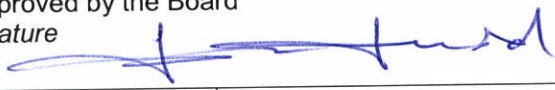




<p align="center">BIOPROPERTIES Pty Ltd</p> <p align="center">Standard Operating Procedure</p>		
<p align="center">BIOPROPERTIES AEC</p> <p align="center">Terms of Reference</p>		<p>Document Ref: ACEC-007 (6)</p> <p>Controlled Copy No:</p> <p>Date issued to Holder:</p>
<p>Written & Approved by the Board</p> <p>Director signature</p> <p>James Judd </p>		<p>Department: AEC</p> <p>Site: Glenorie</p>
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TERMS OF REFERENCE FOR **BIOPROPERTIES** **ANIMAL ETHICS COMMITTEE**

Checked By: Petrina Young		Animal Ethics Secretary	28 / 06 / 2020
DOCUMENT AMENDMENT DETAILS			
<u>Reason for Change to Document</u>	<p>Change expiry from 5 years, to 3 years from date of issue.</p> <p>Amendment to include registration as a Scientific User in Queensland.</p> <p>Clerical changes.</p> <p>Refine the responsibilities of the Committee.</p>		
<u>This Document supersedes:</u>	<p>Doc. Title: Terms of Reference for BIOPROPERTIES AEC</p> <p>Doc. No. ACEC-007</p> <p>Date 9/04/18</p>	<p>Version No. 5</p>	
<u>Document superseded by:</u>	<p>Doc. Title:</p> <p>Doc. No.</p> <p>Date</p>	<p>Version No.</p>	
HOLDERS			
CC Master	Company Master (Housed at Glenorie)		
CC 1	Technical & Marketing Manager		

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1 INTRODUCTION


- 1.1 In accordance with the requirements of the **Animal Research Act 1985** (NSW), the **Animal Research Regulations 2010** and the **Australian Code for the Care and Use of Animals for Scientific Purposes**, 8th Edition 2013 (the Code), as amended by the Regulations, Bioproperties Animal Ethics Committee (AEC) has the responsibility for the consideration of the ethical, welfare and the scientific value of the use of animals for animal research and to monitor the use of animals in the production of vaccines.
- 1.2 Bioproperties will comply with Section 2 of the Code, 'Responsibilities', including those of the Institution, the Animal Ethics Committee, Investigators and Animal Carers, at all times as specified in Chapter 2.1 through to Chapter 2.7.

2 SCOPE

- 2.1 To define the terms of reference that govern the Bioproperties AEC in terms of all aspects of the care and use of animals when the aim is to acquire, develop or demonstrate knowledge in the operations of Bioproperties and Eimeria Pty Ltd (Eimeria) in New South Wales and Victoria.

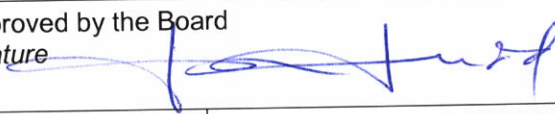
3 ACCOUNTABILITY

- 3.1 Through the AEC Chairperson, the Committee is responsible to the Governing body of Bioproperties and Eimeria. This is achieved by:
 - a) ensuring that the use of animals in animal research is justified, that there is provision for the welfare of those animals, and that the process incorporates the principals of Replacement, Refinement and Reduction.
 - b) requiring that the AEC be aware of and practice the Governing Principals of the Code, in consideration of an animal's welfare from acquisition through to conclusion of use, ensuring that the animals are respected and that their use is ethically justifiable.
- 3.2 The Governing body of Bioproperties and Eimeria are responsible for ensuring that animal research conducted on behalf of the Institution complies with the Code.
- 3.3 The Institution must:
 - a) Ensure, through the operation of an AEC, that all activities involving the care and use of animals comply with the Code;
 - b) Require the AEC to promote compliance with the Code;
 - c) Ensure and support the effective operation of the AEC;
 - d) Identify clear lines of responsibility, communication and accountability;
 - e) Ensure that all people involved in the care and use of animals understand their responsibilities and the requirements of the Code, have the necessary skills and knowledge, and have access to appropriate educational programs and resources; and
 - f) Regularly monitor and review the Institution's compliance with the Code.

