



Animal Ethics Committee Terms of Reference

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1 PURPOSE

The purpose of this document is to outline the responsibilities and the terms of reference of the CSL/Zoetis Animal Ethics Committee. This AEC operates subject to the provisions of the Scientific Procedures Premises Licenses (Victoria) of both CSL Limited and its related bodies corporate in Australia (CSL) and Zoetis (Australia) (Zoetis).

This document will also describe the procedures that must be undertaken by the Committee and by scientific investigators before any scientific activity involving the use of animals can be undertaken.

2 RESPONSIBILITY

CSL and Zoetis are both licensed under Section 29 of the Prevention of Cruelty to Animals Act 1986 (Victoria) to cause or allow scientific procedures to be carried out on CSL owned premises at both Parkville and Woodend, and on other approved sites. The person(s) nominated under Section 26(2) of the Act are responsible for ensuring that all licence conditions are adhered to.

All scientific procedures must be carried out in accordance with the Act, the regulations and the relevant Code *Australian code for the care and use of animals for scientific purposes 8th edition 2013*.

Both CSL and Zoetis must implement processes so that the governing body of that institution or its delegate is assured of compliance with the Code and relevant legislation. The CSL/Zoetis Animal Ethics Committee (AEC) is directly responsible to the governing bodies of both institutions and their delegates. The primary responsibility of the AEC is to ensure that all care and use of animals is conducted in compliance with the Code.

Except, where governing bodies determine otherwise, their delegates and senior institutional management are the heads of the relevant business units that undertake activities approved by the AEC.

No scientific procedure or program involving the use of animals may commence unless and until an AEC has approved the:

- scientific procedures;
- premises at which the scientific procedures are to be carried out; and
- person or persons who will carry out the scientific procedures.

Encapsulated in the Code is the need in scientific activities to consider:

- The replacement of animals with other methods;
- The reduction in the number of animals used; and
- The refinement of techniques used to reduce the impact on animals.

Projects using animals may be performed only after a decision has been made that they are justified, weighing the predicted scientific value of the projects against the potential effects on the welfare of the animals.

Scientific investigators have personal responsibility for all matters relating to the welfare of the animals they use and must act in accordance with all requirements of the Code. This responsibility begins when an animal is allocated to a project and ends with its fate at the completion of the project.

2.1 PERSONNEL

Operators are responsible for:

- following the procedures covered in this policy
- observing all warnings, cautions and notes in this policy
- following instructions given by Supervisors or Managers.

Managers are responsible for:

- training and assessment of staff
- ensuring controlled copies of current policies are available

3 TRAINING

Managers are responsible for ensuring that all personnel using this policy have achieved a level of acceptable competence.

LOCAL POLICY

4 MEMBERSHIP

4.1 AEC COMPOSITION

The AEC has a membership that will allow it to fulfil its terms of reference. There are four categories of membership as outlined in the Code. The key criteria for each member category are shown below.

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. If the business of the AEC relates to the use of animals for teaching only, a teacher with substantial and recent experience may be appointed.-.

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 involved in the care and use of animals for scientific purposes.

Category D A person who is independent of the institution and who has never been involved in the use of animals in scientific or teaching activities using animals, either in their employment or beyond their under-graduate education.

The laboratory animal house manager is also a member of the AEC.

The Chairperson is an additional appointment to the Category A to D members.

An AEC Executive exists to deal with emergencies and urgent modifications to previously approved projects. The AEC Executive must consist of at least three members of the AEC, including one Category C or D member. The AEC executive may not approve new proposals.

The AEC membership cannot be altered without approval from the AEC and agreement from the two governing bodies. Before appointment, all members of the AEC should acknowledge in writing their acceptance of the terms of reference of the AEC and the requirements for confidentiality required by both CSL and Zoetis.

4.2 RESPONSIBILITIES OF THE CHAIR

The Chairperson must:

- 1) ensure that the AEC operates in accord with the principles and requirements of the Code, the relevant policies of the institution(s), and the agreed AEC procedures;
- 2) ensure that proposals are considered by the AEC and the outcomes conveyed to investigators and teachers in a timely manner;
- 3) advise institutional management regarding the level of resources required by the AEC;
- 4) represent the AEC in any negotiations with management;
- 5) oversee all requirements of the AEC to report and review its operation, as outlined in the Code; and
- 6) ensure AEC records are maintained and made available for review by the institution and authorised external reviewers.

4.3 ROLE OF THE EXECUTIVE OFFICER

The Executive Officer will assist the Chair and support the operation of the AEC by:

- 1) being the first point of contact for applicants wishing to access the AEC;
- 2) assisting project applicants through the provision of advice and assistance to researchers regarding ethics applications, procedures and mandatory requirements;
- 3) organizing the distribution of information to members and scheduling meetings and inspections; and
- 4) maintaining other administrative functions of the AEC including documentation of meetings and decisions, database management of all AEC projects and the filing of AEC related correspondence.
- 5) Maintaining sharepoint site that includes AEC forms, guidelines and other information (<http://pkvmoss/Sites/AEC/default.aspx>)

4.4 ROLE OF AWO (ANIMAL WELFARE OFFICER)

- 1) to work with the AEC and the Animal Facility to ensure a high standard of animal ethics is applied in all areas involving the use of animals.
- 2) provide advice on veterinary aspects and the review of protocols involving animals.
- 3) monitor all work involving the use of animals
- 4) assist with the development of policies and the education of researchers.
- 5) The AWO will vote as a Category A member.

