



The Walter and Eliza Hall Institute

Animal Ethics Committee Terms of Reference

Walter & Eliza Hall Institute Animal Ethics Committee

Approved by Animal Ethics Committee on 9 July 2018

11. Aims

The use of animals for scientific purposes in Victoria is governed by the *Prevention of Cruelty to Animals Act 1986* (the Act) and the *National Health and Medical Research Council Australian Code for the Care and Use of Animals for Scientific Purposes 8th Edition 2013* (the NHMRC Code).

The primary role of the Walter and Eliza Hall Institute (the Institute) Animal Ethics Committee (AEC) is to ensure compliance with the relevant legislation and code of practice and that a high standard of animal welfare and an ethical approach towards the use of animals in experimental procedures is uniformly observed across Institute campuses. The Institute's AEC actively seeks to implement refinements to scientific procedures involving animals and aims to promote confidence in the wider community that medical research involving animals is ethical and well regulated.

To fulfill these roles, the Institute's AEC reviews and approves all activities involving animals to ensure that high standards of animal welfare are maintained. The AEC also oversees the development of Standard Operating Procedures (SOPs) related to the use of animals in research and ensures that animal facilities are maintained at a high standard.

The purpose of this document is to outline the operational procedures and policies of the Animal Ethics Committee, following the regulations outlined in the NHMRC Code.

12. Scope of responsibilities

The Animal Ethics Committee shall:

- a. Examine written proposals relevant to the use of animals in scientific research, and decide upon an appropriate outcome. Applications may be approved, conditionally approved, or not approved. The members shall approve only those studies for which the use of animals is justifiably essential and which conform to the requirements of the NHMRC Code, considering ethical and welfare aspects as well as scientific value.
- b. Review guidelines for the care and use of animals and monitor their acquisition, transport, production, housing, and disposal.
- c. Ensure Institute risks relating to animal ethics (including those associated with individual projects) are adequately identified, treated and reported in line with the Institute's risk management framework.
- d. Recommend to the Institute and other animal facilities any measures required to ensure that the standards of the NHMRC Code are maintained. This may include recommendations offered to other animal facilities submitting protocols to the Institute's AEC.

- e. Formally withdraw approval for any project or authorise the treatment or euthanasia of any animal.
- f. Examine and comment upon all plans and policies which outline activities with the potential to affect animal welfare.
- g. Ensure that policies exist to enable staff and students to be adequately supervised and trained in the care and use of animals for scientific purposes.
- h. Report to the Deputy Director (Strategy and Operations) of the Institute in matters relating to animal use and welfare as required by the NHMRC Code.
- i. Perform all other duties required under the NHMRC Code including compliance with policies and guidelines, audits and inspection of animal houses and laboratories and submission of an AEC annual report.
- j. Require all members of the AEC to declare any conflict of interest.
- k. Maintain a register of approved projects.

13. Membership composition

The Institute's AEC must include five categories of membership. The relevant sections (2.2.4 – 2.2.8) from the NHMRC Code are quoted below.

The membership of the AEC must comprise at least one person from each of four categories:

- a. Category A - a person with qualifications in veterinary science that are recognised for registration as a veterinary surgeon in Australia, and with experience relevant to the institution's activities or the ability to acquire relevant knowledge.
- b. Category B - a suitably qualified person with substantial and recent experience in the use of animals for scientific purposes relevant to the institution and the business of the AEC. This must include possession of a higher degree in research or equivalent experience.
- c. Category C - a person with demonstrable commitment to, and established experience in, furthering the welfare of animals, who is not employed by or otherwise associated with the institution, and who is not currently involved in the care and use of animals for scientific purposes. 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 organization.
- d. Category D - a person not employed by or otherwise associated with the institution and who has never been involved in the use of animals in scientific or teaching activities, 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.

The NHMRC Code includes provision for the AEC membership to include person responsible for the routine care of animals within the institution. The Institute's AEC specifies that membership must include representative animal technicians.

The committee must also appoint a Chairperson, who is responsible to guide the operation of the AEC, resolve conflicts of interest related to the business of the AEC, facilitate discussion of any concerns (in confidence if required) and represent the AEC in any negotiations with Institute management.