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4 GOVERNING PRINCIPLES

- 4.1 Each person involved in animal research must consider the Governing Principles when applying the Code to their respective circumstance. The Governing Principles are set out in paragraphs 1.1 - 1.4 of the Code. They are:
- 4.1.1 Respect for animals must underpin all decisions and actions involving the care and use of animals for scientific purposes. This respect is demonstrated by:
- (i) using animals only when it is justified
 - (ii) supporting the wellbeing of the animals involved
 - (iii) avoiding or minimising harm, including pain and distress, to those animals
 - (iv) applying high standards of scientific integrity
 - (v) applying Replacement, Reduction and Refinement (the 3Rs) at all stages of animal care and use:
 - (a) the *Replacement* of animals with other methods
 - (b) the *Reduction* in the number of animals used
 - (c) the *Refinement* of techniques used to minimise the adverse impact on animals
 - (vi) knowing and accepting one's responsibilities.
- 4.1.2 The care and use of animals for animal research must be subject to ethical review.
- 4.1.3 A judgement as to whether a proposed use of animals is ethically acceptable must be based on information that demonstrates the principles in Clause 4.1.1, and must balance whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits.
- 4.1.4 The obligation to respect animals, and the responsibilities associated with this obligation, apply throughout the animal's lifetime, including acquisition, transport, breeding, housing, husbandry, use of the animal in a project, and provisions for the animal at the conclusion of their use.
- 4.2 In NSW, approval shall only be given for animal research that is essential and which complies with the requirements of the Animal Research Act 1985 (NSW), the Animal Research Regulations (2010) and the Code, taking into consideration ethical and welfare aspects as well as scientific value. Submissions and consideration of written applications shall be in accordance with procedures adopted by the Committee and Bioproperties.
- 4.3 In Victoria, approval shall only be given for animal research which meets the requirements of the Prevention of Cruelty to Animals Act 1986 (the POCTA Act) and

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Regulations. An approval can only be given by an AEC that is nominated on the license issued to the Institution unless approval authority is formally delegated to another AEC.

- 4.4 Bioproperties animal welfare activities in Queensland will comply with Biosecurity Queensland, a service of the Department of Agriculture and Fisheries, the Animal Care and Protection Act 2001 (ACPA), and the Code.

5 MEMBERSHIP OF THE BIOPROPERTIES AEC

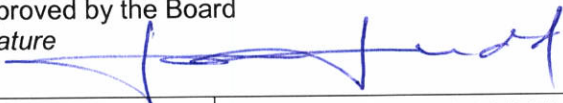
- 5.1 In accordance with the Code, the Bioproperties AEC must comprise at least four persons, one from each of the following categories:

5.1.1 Chairperson

- a) 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 Clause 2.2.4 of the Code).
- b) Institutions should consider appointing a Chairperson who is independent of the care and use of animals for scientific purposes.

5.1.2 Members

- a) Institutions must ensure that membership of the AEC comprises at least one person from each of four categories of membership:
 - (i) Category A—a person with qualifications in veterinary science that are recognized for registration as a veterinary surgeon in Australia, and with experience relevant to the Institution's activities or the ability to acquire relevant knowledge.
 - (ii) 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.
 - (iii) 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 currently involved in the care and use of animals for scientific purposes. Veterinarians with specific animal welfare interest and experience may meet the requirements of this category. While not representing an animal welfare organization, the person should, where possible, be selected on the basis of active membership of and endorsement by, such an organization.
 - (iv) Category D—a person not employed by or otherwise associated with the institution and who has never been involved in the use of animals in scientific or teaching activities, either in their employment or beyond their undergraduate education. Category D members should be viewed by the wider community as bringing a completely

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independent view to the AEC and must not fit the requirements of any other category.

- b) Additional members may be appointed to assist the AEC to function effectively.

5.2 Conflict of Interest

It is mandatory that all members declare any conflict of interest and that there are procedures in place to deal with any conflict of interest that may arise.

5.3 Confidentiality

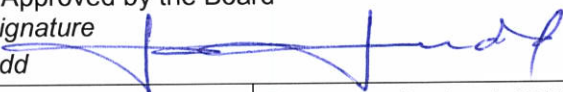
It is a requirement that all Committee members treat all information and discussions as confidential.

5.4 Balance of Membership

Categories C and D must together represent at least one-third of the AEC membership.

6 RESPONSIBILITIES OF THE BIOPROPERTIES AEC

- 6.1 The primary responsibility of the Bioproperties AEC is to ensure, on behalf of Bioproperties, that all activities relating to the care and use of animals for animal research are conducted in compliance with the Code and consistent with the governing principles of the Code, including oversight of the ethical conduct of those whose work involves the use of animals for scientific purposes.
- 6.2 AEC members must comply with the requirements of the Code when considering each application and performing their functions under the Code. Therefore, each member must be familiar with the Code.
- 6.3 The AEC will examine all written applications presented in the approved format concerning animal research and shall:
- review applications for projects and approve only those projects that are ethically acceptable (see Clause 1.3 of the Code) and conform to the requirements of the Code;
 - review the care and management of animals in facilities, including procedures applicable to breeding programs integral to the maintenance of an animal line, and approve only those activities that are ethically acceptable and conform to the requirements of the Code;
 - conduct follow-up review of approved projects and activities (see Clause 2.2.32 [ii] of the Code) and allow the continuation of the approval only for those projects and activities that are ethically acceptable and conform to the requirements of the Code;
 - monitor the care and use of animals, including housing conditions, practices and procedures involved in the care of animals in facilities which conform to the requirements of the Code (section 2: Responsibilities) and take appropriate actions regarding unexpected adverse events;
 - take appropriate actions regarding non-compliance;

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- f) approve guidelines for the care and use of animals on behalf of the Institution;
- g) provide advice and recommendations to the Institution; and
- h) report on its operations to the Institution.

