

Scientific Auditing Services Pty Ltd

External Review

Report:

QUT06082020



Prepared by: Karen Boundy, Senior Auditor, Scientific Auditing Services Pty Ltd.
Provided to Queensland University of Technology, Kelvin Grove, on 16th December 2021.

Acknowledgements

Scientific Auditing Services Pty Ltd has taken all reasonable steps within the time allocated, the budget allowed and in accordance with the Agreement for the Supply of Services, (signed 2021), between Scientific Auditing Services Pty Ltd and Queensland University of Technology associated with Client File ID: QUT06082020 in preparation of this document.

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Acknowledgement of Source Document

The source document for Report QUT06082020 is the *Australian code for the care and use of animals for scientific purposes, 8th Edition, 2013*. Information contained in this report (inclusive of all its parts) may include material adapted or derived from the source document. The source document must always be considered as the definitive reference and all matters relating to the contents of the report and should be managed in direct consultation with the source document.

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Executive Summary

Institutions using animals for scientific purposes, research and teaching, have an obligation under the *Australian code for the care and use of animals for scientific purposes - Edition 8, 2013* (the Code) to undertake a program of external review of their animal ethics systems. This assessment is required to ensure the continued suitability, adequacy and effectiveness of institutional procedures to meet the responsibilities of the Code. To satisfy this obligation, the Queensland University of Technology's Office of Research Ethics & Integrity commissioned a review of its animal ethics system by the independent, external review service provider, Scientific Auditing Services Pty. Ltd. The review was undertaken by a three-member panel, the external review panel (ERP), in line with the provisions outlined in section 6 (s 6.1 - 6.7) of the Code.

The ERP collected information for assessment of the Queensland University of Technology's Animal Ethics Framework (AEF) during the 2021 review period. This included:

- A desk-top assessment of the policies, procedures, forms and records selected from the years 2017 - 2021 were provided for review by the Office of Research Ethics & Integrity (OREI) to provide an overview of the institutional program governing the care and use of animals for scientific purposes.
- Discussions with the OREI and Medical Engineering Research Facility (MERF) staff and AEC chair and selected investigators, representing QUT to provide detail in regard to the processes involved in the Animal Ethics Framework. (7th and 8th of September, 2021)
- Attendance at an Animal Ethics Committee (UAEC) meeting to demonstrate the process of ethical review and monitoring of projects. (Kelvin Grove Campus - 7th of September 2021)
- An on-site inspection of Queensland University of Technology's animal facilities at the Prince Charles Hospital Precinct, Chermside.

The independent external review concluded that the Queensland University of Technology has achieved a high level of conformance with the Code. This is outlined in Part B of this report. The external review panel's conclusion is based on the review findings, detailed in Part D of this report, identified during the review to support the following:

- QUT provides for an ongoing program to maintain this level of conformance with the Code and demonstrates commitment to the review and continual improvement of the systems governing the care and use of animals undertaken by its researchers, technicians and students for scientific purposes.
- The institutional program provides an ethical framework sufficient for the care and use of animals to be subject to ethical review, approval and monitoring by an AEC in accordance with Code requirements.

- The institutional program promotes the application of the governing principles including the 3Rs, (replacement, reduction and refinement), to all those involved in the care and use of animals for scientific purposes.
- The institutional program provides an ethical framework that includes resources and education for AEC members, sufficient to be aware of and meet their responsibilities under the Code.
- QUT provides resources and infrastructure sufficient to maintain adequate animal facilities to support the wellbeing of animals in accordance with the provisions of the Code.
- The UAEC is operating effectively and provides ethical review of the institution's animal use.
- Those caring for and using animals in research, on behalf of QUT, acknowledge the importance of, and contribute to maintaining a high standard of animal wellbeing.

Commendations are provided by the external review panel to recognise behaviours and actions by individuals and teams that support compliance activities in Part C of this report.

No review findings of major concern (where animal wellbeing is compromised and immediate corrective actions are required) were found during the review period.

Review findings requiring consideration and action by the institution were identified relating to following Code provisions:

Clauses 2.2.23 and the related clause 2.3.6.

Recommendations for corrective actions are made in relation to these findings in Part E of this report.

Review Participant Details

Client Details

Queensland University of Technology, Road, Kelvin Grove, Queensland, 4059.

Queensland University of Technology - Liaison Officer:

Anne Walsh – Director,

Office of Research, Ethics & Integrity,

Research Portfolio

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Other Client Representatives:

Selected staff members involved in scheduled meetings and / or facility inspections during the on-site visit, 7th & 8th September, 2021.

AEC Chair and Members:

AEC Chair, appointed AEC members, ex-officio attendees and other invited participants in attendance at the Queensland University of Technology Animal Ethics Committee (UAEC) Meeting, 7th September, 2021.

External Review Panel (ERP) Members employed by Scientific Auditing Services Pty Ltd. (Named Consultants):

Ms Karen Boundy, Senior Reviewer / External Review Panel Leader (Scientific / Technical Representative).

Dr Johanna Toia, External Review Panel Member - (Veterinarian and Educator).

Ms Wendy Mc Cullagh, External Review Panel Member - (Welfare / Animal Care Representative).

Review Brief

Objectives

To evaluate and provide information, through independent external review, regarding the level of conformity to the *Australian code for the care and use of animals for scientific purposes - 8th Edition, 2013* by Queensland University of Technology's animal ethics system.

To contribute to Queensland University of Technology's promotion of animal wellbeing, principles of best practice and application of high standards of scientific integrity within the Queensland University of Technology's animal ethics framework.

Scope of Audit - extent or boundaries:

This audit is conducted for Queensland University of Technology, as part of its responsibility under the compulsory Code, *Australian code for the care and use of animals for scientific purposes - 8th Edition* to undertake a review, using an independent external review of its animal ethics system.

The Scope of the review is limited to:

- QUT's Animal Ethics Administrative Framework - Overall Guidance Documentation - including but not limited to procedures, policies, forms and records that make up the Queensland University of Technology's animal ethics system.
- Operation of the QUT's Animal Ethics Committee and its relationships - Administrative and Operational - including but not limited to forms, policies, procedures (e.g. dealing with conflict of interest, complaint handling, member resignation etc.), meeting structures, authorities, minutes, training, membership make up, meeting frequency and dynamics. Attendance by the External Review Panel at a Queensland University of Technology's Animal Ethics Committee meeting held on 7th of September, 2021.
- QUT's Animal Facilities:
 - Chermside Hospital Precinct - Medical Engineering Research Facility (MERF).
- Selected QUT's Animal Use Activities - Provided by QUT - approved (for >1 year) research / teaching projects. All documentation associated with the approved project, including all amendments, reporting, and related correspondence for the life of the project.

Criteria

- (1) *NHMRC - Australian code for the care and use of animals for scientific purposes - 8th Edition*
[\[https://www.nhmrc.gov.au/guidelines/publications/ea28\]](https://www.nhmrc.gov.au/guidelines/publications/ea28)
- (2) Operating documents specified and supplied by the Queensland University of Technology Office of Research Ethics & Integrity.

Outcome

A Report, with recommendations, of the findings of the independent external review, in relation to the level of conformance of the Queensland University of Technology's animal ethics system with the requirements of the *Australian code for the care and use of animals for scientific purposes - 8th Edition*.

Method Used

The review method included an assessment of the raw data sample collected during the review period. The sample included documentation supplied by Queensland University of Technology and data collected from the on-site visits and collated by Scientific Auditing Services Pty Ltd.

This data was reviewed in relation to the NHMRC published *Australian code for the care and use of animals for scientific purposes 8th Edition 2013* for the identification of areas which may be of concern associated with system conformance.

Recommendations for potential system improvements are included as per client request.

Commendations are derived from the interactions with Queensland University of Technology staff or students and review of the collected sample documentation, including any observations and notations recorded.

General comments are derived from the interactions with Queensland University of Technology staff and review of the collected sample documentation, including observations and notations recorded.

STATEMENT OF CONFORMANCE

The extent to which there is overall conformance with the *Australian code for the care and use of animals for scientific purposes - edition 8, 2013* (the Code) is the subject of external review, QUT06082020.

This review was undertaken, on behalf of Queensland University of Technology, by Scientific Auditing Services Pty. Ltd. in line with the provisions outlined in section 6 (s 6.1 - 6.7) of the Code.

The scope and outcome of the review included:

- the conduct of all people involved in the care and use of animals for scientific purposes on behalf of the institution, including the AEC, institutional officers and administrators, investigators and animal carers (c 6.6 i)
- the adequacy of the institutional program to ensure that the care and use of animals for scientific purposes is conducted in compliance with the Code; is subject to ethical review, approval and monitoring by an AEC; and is conducted in accordance with the AEC approval (c 6.6 ii)
- the adequacy of institutional support, resources and educational programs for the AEC and its members, and for people involved in any aspect of the care and use of animals for scientific purposes, to ensure that they can meet their responsibilities under the Code (c 6.6 iii)
- whether the AEC is operating effectively in accordance with the Code (c 6.6 iv)
- the effectiveness of institutional strategies to promote and monitor the implementation of the governing principles (c 6.6 v)
- whether there is effective monitoring of the wellbeing of animals (c 6.6 iv)
- whether facilities used to house animals are managed to support and safeguard animal wellbeing (c 6.6 vii)

Conclusion

The independent external review has concluded Queensland University of Technology has achieved a high level of conformance with the Code. The institution provides for an ongoing program to support the level of conformance with the Code and was found to have demonstrated a commitment to the review of, and continual improvement to the systems governing the care and use of animals undertaken by its staff and students for scientific purposes. One (1) review finding requiring consideration and action by the institution was identified during the review period and recommendations have been provided by the External Review Panel. The institution has undertaken to consider the findings and recommendations outlined in report QUT06082020 as part of its obligation to ensure its effectiveness in meeting its responsibilities under the Code and providing a robust animal ethics framework QUT06082020.

COMMENDATIONS

Commendations are provided in recognition of the effort made by the institution, groups or individuals in their commitment to ensuring the care and use of animals for scientific purposes achieves a high standard.

The Institution

Queensland University of Technology is commended for:

- promoting responsible and ethical animal use for scientific purposes through its commitment to achieving a high level of compliance to the Code.
- actively promoting the governing principles, including the 3Rs, within the institution and ensuring they are integrated into the animal ethics framework.
- providing governance and resources for the animal ethics framework to oversee the scientific use of animals undertaken at Queensland University of Technology.
- considering and implementing recommendations from the previous independent external review as part of their (QUT 14112016) as part of ongoing commitment to meet the institution's obligations under the Code
- providing resources for the UAEC to operate effectively.
- ensuring the UAEC has the appropriate level of authority and autonomy.
- providing resources for key positions in the animal ethics framework to support and advise the UAEC and investigators with specialist advice on the scientific, veterinary, technical and welfare issues involved in animal use projects including the:
 - Regulatory and committee officers
 - Animal Welfare and Ethics Coordinator (AWEC)
 - Research ethics advisors
 - Animal facility managers and staff
- providing resources for the development and management of the animal facilities to provide a high standard of housing and care.

The Office of Research Ethics & Integrity

The Office of Research Ethics & Integrity is commended for:

- Its cooperation and participation in the external review process. In particular, the OREI Director, AWEC and UAEC Chair for actively participating in the review process.
- providing operational support for, and regulatory advice to, the UAEC.
- their commitment to ensuring the animal ethics framework achieves a high-level of compliance with the Code.
- developing, in consultation with the UAEC, and implementing code related policy and procedures and to provide for a robust animal ethics framework.
- supporting all those involved in the animal ethics framework through the development and implementation of the Ethics Review Manager system, including the animal ethics application for research and teaching.

- the continual program of improvement of the animal ethics system with the development of policies, procedures and processes in line with the Code and the previous independent external review ((QUT141112016).
- providing an effective means of communication between the UAEC and the institution, the UAEC and investigators, and the institution and external agencies including state governments departments and external research institutions.

Research Ethics Advisors (REAs)

REAs are commended for:

- the support they provide to investigators and the UAEC in the planning, preparation and pre-review of animal use projects.

The UAEC Chairperson

The UAEC Chairperson is commended for:

- their cooperation and participation in the external review process including their frank and open interactions with the reviewers.
- providing leadership to the UAEC and support for UAEC members. In particular, supporting new members to understand their individual roles and how the UAEC functions.
- representing the UAEC at an institutional level.
- investing their time and expertise in the overall management of the UAEC and its processes.

The UAEC

The UAEC members are commended for:

- their cooperation and participation in the external review process.
- ensuring the activities involving animals at Queensland University of Technology are ethically reviewed, approved and the wellbeing of animals used is monitored. This was evident in the discussions observed during the UAEC meeting attended by the reviewers.
- their commitment to providing service, to the institution, the UAEC and the animals involved, in particular those who volunteer their time and energy to undertake the responsibility of C - and D - category member roles.
- taking their responsibilities to the UAEC seriously and participating actively in meetings and at inspections to provide oversight in the area of animal wellbeing.
- effectively representing the UAEC at activities external to the institution when required.

Animal Technicians (including the Animal Facility Manager)

The Animal Facility Manager and Animal Technicians / Carers are commended for:

- their cooperation and participation in the external review process. In particular, animal technicians working in the animal facility for discussing their work with, and allowing reviewers to observe them while undertaking their duties.
- the high level of commitment to their work as technicians and to the animals they care for.
- providing environmental enrichment to promote animal wellbeing.
- their skill in maintaining the high standard of management of QUT animal facilities.
- developing and undertaking, in consultation with the Office of Research Ethics & Integrity, a program to ensure those working with animals are competent in the procedures they undertake.
- their efforts in improving communications between themselves, the investigators and the UAEC.
- their caring and professional approach to performing their duties. This was evident in discussions with animal care staff and the observations of activities at QUT animal facilities.

Investigators

Investigators are commended for:

- their cooperation and participation in the external review process, in particular, for discussing their projects with reviewers.
- the high level of commitment to their research work and the animals they use.
- their efforts in adopting the procedures and practices under the animal ethics framework.
- undertaking theoretical and practical training and assessment to ensure they are proficient in the procedures and techniques they apply to their animal use.
- applying the 3Rs to their work and providing for the wellbeing of animals involved. This was evident in discussions with investigators and the observations of activities at QUT animal facilities.

DETAILED REVIEW FINDINGS

SECTION 1 - GOVERNING PRINCIPLES

Governing Principle 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:***
- (vi) knowing and accepting one's responsibilities.***

The institution was found to actively promote and facilitate the adoption of the governing principles at all levels to ensure all those involved with the care and use of animals for scientific purposes associated with the Queensland University of Technology (QUT) consider them when applying the Code to their specific circumstance.

The institution through the Office of Research Ethics and Integrity (OREI) has ensured the governing principles have been integrated into the animal ethics framework at several key stages where they have become part of the routine processes for using animals in research and teaching.

Key areas in which examples of the governing principles, including the 3Rs, were found to have been actively promoted and applied include:

- (1) The policy and procedures governing the animal ethics framework including those procedures for the operation of the University Animal Ethics Committee (UAEC), the submission of applications for ethical clearance, the monitoring of animal use and the operation of the animal facilities.
- (2) The education and competency requirements for all those using animals for research and teaching. The institution has developed policies, procedures and programs to ensure all those involved in the processes involved in animal use have access to educational resources, training programs and undergo assessment ensuring they are aware of their responsibilities and competent to undertake the procedures involved in their specific role.

