable time. Such access shall be specifically arranged only through the Chairperson or Secretary of the Committee. It shall not be necessary for the AEC to state the reason for such an inspection.
- 9.30. The inspection findings will be documented in a report that includes at a minimum:

- Names of all attendees
- Observations
- Identified problems
- Recommended actions
- Ongoing or outstanding issues
- Outcomes

9.31. The inspection report shall be provided to the next scheduled meeting of the AEC.

9.32. The Florey Veterinarian, at their discretion, shall have immediate rights to inspect any animals involved in Florey AEC-approved projects or housed at sites approved by the Florey AEC. A report of such inspections shall be provided to the next scheduled meeting of the AEC.

10. Record of Version

Version	Version reason	Author(s)	Date
2.0	Update	D. Kaiserman	April 2025
1.0	Update based on Independent External Review	D. Kaiserman	April 2024

END OF DOCUMENT

I have read, and agree to abide by, these Terms of Reference.

Signed:

Name:

Date: