

Scientific Auditing Services Pty Ltd

Central Queensland University (CQU)

Animal Ethics External Review

Report: CQU29082019

DRAFT

Draft Prepared by: Karen Boundy, Senior Auditor, Scientific Auditing Services Pty Ltd.
Provided to Central QueenslandUniversity - February, 2021.

Acknowledgements

Scientific Auditing Services Pty Ltd has taken all reasonable steps within in the time allocated, the budget allowed and in accordance with the Agreement for the Supply of Services, (signed 2020), between Scientific Auditing Services Pty Ltd and Central Queensland University associated with Client File ID: CQU29082019 in preparation of this document.

Ownership

Scientific Auditing Services Pty Ltd retains ownership of all copyright, database and other intellectual property contained in this report (exclusive of documents provided by CQU). Non-exclusive license (without the right to sub-license) is granted to CQU.

For any permissions or issues associated with CQU29082019, please contact Scientific Auditing Services Pty Ltd on sciaudit1@tpg.com.au

Acknowledgement of Source Document

The source document for Report CQU29082019 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.

To obtain further information

Email: sciaudit1@tpg.com.au

Telephone: 0499073166

	Contents	Page
Part A	Introduction	
	Title	A 1
	Acknowledgements	A 2
	Contents	A 3
	Executive Summary	A 4 - 5
	Review Participant Details	A 6
	Review Brief	A 7 - A 8
Part B	Statement of Conformance	B 1
Part C	Commendations	C 1 - C 3
Part D	Review Findings	D 1 - D 57
Part E	Summary of Review Findings, Recommendations and Comments Arising from the Review Findings in Part D	E 1 - E 12
Part F	Document List	F 1 - F 6
Part G	Acronyms	G1
Part H	List of Tables	H1

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 CQU's Office of Research Ethics 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 Central Queensland University's Animal Ethics Framework (AEF) during 2020 review period. This included:

- A desk-top assessment of the policies, procedures, forms and records selected from the years 2016 - 2020 were provided for review by the Office of Research Ethics to provide an overview of the institutional program governing the care and use of animals for scientific purposes.
- Discussions with the Ethics Coordinator, Ethics Officer and the Animal Welfare Officer in the Office of Research Ethics on the 6th and 7th of October, 2020 to provide detail in regard to the processes involved in the Animal Ethics Framework.
- Attendance at an Animal Ethics Committee (AEC) meeting to demonstrate the process of ethical review and monitoring of projects. Informal discussions with the AEC members.
- An on-site inspection of CQU's animal facilities at the North Rockhampton campus (Animal House, Laboratories and CQIRP) and discussions with the AEC Chair, Investigators / Teachers, and Animal Technicians on the 6th of October, 2020.
- Off-site discussions (using the on-line platform ZOOM) with two investigators on the 16th October, 2020.

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

- The institution 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.
- The institution 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 AEC is operating effectively and provide ethical review of the institution's animal use.
- Those caring for and using animals in research, on behalf of CQU, acknowledge the importance of, and contribute to maintaining a high standard of animal wellbeing.

Commendations are provided by the ERP 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 were identified relating to following Code provisions:

Clauses [2.1.5 (v) a], [2.1.5 (vii)], [2.2.33 - 2.2.36], 2.3.6, 2.4.34, [2.7.4 (iv), (v), (ix) & (xiii)].

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

Review Participant Details

Client Details

Senior Institutional Representatives:

Dr Grant Stanley
Deputy Vice-Chancellor
Research Division
CQUniversity Australia, Bruce Highway
Rockhampton, Queensland, 4702

CQU - Liaison Officer:

Sue Evans B.Bus (HRM)
Ethics Coordinator
Office of Research Ethics, Research Division
CQUniversity Australia, Building 32, Bruce Highway
Rockhampton, Queensland, 4702
Telephone: 0 7 4923 2603
Email: s.evans@cqu.edu.au

AEC Chair and Members:

The AEC Chair, appointed AEC members in attendance at the AEC Meeting on 7th of October, 2020.

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

Ms Karen Boundy, Senior Reviewer / ERP Leader (Scientific / Technical Representative).
Dr Marc Seifert, ERP Member - (Scientific / Technical Representative).
Dr Johanna (Jo) Toia, External Review Panel Member - (Veterinarian / AEC Representative).

Review Brief

Objectives

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

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

Scope of Audit

This audit is conducted for CQU, 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. This system includes the following areas located in Rockhampton, Queensland.

The Scope of the review is limited to:

- CQU's Animal Ethics Administrative Framework - Overall Governance Documentation - including but not limited to procedures, policies, forms and records that make up the CQU's animal ethics system.
- Operation of the Animal Ethics Committee and their relationships - Administrative and Actual Operation - 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 and AEC meeting agendas & submissions. Attendance by the ERP at the AEC meeting.
- Selected CQU Animal Facility: an inspection of the CQU facilities in North Rockhampton.
- Selected CQU Animal Use Activities - as provided by the Ethics Manager. Documentation included animal use applications, amendments, reports, and related correspondence.

Criteria

- (1) *NHMRC - Australian code for the care and use of animals for scientific purposes - 8th Edition* - <https://www.nhmrc.gov.au/about-us/publications/australian-code-care-and-use-animals-scientific-purposes>
- (2) Animal ethics-related documents supplied by CQU.

Outcome

A report, with recommendations, of the findings of the independent external review, in relation to the level of conformance of the CQU'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 a raw data sample collected during the review period. The sample included documentation supplied by CQU and data collected from the on-line meetings 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.

General comments and commendations are derived from the interactions with CQU staff and review of the collected sample documentation, including any observations and notations recorded.

END

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, CQU29082019.

This review was undertaken, on behalf of Central Queensland University, 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 Central Queensland University 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. Nine (9) review findings requiring consideration and action by the institution were identified during the review period and recommendations for corrective actions have been provided by the External Review Panel. The institution has undertaken to consider the findings and recommendations outlined in report CQU29082019 as part of its obligation to ensure its effectiveness in meeting its responsibilities under the Code and providing a robust animal ethics framework CQU29082019.

COMMENDATIONS

Commendations are provided in recognition of the efforts 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

Central Queensland University (CQU) 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.
- providing governance and resources for the animal ethics framework to oversee the scientific use of animals undertaken at the CQU.
- ensuring resources are available for the CQU AEC to operate effectively.
- ensuring the CQU AEC has the appropriate level of authority and autonomy.
- ensuring resources are available for key positions in the animal ethics framework including the Ethics Coordinator, Ethics Officer, AEC Chair, AWO and Animal Facility Managers to advise the CQU AEC and investigators with specialist advice on the scientific, technical and welfare issues involved in animal use projects.
- ensuring resources are available for the development and management of the animal facilities to provide a high standard of housing and care.
- promoting the governing principles and the 3Rs within the institution and ensuring they are integrated into the animal ethics framework.

The Office of Research

The Office for Research, in particular the Ethics Coordinator and Ethics Officer are commended for:

- its cooperation, co-ordination and participation in the external review process. In particular, the Ethics Coordinator and Ethics Officer for actively participating in the review process.
- providing operational support for and regulatory advice to the CQU AEC.
- establishing and maintaining a friendly and supportive environment for the AEC members.
- its commitment to ensuring the animal ethics framework achieves a high-level of compliance with the Code.
- developing, in consultation with the CQU AEC, and implementing code related policy and procedures and to form the basis of the animal ethics framework.
- supporting researchers through the AEC processes associated with the animal ethics framework.
- ongoing development of the CQU AEC website and development of access to training resources from ANZCCART (COMPASS) and Animal Welfare Victoria.
- providing an effective means of communication between the CQU AEC and the institution, the CQU AEC and investigators, and the institution and external agencies including state governments departments and external institutions.

The CQU AEC Chairperson

The CQU AEC Chairperson is commended for:

- their cooperation and participation in the external review process including their frank and open interactions with the reviewers during the on-site review of facilities including the Animal House, CQIRP and laboratories.
- providing leadership to the CQU AEC and support for CQU AEC members. In particular, supporting new members in understanding their individual roles and how the CQU AEC functions.
- establishing and maintaining a friendly and supportive environment for the AEC members.
- representing the CQU AEC at an institutional level.
- investing time and expertise in the overall management of the CQU AEC and its processes.

The CQU AEC

The CQU AEC members are commended for:

- their cooperation and participation in the external review process.
- ensuring the activities involving animals used at CQU are reviewed, approved and the wellbeing of animals is monitored.
- their commitment to providing service, to the institution, the CQU AEC and the animals used for scientific purposes, in particular those who volunteer their time and energy to undertake the responsibility of C - and D - category member roles.
- taking their responsibility seriously and participating actively to provide oversight in the area of animal wellbeing for animals used for scientific purpose.
- effectively representing the AEC at conferences and meetings outside the institution when the opportunity arises

The AWO

The AWO is commended for:

- their cooperation and participation in the external review process.
- the open and candid discussion about their role and the challenges they face in establishing a relatively new position within the animal ethics framework.
- their commitment to ensuring institutional practices in respect to ensuring animal wellbeing is of a high standard and reflects current best practice
- their efforts in acquiring additional skills and competencies to add to their expertise
- their efforts in developing a system for SOPs in-line with the requirements of the Code
- Their commitment to developing

Animal (Carers) Technicians (including the Animal Facility Managers)

The Senior Animal Technicians / Animal Facility Managers are commended for:

- their cooperation and participation in the external review process. In particular, the Senior Animal Technician at CQIRP for discussing in great detail the operations of the livestock facility and the wellbeing of the animals housed and used in the facility.
- the high level of commitment to their work (at all levels) and the animals they care for.
- providing environmental enrichment and working toward achieving a positive outcome in animal wellbeing.
- their skill in maintaining the specialised equipment in the animal facilities to ensure the environment is managed.
- ensure those working with animals are competent in the procedures they undertake.
- their effort to ensure good communications between themselves, the investigators and the AEC.

Investigators and Teachers

Investigators and Teachers are commended for:

- their cooperation and participation in the external review process. In particular, those involved in the CQIRP tour for discussing in great detail the operations of the livestock and poultry facility and the wellbeing of the animals housed and used in the facility.
- the high level of commitment to their research work and the animals they use.
- the open and candid discussions in regard to the animal ethics framework and the use of animals for research and teaching.
- the commitment to reducing (3'R's) the number of animals they use by using abattoir-sourced specimens for teaching.
- the commitment they demonstrated to maintaining a high level of animal wellbeing and continual review and refining of practices (3'R's) and procedures used on animals in their projects. This was evident at the CQIRP facility with the care of chickens and eggs.
- ensuring students are exposed to, have the resources and opportunity to discuss ethical concepts and best practice related to animal use for research and teaching. This was highlighted in discussions about wildlife field studies where students have access to best practice guidelines for the management pain and distress, and QPWS Rangers to discuss animal stress and wildlife handling.
- their efforts in adopting the procedures and practices under the animal ethics framework.

REVIEW CQU01102015 - 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.***

Central Queensland University (CQU) was found to promote and facilitate the adoption of the governing principles to ensure all those involved with the care and use of animals for scientific purposes associated with the institution are familiar with their responsibilities under, and comply with the *Australian code for the care and use of animals for scientific purposes - 8th edition 2013* (the Code).

The institution, through the Office for Research Ethics (ORE), are responsible for ensuring the governing principles have been integrated into the animal ethics framework at key stages to become part of the routine processes involved the use of animals in the research and teaching projects they undertake.

Key areas in which examples of where the governing principles were found to be integrated as part of the routine process for the care and use of animals at CQU include:

- (1) the policy and procedures governing the animal ethics framework. Development of overarching policies and procedures for the operation Animal Ethics Committee (AEC), the use of animals by researchers and Teachers and the operation of the animal facilities are based on the Code's key principles to provide ethical guidance for the decisions of all stakeholders.
- (2) the education and competency requirements for those using animals for research and teaching. Those employed in specific research, animal care and teaching roles undergo institutional processes to ensure they possess the appropriate qualifications, skills and experience to fulfil their responsibilities related to the ethical care and use of animals.

- (3) the application process for the approval of activities involving animals in research or teaching. This includes providing guidance to ensure researchers and Teachers are aware of, consider and apply the governing principles when planning a project or activity. This includes providing sufficient information for the AEC to make an ethical judgement regarding whether:

- the proposed use is justified,
- the use of animals essential
- the work has scientific or educational merit.

There is a clear expectation that those involved in the use of animals for scientific purposes will refer to, be familiar with and apply the governing principles to their specific situation.

- (4) providing adequately resourced, monitored and maintained facilities for the care and use of animals to ensure animals used for research and teaching are provided with appropriate care to support their wellbeing.

Processes observed during the review, including the assessment of documents, observations and information recorded during the on-site visit and the AEC meeting (07 October 2020) attended provided sufficient evidence that governing principle 1.1 is applied to ensure respect for animals underpins their decisions and actions when caring for and using animals for research and teaching under the registration of CQU.

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

CQU's 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 establishment and maintenance of the CQU AEC, operating in-line with the provisions outlined in Chapters 2.2 and 2.3 of the Code. Please refer to the review findings for Section 2: Chapters 2.2 and 2.3 for details regarding how the institution fulfils its obligations and the level of conformance with the Code requirements that has been achieved.
- a requirement for Investigators to obtain approval from an AEC for all projects prior to the commencement of animal use.
- a requirement for Investigators to obtain ethical clearance from an AEC or its executive for modifications to approved projects prior to that amendment being implemented
- AEC oversight to ensure projects are compliant through annual and completion reports or at any time when investigation, intervention or additional follow-up actions are necessary, for example, following a complaint or unexpected or adverse event. This includes implementing processes for the management of unexpected adverse events or incidents that includes review by the AEC.
- implementing processes to manage instances where Investigators fail to comply with institutional processes and the Code.
- support for the AEC 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 AEC meeting (07 October 2020) attended provided evidence that governing principle 1.2 is applied within the institution and there are adequate resources and processes in place to ensure activities and projects are subject to continued, consistent ethical review.

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.

CQU's animal ethics framework provides processes to ensure the AEC receives *Animal Ethics Applications* for the use of animals in research and teaching (Documents 15a & 15b), *Modification Requests* for any variation to approved work (Document 16) and monitoring reports (Documents 17, 18 & 19) that allow them to review animal use and decide whether the proposed use of animals is ethically acceptable. The AEC's decision is based on how the information provided by the Investigator or Teacher demonstrates they have considered and applied principles in Clause 1.1, and whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits.