- (3) Support for investigators and teachers in planning, applying for, and reporting on a project or activity involving animal use in research or teaching. The institution provides support and specific guidance through:
- documents that include information, questions and prompts to ensure investigators and teachers consider and apply the governing principles when planning to use animals ensuring that the proposed use is justified, that animals are essential and there is scientific or educational merit.
 - specialist advice, the Animal Welfare and Ethics Coordinator (AWEC) and dedicated ethics-related staff appointed within faculties as Research Ethics Advisors (REAs).

c 1.1

Governing Principle 1.2: The care and use of animals for scientific purposes must be subject to ethical review.

The QUT animal ethics framework was found to support and manage processes to ensure that those involved with the use of animals for scientific purposes have all projects and activities, assessed and approved by an AEC prior to the commencement of work. This framework includes:

- the UAEC, operating in line with the provisions outlined in chapters 2.2 and 2.3 of the Code.
- a requirement for investigators to obtain ethical clearance from the UAEC for all projects and any variations or modifications (major or minor) to approved projects prior to commencement.
- the UAEC follow-up review of projects to ensure they conform with their ethical clearance through annual and completion reports.
- implementing processes for the management of unexpected or adverse events including review by the UAEC.
- implementing processes to manage instances where investigators fail to comply with institutional process and the Code.
- support for the UAEC in the decision making process from qualified and experienced scientific, veterinary, regulatory and technical advisors.

Processes observed during the review, including the assessment of documents, observations recorded during the on-site visit and the UAEC meeting attended by the External Review Panel (ERP) (07 & 08 September, 2021) provided evidence that governing principle 1.2 is applied to the animal ethics system used within the institution.

c 1.2

Governing Principle 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 1.1, and must balance whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits.

The QUT animal ethics framework was found to provide processes to ensure the UAEC receives applications and reports that allow them to undertake ethical review of animal use activities and decide whether a proposed use of animals is ethically acceptable based on information that demonstrates the principles in Clause 1.1, and balance whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits. This was found to be done by:

- QUT through the OREI providing appropriate application and reporting formats via Infonetica Ethics Review Manager® (ERM). Prior to undertaking any animal use applications are assessed and those that involve the care and use of legally defined animals for scientific purposes are submitted to the UAEC for review and consideration of approval.
- the animal ethics (ERM) application (Documents 70 & 71) requiring investigators to address whether the potential effects on the wellbeing of the animals involved are justified by the potential benefits in Section 4: *Project Justification*. Investigators are required to provide sufficient information to satisfy the UAEC that this has been considered and justification for use has been adequately addressed prior to granting approval.
- the format of the animal ethics on-line ERM application (Documents 70 & 71) meeting the requirements outlined in chapter 2.7 of the Code and reflecting Code provision 1.1. UAEC processes demonstrated the committee members base their decisions on the information provided in the application and may in addition actively seek further information or clarification from investigators and other expert sources when required. The UAEC may also place conditions on the approval to ensure they have sufficient assurances that the animal use meets the requirements of ethical acceptability.
- investigators providing the UAEC with information in relation to annual progress (Document 73), completion (Document 74) and variation (Document 72) to existing approved projects, ensuring they continue to be monitored and any outcomes or variations assessed for ethical acceptability.

Processes observed during the review, including the assessment of documents, observations recorded during the on-site visit and the AEC meeting attended by the ERP (07 & 08 September, 2021) provided evidence governing principle 1.3 is applied to the animal ethics system used within the institution.

Governing Principle 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.

The QUT animal ethics framework was seen to promote respect for animals, and the responsibilities associated with this obligation ensuring it is applied throughout the animal's lifetime. Examples of how the institution meets this requirement was found in the following areas:

- Providing ethical oversight of projects through UAEC application and reporting processes for animal use activities

The application process requires investigators to consider and complete the on-line application, providing sufficient information to satisfy the UAEC that the use is ethically acceptable and complies with the requirements of the Code. The UAEC was seen to continue monitoring activities that impact on the animal's wellbeing throughout the animal's lifetime through annual, completion and unexpected or adverse event or incident reporting. The UAEC undertakes routine on-site inspections of animal facilities to ensure animal use activities proceed in accordance with its approval and that facilities, the animals and their environment are managed appropriately to support the animal's wellbeing throughout its lifetime.

- Ensuring oversight and support for the management of animals used and those involved in the use of animals

Oversight and support in all aspects of animal use was evident in the structure and management of the animal facilities, the use of animals and in UAEC processes.

- Providing opportunities for education and training to the investigators and animal carers / technicians to ensure a high level of skill in animal handling

In-house education and training opportunities are provided by qualified and experienced staff to ensure those caring for and using animals are aware of their responsibilities and undergo animal handling training. Animal facility staff undergo an induction process that includes training to ensure animals and facilities are well maintained.

Processes observed during the review, including the assessment of documents, observations recorded during the on-site visit and the UAEC meeting attended by the ERP (07 & 08 September, 2021) provided evidence governing principle 1.4 is applied to the animal ethics system used within the institution.

c 1.4

END OF COMMENTS RELATING TO SECTION 1

SECTION 2 - RESPONSIBILITIES

Chapter 2.1- Responsibilities of institutions

The governing body of the institution, QUT, is responsible for ensuring that the care and use of animals for scientific purposes conducted on its behalf complies with the Code.

QUT is registered in its home state of Queensland as a user of animals for scientific purposes and also holds accreditations in New South Wales and the Northern Territory (Document 2).

QUT has undertaken to establish, support and provide authority to an animal ethics framework that includes an AEC, promotes and monitors compliance with the Code and ensures all those involved in the use of animals are aware of, accept and acknowledge their responsibilities under the Code.

c 2.1.1 - c 2.1.2

QUT was found to:

Ensure compliance through an animal ethics committee

The institution provides resources and support for an animal ethics framework that includes the UAEC. Please refer to the review findings for Section 2, Chapters 2.2 and 2.3 for details in regard to the AEC.

c 2.1.3

QUT may use an external AEC or share an AEC with another institution

c 2.1.4

Promote compliance

The institution promotes compliance by:

- nominating the position of Vice-Chancellor and President as the Senior member of the institution with the authority for the overall institutional governance in respect to the care and use of animals. *“University Animal Ethics Committee is a management committee accountable to the Vice-Chancellor Research and President through the Deputy Vice-Chancellor Research and Vice-President .”* (Document 1)
- providing the animal ethics framework with adequate resources to ensure that the UAEC and people involved in the care and use of animals can meet their responsibilities, including monitoring animals and managing adverse impacts on their wellbeing. This includes resourcing the OREI to provide administrative support and assist in the development of procedures and processes to support the animal ethics framework including the operation of the UAEC. During the on-site visit the External Review Panel (ERP) met with the OREI team that supports the animal ethics framework.

The team included the Director (OREI), Manager (OREI), Research Governance and Compliance Coordinator, UAEC Chair, AWEC, Research Ethics Officer, and the Committees Officer. Discussions centred on the administration of the framework and the recent introduction of the ERM system. Support for the maintenance and ongoing improvement to the structure of the framework including refinements to the animal ethics processes, support for animal facilities and monitoring of compliance from within the system were evident.

c 2.1.5 (ii)

- promoting and facilitating adoption of the governing principles of the Code through the animal ethics framework. The governing principles form the basis of the processes, procedures and forms used by those involved in the use of animals for scientific purposes. Education and training for all participants involved promoting an understanding of the governing principles and how to apply them within their individual circumstances (Documents 2 - SOP 4: *Training and competency assessment* & 47).

c 2.1.5 (iii)

- publishing the institutional policies and procedures on the QUT public website and through the internal QUT intranet for all relevant people including AEC members to have access.

c 2.1.5 (iv)

- ensuring that guidelines for animal care must include:
 - (a) how the competence of people involved in the care and use of animals will be assessed and ensured. QUT provides an SOP for training and competency assessment for those involved in the care and use of animals (Document 2 - SOP4: *Training and competency assessment*).
 - (b) strategies to ensure the maintenance of the health status of the animals that safeguards animal wellbeing and meets the requirements of their proposed use are outlined in the animal facilities. Facilities were found to have support and procedures for the management and maintenance of QUT sites and animals housed or free-living at those locations. The AWEC and UAEC monitor the projects, activities and animal facilities to ensure these procedures are in place, comply with the Code, are appropriate for the animals on-site and reflect current best practice.
 - (c) monitoring and assessment of animals to ensure that any harm, including pain and distress, is promptly detected and managed were identified to be available through the organisational structure (including the availability of veterinarians, researchers and technicians) and through the procedures (approved projects and SOPs) for monitoring animals in animal facilities.

- (d) the management of unexpected adverse events (UAE) and emergencies is provided in an SOP (Document 2 - SOP18: *Adverse event reporting and handling*). Accompanying the SOP is a flowchart outlining the process if an adverse event occurs (Document 2 - Appendix 4: *Unexpected Adverse Event Process*).
- (e) the approval in advance for the immediate use of animals, if required, for the diagnosis of unexplained and severe disease outbreaks, or morbidity / mortality in animals or people. Reference to this clause was identified as a UAEC Executive function (Doc 2 - SOP 2: *Executive* [2.1 (vii)]).

c 2.1.5 (v) a - e

- providing access to veterinary advice for the management and oversight of a program of veterinary care, quality management and project design to safeguard animal wellbeing. Access to QUT Veterinarians, the AWEC and additional veterinary specialist advice and support was found to be available to researchers, teachers and animal facility / field staff.

c 2.1.5 (vi)

- the institution appointing an AWEC, in 2018, to ensure activities proceed in compliance with the Code and the decisions of the UAEC. This a full-time role is currently held by an appropriately qualified and experienced veterinarian. (Document 115)

c 2.1.5 (vii)

Ensure and support the effective operation of the animal ethics committee

The institution provides support and resources through the OREI for the effective operation of the UAEC in accordance with Section 2, Chapter 2.2 of the Code. The University Animal Ethics Committee is regulated by Council Procedure No 1 (Committees), with the exceptions of sections 6.15 (the holding of multiple positions by a single member, 7.7 (quorum), 7.10 (determining questions before a committee) and 9 (decisions between meetings) which are inconsistent with requirements of the Scientific Use Code. (Document 3)

Specific governance documents for the UAEC includes a publicly available TOR (Document 1 - *UAEC Charter*) https://www.mopp.qut.edu.au/D/D_06_07.jsp and the *UAEC Standard Operating Procedures* (Document 2) that includes procedures for reviewing, approving and monitoring the care and use of animals, communication between the UAEC and institution and the management of non-compliance and complaints.

c 2.1.6 (i - v)

Identify clear lines of responsibility, communication and accountability

The institution provides:

- (a) processes for identifying the person responsible at any given time through the UAEC review of ethical acceptability and monitoring of animal activities and projects. Animal Ethics Applications, variations and reports require detailed information to be provided by investigators. Information

including identification of the Chief Investigator, all those involved in the care and use of animals, their specific qualifications, experience (or how training will be provided to reach competency) and how they will undertake the procedures and monitoring responsibilities. In the animal facilities qualified, competent staff provide routine care and monitor animals.

- (b) provides information including a flowchart that outlines the processes for managing UAEs and emergencies outlining the steps and responsibilities of those involved (Document 2).
- (c) emergency procedures including contact numbers and access to specialist information (e.g. OGTR) to ensure disease outbreaks and emergencies, such as fire, power failure and biosafety issues, are promptly detected and effectively managed. Appropriate procedures were identified in animal facilities outlining actions and responsibilities in the case of emergencies.

c 2.1.7(i)

Procedures were available for addressing animal ethics-related complaints and non-compliance. Please refer to the review findings for Section 5 for details in regard to procedures for addressing complaints and non-compliance.

c 2.1.7(ii)

Ensure understanding of responsibilities

The institution has provided the animal ethics framework to ensure all people involved in the care and use of animals understand their responsibilities and the requirements of the Code, are competent for the procedures they perform or are under the direct supervision of a person who is competent to perform the procedures, and have access to appropriate education programs and resources. Please refer to the comments made for c 2.1.5 (v) a.

Institutional employment processes ensure those engaged to provide care for and use animals on behalf of the institution have the necessary qualifications and experience to undertake their duties. An example of the QUT requirements for employment were provided for a position at QUT [specifically for the AWEC position] (Document 115). The example provides a detailed outline of the employment criteria including qualifications, knowledge and experience required to undertake the specialist role within the institution.

c 2.1.8 (i - ii)

The institution encourages the adoption of best practice in the care and use of animals in research and teaching.

c 2.1.8 (iii)

Discussions with MERF staff and the review of UAEC inspection reports, competency records and discussions on-site (08 September, 2021) verified that staff undertaking animal care and management were competent, adequately supervised and had access to appropriate resources.

c 2.1.8 (iv - v)

It appeared adequate numbers of staff were available in on-site (MERF) facilities in relation to the number of animals present at the time of the review. Management of staffing for the Pinjarra Hills facility was discussed during the on-site visit and appeared adequately addressed. Records indicate appropriate staffing levels at QUT sites where animal housing and habitats are maintained. (Documents 87 - 103).

c 2.1.8 (iv)

Veterinary assistance and diagnostic services were found to be available as required in the animal facilities. This includes the on-site veterinarians and specialist off-site veterinary diagnostic services.

c 2.1.8 (v)

The institution is committed to and provides health and safety framework outlined in the QUT *Manual of Policies and Procedures (A/9.1 Health, safety and environment)* on their website: https://www.mopp.qut.edu.au/A/A_09_01.jsp#A_09_01.04.mdoc

c 2.1.8 (vi)

Please refer to the review finding for Section 2 - Chapter 2.6.

c 2.1.8 (vii)

Monitor and review compliance

QUT monitors and reviews institutional compliance with the Code by:

- (i) establishing a schedule for independent external review every four (4) years (Code: Section 6) including reviews QUT14112016 and QUT06082020 to meet State and Territory reporting obligations.
- (ii) assessing a written review of the operations of the UAEC annually. The annual report of the operations of the UAEC (Documents 11 - 14) is prepared by the OREI and the UAEC chair and endorsed by the UAEC membership. It is provided to the QUT Council through the Deputy Vice-Chancellor and Vice-President (Research), Audit and Risk Committee, University Research Committee (URC) and University Academic Board. The report includes information on the operations of the UAEC as recommended by the Code (c 2.3.29 [i - v]) and includes details of adverse events reports and compliance and monitoring activities in line with State and Territory reporting obligations.

c 2.1.9 (i)

c 2.1.9 (ii & iii)

No comment required

c 2.1.10.