Additional members with skills and background of value to the AEC may be appointed. The AEC may invite people with specific expertise to provide advice, as required.

Categories C and D must together represent at least one third of the AEC membership.

14. Quorum

The quorum shall consist of at least 6 members present: the Chairperson, one representative from Category A, B, C and D and an animal technician. The quorum must also be at least one-third Category C and D members.

AEC members must notify the AEC Convener as soon as possible if they are unable to attend a meeting. Alternatively, arrangements may be made to enable absent members to participate remotely, for instance the use of videoconferencing or teleconferencing. If it is not possible to satisfy the requirements of the quorum, then the meeting shall either be cancelled or rescheduled.

15. Meeting frequency

Meetings shall be scheduled approximately every 6-8 weeks (7 meetings per calendar year). Any increase in the frequency of meetings should be discussed and approved by the AEC.

16. Appointment, reappointment and retirement of members

Procedures for appointing members are as follows:

- a. Category A: An *ex officio* position for the Institute Veterinarian or suitably qualified person internal or external to the Institute.
- b. Category B: All members are required to be currently employed by the Institute in a research position. Potential members are either personally invited, or identified by response to a call for expressions of interest which is advertised on the Institute's intranet. Members are selected based upon their past and current experience with animal experimentation, and their specific knowledge base.
- c. Category C: Potential members will be sought through contacting animal welfare organisations. If this is method is unsuccessful, further approaches may be pursued, for instance online advertisements. Members are selected based upon their suitability to fulfill the requirements of a Category C member.
- d. Category D: Potential members are identified through recommendation by existing AEC members or other Institute employees. If this is method is unsuccessful, further approaches may be pursued, for instance online advertisements. Members are selected based upon their suitability to fulfill the requirements of a Category D member.
- e. Other members: If required, any additional members with relevant skills and background are appointed at the discretion of the AEC.

Apart from *ex officio* members, the recommended term of office shall be 5 years, with the possibility of re-appointment for an additional 5 years. Extensions to terms of appointment may be offered upon recommendation of the committee.

Members are made aware that their continued participation in the AEC is voluntary. If a member

wishes to retire, they should notify the AEC Convener as soon as possible.

7. Voting rights of members

If a situation arises in which the Chairperson calls for a vote, all members have the right to vote, except:

- a. Under circumstances in which a conflict of interest might exist.
- b. Where a member is co-opted to the committee for the purposes of providing expertise on specific issues, and hence takes no real part in the proceedings of the Committee other than offering expert advice on the issues concerned.
- c. Additional members of the committee (not fulfilling the positions of Category A, B, C or D) not nominated to possess voting rights.
- d. The AEC Convener does not have voting rights.

8. Acceptance of terms of appointment

The NHMRC Code states (section 2.2.11): "Before appointment, all members of the AEC should acknowledge in writing their acceptance of the terms of reference of the AEC and any requirements for confidentiality required by the institution."

All new AEC members must sign the Institute's AEC Acceptance of Terms of Appointment document. If the AEC Terms of Reference document is updated, all current members must also sign the document to confirm their acceptance of the new Terms of Reference.

9. Confidentiality and Security

- a. New external AEC members (not Institute employees) must sign the Institute's *AEC Acceptance of Terms of Appointment* document. This agreement allows the AEC member to seek expert advice on documents and information not marked Commercial-in-Confidence, providing such advice sought is on a confidential basis and the member does not disclose any sensitive aspects of the document, such as the details of a particular experiment proposed by a particular researcher.
- b. New AEC members who are internal Institute staff are required to sign a confidentiality agreement as a condition of their employment with the Institute.
- c. Documentation to be used in AEC meetings will be electronic (PDF format). All files will be accessed online via a secure server available only to AEC members. The AEC Convener will be responsible for deleting these documents from the server after the meeting.
- d. AEC iPads are the property of the Institute and are issued to AEC members for the term of their tenure on the AEC. Conditions of use are outlined in the Provision of Institute iPads form signed by the AEC member when the iPad is issued. AEC members are responsible to ensure appropriate security of the iPads in their possession, including confidentiality of documentation.
- e. If excess hard copies of AEC documents exist, the AEC Convener will be responsible for destroying these documents in a confidential manner.
- f. All files maintained by the AEC Convener, Institute Veterinarian/Head of Bioservices and animal facility personnel must be located in a secure area.

