

# THE FLOREY ANIMAL ETHICS COMMITTEE

## TERMS OF REFERENCE

### AND PROCEDURAL GUIDELINES

## Responsibilities

**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 care and use of animals for scientific purposes is conducted in compliance with the following:**

- National Health and Medical Research Council *Australian Code for the Care and Use of Animals for Scientific Purposes*, 8th Edition 2013;
- State legislation (Victorian *Prevention of Cruelty to Animals Act 1986* (POCTA) and the *Prevention of Cruelty to Animals Regulations 2008*);
- Florey Institute of Neuroscience and Mental Health policies, procedures and guidelines.

In fulfilling this function, the AEC will:

- ensure that all approved projects are ethically acceptable, and the use of animals is justified;
- ensure that animal breeding, animal care and husbandry complies with the requirements of the Code;
- give due consideration to the welfare of these animals and avoid or minimise harm to them (including animal pain and distress);
- apply the highest standards of ethical and scientific integrity;
- incorporate the principles of Replacement, Reduction and Refinement at all stages; and
- fulfil all other responsibilities in compliance with State legislation and the *Australian Code for the Care and Use of Animals for Scientific Purposes*, 8th Edition 2013.

## Terminology:

- The Florey Animal Ethics Committee, hereafter referred to as the “AEC”.
- The Florey Institute of Neuroscience and Mental Health and any associated organisations, hereafter referred to as the “The Florey”.
- The Kenneth Myer Building in Parkville and the Florey Austin Campus building, hereafter referred to as the “KMB”.
- The Howard Florey Laboratories, hereafter referred to as “HFL”.
- The *Australian Code for the Care and Use of Animals for Scientific Purposes*, 8<sup>th</sup> edition 2013, hereafter referred to as “The Code”.
- The Victorian Prevention of Cruelty to Animals Act 1986 (POCTA) and Amendment Regulations 2001, hereafter referred to as “The Act”.
- The Victorian Government Regulator, Animal Welfare Victoria (AWV).
- The Nominated Person of the Scientific Procedures Premises Licence/s; hereafter referred to as the Florey “Licence Nominee”.

## Licence Designations

This document refers to the following POCTA scientific licences:

SABL20349 – The Florey Breeding

SPPL20221 – The Florey

SPPL20195 – University of Melbourne at the Melbourne Brain Centre (Parkville)

## **TERMS OF REFERENCE (TOR)**

### **Scope of AEC Responsibilities**

1. **Approve guidelines for the care and use of animals.** Approve Florey animal welfare guidelines and comment on Florey plans and policies which may impact on animal welfare. (Code Section 2.3.2 vii; 2.3.26)
2. **Monitor the care and use of animals.** Approve and monitor the acquisition, transportation, husbandry and fate of all animals used in scientific experimentation. (Code 2.3.17-2.3.23)
3. 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. (Code 2.3.2 (iv))  
Inspections must be conducted at least annually, and involve at least one Category C or D member, at least one Category A or B member, a Category E member and/or Animal Facility Manager, and a Chairperson or Deputy Chairperson.
4. **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 relevant State legislation and The 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)
5. **Review and approve new and ongoing activities.** (Code 2.3.3-2.3.16)  
Rigorously examine and review submissions, and either approve, recommend modification/s or reject:
  - 5.1 Project applications and amendments relating to the use of animals in breeding and scientific experimentation;
  - 5.2 Standard Operating Procedures (SOPs), with each SOP to be reviewed triennially;
  - 5.3 Phenotype reports for genetically modified animals that may have specific welfare needs;
  - 5.4 Delegation of responsibility/Fieldwork requests from other universities and research institutions.
6. Approve only those applications for which animal use is essential and justified and conform to the requirements of the Code. (Code 2.3.2 (i))  
This should include consideration of factors such as:
  - ethics,
  - the anticipated scientific or educational value;
  - the impact or burden on the animal/s;
  - the principles of Replacement, Reduction, Refinement;
  - the qualifications and experience of the personnel performing or supervising the use of animals for teaching and research;
  - use of terminology that is easily understood by a lay member with little or no scientific background, and includes a lay-level summary.
7. Approve applications for 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))

