

TERMS OF REFERENCE

1. PURPOSE

The purpose of this document is to set out the Terms of Reference of the CSL Limited Animal Ethics Committee (AEC). The AEC is established to ensure ethics review, approval and monitoring of animal care and use at CSL Limited, in Victoria, Australia, in accordance with the Australian Code for the care and use of animals for scientific purposes 8th edition 2013 (*Animal Code*), the Australian Code for the Responsible Conduct of Research 2018 (*Code*), the Prevention of Cruelty to Animals Act 1986 (Vic) and associated Regulations 2008 (Vic), and any other relevant guidelines.

The CSL Limited Animal Ethics Policy outlines the high level principles pertaining to animal welfare and ethics, along with the procedures for gaining and maintaining related approvals.

2. GOVERNING BODY

The AEC reports externally to the Regulator (currently the Victorian Department of Economic Development, Jobs, Transport and Resources [DEDJTR]) 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 Senior Director, Quality 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 Animal 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.

3.1 The AEC will:

- (i) review applications for projects or activities relating to the care, management and use of animals at CSL Limited according to the requirements of the Animal Code, and approve only those projects or activities that are ethical and conform with the Animal 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 Animal 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) receive reports on and take appropriate action in relation to unexpected adverse events;
- (v) receive reports on and take appropriate action in relation to non-compliance;
- (vi) review guidelines for the care, management and use of animals, including standard operating procedures, and approve as appropriate;

- (vii) provide advice and recommendations to the organisation, including any measures required to ensure compliance with the Animal Code and input to organisational policies and procedures relating to the care, management and use of animals;
- (viii) report regularly on its operations to the institution (see Section 8, Reporting); and
- (ix) undertake any other duties required of an AEC under the Animal 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 CSL Limited AEC Operating 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, in accordance with the Animal Code provisions;
- (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; and
- (vi) a person responsible for the routine care of animals at CSL Limited.

5.2 An Animal Welfare Officer/s will also form part of the AEC membership.

5.3 An AEC Executive is established and will operate in accordance with the Animal Code.

5.4 The balance of membership will be in accordance with the provisions of the Animal Code, with Category C and D members together to represent at least one third of the membership.

5.5 The AEC may invite persons to attend a meeting to provide expertise and advice, or to observe.

5.6 External members will be remunerated for their services, via provision of a sitting fee.

5.7 All AEC members will follow the AEC Operating Procedures.

- 5.8 All appointments to the AEC will be made by the Senior Director, Quality at Seqirus as the SPPL Nominee, in consultation with the AEC Chairperson and Executive Officer.
- 5.9 AEC members will be appointed for a period of 3 years and may be eligible for reappointment after that time.

6. CONFLICTS OF INTEREST

AEC members will identify, report and manage conflicts of interest in accordance with the Animal Code and CSL Limited Policy 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 and the outcomes of these reviews;
 - (ii) physical facilities for the care and use of animals at CSL Limited;
 - (iii) actions that have supported the educational and training needs of AEC members and people involved in the care and use of animals;
 - (iv) administrative or other difficulties experienced; and
 - (v) any matters that may affect the ability of CSL Limited to maintain compliance with the Animal Code and, as appropriate, suitable recommendations.
- 8.2 The AEC shall evaluate its performance annually, 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 and approved by the Senior Director, Quality as the SPPL Nominee. These Terms of Reference were approved on <dd Month 2018>.



Effective

Signatures

User	Date	Reason
Smoljko, Milka AU/PKV	10/04/2018 04:01:14	I am providing Functional approval
Franchina, Phil AU/PKV	10/04/2018 04:11:35	I am providing Functional approval
Sadat, Tariq AU/BIO	10/04/2018 05:07:37	I am providing quality approval

Effective