10. Conflict of interest

The agenda for each meeting must state at the beginning of the document: "Members are required to refrain from voting and absent themselves from the discussion of an item of business in which they have a conflict of interest." The minutes of the meeting should record that the committee has adhered to its policies regarding conflict of interest.

If the chairperson or an AEC member has a conflict of interest regarding an application or other item considered by the AEC:

- a. In the case where the Chairperson has a conflict of interest:
 - i. the Chairperson vacates the Chair;
 - ii. the meeting is chaired by a Deputy/Acting Chairperson for that item of business;
 - iii. the Chairperson absents himself/herself from the meeting during discussion of his/her proposal and only responds to questions directed to him/her upon return should they be put forward. The Chairperson will not participate in voting on the proposal;
 - iv. The Chairperson assumes the Chair at the conclusion of AEC consideration of that proposal.
- b. In the case where an AEC member has a conflict of interest:
 - i. the member concerned absents himself/herself from the meeting during discussion of his/her proposal and only responds to questions directed to him/her on his/her return to the meeting;
 - ii. the member will not participate in voting on the proposal;
 - iii. the AEC must remain in quorum during the absence of the committee member.

11. Approval Process

I. Consideration of Proposals

- a. The types of documents requiring AEC approval include:
 - i. New project applications
 - ii. Amendments to previously approved projects (e.g. new procedures, modifications to previously approved procedures, increases in animal numbers)
 - iii. New staff or changes to staff responsibilities
 - iv. New strains of animals
 - v. Reports or other correspondence
- b. Although there is no limitation regarding the number of revisions which are allowed within the approved duration of the research project, revisions to existing projects are only permitted when there is no substantial change in the overall nature or direction of the project. Whether an experimental proposal should be considered as a revision to an existing project or require a new project application is a matter for the committee to decide.
- c. Approval for projects is valid for a period of 3 years. Extensions to this period will be considered upon application to the committee. The maximum period of extension is 12 months.
- d. If the researcher wishes to continue a project for an additional 3 years, the researcher must submit a new project application in a timely manner, allowing sufficient time for the AEC to consider the new project application before the expiry of their current project.

- e. Only those research projects which conform to the requirements of all relevant sections of the NHMRC Code and government legislation may be approved.
- f. Decisions should be made by consensus. Cases in which consensus cannot be reached should follow the guidelines listed in part iii below.
- g. AMS project records shall be updated as soon as possible after AEC meetings to inform applicants of AEC decisions.
- h. Records of all approved proposals shall be maintained on AMS.
- i. Decisions shall be made as promptly as possible.
- j. Research projects involving the use of animals must not commence before procedures are approved on AMS.

II. Conditions of approval

- a. All AEC applications are approved subject to the following conditions:
 - i. Researchers must report upon the project at least annually through submission of an Annual Report to the AEC.
 - ii. Researchers must review the animal number figures for inclusion in the Institute's Annual Return to the Victorian Government Department of Economic Development, Jobs, Transport and Resources (DEDJTR) (see section 19. Licensing and Regulatory Compliance.)
 - iii. Researchers must submit a Final Report to the AEC upon completion (regardless of whether or not they are submitting a renewal application to continue the work.)
 - iv. Any unexpected adverse events must be immediately reported to the AEC through submission of an Adverse Event Report (as outlined in the AEC's procedure document Adverse Events Reporting.)
 - v. In some cases, the AEC may approve procedures as preliminary pilot studies and require submission of a Pilot Report. Specific directives of the AEC would be outlined in correspondence to the applicant.
 - vi. The AEC may decide to suspend or withdraw approval for a project if considered necessary.
 - vii. If considered necessary by the AEC, the committee may conduct a formal audit of research projects and records related to animal experimentation.
- b. If the AEC decision is to grant the project overall status of "Approved", this indicates that experiments are approved to commence. This approval is subject to the conditions outlined in part (a) only.
- c. If the AEC decision is to grant the project overall status of "Conditionally Approved", this indicates that the project may be partially approved (i.e. some aspects of the project may be approved, other aspects are not approved). Approval is subject to the conditions outlined in part (a). In addition, further procedures must be followed:
 - i. The AEC will clearly outline their comments and questions regarding the application. This will be recorded on AMS by the AEC Convener.
 - ii. Individual procedures may be marked as "Approved" or "Not Approved." Work may commence or continue upon procedures marked "Approved", however no work may be pursued under procedures which are "Not Approved."
 - iii. To respond to AEC comments, the applicant must update their application as

requested by the committee. The AEC Convener must check the updates to the application to determine whether the committee's questions are satisfactorily answered.