5 TERMS OF REFERENCE

The AEC must adhere to the following terms of reference:

5.1 *The approval of guidelines for the care of animals that are bred, held and used for scientific purposes by:*

- i) the review and approval of standard operating procedures (SOPs) for use in the management of holding and breeding facilities; and
- ii) reviewing relevant SOPs once every three years or whenever a change to the procedure is proposed.

5.2 *The monitoring of the acquisition, transportation, production, housing, care, use and fate of animals by:*

- i) reviewing the relevant sections of the project proposal against the Code and other guidelines and standards developed for the ethical treatment of animals that are considered acceptable by the AEC;
- ii) AEC members carrying out inspections of licensed premises and activities at Parkville and Woodend at least annually or more frequently if deemed necessary by the AEC;
- iii) authorising delegates to carry out inspections of field sites and activities on behalf of the AEC if required for a particular project;
- iv) receiving and reviewing reports on unexpected or adverse effects that impact on the welfare of animals used for scientific purposes; and
- v) Receiving and reviewing annual project reports and ensuring that animal use is consistent with the approved project application.

Resolving any conflict of interest that may arise, that is, any situation where a member of an AEC has an interest that may be seen to influence the objectivity of a decision.

5.3 *Recommend to the institution(s) any measures needed to ensure that the standards of the Code are maintained by:*

- 1) identifying and reporting instances of non-compliance and recommending remedial action to the facility manager, principal investigator(s) and animal carer(s) where appropriate. The AEC must monitor the standard of the facilities/infrastructure, animal management and staff competencies.
- 2) advising institutional management regarding the level of resourcing required by the AEC through the Chair;
- 3) reporting significant contraventions of the Code or approved project procedure through the Chair to project or facilities management where appropriate.

5.4 *AEC members will be appointed or retired according to the following sequence of events.*

- i) Membership needs of the CSL/Zoetis AEC will be monitored by the AEC under the direction of the Chair.
- ii) If a new member is required, the AEC will call for expressions of interest through the Secretary and/or make direct approaches to representative groups such as RSPCA or research bodies of the two institutions.
- iii) Written expressions of interest or membership proposals will be reviewed by the Chair in consultation with the AEC.
- iv) Selected candidates will meet with the Chair with support from the Secretary to review their suitability and to acknowledge their acceptance of the terms of reference of the AEC.
- v) Where agreement is met, the accepted candidate must sign a Confidentiality Agreement with both CSL and Zoetis.
- vi) The new member will then be introduced at their first attendance of full meeting of the AEC.
- vii) The AEC Secretary will maintain a record of all appointments and must advise the Bureau of Animal Welfare by e-mail of changes of membership to the AEC within 14 days of new appointment.
- viii) A member may resign from the AEC at any time by advising the Chair in writing. The Chair will advise the AEC Secretary to circulate the letter of resignation to the AEC members.
- ix) The Chair may ask a member to retire from the AEC following consultation with the AEC if it is deemed to be in the best interests of the AEC.

5.5 *Tenure of Membership*

Category A and B members are staff belonging to both organisations with a detailed knowledge of the work undertaken by each organisation. AEC membership tenure is determined by employment in a specialised role.

Category C and D members will have an initial tenure of 3 years, with successive 3 year periods approved by majority vote of the AEC.

5.6 *The AEC will require that all members declare any conflict of interest by:*

- i) requiring members to disclose the nature of their interest and conflict as soon as practicable after they become aware of anything that may be reasonably considered to be a conflict of interest.

5.7 *The AEC will deal with situations in which a conflict of interest arises by:*

- i) requiring a member whose objectivity may be influenced by an interest, including consideration of a proposal submitted by that member, be excused during the decision-making phase and take no part in the decision making process;
- ii) reviewing and responding to any concern raised by another party that an AEC member has an interest that may have influenced the objectivity of an AEC decision.

5.8 *The AEC will examine and approve, subject to modification, or reject written proposals relevant to the use of animals for scientific purposes by:*

- i) considering new project proposals and approved project modifications and reviewing Executive decisions on minor modifications at quorate meetings.
- ii) seeking clarification of and/or amendments to a proposal from the project applicant either by inviting the applicant to attend an AEC meeting, via telephone link or by written response through the AEC Executive Officer;
- iii) seeking comment or clarification from other person(s) with specific expertise on relevant matters either at an AEC meeting or through written references or responses through the AEC Executive Officer;
- iv) making decisions on the basis of consensus wherever achievable. Where 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. 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.