This was demonstrated by:

- the process Investigators follow to provide sufficient justification for the use of animals in their projects for submission and AEC assessment. Sufficient justification must be established before approval is granted and use may commence.
- procedures the AEC follow when determining whether the use of animals is ethically acceptable. The AEC may seek further information or clarification from Investigators and other expert sources if required to, to make their decisions. The AEC 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 information to allow the AEC to monitor the annual progress or the completion of a project, any modification to the protocol of the existing approved project or any actions taken to address an unexpected or adverse event.
- the AEC continuing to monitor activities and projects to ensure the use of animals is remains ethically acceptable and the work continues to meet institutional and Code requirements. This is achieved by the review of annual progress or completion reports, requests to modify the protocol of an existing approved project or any actions taken to address an unexpected or adverse event.

Information collected during the assessment period, including the review of AEC meeting minutes (Documents 21b, 22b & 23b), observations recorded at the AEC meeting (07 October 2020) attended, discussions with the AEC Chair, ORE Staff, Investigators, Teachers and Animal Technicians on-site at the Rockhampton campus, provided evidence that governing principle 1.3 is applied and the AEC approves only the use of animals that clearly justifies the use of animals only when the potential benefits of the use outweigh the potential effects on the wellbeing of animals.

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.

CQU's animal ethics framework promotes respect for animals, and the responsibilities associated with this obligation ensuring it is applied throughout the animals lifetime. The institution meets this requirements by:

- providing ethical oversight of projects through the AEC application and reporting processes for animal use activities

Requests for new projects or modification of approved work requires Investigators to consider and complete the on-line application or request, providing sufficient information to satisfy the AEC that the use is ethically acceptable and complies with the requirements of the Code. The process allows the AEC members to ask questions and make comments about the work to ensure they have a sufficient understanding on which they base their decisions as to whether the work is approved or if they will place conditions on how the activity will proceed. The AEC was seen to continue monitoring activities that impact on the animal's wellbeing throughout the animal's lifetime through annual, completion and unexpected adverse event reporting. The AEC undertake routine on-site inspections of animal facilities to ensure animal use activities proceed in accordance with the approval and that facilities, the animals and their environment are managed appropriately to support the animal's wellbeing throughout its lifetime. Researchers and Teachers at CQU are available to the AEC to provide additional information and assurance that the work is proceeding as approved.

- 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 management of the CQU animal facilities, the use of animals and in AEC processes. To support the care and use of animals used for scientific purposes the AEC reviews and approves animal housing, husbandry and use. Examples of procedures for routine management and experimental procedures were seen during the review.

- monitoring the qualifications and experience of Staff at the Rockhampton campus caring for and using animals demonstrated they are aware of their responsibilities and undergo on-site specialist facility training. New Staff and Students undergo an induction process that includes training and supervision by competent Staff to ensure animal wellbeing and the facilities are maintained to a high standard.

Processes observed during the review, including the assessment of documents, observations recorded during the on-site visit, discussions the AEC Chair, ORE Staff, Investigators, Teachers and Animal Technicians on-site at the Rockhampton campus provided evidence that governing principle 1.4 is applied and the responsibility to respect and support animals throughout their lifetime is addressed at all levels.

END OF REVIEW FINDINGS RELATING TO SECTION 1

SECTION 2 - RESPONSIBILITIES

Chapter 2.1- Responsibilities of institutions

The governing body of the institution, Central Queensland University (CQU), is responsible for ensuring that the care and use of animals for scientific purposes conducted on behalf of the institution complies with the code.

CQU is registered in its home state of Queensland as a user of animals for scientific purposes and holds license or registration in New South Wales, Victoria, South Australia, Tasmania and Western Australia (Document 12c).

CQU 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

Ensure compliance through an animal ethics committee

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

c 2.1.3

CQU does not 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 Deputy Vice-Chancellor Research (DVCR) as the Senior member of the institution with the authority for the overall institutional governance of the in respect to the care and use of animals.
- providing the animal ethics framework with adequate resources to ensure that the AEC 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 ORE to provide management and undertake the development of procedures and processes to support the animal ethics framework including the operation of the AEC.

c 2.1.5 (i)

c 2.1.5 (ii)

- promoting and facilitating adoption of the governing principles of the Code through providing for the animal ethics framework. This has included making a policy statement, the *CQU Statement of Principles Guiding the Use of Animals in Teaching and Research at Australian Universities* (Document 2) that outlines adherence to the Governing Principles, including the 3'R's - *Replacement, Reduction, Refinement*. Resources are provided to the ORE to provide governance and develop procedures and processes in-line with the governing principles and integrating these into animal research and teaching undertaken on behalf of the institution.
c 2.1.5 (iii)
- by publishing the institutional policies and procedures on the CQU website <https://www.cqu.edu.au/policy>, and through the dedicated CQU Animal Ethics webpage <https://www.cqu.edu.au/research/current-research/ethics-committees/animal-ethics> for all relevant people including AEC members to have access.
c 2.1.5 (iv)
- developing and promoting guidelines in consultation with, and approved by the AEC for the care and use of animals within the institution.

Guidelines must include:

- (a) how the competence of people involved in the care and use of animals will be assessed and ensured. The AEC Chair, ORE Ethics Officers and AEC members are provided with induction and training, education and networking opportunities.

No formal procedure or process was identified, however progress has been made since review CQU01102015 to ensure those involved in the animal ethics framework are competent to undertake their specific roles. Competencies are not currently recorded except for induction records and conference attendance for AEC members. The expectation is that Investigators and Teachers will provide competency information in applications. Students are monitored and supervised and recording of training and competencies is done in individual units, however it is unclear if this is consistently achieved.

c 2.1.5 (v) a

- (b) strategies to ensure the maintenance of a health status of the animals that safeguards animal wellbeing and meets the requirements of their proposed use were identified as available through the animal ethics framework documentation, including in approved projects and Standard Operating Procedures (SOPs) for routine management of animals at animal facilities.

c 2.1.5 (v) b

- (c) monitoring and assessment of animals to ensure that any harm, including pain and distress, is promptly detected and managed were identified as available through the animal ethics framework documentation and through the monitoring procedures for animals in animal facilities. It was established on-site that operations at CQIRP and the Animal House included adequate monitoring of animals, security and veterinary support.

c 2.1.5 (v) c

- (d) the management of unexpected adverse events (UAE) and emergencies is provided through the AEC procedures (Documents 4, 5 & 6). A detailed procedure including a reporting form (Document 19) for UAEs is available to Investigators, Teachers and Animal Technicians. Reminders are provided on the AEC Webpage : <https://www.cqu.edu.au/research/current-research/ethics-committees/animal-ethics> - *“Researchers are required to report to the AEC any unexpected adverse events which happen to animals during their research. The Chair of the AEC (or Secretary if Chair is unavailable) must be notified by telephone within 24 hours of such an event, and the Adverse Event Form must be submitted as soon as practicable. In determining what is considered an adverse event, researchers are encouraged to visit the [Department of Agriculture and Fisheries](#) website.”*

c 2.1.5 (v) d

- (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. The *AEC Operating Policy and Procedure* (Document 5) states, “ *In accordance with clause 2.1.5(e) of the Code, on notification of an instance of unexplained and severe disease outbreaks, or morbidity/mortality in animals or people, the Chair, in consultation with the Animal Welfare Officer, are authorised to approve the immediate use of animals to undertake diagnosis, by appropriated qualified personnel. This approval will be based on guidance from the Department of Agriculture and Fisheries.*”

c 2.1.5 [v] 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 an on-Staff Veterinarian, the Animal Welfare Officer (AWO) and additional veterinary support is available to researchers, Teachers and animal facility / field Staff from local Veterinarians.

c 2.1.5 (vi)

- the institution created a position for an AWO in 2018 after consideration of recommendations made from the previous external review (CQU01102015) and employs a part-time (1 - 3 days / week) Veterinarian in the position of AWO to ensure that activities proceed in compliance with the Code and the decisions of the AEC. At the time of review this position had an active role in:
 - advising the AEC, Investigators and Animal Technicians
 - investigating of UAEs
 - developing a register of SOPs
 - developing training and competency procedures and resources
 - providing veterinary support

It was clear in discussions with the AWO, Investigators, the AEC Chair and the Ethics Coordinator that the position of AWO had become an invaluable resource in CQU's ongoing commitment to maintaining high levels of compliance with the Code and its obligation to the State and Territory legislation for registration and licensing as a user of animals for scientific purposes.

However this position appears to have some challenges, particularly in the definition of the role, responsibility and authority to undertake the expected duties. This appeared to have caused some issue over where the AWO's authority lies in regard to assessing competencies, application of standard practices (industry / commercial and research / teaching setting), advice to animal facilities and the provision veterinary services. At the time of review the position was working three (3) days per week and due to institutional consideration resulting from COVID-19 restrictions it was expected to decrease to one (1) day per week.

c 2.1.5 (vi)

Ensure and support the effective operation of the animal ethics committee

The institution provides support and resources through the ORE for the effective operation of the CQU AEC in accordance with Section 2, Chapter 2.2 of the Code. This includes a publicly available CQU AEC TOR (Document 4) and *AEC Operating Policy and Procedure* (Document 5) <https://www.cqu.edu.au/research/current-research/ethics-committees/animal-ethics> that includes procedures for reviewing, approving and monitoring the care and use of animals, communication between the AEC 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 AEC review of ethical acceptability and monitoring of animal activities and projects. Animal Ethics Applications, modifications and reports require detailed information to be provided by Investigators. Information including identification of the Chief Investigator or Teacher, 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.
- (b) information as a condition of AEC approval (Document 6 &19), that a researcher must report unexpected adverse events and provides a *Unexpected Adverse Event form* (Document 13) to do so.
- (c) emergency procedures to ensure disease outbreaks and emergencies, such as fire, power failure and biosafety issues, are promptly detected and effectively managed.(Document 6) Procedures were identified in animal facilities outlining actions and responsibilities in the case of emergencies.

c 2.1.7(i)

Ensure understanding of responsibilities

- (i) 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.**
- (iii) The institution encourages the adoption of best practice in the care and use of animals in the research and teaching. This was seen by the participation of a Senior Lecturer contributing as a Lead Editor to the production of reference material focused on wildlife research and ethical issues. In discussions with Investigators it was established that resources to ensure adherence to current best practice is supported by access to government (QPWS) and industry (commercial livestock) advisors and standards (as minimum standards).

c 2.1.8 (i - ii)

c 2.1.8 (iii)

- (iv) Institutional employment processes ensure those engaged to provide care for and use animals on behalf of CQU have the necessary qualifications and experience to undertake their duties. It appeared adequate numbers of Staff were available in on-site facilities in relation to the number of animals present at the time of the review. (Taking into account COVID-19 restrictions)

c 2.1.8 (iv - v)

- (vi) Veterinary assistance and diagnostic services were found to be available as required by the animal facilities. This included specialist Veterinarians and the AWO.

- (vii) The institution is committed to and provides health and safety information on their website: <https://www.cqu.edu.au/about-us/structure/directorates/people-and-culture-directorate/health-and-safety-contacts>.

c 2.1.8 (vi)

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

c 2.1.8 (vii)

Monitor and review compliance

CQU 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 CQU01102015 and CQU 29082020 to meet State and territory reporting obligations.
- (ii) assessing a written review of the operations of the AEC annually (Documents 12a, 12b & 12c). The annual report is prepared by the Ethics Coordinator provided to the AEC Chair and AEC for review then submitted to DVCR for review by the research Committee. The report includes information on the operations of the AEC in regard to the review and monitoring of projects, AEC processes, facility inspections, compliance issues, complaints and adverse events.
- (iii) The annual review process by the institution of the AEC to assess the effectiveness of its processes regarding complaints and non-compliance is outlined in the annual report.

c 2.1.9 (i - iii)

No comment in regard to c 2.1.10.

Table 1: Section 2 - Chapter 2.1 Review Findings Identified as Areas Highlighted for Review by the Institution.

Code Reference	Review Finding
c 2.1.5 (v) a	<p>Guidelines must include how the competence of people involved in the care and use of animals will be assessed and ensured. The AEC Chair, ORE ethics officers and AEC members are provided with induction and training, education and networking opportunities. No formal procedure or process was identified, however progress has been made since review CQU01102015 to ensure those involved in the animal ethics framework are competent to undertake their specific roles. Competencies are not currently recorded except for induction records and conference attendance for AEC members. The expectation is that investigators and teachers will provide competency information in applications. Students are monitored and supervised and recording of training and competencies is done in individual units, however it is unclear if this is consistently achieved.</p>
c 2.1.5 vii	<p>The institution created a position for an AWO in 2018 after consideration of recommendations made from the previous external review (CQU01102015) and employs a part-time (1 - 3 days / week) Veterinarian in the position of AWO to ensure that activities proceed in compliance with the Code and the decisions of the AEC. At the time of review this position had a role in:</p> <ul style="list-style-type: none"> ▶ advising the AEC, investigators and animal technicians ▶ investigating of UAEs ▶ developing a register of SOPs ▶ developing training and competency procedures and resources ▶ providing veterinary support <p>It was clear in discussions with the AWO, investigators, the AEC and the ethics coordinator that the position of AWO had become an invaluable resource in CQU's ongoing commitment to maintaining high levels of compliance with the Code and its obligation to the State and Territory legislation for registration and licensing as a user of animals for scientific purposes. However this position appears to have some challenges, particularly in the definition of the role, responsibility and authority to undertake duties in regard to the role. This appeared to have caused some issue over where the AWO's authority lies in regard to assessing competencies, application of standard practices (industry / commercial and research / teaching setting), advice to animal facilities and the provision veterinary services. At the time of review the position was working three (3) days per week and due to institutional consideration resulting from COVID-19 restriction it was expected to decrease to one (1) day per week.</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 2.1

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

Responsibilities

During the review evidence through review of governance documents and discussion with the Ethics Manager and AEC Chair was identified to demonstrate how CQU meets its responsibilities regarding the governance of the AEC.

c 2.2.1 (i - v)

Ensure appropriate animal committee membership

Composition of the animal ethics committee

CQU meets these responsibilities by:

- 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 a Chair to guide the operation of the AEC. The CQU AEC Chair is an appointment from within the institution and not independent of the use of animals for research and teaching as recommended in c 2.2.2. They hold a Senior position in the institution as a member of the Academic Staff engaged in research and teaching within the School of Health, Medical and Applied Sciences.

c 2.2.2 - c 2.2.3

- appointing multiple appointments to each of the categories A-, B-, D- and one C-member. The ORE are trying to recruit an additional C-member and have recently added a D-member to the committee. **Please refer to the comments made for c 2.3.6.**

c 2.2.4

- appointing an additional member to the core membership to advise the AEC. An additional appointment of a Senior Animal Technician / Animal Facility Manager - a person who is responsible for the routine care of animals from within the institution undertaking research or teaching. This appointment to an AEC is a mandatory requirement for an institution to hold a licence in South Australia.

c 2.2.5

- supporting the AEC meetings with several non-member positions including the AWO, Ethics Coordinator and the AEC Minutes Secretary (Ethics Officer) are present to provide technical, administrative and regulatory support for the AEC.