END OF COMMENTS RELATING TO CHAPTER 2.1

Chapter 2.2 - Responsibilities of institutions regarding the governance of an animal ethics committee

Responsibilities

The review of governance documents and discussions with the OREI and UAEC chair demonstrated how QUT meets its responsibilities regarding the operation of the UAEC.

c 2.2.1 (i - v)

Ensure appropriate animal committee membership:

Composition of the animal ethics committee

The institution meets these responsibilities by:

- the Vice-Chancellor and President nominating a chair to guide the operation of the UAEC. The UAEC chair is an appointment from within the institution and not independent of the use of animals for research and teaching. The current UAEC Chair has previously held senior positions in the institution as a member of the Academic Staff engaged in research and teaching as well as Dean of the Faculty of Health and as a member of the Executive Staff as a former Deputy Vice-Chancellor.

c 2.2.2 - c 2.2.3

- appointing a membership consistent with the Code requirements outlined in Section 2 including the appointment of a chairperson and a core membership of the four (4) categories, A, B, C and D.

c 2.2.2 - c 2.2.4

- appointing multiple appointments to each of the categories A-, B-, D- and two C-members (Document 2021 Meeting Dates & Members). The UAEC (2021) has the following voting appointments:
 - Three (3) A-members (one (1) A-member resigned June 2021)
 - Four (4) B-members
 - Two (2) C-members
 - Six (6) D-members (one (1) D-member resigned September 2021)

c 2.2.4

- supporting the UAEC at the meetings with several member and non-member positions including the MERF Operations Manager (Animal Facility member), the AWEC, Research Ethics Officer and OREI Committees Officer (Secretary). These positions are present to provide technical, administrative and regulatory support for the UAEC.

c 2.2.1 (i) and c 2.2.2 - c 2.2.7

- ensuring all appointments meet and are acknowledged as accepted under the processes of the Queensland Department of Agriculture and Fisheries - Biosecurity Queensland as complying with the Code and State requirements. These appointments are provided to other State and Territory Regulators as required to meet the obligations in those particular jurisdictions.

(As per State / Territory Government requirement)

- at the time of the review the UAEC had a total membership of sixteen (16) with eight (8) C- and D-members and one additional appointment under Code sections c 2.2.5 & c 2.2.6. The AEC has the correct balance of C-and D- members making up at least 1/3 of committee membership.

c 2.2.8

- including an appointment, re-appointment and retirement procedure in the TOR (Documents 2 - *Section 12: Appointment, resignation and termination of committee members*) that outlines the processes for appointment, re-appointment or retirement of AEC members. *The University Animal Ethics Committee is regulated by Council Procedure No 1 (Committees), with the exceptions of sections 6.15 (the holding of multiple positions by a single member, 7.7 (quorum), 7.10 (determining questions before a committee) and 9 (decisions between meetings) which are inconsistent with requirements of the Scientific Use Code.*(Document 3)

c 2.2.9

- requiring new and returning AEC members to undertake an agreement that includes:
 - agreement to be bound by the Committee terms of reference (MOPP D/ 6.7 University Animal Ethics Committee charter),
 - agreement to declare conflicts of interest,
 - agreement to treat all information as confidential.

(Document 2 - SOP 12: *Appointment, resignation and termination of committee members [clause 12.21]*)

c 2.2.10

- providing induction to new and returning members. New members appointed to the UAEC are provided with introductory information and an induction pack that includes:
 - Weblinks to the:
 - The Australian code for the care and use of animals for scientific purposes*
 - QUT Appendix 2 Council Procedure¹ - Committees
 - Appendix 5 - QUT Committee Structure

- QUT Manual of Policies and Procedures, specifically MOPPs A/7.1, B/8.7, D/2.6, D/2.7 and D/6.7
- An electronic copy of the Committee Standard Operating Procedures
- Statement of undertaking (*to be signed and returned to the Committees Officer*)
- Instructions and procedures for disclosures of interests
- The Committee meeting schedule and a list of current members
- Operational information about the Committee and OREI (including links to resources)
- Web links to QUT animal ethics training
- Guidance on how to access Committee documents and review ethics applications

In addition to the induction pack:

- Orientation is provided by the UAEC Chair and OREI.
- Mentoring (partnering with another UAEC member) may also be offered to a new member.

(Document 2 - SOP 13: Induction of new committee members).

c 2.2.12

Responsibilities of the chairperson

The UAEC chair was identified during the review to impartially guide the AEC meeting (07 September, 2021) and adhere to the meeting procedures including conflict of interest and maintenance of quorum. In discussions it was established the chair has established and effective lines of communication within the institutional hierarchy to make representation, on the UAEC's behalf, when required.

c 2.2.13

Responsibilities of members

Members have access to, and are encouraged to familiarise themselves with the UAEC Charter (TOR) (Document 1), *UAEC Standard Operating Procedures* (Document 2) and the Code to ensure they understand their roles and meet their responsibilities as UAEC members. Observations recorded at the UAEC meeting (07 September, 2021) and discussions with the UAEC chair and OREI established that members understood their responsibilities under the Code and contributed to UAEC business including providing their individual opinions in regard to the review and monitoring of animal use projects and activities.

c 2.2.14 - c 2.2.15

UAEC members understood the requirements of conflict of interest, made appropriate declarations of any actual, perceived or potential conflict of interests prior to their appointment to the committee or with items on the UAEC meeting agenda prior to the meeting date or at the time of the meeting (if an instance arises) before items are discussed (Documents 2, 4 & 110 [a, c & d]).

c 2.2.16

Confidentiality requirements are outlined by the institution (Documents 1, 2 & 3). New members are briefed on their responsibility to uphold confidentiality through the induction process and sign a confidentiality agreement prior to appointment to the AEC.

c 2.2.17

Ensure the animal ethics committee has a terms of reference

QUT provides a publicly available (https://www.mopp.qut.edu.au/D/D_06_07.jsp) *UAEC Charter* (TOR) (Document 1) and a *UAEC Standard Operating Procedures* (Document 2) accepted under the processes of the Queensland Department of Agriculture and Fisheries - Biosecurity Queensland as complying with the Code. The Charter (TOR) is provided to other State and Territory Regulators as required to meet the obligations in those particular jurisdictions.

c 2.2.1 (ii) and 2.2.18 (i - iii)

Provide the animal ethics committee with adequate resources

The institution resources the UAEC through the OREI to support its operation and meet its responsibilities under the Code by providing financial, administrative, educational (including induction) and operational assistance. The UAEC is provided with sufficient resources to maintain its operations.

c 2.2.1 (iii) and c 2.2.19 (i - ii)

Establish procedures for animal ethics committee governance and operation

QUT has established a suite of policies and procedures to govern UAEC operation, ensuring it is able to meet its responsibility for the ethical oversight of animal use on behalf of the institution in accordance with the Code. Documentation, including the Charter (TOR) (Document 1) and *UAEC Standard Operating Procedure* (Document 2) support the UAEC operations by outlining procedures for:

- the management of conflict of interest. (Document 2 - SOP 15: *Conflicts of Interest*)

c 2.2.21

- maintaining confidentiality. (Document 110e)

c 2.2.22

- forming AEC executive delegations. (Document 2 - SOP 2: *Executive*) The UAEC Executive is an active delegation of the Committee within the institution. The AWEC plays an active role in supporting the UAEC Executive to undertake their responsibilities by assisting members and the Chair with the review, investigation, expert advice and follow-up regarding submissions. The UAEC has provided guidance to define what are considered minor and major variations to projects (Document 2 - SOP 6: *Variations to approved projects / activities*). During the review it was established that the authority delegated to the executive by the UAEC includes the activities outlined in section 2: responsibilities - Chapter 2.2 *Responsibilities of institutions regarding the governance of an animal ethics committee*: c 2.2.23 . It was identified during the review, the role of the UAEC executive has been expanded since the previous external review in 2017 with several new delegations to including:

- provide project extensions; generally up to two years where suitable justification is provided;
- review annual progress reports and approve continuation of projects that continue to align with the Code;

It is acknowledged that the UAEC is resourced and support by the institution, particularly in the support of the AWEC. In discussions with the Chair, AWEC and Director (OREI) it was established established that this includes a rigorous process for reviewing submissions and ensuring appropriate outcomes. However, the additional responsibilities delegated by the UAEC may be considered outside the scope of the executive and reside with the deliberations of a quorate AEC, specifically the provision of extensions to approved projects and the review of annual progress reports.

c 2.2.23

- the ERM processes for submission, receipt and processing of applications and reports by the OREI. (Document 50)

c 2.2.24

- managing quorum. (Document 2 - SOP 14: *Conduct of committee meetings*)

c 2.2.25

- documented meeting procedures include:
 - the timely distribution of papers to AEC members is stated as 7 working days before a meeting (Document 3 - 7: *Ordinary meetings* [7.4 - 7.6: *Notice of meetings and agenda*])

- the conduct of quorate meetings, including circumstances where a face-to-face meeting is not possible—for example, through the use of videoconferencing and web- conferencing or, in special circumstances, teleconferencing (Document 2 - SOP 14: *Conduct of committee meetings* [14.1 - 14.8: *Number and timing of meetings; Attendance at meetings; Quorum*])
- managing any conflicts of interest during the AEC meeting (Document 2 - SOP 14: *Conduct of committee meetings* [14.9: *Conduct of meetings*] & SOP 15: *Conflicts of Interest*)
- meeting frequency (Document 2 - 5: *Conduct of committee meetings*)
- review of new (Documents 2 & 110a) and ongoing proposals **Please refer to the Review Findings for c 2.2.23 for comments regarding the review of on-going proposals.**

c 2.2.26 (i - v)

The UAEC provides prompt notifications of its decisions. Decisions of the Committee are reported to applicants within a reasonable timeframe. “ *Decisions of the full Committee are reported typically within one week of the meeting.*” (Document 2 - SOP 16: *Notification of decisions made by the Committee* [16.1])

c 2.2.27

“*The Committee endeavours to openly communicate with applicants to resolve outstanding requests for further information, clarification or modification of projects. The Committee may nominate one (or more) of its members to communicate directly with the applicant or invite the applicant to attend a subsequent Committee meeting.*” (Document 2 - SOP 16: *Notification of decisions made by the Committee* [16.3])

c 2.2.28

Complaints and non-compliance relating to animal ethics are addressed in the *UAEC Standard Operating Procedure* (Document 2 - SOP 19: *Complaints reporting and handling* & SOP 21: *Managing alleged non-compliance*). **Please refer to the Review Findings for Section 5 for further detail.**

c 2.2.29

The OREI maintains records relating to the Committee as outlined in the UAEC Standard Operating Procedures (Document 2 - SOP 23: *Record keeping*).

Records maintained include:

- a register of all applications to the Committee, including the outcomes of deliberations
- minutes that record decisions and other aspects of the Committee's operation
- records of inspections conducted by the AEC

c 2.2.30

During the on-site inspection the records reviewed on-site included copies of the approved projects and activities. These were accessible to the appropriate facility staff including animal carers.

c 2.2.31

The institution has developed and provides the required documentation through ERM. Documentation has been developed for:

- applying for animal ethics review and approval of work involving the use of animals for teaching or research (Documents 70 & 71)
- requesting variation to an approved project, (Document 72)
- reporting the progress of, or completion of an approved activity or project (Documents 73 [a & b])
- reporting of an adverse incident or event (Document 74)

c 2.2.32

The institution in consultation with the UAEC allows the use of SOPs. There is a process for preparing and managing SOPs that includes a:

- UAEC approval process (Document 2 - SOP 5: *Types of applications* [5.27 - 5.35: *Standard Operating Procedures*])
- standard template for preparing SOPs (Document 105)
- webpage guide for investigators outlining the application process for SOPs
- summary of approved and archived SOPs (Document 104)

Examples of the SOPs were provided for review. SOPs for procedures used in the animal facilities (Documents 106 [a - c]) and SOPs in wildlife studies (Documents 108 - Bat-related SOPs) were reviewed. The format of the SOPs reviewed met with the requirements of the Code. In discussions with the AWEC, UAEC Chair and Director (OERI) it was established only approved SOPs were available for use by relevant people and expired SOPs were archived and not in circulation but retained for reference. SOPs are listed in projects and checked for current approval. An example of this was identified in a teaching project.

(Document 109 [11]: *01 h Steck_MERF animal handling_Appl_V02*) It was detected prior to UAEC approval that the application included expired SOPs, the investigator was provided with feedback (Document 109 [1]: *01 e UAEC_Feedback_Steck_20190806*) and appropriate action to correct the issue occurred.

c 2.2.33 - c 2.2.36

Conduct an annual review of the operation of the animal ethics committee

The UAEC provides a written report to the institution for review to ensure its processes are effective and consistent with the Code and institutional policy. The institution has met its responsibilities under the code by receiving annual reports (Documents 11 - 14) from the UAEC for review by the QUT Council through the Deputy Vice-Chancellor and Vice-President (Research), Audit and Risk Committee, University Research and Innovation Committee and University Academic Board. In discussions with the UAEC chair and OREI it was established that the UAEC chair has opportunity for a face-to-face meeting with senior representatives of the institution including the Deputy Vice Chancellor (Research) at least annually.

c 2.2.37

Table 1: Section 2 - Chapter 2.2 Review Findings identified as areas highlighted for review by the institution.

Code Reference	Review Finding
<p>c 2.2.23 Related to c 2.3.6</p>	<p>Establish procedures for animal ethics committee governance and operation</p> <p>QUT has established a suite of policies and procedures to govern UAEC operation, ensuring it is able to meet its responsibility for the ethical oversight of animal use on behalf of the institution in accordance with the Code. Documentation, including the Charter (TOR) (Document 1) and <i>UAEC Standard Operating Procedures</i> (Document 2) support the AEC operations by outlining procedures for forming AEC executive delegations. (Document 2 - SOP 2: <i>Executive</i>) The UAEC Executive is an active delegation of the Committee within the institution. The AWEC plays an active role in supporting the UAEC Executive to undertake their responsibilities by assisting members and the Chair with the review, investigation, expert advice and follow-up regarding submissions. During the review it was established that the authority delegated to the executive by the UAEC includes the activities outlined in section 2: responsibilities - Chapter 2.2 <i>Responsibilities of institutions regarding the governance of an animal ethics committee</i>: c 2.2.23 . It was identified during the review, the role of the UAEC executive has been expanded since the previous external review in 2017 with several new delegations including:</p> <ul style="list-style-type: none"> ▸ provide project extensions; generally up to two years where suitable justification is provided; ▸ review annual progress reports and approve continuation of projects that continue to align with the Code; <p>It is acknowledged that the UAEC is resourced and support by the institution, particularly in the support of the AWEC. In discussions with the Chair, AWEC and Director (OREI) it was established that this is includes a rigorous process for reviewing submissions and ensuring appropriate outcomes. However the additional responsibilities delegated by the UAEC may be considered outside the scope of the executive and reside with the deliberations of a quorate AEC, specifically the provision of extensions to approved projects and the review of annual progress reports.</p>

Please refer to PART E of the Review report for comments and recommendations relating to the review findings listed in Table 2.

END OF REVIEW FINDINGS RELATING TO SECTION 2 - CHAPTER 2.2

Chapter 2.3 - Responsibilities of animal ethics committees

During the review period evidence was found to demonstrate how the UAEC meets its responsibilities to provide the ethical review, approval and monitoring of animal use for scientific purpose on behalf of the institution.

c 2.3.1 - 2.3.2 [i - ix]

Review and approval of new and ongoing activities

The UAEC meets its responsibilities by reviewing and monitoring new projects and in relation to making a judgement as to whether the proposed use of animals is ethically acceptable. Judgements were seen to be based on information submitted by applicants in the accepted Animal Ethics formats and any additional information that has requested by the UAEC during their review. A consensus decision was based on whether the applicant had provided adequate information for the UAEC members to assess whether the proposed activities are justified and meet the requirements of ethical acceptability.

The UAEC meeting process (07 September, 2021) was observed, on-site, by the ERP. Eleven (11) UAEC members including the Chair and one (1) c 2.2.5 / c 2.2.6 member attended the meeting. In addition four (4) representatives from the OREI were present including the AWEC, the Committee's secretary, the research ethics officer and an ERM support officer. Nine (9) Committee members attended via video-link with apologies from two (2) members (A & B).