8. Be satisfied that staff are appropriately qualified and experienced, and that such staff records are maintained on a Skills Register. In addition, support ongoing training of Florey staff.
9. Delegate to the AEC Executive the responsibility for approving out-of-session applications for minor amendments to already-approved applications. A minor amendment may include:
  - a change to an approved project or activity, only where the proposed change is not likely to increase the level of burden to the animals, including pain and distress.
  - A change to an approved project to add appropriately qualified and experienced staff and students.

The AEC Executive Committee shall not approve any new pilot projects or applications.

10. Delegate to the AEC Executive the responsibility to review and give final approval to applications where the AEC's decision at the meeting (despite in-principle approval) was **approval "deferred subject to modifications to the satisfaction of the AEC"**. Approval will be given after the Executive is satisfied that the revised application has incorporated the minor changes or clarifications sought by the AEC.
11. Delegate to the AEC Executive the authority to vary conditions of any AEC application only in the case of an emergency, or when the welfare of animals is a concern, e.g. suspend approval of a project.
12. A meeting of the AEC may delegate to the Chairperson the responsibility to review and give final approval to applications approved with a condition(s) where only very minor or administrative changes are required.
13. All decisions made by the AEC Executive or Chairperson out-of-session will be reviewed and ratified by the entire AEC at the next quorate meeting.
14. Annually Review all current and completed projects. Review Closure Reports for projects completed or expired during the year. Conduct an annual review of progress of approved projects, to allow the continuation of their approval.  
(Refer to Clauses 2.2.32 (ii) and 2.3.2 (iii) of the Code).
15. **Take action regarding unexpected adverse events.** Take appropriate actions regarding unexpected adverse incidents. The AEC shall ensure that a robust enquiry/review is conducted in the event of an adverse incident. Actions may include consulting with relevant people and, where necessary, suspending or withdrawing approval for the project or activity. Refer to the document "*Reporting of Animal Incidents and Adverse Events*" for details. (Code 2.3.2 (v); 2.3.24)
16. **Review complaints**, on a confidential basis, from animal house staff, researchers or others on conduct relating to the use of animals and instigate corrective or disciplinary procedures as outlined in institutional procedures.
17. **Take appropriate actions regarding non-compliance.** Where deemed necessary by the AEC or its Executive, withdraw approval for any project or activity, thus causing cessation of all experimentation. Withdrawal or suspension of approval will occur for any project or activity that is conducted in a manner not compliant with the Code, Act and/or Regulations. Refer to the document "*Procedures for responding to complaints and non-compliance with animal welfare legislation, the Australian code for the care and use of animals for scientific purposes, or animal ethics committee decisions*" for details. (Code 2.3.2 (vi); 2.3.25)

18. Minutes of every AEC meeting will be prepared by the AEC Secretariat, a draft of which shall be circulated to all AEC members with opportunity for input. Comments from all category members shall be given due regard in the Minutes approval process. The Minutes approved by the AEC will be maintained as a record, and copies provided to the Licence Nominee and the Director of The Florey. (Code 2.3.2 (ix))
19. Maintain accurate records of all projects, amendments, adverse incidents, SOPs, approved personnel and personnel changes.
20. **Report annually to The Florey** as per sections 2.3.2 (ix) & 2.3.28-29 of The Code. Comply with the reporting requirements of The Florey, the POCTA Act and Regulations, and the Code.
21. Conduct an annual Animal Ethics induction and information session for The Florey HFL and KMB personnel involved with animal experimentation. Attendance, or completion of other suitable Animal Ethics training, is mandatory for new research staff and students.
22. Encourage and facilitate AEC-related training and conference attendance for all AEC members.
23. Perform all other duties as prescribed by The Code and POCTA legislation.