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.

(State / Territory Government requirement)

- at the time of the review the AEC had a total membership of nine (9) with three (3) C- and D-members and an additional D-member appointed but attending as an observer. Note: One (1) D-member had recently retired and one (1) D-member had recently been accepted under the processes of the Queensland Department of Agriculture and Fisheries - Biosecurity Queensland as meeting the requirements D-membership. With the addition of the new D-member the AEC was at 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 (Document 4 - Sections - 5: *Membership and Terms of Office* and 11: *Conflict of Interest*) that outlines the processes for inviting expression of interests (EOI) or re-appointment for AEC membership, processing requests and appointing new- or re-appointing existing members. Retirement of AEC members is by written request from the DVCR or by written self-nomination.

c 2.2.9

- requiring new AEC members to make a written declaration of any real, perceived or potential conflict of interest prior to appointment, accept the TOR and sign a confidentiality agreement prior to appointment. (Document 41)

c 2.2.10

- providing induction to new members including the issue of an induction package (Document 42), a face-to-face meeting with the AEC Chair and Ethics Officer and complete on-line training. A training package (Animal Welfare Victoria) is currently being assessed by the AWO for use at CQU and has been provided to the newest member appointment (D-member).

c 2.2.11

- continuing to source and provide additional training. An induction package is currently being introduced, with the recently appointed D member the first to undertake this process. It includes access to on-line education (developed by Animal Welfare Victoria), ANZCCART information package, the Code, TOR, *AEC Operating Policy and Procedure* and a face-to-face induction process by the Ethics Officer and AEC Chair.

c 2.2.12

Responsibilities of the Chairperson

The AEC Chair was identified during the review to impartially guide the AEC meeting (7th October, 2020) and adhere to the meeting procedures including conflict of interest and maintenance of quorum. In discussions it was established the Chair has effective lines of communication within the institutional hierarchy to make representation, on the AEC's behalf, when required.

c 2.2.13

Responsibilities of members (c 2.2.14 - c 2.2.17)

Members have access to, and are encouraged to familiarise themselves with the AEC TOR (Document 4), *AEC Operating Policy and Procedure* (Document 5) and the Code to ensure they understand their roles and meet their responsibilities as AEC members. Discussions with the AEC Chair, Ethics Coordinator and Ethics Officer established that members understood their responsibilities and contributed to the business of the AEC including providing opinions in regard to the review and monitoring of animal use projects and activities.

c 2.2.14 - c 2.2.15

AEC members declared any actual, perceived or potential conflict of interests prior to their appointment to the committee in writing or with items on the AEC meeting agenda prior to the meeting date or at the time of the meeting (if an instance arises) before items are discussed.

c 2.2.16

Confidentiality requirements are outlined in the *AEC Operating Policy and Procedure* (Document 5). 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

CQU provides a publicly available ([athttps://www.cqu.edu.au/_data/assets/pdf_file/0021/121728/Animal-Ethics-Committee-Terms-of-Reference.pdf](https://www.cqu.edu.au/_data/assets/pdf_file/0021/121728/Animal-Ethics-Committee-Terms-of-Reference.pdf)) TOR (Document 4) accepted under the processes of the Queensland Department of Agriculture and Fisheries - Biosecurity Queensland as complying with the Code. The 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 AEC through the ORE to support its operation and meet its responsibilities under the code by providing financial, administrative, educational (including induction) and operational assistance. The AEC is provided with sufficient resources to maintain its operations. External Committee members will be provided with access to any resources they reasonably require to fulfil their duties as a Committee member (Document 4 - *Access to resources*)

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

Establish procedures for animal ethics committee governance and operation

CQU has established a suite of policies and procedures to govern AEC 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 TOR (Document 4) and *AEC Operating Policy and Procedure* (Document 5) support the AEC operations by outlining procedures for:

- the management of conflict of interest. Procedures for conflict of interest are outlined in the TOR (Document 4) and the *AEC Operating Policy and Procedure (Document 5)*. *The Committee will deal with situations in which a conflict of interest arises, including any situation where a member has an interest that may be seen to influence the objectivity of a decision by requiring the member whose objectivity may be influenced by an interest (including consideration of a proposal submitted by that member) to leave the room prior to any discussion of the identified item, returning only at the invitation of the remaining members to provide clarification on issues raised (after which the member will again be requested to leave), or returning only when a decision has been finalised*

c 2.2.21
- maintaining confidentiality. Confidentiality requirements are outlined in the *AEC Operating Policy and Procedure (Document 5)*. AEC members sign a confidentiality agreement as outlined in the TOR (Document 41h).

c 2.2.22
- forming AEC executive delegations. Procedures are outlined in the TOR (Document 4 - Section 9: *Executive Committee*)

c 2.2.23
- the processes for submission, receipt and processing of applications and reports by the ORE / AEC. This includes access via the webpage <https://www.cqu.edu.au/research/current-research/ethics-committees/animal-ethics> and ... *applications are required to be entered via the online application process, available at myresearch.cqu.edu.au.*

c 2.2.24

- managing quorum. Procedures are outlined in the TOR. *The Committee shall have a quorum which must include at least one member from each Category A, B, C and D at all times throughout the duration of the meeting, including after the withdrawal of any members with a conflict of interest. If the Committee has more than four members, Categories C plus D must represent no less than one third of the members.* (Document 5 - 4 Procedures: Establishment of Quorum) **Please refer to the comments made for c 2.3.6.**

c 2.2.25
- the timely distribution of papers to AEC members is stated as 10 days before a meeting

c 2.2.26 (i)
- the conduct of quorate meetings, “*The Committee shall have a quorum which must include at least one member from each Category A, B, C and D at all times throughout the duration of the meeting, including after the withdrawal of any members with a conflict of interest. If the Committee has more than four members, Categories C plus D must represent no less than one third of the members. The Code requires that Committee meetings must be held face-to face where practical, with video or web conferencing, as a first preference used where necessary to establish quorum. In exceptional circumstances the use of teleconferencing is permissible. If quorum is not achieved at the commencement of the meeting, the Committee may:*

 - *contact non-attending members to ascertain whether they would be prepared to participate by videoconference (if possible) or by telephone. If acceptable, then the meeting could proceed to discussion of all business items, or*
 - *cancel the meeting and ask the Secretary to re-convene the full Committee at the earliest possible date.”*

(Documents 4 - 10: Quorum, - 12: Meetings & Document 5 - 4: Procedures: The Establishment of Quorum [4.9 - 4.11]) **Please refer to the comments made for c 2.3.6.**

c 2.2.26 (ii)
- Managing any conflict of interest during the AEC meeting by, “*requiring the member whose objectivity may be influenced by an interest (including consideration of a proposal submitted by that member) to leave the room prior to any discussion of the identified item, returning only at the invitation of the remaining members to provide clarification on issues raised (after which the member will again be requested to leave) or returning only when a decision has been finalised.*” (Document 4 - 11: Conflict of interest) Specific procedures are provided (Document 4 - 4: Procedures: Conflicts of Interest [4.1 - 4.3])

c 2.2.26 (iii)
- Meeting frequency - *The Committee will meet monthly (<https://www.cqu.edu.au/research/current-research/ethics-committees/animal-ethics>) and will advise the University community of the meeting dates, including closing dates for applications to be considered at each meeting. AEC meetings shall be held at least six times per year.* (Documents 4 - 12: Meetings & Document 5 - Procedures: Meeting Frequency [4.4])

c 2.2.26 (iv)

- Review of new and ongoing proposals, “ (Document 5 - 4 *Assessing proposals* [4.14 - 4.17])

c 2.2.26 (v)

The AEC are to provide prompt notifications of its decisions, “*As far as practicable, within 10 working days of any decision on a proposal, the Secretary will advise the proposer/s in writing of the Committee’s decision.*”

c 2.2.27

In discussions during the on-site review it was established that Investigators, Teachers, Animal Technicians and Students are able to communicate with the AEC via the AEC Chair, Ethics Coordinator and Ethics Officer when seeking assistance or other information by meeting with them face-to-face, by telephone or written communication.

c 2.2.28

Complaints and non-compliance are addressed in the *AEC Complaints and Grievance Policy and Procedure* (Document 7) and management of non-compliance is addressed in more detail in the *AEC Operating Policy and Procedure* (Document 5 - 4: Procedure: *Non-compliance with the Code*)

Please refer to the Review Findings for Section 5 for further detail.

c 2.2.29

Records and documentation, “The Secretary will maintain a record of agendas, reports and other aspects of the Committee’s operation” and “*The Secretary will maintain records relating to the Committee, including:*

- *a register of all applications to the Committee, including the outcomes of deliberations*
- *a copy of each project/protocol and application submitted for approval by the Committee, including any permits, licenses or other relevant documentation or correspondence in the form in which they were approved*
- *minutes that record decisions and other aspects of the Committee’s operation*
- *records of inspections conducted by the Committee, and*
- *a copy of all reports to governing bodies and the University.”*

(Document 5 - *Record Keeping*)

c 2.2.30 - c 2.2.31

Documentation has been developed for:

- applying for animal ethics review and approval of work involving the use of animals for teaching or research (Documents 15a & 15b)
- requesting modification to an approved project, (Document 16)
- reporting the progress of, or completion of an approved activity or project (Documents 17 & 18)
- reporting of an adverse incident or event (Document 19)

c 2.2.32

The institution in consultation with the AEC allows the use of SOPs (or SRPs - Standard Research Procedures). Examples of both formats were provided for review. It is the role of the AWO (outlined in the Annual report to the institution - Document 12c), *"to review the SOPs and draft SOP documents from a range of existing and / or previous project examples."* At the AEC meeting (07 October 2020) there was discussion of SOPs and it was evident from that discussion the process for using SOPs, their development, review and approval was still in the early stages. It was evident that the process is complex as it is also related to competency assessment and assurance that is currently being developed. At the time of the review the AWO had developed a format for SOPs, established a register, and had begun reviewing and submitting SOPs for comment and approval by the AEC. SOPs being used in some areas are not in the new SOP format and it is unclear what their current approval and review status is (although they do appear on the register and some are approved, filed for review or at the time of review before the AEC for review (Documents 33, 34, 35 & 36). It appears this has been a disjointed process due to the COVID-19 restrictions.

Discussions with the AWO, Ethics Coordinator and Investigators outlined the current system of SOPs detailing the challenges involved in reviewing and developing the current system. It was clear from the discussions that there are some issues in the development of this system with resourcing and authority that is causing some tensions and impeding the compliant implementation of the process.

c 2.2.33 - c 2.2.36

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

The AEC has a responsibility to provide 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 21a, 12b & 12c) from the AEC for review by the the DVCR and the Research Committee (of which the AEC Chair is a non-executive member). In discussions with the AEC Chair and Ethics Coordinator it was established that the AEC Chair has opportunity for a face-to-face meeting with Senior representatives of the institution including the DVCR at least annually. The proximity of the ORE, AEC Chair and DVCR provides opportunity for an open line of communication.

c 2.2.37

Table 2: Section 2 - Chapter 2.2 Review Findings Identified as Areas Highlighted for Review by the Institution.

Code Reference	Review Finding
c 2.2.33 - c 2.2.36	<p>The institution in consultation with the AEC allows the use of SOPs (or SRPs - Standard Research Procedures). Examples of both formats were provided for review. It is the role of the AWO (outlined in the Annual report to the institution - Document 12c), <i>"to review the SOPs and draft SOP documents from a range of existing and / or previous project examples."</i> At the AEC meeting (07 October 2020) there was discussion of SOPs and it was evident from that discussion the process for using SOPs, their development, review and approval was still in the early stages. It was evident that the process is complex as it is also related to competency assessment and assurance that is currently being developed. At the time of the review the AWO had developed a format for SOPs, established a register, and had begun reviewing and submitting SOPs for comment and approval by the AEC. SOPs being used in some areas are not in the new SOP format and it is unclear what their current approval and review status is (although they do appear on the register and some are approved, filed for review or at the time of review before the AEC for review (Documents 33, 34, 35 & 36). It appears this has been a disjointed process due to the COVID-19 restrictions. Discussions with the AWO, Ethics Coordinator and Investigators outlined the current system of SOPs detailing the challenges involved in reviewing and developing the current system. It was clear from the discussions that there are some issues in the development of this system with resourcing and authority that is causing some tensions and impeding the compliant implementation of the process.</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 CQU AEC 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])

Noted: The agenda for the AEC meeting (07 October 2020) attended by the External Review Panel (ERP) was limited to discussions of one new application. The number of new applications submitted to the AEC in 2020 had decreased during the period of COVID-19 restrictions.

The AEC meets its responsibilities by:

Review and approval of new and ongoing activities

The AEC meets its responsibilities by reviewing and monitoring new and ongoing projects and by assessing the information submitted by Investigators and Teachers in the appropriate Animal Ethics formats (Documents 15 - 19) and providing a decision regarding the work's or actions for ethical acceptability. The meeting process was observed by the External Review Panel (ERP) at the AEC meeting (07 October 2020). Two (2) AEC members (an A- and a B-member) attended via video-link with apologies from two (2) members (a D-member and the c 2.2.25 appointed member). The absent D-member had provided comment in regard to the new application (Document 30g) which was read out the beginning of the discussion.

Attendance at AEC (07 October 2020) meeting demonstrated that the conflict of interest procedures are adhered. One of the B-members present declared a conflict of interest (Chief Investigator of the new project submitted for approval) and left the meeting for deliberations and the final vote. Other instances recorded in the minutes (Document 22b: *Item 6.1.1*) confirmed the conflict of interest process where members with a conflict of interest absented themselves from the meeting was routinely observed.