During the UAEC meeting the committee engaged in detailed discussions of the activities submitted:

- monitoring activities or reports, including:
 - executive activity for ratification (6 items)
 - the AWEC monitoring report
 - facility inspections (MERF, Pinjarra Hills Adjustment Facility)
- one (1) new application
- three (3) variations to approved protocols
- one (1) adverse event

c 2.3.3 - c 2.2.5

During the review it was established that the authority delegated to the executive by the UAEC included reviewing annual progress reports and approving the continuation of projects that continue to align with the Code.

These additional responsibilities delegated by the UAEC may be considered outside the scope of the executive and reside with the deliberations of a quorate AEC. Please refer to the Review Findings for c 2.2.23.

c 2.3.6

The UAEC members provided feedback about the submissions, including comments, questions and suggestions for the applicant based on the information provided.

The UAEC was found to:

- provide judgement in regard to projects and activities in line with the procedures outlined in the UAEC Standard Operating Procedures (Document 2 - SOP 16: *Notification of decisions made by the Committee*).
- review projects, and may make the following decisions:
 - Confirmed as Approved – with or without specific conditions of approval.
 - Confirmed as Approved - provide matters raised to applicant for noting only...
 - Confirmed as Approved - conditional on review of response to the following matters...
 - Resubmission of application required for clarity...
 - Not approved
(Document 2 - SOP 16: *Notification of decisions made by the Committee* [16.2 [i - v]]).
- The UAEC has the authority to suspend or withdraw approval for projects or activities (Document 2 - SOP 20: *Procedures for suspension or withdrawal of approval*).

c 2.3.7 - c 2.3.9

The UAEC has, and follows the procedure for managing conflict of interest (Document 2 - SOP15: Conflict of interest [15.8: Committee member conflicts of interest]). The procedure was followed in the meeting attended by the ERP (07 September, 2021) and examples were identified in the minutes of previous UAEC meetings (Documents 113 [a-d]).

c 2.3.12

Review of the animal ethics applications, including variations (Documents 108, 109, 114 [k-i]) demonstrated that the UAEC, as far as practical, adheres to its procedures to make prompt decisions.

c 2.3.13

Attendance at the UAEC meeting (07 September, 2021) confirmed that a quorum (A, B, C & D members present) was maintained and the C- and D- member balance of (total membership 11:4 C & D members present) was in line with the Code requirement of one-third of members present. One B-member left the meeting approximately 40 minutes before the meeting concluded which had no negative impact on quorum or the C-/ D-member balance. Review of the minutes of four (4) previous UAEC meetings (Documents 113 [a-d]) confirmed that the requirements for quorum and C-/ D-member balance are consistently maintained.

It was identified that pilot studies may be submitted by investigators for approval by the UAEC under the same review process used for a full application. Examples were identified in the review documents where pilot studies had been submitted to the UAEC and approved (Document 114i).

c 2.3.14

Reuse is specifically addressed in the application (Document 80), *"Please describe and justify the reuse or repeated use of an animal(s). Describe the total cumulative effects on the animal's lifetime, including:*

- (i) the pain and distress and any potential long-term effects*
- (ii) the time allowed for recovery between activities*
- (iii) whether the animal has fully recovered*
- (iv) the pain and distress likely to be caused by the next activities*
- (v) the total time the animal will be used (including the time of previous activity)*
- (vi) justify why any repetition is required. For re-use, the previous ethics number should also be included."*

Investigators must provide sufficient justification to satisfy the AEC in their applications.

c 2.3.15

Approvals are normally issued for a period of three years. An extension of approval for up to two years may be considered by the UAEC Executive. **Please refer to the Review Findings for c 2.2.23 for comments regarding the review of on-going proposals.**

c 2.3.16

Monitoring the care and use of animals

The UAEC monitors the care and use of animals through annual inspection reports of animal facilities and projects in accordance with the procedures. Evidence of inspections, including any actions or follow-up correspondence arising from the visits, and facility reports were found to be documented and recorded in the minutes provided for review. Examples of inspection reports of facilities and projects were provided for review (Documents 90, 91, 92, 94 - 102). In ten (10) of the thirteen (13) inspection reports (2018 - 2021) provided for review C- and/or D-members were present. Records of inspections follow a consistent format and records are maintained by the OREI. Observations recorded included the identification of any negative

issues or problems and highlighted positive outcomes including environmental enrichment and good hygiene practices.

c 2.3.17 - c 2.3.23

Taking action regarding unexpected adverse events

The institution has documented processes (Document 2 - SOP 18: *Adverse event reporting and handling*) for the UAEC and investigators to follow and a reporting form (Document 74) for reporting UAEs. The management of unexpected adverse events is detailed and outlines responsibilities of those involved, timeframes for reporting, a flowchart (Document 2 - Appendix 4 – *Unexpected Adverse Event Process*) to illustrate the decision making process. Review of the UAEC minutes demonstrated that the UAEC, with support from the AWEC and UAEC Executive, receives UAE reports, makes recommendations and follows-up actions. (Document 2 - SOP 18: *Adverse event reporting and handling* & Flow Chart: Appendix 4 – *Unexpected Adverse Event Process*)

c 2.3.24

Taking action regarding non-compliance

The institution and UAEC have procedures in place to manage non-compliance (Document 2 - SOP 19 & 21, Documents 7 & 8). The procedures were demonstrated through the investigation of a concern and an adverse event (Document 14 - Appendix 3: Project #15-0509) identifying a non-compliance with the studies protocol and ethics reporting requirements. The resulting actions, *“The potential reasons for the non-compliance were reviewed and additional measures have been implemented by the research team to minimise the potential for future non-compliance. The UAEC implemented additional reporting requirements to enhance oversight of future and current longer-term studies to mitigate the risk of future non-compliance. The UAEC complied with Code requirements (2.3.25), and the matter reported to the Director of the Office of Research Ethics and Integrity,...; and the Director of MERF,... The non-compliance did not meet the criteria necessary to be reportable to government authorities (5.12),”* demonstrated the processes undertaken by the institution.

c 2.3.25

Approving guidelines for the care and use of animals

The UAEC, considers and approves guidelines for the care and use of animals referred to it by the institution including policy and procedures for monitoring and maintaining the wellbeing of animals. The UAEC is presented with items from the institution, OREI and AWEC in regard to animal care and use procedures (see c 2.1.5 (v) through the agenda for discussion and endorsement / approval. (Documents 112a: item 4.2 & 112b: Items 4.2 & 4.5)

c 2.3.26

Providing advice and recommendations to the institution

The UAEC, under its charter (TOR) (Document 1) provides advice and makes recommendations to the institution through the annual reporting process and AEC chair's face-to-face meetings with the institutional representative, the Deputy Vice Chancellor and Vice-President (Research). It was established in discussions

with the OREI and UAEC chair that the UAEC is able to provide comment or make recommendation on a range of issues related to the care and use of animals, animal facilities associated with QUT and any matters that may affect how it fulfils its obligations under the Code.

c 2.3.27

Reporting to the institution

The annual report of the operations of the UAEC (Documents 11 - 14) is prepared by the OREI and the UAEC chair and endorsed by the UAEC membership. It is provided to the QUT Council through the Deputy Vice-Chancellor and Vice-President (Research), Audit and Risk Committee, University Research Committee and University Academic Board. The report includes information on the operations of the UAEC as recommended by the Code (c 2.3.29 [i - v]). The reports includes :

1. UAEC membership
2. Meetings
3. Key developments
4. Administrative or other difficulties experienced
5. Applications
6. Facilities and field sites
7. Training and Education
8. Compliance Monitoring
9. Reporting
10. Types of submissions
11. AEC Application types received
12. Adverse events, concerns and complaints

c 2.3.28 - c 2.3.29

Table 2: Section 2 - Chapter 2.3 Review Findings identified as areas highlighted for review by the institution.

Code Reference	Review Finding
c 2.3.6	<p>During the review it was established that the authority delegated to the executive by the UAEC included reviewing annual progress reports and approving the continuation of projects that continue to align with the Code.</p> <p>These additional responsibilities delegated by the UAEC may be considered outside the scope of the executive and reside with the deliberations of a quorate AEC. Please refer to the Review Findings for c 2.2.23.</p>

Please refer to PART E of the Review report for comments and recommendations relating to the review findings listed in Table 1.

END OF REVIEW FINDINGS RELATING TO SECTION 2 - CHAPTER 2.3

Chapter 2.4 - Responsibilities of investigators

QUT investigators have access to a system that enables them to fulfil their responsibilities under the Code. Access to education and training, procedures and forms by the institution provides structure and support so they understand their responsibilities and can meet their obligations under the Code in regard to using animals for scientific purposes.

During the review period (07th & 08th September, 2021) the ERP met with investigators from different research areas within the institution including the School of Biology & Environmental Science and the School of Mechanical, Medical and Process Engineering to discuss how they plan projects, work within the UAEC processes and use animals in the QUT animal facilities (Pinjarra Hills, MERF & SERF) or at locations outside the institution. Investigators demonstrated a comprehensive knowledge of the Code, animal ethics procedures and awareness of their responsibility for ensuring their use of animals was in line with the Code requirements and institutional expectations for the use of animals for scientific purposes.

c 2.4.1 - c 2.4.5

Planning Projects

To proceed with a project, investigators were found to complete an animal ethics application and provide attachments in relation to animal requirements, timelines, project administration and safety for ethical review and approval by the UAEC in accordance with the institutional procedures (Documents 108₁₇, 109₁₁, 114k & 114i). The application system is designed to ensure the investigator has considered and applied the governing principles and specific Code requirements to the animal use associated with their planned research. The investigator is required to provide information in the UAEC format outlining the use in sufficient detail to satisfy the UAEC that the proposed animal use falls within ethics guidelines. Animal ethics applications reviewed (Documents 108₁₇, 109₁₁, 114k & 114i) provided examples of responses to the questions (Documents 57, 58, 70 & 71) regarding animal use projects. Investigators were found to have provided information in their responses to questions in the application or as requested to provide additional information to the UAEC in relation to:

- Using animals only when justified. c 2.4.8 (i - iv)
- Applying high standards of scientific integrity. c 2.4.8 (v - viii)
- The 3Rs. c 2.4.8 (ix - x)
- Supporting the wellbeing of animals. c 2.4.8 (xi - xiv)
- Avoiding or minimise harm, including pain and distress. c 2.4.8 (xv - xvii)
- Accepting responsibilities. c 2.4.8 (xviii - xxi)

Investigators identify and provide detail if they are involved in collaborative studies.

c 2.4.9

Obtaining approval from the AEC

Before commencing a project or amending an approved project, investigators submit a completed animal ethics application (Document 70 & 71) or variation (Document 72) request using the ERMS application to the UAEC for approval. In addition, investigators must provide information to support their submission to the UAEC during the review process, if requested, before approval is granted and the work can commence. The investigator is not permitted to commence an animal use project or activity or implement an amendment until they have formal UAEC approval.

c 2.4.10 (i-ii)

Investigators will only have their projects assessed by the UAEC for approval if the submission follows the correct procedures and is in the accepted UAEC on-line format.

c 2.4.11

Investigators are required to use plain English when preparing applications. Investigators provide project summaries to give a basic overview of the work and supply sufficient information for all UAEC members to participate effectively in the assessment of the applications.

c 2.4.12

Conducting and reviewing projects

To undertake an approved project, the investigator agrees to, and undertakes to adhere to the conditions imposed by the UAEC. An example of an approval notification to investigators containing the conditions of approval was provided for review. (Document 82)

c 2.4.13

Investigators are required to act in accordance with the conditions of UAEC approval and the requirements of the Code and to respond promptly to the requests and instructions of the UAEC. This includes ceasing the conduct of a project or any part of a project if approval from the UAEC is suspended or withdrawn.

c 2.4.14

Investigators submit an application for ethical review approval by the AEC. The application prompts the investigator to consider Code requirements. The investigator provides information in this format outlining the animal use involved in sufficient detail to satisfy the AEC the use is ethically acceptable. Completed and approved applications reviewed (Documents 108¹⁷, 109¹¹, 114k & 114i) provided examples of responses demonstrating the investigator's consideration of Code requirements when answering the UAEC's questions

regarding the conduct of the project. Investigators provided information in their responses to questions in the application or requests from UAEC during the review process relating to the following:

- Apply high standards of scientific integrity.
- Support the wellbeing of animals.
- Avoid or minimise harm, including pain and distress.
- The 3Rs.
- Accept responsibilities.
- Provisions for animals at the conclusion of their use and disposal of carcasses and waste material.
- Projects involving hazards.

c 2.4.15 - c 2.4.29

Maintaining records

Investigators at QUT were found to maintain records that include the care and use of animals, monitoring (monitoring sheets) and assessment. Examples were reviewed and found that investigators keep records in accordance with the requirements of their research groups, animal facilities and those required by the UAEC in their projects. The ERP saw examples of animal care, use and monitoring records. Records kept by investigators were viewed at MERF and found to be adequate.

c 2.4.30 - c 2.4.33

Reporting

The document review provided examples of documents submitted by investigators including, progress and final reports, unexpected adverse event reports and other correspondence to requests from the UAEC. (Documents 108 & 109)

c 2.4.34

END OF COMMENTS RELATING TO CHAPTER 2.4

Chapter 2.5 - Responsibilities of animal carers

QUT animal carers (animal technicians) were found to be provided with a system that enabled them to meet the requirements of the Code. The provision of information, processes and procedures, access to education and training by the institution gives structure and support so they may meet their obligations under the Code.

At the time of the on-site review, the ERP visited QUT's Animal Facilities at the Prince Charles Hospital, MERF. The on-site visit allowed inspection of the infrastructure and discussion surrounding the processes involved in caring for animals used for research with the facility management and animal technicians.

During the review visit the ERP observed investigators, teachers and animal carers preparing pigs and sheep for surgical procedures associated with activities involved in UAEC-approved research and teaching. In both (animals unconscious without recovery) activities a high level of care was observed to ensure the animal's wellbeing was a priority before and during the procedures. Technical staff ensured animals were managed in accordance with their species and prepared appropriately for the required use. Lengthy discussion surrounding the conduct of both procedures (sheep and pigs) highlighted the training and expertise technicians required to undertake their roles. Technicians demonstrated that they had a sound knowledge of the projects and in particular, preparing and monitoring the animals in preparation for the procedures involved. Technicians were aware of, and prepared for, any potential for adverse events that may negatively impact the animal or the integrity of the work.

The QUT Animal Facilities are managed to maintain a high standard and are appropriate for the animals they accommodate. Modifications to equipment and custom-designed equipment for housing and handling animals to ensure the wellbeing of both operators and animals are considered was demonstrated in the facility. Staff at MERF have invested time and expertise into ensuring the wellbeing of animals, in particular, those undergoing restraint or confinement, are considered and equipment engineered to provide the best possible environment to promote wellbeing. All those encountered during the tour demonstrated a commitment to ensuring an optimal standard of animal wellbeing is consistently maintained. There was a high level of understanding of the animal ethics framework, the animals housed in the facilities, the procedures used and the Code.

Responsibilities

Those caring for animals at QUT were found to undertake the responsibilities outlined in Section 2: Chapter 2.5 in collaboration with animal facility manager, investigators, teachers, the AWEC, veterinary and technical staff, the UAEC and the institution.

