

DPIPWE

Operating Procedures

for the

Animal Ethics Committee

February 2017

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1 INTRODUCTION

Section 2.2 of the *Australian Code for the Care and Use of Animals for Scientific Purposes, 8th Edition, 2013* (the Code) provides for an Institution to establish and document procedures that will enable its Animal Ethics Committee's (AEC's) compliance with the provisions of the Code.

The Department of Primary Industries, Parks, Water and Environment (DPIPWE) AEC comprises a Chairperson and category A, B, C, and D members, as described in section 2.2.4 of the Code.

The following document details the operating procedures approved by the Secretary, DPIPWE and noted by the DPIPWE AEC on 3 February 2017.

2 ANIMAL ETHICS COMMITTEE

2.1 MEMBERSHIP

- i. Members of the AEC are appointed by the Secretary, DPIPWE. The AEC must have a membership that will allow it to fulfil the Terms of Reference. Membership of the AEC is as outlined in the Code.
- ii. The term of membership is for three years with possible re-appointment for a further three-year term.
- ii. Membership will comprise the following Categories:
 - The Chairperson: Institutions must appoint a chairperson of the AEC. Institutions should consider appointing a chairperson who holds a senior position in the institution. If the chairperson is an external appointee, institutions must provide the chairperson with the necessary support and authority to carry out the role. The chairperson may be appointed in addition to Category A to D members (see Code 2.2.2);
 - At least one person from the following Categories:
 - 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;
 - 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;
 - Category C: A person with demonstrable commitment to, and established experience in, furthering the welfare of animals, and 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. While not representing an animal welfare organisation, the person should, where possible, be selected on the basis of active membership of and endorsement by such an organisation; and

- Category D: A person not employed or otherwise associated with the institution and who has never been involved in the use of animals in scientific or teaching purposes, either in their employment or beyond their undergraduate education.
- Categories C and D together must represent at least one third of the AEC membership. (See Code 2.2.8)
- Institutions may invite people with specific expertise to provide advice as required.

2.2 MEETING PROCEDURES

- i. The AEC will determine its meeting frequency. The minimum will be four meetings per calendar year.
- ii. A quorum is established by the presence of at least one member from each of the AEC categories A, B, C and D and the Chairperson.
- iii. The costs of the AEC meetings are provided from the Animal Ethics Committee Account administered by the Policy Branch, Strategic Services Division, DPIPWE.
- iv. The AEC will be provided with material for meetings with at least one week to read and consider the documents.
- v. Wherever possible the Committee makes decisions by consensus.
- vi. If consensus cannot be reached after reasonable effort to resolve differences, the AEC will proceed to a majority decision. (See 3.3.ix)
- vii. Members may participate in meetings by video conference or tele-conference if it is not practical for them to attend in person. The conferencing feature must be utilised so that all participating members can see and/or hear each other during discussions and decision-making.
- viii. Any members of the AEC who have a conflict of interest in a project proposal must declare that interest prior to discussions and deliberations in respect to the project. They must withdraw from the meeting for the purposes of decision making. (See Code 2.3.12) This action will be minuted.
- ix. Once such members have withdrawn from the meeting the remaining members must constitute a quorum, ie one member from each of the membership categories A,B,C and D. If there is not a quorum the matter will be decided as soon as possible as an out-of-session decision of the Committee.
- x. Non-members of the AEC, with the exception of Inspectors under Part 5 the Tasmanian *Animal Welfare Act 1993* (the Act), may attend AEC meetings only with the approval of the Chairperson. Researchers (including applicants) may be invited to a meeting to give educational presentations within the area of their expertise.
- xi. Minutes of the meetings are maintained, which record the attendance, decisions and other aspects of the AEC's deliberations.

2.3 EXECUTIVE DECISIONS

- i. The AEC Executive will consist of the Chairperson, and at least one member from Category C and D [See Code 2.2.23(i)] as elected by the Committee.
- ii. The Executive may be delegated to provisionally approve minor amendments. The Executive may not assess and approve new applications, Annual and Final reports, major amendments or Unexpected Adverse Event reports.

A minor amendment is limited to:

- a. *Changes in personnel;*
 - b. *Extensions of time where it is considered that there is no impact on animal welfare;*
 - c. *Minor experimental design changes not likely to impact on animal welfare; and*
 - d. *Specific delegations made by the full Committee at the time of project approval to be implemented by the Executive.*
- iii. Any member of the Executive may request that the matter under consideration be referred to the next AEC meeting.
 - iv. An amendment is considered *provisionally* approved when the Executive reaches a consensus decision. If consensus cannot be reached, the decision is referred for consideration at the next AEC meeting.
 - v. Decisions by the Executive must be tabled and ratified at the next AEC meeting [see Code 2.2.23(ii)].