The AEC members reviewed, discussed, provided comment and requested additional information from the Applicant before making a judgement on the applications ethical acceptability. At the AEC meeting (07 October 2020) the application was approved after additional information had been provided by the Investigator. The AEC requested that the Applicant provide some additional confirmation, sign-offs and non-animal ethics information before commencement of the work. All members of the AEC present were seen to contribute to the discussions with comments and questions for the Applicant and after debate consensus was reached.

c 2.3.3 - c 2.2.12

Review of the research and teaching applications (Documents 28 & 29) provided for review demonstrated that the AEC, as far as practical, adheres to its procedure (Document 5 - *Prompt notification of decisions: 4.24*) for notifying Investigators and Teachers in regard to their submissions.

c 2.2.13

Attendance at AEC meeting (07 October 2020) confirmed that a quorum (A, B, C & D members present) was maintained and the C- and D- member balance of (total membership 9:2 C & D members present) was not in-line with the Code requirement of one-third of members present. Present at the meeting was a newly appointed D-member participating in the meeting for the first time.

Review of the minutes (Documents 21b, 22b, 23b & 30c) identified that the balance of C and D members in the total membership of appointed members was not achieved at 3 meetings held during 2020 (Documents 21b, 22b, 23b & 30c). All meetings were quorate and in 2 of the 3 meetings the absent D-member submitted comments.

c 2.3.6

It was identified that pilot studies may be submitted by Investigators for approval by the AEC under the same review process used for a full application.

c 2.3.14

Reuse of animals is addressed in the Animal Ethics Application (Documents 15a & 15b) by the Investigator and assessed by the AEC in the project review process. The reuse and repeated use of animals is addressed in questions RRR5 and RRR6 for both application forms and also PDC1 for wildlife studies. Questions RRR5 and RRR6 are yes or no answers while PDC1 requires an explanation .

There is no specific requirement to justify the reuse other activities. Please refer to the comments made for c 2.7.4 (v).

c 2.3.15

In determining the duration of approval for individual projects, the Committee will take into account the number of years for which the project is funded, any milestones or stages outlined in the project, and any formal agreements between the University and the funding bodies. The AEC assesses the information in the application including how long the project is funded for and , any milestones or stages outlined in determining the duration of approval. For example the research project for review is approved for two (2) years and the teaching project is approved for 3 years. The research project listed a funding period provided as (1) year from 2018 - 2019.

c 2.3.16

Monitoring the care and use of animals

The AEC monitor the care and use of animals through annual inspection reports of animal facilities and projects. Evidence of routine 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 25a - 25j). In seven (7) of the nine (9) inspection reports (2018 - 2019) provided for review C- and/or D-members were present. All inspections undertaken in 2019 included a C- and / or D-member. Records of inspections follow a consistent format and records are maintained by the ORE. However it was unconfirmed that all members

present signed off on the inspection as signatures were not on the copy provided for review. Inspections reports provide a brief outline of infrastructure, husbandry, monitoring and protocols. Any problem areas may be identified and actions to rectify problems recommended. Please note: 2020 had a disrupted schedule due to the COVID-19 restrictions, the AEC sought to use alternative methods including photographs and video in the interim.

It is noted that inspections of interstate (Victorian) sites have been delayed due to COVID-19 travel restrictions and the ORE have undertaken to liaise with the interstate institution using the CQU AEC and State Regulators to negotiate an acceptable outcome (Document 21b).

c 2.3.17 - c 2.3.23

Taking action regarding unexpected adverse events

The AEC have a documented process and form (Document 19) for managing UAEs (Document 5 - Procedures: *Unexpected adverse events and Appendix A: Unexpected adverse events and Appendix B: AEC Administration processes*). To support the management of unexpected adverse events and include a procedure and reporting form (Document 19). At the time of review the ORE submitted a Decision-Tree or Course of Action (version 3) to assist with decisions for the management of UAEs and the AEC has reviewed and made suggestions for additions to the process including clear timeframes, references to the Code, an 'Urgent Action' directive and the contact for the AWO. The committee considers this to be a valuable tool and felt it would give Investigators and Teachers, including those based off-campus a clear and consistent structure for managing UAEs. The AEC discussed a UAE that had occurred at an interstate institution using the CQU AEC during the AEC meeting (07 October 2020). Discussions of the incident, how it was managed and the responsibilities under the formal agreement (Document 37a & 37b) led to an outcome to review the management of the incident and follow-up on submission of a report form as it was submitted by email (Document 30I). It was agreed that the proposed version of the Decision-Tree would assist with this process in the future.

c 2.3.24

Taking action regarding non-compliance

The institution and AEC have procedures in place to manage non-compliance (Documents 5 & 6 - Procedures: *Non-compliance with the Code* [4.46] & [4.22 - 4.21]) No examples were identified during the review period. Instances where potential non-compliance were identified were follow-ed up by the AEC Chair or ORE and managed to achieve a compliant result, including submissions of annual or final reports.

c 2.3.25

Approving guidelines for the care and use of animals

The AEC, considers and approves guidelines for the care and use of animals referred to it by the institution including procedures for monitoring and maintaining the wellbeing of animals and UAEs and approval in advance for disease outbreaks. Examples include the processes for approving SOPs / SRPs for the care of cattle and sheep at CQIRP (Documents 35 & 36).

c 2.3.26

Providing advice and recommendations to the institution

The AEC, under its TOR (Document 4 & Document 5 - *Procedures: Providing Advice to, and reporting to the institution*) provides advice and makes recommendations to the institution through the annual reporting process and AEC Chair or the Office for Research. It was established in discussions with the AEC Chair and Ethics Coordinator that the AEC are able to provide comment or make recommendation on a range of issues

related to the care and use of animals, animal facilities associated with CQU and any matters that may affect how it fulfils its obligations under the Code.

c 2.3.27

Reporting to the institution

A written annual report is prepared by the Ethics Coordinator, approved by the AEC and the AEC Chair before being provided to DVCR for review by the institution. The AEC annual reports (Documents 12a, 12b & 12c) submitted to the institution provide information on:

- Major events
- External review
- On-site and Off-site inspection of animal facilities that includes the physical facilities for the care and use of animals by the institution.
- Compliance reporting - outlining the timeline for reporting to all State and Territory authorities where CQU is registered or holds a licence. (Use or supply of animals for scientific purposes)
- Committee matters:
 - Applications including numbers and types of projects and activities assessed, and approved or rejected.
 - Policy and procedures - further development or review of governance documentation.
 - Training including actions that have supported the educational and training needs of AEC members and people involved in the care and use of animals. This includes formal in-house or external training, attendance at ANZCCART, ANZLAA or networking and other opportunities for professional development.
 - Breach of ethical conduct (Nil reported for 2018 - 2020)
 - Adverse Events
 - Complaints (Nil reported for 2018 - 2020)
 - AEC Meetings outlining the number of meetings for the year
 - AEC membership outlining the membership and attendance for the year
 - The three R's's: Replacement, Reduction, Refinement outlining any promotion of the 3 'R's within the institution, for e.g. Training.
 - Recommendations to the Research Committee any resourcing requests for e.g. training or additional diagnostic requirements or external review to comply with State and Territory regulations.
 - Other issues including the results and suggestions arising from the AEC's self-evaluation surveys.
- Current Projects - a table listing current projects for the year.

c 2.3.28 - c 2.3.29

Table 3: 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>Attendance at AEC meeting (07 October 2020) confirmed that a quorum (A, B, C & D members present) was maintained and the C- and D- member balance of (total membership 9:2 C & D members present) was not in-line with the Code requirement of one-third of members present. Present at the meeting was a newly appointed D-member participating in the meeting for the first time. Review of the minutes (Documents 21b, 22b, 23b & 30c) identified that the balance of C and D members in the total membership of appointed members was not achieved at 3 meetings held during 2020 (Documents 21b, 22b, 23b & 30c). All meetings were quorate and in 2 of the 3 meetings the absent D-member submitted comments.</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 2.3

SECTION 2.4 - Responsibilities of Investigators

CQU Investigators (and Teachers) are required to acknowledge and work within the Animal Ethics Framework to meet their responsibilities under the Code in regard to their use of animals for scientific purposes.

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 may meet their obligations under the Code.

c 2.4.1 - c 2.4.5

Planning Projects

To proceed with a project, Investigators were found to complete an Animal Ethics Application form (Document 15a & 15b) for ethical review and approval by the AEC in accordance with the institutional procedures. The application form is designed to ensure the Investigator has considered and apply the governing principles and specific Code requirements to the animal use associated with their planned research (please refer to the review findings - Chapter 2.7 of the Code for the detail included in application forms). The Investigator is required to provide information in the AEC format outlining the use in sufficient detail to satisfy the AEC that the proposed animal use falls within ethics guidelines. Animal research and teaching applications reviewed (Documents 28c, 29b & 30g) provided examples of responses to the AEC's questions regarding research and teaching projects. Investigators and Teachers were found to have provided information in their responses to questions in the application form or as requested Documents 28k & 29i) provide additional information to the AEC 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 and Teachers identify if they are involved in collaborative studies in the Animal Ethics Application form (Document 15a & 15b - *Collaboration: C1 - C5*).

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 15a & 15b) or Modification request (Document 16) to the AEC for approval. In addition Investigators must provide information to support their submission to the AEC during the review process, if requested, before approval is granted and the work can commence (Documents 28k & 29k). The Investigator is not permitted to commence animal use project or activity or implement an amendment until they have written AEC approval.

c 2.4.10 (i-ii)

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

c 2.4.11

Investigators were found to use plain English (lay language) as instructed in the guidance documents for preparing applications (Documents 15a & 15b) avoiding the use of technical language so that they can be understood by an educated person without a scientific background. The projects provided for review included plain English descriptions responses where appropriate.

c 2.4.12

Conducting and reviewing projects

To undertake an approved project, the Investigator agrees to and adhere to the standard conditions or any other conditions imposed by the AEC. In the projects reviewed Investigators were seen to have signed the forms to agree to the AEC conditions and been issued with an *AEC Meeting Outcome* email clearly outlining these conditions (Documents 28a & 29c).

c 2.4.13

Investigators and Teachers are required to act in accordance with the conditions of AEC approval and the requirements of the Code.

c 2.4.14

Investigators and Teachers submit an application for ethical review and approval by the AEC. The on-line form and guidance documents prompt 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 ethical acceptable. Completed Animal Ethics Applications reviewed (Documents 28c, 29b & 30g) provided examples of responses demonstrating the Investigator's consideration of Code requirements when answering the AEC's questions regarding the conduct of the project. **Please refer to the comments made for c 2.7.4 (ii - xxiii) for additional information.**

Investigators provided information in their responses to questions in the application 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
- Using privately animals An example was provided of a *Producer Consent form* (Document 45). This form details specific information in regard to the use of privately owned animals and is supplemental to the approved AEC activity.

c 2.4.15 - c 2.4.29

Maintaining records

Investigators at CQU (CQIRP) were found to maintain records that include the care and use of animals, monitoring and assessment. These records were made available to the AEC during facility inspections and external reviewers during review CQU29082920. The ERP saw examples and discussed animal care records that logged the husbandry and monitoring procedures performed in the facility. These records demonstrated a consistent and thorough system of recording information including the physical environment, husbandry, experimental procedures and general health for animals (cattle, pigs, sheep & poultry).

c 2.4.30 - c 2.4.33

Reporting

The document review provided examples of documents submitted by Investigators including, progress (Document 28h, 28i & 29f) and final reports (Document 28j), unexpected adverse event reports (Document 30i) and other correspondence to requests from the AEC.

The example of an adverse event report seen during the review was submitted by an Investigator from an institution external to CQU that accesses the CQU AEC. The report was not submitted on the standard form but via a detailed email outlining the incident. The AEC had undertaken at the meeting (07 October 2020) to follow-up with the Investigator in regard to the required reporting procedures.

c 2.4.34

Table 4: Section 2 - Chapter 2.4 Review Findings Identified as Areas Highlighted for Review by the Institution.

Code Reference	Review Finding
c 2.4.34	<p>The document review provided examples of documents submitted by Investigators including, progress (Document 28h, 28i & 29f) and final reports (Document 28j), unexpected adverse event reports (Document 30i) and other correspondence to requests from the AEC. The example of an adverse event report seen during the review was submitted by an Investigator from an institution external to CQU that accesses the CQU AEC. The report was not submitted on the standard form but via a detailed email outlining the incident. The AEC had undertaken at the meeting (07 October 2020) to follow-up with the Investigator in regard to the required reporting procedures.</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 2.4

Chapter 2.5 - Responsibilities of animal carers

CQU Animal carers (including Animal Technicians, Investigators, Teachers and Students) 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 CQU's Rockhampton campus including the small animal house, labs where animals are used and the CQIRP animal facility. The on-site visit allowed inspection of the infrastructure and discussion surrounding the processes involved in caring for animals used for research and teaching with the AEC Chair, Investigators, Teachers and Animal Technicians.

From the discussions it was evident that animal carers have good lines of communication within the animal ethics framework and the facilities are managed to maintain a high standard appropriate for the animals they accommodate. All those involved demonstrated a high level of commitment to caring for the wellbeing of the animals in their care and the for work they undertake. There was a high level of understanding of the animal ethics framework and solid knowledge of the Code.

Responsibilities

Those caring for animals at CQU were found to undertake the responsibilities outlined in Section 2: Chapter 2.5 in collaboration with Chief Investigators, the AEC and the institution.

c 2.5.1 - c 2.5.13

Support animal wellbeing

Animal carers at CQU were found to support animal wellbeing by:

- providing for the species-specific needs of the animals and provide care and enrichment suitable for their physiological and behavioural needs. This was evident in the management of cattle, sheep and poultry housed in the CQIRP facility and in the animal house (no laboratory animals, rats or mice, were housed in the facility at the time of the review)
- using procedures and practices appropriate for the animals 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 carers were found to be responsible for the day-to-day care of animals in the animal facilities including husbandry and monitoring. Training and guidelines for the maintenance of the animals and their environment is provided and Staff and Students undergo induction and are supported and supervised by the facility, research and teaching Staff including access to specialist veterinary services at the facility. Through discussions during the on-site visit 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, biosecurity information and security services were identified.