Support animal wellbeing

Animal technicians were observed to support animal wellbeing by:

- providing for the species-specific needs of the animals they care for and provide care and enrichment suitable for their physiological and behavioural needs.
- using procedures and practices suitable for the animal species they care for.
- ensuring the health and biosecurity status of the animals is maintained and meets the requirements for the proposed use.

c 2.5.4 [i-iii]

Avoid or minimise harm, including pain and distress, to animals

Animal technicians were found to be responsible for the day to day care of animals in the animal facilities including husbandry and monitoring. Through discussion with Animal House management and staff it was found that prompt actions in cases of unexpected adverse events or emergency situations formed part of their duties and procedures including emergency contacts were identified. This was supported by discussions with managers and investigators that commended animal carers for the excellent commitment and skills they demonstrate in working with animals.

c 2.5.5 - c 2.5.6

Ensure provisions for animals at the conclusion of their use, and disposal of carcasses and waste material

The animal ethics application requires the information relating to the fate of animals including euthanasia and tissue sharing. The disposal of biological waste resulting from the use of animals was seen to be appropriately controlled with facilities for treatment, storage and disposal. Procedures were observed to include, the use of freezers, pathological waste bins and autoclaves.

c 2.5.7 - c 2.5.10

Maintain records

Animal technicians were seen to maintain comprehensive records that include the care and monitoring of animals and, for breeding facilities, the health status and breeding performance of animals (see Clauses c 3.1.22, c 3.2.2 and c 2.4.27 [v]). Animal technicians made these records available to the institution, the UAEC, authorised external reviewers and investigators.

Records of animal monitoring inspected were sufficient to enable the UAEC to verify that the wellbeing of animals has been monitored, and allow review and critical investigation of the cause(s) of and responses to unexpected adverse events as a basis for future prevention strategies. The ERP saw examples of animal care records that logged the monitoring, husbandry and other procedures performed in the facilities.

c 2.5.11 - c 2.5.13

People managing and supervising breeding and holding facilities

Animals held in the Animal Facilities are managed by competent QUT staff (competency records available). There are animal facility managers to manage the various animal facilities that provide habitat for wildlife and the routine care and maintenance of housed animals. Animal Facility Managers are supported by a group of animal technicians, experienced veterinarians, the AWEC and other highly-specialised and qualified staff. The animal facility manager is a central role within the research facilities that requires support and authority from the institution to fulfil their obligations to ensure the Animal Facilities can effectively provide animal-related services to ensure that the Code requirements and institutional expectations are met and animal wellbeing is consistently of a very high standard.

The animal facility managers meet their responsibility under the Code.

c 2.5.14 - c 2.5.17

END OF COMMENTS RELATING TO CHAPTER 2.5

Chapter 2.6 - Other responsibilities of institutions, investigators and animal ethics committees

QUT provides procedures for working with other organisations and staff (Document 2 - SOP 10: *Working with other organisations and transferring approvals*). Since the previous review (QUT14112016) these procedures have been reviewed and form a comprehensive guideline to manage the relationships and responsibilities involved in working with external institutions, AECs and individuals.

Institutions and individuals that use an external animal ethics committee

QUT has established procedures outlining the responsibilities of institutions and individuals that use an external AEC. These procedures establish that QUT may be involved as the '*Host Institution*' (where work is wholly or primarily undertaken) or if not the host, the '*Secondary Institution*'. Procedures define what relationships between QUT and any external institutions and investigators exist and where the responsibilities lie to ensure the use of animals is reviewed, approved and monitored (Document 2 - SOP 10.16 - 10.21). The guidelines provide for oversight by the OREI to ensure QUT and its investigators and teachers are able to meet their obligations under the Code and that the wellbeing of animals is supported and safeguarded.

c 2.6.1 - c 2.6.2

Projects involving more than one institution and/or AEC

In work where QUT investigators are involved in collaborations and QUT is the '*Host Institution*' QUT will assume the responsibilities in regard to approving and overseeing the project work (Document 2 - SOP 10: provisions 10.16 - 10.19). Where QUT is established as the '*Secondary Institution*' (Document 2 - SOP 10: provision 10.20), QUT investigators are required to provide an administrative review application (Document 2 - SOP 5: *Types of Applications*; provisions 5.11 - 5.17) to the OREI for review against a checklist (Document 2 - Appendix 1: UAEC Administrative Review Checklist).

c 2.6.3

For projects involving more than one institution and / or AEC, a procedure to outline the responsibilities of those involved, including a formal agreement is detailed in the UAEC Standard Operating Procedures (Document 2 - SOP10: provisions 10.22 - 10.28).

Examples of formal agreements with institutions external to QUT were found to provide assurance that the role of each party involved were able to meet their responsibilities under the Code. (Documents 25 - 31)

c 2.6.4 - c 2.6.7

Investigators are provided with guidance to ensure they understand their responsibilities in regard to collaborative work, *“Investigators must notify the AEC in writing if they are involved in collaborative studies, using animals at another institution, or if they are named in an application to the AEC of another institution “* (Document 47) and *“QUT investigators engaged in animal research projects involving external collaborators are required to notify the UAEC of their relationship with other institutions”* (Document 2 - SOP10: Working with other organisations and approvals).

c 2.6.8

Projects conducted by Australian investigators and institutions in other countries

Procedures were identified (Document 2 - SOP 11: *Projects conducted by QUT investigators in other countries*) and found to be available.

c 2.6.9 - c 2.6.14

END OF COMMENTS RELATING TO CHAPTER 2.6

SECTION 2.7 - Responsibilities of Institutions when developing an Animal Ethics Committees Application Form.

QUT has developed, in consultation with the OREI and UAEC, an on-line application system, Ethics Research Manager (Infonetica Ltd.), to manage animal ethics applications and reports that require UAEC approval. The system is made up of questionnaires to capture specific information required for the UAEC to assess a project for ethical acceptability. (Documents 70, 71, 76 & 77). The ERM system was introduced just prior to the review period and the transition from the previous system was observed. It was noted that this system was being well supported by the institution. The system allows for customised formats for different types of animal use including:

- Animal Research - [ERM relevant sections 1, 4, 5, 6, 8, 9,10,11,12 &13] (Document 70)
- Animal Teaching - [ERM relevant includes sections 1, 4, 5, 7, 8, 9,10,11,12 &13] (Document 71)
- Animal Outside Scope - [ERM relevant includes sections 1, 2,10,11,12 &13] (Document 76)
- Animal Tissue Use - [ERM relevant includes sections 1, 3,10,11,12 &13] (Document 77)

For ease of review the OREI provided separate ERM application formats (Document 70, 71, 76 & 77) and a full version of an ERM application (Document 80) inclusive of all component sections (1 - 13) and guidance where questions relate to specific types of applications so reviewers could identify and understand the process where specific sections relate to specific activities for example, Section 2.1: *Outside Scope* or Section 3.1: *Tissue Use* or Section 6: *Research Design* or Section 7: *Teaching Design*.

c 2.7.1 - c 2.7.2

Comprehensive guidance is provided (Documents 50, 70 & 71) for completing an application. Instructions to all applicants include:

- *It is important for you to remember the composition of the ethics committee when completing the form. **Applications must be written in lay language primarily for an interested, intelligent person without a scientific background, not for a specialist.** When assessing applications it is often difficult for the Committee to obtain a picture of what happens to individual animals from the beginning to the end of the project. The Committee must assess the impact on animals of all procedures and of the project as a whole, and also ensure the proposed harm to the animals is outweighed by the scientific benefit of the project. Your application should therefore **clearly describe what is happening to animals and what is being done to ensure their well-being.***

- *Briefly summarise the project in lay language (max 250 words). You should write this entirely in plain English for a non-scientific audience. The audience should be able to understand what the whole project is about from this one paragraph simple overview (1.1.2 Project Summary)*
- *Provide a clear justification for your project **using plain English** (4.1.3 What are the aims and significance of the project?)*
- *Using plain English, briefly explain what you propose to do with the animals and how the potential benefits of the project justify any possible effects on the wellbeing of the animals involved (4.1.4 HARM vs BENEFIT ANALYSIS).*

c 2.7.3

Table 3 - Review of the Animal Ethics ERM Application

Governing Principle 1.1 Reference	Code Reference	Review Finding (Documents 70 & 71 are the focus of this table only - for other formats please refer to Review findings comments for c 2.7.1 - c 2.7.2)
Using animals only when it is justified (1.1 - 1.7)	c 2.7.4 (i - v)	<p>The Code requirements for c 2.7.4 (vi - vii) are adequately addressed in the questions in the animal ethics applications (Documents 70 & 71) under the following section headings of the application forms:</p> <ul style="list-style-type: none"> • 04 Project Justification 2.4.7 (i, ii, iii, iv) • 08 Project Methodology 2.4.7 (v [a])* <p>*Included under the application:</p> <ul style="list-style-type: none"> ▸ Please provide justification for any unrelieved pain and distress. ▸ describe the specific intervention criteria and humane endpoints for animals in the study ▸ reuse or repeated use of an animal(s). <p>Direct references to the following were found in guidance (Document 50):</p> <ul style="list-style-type: none"> ▸ Death as an endpoint (2.4.7 v [a]) ▸ Prolonged restraint (2.4.7 v [a]) <p>The use of Non-human primates (2.4.7 v [b]) is not directly referenced in applications or guidance. No projects involving the use of primates was identified during the review period.</p>
Applying high standards of scientific integrity (1.15 & 1.17)	c 2.7.4 (vi - vii)	<p>The Code requirements for c 2.7.4 (vi - vii) are adequately addressed in the questions in the animal ethics applications (Documents 70 & 71) under the following section headings of the application forms:</p> <ul style="list-style-type: none"> • 04 Project Justification 2.4.7 (vi) • 05 Animal Use Summary 2.4.7 (vii [a]) • 09 Animal Welfare 2.4.7 (vii [b])

Governing Principle 1.1 Reference	Code Reference	Review Finding (Documents 70 & 71 are the focus of this table only - for other formats please refer to Review findings comments for c 2.7.1 - c 2.7.2)
Applying Replacement, Reduction and Refinement (the 3Rs) (1.18 - 1.30)	c 2.7.4 (viii - x)	<p>The Code requirements for c 2.7.4 (viii - x) are adequately addressed in the questions in the animal ethics applications (Documents 70 & 71) under the following section headings of the application forms:</p> <ul style="list-style-type: none"> • 04 Project Justification 2.4.7 (viii) • 06 Research Design 2.4.7 (viii & [ix]a) • 07 Teaching Design 2.4.7 (viii & [ix]b) • 08 Project Methodology 2.4.7 (viii) • 09 Animal Welfare 2.7.4 (x)
Supporting the wellbeing of animals (1.8 & 1.9)	c 2.7.4 (xi - xiii)	<p>The Code requirements for c 2.7.4 (xi - xiii) are adequately addressed in the questions in the animal ethics applications (Documents 70 & 71) under the following section headings of the application forms:</p> <ul style="list-style-type: none"> • 01 Administration Introduction 2.4.7 (xii) • 09 Animal Welfare 2.4.7 (xi, xiii)
Avoiding or minimising harm, including pain and distress, to animals (1.10 - 1.14)	c 2.7.4 (xiv - xv)	<p>The Code requirements for c 2.7.4 (xiv - xv) are adequately addressed in the questions in the animal ethics applications (Documents 70 & 71) under the following section headings of the application forms:</p> <ul style="list-style-type: none"> • Assessment of potential impact (c 2.7.4 [xiv]) <ul style="list-style-type: none"> ▸ 08 Project Methodology ▸ 09 Animal Welfare • Monitoring and Assessment (c 2.7.4 [xv]) <ul style="list-style-type: none"> ▸ 08 Project Methodology ▸ 09 Animal Welfare ▸ 12 Supplementary Information ▸ 10 Compliance

Governing Principle 1.1 Reference	Code Reference	Review Finding (Documents 70 & 71 are the focus of this table only - for other formats please refer to Review findings comments for c 2.7.1 - c 2.7.2)
Knowing and accepting responsibilities (1.31 - 1.32)	c 2.7.4 (xvi - xxiii)	<p>The Code requirements for c 2.7.4 (xvi - xxiii) are adequately addressed in the questions in the animal ethics applications (Documents 70 & 71) under the following section headings of the application forms:</p> <ul style="list-style-type: none"> • 01: Administrative Introduction 2.4.7(xvii) • 10: Compliance 2.4.7 (xx, xxi) • 11: Personnel 2.4.7 (xvi, xviii, xxii) • 13: Declarations 2.4.7 (xvi, xix, xxiii)

Information to be provided to an animal ethics committee for activities associated with the care and management of animals in facilities

Activities related to the care and management of animals are provided to the UAEC in projects and SOPs. Examples of activities associated with the care and management of animals was identified in the UAEC approved projects (Document 80 - section 09: Animal Welfare), UAEC approved projects (Document 107) and SOPs (Documents 104)

c 2.7.5

Information to be provided to an animal ethics committee for an amendment to an approved project or activity

In the case of amendments to approved activities and projects, a variation request (Documents 72) is available and includes relevant information for review and approval by the UAEC in the case of major variations and the UAEC-executive in the case of minor amendments. UAEC executive decisions in regard to minor variations are considered for ratification at the next quorate meeting of the UAEC.

c 2.7.6

END OF REVIEW FINDINGS RELATING TO SECTION 2 - CHAPTER 2.7

SECTION 3 - ANIMAL WELLBEING

SECTION 3.1 - Strategies to Support and Safeguard Animal Wellbeing

The planning and conduct of projects and activities by QUT staff were found to provide strategies to support and safeguard the wellbeing of animals used in approved research and teaching. The institution provides a framework to review and monitor animal use to ensure that projects and activities are ethically acceptable and those engaged in the care and use of animals are qualified and competent to undertake their responsibilities. Investigators and teachers detail information on how they will support animals during the conduct of research and teaching activities. Animal facilities co-ordinate the management and care of animals taking into account their species-specific requirements and monitor and manage animals in line with the approved projects and activities.

c 3.1.1

Identifying known and potential causes of adverse impacts on animal wellbeing

The animal ethics application, SOPs and management in the animal facility address, the acquisition, transport, housing and care, social and physical environment, handling, restraint, sample collection, non-surgical procedures, anaesthesia, surgical procedures, genetic modification, humane killing and provisions for the animal at the conclusion of their use.

c 3.1.2 - 3.1.4

Take steps to avoid or minimise adverse impacts on animal wellbeing

The Animal Facility supports and safeguards the animal's wellbeing by providing information regarding how the animals will be managed taking into account the species or strain of animals being used. Steps taken include identifying how the animals will be managed to ensure their species-specific or strain-specific physiological and behavioural needs are met, the procedures involved in the use, the animal's living conditions, how they are identified, monitoring and assessment.

c 3.1.5 - 3.1.13

Avoiding or minimising harm, including pain and distress

Examples of steps taken to avoid and minimise harm were identified during the review period.

This included UAEC approved applications for projects that specifically addressed:

- the justification for use of animal species
- the competency of those involved in the care and use
- avoiding or minimising known or potential causes of pain and distress
- monitoring procedures including how animals will be monitored, intervention points and humane endpoints
- the use of anaesthetics and analgesia

c 3.1.14 - 3.1.19

Monitor animals and take appropriate action

Examples of how animals are monitored and records of actions taken were seen in the assessment approved applications and reports during the inspection of on-site animal facilities during the review.

These included:

- procedures for monitoring and reporting
- how animals will be monitored, including methods, frequency, copies of monitoring score sheets and the details of treatment, withdrawal or intervention points.
- monitoring records, annual progress and unexpected adverse event reports
- SOPs including those for humane killing.
- evidence of necropsy and diagnostic testing

c 3.1.20 - 3.1.25

Set intervention points and experimental humane endpoints

Examples of steps taken to set intervention points and experimental humane endpoints were identified during the review period.

