

Policy

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PURPOSE

The purpose of this document is to set out the Terms of Reference of the CSL Limited Animal Ethics Committee (AEC).

SCOPE

The scope of this policy extends to the operation of the CSL Limited Animal Ethics Committee (AEC) and its oversight of all animal usage under the CSL Limited Scientific Procedures Premises Licence (SPPL) at Parkville, Woodend Field Station, Broadmeadows and CSL at the Bio21 Institute.

DEFINITIONS/ABBREVIATIONS

Term / Abbreviation	Description
AEC	Animal Ethics Committee
SPPL	Scientific Procedures Premises Licence

RESPONSIBILITY

PERSONNEL

Operators are responsible for:

- following instructions given by Supervisors or Managers.

Managers are responsible for:

- ensuring controlled copies of current policies are available

TRAINING

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

CSL Limited AEC Terms of Reference

1 INTRODUCTION

The AEC is established to ensure ethical review, approval and monitoring of animal care and use at CSL Limited, in Victoria, Australia, in accordance with the following:

- a) Australian Code for the care and use of animals for scientific purposes 8th edition 2013 (*Australian Code*);
- b) Australian Code for the Responsible Conduct of Research 2018 (*Code*);
- c) *Code of Practice for the Housing and Care of Laboratory Mice, Rats, Guinea Pigs and Rabbits*;
- d) *Prevention of Cruelty to Animals Act 1986* (Vic);
- e) *Prevention of Cruelty to Animals Regulations 2019*;
- f) Any other relevant legislation, guidelines and codes of practice;
- g) Relevant institutional policies and procedures

2 GOVERNING BODY

The AEC reports externally to the Victorian State Government and is the nominated AEC for the CSL Limited Scientific Procedures Premises Licence [SPPL].

The AEC reports internally and is accountable to the Board of Directors, as the governing body of the organisation, through Global Head, Quality Systems and Compliance at Seqirus (a CSL Limited Company).

3 RESPONSIBILITIES

The primary responsibility of the AEC is to ensure that all projects and activities relating to the care and use of animals at CSL Limited, are conducted in compliance with the Australian Code. In fulfilling this function, the AEC will ensure that all animal use is justified, adequate provision is made for the welfare of animals and the principles of Replacement, Reduction and Refinement are incorporated.

THE AEC WILL:

- (i) review applications for projects or activities relating to the care, management and use of animals, including breeding programs, at CSL Limited according to the requirements of the Australian code, and approve only those projects or activities that are ethical and conform with the Australian code;
- (ii) monitor and conduct follow up reviews of approved projects and activities, including receipt of progress and final reports, to ensure that these continue to be ethical and conform with the Australian Code;
- (iii) monitor the care, management and use of animals at CSL Limited, including housing and facility conditions, as well as related practices and procedures;
- (iv) monitor colony management and breeding programs of specified and non-specified animals, as well as related practices and procedures;
- (v) receive reports on and take appropriate action in relation to unexpected adverse events;
- (vi) receive reports on and take appropriate action in relation to non-compliance;
- (vii) receive complaints about the care and use of animals or the operation of the AEC, from any relevant party and investigate as appropriate;
- (viii) review guidelines for the care, management and use of animals, including standard operating procedures, and approve as appropriate;

- (ix) provide advice and recommendations to the organisation, including any measures required to ensure compliance with the Australian Code and input to organisational policies and procedures relating to the care, management and use of animals;
- (x) report regularly on its operations to the institution (see Section 8, Reporting); and
- (xi) undertake any other duties required of an AEC under the Australian Code.

3.2 In discharging its responsibilities, the AEC may seek assistance of such experts, or regulatory and advisory bodies, as it chooses.

4 OPERATION

The AEC operates in accordance with the governance and administrative procedures documented in the relevant institutional policies and procedures.

5 MEMBERSHIP

5.1 The composition of the AEC will align with the membership provisions of the *Animal Code*, with the minimum membership to comprise:

- (i) a Chairperson – appointed by the organisation
- (ii) a Category A member – a veterinarian with relevant experience and knowledge;
- (iii) a Category B member – a suitably qualified researcher with recent and relevant experience in the use of animals for scientific purposes;
- (iv) a Category C member – a person with a demonstrable commitment to, and experience in, animal welfare and who is not employed or otherwise associated with CSL Limited, and who is not currently involved in animal research;
- (v) a Category D member – a community representative who is not employed or otherwise associated with CSL Limited, and has never been involved in the use of animals in scientific or teaching activities;

5.2 In addition to the requirements of the Australian code, the AEC may include as a non-voting member, an Animal Welfare Officer.