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 within facilities for treatment, storage and disposal.

c 2.5.7 - c 2.5.10

Maintain records

Animal carers were seen to maintain records that include the care and monitoring of animals including stock records, health status and movement of animals. Animal carers made these records available to the institution, the AEC, Authorised External Reviewers and Investigators.

Records of animal monitoring reviewed on-site were sufficient to enable the AEC to verify that the wellbeing of animals is monitored, and allows for adequate review and critical investigation of the cause(s) and subsequent responses to unexpected adverse events as a basis for future prevention strategies. Examples were discussed including actions to prevent predation of livestock (cattle & sheep), heat stress and faulty incubators (poultry).

The ERP saw examples of animal care records that logged the environmental 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

Discussions and observations undertaken during the review provided detailed information and demonstrated a thorough knowledge of the animals and the facility. There is no one position that has oversight for all CQU animal facilities.

The Animal House has a Manager (away on a field project at the time of the review) who is a qualified Senior Technician with experience in research and teaching using laboratory and wildlife animals oversees the small animal facility that houses rodents (no rodents on-site at the time of the review). This position is a 2.2.25 appointment to the AEC.

CQIRP accommodates:

- cattle - a small herd used for teaching,
- sheep - a small flock for used for teaching,
- pigs - no pigs on site at the time of the review and
- poultry - for commercially-funded research

The animals are managed by competent CQU Staff including Investigators, Teachers and the Senior Technician with support from the AEC Chair, CQU or local Veterinarians. Animals are under the care of the Chief Investigator and the team associated with the AEC approved project. There is a full-time Senior Technician to oversee the routine care and maintenance of CQIRP livestock. Poultry are closely managed by the Chief Investigator and their team that includes a poultry-specialist Veterinarian.

Please Note: Belmont Research Station has a property manager. (Not visited during the review)

Facilities appeared well resourced with staffing levels appropriate for the number of animals observed and resources for equipment, maintenance and improvements available for infrastructure. Animals observed on-site appeared to be managed, appropriately housed and maintained at a high standard of wellbeing.

Please note: Due to COVID-19 it is unlikely that funds will be available for capital works projects unless deemed essential. This has the potential to adversely affect animal facilities on site at the Rockhampton campus and at Belmont Research Station.

c 2.5.14 - c 2.5.17

END OF REVIEW FINDINGS RELATING TO SECTION 2 - CHAPTER 2.5

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

Institutions and Investigators that use an external animal ethics committee

CQU (as the 'host' institution) agrees to accept, review and monitor animal use activities from other institutions or Investigators external to CQU (the 'second' institution) for approval and oversight by the CQU AEC.

CQU provides guidance in the (Document 2 - 4: *Procedures* - 4.47) and a formal agreement to ensure all parties are aware of, and can meet their responsibilities under the Code. An example formal agreement (specific to the CQU / external party relationship) was provided for review included the that specific requirements of c 2.6.2. (Documents 37 a & 37b)

CQU does not use an AEC established by another institution, to provide ethical oversight for its animal use activities undertaken by Investigators or Teachers on behalf of CQU.

c 2.6.1 - c 2.6.3

Projects involving more than one institution and/or animal ethics committee

CQU provides guidance in the (Document 2 - 4: *Procedures* - 4.43) and a formal agreement, the *Collaborative Agreement - Animal Ethics* for collaborations involving CQU Investigators and Teachers, animal facilities or projects associated with another institution and / or AEC. An example (specific to the CQU / external party collaboration) of a completed *Collaborative Research Application form* that clearly sets out the responsibilities of each AEC was provided for reviewed. (Document 38)

At the time of the review CQU had entered into an agreement with external parties (AgForce) in regard to stock and facilities at the Belmont Research Station. No agreements were sighted during the review and there was some dissatisfaction with management at the property. Activity at Belmont Research Station was on hold at the time of review and was subject to discussion in regard to maintenance issues at that site. This was an item that has been retained on the AEC's Action Sheet for several months.

c 2.6.4 - c 2.6.8

Projects conducted by Australian Investigators and institutions in other countries

CQU provides guidance to Investigators and Teachers for the use of animals in projects overseas through the application process (Document 2 - 4: Procedures 44 - 45). Guidance includes, " *When considering approval for a project to be conducted in another country, the Committee may accept approval granted by a local AEC or its equivalent if it is satisfied that outcomes would be equivalent to those expected through application of the Code ,*" and ' *The Committee must ensure that animal use and care in the other country is adequately monitored. The Committee may appoint an agent or delegate to conduct the monitoring and inspection on its behalf .*"

At the time of the review the CQU ORE had been investigating the animal welfare requirements in other countries (Indonesia and Argentina). Investigators and Teachers are required to adhere to institutional processes to obtain AEC approval for anyone of animals for scientific purposes and comply with the institution's review, monitoring and reporting requirements.

c 2.6.9 - c 2.14

END OF REVIEW FINDINGS RELATING TO SECTION 2 - CHAPTER 2.6

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

CQU has developed, in consultation with the AEC, an application form for research and a separate form for teaching, (Documents 15a & 15b) applications for AEC approval to commence a project or activity using animals.

The institution has developed, in consultation with the AEC, an application form for the modification or amendment of an AEC approved teaching or research project or activity (Document 16).

c 2.7.1

The institution provides on-line application forms that allow for the provision of information required by the AEC to assess the ethical acceptability of the proposed use of animals.

c 2.7.2

The guidance document (Document 13) for completing an application form instructs Investigators and Teachers to, " *Write the application in plain English. Define and explain all terminology and acronyms. Check your spelling,*" and, "*The project description should be brief and descriptive of the project and in plain English.*" The institution clearly states in the application (Documents 15a & 15b), "*Your response should be directed to an educated, non-scientific audience and please ensure any acronyms are explained.*"

c 2.7.3

CQU provides an on-line Animal Ethics Application form for research (RA) and a separate form for teaching (TA) , (Documents 15a & 15b) allowing the Applicant to provide the information listed in c 2.7.4 [i - xxiii] as appropriate to their particular circumstances.

Table 5 - Review of the Animal Ethics Research (RA) and Teaching (TA) Applications (Documents 15a & 15b)

Governing Principle 1.1 Reference	Code Reference	Addressed in Review Application (RA) & Teaching Application (TA)
Using animals only when it is justified (1.1 - 1.7)	c 2.7.4 (i - v)	<p>(i) (RA) & (TA) question O9.</p> <p>(ii) RA question O11 and TA questions T1 & T2.</p> <p>(iii) RA questions A2, RRR1.1, RRR1.2, RRR2 & RRR3 and TA questions A2, RRR1.1, RRR1.2, RRR2, RRR3 and RRR3.1.</p> <p>(iv) RA question O11 (in part – only potential benefits of the project) and TA not specific question. Both application forms allow the provision of information in various other questions (relating to potential benefits, 3Rs etc) for the AEC to consider ethical acceptability, however, it would be beneficial for Investigators to state in their own words their justification as to the ethical acceptability and whether potential benefits of the work ethically outweigh the potential impacts.</p> <p>(v) The reuse and repeated use of animals is addressed in questions RRR5 and RRR6 for both application forms and also PDC1 for wildlife studies. Questions RRR5 and RRR6 are yes or no answers while PDC1 requires an explanation. There is no specific requirement to justify the other activities.</p>
Applying high standards of scientific integrity (1.15 & 1.17)	c 2.7.4 (vi - vii)	<p>(vi) Question O9 in both applications and also question O10 in the research application form. Question O9 requires a statement of aims while question O10 expands on the relationship of the aims of the proposed work with previous or ongoing studies and why existing knowledge is inadequate.</p> <p>(vii) Research Application Form questions L1, L1.2, L1.2.1, L1.3, A1, A3, A4, RRR5 and PDO1. Teaching Application Form questions L1, A3, RRR5</p>

Governing Principle 1.1 Reference	Code Reference	Addressed in (RA) & (TA) forms address c 2.7.4
Applying Replacement, Reduction and Refinement (the 3Rs) (1.18 - 1.30)	c 2.7.4 (viii - x)	<p>(viii) Both application forms questions RRR1.1, RRR1.2, RRR1.3</p> <p>(ix) Research Application Form questions A2 and RRR1.2 Teaching Application Form questions A2, RRR1.2 and T5 (in part).</p> <p>(x) Research Application Form question RRR11. Teaching Application Form questions RRR11 and RRR12</p>
Supporting the wellbeing of animals (1.8 & 1.9)	c 2.7.4 (xi - xiii)	<p>(xi) Research Application Form question L1, L1.2, L1.2.1, L1.3, PD2, PDC0, PDC2, PDC4, PDC8 to PDC16, PDC19, PDT1, ACW1 to ACW11. Teaching Application Form questions L1, L1.1, PD2, ACW1 to ACW11.</p> <p>(xii) Research Application Form question L1, L1.2, L1.2.1 and L1.3, Teaching Application Form questions L1 and L1.1.</p> <p>(xiii) No specific question to address this included.</p>
Avoiding or minimising harm, including pain and distress, to animals (1.10 - 1.14)	c 2.7.4 (xiv - xv)	<p>(xiv) General animal welfare considerations in questions ACW1 to ACW11 (both applications).</p> <p>The Research Application has additional requirements for observation studies (PDO1 to PDO6), Capture and trapping (PDC0 to PDC21), euthanasia (PDE1, PDV1 and PDV2), marking and trapping (PDM1 to PDM11) and transportation (PDT1 to PDT9).</p> <p>(xv) Various throughout the application forms, and specifically PDM7 and ACW2 to ACW11.</p>

Governing Principle 1.1 Reference	Code Reference	Addressed in (RA) & (TA) forms address c 2.7.4
<p>Knowing and accepting responsibilities (1.31 - 1.32)</p>	<p>c 2.7.4 (xvi - xxiii)</p>	<p>(xvi) Under personnel in both applications, a person's position in the project is given. Item (d) of the Chief Investigator's/Teacher-in-Charge's declaration states "to accept for the duration of this activity full responsibility for the welfare of all animals used in this research/teaching project".</p> <p>(xvii) For teaching and research applications, a title is required in question O2 and all people involved in the project are listed under personnel. This includes a description of their role in the project and the activities that they will conduct.</p> <p>(xviii) Each application requires all personnel to:</p> <ul style="list-style-type: none"> • Please outline your relevant qualifications • Please outline your experience and training in animal research, with particular reference to the species you are intending to use in this application <p>The declaration for the Chief Investigator/Teacher in-charge requires:</p> <ul style="list-style-type: none"> • (f) only personnel with a respect for animal welfare and competent to perform the work in this research project/teaching activity that involves the use of the animals will be permitted to use the animals in this research project. <p>(xix) Details for funding for the research project applications are required in F1 to F4. The declaration for the Chief Investigator/Teacher in-charge requires:</p> <p>(j) adequate resources will be available to undertake the research project</p> <p>(xx) All personnel are listed in each application.</p> <ul style="list-style-type: none"> • The teaching application's questions P2 and P3 allow for Staff from other institutions to also be listed. • The research application allows for collaboration details (questions C1 to C5) to be included. Question L1.3 requires details of location/facilities outside CQUniversity. <p>(xxi) The research application requires potential conflicts of interest of funding bodies (Question F4) and any team member (question P4) to be declared. The teaching application requires only team member conflict of interest to be declared (question P4).</p> <p>(xxii) The applications have extensive requirements for other details:</p> <ul style="list-style-type: none"> • Collaborations (C1 to C5) (Research Application only) • Indigenous considerations (L1.2.3) (Research Application only) • Licenses (LP1) • Risk management (RM1 to RM5) • Data management (DS1 to DS4) <p>(xxiii) Both the research and teaching applications require suitable declarations by the Chief Investigator and Teacher-In-Charge.</p>

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

Some activities related to the care and management of animals are provided to the AEC in SOPs or SRPs. An example for the care and management of Cattle Management at CQIRP (Document 35) was reviewed .

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 Modification request (Document 16) is available and includes relevant information for review and approval by the AEC.

c 2.7.6

Table 6: Section 2 - Chapter 2.7 Review Findings Identified as Areas Highlighted for Review by the Institution.

Code Reference	Review Finding
2.7.4 (iv)	RA question O11 (in part – only potential benefits of the project) and TA not specific question. Both application forms allow the provision of information in various other questions (relating to potential benefits, 3Rs etc) for the AEC to consider ethical acceptability, however, it would be beneficial for Investigators to state in their own words their justification as to the ethical acceptability and whether potential benefits of the work ethically outweigh the potential impacts.
2.7.4 (v)	The reuse and repeated use of animals is addressed in questions RRR5 and RRR6 for both application forms and also PDC1 for wildlife studies. Questions RRR5 and RRR6 are yes or no answers while PDC1 requires an explanation. There is no specific requirement to justify the other activities.
2.7.4 (ix)	Research Application Form questions A2 and RRR1.2 Teaching Application Form questions A2, RRR1.2 and T5 (in part).
2.7.4(xiii)	No specific question to address this included..

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 2.7

SECTION 3.1 - Strategies to Support and Safeguard Animal Wellbeing

In the planning stages of any animal use Investigators and Teachers are required to identify, consider, avoid or minimise pain and distress, monitor and establish appropriate parameters to support animal wellbeing. Investigators and Teachers, in completing the animal ethics on-line application form are prompted by the questions to ensure adequate consideration is given to safeguarding animal wellbeing. The planning and conduct of activities involving the care and use of animals was found to support and safeguard animal wellbeing.

c 3.1.1

The AEC must be satisfied with the information provided in the Animal Ethics Application that these requirements are met. The AEC monitors projects to ensure animal wellbeing is being safeguarded, this includes inspecting sites where animals are kept.