This included UAEC approved applications for projects that specifically addressed intervention points and humane killing and included timeframes for the collection of valid data.

c 3.1.26 - 3.1.28

Review the effectiveness of strategies to support and safeguard animal wellbeing and Implement changes to the strategy to ensure its ongoing effectiveness

Annual reports of the progress of projects are required for each project and adverse event reporting procedures are available to investigators and animal technicians.

c 3.1.29

Any modification to an approved project must be reviewed and approved through the processes of the UAEC including the UAEC executive process (if a minor modification) and not implemented until approval is given.

c 3.1.30

For those involved in the use of animals, including the Project Leader and other participants, their qualifications and responsibilities are detailed in the animal ethics application.

c 3.1.31

END OF REVIEW FINDINGS RELATING TO SECTION 3 - CHAPTER 3.1

SECTION 3.2 Animal Care and Management

The review included a tour of the Medical Engineering Research Facilities (GLP-Accredited) located within the Prince Charles Hospital Precinct in Chermside, Brisbane. The purpose-built animal facility includes:

- Outdoor animal handling and housing (sheep & pigs)
- Indoor custom-built handling and holding rooms (rodents, rabbits, sheep & pigs)
- surgical suites and recovery rooms
- laboratories (PC2)
- Offices and associated meeting areas.

At the time of the review. The ERP had an opportunity to observe and discuss the daily management of the facility with the facility's operations manager, veterinarian and animal facility manager (MERF).

At the time there were a small number of animals (rats & sheep) being housed on-site and it was noted that management of the animals and facilities had been maintained to a high level with a contingency plan enacted to provide for the maintenance of appropriate levels of animal wellbeing and minimal disruption due to any COVID-19 restrictions.

During the review visit the ERP observed investigators, teachers and animal carers preparing pigs and sheep for surgical procedures associated with activities involved in UAEC-approved projects. In both (animals unconscious without recovery) activities a high level of care and project management was observed to ensure the animal's well-being was a priority during the procedures and the outcome of the activities provided were valid and meet their required outcomes.

Documentation for managing and monitoring how animals are accommodated, used and cared for in the facility were provided for review and found to be comprehensive.

Discussions during the on-site visit related to animal health monitoring and breeding, transport of animals, admission of new animals to the facilities, acclimatisation, housing, husbandry and maintenance of indoor and outdoor facilities.

From the information provided for review, the ERP was satisfied the UAEC monitors the animal facilities and projects to ensure they support and safeguard animal wellbeing during their care and management.

Animal Facility discussions included:

- staff outlining their qualifications, training and experience working with animals in the facility.
- comprehensive knowledge of animal ethics and the UAEC procedures.
- outlining examples of the management of the animals including:
 - routine husbandry, health surveillance, handling and experimental procedures
 - preparing (selection, acclimatisation and monitoring) of animals for research projects
 - animal monitoring and the maintenance of various breeding lines, stock and experimental animals.
 - intervention points and humane killing
 - veterinary support and care
 - outlining procedures for emergencies, facility maintenance, animal health, hygiene and biosecurity. Appropriate emergency and biosecurity signage was identified for the site.
 - managing UAs and their immediate and corrective actions were outlined. The facility appeared to be maintained at an appropriate level to maintain a high standard of animal wellbeing.
 - detailing procedures and reviewing records for the facilities that provide specialised breeding services, housing, care, management, and the monitoring of animal health and environmental conditions.

c 3.2.1 - c 3.2.12

Specific observations of physical facilities recorded by the ERP at the time of the review included:

Housing and care

In the animal house animals (rodents, sheep and pigs) are provided with accommodation, physical and appropriate social environmental conditions, food, water and husbandry practices to meet species-specific or strain-specific physical and behavioural needs. It was found that if the requirements of a project or activity preclude or modify these conditions, special ethical consideration and specific AEC approval is required (see Clauses 1.9 and 3.1.5).

c 3.2.13

The animal house is staffed, designed, constructed, equipped, maintained and managed to achieve a high standard of animal care and is suitable for the type of animals kept and the aims of the activities undertaken.

c 3.2.14

Animal facilities

The animal facilities visited are designed and operated to:

- control environmental factors such as air quality, temperature, humidity, light and noise within limits compatible with the health and wellbeing of the species held. Capacity for control of the microclimate by the caging systems are taken into account.
- enable appropriate segregation of species or activities that might affect other animals held in the same facility.
- maintain quarantine and biosecurity requirements.
- exclude vermin.
- limit contamination associated with the keeping of animals, and the delivery of food, water and bedding.
- prevent the entry of unauthorised people and other animals.

c 3.2.17

The Animal Facilities were clean, tidy and in good repair. Walls and floors are constructed of safe, durable materials that can be cleaned and disinfected. There is adequate storage areas for food and equipment, a reticulated water supply and proper facilities for drainage.

c 3.2.18

Ammonia levels are monitored.

c 3.2.19

Chemicals including detergents and disinfectants were seen to be appropriate for the purpose.

c 3.2.20

Pens, cages and containers

Vehicles, trailers, cages and containers (used for transporting animals) seen in the Animal Facility were constructed of safe, durable materials, clean, maintained in good repair, secure and escape-proof, were protective against climatic extremes, designed to minimise injury to animals, large enough for the species and the number of animals held and compatible with the behavioural needs of the species. It was noted, in particular, vehicles and trailers for transporting larger animals (sheep & pigs) between the Pinjarra Hills farm site and MERF were modified to ensure animals were provided with very comfortable and secure transport.

c 3.2.21 - 3.3.23

Food and water

Animals observed, at MERF, had access to appropriate, uncontaminated, nutritionally adequate food of a quantity and composition. Clean, fresh drinking water was seen to be available and was suitable for the species. Review of UAEC animal facility inspection reports for QUT animal facilities provided information, in regard to provisions for animals in the Animal Facilities, that demonstrated the supply of food and water is in line with the Code requirements.

c 3.2.24 - 3.3.25

From the information provided for review the ERP was satisfied the QUT animal facility staff are adequate qualified, competent and manage the animals and facilities to ensure animal wellbeing is of a high standard during their care and management.

END OF REVIEW FINDINGS RELATING TO SECTION 3 - CHAPTER 3.2

SECTION 3: Chapter 3.3 - Specific procedures Chapter 3.3

General requirements that apply to all procedures

Procedures used for the care and management of animals and procedures used during the conduct of approved projects were found to :

- be appropriate for the species (rodents, rabbits, pigs sheep & wildlife spp.) and the circumstances of their use at the institution
c 3.3.1(i)
- accord with what is current best practice including citing recent references from accepted sources
c 3.3.1(ii)
- be compatible with the purpose and aims of the project or activity
c 3.3.1(iii)
- cause the least harm, including pain and distress, to the animals
c 3.3.1(iv)
- be performed competently, and by a person who is competent for the procedures, or under the direct supervision of a person who is competent to perform the procedures. QUT was found to have a program of training and competency assessment that assures animal carers and investigators are proficient in the procedures involved in their activities and projects. Supervision and technical assistance was seen to be available in the animal facilities.
c 3.3.1(v)

Handling and restraining animals

Handling and restraint of large animals, laboratory animals and wildlife were found to be considered and addressed in the planning of activities and projects and identified in the animal ethics applications submitted to the UAEC for approval.

Animal technicians and investigators undergo induction, training and competency assessment to ensure methods used in handling and restraint are appropriate and are competently performed.

Justification for prolonged handling and restraint of animals, if used, is included in the animal ethics applications submitted to the AEC for approval.

c 3.3.2 - c 3.3.4

Routine husbandry procedures

Routine husbandry procedures used on the animals were found to be approved and are undertaken in the animal facilities by qualified and competency-assessed animal carers or investigators in accordance with animal facility procedures. SOPs (Document 104 - various) for the husbandry were identified and included:

- Sheep Husbandry at the MERF Main Facility, Prince Charles Hospital
- Sheep Husbandry at the QUT MERF Agistment Facility
- Pig husbandry
- Pig Husbandry at Agistment Facility
- Rodent- husbandry and PC2 cage management.
- Day to day care and monitoring of fish and crustaceans
- Cane Toad husbandry

Any specific or additional husbandry or variation to a normal practice included in the application requires UAEC approval. The investigator or teacher details information regarding the qualifications and experience of those involved in the project.

c 3.3.5

Identification of animals

The methods of identification observed during the onsite visit were found to be:

- species appropriate
- compatible with the project's aims and purpose
- involve non-invasive methods whenever possible. The use of invasive methods must conform with Clause 3.3.1
- cause the least harm, including pain and distress, to the animals.
- Procedures and SOPs were found to be available for identification of laboratory and field animals. (e.g. Document 104 - SOP 1500001204: Sheep - Ear Tagging)

c 3.3.6 (i - iv)

Injections, blood sampling and non-surgical procedures

The methods used for injections, blood sampling and non-surgical procedures are outlined in the animal ethics application (or referenced to an approved SOP) and investigators and teachers are required to provide the details of any procedures used in the activity or project with sufficient detail for the UAEC to make an assessment on its ethical acceptability.

c 3.3.7

The methods or procedures in projects using animals are outlined in the animal ethics application (or referenced to an approved SOP) and investigators and teachers are required to outline the details of any procedures used in the activity or project with sufficient detail for the UAEC to make an assessment on its ethical acceptability. A demonstration during the on-site review of two (2) approved terminal surgery projects involving:

- anaesthesia, analgesia and sedation, and management of pain and distress

c 3.3.8 - 3.3.15

- surgical procedures

c 3.3.16

In both projects the animals undergoing the surgical procedures were administered sedation, anaesthesia, analgesia and continually monitored for signs of pain and distress in accordance with the procedures outlined in the UAEC approved applications (Documents 117 & 118).

c 3.3.8 - 3.3.15

Postprocedure care

The methods used for post-procedure care are outlined in the animal ethics application (or referenced to an approved SOP) and investigators and teachers are required to outline the details of any management used in the activity or project with sufficient detail for the AEC to make an assessment on its ethical acceptability.

c 3.3.17

Creation and breeding of new animal lines where the impact on animal wellbeing is unknown or uncertain

Breeding of new lines with uncertain or unknown impacts on animal wellbeing is considered and undergoes administrative approval (if approved by an external AEC and at an institution external to QUT). In discussions with the Animal Facility Manager the activity and its outcomes are monitored, recorded and assessed. No breeding activities were seen during the on-site review.

c 3.3.24 (i - iv)

In line with Code requirements for ethical assessment and approval the following activities are subject to the UAEC approval processes.

- Projects involving the fetus and embryo. c 3.3.21 - 3.3.22
- Induction of tumours. c 3.3.23
- Modification of behaviour and neurological function. c 3.3.25 - 3.3.30
- Immunomodulation and production of antibodies. c 3.3.31 - 3.3.32

Wildlife and Field Techniques

No field sites were visited by the ERP during the review period.

Discussions with an investigator / teacher from the School of Biology & Environmental Science included an outline of their teaching and field activities involved in environmental science, ecological research and conservation biology. During the discussion the investigator discussed procedures involved in their activities with frogs, bats and birds. It was established that in the initial submission of the application included details of permits, participant qualifications and competency (including specialist veterinary assistance and volunteers), to undertake the procedures for trapping, capture, handling, monitoring and humane killing (if required).

Procedures involved in wildlife studies were found to be considered and addressed in the planning of activities and projects and identified in approved animal ethics applications (Document 108₁₇ - 01 k ETH_AnimalRESEARCHAPP_VGorecki_20170808_changes visible & Document 114i [pilot study - please note the approved application was included in an application for variation of an approved protocol]).

Information in line with the Code requirements is required to be included in the application for projects and activities involving wildlife were found to include:

- general considerations in regard to methods, techniques, procedures used in the work and how pain and distress will be avoided or minimised
- how animals will be captured and handled
- what equipment, how it will be used to trap or contain animals and how trapped animals will be managed
- how will animals be transported, held and released
- details of any devices to track the movement of wildlife

- details of any activities that disturb or interfere with animals or their habitat.

- the collection of voucher specimens

- Studies involving vertebrate pest animals

c 3.3.33 - c 3.3.44

- Humane killing

c 3.3.45 - c 3.3.46

END OF COMMENTS RELATING TO CHAPTER 3.3

Chapter 3.4 - Provisions for animals at the conclusion of their use

It was identified that the institution, through the competency training, assessment and supervision of those involved in the care and use of animals for scientific use, ensure investigators and technicians understand their responsibilities in relation to chapter 3.4. The review found sections of the ERM application(s) for animal use require the investigator to address the fate of animals at the conclusion of use, including details of any methods of humane killing or release, for approval by the UAEC.

There is no documented process for re-housing outlining the Code requirements however a facility is available on the application form(s) to outline any adoption or rehoming options that may be available at the conclusion of the animal's use. There is a requirement to, *"Please provide additional details of what will happen to the animals at the completion of the project (i.e. that are not humanely killed)."*

(Document 80).

c 3.4.1(i) & c 3.4.2 - c 3.4.3

There is a facility available on the application form(s) to outline a return to normal husbandry conditions or natural habitat at the conclusion of the animal's use. There is a requirement to, *"Please provide additional details of what will happen to the animals at the completion of the project (i.e. that are not humanely killed)."*

(Document 80).

c 3.4.1(ii) & c 3.4.4 - c 3.4.5

Humane Killing is addressed in the application (Document 70 & 71), *"Method of Euthanasia/Humane killing: How will this be done? Where will this be carried out? Who will do it and what is their experience in the techniques to be used?."* Examples of humane killing were found to be included in applications for approval and in UAEC- approved SOPs (Documents 108 & 104)

c 3.4.1(iii)

Reuse is specifically addressed in the application (Document 70 & 71), *"Have, or will, any of the animals be re-used in other experiments? If so, please specify the AEC protocol number (if known) and justify their use in this project by discussing the benefits balanced against the adverse effects on these animals."*

c 3.4.1(iv)

The institution was found to encourage tissue sharing and address this in the application (Document 70 & 71). The institution also monitors the use of animal tissues through an animal ethics application format (Document 77)

c 3.4.1(v)

END OF REVIEW FINDINGS RELATING TO CHAPTER 3.4

END OF REVIEW FINDINGS RELATING TO SECTION 3

SECTION 4: THE CARE AND USE OF ANIMALS FOR THE ACHIEVEMENT OF EDUCATIONAL OUTCOMES IN SCIENCE

Responsibilities

Institutions

The review found the institution fulfils its responsibility by providing for a framework to govern the care and use of animals for scientific purposes in accordance with the requirements of the Code.

It was found to meet these responsibilities by:

- providing governance through the animal ethics framework for teaching activities undertaken at its institution as outlined in Chapter 2.1.

c 4.1

- providing governance of the UAEC to oversee the care and use of animals in teaching activities are as outlined in Chapter 2.2.

c 4.2

Information outlining why animals used in a teaching activity is essential to achieve an educational outcome in science, as specified in the relevant curriculum or competency requirements, and suitable alternatives to replace the use of animals to achieve the educational outcome are not available, is addressed in the (Document 71 - Section 4: *Project justification*), submitted for review to the UAEC.

c 4.3

The person with ultimate responsibility is identified in the Animal Ethics Application (Documents 71 - Section 13: *Declarations*), submitted for review and approval by the UAEC. The information submitted includes:

- (i) a declaration that all people involved understand and accept their role and responsibilities
- (ii) a declaration that procedures and resources are in place so that all people involved can meet their responsibilities
- (iii) qualifications and experience that demonstrates the level of competency in respect to the care and use of the animals involved in the activity.

c 4.4 (i - iii)

Primary and secondary sectors (including secondary agricultural colleges)

Code clauses 4.5 - 4.7 are not relevant to the business of the institution.