- iv. The applicant's modifications to the project, as requested by the AEC, will be reviewed at the next available AEC meeting to consider approval. Minor amendments that do not impact animal welfare could be considered by an Executive of the Committee out of session.
 - v. If after further consideration the AEC is unwilling to approve a procedure or other aspect of a project, they may request that procedure or other aspect to be deleted in order to grant approval to the rest of the project.
- b. If the AEC decision is to grant the project overall status of "Not Approved", this indicates that experiments may not be conducted under the project. The AEC may agree to reconsider the application at a future meeting, subject to modifications and/or further correspondence. If the AEC decides to suspend or withdraw approval for a previously approved project, that project will be granted "Not Approved" status.

III. Resolution of Disagreements

- a. Any concerns held by the members of the committee shall be expressed during discussion of that application. If agreed by the committee, such concerns shall be conveyed to the applicant in correspondence (i.e. the decision will be "Conditionally Approved" or "Not Approved", as outlined above in 11 ii. Conditions of Approval.)
- b. If directed by the AEC, the researcher may be invited to the meeting to answer questions in person and further explain the proposal.
- c. When all questions and concerns appear to be answered, the Chairperson will then ask whether or not all members of the AEC agree that the proposal may be approved, subject to any changes which have been requested and recorded. If members wish to have their abstention recorded, they should request this. If they vote "No", this should be recorded in the minutes of the meeting, including the reasons for their disagreement. Further discussion or reassessment at a future meeting may be required, as directed by the Chairperson.
- d. If a vote upon an application is required, procedures should follow those outlined in section 7. Voting Rights of Members.
- e. If an AEC member is concerned about the final decision of the committee or has any other concerns regarding the AEC, they should discuss this in confidence with the Chairperson. The Chairperson will make a decision regarding the appropriate action. Further discussion with the Deputy Director (Strategy and Operations) will be available if required, as outlined in the *Animal Welfare and AEC Complaints Procedure*.
- f. If a Institute staff member or student has concerns regarding AEC decisions and/or processes, this will be initially mediated by the AEC Convener and passed on to the AEC for discussion if required, as outlined in the *Animal Welfare and AEC Complaints Procedure*.
- g. As stated in the NHMRC Code section 5.6, "The ultimate decision regarding the ethical acceptability of an activity lies with the AEC and must not be over-ridden."

12. AEC Executive Committee and Out of Session Consideration

For applicants requesting out of session consideration, an e-mail will be sent to committee members. Members will be given an opportunity to review the application. To finalise an executive decision, a minimum quorum of members must respond. The Executive quorum is as follows:

- Chairperson
- Category A member
- A Category B member
- A Category C member or a Category D member

Executive consideration must only be offered for applications involving minor modifications of previously approved projects.

Minor amendments that can be dealt with by the Executive include:

- a. Addition of investigators
- b. A small change in an experimental procedure
- c. A change in animal numbers
- d. An extension of duration of validity for the project

For option b above, a change to an experimental procedure considered to be a minor amendment must not be likely to cause harm to animals (including pain and distress) or increase the overall negative impact upon animals, or significantly change the direction of the experimental procedure. New project applications or new procedures added to previously approved projects must not be considered by the Executive.

The initial assessment of suitability for out of session Executive consideration should be made by the AEC Convener. Executive consideration should be offered only in exceptional circumstances of extreme urgency, for instance if there is a time constraint for the experiment. Researchers must provide a suitable justification for their request.

The Executive members must unanimously approve the application before the commencement of any experimental procedures. The AEC Convener will inform the researcher(s) by e-mail and update the project on AMS. The application will be presented to the full AEC for ratification at the next meeting.