Investigators and Teachers demonstrate they have given adequate attention to this by:

Identifying known and potential causes of adverse impacts on animal wellbeing

This is done by detailing in the Animal Ethics Application, the acquisition, capture, 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

Investigators and Teachers support and safeguard the animals' 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

Avoiding or minimising adverse impacts on the animal's wellbeing and setting intervention points and humane endpoints was discussed for routine husbandry and experimental procedures with examples of proposed and completed monitoring forms made available for review during the inspection. Procedures were also available or included in projects to support the wellbeing of animals. Discussions on-site with Investigators, Teachers and Technicians provided details of how they monitor the animals to avoid unnecessary pain and distress in the layers, broilers and hatchlings. Potential causes of pain and distress including overhanding, adverse environmental conditions and hatching difficulties are eliminated or managed through strict monitoring practices by competent staff.

c 3.1.14 - 3.1.19

Monitor animals and take appropriate action

Investigators and Teachers provide an outline of how animals will be monitored, this may include copies of monitoring sheets and include details of treatment, withdrawal or intervention points. The Investigator or Teacher must comply the conditions of approval including keeping monitoring records and reports to the AEC annually and in the case of an adverse event. Detailed examples provided in discussions of poultry monitoring demonstrated that Investigators and Teachers act promptly and take appropriate actions. In particular in unexpected and emergency situations including equipment faults or sudden climatic events.

c 3.1.20 - 3.1.25

Set intervention points and experimental humane endpoints

Investigators and Teachers address intervention points, end-points if pain and distress are predicted or unavoidable consequences of a project and death as an end point in the Animal Ethics Application where there must be justification for the use and the details of the use are outlined. Investigators and Teachers provide information for the AEC to decide whether the justification and details of use are sufficient to approve the project.

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

Formal review and monitoring processes by the AEC are in place for the lifetime of the project, these included the use of the *Modification Request* form (Document 16), the *Annual or Final Report* form (Documents 17 & 18) and the *Unexpected Adverse Event* form (Document 19).

c 3.1.29

Implement changes to the strategy to ensure its ongoing effectiveness

As a condition of AEC approval, Investigators and Teachers submit any amendment or modification to an activity or project for approval by the AEC.

c 3.1.30

Accept responsibilities

The person responsible for the wellbeing of animals at any given time is identified in the Animal Ethics Application and acknowledges that they understand and accept their responsibilities by signing a declaration outlining the details of their responsibilities.

c 3.1.31- 3.1.32

END OF REVIEW FINDINGS RELATING TO SECTION 3 - CHAPTER 3.1

SECTION 3.2 Animal Care and Management

The review included a tour to the CQIRP facility, the Animal House and laboratories where animals are used at CQU's Rockhampton campus, review of documentation related to the projects undertaken at this facility and discussions with the Investigators, Teachers, Large Animal Technician and the AEC Chair.

At the time of review minimal numbers of animals were being maintained on-site due to the circumstances related to COVID-19 restrictions.

Documentation demonstrating how animals are acquired, accommodated, used and cared for in the facility was provided for review. Documentation included applications and reports (annual progress, completion and unexpected adverse reports) submitted to the AEC. CQU also provided for review, AEC inspection reports for projects and on-site facilities (Documents 25a - 25j) and other locations where animals were used including Belmont Research Station. Activity at Belmont Research Station was on hold at the time of review and was subject to discussion in regard to maintenance issues at that site. This was an item that has been retained on the AEC's Action Sheet for several months.

Due to COVID-19 it is unlikely that funds will be available for capital works projects unless deemed essential. This has the potential to adversely affect animal facilities on site at the Rockhampton campus and at Belmont Research Station. As this develops CQU will continue to assess, consider and take any action to manage the situation.

Discussions during the on-site visit related to animal health, acquisition and breeding, transport of animals, admission of new animals to breeding and holding facilities, acclimatisation and conditioning, housing and care, indoor facilities, tanks, food and water (environment).

From the information provided for review, the External Review Panel were satisfied the the AEC monitors facilities and projects to ensure they support and safeguard animal wellbeing during their care and management.

The CQIRP facility discussions included:

- staff outlining their qualifications and experience working with animals (sheep, cattle & poultry) and demonstrated a comprehensive knowledge of animal ethics and the AEC procedures.
- the management of the animals including:
 - routine livestock husbandry, health surveillance, low-stress handling and experimental procedures
 - improvements in the facilities including infrastructure, equipment and security since the last review in 2016
 - preparing (selection, acclimatisation and monitoring) of animals for research projects and teaching activities

- specific management and experimental procedures used for poultry (broilers, layers and egg-hatching)
 - animal monitoring and the maintenance of the livestock and poultry facility.
 - intervention points and humane killing
 - veterinary support and care.
- outlining procedures for emergencies, site maintenance, animal health, hygiene and biosecurity. Appropriate emergency and biosecurity signage was identified for the site. Examples of UAE 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 acquisition, breeding, housing, care, management, and the monitoring of animal health and environmental conditions.
 - The tour of the laboratories, indoor and outdoor facilities, specially designed equipment (mice at CQIRP Laboratory G19) and the general layout of the facilities.
 - Discussion around animal management in regard to the restrictions placed on Staff and sites during COVID 19 and the effect this has had on managing projects and animals to avoid wastage.

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 (no animals present) animals are provided with accommodation, physical and social environmental conditions, food, water and care 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 and CQIRP facilities are Staffed (Investigators, Teachers and Students), designed, constructed, equipped, maintained and managed to achieve a high standard of animal care and they are suitable for the type of animals kept and the aims of the activities undertaken.

c 3.2.14

Animals held outdoors at CQIRP were observed to be protected from adverse environmental conditions and predation, and provided with access to adequate shelter, food and water.

c 3.2.15

Indoor facilities

The animal house and poultry housing at CQIRP 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 or by the individual animals should be taken into account
- enable appropriate segregation of species or activities that might affect other animals held in the same facility
- 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 house (no animals present) and poultry housing at CQIRP was clean, tidy and in good repair . Walls and floors are constructed of safe, durable materials that can be cleaned and disinfected readily. 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 in the animal house - no animals present.

c 3.2.19

Chemicals seen in the animal house and CQIRP facilities, including detergents, disinfectants, deodorisers and pesticides were seen to be appropriate for the purpose.

c 3.2.20

Pens, cages and containers

Pens, cages and containers seen in the animal house and at CQIRP were constructed of safe, durable materials, clean, maintained in good repair, secure and escape-proof, were protective of animals 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

The number of animals (CQIRP only) in, and placement of, cages, pens or containers did enable the social and environmental conditions for the species to be maintained.

c 3.2.21 - 3.3.23

Food and water

Animals observed at CQIRP 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. Provisions in the Animal House indicate that the supply of food and water is in-line with the requirements.

c 3.2.24 - 3.3.25

From the information provided for review the External Review Panel were satisfied the CQU Staff manage the 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

Specific procedures involved in the care and use of animals are outlined in Animal Ethics Applications or SOPs and approved by the AEC. It was identified that procedures identified during the review were appropriate for the species (cattle, sheep, poultry, fish and mice) accord with best practice, are compatible with the aims of the activities, cause the least harm, are performed competently. Examples of procedures were found detailed in the projects and SOPs submitted to the AECs for approval.

Examples included:

- Handling and restraint of animals - procedures used and taught for handling and restraint were discussed with CQIRP staff and it was established that livestock & poultry handling is low-stress to accord with best practice, in particular poultry undergo minimal handling to avoid the stress caused by overhandling.

c 3.3.2 - c 3.3.4

- Routine husbandry practices - routine husbandry at CQIRP is undertaken by experienced and qualified Teachers, Investigators and the Large Animal Technician supported, as required by a local veterinary clinic. Wildlife and laboratory animals are managed and cared for by an experienced and qualified Senior animal Technician supported by the teaching and research Staff, a local veterinary clinics, wildlife carers and Queensland Parks and Wildlife Service (QPWS) advice.

c 3.3.5

- Identification of animals - CQIRP sheep and cattle are fitted with identification tags under the National Livestock Identification Scheme (NLIS), poultry are identified by their locations and groups, there were no rodents or pigs present at the time of the review.

c 3.3.6

- Injections, sampling (non-invasive) and non-surgical procedures, the use of anaesthetics, analgesia and sedation, the management of pain and distress and care of animals post-procedure - was discussed on-site and in on-line interviews. It was established that procedures used are approved by the AEC in animal ethics projects or SOPs. Veterinary assistance and advice is available from local veterinary clinics or on-site Veterinarians including the AWO.

c 3.3.7 - c 3.3.18)

- **Please note:** Not all categories of procedures were identified during the review - comments are based on the details and descriptions of procedures. For example, no Induction of tumours (c 3.3.23) or Immunomodulation and the production of antibodies (c 3.3.31 - c 3.3.32) were identified in the information contained in the data sample.

Wildlife and field techniques

Details specific to wildlife are addressed in the Animal Ethics Application. Investigators and Teachers are required to outline the details of activities including capture, handling, trapping, transport, holding, release, tracking, interference and the collection of voucher specimens used in the activity or project with sufficient detail for the AEC to make an assessment on its ethical acceptability. Studies involving vertebrate pest animals are not specified however they may be submitted under the same conditions of approval as other wildlife. Some procedures, such as handling noxious fish, handling cane toads and capturing mud crabs are either approved (mud crabs) or being reworked prior to AEC consideration.

c 3.3.33 - 3.3.45

Humane killing

The methods used for humane killing are outlined in the Animal Ethics Application and Investigators and Teachers are required to outline the details of the methods of euthanasia used in the activity or project with sufficient detail for the AEC to make an assessment on its ethical acceptability. SOPs are available for the humane killing of rodents, sheep and cattle (Document 27). The humane killing of poultry was discussed in with Investigators at CQIRP and the detailed plan for scheduled euthanasia includes a well-planned procedure that is undertaken quietly, quickly and with a Veterinarian present to monitor the procedure. The procedures involved in the humane killing of poultry (eggs, layers and broilers) were found to be consistent with accepted procedures and monitored by a poultry Veterinarian. Veterinary assistance is sought for the euthanasia of large animals (sheep, cattle or pigs) if required. Humane killing of wildlife (fish) was discussed and current recommendations (MS222) are used if there is a need to euthanise fish. An example of this was identified in the Animal Ethics Application submitted for approval at the AEC meeting (07 October 2020) (Document 30g). In cases where other wildlife (reptiles, mammals and amphibians) is required to be euthanised specialist advice, including veterinary assistance is sought.

c 3.3.45 - c 3.3.46

END OF REVIEW FINDINGS RELATING TO SECTION 3 - CHAPTER 3.3

SECTION 3: Chapter 3.4 - Provisions for animals at the conclusion of their use

CQU Investigators and Teachers ensure that provisions for animals at the conclusion of the use is identified include rehoming, the return to normal husbandry conditions or natural habitat, humane killing, reuse and tissue sharing. Information is provided in the Animal Ethics Application (Document 15a & 15b - *Fate of the Animals*) submitted to the AEC.

CQU:

- provides access to veterinary support from on-site or local Veterinarians or the AWO to undertake humane killing when necessary.
- provides SOPs for humane killing
- encourages tissue sharing
- requires Investigators and Teachers to address the fate of animals at the conclusion of use in the Animal Ethics Application (Document 15a & 15b - *Fate of the Animals*) for approval by the AEC.

c 3.4.1 - c 3.4.5

END OF REVIEW FINDINGS RELATING TO SECTION 3 - CHAPTER 3.4

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 frame work 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 CQU AEC to oversee the care and use of animals in teaching activities 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 Animal Ethics Teaching Application (Document 15b), submitted for review by the AEC.

c 4.3

The person with ultimate responsibility is identified in the Animal Ethics Teaching Application (Document 15b), submitted for review and approval by the AEC. The information submitted includes:

- (i) a declaration that 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 found to be relevant to the business of the institution. The institution does participate in providing vocational qualifications through an affiliation with Technical and Further Education Queensland (TAFE QLD).

Animal Ethics Committees

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

c 4.8

Teachers as Investigators and animal carers

Teachers at CQU were found 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

The responsibility to educate students about animal ethics is the responsibility of the Chief Investigator (Teacher). Arrangements for students to discuss the ethical, social and legal issues are outlined in the Animal Ethics Teaching Application (Document 15b - *Teaching* - Question T 7). CQU Teaching staff discuss animal ethics with students and require that a level of understanding be achieved. Examples provided included:

- general discussions during in classes and practical sessions,
- required readings including relevant sections of the Code, the *Guide to Acceptable Procedures & Practices*.
- presentations from QPWS Officers

c 4.12

Employment processes to ensure those engaged to teach (including the care and use animals) on behalf of CQU have the necessary qualifications and experience to undertake their duties. Qualifications to participate in the teaching activities using animals is outlined in the Animal Ethics Teaching Application (Document 15b - *Personnel* - Table 1).

c 4.13

Rehoming is an option addressed in the Animal Ethics Teaching Application (Document 15b - *Fate of the Animals*) at the conclusion for animals at the conclusion of use and is subject to AEC approval.

c 4.14 (i- iii)

Obtaining approval from an animal ethics committee

Teachers apply to the AEC using the on-line Animal Ethics Teaching Application (Document 15b) form for animal use activities. In the application sufficient information must be provided for the AEC to be satisfied that the work meets the Code and any institutional requirements for approval.

c 4.15

Information regarding locations, times, animals or students that may differ during an approved teaching activity are required to be provided to the AEC via a modification request for approval prior to the implementation of the change. Minor modifications may be reviewed and approved by the AEC Executive.

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.

Some activities occur on Belmont Research Station and other CQU locations, these may qualify as not requiring approval however it is advised to review each specific situation and seek advice from the AEC Chair, AWO or ORE. In specific situations institutional requirements, for example a *Producer Consent form* (Document 45) may be required.

c 4.17 (I - iv)

END OF REVIEW FINDINGS 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

The institution 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. These policy and procedures, (Documents 4, 5, 6 & 7) are publicly available on the CQU Animal Ethics Committee Webpage and in particular webpage: https://www.cqu.edu.au/_data/assets/pdf_file/0018/121725/Animal-Ethics-Committee-Complaints-and-Grievances-Policy-and-Procedure.pdf (Document 7). In addition, “if there is a concern about a research project being conducted by CQUniversity, you can confidentially report this to the Ethics Coordinator,” via a direct telephone or email contact <https://www.cqu.edu.au/research/current-research/ethics-committees>.

c 5.1

The institutional policy (Document 7 - 3: *Policy Statement*) outlines procedures to address complaints and non-compliance in regard to :

- complaints concerning the care and use of animals by the institution, including conscientious objection in the case of teaching activities.
- complaints concerning the Committee process of review of an application or report, including resolution of disagreements between Committee members and the Committee and Investigators
- complaints concerning the process for independent external review
- non-compliance with the Code by any party or person involved in the care and use of animals including Investigators, animal carers, the Committee, governance officials, and external parties subject to agreements (c 2.6.3 - 2.6.7). Non-compliance may also involve breaches of relevant state or territory legislation (c 5.12).

c 5.1(i - iv)

Institutional procedures (Document 7 - 4: *Procedure - Enquiries, complaints and disputes [4.6 - 4.10]*) outline the mechanisms for the General Public, Students and Investigators to make a an enquiry or complaint or raise a grievance in relation to the animal ethics framework including, the use for animals for scientific purposes and the AEC processes.

c 5.2 (i - vii)

Institutional procedures (Document 7 - 4: *Procedure - Multi-institutional projects [4.13]*) state For projects involving more than one institution and/or AEC, procedures should include mechanisms for reporting between the relevant institutions and AECs on complaints and non-compliance.

c 5.3

Receiving, investigating and addressing complaints

Complaints concerning the care and use of animals and animal ethics committee process

A process for receiving, investigating and addressing complaints was identified in the CQU procedures (Documents 5: *Receiving complaints - [4.40]* and 7 - 4: *Procedure - [4.1]*) and Code of Conduct (Document 3)

No complaints during the 2017 - 2020 period were recorded.

c 5.4 - c 5.6

Complaints concerning the process for independent external review and

No institutional procedures for addressing complaints concerning the process for independent external review c 5.1 (iii) however the institution and the independent external review service provider enter into a formal agreement that provides an avenue for addressing complaints (Document 46).

c 5.7

Referral to a person or agency external to the institution.