Animal Ethics Committees

Please refer to the review findings for Section 2 - Chapter 2.3 for details of how the UAEC undertakes to meet its responsibilities.

c 4.8

Teachers as investigators and animal carers

Teachers at QUT were found to have the same responsibilities under the animal ethics framework and be subject to the same processes for undertaking animal use projects for achieving educational outcomes as Investigators and Animal Carers.

c 4.9 - c 4.11

Teachers detail how they intend to educate students about animal ethics in the animal ethics application (Document 71). Question 7.1.9 asks, *“Describe the prior instructions students/participants will be given on the ethical and legal expectations which apply to using animals for scientific purposes.”*

An example of how teachers respond to this requirement was identified, *“Prior to practical training, trainee students/staff are required to complete QUT AEC online training on legislation, codes, guidelines and QUT policies and procedures relating to the care and use of animals for scientific purposes. The trainee students/staff are also required to gain basic knowledge and understanding of the rodent techniques defined in the relevant educational material/resources provided by OREI and MERF,”* (Document 01 h Steck_MERF animal handling_Appl_V02).

c 4.12

Employment processes to ensure those engaged to teach (including the care and use animals) on behalf of QUT have the necessary qualifications and experience to undertake their duties. Qualifications and competencies, specific to animal care and use, required to participate in the teaching activities using animals are outlined in the UAEC SOP (Documents 2 - SOP 4: *Training and competency assessment*). Electronic records of competency are maintained in the Blackboard. The AWEC monitors compliance in regard to training and competencies. All those using animals in teaching must undertake animal ethics on-line training prior to commencing animal-related teaching activities. The UAEC is provided with access to the competency records including those submitted as part of the animal ethics application.

c 4.13

Details for rehoming animals is included in the animal ethics application (Document 71 - Section 9: Question 9.1.10 *“What will happen to animals at the completion of the project?”*), if the rehoming box is checked the applicant must provide details of the rehoming action for UAEC review. (Document 71 - Section 9: Question 9.1.10.3 *Please provide additional details of what will happen to the animals at the completion of the project (i.e. that are not humanely killed)*).

Please refer to the review findings for Section 3 - c 3.4.1 (i) & c 3.4.2 - c 3.4.3 for related information.

c 4.14 (i- iii)

Obtaining approval from an animal ethics committee

Teaching projects were found to be submitted to, and approved by the UAEC. Examples of teaching projects included:

- QUT/MERF small animal handling and procedures training (Documents 109 - 01 h Steck_MERF animal handling_Appl_V02)
- Management of vascular complications in spinal surgery: an education program (Document 114k)

Teachers apply to the UAEC using the Animal Ethics Application (Documents 71) for animal use activities. In the application sufficient information must be provided by the teacher for the UAEC to be satisfied that the work meets the Code and any institutional requirements for approval.

c 4.15

Information regarding different locations, times, animals or students and the repeat of an approved teaching activity are required to be provided to the AEC using the on-line Animal Ethics Application (Documents 71 - Section 1: Administrative Introduction - Questions 1.1.3 & 1.1.3.1-4 and Section 7: Teaching Design).

c 4.16

AEC approval is not required for the training and application of agricultural extension work practices, or the training of students in veterinary science, veterinary nursing or animal technology to achieve competency-based outcomes in routine procedures if all of the following apply:

- (i) the animals are at their home property or a premises licensed by a state or territory Veterinary Surgeons Board
- (ii) the procedures would normally occur as part of routine management or veterinary clinical management of the animal
- (iii) the animals are not subjected to anything additional to routine management or veterinary clinical management of the animal
- (iv) the Teacher is competent to carry out the procedure.

No comment

c 4.17 (i - iv)

END OF COMMENTS RELATING TO SECTION 4

SECTION 5 - COMPLAINTS AND NON - COMPLIANCE

The institution has developed policy and procedures for addressing complaints and non-compliance relating to the care and use of animals for scientific purposes.

Responsibilities

QUT has met its responsibility of ensuring procedures are available for addressing complaints and non-compliance relating to the care and use of animals for scientific purposes. Evidence of this requirement being met was found in the institution-wide (Document 7 & 8) and animal ethics-specific guidance publicly available on the QUT's webpages (Document 41).

Policy, procedures and contacts to advice in regard to complaints and non-compliance, are available on the QUT Governance and Policy Webpage:<https://www.qut.edu.au/about/governance-and-policy/report-a-concern> and the Animal Ethics Applications and Projects webpage: Concerns, complaints and adverse events (Document 41). Specific guidance on how the institution manages complaints and non-compliance related to animal ethics is provided in the UAEC SOP (Document 2 - SOP 19: *Complaints reporting and handling* & SOP 21: *Managing alleged non-compliance*).

c 5.1

The animal ethics complaints and non-compliance processes (Document 41) outlines procedures to address complaints and non-compliance in regard to:

- giving priority consideration to the wellbeing of the animals underpins the procedures involved in managing complaints and non-compliance and ensure that activities with the potential to adversely affect animal wellbeing cease immediately (Document 2 - 19: *Complaints reporting and handling* [19.12])

c 5.2 (i)

- clearly defining the mechanisms for receiving, investigating and addressing complaints. Procedures outline the process for reporting and handling complaints about the care and use of animals for scientific purposes and the Committee review process. (Document 2 - 19: *Complaints reporting and handling*)

c 5.2 (ii)

- clearly defining the mechanisms for addressing non-compliance with the Code. Procedures outline the process for investigating and managing alleged non-compliance.(Document 2 - SOP 21: *Managing alleged non-compliance*)

c 5.2 (iii)

- clearly defining the responsibilities of all parties and expectations (Document 2 - SOP 19 & 21, Documents 7 & 8)

c 5.2 (iv)

- ensuring fair, prompt, timely, effective, confidential processes that accord with procedural fairness, the principles of natural justice and protection of whistleblowers (Documents 2 - SOP 19 & 21, Documents 7 & 8)

c 5.2 (v)

- Identifying and ensuring appropriate reporting to the institution, AEC, state or territory government authorities, and any other relevant bodies. (Documents 2 - SOP 19 & 21, Documents 7 & 8)

c 5.2 (vii)

- It was found that the institution has made these procedures available through the QUT Policy and procedures: <https://www.mopp.qut.edu.au> and through the QUT intranet.

c 5.2 (vii)

Procedures for the reporting of complaints and non-compliance for projects involving more than one institution / AEC were identified. (Document 2 - SOP 10: *Working with other organisations and transferring approvals*

& SOP 19: *Complaints reporting and handling* [19.26 - 19.28 - *Complaints concerning projects that involve more than one institution and/or AEC*] & SOP 21: *Managing alleged non-compliance*) It was found to refer to the terms outlined in formal agreements between institutions (Documents 25 - 31) where a formal agreement exists outlining the responsibilities of all involved in the agreement in the case of instances of non-compliance.

c 5.3

Receiving, investigating and addressing complaints

Complaints concerning the care and use of animals

Institutional procedures for addressing complaints concerning the care and use of animals are in line with the Code (c 5.4 - c 5.5) and with the *Australian code for the responsible conduct of research*. (Document 2 - SOP 19: *Complaints reporting and handling* [19.10 - 19.14: *Complaints concerning the care and use of animals* & 19.15 - 19.16: *UAEC process for investigating complaints related to UAEC approval*].

c 5.4 - c 5.5

Complaints concerning the animal ethics committee process

Institutional procedures for addressing complaints concerning the UAEC process are in line with the Code (c 5.6. (Document 2 - SOP 19: *Complaints reporting and handling* [19.17 - 19.25: *Complaints concerning the animal ethics committee process*])

No complaints during the 2017 - 2020 period were identified in the review.

c 5.6

Complaints concerning the process for independent external review

Institutional procedures for addressing complaints concerning the process for independent external review (c 6.5) were identified, *"If QUT or the UAEC have any concerns or complaints with the conduct of the external review or the outcomes of the final report these issues shall be raised with the reviewer to resolve the matter in accordance with the procedures outlined in the service agreement."* (Document 2 - SOP 19: *Complaints reporting and handling* [19.29: *Complaints concerning the process for independent external review*]). The institution and the independent external review service provider enter into a formal agreement that provides an avenue for addressing complaints. (Document 121).

c 5.7

Referral to a person or agency external to the institution

Complaints and non-compliance procedures do not identify a person or agency external to QUT but provide a facility for a complainant to seek external advice, *"If the complainant considers their complaint has not been resolved satisfactorily after consideration by the Deputy Vice-Chancellor and Vice President (Research) the person may wish to raise the complaint with an external party. The Deputy Vice-Chancellor and Vice President (Research) may assist with identifying a suitable external individual or agency to review the complaint upon request."* (Document 2 - SOP19: *Complaints reporting and handling* [19.9])

c 5.8

Addressing non-compliance

The institution was found to address non-compliance with the Code, so that behaviours that create and support compliance are encouraged, and behaviours that compromise compliance are not tolerated, through preventative education, actively promoting the governing principles, providing an ethical framework that encourages compliance and ensuring procedures are in place to manage instances of non-compliance (Document 2 - SOP 21: *Managing alleged non-compliance* & Document 8). The procedures were demonstrated through the investigation of a concern and an adverse event (Document 14 - Appendix 3: Project #15-0509) identifying a non-compliance with the studies protocol and ethics reporting requirements.

The resulting actions, *"The potential reasons for the non-compliance were reviewed and additional measures have been implemented by the research team to minimise the potential for future non-compliance."*

The UAEC implemented additional reporting requirements to enhance oversight of future and current longer-term studies to mitigate the risk of future non-compliance. The UAEC complied with Code requirements (2.3.25), and the matter reported to the Director of the Office of Research Ethics and Integrity,...; and the

Director of MERF,.... The non-compliance did not meet the criteria necessary to be reportable to government authorities (5.12),” demonstrated the processes undertaken by the institution.

c 5.9

The institution through the OREI maintains records associated with UAEC business including those relating to the investigation of complaints and non-compliance. These records include a register of all identified non-compliance and are recorded in UAEC meeting agendas and minutes under the heading, *Concerns, complaints and adverse events* and are provided to the institution in annual reports (Documents 11, 12, 13, 14) as an appendix tabling adverse events, concerns and complaints reported for the calendar year.

c 5.10

Advising regulatory authorities

No comment

c 5.11 - c 5.12

END OF REVIEW FINDINGS RELATING TO SECTION 5

SECTION 6 - INDEPENDENT EXTERNAL REVIEW OF THE OPERATION OF INSTITUTIONS

The institution has a review schedule to assess its level of compliance with the Code, and to ensure the continued suitability, adequacy and effectiveness of its procedures to meet its responsibilities under the Code by engaging an external review provider, Scientific Auditing Services Pty Ltd. to undertake an independent external review - QUT06082020.

c 6.1

Responsibilities

The institution was found to meet its responsibilities to organise an independent external review by:

- by contracting Scientific Auditing Services P/L for the review to be conducted by external people who are independent of the institution and the activities conducted on behalf of the institution, and who have appropriate qualifications and/or experience relevant to the activities of the institution.

c 6.2 (i)

- establishing, and accepting the procedures of Scientific Auditing Services P/L, that require members of the review panel to declare their interests, and ensure conflicts of interest are managed appropriately.

c 6.2 (ii)

- ensuring, through the processes of Scientific Auditing Services P/L, that members of the review panel are advised of requirements for confidentiality.

c 6.2 (iii)

- providing the review panel with the necessary authority and resources to conduct the independent review of the activities of the institution. This has included providing Scientific Auditing Services P/L with access to people, information, records and premises, and provision of reasonable assistance.

c 6.2 (iv)

- Please note that c 6.2 (v & vi) are to be considered and acted upon by the institution after the report has been accepted by the institution.

c 6.2 (iv)

- Please note that (c 6.2 [v & vi]) are to be considered and acted upon by the institution after the report has been accepted by the institution.

QUT provided the report from the most recent external review, QUT14112016, in 2017 undertaken by the Scientific Auditing Services. The institution, in the 4 year period between independent external reviews has considered and adopted recommendations provided in the Report QUT14112016.

c 6.3

Review Panel

The independent ERP has met its responsibilities in undertaking a review of the QUT animal ethics framework and:

- providing written declaration detailing from each ERP member any actual or potential conflicts of interest to Scientific Auditing Services P/L.

c 6.4 (i)

- signing an agreement with Scientific Auditing Services P/L (Document 121) that included a confidentiality clause specific to review QUT06082020.

c 6.4 (ii)

- developing a process and schedule with the OREI for the manner in which review QUT06082020 is conducted including a desktop review of documents, attendance at an AEC meeting (07 September, 2021), an on-site visit to the MERF Animal Facilities at the Chermside Campus, and meetings with QUT managers and administrators, the UAEC chair, investigators and animal facility staff.

c 6.5 (i)

- documenting the findings and providing recommendations from the review in a report presented to the institution in November, 2021.

c 6.5 (ii)

Scope and outcomes of the independent external review

The external review report QUT06082020 in its entirety includes information regarding:

- the conduct of all people involved in the care and use of animals for scientific purposes on behalf of the institution, including the AEC, institutional officers and administrators, investigators and animal carers

c 6.6 (i)

- the adequacy of the institutional program to ensure that the care and use of animals for scientific purposes is conducted in conformance with the Code; is subject to ethical review, approval and monitoring by an AEC; and is conducted in accordance with the AEC approval

c 6.6 (ii)

- the adequacy of institutional support, resources and educational programs for the AEC and its members, and for people involved in any aspect of the care and use of animals for scientific purposes, to ensure that they can meet their responsibilities under the Code
c 6.6 (iii)
- whether the AEC is operating effectively in accordance with the Code
c 6.6 (iv)
- the effectiveness of institutional strategies to promote and monitor the implementation of the governing principles
c 6.6 (v)
- whether there is effective monitoring of the wellbeing of animals
c 6.6 (vi)
- whether facilities used to house animals are managed to support and safeguard animal wellbeing
c 6.6 (vii)
- if applicable, an assessment of the report from the previous external review and actions taken in response to recommendations in that report.
c 6.6 (viii)

The external review in its entirety has provided recommendations that:

- identify areas of concern that may be found to be non-compliant in a regulatory compliance review. The findings related to this provision is detailed in Section E of report QUT06082020.
c 6.7 (i)
- support strategies for short-term and long-term continual improvement. The findings related to this provision is detailed in Section E of report QUT06082020.
c 6.7 (ii)
- give recognition to behaviours and actions by individuals and teams that support conformance with the Code. The findings related to this provision is detailed in Section C of report QUT06082020.
c 6.7 (iii)

END OF REVIEW FINDINGS RELATING TO SECTION 6

TABLE 4: Summary of Review Findings, Recommendations and Comments Arising from the Review Findings in Part D