5.3 The AEC will include, as non-voting members, the AEC Executive Officer and a person/s responsible for the routine care of animals at CSL Limited.

5.4 An AEC Executive may be constituted from time to time, and will operate in accordance with the Australian Code and any other relevant institutional policies and procedures

5.5 The balance of membership of the AEC will be in accordance with the provisions of the Australian code. To achieve a quorum, Category C and D members together MUST represent at least one third of voting members present at an AEC meeting.

5.6 The voting status for each member, including the Chair, will be nominated on the Scientific Procedures Premises Licence, contemporaneous records of which will be maintained by the AEC Executive Officer

5.7 The AEC Executive Officer MUST notify Animal Welfare Victoria (AWV) within 7 days of the resignation of a member.

- 5.8 Before appointment of a new AEC member, the AEC Executive Officer MUST notify AWV, which will approve the appointment in writing.
- 5.9 New AEC members must attend an AWV training session within 6 months of their appointment.
- 5.10 The AEC may invite persons to attend a meeting to provide expertise and advice, or to observe.
- 5.11 External members will be provided a 'sitting fee' in accordance with the relevant provisions of the Australian Code.
- 5.12 All AEC members will follow relevant institutional policies and procedures relating to the operation and functioning of the AEC.
- 5.13 All appointments to the AEC will be made by the Global Head, Quality Systems and Compliance at Seqirus as the SPPL Nominee, in consultation with the AEC Chairperson and AEC Executive Officer.
- 5.14 AEC members will be appointed for a period of 3 years and may be eligible for reappointment after that time, at the discretion of the SPPL Nominee.
- 5.15 Written confirmation of reappointment will be provided to members prior to expiration of existing membership.
- 5.16 AEC members may be terminated without notice. The SPPL Nominee will advise the member, in writing, of the termination.
- 5.17 AEC members may resign from the AEC without notice, by providing the AEC Executive Officer written confirmation of resignation.

6 CONFLICTS OF INTEREST

AEC members will identify, report and manage conflicts of interest in accordance with the Australian Code and institutional policies and procedures

7 CONFIDENTIALITY

AEC documentation and proceedings will be treated as confidential, although the AEC may disclose information to appropriate internal or external bodies/persons, at its discretion and/or as required.

8 REPORTING

8.1 The AEC will regularly report (at least annually, on a calendar year basis) to the Board of Directors on matters including:

- (i) numbers and types of projects and activities reviewed;
- (ii) the outcomes of project reviews;
- (iii) physical facilities for the care and use of animals at CSL Limited;
- (iv) actions that have supported the educational and training needs of AEC members and people involved in the care and use of animals;
- (v) administrative or other difficulties experienced; and
- (vi) any matters that may affect the ability of CSL Limited to maintain compliance with the Australian code and, as appropriate, suitable recommendations.

8.2 The AEC shall evaluate its performance annually, in accordance with the relevant provisions of the Australian code, with an emphasis upon continuous improvement in its processes and operations.

8.3 The AEC will assist CSL Limited in reporting to the Regulator, as required.

9 APPROVAL

The AEC Terms of Reference will be reviewed biennially or more frequently as appropriate, by the AEC, the SPPL Nominee and any other relevant people.

REFERENCES

Doc ID	Title
GUI-000094645	Australian Code for the Care and Use of Animals for Scientific Purposes
N/A	Australian Code for the care and use of animals for scientific purposes 8th edition 2013 (Australian Code)
N/A	Australian Code for the Responsible Conduct of Research 2018 (Code)
N/A	Code of Practice for the Housing and Care of Laboratory Mice, Rats, Guinea Pigs and Rabbits
N/A	Prevention of Cruelty to Animals Act 1986 (Vic)
N/A	Prevention of Cruelty to Animals Regulations 2019

Electronic Signatures

User	Date	Justification
Gakias, Vicky AU/PKV	09-Jun-2022 07:53:24	I am providing Functional approval
Smoljko, Milka AU/PKV	09-Jun-2022 22:15:20	I am providing quality approval

Effective