CQU AEC complaints and non-compliance procedures makes no reference to referral to a person or agency external to the institution.

c 5.8

Addressing non-compliance

The institution has procedures for addressing non-compliance with the Code (Document - Section 4: *Procedures - Non-Compliance with the Code [4.46]* and Document 5 - Section 4: *Procedures - Addressing non-compliance [4.11]*). No matters involving non-compliance during the 2017 - 2020 period were recorded.

c 5.9

The institution through the ORE maintains records associated with AEC business including breaches of the Code.

c 5.10

Advising regulatory authorities

The AEC reports annually to the regulatory authorities of the relevant state governments regarding animal use, depending on the requirements of each state, the institution reports on the specific format for each jurisdiction that may or may not include details of alleged breaches of legislation that had a significant impact on animal wellbeing.

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 - Review CQU29082019

The institution initiated 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.

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)

CQU provided the report from the most recent external review (CQU01102015) in 2016 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 CQU01102015.

c 6.3

Review Panel

The independent external review panel has met its responsibilities in undertaking a review of the CQU animal ethics framework and:

- providing written declaration detailing from each external review panel 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 that included a confidentiality clause specific to review CQU29082019.

c 6.4 (ii)

- developing a process and schedule with the ORE for the manner in which review CQU29082019 is conducted including a desktop review of documents, attendance at an AEC meeting (06 October, 2020), an on-site visit to the Animal Facilities Rockhampton Campus, including CQIRP and meetings (face-to-face and ZOOM) with the AWO, Ethics Officer, Ethics Coordinator and AEC Chair and Members, Investigators and Animal Care Staff.

c 6.5 (i)

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

c 6.5 (ii)

Scope and outcomes of the independent external review

The external review report CQU29082019 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 it's 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 CQU29082019.
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 CQU29082019.
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 CQU29082019.
c 6.7 (iii)

END OF REVIEW FINDINGS RELATING TO SECTION 6

TABLE 7: 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 CQU's procedures are effective and adequate to meet its responsibilities under the 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 review by the institution:</p> <ul style="list-style-type: none"> • c 2.1.5 (v) a • c 2.1.5 (vii) • c 2.2.33 - c 2.2.36 • c 2.3.6 • c 2.4.34 • c 2.7.4 (iv), (v), (ix) & (xiii) <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>

CR1	Code Reference for SNC Clause 2.1.5 [v] a	<p>Promote compliance</p> <p><i>Institutions must promote compliance with the Code by ensuring that guidelines for animal care and use are developed in consultation with the AEC, approved by the AEC, and implemented and promoted within the institution.</i></p> <p><i>Guidelines must include: how the competence of people involved in the care and use of animals will be assessed and ensured</i></p>
RF1	Review Finding in relation to Clause 2.1.5 [v] a	<p>Guidelines must include how the competence of people involved in the care and use of animals will be assessed and ensured. The AEC Chair, ORE ethics officers and AEC members are provided with induction and training, education and networking opportunities. No formal procedure or process was identified, however progress has been made since review</p> <p>CQU01102015 to ensure those involved in the animal ethics framework are competent to undertake their specific roles. Competencies are not currently recorded except for induction records and conference attendance for AEC members. The expectation is that investigators and teachers will provide competency information in applications. Students are monitored and supervised and recording of training and competencies is done in individual units, however it is unclear if this is consistently achieved.</p>
R1	Recommendation in relation to Clause 2.1.5 [v] a	<p>Outline the procedure for assessing how the competence of researchers and teachers is assessed. It is recommended that all people using animals for research or teaching have their experience and qualifications including Animal Ethics (CQU) induction and training (for example ComPass or similar) documented to ensure the AEC has a consistent and complete record of an individual's competency to undertake the procedures involved in using animals for</p>

<p>C1</p>	<p>Comment in relation to Clause 2.1.5 [v] a</p>	<p>A general trend we are seeing across the industry is toward developing system to ensure researchers, technicians, teachers and others are able to formally document not only their qualifications and experience but also competencies in specific procedures and techniques. The advantage of keeping this in one register is that it is recorded in one place and can be added to easily. Some institutions are then leaving it off the animal ethics approval or just providing a code or similar. The AEC still has access and is easy to identify a gap in training or if a refresher or skill update is required. Also is seen as an advantage because it can be in a format that is transportable for future employment, available as a skill-set and accepted at other institutions.</p>
<p>CR2</p>	<p>Code Reference for SNC Clause 2.1.5 vii</p>	<p>Promote compliance <i>Institutions must promote compliance with the Code by considering the appointment of an officer with veterinary or other appropriate qualifications who is authorised by the institution to ensure that activities proceed in compliance with the Code and the decisions of the AEC.</i></p>

<p style="text-align: center;">RF2</p>	<p style="text-align: center;">Review Finding in relation to Clause 2.1.5 vii</p>	<p>The institution created a position for an AWO in 2018 after consideration of recommendations made from the previous external review (CQU01102015) and employs a part-time (1 - 3 days / week) veterinarian in the position of AWO to ensure that activities proceed in compliance with the Code and the decisions of the AEC. At the time of review this position had a role in:</p> <ul style="list-style-type: none"> ▶ advising the AEC, investigators and animal technicians ▶ investigating of UAEs ▶ developing a register of SOPs ▶ developing training and competency procedures and resources ▶ providing veterinary support <p>It was clear in discussions with the AWO, investigators, the AEC and the ethics coordinator that the position of AWO had become an invaluable resource in CQU's ongoing commitment to maintaining high levels of compliance with the Code and its obligation to the State and Territory legislation for registration and licensing as a user of animals for scientific purposes. However this position appears to have some challenges, particularly in the definition of the role, responsibility and authority to undertake duties in regard to the role. This appeared to have caused some issue over where the AWO's authority lies in regard to assessing competencies, application of standard practices (industry / commercial and research / teaching setting), advice to animal facilities and the provision veterinary services. At the time of review the position was working three (3) days per week and due to institutional consideration resulting from COVID-19 restriction it was expected to decrease to one (1) day per week.</p>
<p style="text-align: center;">R2</p>	<p style="text-align: center;">Recommendation in relation to Clause 2.1.5 vii</p>	<p>It is recommended that the institution assess the AWO and clarify its priorities in managing SOPs, setting-up a competency assessment and recoding system, veterinary & diagnostic support to the AEC and animal carers and users, compliance monitoring. Provide authority for the position to undertake its work. Assess how much time the position will need to achieve its priorities.</p>

C2	Comment in relation to Clause 2.1.5 vii	<p>When discussing the AWO role with Investigators, Teachers, Technicians, the AWO, AEC Chair and Ethics Coordinator all agreed that it was a valuable position but everyone seemed to have a slightly different idea of what the role was and what authority it has. There was also agreement that there was a lot of work involved to develop the SOPs and document competency. There were also issues with veterinary (clinical) versus commercial/industry practices that had caused some tension.</p>
CR3	Code Reference for SNC Clauses 2.2.33 - 2.2.36	<p>Standard operating procedures</p> <p><i>Institutions, in consultation with the AEC, may allow the AEC to consider and approve standard operating procedures (SOPs) relating to the care and use of animals. Reference to SOPs can help people prepare applications to the AEC, but may make it more difficult for the AEC to apply rigour when evaluating procedures described in applications. An SOP must only be referenced in an application under the following conditions:</i></p> <ul style="list-style-type: none"> (i) <i>the SOP must have current approval from the AEC</i> (ii) <i>the SOP must include in its title the date of approval or last review by the AEC</i> (iii) <i>investigators named in the application must be competent to implement the SOP</i> (iv) <i>any variation to an SOP must be described in the application and should be considered as a prompt for review of the SOP.</i> <p style="text-align: right;">c 2.2.33</p> <p><i>New SOPs must not be used until approved by the AEC, and may be included with an application for consideration by the AEC.</i></p> <p style="text-align: right;">c 2.2.34</p> <p><i>If an approved SOP is not reviewed by the AEC within three years of its approval, approval for the SOP lapses, and the SOP cannot be used.</i></p> <p style="text-align: right;">c 2.2.35</p> <p><i>Approved SOPs must be made available to all relevant people, including AEC members.</i></p> <p style="text-align: right;">c 2.2.36</p>

<p style="text-align: center;">RF3</p>	<p style="text-align: center;">Review Finding in relation to Clauses 2.2.33 - 2.2.36</p>	<p>The institution in consultation with the AEC allows the use of SOPs (or SRPs - Standard Research Procedures). Examples of both formats were provided for review. It is the role of the AWO (outlined in the Annual report to the institution - Document 12c), <i>"to review the SOPs and draft SOP documents from a range of existing and / or previous project examples."</i> At the AEC meeting (07 October 2020) there was discussion of SOPs and it was evident from that discussion the process for using SOPs, their development, review and approval was still in the early stages. It was evident that the process is complex as it is also related to competency assessment and assurance that is currently being developed. At the time of the review the AWO had developed a format for SOPs, established a register, and had begun reviewing and submitting SOPs for comment and approval by the AEC. SOPs being used in some areas are not in the new SOP format and it is unclear what their current approval and review status is (although they do appear on the register and some are approved, filed for review or at the time of review before the AEC for review (Documents 33, 34, 35 & 36). It appears this has been a disjointed process due to the COVID-19 restrictions. Discussions with the AWO, Ethics Coordinator and Investigators outlined the current system of SOPs detailing the challenges involved in reviewing and developing the current system. It was clear from the discussions that there are some issues in the development of this system with resourcing and authority that is causing some tensions and impeding the compliant implementation of the process.</p>
<p style="text-align: center;">R3</p>	<p style="text-align: center;">Recommendation in relation to Clauses 2.2.33 - 2.2.36</p>	<p>Continue to provide resources to the AWO and develop the SOPs. Ensure Investigators and Teachers are provided support to understand the Code requirements for SOPs and encourage the use of the correct format and approval by AEC.</p>

<p>C3</p>	<p>Comment in relation to Clauses 2.2.33 - 2.2.36</p>	<p>The use of SOPs are permitted under the Code and can be a useful resource. The Code stipulates that if they are in use they must comply with the Code requirements. It is important that they reflect the standard practice used, that may be a commercial or industry standard as long as it ensures that an acceptable / optimal level of animal wellbeing for the procedure is ensured.</p>
<p>CR4</p>	<p>Code Reference for SNC Clause 2.3.6</p>	<p><i>Review and approve new and ongoing activities</i> <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>RF4</p>	<p>Review Finding in relation to Clause 2.3.6</p>	<p>Attendance at AEC meeting (07 October 2020) confirmed that a quorum (A, B, C & D members present) was maintained and the C- and D- member balance of (total membership 9:2 C & D members present) was not in-line with the Code requirement of one-third of members present. Present at the meeting was a newly appointed D-member participating in the meeting for the first time. Review of the minutes (Documents 21b, 22b, 23b & 30c) identified that the balance of C and D members in the total membership of appointed members was not achieved at 3 meetings held during 2020 (Documents 21b, 22b, 23b & 30c). All meetings were quorate and in 2 of the 3 meetings the absent D-member submitted comments.</p>
<p>R4</p>	<p>Recommendation in relation to Clause 2.3.6</p>	<p>Continue to actively recruit new C- & D-members.</p>

<p>C4</p>	<p>Comment in relation to Clause 2.3.6</p>	<p>This is a common issue for AECs, particularly those in regional locations. The ORE continually seeks new members and has been an exhaustive search. The challenge is to have enough present at the AEC meetings. It is particularly difficult when the total membership includes the Chair and a c 2.2.25 appointment.</p>
<p>CR5</p>	<p>Code Reference for SNC Clause 2.4.34</p>	<p>Reporting <i>Investigators must provide the following to the AEC in accordance with AEC and institutional policies and procedures (see Clauses 2.2.24 and 2.2.32):</i></p> <ul style="list-style-type: none"> <i>(i) an annual report for an approved project, regardless of the duration of AEC approval for the project</i> <i>(ii) prompt notification of any unexpected adverse events (see Clause 2.1.5 [v] [d])</i> <i>(iii) a final report on outcomes as soon as practicable after completion or discontinuation of a project</i> <i>(iv) reports on the creation and maintenance of genetically modified animals (see Clause 2.4.27 [vi])</i> <i>(v) any other reports as required by the AEC.</i>
<p>RF5</p>	<p>Review Finding in relation to Clause 2.4.34</p>	<p>The document review provided examples of documents submitted by Investigators including, progress (Document 28h, 28i & 29f) and final reports (Document 28j), unexpected adverse event reports (Document 30i) and other correspondence to requests from the AEC. The example of an adverse event report seen during the review was submitted by an Investigator from an institution external to CQU that accesses the CQU AEC. The report was not submitted on the standard form but via a detailed email outlining the incident. The AEC had undertaken at the meeting (07 October 2020) to follow-up with the Investigator in regard to the required reporting procedures.</p>

R5	Recommendation in relation to Clause 2.4.34	Provide the UAE Flow Chart / Decision-Tree once approved to the external institutions and individuals that use the CQU AEC or have their facilities used by CQU Investigators and Teachers. It is an invaluable tool to make those using animals aware of the Institution's expectation of ensuring that UAEs are managed appropriately. Provide access on the website for the CQU Animal Ethics Committee to the flow chart and links to the UAE reporting form.
C5	Comment in relation to Clause 2.4.34	The UAE Flow Chart / Decision-Tree is in use successfully in many Institutions and feedback is that it useful, provides understanding and quick access to UAE reporting and veterinary or technical support.
CR6	Code Reference for SNC Clause 2.7.4 (iv)	<p>Information to be provided to an animal ethics committee for a project: <i>Using animals only when it is justified (see Clauses 1.1 [i] and 1.5–1.7)</i></p> <p><i>The application form to commence a project must allow the applicant to provide the following information, as appropriate for the circumstances.</i></p> <p><i>Information to support the case for ethical acceptability of the proposed use of animals, based on whether such use demonstrates the principles of the Code, and balancing whether the potential effects on the wellbeing of the animals involved is justified by the potential benefits.</i></p>
RF6	Review Finding in relation to Clause 2.7.4 (iv)	Research Application question O11 (in part – only potential benefits of the project) and TA not specific question. Both application forms allow the provision of information in various other questions (relating to potential benefits, 3Rs etc) for the AEC to consider ethical acceptability, however, it would be beneficial for Investigators to state in their own words their justification as to the ethical acceptability and whether potential benefits of the work ethically outweigh the potential impacts.