6.4 To achieve this the AEC will:

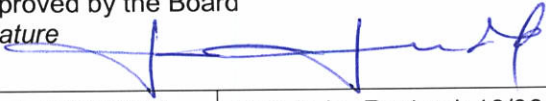
- a) conduct a minimum of four (4) meetings per year, generally the first Wednesday or Thursday of the months of February, May, August and November;
- b) where necessary, impose conditions of approval, listing any measures needed to ensure that the standards of the Code are maintained;
- c) withdraw approval for any project which no longer complies with the Acts or no longer complies with the approval conditions, in accordance procedures adopted by the Committee and Bioproperties;
- d) maintain a register of all approved applications;
- e) be aware of and, where required to do so under the Act and Code, approve the procedures on housing and handling of animals and embryos at Bioproperties-Glenorie and Eimeria-Werribee facilities, and where necessary for pen trials and field trials in other facilities where an application has been approved by the Bioproperties AEC. These procedures include the acquisition, transport, production, inoculation, health monitoring, care and disposal of animals and embryos;
- f) where required to do so under the Code, review and comment on all Bioproperties and Eimeria facility plans and policies and perform annual facility inspections;
- g) approve the thresholds for the treatment or humane euthanasia of any animal;
- h) examine and comment on all AEC applications (or those of any other institution, body or holder of an animal research license for which it has responsibility) which may affect animal welfare;
- i) recommend to the Institution any measures needed to ensure that standards of the current legislation and the Code are maintained; and
- j) perform all other animal ethics' related duties imposed on Bioproperties and Eimeria by current applicable legislation, including reporting and licensing.

7 RESPONSIBILITIES OF THE CHAIRPERSON

7.1 The Chairperson should hold a senior position in Bioproperties and have the ability to meet the responsibilities as outlined in the Code.

7.2 The Chairperson must:

- a) ensure that the AEC operates in accordance with the principles and requirements of the Code, the relevant policies of the Institution and the agreed AEC procedures;
- b) ensure that an agenda is produced prior to each meeting and that the meeting will consider AEC business as required to fulfil the Committee's responsibilities;

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- c) ensure that applications are considered by the AEC and that the outcomes are conveyed to the Principal Investigators and Researchers in a timely manner;
- d) oversee all requirements of the AEC to report and review its operation as outlined in the Code; and
- e) ensure that AEC records are maintained and made available for review by the Institution and authorized external reviewers.

7.3 The AEC Members must:

- a) decide whether, in their own judgement, an application or other matter under consideration by the AEC is ethically acceptable (see Clause 1.3 of the Code) and meets the requirements of the Code.
- b) To fulfill this responsibility, Members should:
 - (i) be familiar with all relevant legislation, including Regulations and the Code and other policies and guidelines relevant to the business of the AEC;
 - (ii) provide opinions on the ethical acceptability of applications and other matters under consideration by the AEC;
 - (iii) during their appointment to the AEC and before any deliberations of the AEC, members must declare any interest that could influence the objectivity of their decision making; and
 - (iv) maintain confidentiality regarding the content of applications and the deliberations of the AEC, in accordance with institutional requirements.

8 REPORTING

- 8.1 The AEC must comply with the reporting requirements of the Code with all annual reports and findings to be copied to the Boards of Bioproperties and Eimeria.
- 8.2 The AEC must submit a written annual report to NSW DPI and to the Governing body of Bioproperties and Eimeria. The report should include:
 - a) numbers and types of projects assessed and approved or rejected;
 - b) the physical facilities for the care and use of animals by the Institution;
 - c) activities that have supported the educational needs of AEC members and/or personnel involved in the care and use of animals;
 - d) administrative or other difficulties being experienced; and
 - e) any matters that may affect the Institution's ability to maintain compliance with the Code and if necessary, the provision of suitable recommendations.
- 8.3 Through the AEC Chairperson, the Board of Bioproperties and Eimeria will ensure that each Company is aware of the content of the annual report and address any concerns that the DPI may express.
- 8.4 The Committee may also report as required (eg. Animal Use Statistics) to other States and Territory Governments.

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9 TRAINING

9.1 Bioproperties and Eimeria will provide and facilitate training for Principal Investigators, Researchers and Animal Husbandry Technicians in the care and use of animals for scientific purposes as required, and will include training in:

- a) animal care, husbandry and welfare procedures;
- b) animal care emergency procedures; and
- c) monitoring procedures and record keeping.

10 REFERENCES

- *Animal Research Act 1985 (NSW)*
- *Animal Research Regulations 2010*
- *Australian Code of Practice for the Care & Use of Animals for Scientific Purposes*, 8th edition 2013 as amended by the Regulations.
- ACEC-001 ACEC Inspection
- ACEC-002 ACEC Meeting Protocols