2.4 COMMITTEE DECISIONS

- i. All other amendments are deemed to be ‘major’ and will only be considered by the Committee in-session.
- ii. At the discretion of the Committee a major amendment may be considered out-of-session by the Committee if there is a justifiable urgent reason to do so.
- iii. Decisions by the Committee out-of-session must be noted at the next AEC meeting.

2.5 APPOINTMENT OF THE AEC ANIMAL MONITORING OFFICER

- i. The Animal Monitoring Officer (AMO) will be appointed by the Secretary, DPIPWE, as head of the Institution, by instrument of writing.
- ii. The role of the AMO is to assist the AEC and monitor projects by inspecting sites, facilities and animals at those sites and facilities.
- iii. The AEC EO keeps the AMO informed by forwarding copies of projects accepted by the Committee and reports from investigators. The AMO has access to certificates of approval and other relevant AEC information on the “Document One” electronic database as a member of the AEC Security Group.
- iv. The AMO may attend meetings of the AEC and although not eligible to vote, may participate fully in discussions.

2.6 KEEPING OF RECORDS

The AEC Executive Officer (EO) shall ensure that an electronic record is kept on the Department's EMRS of all relevant documents pertaining to AEC matters.

3 APPLICATION ASSESSMENT PROCESS

3.1 EXTERNAL INSTITUTIONS

- i If an institution applies for a licence to conduct animal research in Tasmania but is too small or otherwise unable to constitute an animal ethics committee (AEC) for work conducted within Tasmania, it may seek to use the services of the DPIPWE AEC as an External Institution.
- ii The External Institution is required to write to the General Manager, Biosecurity Tasmania requesting approval to use the DPIPWE AEC addressing the criteria in the suggested [Sharing Agreement pro forma application letter](#).

3.2 SUBMISSION OF APPLICATIONS

- i. Applications are to be completed in the format provided.
- ii. Applications will be recorded as received by the AEC when forwarded to the AEC EO.
- iii. Each application is then allocated a unique project identification number, which must be used in all correspondence pertaining to that project.
- iv. The applicant is responsible for ensuring that the Chief Investigator and Alternative Chief Investigator have completed AEC training or are registered for the next available AEC training session. (See [Policy Statement: Investigator Training](#).)
- v. All sections of an application must be completed in detail.
- vi. To ensure that all AEC members are provided with sufficient information to participate in the assessment of applications, it is essential that they are written in *plain English*. Where the use of scientific language is deemed unavoidable, applicants must ensure that a suitable lay description or glossary of terms is provided.
- vii. Applicants should endeavour to obtain all declaration signatures prior to submission. The Committee reserves the right to defer until the next meeting any application or request where signatures are not completed by the submission deadline.
- viii. Applications will be considered at quorate AEC meetings only.
- ix. Applications must be received by the AEC EO by the publicised submission deadlines to be considered at the next AEC meeting. Applications received after these dates will be deferred to the following submission period, or will be considered for late acceptance should there be extenuating circumstances

- x. At the discretion of the AEC, an urgent application may be considered out-of-session should the immediate use of animals be required for the diagnosis of unexplained and severe disease outbreaks, or morbidity/mortality in animals or people.

3.3 ASSESSMENT OF APPLICATIONS

- i. Applications will be evaluated according to the Code and in a manner that is fair to applicants and acceptable to AEC members. In reviewing applications, the AEC shall refer to the Code, the Act and any other relevant guidelines and standards developed for the ethical treatment of animals.
- ii. If an application being assessed involves more than one institution, each with its own licensed AEC, the EO will notify all other relevant AECs about the application and provide copies of relevant documentation.
- iii. The AEC will seek independent advice where necessary.
- iv. Further clarification will be sought from applicants where this will assist with assessing an application. All communications between applicants and Committee members on AEC matters will be via the AEC EO.
- v. Only proposals for which animals are essential and justified and which conform to the requirements of the Code will be approved.
- vi. All materials in support of applications are confidential and are treated accordingly. Confidentiality extends to all items sent electronically.
- vii. The AEC will approve, modify or reject applications, taking into consideration ethical and welfare aspects, as well as the scientific or educational value of the application, as defined by the Code. AEC decisions include:
 - “Approved with standard conditions”: The proposed use of animals is approved and work using animals may commence.
 - “Approved with additional conditions”: The use of animals is approved and work may commence. However, the Committee has placed additional restrictions, requirements or conditions on the approval, which must be adhered to.
 - “Approved, subject to the receipt of satisfactory further information within 14 days of request”: The AEC views the application favourably, and the use of animals is approved, provided that additional information is received and considered within the requested timeframe. If not received within this timeframe, the decision proceeds to “Not approved (further information required)”.
 - “Not approved (further information required)”: The Committee views the application favourably, however, cannot approve the proposed use of animals until further satisfactory information is provided and considered.
 - “Not approved”: The proposed use of animals is not approved. Re-submission of the application unchanged will not change the outcome.

