

OZGENE PTY LTD

OZGENE ANIMAL ETHICS COMMITTEE

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1 ESTABLISHMENT

The nature of Ozgene's core business is contract research and development for the generation of genetically modified (GM) animals. Ozgene customers consider alternatives and determine via their respective Animal Ethics Committees that animal models are essential and justified on the grounds of the anticipated scientific value. At this point, Ozgene cannot make any consideration of alternatives to using animals.

- 1.1 Ozgene Animal Ethics Committee ("the Committee") was established in May 2006 and is an advisory Committee to the Chief Executive Officer.
- 1.2 The Committee was established to ensure that all animal care and use complies with the Australian Code of Practice for the Care and Use of Animals for Scientific Purposes ("the Code of Practice").
- 1.3 The role of the Committee is to ensure that the welfare of Ozgene animals is provided for and incorporates the principles of Replacement, Reduction and Refinement.

2 FUNCTIONS OF THE COMMITTEE

- 2.1 Examine written proposals contributing to the generation of GM animal models required for research, taking account of the ethical, welfare, scientific and educational aspects, as defined in the Code of Practice.
- 2.2 Maintain a register for all proposals and projects, including outcomes of the Committee's deliberations.
- 2.3 The Committee may approve, approve with conditions, or reject a proposal. It may also withdraw approval, where the practices being applied are inconsistent with the Code of Practice.
- 2.4 Approve guidelines for the care of animals that are bred, held, and used for scientific purposes.
- 2.5 Monitor the acquisition, transportation, production, housing, care, use and disposal of animals.
- 2.6 Authorize the emergency treatment or humane killing of any animal.
- 2.7 Make recommendations on any measures needed to ensure that the standards of the Code of Practice are maintained.
- 2.8 Examine and comment on Ozgene plans, policies or procedures that may affect the welfare of animals.
- 2.9 Perform all other duties required by the Code of Practice.

3 COMMITTEE MEMBER APPOINTMENT & MEMBERSHIP

- 3.1 Only the Chief Executive Officer of Ozgene is empowered to appoint an Animal Ethics Member to the Committee.
- 3.2 The Committee must comprise of at least one Member for each of the following defined categories:

<u>Category A:</u> A person with qualifications in veterinary science, with experience relevant to the activities as mandatory.

Category B: A person with substantial recent experience in the use of animals in scientific activities.

<u>Category C:</u> A person with demonstrable commitment to, and established experience in, furthering the welfare of animals, who is not employed by or otherwise associated with Ozgene, and who is not involved in the care and use of animals for scientific purposes.

<u>Category D:</u> A person who is both independent of Ozgene and who has never been involved in the use of animals in science. Should be viewed by the wider community as bringing a completely independent view to the AEC.

Vivarium Representative: An Ozgene staff member who is involved in the routine care of animals.

<u>Chair</u>: A person from outside the institution, or in the case of emergency, from within the institution to take on the responsibilities of Chair to the Committee.

3.3 The Chief Executive Officer should appoint up to two people, a Primary Member, and an Alternate Member, to each of the following categories, but must appoint at least one person to hold office in each Category at any time.

Where an office in a Category becomes vacant, the Chief Executive Officer must appoint a person to office in the respective Category as soon as is practical, whilst ensuring that the person appointed meets the defined criteria of such Category.

4 TERMS OF OFFICE

- 4.1 The term of office of all Members, including the Chair shall be for three years, concluding on 30 May.
- 4.2 A Member who continues to hold the required qualifications for office may be reappointed for a further term or terms
- 4.3 A termination of membership will require three months' notice.
- 4.4 Committee members cannot be removed from office unless they default to exercise their duties and attend Committee meetings regularly.

5 CALLING MEETINGS

- 5.1 A Committee meeting may only convene when Committee members are given notice of such meeting and a quorum of members, in accordance with section 6 of these terms, attends such meeting.
- 5.2 For a Committee meeting to be validly held, all Committee members permitted to attend and validly appointed in accordance with section 3 of these terms shall be notified that such meeting will be held not less than 7 calendar days prior to the meeting date.
- 5.3 A notice issued in accordance with section 5.2, must specify the following:
- 5.3.1 The date and time of the meeting;
- 5.3.2 The place of the meeting;
- 5.3.3 The means of meeting; in person or via a permitted alternative as specified in section 6.3 of these terms;
- 5.3.4 The agenda for the meeting; and
- 5.3.5 Annex any proposals to be assessed at the meeting.

6 OUORUM

- 6.1 The quorum for meetings of the Committee shall be one member from each of Category's A, B, C and D.
- 6.2 If more than four AEC members are present, Category C plus D must represent not less than one third of those members present.
- 6.3 Where a face-to-face meeting is not possible, the use of video-linking, teleconferencing or similar technology is permissible.
- 6.4 Each member has full right to approve or deny approval of proposals.
- 6.5 If Category C and D represent less than one third of the members present, the Alternate members from Categories A, B and Vivarium shall refrain from discussions and approval and will attend as guests.
- 6.6 The Committee may invite people with specific expertise to provide advice as required.

6.6.1 Committee invitees, in accordance with 6.6, are to provide advice only to the Committee and are not permitted to pass vote on any proposal.

7 MODE OF OPERATION

- 7.1 The Animal Ethics Committee shall meet as frequently as necessary but at least four times a year.
- 7.2 Any permanent member of staff may ask the Chair for permission to attend a meeting (with rights of audience only).
- 7.3 Committee Members must declare any conflict of interest and be excused from attending meetings where discussion and consensus approval on this matter takes place. The non-conflicted respective Category Member must attend in their place.

8 REPORTING MECHANISMS

- 8.1 The Committee must report at least by way of its minutes to the Chief Executive Officer. The Chief Executive Officer may refer any matter from the Committee to any other committee of the organization, where this is relevant and necessary or appropriate.
- 8.2 The Committee will report annually on its activities to the Chief Executive Officer. At a minimum this annual report shall include the following matters:
- 8.2.1 the number of projects and activities assessed, and whether the activities were approved, approved with conditions, or rejected.
- 8.2.2 the facility inspection outcome
- 8.2.3 actions that have supported the educational and training needs of AEC members and people involved in the care and use of animals.
- 8.2.4 any matters that may affect the Institute's ability to maintain compliance with the Code and, if appropriate, suitable recommendations.

9 COMMITTEE APPROVAL

The Terms of Reference were approved by Ozgene Animal Ethics Committee

Signature: P.J. Guffelle

Name: Penney Griffiths

Position: Chairperson, Ozgene Animal Ethics Committee

Date: 18 September 2023