Note: Where further information is sought on an application before a consensus can be reached, the matter can be referred to a sub-committee for review before the next meeting. The meeting minutes must specify what further information is required, the acceptance criteria and who is appointed for the final review. At the next AEC meeting a Progress Report outlining the status of outstanding matters from the last meeting must be included in the meeting agenda.

A final decision may be carried over until subsequent meetings of the AEC and the project applicant may be invited to address the AEC at this time.

5.9 *The AEC will approve only those studies for which animals are essential and their use is justified and which conform to the requirements of the Code. This should take into consideration factors including ethics, the impact on the animal or animals and the anticipated scientific or educational value by proposals relevant to the use of animals for scientific purposes by:*

- i) assessing applications for the use of animals for scientific purposes only after the committee has received an application form that is completed to the AEC's satisfaction;

- ii) evaluating whether the information presented by the applicant provides appropriate justification for the proposed animal use, accurately details the impact on the animals and shows means by which impact can be minimised, and that it complies with the principles of Replacement, Reduction and Refinement;
- iii) approving only projects where the use of animals is both essential and justifiable as well as conforming to the requirements of the Code;
- iv) requesting further clarification or advice on the assessment of particular projects from appropriately qualified people if necessary. The AEC should ensure that advice can be sought from outside experts without breaching confidentiality;
- v) monitoring projects at least annually through the review of Annual Reports submitted by the project investigator.

5.10 *The AEC may withdraw approval for any project when:*

- i) an animal is used in a way that is different from what was approved in the initial application or in subsequently approved modifications to a project;
- ii) written advice is received from a veterinarian or another person approved by the Chairperson that in their opinion there is an actual or potentially significant welfare impact on the animal that is attributable to the conduct of the study, if this outcome has not been previously assessed and approved by the AEC;
- iii) the AEC decides that the approval for a project or a procedure within the project should be withdrawn and the project manager is advised through the Chair.

Note: The AEC must consider any objection raised and additional information provided by the project manager. The manager may be invited to address the AEC at its next meeting.

If the matter is not resolved, the manager may lodge a grievance against the AEC decision through executive management of that institution that is responsible for that project.

5.11 *The AEC may authorise the emergency use, treatment or euthanasia of any animal when:*

- i) the immediate use of animals is required for the diagnosis of unexplained and severe disease outbreaks, or morbidity/mortality in animals or people; or
- ii) following an examination of the animal and recommendation by a veterinarian or another person approved by the Chair; or when
- iii) the AEC or its Executive decides that the treatment or euthanasia is in the best interests of the animal.

Note: If emergency treatment or euthanasia is deemed necessary, the Chair must ensure that reasonable steps are taken to contact the project manager or investigator, advise them of the expert's opinion and consider any objection raised by the project team members. All advice and decisions should be documented by the Chair.

Where a project uses animals that are not owned by either CSL or Zoetis, the owner of the animals must be informed and agree to these Terms of Reference

Any decisions made by the Executive must be reviewed at the next quorate meeting of the AEC.

5.12 *The AEC will examine and comment on institutional policies of CSL or Zoetis that may affect the welfare of animals used for scientific purposes by:*

- i) reviewing institutional plans and policies affecting the provision of resources for the housing, care, management and welfare of animals for use in scientific procedures;
- ii) considering information provided or comments raised by any person regarding the care and use of animals under the custody of the AEC;
- iii) considering feedback/reports from audits or inspections carried out on behalf of the AEC or by external regulators;
- iv) making recommendations to institutional management through the Chair that reflect a consensus view of the AEC; and
- v) including in the Annual Report any matters that may affect the institution's ability to maintain compliance with the Code and if necessary the provision of suitable recommendations.

5.13 *The AEC will maintain a record of proposals and projects by:*

- i) assigning the Executive Officer to retain, on file, all documentation associated with AEC business; and
- ii) assigning the Secretary to maintain an electronic database of all projects approved by the AEC.

5.14 *The AEC will comply with the reporting requirements of CSL, Zoetis and the Code by:*

- i) submitting an Annual Report of specified topics in the Code to the boards or delegates of CSL and Zoetis; and
- ii) promptly reporting to the AEC Executive Officer any event or issue that may need to be referred to the Chair and consequently to senior institutional management.

5.15 *The AEC will perform other duties required by the Code.*

6 THE ROLE OF THE INVESTIGATOR

6.1 INVESTIGATOR RESPONSIBILITIES

The investigator has personal responsibility for all matters related to the welfare of the animals they use and must act in accordance with all requirements of the Code. This responsibility begins when an animal is allocated to a project and ends with its fate at the completion of the project.

The investigator must not begin any scientific activity involving the use of animals before a written proposal has been examined and written approval given by the AEC. The investigator must adhere to all requirements of the AEC.

REFERENCES

Doc ID

Title

Prevention of Cruelty to Animals Act, 1986 (Victoria).
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Australian code of practice for the care and use of animals for scientific purposes. 8th Edition, 2013.