Alternatively, the AEC may consider other mechanisms to facilitate review of applications or discuss other issues outside of scheduled meetings, which may include:

- Calling an additional face-to-face meeting
- Videoconference
- Teleconference

These mechanisms may be considered for applications which do not fit the requirements of the AEC Executive outlined above, or for any serious problems requiring the immediate attention of the AEC. These procedures will be enacted only in exceptional circumstances and must be considered upon a case-by-case basis with consideration to the availability of AEC members and level of urgency of the application or problem. The method of discussion should be unanimously approved by the entire AEC. Efforts should be made to involve all members of the AEC in the decision. If this is not possible, the members who wish to abstain must explicitly state this in correspondence and grant permission for the decision to be made in their absence. The minimum number of members involved in the decision must

include a quorum (as outlined in section 4. Quorum.)

13. Inspection of Animal Facilities

- a. Where possible, visits to Animal Facilities should be conducted immediately before the AEC meeting. The visit shall be an agenda item for discussion by the full AEC, and this discussion will be presented in the minutes for the meeting and in the AEC annual report.
- b. All animal facilities must be visited at least once per year. Additional or alternate times for visits may be organised as required.
- c. As required by the NHMRC Code, the visiting group must include at least one Category C or D member of the AEC. Other members of the AEC are encouraged to attend.
- d. Any concerns regarding the facilities or standard of animal care must be promptly reported as outlined in the document *Animal Welfare and AEC Complaints Procedure*.

14. Reporting of Complaints, Non-Compliance and Adverse Events

- a. If animal technicians, researchers or other staff have any concerns about the welfare of animals held in the Institute, these concerns shall be reported to the Institute Veterinarian/Head of Bioservices, Chairperson, or another member of the AEC. All complaints, concerns or enquiries shall be investigated promptly and treated with the utmost confidence. A report should be made to the full committee. Further guidance regarding animal welfare complaints can be found in the document *Animal Welfare and AEC Complaints Procedure*.
- b. If an instance of non-compliance with AEC approvals and/or animal welfare legislation is identified, this should be immediately dealt with according to the level of severity as outlined in the document *Animal Welfare Non-Compliance Procedure*.
- c. If an unexpected adverse event is encountered, this must be promptly reported to the AEC following the guidance in the document *Adverse Events Reporting Procedure*.

14. External Institutes

The Institute's AEC encourages collaboration with other research institutes. Depending upon the nature and logistical requirements of the work, one of the following arrangements will be made:

- a. If an external researcher (not employed by Institute) wishes to perform experiments in Institute animal facilities following protocols approved in a Institute AEC project, the Principal Investigator of the Institute's AEC project must submit an application to the AEC to add the external researcher as an investigator in their project. This application should provide full contact details and clearly outline the researcher's level of experience and any training requirements. The researcher must sign the Institute's AEC Certification for External Staff form, follow the directives regarding quarantine and security access, and fulfill any additional requirements requested by the AEC. Approval must be granted by the AEC before experiments commence.
- b. If an external researcher wishes to conduct experiments in the Institute's animal facilities following protocols outlined in a project approved by an AEC external to the Institute, they (or the relevant AEC administrative officer) must contact the AEC Convener and provide the full project approved by the administering AEC. The request must clearly outline the delegation of responsibility to the Institute AEC, and this delegation must be accepted by the Institute AEC

at their next available meeting. Additional paperwork may be provided if required. The AEC Convener must contact the relevant AEC to confirm the Institute AEC's acceptance.

- c. If an Institute researcher wishes to perform experiments in an external animal facility following protocols approved in an external AEC project, they must follow the directives as determined by the administering AEC.
- d. If an Institute researcher wishes to perform experiments in an external animal facility following protocols approved in an Institute AEC project, they must submit an application to the Institute's AEC specifying the location and contact details of the facility. Upon approval by the Institute's AEC, the AEC Convener will contact the relevant AEC. The request must clearly outline the delegation of responsibility to the external AEC, and this delegation must be accepted by the external AEC at their next available meeting. Additional paperwork may be provided if required. The AEC Convener will request the administrative officer of the relevant AEC to confirm their AEC's acceptance of the delegation.