### **Number of Committees and the Florey AEC Executive**

The Florey may appoint as many Animal Ethics Committees (AECs) as determined by the Director of The Florey upon the advice of the Chairpersons of the AECs and the Florey Licence Nominee. Before appointing a new AEC The Florey must first formally notify the government regulator (Animal Welfare Victoria) of the proposal.

**Each AEC shall appoint its own Executive** (e.g. AEC1 Executive, AEC2 Executive, etc.) for the purpose of reviewing revised applications and approving these on behalf of the AEC (Refer to points 9, 10 & 11 below). As a minimum, this Executive shall consist of the AEC Chair and a Category C or Category D member. Other self-nominated members of the AEC may join the Executive for the purpose of reviewing specific applications as deemed appropriate.

## Membership

### Membership Requirements for Code Compliance (Code 2.2.2-12)

The Code requires a minimum of four AEC members, including at least one separate person for each of the following categories A, B, C & D.

- Categories C & D must together represent at least one-third of the AEC membership. (Code 2.2.8)

*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 shall 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.

**To assist the AEC to function effectively The Florey may appoint as members additional people with skills and background of value to the AEC.** These additional people may perform more than one role. The Florey will appoint to the AEC:

- One or more Deputy Chairpersons, drawn from the AEC membership. A Deputy Chairperson is not mandatory for a quorate meeting;
- A Secretary, who shall be a member of the Florey AEC. A Secretary is not mandatory for a quorate meeting.
- “*Category E*” A person responsible for the routine care of animals from within The Florey. This member is not mandatory for a quorate meeting.
- Other members, as determined by the Director of The Florey upon the advice of the Chairpersons of the Animal Ethics Committees and the Licence Nominee. These members are not mandatory for a quorate meeting.

## Office Holders

*Chairperson* - The Chairperson shall be appointed by the Director of The Florey following AEC consultation and recommendation. 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)

The Chairperson should possess the following attributes:

- (i) the necessary skills to manage the business of the AEC,
- (ii) the capacity to remain impartial, and the ability to negotiate and resolve conflict,
- (iii) a thorough understanding of the ethical and welfare issues in the use of animals for scientific purposes including an understanding of The Code and State legislation, and
- (iv) acknowledged skills in the management of experimental personnel and their wellbeing.

*Deputy Chairperson/s* - A Deputy Chairperson may assume the role of Chair if the Chair is absent. A Deputy Chairperson shall be a current member of the AEC and shall be appointed by the Director of The Florey following AEC consultation and advice.

This person shall bring to the position:

- (i) impartiality and a high degree of independence,
- (ii) a thorough knowledge of business and meeting procedures,
- (iii) a good understanding of the culture of The Florey, and
- (iv) a demonstrable commitment to animal welfare.

*Secretary* - The AEC Secretary shall be appointed by the Director of The Florey upon the recommendation of the AEC.

This person shall bring to the position:

- (i) a thorough knowledge of business and meeting procedures,
- (ii) a thorough knowledge and understanding of the ethical and welfare issues in the use of animals for scientific purposes including an understanding of the Code and relevant State legislation, and
- (iii) the ability to provide impartial advice to the AEC on all AEC-related matters.

*Minute Recording Secretary* – The AEC will be supported by an administrative assistant, appointed by Florey Management. (Code 2.2.19)

## **Appointment, Reappointment and Retirement of Members**

The AEC Chairperson will advise the Licence Nominee and the Director of The Florey regarding the appointment, reappointment, retirement or resignation of AEC members.

- If there is to be a change in the membership of an Animal Ethics Committee nominated by the licence holder, the Florey Licence Nominee must notify Animal Welfare Victoria of the proposed change before the change is made.

### **Terms of Appointment**

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**

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 and Animal Welfare Victoria.