- viii. The AEC strives to reach decisions by consensus. If the Chairperson deems that a consensus has been reached, they may propose that it be recorded as a decision in the meeting minutes, provided there is no objection.
- ix. If consensus cannot be reached after reasonable effort to resolve differences, the AEC should explore ways of modifying the project with the applicant(s) that may lead to consensus. If consensus is still not 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.
- x. If an application is not approved, the Chief Investigator will be informed and invited to discuss possible avenues for its re-consideration by the AEC.
- xi. Certificates of approval will be issued for the length of the project up to a maximum of three years. However, in determining the duration of approval, the AEC will take into consideration the number of years for which the project is funded, any milestones or stages outlined in the project, and any formal agreements between the institution and funding body.
- xii. Any amendments from the original project parameters outlined in an application need to be approved by the AEC, or the AEC Executive in the case of minor amendments (period extension, project team variation) depending on the degree of change, prior to implementation.
- xiii. Decisions of the AEC must be made as promptly as possible.

3.4 CONSIDERATION CRITERIA

The following criteria are used when considering projects:

- i. In terms of project justification, does achieving the aim of the project support the use of the animals proposed?
- ii. Does the methodology and experimental design provide a good chance that the aims of the project can be realised?
- iii. Has replacement been adequately considered?
- iv. Has reduction been adequately considered?
- v. Has refinement been adequately considered?
- vi. Is the experience of the investigators appropriate?
- vii. Have investigators completed an AEC training Program?
- viii. How might the project best be monitored?
- ix. Have any potential adverse incidents been identified and what mitigation measures are in place to prevent their occurrence?
- x. Does the project have adequate funding in place? If so, is the funding sufficient to cover the requested period of approval and the outlined project activities?

- xi What permits are required for the undertaking of the outlined project activities?
- xii. What institutional policies will affect the use and treatment of animals during the project? Have copies of these policies been provided to the AEC?
- xiii What is the level of risk attributable to the project? (See [Risk Assessment Framework](#))

4 MONITORING, INSPECTIONS AND COMPLIANCE

4.1 MONITORING

- i. The AEC must monitor all activities relating to the care and use of animals (including the acquisition, transport, breeding, housing and husbandry of animals) on a regular and ongoing basis to assess compliance with the Code and decisions of the AEC. The AEC must ensure that identified problems and issues receive appropriate follow-up and, if necessary, refer suspected breaches of the Code to the institution. (See Code 2.3.18). The AEC will determine the frequency and timing of inspections. Influencing factors include the number and accessibility of sites, the number and types of projects and activities, and whether inspections can be combined with scheduled AEC meetings. In addition, the AEC may decide that certain projects or activities require more frequent inspection than others, for example, the level of identified risk. Inspections may be announced or unannounced.
- ii. Chief Investigators are required to detail in an application how the project might best be monitored.
- iii. Monitoring may include, but is not limited to, the following activities:
 - AEC consideration of annual reports;
 - site visits by AEC members or delegates;
 - videos or photographs (See [Policy Statement: Video Footage and Photographs](#));
 - reports;
 - access to records kept by the investigators or animal facility managers, noting issues of confidentiality and intellectual property associated with those records;
 - presentations to the AEC; and/or
 - inspections and reports completed by the appointed Animal Monitoring Officer (AMO).
- iv. A list of animal holding sites will be maintained by the AEC EO. The AEC will maintain records of inspections that include the names of attendees, observations, any identified problems, recommended actions, ongoing or outstanding issues, and outcomes [See Code 2.2.30 (iii)].

4.2 INSPECTIONS

- i. An appointed AMO and/or AEC members may monitor projects by inspecting sites, facilities and animals at those sites and facilities.
- ii. Inspection findings will be reported back to the Committee through the AEC EO.
- iii. Inspections may include:
 - scheduled visits as part of a pre-arranged timetable or as condition of approval;
 - ad hoc visits on an opportune basis; or
 - emergency visits; for example, following an adverse incident.