At all times, the utmost efforts will be made to ensure clear communication between AECs and researchers. If any problems arise (including complaints, non-compliance or adverse events) these will be dealt with collaboratively by the Institute's AEC and the external AEC.

16. Records and Documentation

All records are maintained on AMS. This includes AEC projects (including a history of revisions), AEC correspondence, reports from the researchers to the AEC, strain information, records of experiments and animal numbers.

The AEC Convener is responsible to update the AEC applications following AEC meetings, approve applications out of session (if directed to do so by the AEC) and perform any other duties related to the maintenance of records on the Ethics module of AMS.

Researchers are responsible to ensure that their AEC projects correctly reflect the experiments they plan to perform, submit AEC applications for any new experiments and await approval before commencing work. Principal Investigators of AEC projects are ultimately responsible to ensure that all work conducted by their staff is within the approval of the AEC and animal welfare legislation.

When performing animal experiments and requesting technical help, the researcher in charge of the experiment is responsible to accurately record this information in the Jobs module of AMS. Animal technicians are responsible for ensuring that the researchers have entered job requests correctly and updating AMS after completion of the job. Any animal welfare observations or additional notes should be entered.

Training records for researchers and animal technicians are maintained by the Senior Animal Supervisor in charge of training. Protocols for training are developed and reviewed by the Animal Facility Manager and a committee of Senior Animal Technicians.

17. Administrative Procedures

I. Submission of AEC applications and reports

All applications and reports to the AEC must be submitted using the appropriate online form available on AMS. Instructions for using AMS and advice regarding specific types of applications and procedures are available on the AEC site on Catalyst. Training in AMS can be provided by the AEC Convener or other Bioservices staff. Any technical problems must be reported to the ITS Helpdesk.

Prior to final submission of applications, applicants should notify the AEC Convener to request review of a draft. Pre-review of applications is strongly encouraged as this is proven to increase the efficiency of the AEC process. The Institute Veterinarian/Head of Bioservices and Animal Facility Manager are also available to consult researchers upon specific questions regarding animal welfare and logistics.

The applicant must also consider whether their proposed experiments require additional approval from other committees (e.g. Institute Biosafety Committee, Human Research Ethics Committee.) If approval from another committee is required, the applicant must produce evidence of prior approval, or inform the AEC regarding an application not yet submitted or pending approval. The AEC will accept applications for review prior to the approval of other committees, however the final approval of the AEC is conditional upon the approval of the required committees.

II. Receipt of submissions

To be accepted for review at an AEC meeting, the applicant must submit the application before the corresponding deadline. A list of deadline and meeting dates for the calendar year is published on the Catalyst AEC site before the end of the previous year. The AEC Convener posts further reminders on Catalyst closer to the deadline date. Extensions to deadlines may be discussed and granted at the AEC Convener's discretion.

Only applications in final "Submitted" (i.e. certified by the Principal Investigator) status on AMS will be considered to be complete. Applications in "Draft" or "Pending" status are not considered to be submitted, and will not be accepted for an AEC meeting except if granted special permission by the AEC Convener (e.g. if there is a technical problem with AMS.)

III. Preparation of documents for AEC discussion

The AEC Convener is responsible to monitor the list of submissions on AMS and ensure that all eligible documents are included in the agenda for the AEC meeting. The AEC Convener prepares the documents and ensures that all relevant information is presented for the review of the committee. This may include:

- For new project applications: The entire project is presented for the review of the AEC, including a list of the strains of animals to be used in the project, and any other attachments as required.
- For amendments to previously approved projects: Generally, only the new procedure or modified procedure is presented for review. Other procedures or sections of the project are provided as attachments if required.
- For new investigators added to previously approved projects: Generally, only the

information for the new investigator is given, unless there is other information relevant to the application.

- For outstanding applications discussed at previous meetings: The modifications relevant to each of the AEC's comments will be presented point by point. Full procedures or additional attachments may be provided if relevant.
- For reports (including adverse event, pilot, annual and final reports): The report is provided with any relevant attachments.
- New and emerging risks should be a standing item on the AEC agenda, to enable any such risks to be considered and appropriate action to be taken.