These expressions of interest will be assessed by the Licence Nominee, AEC Chairpersons and members of the Executive Committee. Ineligible candidates will be advised, and interviews of eligible candidates will be conducted where required. Final appointment requires approval of candidates by Animal Welfare Victoria.

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**

Members shall be retired in one of three ways: by written self-nomination; at the end of their term; or as requested in writing by the Director, where a breach of the Code of Conduct has been established, on the advice of the Chair.

When a member retires or resigns, the Licence Nominee will notify AWV within 7 business days

### **Equality**

As far as possible, the Committee will strive for gender equality as outlined in the Florey Equality in Science guidelines.

### **Confidentiality Agreement**

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. Members must maintain confidentiality regarding the content of Applications and the deliberations of the AEC. (Code 2.2.17)

## **AEC GOVERNANCE**

### **Evaluation and Review of the AEC**

The Florey Licence Nominee will oversee the functions of all Florey Animal Ethics Committees.

- All administrative or procedural queries will be forwarded to the Florey Licence Nominee for resolution.
- Minutes of all AEC meetings will be forwarded to the Florey Licence Nominee.

### **Terms of Reference**

The Florey Licence Nominee shall review the terms of reference of the AEC every three years, in conjunction with the Committee.

### **Institutional Annual Review** (Code 2.2.37)

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:

1. Conducting an annual review of the operations of the AEC.
2. Conducting an annual review of the effectiveness of its processes regarding complaints and non-compliance.

**The Annual Review of the Operations of the AEC** must include an assessment of the AEC Annual Report to the Florey, and one or more meetings between the Florey Licence Nominee and the AEC Chairperson/s.

### **Independent External Review**

In accordance with The Code, 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)

- The inspection and audit reviews conducted by the government regulator, Animal Welfare Victoria fulfil the requirements of an independent external review.
- The AEC Terms of Reference, and a summary of the independent external review report, must be made publicly available. (Code 2.2.18)



## **AEC OPERATION and PROCEDURES**

### **Frequency of AEC Meetings**

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

### **Institutional Support for the AEC**

The Code (Section 2.1.6; 2.2.1(iii)) requires The Florey to provide the AEC with appropriate administrative assistance and resources. Such administrative assistance may be provided by a Minute Recording Secretary.

### **Preparation for Meetings**

- AEC members shall have, at their discretion, unlimited access to experimental personnel to discuss and investigate issues of protocols, efficacy and animal welfare.
- Committee members are required to fully prepare for each meeting and read the documentation in advance.
- 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)
- 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**

At the discretion of the AEC Chair or Secretary, observer status may be offered to individuals to attend an AEC meeting.

### **Interview of Applicants**

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 Assistant and the AEC Secretary will communicate with Applicants about these matters.

### **Interview Regarding Adverse Event Reports (AIRs)**

Personnel submitting AIRs will be interviewed at the discretion of the AEC. Personnel must be available for interview at those meetings when their AIR will be discussed by the AEC. The AEC Administrative Assistant and the AEC Secretary will communicate with the relevant personnel about these matters.

## Administrative Processes

### 1. Applications

#### 1.1 New Applications

- (a) AEC applications at The Florey HFL and KMB must be made on **Florey AEC application forms** and submitted to The Florey AEC for consideration and approval. Only complete applications will be accepted for review. A complete application is one that is submitted on time with all the required signatures and relevant forms.
- (b) 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.

#### 1.2 Minor Amendment Applications

A minor amendment may include:

- 1.2.1 Addition of suitably experienced personnel to an approved project;
- 1.2.2 A change to an approved project or activity only where the proposed change is not likely to increase the level of burden to the animals, including pain and distress;
- 1.2.3 A change of Chief Investigator;
- 1.2.4 A change of animal numbers;
- 1.2.5 A change of animal species, strain or breed;
- 1.2.6 Extension of project approval period;
- 1.2.7 Addition of experiments where the proposed change(s) is not likely to increase the level of burden to the animals, including pain and distress

1.3 The AEC will determine whether Amendment Applications other than those listed in section 1.2 are acceptable, or require submission as a New Application.