4.3 COMPLIANCE

- i. Under section 1.3.1 of the Code Institutions, AECs and people involved in any aspect of the care and use of animals for scientific purposes must be aware of and accept their responsibilities and act in accordance with the Code. It is the DPIPWE AEC's responsibility to take an appropriate course of action for any case of non-compliance with the Code (2.1.6) with respect to projects approved by the AEC.
- ii. If an investigator fails to comply with the Code, the AEC can decide to suspend, require modification or cancel a certificate of approval.
- iii. Situations deemed to be a breach of or non-compliance (including inadvertent non-compliance) with the Code will be assessed in accordance with the [AEC Compliance Policy](#). This assessment will inform the decision to continue, suspend, require modification or cancel a certificate of approval.
- iv. Possible compliance actions taken by the AEC in response to non-compliance can be split into three broad categories:
 - communication and encouragement of compliance;
 - enforcement action through the issuing of warnings, notices or similar within the powers of the AEC; and
 - referral to the Regulator, Animal Research for further investigation.These actions may include, but are not limited to:
 - monitoring and inspection of a facility or project;
 - issuing of a formal caution, notice or direction;
 - imposing additional conditions on a project;
 - suspending or withdrawing approval for a project;
 - suspension of an investigator from a project;

- requiring an investigator to undertake further relevant training/education;
 - requiring the modification of a project;
 - recommending disciplinary action to the investigator's manager;
 - referring the matter to the Animal Biosecurity and Welfare Branch for investigation of alleged breaches of the Act. This may result in infringement (a fine) or prosecution; and
 - advising relevant State Government authorities of alleged breaches of other legislation
- v. Serious non-compliance can be defined as, but is not limited to, critical injury or death of an animal, stemming from unapproved procedures or misuse of an approved procedure, or the continuation to use animals without approval. Such cases will be referred to the Animal Biosecurity and Welfare Branch, DPIPW, for further investigation and possible action, pursuant to the Act.
- vi. In cases of emergency, a representative from DPIPW's Animal Biosecurity and Welfare Branch, in consultation with the AEC Chairperson, can authorise the treatment or euthanasia of any animal if required on welfare grounds, after reasonable effort has first been made to contact the Chief Investigator.
- vii. For repeated non-compliance or cases of serious non-compliance the Chief Investigator may be suspended from acting in this capacity for a period of time until the AEC and the responsible Institution are satisfied that the investigator has undertaken sufficient training to resume the role effectively. This will occur in consultation with the Institution.

5 REPORTING

5.1 REPORTING BY INVESTIGATORS

- i. Investigators are required to report to the AEC in accordance with:
- any specified condition of the certificate of approval;
 - the requirement to report annually one month prior to the anniversary of the certificate of approval for ongoing projects; and
 - the requirement to report within one month of the completion of the project.
- ii. Annual and final reports are to be completed in the format provided.
- iii. To ensure that all AEC members are provided with sufficient information to participate in the assessment of reports, it is essential that they are written in *plain English*. Where the use of scientific language is deemed unavoidable, applicants must ensure that a suitable lay description or glossary of terms is provided.
- iv. At a minimum, annual and final reports must provide information about:

- the progress achieved to date and, for annual reports, the next steps of the project;
 - how the project is meeting or has met its stated aims;
 - any problems that may have interfered with the progress of the project;
 - any unexpected adverse events that occurred, actions taken to prevent re-occurrence, and the success of these actions;
 - the number of animals used, and if appropriate, an explanation for the variation from the number of animals approved;
 - whether the wellbeing of the animals is/was consistent with that anticipated in the application; and
 - for annual reports, any anticipated changes to the project.
- v. The AEC will review reports taking into consideration ethical and welfare aspects, the progress achieved, and whether or not the project is meeting its stated aims. On the basis of the information provided in the report, the AEC will make one of the following decisions:
- “Approved”: The continued use of animals is approved (annual report) or the project can be closed (final report);
 - “Approved with conditions”: The continued use of animals is approved, subject to additional restrictions, requirements or conditions placed on the project, which must be adhered to;
 - “Approved, subject to the receipt of satisfactory further information within 14 days of request”: The AEC views the report favourably, and the continued use of animals is approved, provided that additional information is received and considered within the requested timeframe. If not received within this timeframe, the decision proceeds to “Not approved (further information required)”;
 - “Not approved (further information required)”: The AEC views the report favourably, however, cannot approve the continued use of animals until further satisfactory information is provided and considered; and
 - “Not approved”: The report is not approved. Resubmission of the report unchanged will not alter the outcome (not applicable to final reports).
- vi. On the basis of the above decisions, the AEC will determine that a project may either continue, be suspended, require modification, be closed, or be discontinued.
- vii. Chief Investigators are required on an annual basis to submit dated digital photographs or dated video footage of any facilities used for housing or retaining animals. (See [Policy Statement: Video Footage and Photographs](#))