	<p>The clauses listed in this table have been identified during the review period as requiring review by the institution to ensure QUT's procedures are effective and adequate to meet its responsibilities under the Australian code for the care and use of animals for scientific purposes - 8th Edition.</p> <p>The following Code provisions (clauses) have been identified for further consideration by the institution:</p> <ul style="list-style-type: none"> • c 2.2.23 (Related to c 2.3.6) <p>Recommendations and comments made by the External Review Panel in relation to the listed clauses have been made to assist the institution in its efforts to continually improve its animal ethics framework and maintain its high level of compliance with the Australian code for the care and use of animals for scientific purposes - 8th Edition.</p> <p>For Reference CR : Code Reference RF : Review Finding from Part D R : Recommendation C : Comment</p>	

<p>CR1</p>	<p>Code reference for review finding relating to Clause 2.2.23</p>	<p>Animal Ethics Committee Executive</p> <p><i>If established, an AEC Executive:</i></p> <ul style="list-style-type: none"> <i>must include the chairperson and at least one member from Category C or D (see Clause 2.2.4)</i> <i>may be delegated to approve minor amendments to approved projects or activities, for ratification at the next AEC meeting. The AEC should provide guidance on the type of activity that would be a minor amendment. A minor amendment may include a change to an approved project or activity where the proposed change is not likely to cause harm to the animals, including pain and distress</i> <i>must not approve new applications.</i> <p style="text-align: right;">c 2.2.23</p> <p>Review and approve new and ongoing activities</p> <p><i>The AEC must consider and approve applications for new projects and activities, and the ongoing approval for existing projects and activities, only at quorate meetings of the AEC (see Clauses 2.2.25 and 2.3.12)</i></p> <p style="text-align: right;">c 2.3.6</p>
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<p>RF1</p>	<p>Review Finding in relation to Clause 2.2.23 (Related to c 2.3.6)</p>	<p>QUT has established a suite of policies and procedures to govern UAEC operation, ensuring it is able to meet its responsibility for the ethical oversight of animal use on behalf of the institution in accordance with the Code. Documentation, including the Charter (TOR) (Document 1) and <i>UAEC Standard Operating Procedures</i> (Document 2) support the AEC operations by outlining procedures for forming AEC executive delegations. (Document 2 - SOP 2: <i>Executive</i>) The UAEC Executive is an active delegation of the Committee within the institution. The AWEC plays an active role in supporting the UAEC Executive to undertake their responsibilities by assisting members and the Chair with the review, investigation, expert advice and follow-up regarding submissions. The UAEC has provided guidance to define what are considered minor and major variations to projects (Document 2 - SOP 6: <i>Variations to approved projects / activities</i>). During the review it was established that the authority delegated to the executive by the UAEC includes the activities outlined in section 2: responsibilities - Chapter 2.2 <i>Responsibilities of institutions regarding the governance of an animal ethics committee</i>: c 2.2.23 . It was identified during the review, the role of the UAEC executive has been expanded since the previous external review in 2017 with several new delegations to including:</p> <ul style="list-style-type: none"> ▸ provide project extensions; generally up to two years where suitable justification is provided; ▸ review annual progress reports and approve continuation of projects that continue to align with the Code; <p>It is acknowledged that the UAEC is resourced and support by the institution, particularly in the support of the AWEC. In discussions with the Chair, AWEC and Director (OREI) it was established that this includes a rigorous process for reviewing submissions and ensuring appropriate outcomes. However, the additional responsibilities delegated by the UAEC may be considered outside the scope of the executive and reside with the deliberations of a quorate AEC, specifically the provision of extensions to approved projects and the review of annual progress reports.</p>
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R1	Recommendation in relation to Clause 2.2.23	<p>(1) Review the activities in relation to the Code clauses 2.2.23 and 2.3.6 and the policy advice provided on the DAF website under the heading 'Meetings' : https://www.business.qld.gov.au/industries/farms-fishing-forestry/agriculture/livestock/animal-welfare/animals-science/animal-ethics-committee/terms</p> <p><i>"New approvals, the review of Annual Progress Reports and approval of modifications to projects that are not minor must only be considered at a quorate AEC meeting. Decisions/appraisal of these matters must not be made 'out-of-session'. Where a decision on these matters is required before the next scheduled meeting, the AEC must be convened to meet and consider the matter."</i> https://www.business.qld.gov.au/industries/farms-fishing-forestry/agriculture/livestock/animal-welfare/animals-science/animal-ethics-committee/terms</p> <p>(2) Contact DAF in relation to this process to establish how this aligns with the policies established by Biosecurity Queensland's Animal Welfare and Ethics Unit.</p>
C1	Comment in relation to Clause 2.2.23	<p>The ERP have no concerns that the wellbeing of animals is compromised or that project extensions or reporting is not rigorously reviewed in relation to the Code requirements. It is felt that these processes could fall outside the intent of the Code to allow all members A, B, C & D to review these submissions from their own particular perspective and form their own opinions from that perspective as to whether a project or any extension to the approval are still meeting the governing principles that underpins the Code.</p>

DOCUMENT LIST

Docu- ment	
	Please Note - All hard copy and electronically sourced and stored documents that were used for review are listed in this table. E-documents were supplied by Queensland University of Technology or found on the website https://www.qut.edu.au/research/why-qut/ethics-and-integrity during the course of Review QUT06082020
	Governance (Institutional Policy and Procedure)
1	QUT – MOPP – D_6.7 University Animal Ethics Committee Charter (TOR)
2	SOP_UAEC_Aproved_version_June_2021
3	QUT – MOPP – Appendix 2 Council Procedure 1 – Committees
4	QUT – MOPP – B_8.7 Conflict of interest
5	QUT – MOPP – D_2.3 Research Governance Framework
6	QUT – MOPP – D_2.4 Monitoring of approved research
7	QUT MOPP – D_2.6 QUT Code for responsible conduct of research
8	QUT MOPP – D_2.7 - Managing and investigating potential breaches of the QUT Code for responsible conduct of research
9	Guideline on Conscientious Objection_May 2018
10	Webpage – Conscientious objection
	Annual Reports for Research Committee
11	RPT UAEC 2017 Annual report
12	RPT UAEC 2018 Annual report
13	RPT UAEC 2019 Annual report
14	RPT UAEC 2020 Annual report
	UAEC Self-Assessment Reports
15	2018 UAEC Self-Assessment Report
16	2020 UAEC Self-Assessment Report
17	RA Self-Assessment Report to Council

	Compliance Reports to Qld and NSW
18	QLD DAF 2020 – animal use statistics report – general – excel spreadsheet
19	QLD DAF 2019 – animal use statistics report – general – excel spreadsheet
20	NSW DPI 2020 – animal use statistics report– excel spreadsheet
21	NSW DPI 2020 – Form L
22	NSW DPI 2019 – animal use statistics report – excel spreadsheet
23	NSW DPI 2019 – Form L
	Previous Review Reports
24	PART A – Introduction PART B – Statement of conformance PART C – Commendations PART D – Review Findings PART E – Non-conformance PART F – Document List PART G – Report Acronyms and Abbreviations
	Inter- institutional Agreements
25	MERF Service Agreement (Animal) Template
26	AMEM_QUT and UQ_AEC_August2021 (MOU)
27	QUT-UQ AEC CCRG project agreement – 20210629
28	QUT and DAF AEC agreement – 20210408
29	QUT Signed Agreement 5 April 2017 (QUT-UQ)
30	QUT-QIMR SOP March 2016
31	QUT- QIMR SOP August 2021
	QUT Animal Ethics-Related Webpages
32	Getting started with animal ethics
33	Do I need approval
34	Animal ethics guidance and the 3Rs

35	Apply for approval
36	Working at other sites
37	UAEC meeting dates
38	Manage approved projects
39	Variations to an approved project
40	Progress and final reports
41	Concerns, complaints and adverse events
42	Animal ethics training
43	Animal ethics support
44	About the University Animal Ethics Committee
45	QUT File and Data Management 101 – training
	Education and Guidance
46	Adverse events on migrated projects
47	Animal ethics online training
48	Appendix – Drone study outline
49	Drone – Wildlife guidance document
50	ERM Animal Ethics report form guidance document
51	Guidelines for rodent survival surgery
52	QUT ANZCCART presentation 2021
53	UAEC spotlight series1 – Replacement
54	Variations to migrated projects – Exec review
	Pre-ERM - Animal Ethics Application and Guidance
55	00 a _Updated Research Application Guidance document
56	00 b_ Updated Teaching Application Guidance document
57	01 a_ Updated ETH_Animal Research application form
58	01 b_ Updated ETH_Animal Teaching application form
59	01 c_ Ethics SOP title – proforma

60	01 d_ ETH_Genetic Modification Animal Report form
61	ARRIVE Guidelines Checklist
62	ARRIVE Guidelines from NC3Rs
63	Australian Code for the Care and Use of Animals for Scientific Purposes
64	FRM_UAEC training record template2
65	FRM_UAEC training record template
66	Guidelines to promote the wellbeing of animals
67	NHMRC Best practice methodology in the use of animals for scientific purposes 2017
68	PREPARE Checklist_animals_NORECOPA
69	Old system – Response to applicant Resubmission
	ERM - Animal Ethics Applications and Reports (in use)
70	Animal research application
71	Animal teaching application
72	Variation form
73a	Animal annual progress report
73b	Animal final report
74	Adverse event form
75	Animal 'other' report
76	Animal Outside scope application
77	Animal Tissue Use application
78	Animal 'Specific conditions' report
79	Animal usage form
80	Full ERM application form
81	List of Project specific administered agents doc
82	ERM Approval email and attachment
	Additional documents (Pre-ERM)
83	Animal Ethics Final Report Template – 2020

84	Animal Ethics Progress Report Template – 2020
85	Online proforma – Animal ethics adverse event form
85	Online proforma – Animal ethics variation request form
	Animal Facility Inspections
86	Schedule of UAEC facility inspections
87	2019 MERF annual report on activities
88	2020 MERF annual report on activities
89	2020 SERF annual report on activities
90	2018 Banyo Aquaculture facility report
91	2018 MERF BRF TPCH annual facility report
92	2018 GPTF annual facility report
93	2018 SERF interim report on activities
94	2018 MERF PJH property annual report
95	2019 Banyo Aquaculture facility report
96	2019 GPTF annual facility report
97	2019 MERF PJH property annual report
98	2019 MERF BRF TPCH annual facility report
99	2019 SERF annual facility report
100	2020 MERF PJH property annual report
101	2020 MERF BRF TPCH annual facility report
102	2021 MERF BRF TPCH annual facility report
103	2021 SERF annual facility report
	SOPs
104	List of approved SOPs – Excel
105	Template – SOP (Old version, pre-ERM)
106a	MERF_SOP_AC_RAT_Intraperitoneal Injection
106b	MERF_SOP_AC_RAT_Intravenous Injection

106c	MERF_SOP_AC_RAT_Subcutaneous Injection
	Current Projects
107	List of current approved animal ethics projects
	Project Dossiers (Complete Projects)
108 _(1 - 50)	<p>1700000540 Research project (Prof Stuart Parsons)</p> <p>Series of documents relating to project including ethics application form, approval certificate, email correspondence, ethics progress report, ethics variation request, ethics final report and print out of QUT Animal Ethics Wiki relating to this project</p> <p>NOTE: Documents will be individually identified if referred to in the report.</p>
109 _(1 - 22)	<p>1900000568 Teaching project (Dr Roland Steck)</p> <p>Series of documents relating to project including ethics application form, approval certificate, email correspondence, pilot study plan, ethics variation request, progress reports and print out of QUT Animal Ethics Wiki page relating to this project</p> <p>NOTE: Documents will be individually identified if referred to in the report.</p>
	AEC induction docs
110a	Member Induction Manual
110b	2021 UAEC Meeting dates & Members
110c	QUT Disclosed Interests form 2021- GLS version
110d	QUT Disclosed Interest Form- Example
110e	UAEC Undertaking form
110f	Kelvin Grove campus Map
	AEC Documents
111a	RA Attendance Register 2017
111b	RA Attendance Register 2018
111c	RA Attendance Register 2019
111d	RA Attendance Register 2020
111e	RA Attendance Register 2021

	Agenda and Minutes
112a	Agenda – 20210504
112b	Agenda – 20210601
112c	Agenda – 20210706
112d	Agenda – 20210803
113a	RA – minutes - 20210504
113b	RA – minutes - 20210601
113c	RA – minutes – 20210706
113d	FINAL_UAEC_Minutes_21080303 (From AEC meeting 210907 as per Agenda item 2.1)
	AEC Meeting Documents
114a	1_UAEC_AGENDA_210907
See 113d	2.1_FINAL_UAEC_Minutes_210803
114b	2.2_Post Meeting Action Sheet_210803
114c	4.3.0_SUB_Monitoring_210907
114d	4.3.1_ATT Approvals between meetings_210907
114e	4.3.2.1_ATT Schedule of UAEC facility inspections_210907
114f	4.3.2.2_DRAFT RPT_Facility Inspection-MERF_PJH_agistment_property_20July2021
114g	4.3.3_ATT Status of pending responses_210907
114h	4.3.4_ATT Specific conditions of approval_210907
114i	4.3.5_AWEC monitoring report 210907_comb
114j	5.1_REPORT_Concerns_Complaints_AEs_210907
114k	5.2.1_Manage of vascular comp in spinal surgery an edu program
114i	5.3.1_The koala pouch microbiome effect on reproductive outcomes
114m	5.3.2_A new concept for auto bone graft ectopic bone form rat model
114n	5.3.3_Therap ultras device develop scan ultras (SUS) sheep
114o	5.5_UAEC SOP amendments 210907

	AWEC job description
115	Animal Welfare and Ethics Co-ordinator (AWEC) PD
	Call for submissions
116a	DVC Email to QUT Staff
116b	Call for Written Submissions document Terms of Reference
116c	Webpage – About the University Animal Ethics Committee (UAEC)
	Documents provided during on-site visit (07 &08 September 2021)
117	Approved Animal Research Application No 2000000018
118	Approved Animal Research Application No 1800001138
119	Biography Associate Professor Melanie de Laat
120	Biography Associate Professor Susan Fuller
	Independent External Review Contract
121	Independent External Review Service Provider Agreement with the Queensland University of Technology

ACRONYMS AND ABBREVIATIONS USED IN THIS REPORT

TABLE 5: List of acronyms and abbreviations that may be found in review report

QUT06082020

Acronym or Abbreviation	Meaning
3Rs	The Principles of Replacement, Reduction and Refinement
AEC	Animal Ethics Committee
AFM	Animal Facility Manager
AWEC	Animal Welfare and Ethics Coordinator
DAF	Queensland Department of Agriculture and Fisheries
ERP	External Review Panel
IVCs	Individually ventilated cages
NHMRC	National Health and Medical Research Council
OREI	Office of Research Ethics & Integrity
QLD	Queensland
c	Clause
SOPs	Standard Operating Procedures
the Code	<i>Australian code for the care and use of animals for scientific purposes 8th Edition 2013</i>
UAEC	University Animal Ethics Committee

LIST OF TABLES IN REPORT**TABLE 7: List of Tables**

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D19	Table 1: Section 2 - Chapter 2.2 Review Findings identified as areas highlighted for review by the institution.
D25	Table 2: Section 2 - Chapter 2.3 Review Findings identified as areas highlighted for review by the institution.
D36 - D38	Table 3: Review of the Animal Ethics Application
E1 - E4	Table 4: Summary of Review Findings, Recommendations and Comments Arising from the Review Findings in Part D
G1	Table 5: List of acronyms and abbreviations that may be found in review report QUT06082020
H1	Table 6: List of Tables