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

- (a) 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.
- (b) Approved SOPs must be made available to all relevant people, including AEC members. They will be accessible via the Florey Intranet- "Nucleus".
- (c) 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. SOPs with lapsed or expired approval cannot be used. (Code 2.2.35)

### 2. Meeting Procedures

- (a) An Agenda shall be prepared by the Recording Secretary in consultation with the AEC Chairperson and/or AEC Secretary and the link to the electronic documents forwarded to all AEC members at least 10 working days prior to the scheduled meeting.
- (b) All items for the meeting agenda should be submitted to the Recording Secretary no less than 12 working days prior to a scheduled meeting of the AEC. All necessary meeting documents shall be made accessible electronically to each AEC member 10 working days

prior to the date of the meeting. Under extenuating circumstances, additional items may be provided via e-mail at least 48 hours prior to the meeting.

- (c) Items of clarification or of minor correction may be sent to AEC members via e-mail and link to the electronic documents.
- (d) 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.
- (e) An application lacking a signature(s) and/or completed on a non-current form will not be accepted.
- (f) Only investigators listed on the Project Application documentation approved by the AEC may be involved in the project. Additional investigators may apply to the AEC, via an amendment request, to have their name added to the project at a future date.
- (g) A **quorate meeting** shall consist of at least one member from each of the Categories A to D including after the withdrawal of any members with a conflict of interest. Categories C and D must represent no less than one third of the AEC member attendees. 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.
- (g) All AEC members are required to declare, at the beginning of each meeting, any conflict of interest and deal with situations in which such conflict of interest arises. (Code 2.2.16)
- (h) The AEC shall ratify amendments approved by the Executive Committee out-of-session.
- (i) Approval/modification/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)
- (j) 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 instance the Chairperson shall have a casting vote.
- (k) The AEC may decide that an application to commence a project, or amend an approved project, is:
  - Approved without conditions;
  - Approved with conditions;
  - Approval decision deferred, subject to modification of the Application to the satisfaction of the AEC;
  - Not approved, but may be revised and resubmitted to the AEC;
  - Not approved.

- (l) The AEC may decide that following review of the annual report for an approved project, the approval is continued, suspended, modified, or discontinued.
- (m) Minutes shall be kept of all AEC meetings and circulated to all Committee members within ten working days of the meeting for their comments. They shall e-mail their comments to the AEC Administrative Officer within 5 working days from receipt of this document. The Minutes will be updated accordingly by the Administrative Officer and shall be regarded as “Draft Minutes” until adoption at a quorate meeting of the AEC, after which the “Draft Minutes” will become “Minutes”. The “Minutes” shall be sent by email to the Florey Director, the Licence Nominee, the Florey Head of Scientific Operations, and the members of the Florey AEC Executive Committee.
- (n) **Upon completion of the “Minutes”, the AEC Administrative Officer shall send an official e-mail detailing the application outcome to the applicant(s) within 20 working days after the meeting.** This approval notice must include any conditions of approval such as the submission of phenotype reports, the submission of interim reports from pilot studies, a Florey vet signing off on new procedures, and the like.

The table below shall serve as a guide to the timeline of the animal ethics application process, including deadline dates.