- viii. The AEC Chairperson will provide in writing to the Chief Investigator, and the Institution, if appropriate, the reasons why an action has been taken to suspend or cancel, or amend the conditions of a certificate of approval.

5.2 REPORTING OF UNEXPECTED ADVERSE EVENTS

- i. An unexpected adverse event is an event which impacts or may impact negatively on the wellbeing of an animal. It includes animal escapes, unexpected illness, injury or death, and emergency treatments or euthanasia.
- ii. Injuries to investigators, teachers and animal facility managers are also to be reported as unexpected adverse events.
- iii. All unexpected adverse events must be reported to the AEC EO via email or telephone within two days of the event. If an urgent response is required, the Chairperson may take action, including requesting an Unexpected Adverse Event report. Otherwise the Committee is notified to determine whether one is required.
- iv. The Unexpected Adverse Event report is required within seven days of being requested and should include:
 - analysis of the event;
 - impacts on animal welfare;
 - mitigating actions taken;
 - implications for the project;
 - contingencies or modifications to the project that will be adopted to resolve a re-occurrence of the unexpected adverse event; and/or
 - any other ramifications.
- v. When an animal dies unexpectedly, or is euthanised due to unforeseen complications, an autopsy must be performed by a suitably qualified person or a person directed by a veterinarian unless approval is given, by exception, that it is not required. In addition, if the carcass is in a suitable state, an appropriate sample is to be submitted to the Mt Pleasant Animal Health Laboratory for additional analysis. This information, including all laboratory reports, is to be provided to the AEC.
- vi. Unexpected Adverse Event reports are circulated to the AEC for consideration out-of-session and decisions tabled and noted at the next AEC meeting.
- vii. Based on the information provided in the Unexpected Adverse Event report, the autopsy report and any other relevant information, the AEC may suspend or cancel, or amend the conditions of, a certificate of approval, if it considered warranted.
- viii. The AEC Chairperson will provide in writing to the Chief Investigator the reasons why an action has been taken to suspend or cancel, or amend the conditions of, a certificate of approval.

- ix. The reporting of unexpected adverse events by the AEC Chairperson to the Secretary, DPIPWE will be determined by the Committee according to the level of risk. That is, whether they have a high public interest risk - examples being a significant mortality event associated with infectious disease, serious compliance breaches and DPIPWE reputation. A report would be provided to the head of the external Institution if one is involved and it is considered appropriate.
- x. The Chief Investigator is to be advised that a report is to be submitted to the Secretary, DPIPWE or the head of the external institution.

5.3 REPORTING BY AEC TO THE INSTITUTION

The AEC will prepare a written report on its activities for the previous year to the Secretary, DPIPWE by 30 June each year. The report will include, as a minimum, the information specified in the Code for reporting to the institution.

6 COMPLAINTS PROCEDURE

6.1 COMPLAINTS ABOUT THE ANIMAL ETHICS COMMITTEE PROCESS

- i. Where complaints concerning the AEC process of consideration of an application or report cannot be resolved by communication between the complainant (the applicant or Chief Investigator) and the AEC, the complainant may appeal to the Secretary, DPIPWE who may appoint a nominee to undertake a review when:
 - the AEC refuses to grant approval for a project;
 - the AEC suspends or cancels a project;
 - the AEC imposes conditions the Chief Investigator believes to inappropriate or unreasonable; or
 - there are concerns regarding the decisions, behaviour, beliefs (including conflicts of interest) or procedures of the AEC, including against the Chairperson, or individual members of the Committee.
- ii. A concern/complaint may be raised verbally or in writing in the first instance to allow for informal resolution of an issue.
- iii. An application of formal complaint must be in writing and addressed to the Secretary, DPIPWE.
- iv. All concerns or grievances raised will be treated in the strictest confidence and in accordance with the principles of natural justice.
- v. Following the review the AEC may need to review its process in reaching its decision and re-evaluate its decision. However, the ultimate decision regarding the ethical acceptability of an activity lies with the AEC and must not be over-ridden.