If a judgement is required upon the amount of information to be provided for AEC review, the AEC Convener has the authority to make this decision (with consideration to the expected informational standards of the committee and with a view to expediency of review.) If any AEC member identifies an error or wishes to request further information, they should contact the AEC Convener for assistance.

The documents for AEC meetings will be presented in a standard format approved by the AEC and subject to modification at any time.

Upon completion of document compilation, the AEC Convener shall inform the AEC members that the documents are ready for download. The committee shall be given 7-14 days' notice to download and review the documents. Any technical issues should be reported to the AEC Convener as soon as possible.

If a researcher wishes to submit an application but misses the submission deadline for a meeting and the documents have already been sent to the committee, under some circumstances the application may be accepted. This decision shall be made at the discretion of the AEC Convener, and shall only be offered in exceptional, urgent cases in which the application is simple to review – the guidelines for acceptable applications are the same as those outlined in section 13. Executive. These documents shall be tabled at the AEC meeting in a separate agenda and shall be sent to AEC members at least one working day before the meeting.

IV. Communication of AEC decisions to applicants

During the AEC meeting, the Chairperson shall ensure that the decision upon each application is clearly stated and understood by all committee members and the AEC Convener. If any person is unsure about the final decision, they should ask for clarification. The meetings will be recorded as an audio file and stored by the AEC Convener for future reference.

After the AEC meeting, the AEC Convener must write a summary of the AEC's decision and comments (if relevant) for all applications. If necessary, AEC members may be consulted for their feedback during this process. The AEC Convener is responsible to update AMS with the AEC's decision. Communications regarding AEC decisions shall be completed as quickly as possible.

18. Governance

The AEC provides an Annual Report to the Institute's Board of Directors. This report is written and submitted by the AEC Convener. As specified in the NHMRC Code section 2.3.29, the content of the annual

report must include the following:

- a. numbers and types of projects and activities assessed, and approved or rejected
- b. the physical facilities for the care and use of animals by the institution
- c. actions that have supported the educational and training needs of AEC members and people involved in the care and use of animals
- d. administrative or other difficulties experienced
- e. any matters that may affect the institution's ability to maintain compliance with the Code and, if appropriate, suitable recommendations.

The Board are asked to acknowledge receipt of the report and provide any comments or questions to the AEC Convener.

The Chairperson meets annually with the Deputy Director (Strategy and Operations). If any additional issues regarding animal welfare and/or the AEC arise which require the attention of Institute senior management, the Chairperson and/or the Institute Veterinarian/Head of Bioservices will contact the Deputy Director (Strategy and Operations).

19. Licensing and Regulatory Compliance

The Walter and Eliza Hall Institute Animal Ethics Committee is licensed by and subject to regulation by Victorian Government.

I. Annual Return

All licensed scientific establishments are required by Government legislation to complete an Annual Return of Animal Usage for the SPPL (Scientific Procedures) and SABL (Breeding) licenses. The return includes all animals used within a calendar year, and must be submitted to the Scientific Procedures Licensing Office of DEDJTR by 31st March of the following year. A form is supplied for the purpose.

The Annual Return forms shall be submitted by the AEC Convener, with support from other Bioservices staff as required. The data for the Annual Return will be automatically generated by AMS. All Principal Investigators of AEC projects which are valid during the calendar year will be contacted with a request to review the figures for their project(s), and either approve the figures or contact the AEC administration mailing list if they believe that the figures are incorrect. The Principal Investigators must respond within a designated deadline. If no response is received, the figures from AMS will be included in the Annual Return and the Principal Investigator is responsible to directly contact DEDJTR if modifications are required.

II. Variations to Scientific Licenses

DEDJTR must be promptly notified of any variation to the scientific licenses (SPPL and SABL) including the following:

- Change of License Nominee (or change of contact details for License Nominee)
- Modifications to animal facilities or holding rooms
- Changes to AEC membership

III. Auditing

The AEC may be audited by external regulatory bodies (DEDJTR) or internally audited by Institute management, as directed by the individuals responsible for performing these audits.

20. Budget

The running costs of the AEC will be paid by the Institute. Requisitions and invoices will be processed internally through a financial cost code. The AEC Convener, Institute Veterinarian/Head of Bioservices and Head of Laboratory Operations will be responsible to submit and approve AEC expenses.