<b>Timeline of the Animal Ethics Application Approval Process</b>		
<b>Day #</b>	<b>Time details</b>	<b>What happens</b>
Day -16	12 working days before AEC meeting	Submission deadline for all applications
Day -10	10 working days before AEC meeting	All Meeting Agenda application documents sent to AEC members
Day zero	2nd Wednesday of the month	AEC meeting
Day +10	10 working days after AEC meeting	Draft Minutes sent to AEC members for comments
Day +15	15 working days after AEC meeting	"Draft Minutes" finalised for adoption at a quorate meeting
Day +15	15 working days after AEC meeting	Application outcomes e-mailed to applicants

### 3. Out-of-session Amendment Applications

- 3.1 An amendment application submitted for AEC Executive consideration outside of the regular AEC meetings must first have the prior approval of the AEC Chairperson and/or the AEC Secretary of the next scheduled AEC meeting. Such out-of-session amendment applications will only be considered in **emergency situations** where the application cannot be held in abeyance until the next scheduled meeting. Clear and specific justification must be given by the applicant(s) and these must relate primarily to issues of animal welfare or sudden and unexpected incidents which may have arisen. If circumstances are warranted, such applications will be forwarded to members of the AEC Executive Committee by email on the last working day of the week for a response within four days.
- 3.2 In accordance with the Code, minor amendments to add expert personnel may be considered and approved outside of regular AEC meetings by the Florey AEC Executive. Such minor amendments may be considered by the AEC Executive out of session subject to: 1) a justification why the application cannot wait until the next scheduled AEC meeting, and 2) an explicit written statement by the PI or by CAS that the competence of said added personnel to perform the stated relevant technique is deemed at “expert” level.

### 4. Procedures for responding to Adverse Incident Reports (AIRs)

An adverse incident is any event that is not anticipated within an approved animal ethics project -or was expected but has occurred at a frequency or severity in excess of that forecasted -which impacts negatively on the wellbeing of animal(s). This can be a single or cumulative event, and will normally involve unexpected mortality, morbidity or injury. Sudden deaths, and husbandry-related accidents (such as flooding), are included.

- Adverse incidents are reported to the Florey Veterinarians, Animal Facility Manager, Florey AEC Chairs or AEC Secretariat, as detailed in the document “*Reporting of Animal Incidents and Adverse Events*”.
- When an Adverse Event Report (AIR) is received, the AEC Secretary will include this with AEC Meeting Agenda documents, or forward this immediately to AEC members, depending on the degree of urgency as determined by the AEC Chair.
- The AIR will be discussed at an AEC meeting, and the relevant researcher or animal facility manager interviewed.
- The AEC will determine any corrective actions required, on a case-by-case basis, in accord with the Florey document “*Reporting of Animal Incidents and Adverse Events*”.

### 5. Procedures for Responding to Complaints and Non-compliance (Code 2.2.29; 2.3.2 (vi); 2.3.25)

Refer to the document “*Procedures for responding to complaints and non-compliance with animal welfare legislation, the Australian code for the care and use of animals for scientific purposes, or animal ethics committee decisions*” for details.

## **6. Grievance Procedure**

The AEC and The Florey shall abide by the Grievance procedure as outlined in The Code or as recommended by Animal Welfare Victoria (AWV). Complaints shall be treated in confidence and the Florey shall make diligent efforts to protect the positions and reputations of those persons who, in good faith, air their grievances.

Irreconcilable differences between the AEC and an investigator must be referred to the Florey Licence Nominee for review of the due process.

## **7. Facilities Inspection**

- 7.1 The frequency and timing of inspections is determined by the AEC, but inspection of animal facilities must be at least once per year and involve at least one Category C or D member, at least one Category A or B member, a Category E member or Animal Facility Manager, and a Chairperson.
- 7.2 All AEC members shall have ready access to animal housing facilities at any reasonable time. Such access shall be specifically arranged only through the Chairperson/and or Secretary of the Committee. It shall not be necessary for the AEC member to state the reason for such an inspection.
- 7.3 The inspection findings will be documented for endorsement by the AEC members involved. The inspection report shall include details of any identified problems and recommendations, and be provided to the next scheduled meeting of the AEC.
- 7.4 The Florey veterinarian, at his or her discretion, shall have immediate rights to inspect any animals involved in Florey AEC-approved projects. A report of such inspections shall be provided to the next scheduled meeting of the AEC.

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