R6	Recommendation in relation to Clause 2.7.4 (iv)	Applications forms include a question specifically relating to c 2.7.4 (iv) which allows Investigators to explain to the AEC how the potential effects on animal wellbeing of the animals involved is justified by the potential benefits.
C6	Comment in relation to Clause 2.7.4 (iv)	No comment
CR7	Code Reference for SNC Clause 2.7.4 (v)	<p>Information to be provided to an animal ethics committee for a project: <i>Using animals only when it is justified (see Clauses 1.1 [i] and 1.5–1.7)</i></p> <p><i>The application form to commence a project must allow the applicant to provide the following information, as appropriate for the circumstances:</i></p> <p><i>Particular justification for activities that involve:</i></p> <p><i>(a) severe compromise to animal wellbeing, and for which Replacement, Reduction and Refinement (the 3Rs) cannot be fully applied for the project to proceed, including:</i></p> <ul style="list-style-type: none"> <i>• unrelieved pain and distress, including where the planned endpoints will allow severe adverse effects to occur (see Clauses 1.12 and 3.1.18–3.1.19)</i> <i>• death as the endpoint (see Clause 1.13)</i> <i>• reuse and repeated use of animals (see Clauses 1.22–1.24 and 2.3.15)</i> <i>• prolonged restraint or confinement (see Clause 3.3.4)</i> <p><i>(b) use of non-human primates</i></p>

RF7	Review Finding in relation to Clauses 2.7.4 (v)	The reuse and repeated use of animals is addressed in questions RRR5 and RRR6 for both application forms and also PDC1 for wildlife studies. Questions RRR5 and RRR6 are yes or no answers while PDC1 requires an explanation. There is no specific requirement to justify the other activities.
R7	Recommendation in relation to Clauses 2.7.4 (v)	Include a question which requires specific justification for the activities listed in 2.7.4(v).
C7	Comment in relation to Clause 2.7.4 (v)	No comment
CR8	Code Reference for SNC Clause 2.7.4 (ix)	<p>Information to be provided to an animal ethics committee for a project: Applying Replacement, Reduction and Refinement (the 3Rs) (see Clauses 1.1 [v] and 1.18–1.30)</p> <p><i>The application form to commence a project must allow the applicant to provide the following information, as appropriate for the circumstances:</i></p> <p><i>The number of animals required and the justification for this number. Where appropriate, information must be provided on:</i></p> <p style="padding-left: 40px;"><i>(a) experimental design and statistical considerations</i></p> <p style="padding-left: 40px;"><i>(b) for teaching projects, the ratio of students to animals, and the number of times that each animal will be used in each class, and/or handled per day and/or per week</i></p>
RF8	Review Finding in relation to Clause 2.7.4 (ix)	Research Application Form questions A2 and RRR1.2 Teaching Application Form questions A2, RRR1.2 and T5 (in part).

R8	Recommendation in relation to Clause 2.7.4 (ix)	Teaching Application Form include all questions on all points relating to 2.7.4(xi)(b), including ratio of Student to animal and number of times an animal will be used in each class and/or handled per day and/or per week.
C8	Comment in relation to Clause 2.7.4 (ix)	No comment
CR9	Code Reference for SNC Clause 2.7.4(xiii)	<p><i>Information to be provided to an animal ethics committee for a project: Supporting the wellbeing of animals (see Clauses 1.1 [ii] and 1.8–1.9)</i></p> <p><i>The application form to commence a project must allow the applicant to provide the following information, as appropriate for the circumstances:</i></p> <p><i>Details and justification for care and management of animals that does not accord with current best practice.</i></p>
RF9	Review Finding in relation to Clause 2.7.4(xiii)	No specific question to address this included.
R9	Recommendation in relation to Clause 2.7.4(xiii)	Include a question which requires details and justification for any care and management of animals that does not accord with current best practice.
C9	Comment in relation to Clause 2.7.4(xiii)	No comment

DOCUMENT LIST

Document Number	
	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 Central Queensland University or found on the website https://www.cqu.edu.au/research/current-research/ethics-committees/animal-ethics during the course of Review CQU29082019 .
	CQU Core Policy and Governance
1	CQUniversity Policy and Procedure for Research Involving Humans-and-or-Animals-for-Ethical-Clearance-Policy-and-Procedure https://www.cqu.edu.au/_data/assets/pdf_file/0015/121731/Research-Involving-Humans-and-or-Animals-for-Ethical-Clearance-Policy-and-Procedure.pdf
2	Statement-of-Principles-Guiding-the-Use-of-Animals-in-Teaching-and-Research-at-Australian-Universities https://www.cqu.edu.au/_data/assets/pdf_file/0016/121732/Statement-of-Principles-Guiding-the-Use-of-Animals-in-Teaching-and-Research-at-Australian-Universities.pdf
3	CQU Code of Conduct https://www.cqu.edu.au/_data/assets/pdf_file/0022/121729/Code-of-Conduct-for-Research.pdf
	AEC Policy and Procedures
4	TOR https://www.cqu.edu.au/_data/assets/pdf_file/0021/121728/Animal-Ethics-Committee-Terms-of-Reference.pdf
5	ANIMAL ETHICS COMMITTEE OPERATING POLICY AND PROCEDURE https://www.cqu.edu.au/_data/assets/pdf_file/0020/121727/Animal-Ethics-Committee-Operating-Policy-and-Procedure.pdf
6	ANIMAL ETHICS COMMITTEE MONITORING POLICY AND PROCEDURE https://www.cqu.edu.au/_data/assets/pdf_file/0019/121726/Animal-Ethics-Committee-Monitoring-Policy-and-Procedure.pdf
7	17_Animal Ethics Committee Complaints and Grievance Policy and Procedure ANIMAL ETHICS COMMITTEE COMPLAINTS AND GRIEVANCES POLICY AND PROCEDURE https://www.cqu.edu.au/_data/assets/pdf_file/0018/121725/Animal-Ethics-Committee-Complaints-and-Grievances-Policy-and-Procedure.pdf
8	Meeting and Submission dates https://www.cqu.edu.au/research/current-research/ethics-committees/animal-ethics
	2020 Approved Projects and Facilities List
9	AEC Active Projects_11 September.xls
10	Animal Facilities at Central Queensland University.docx
	External and AEC Annual Reports to the Institution

11	Combined 2016 Report document.pdf (2016 External Review Report)
12	2016 Annual Report_Research Committee.pdf - Shortcut.Ink (Unable to access document)
12a	CQU_AEC_AnnualReport_2017.pdf
12b	CQU_AEC_AnnualReport_2018.pdf
12c	CQU_AEC_AnnualReport_2019.pdf
	Animal Ethics Application forms, Report Forms and Guidance (submitting an application)
13	ANIMAL ETHICS COMMITTEE APPLICATION FORM GUIDELINE https://www.cqu.edu.au/_data/assets/pdf_file/0016/121723/Animal-Ethics-Committee-Application-Form-Guideline.pdf
14	CQUni RM Manual_version 7.2 - compiled November 2020.pdf
15a	Blank Research Application.pdf
15b	Blank Teaching application.pdf
16	Modification form.pdf
17	Annual report form.pdf
18	Final report form.pdf
19	Adverse event form.pdf
20	AEC Meeting outcome - 0000021151.pdf
	Agenda and Minutes
21a	AEC_April_2020_Agenda.doc
21b	Confirmed Minutes AEC_April 2020.docx
22a	AEC_June_2020_Agenda.doc
22b	Unconfirmed Minutes AEC_June 2020.docx
23a	AEC_May_2020_Agenda.doc
23b	Confirmed Minutes AEC_May 2020.docx
	Facility Inspection Reports
24	aec_Monitoring_Form_approvedbyRECAB07Mar2006 (Blank Form)
25a	2018: aec_Monitoring_Form_Animal House_30 Nov 18.doc
25b	2018: aec_Monitoring_July 2018.pdf
25c	2018: Hatching Inspection with pictures.docx
25d	2019: AEC Monitoring Report_21403_June 19.doc
25f	2019: AEC Monitoring Report_21444_June 19.doc
25g	2019: AEC Monitoring Report_21547_June 19.doc

25h	2019: AEC Monitoring Report_Belmont_October 19.doc
25i	2019: aec_Monitoring_Animal House_version 2.doc
25j	2019: aec_Monitoring_Poultry Sep 2019.doc
	Standard Operating Procedures (Animal Use)
26	SOP Template.docx
	Approved SOP Listing
27a	~\$B004 Oral gavage dosing for rats
27b	FAC001 Operation of EASY 400 Cabinet Washer
27c	FAC001 Operation of EASY 400 Cabinet Washer
27d	LAB001 Transporting animals from Rockhampton airport
27e	LAB002 Transporting animals across campus (by foot)
27f	LAB003 General handling of rats (non-infectious)
27g	LAB004 Oral gavage dosing for rats
27h	LAB005 Intraperitoneal injection in rats
27i	LAB006 SC Injection
27j	LAB007 Blood collection from the abdominal vena cava
27k	LAB010 Von Frey's assessment of mechanical nociception
27l	LAB011 Oral glucose tolerance test (OGTT) in rats
27m	LAB012 Blood pressure and heart rate readings in rats
27n	LAB013 Heart rate variability reading in rats
27o	LAB014 Uninephrectomy in rats
27p	LAB015 Streptozotocin-induced diabetes mellitus via intravenous injection
27q	PLM002 Setup and Use of Walkover Weighing System for Cattle
	Research Project_ 21151 Bhattarai
28a	Research project_ 21151 Bhattarai: AEC approval - 0000021151.msg
28b	Research project_ 21151 Bhattarai: Animal Ethics Report for 2018.pdf
28c	Research project_ 21151 Bhattarai: Biochar application_22 June.pdf
28d	Research project_ 21151 Bhattarai: Biochar as a feed additive to improve poultry production in the tropics.pdf
28e	Research project_ 21151 Bhattarai: Outcome of committee consideration - not yet approved.msg
28f	Reports: Animal Ethics Report for 2018
28g	Reports: Animal Use to Date 21151
28h	Reports: Annual report for 2018

28i	Reports: Annual report for 2019
28j	Reports: Final report 2020
28k	Response: 21151 Table for ethics responses (22062018)
28l	Committee Response: Demack
28m	Committee Response: Graham
28n	Committee Response: Johnstone
28o	Committee Response: Neilsen
28p	Review: 21151 Table for responses
	Teaching Project_21541 Manning - AGRI11003
29a	Teaching project_21541 Manning: Animal Use to Date
29b	Teaching project_21541 Manning: Application_21541
29c	Teaching project_21541 Manning: Approval email 0000021541
29d	Teaching project_21541 Manning: Outcome of committee consideration - not yet approved.msg
29f	Teaching project_21541 Manning: Reports: 2019 report.pdf
29g	Response: Application
29h	Response: Manning_21541_Table for responses JM.docx
29i	Response: Manning_21541_Table for responses JM.pdf
29j	Response: RIST Diploma of Agriculture AE 2019
29k	Response: Response.pdf
29l	Review: Manning_21541_Table for responses.docx
29m	Submission: Activity Risk Assessment 2019_AGRI11003.docx
29n	Submission: AGRI11003 Unit plan 2019 draft.pdf
29o	Submission: Application_21541.pdf
29p	Submission: Application.pdf
29q	Submission: QATC staff declarations.pdf
29r	Submission: RE AEC applications.msg
	AEC Meeting 07 October 2020
30a	Agenda October CQU AEC
30b	Final October AEC Agenda
30c	Agenda Item 5 Previous Minutes 09/2020 unconfirmed
30d	Agenda Item 6 Action Table
30i	Agenda Item 7 Register of Active Projects
30f	Agenda Item 8 Correspondence - In & Out EXPAND

30g	Agenda Item 9.1.1 New Application No 22575
30h	Agenda Item 9.3 ? Sally Haynes (Not Sure if this is a Ratification)
30l	Agenda Item 9.3 Ratifications
30j	Agenda Item 9.5 Final Reports
30k	Agenda Item 9.6.1 AEC Inspection Schedule
30l	Agenda Item 9.7.1 Adverse Events
30m	Agenda Item 10.1 - 10.3 Other Business
30n	Agenda Item 10.4 Other Business EXPAND
30o	Agenda Item 10.5 SOP
30p	Internal Research Grants Variation request (provided at CQ AEC Meeting)
30q	<i>"Automated shepherds: responsive of captive dingoes to sound and an inflatable, moving effigy."</i> (provided at CQ AEC Meeting)
	Requested Documents (not included in Document List for Desktop Review)
31	aec_Monitoring_Form_approvedbyRECAB07Mar2006.doc
32	Updated_Updated_Inspection_information sheet.docx
33	SRP collars and ear tags 2019.pdf
34	SRP walk-over-weigh 2019.pdf
35	Standard Practice for Cattle at CQIRP.pdf
36	Standard Practice for Sheep at CQIRP 2019 and attachments.pdf
37a	Formal Agreement: Extension to Agersens agreement_CQU signature
37b	Formal Agreement: I_Agersens signed agreement
38	Collaboration Agreement: 19912_Jordensen_Collaboration Agreement_Signed
39	Example formal memo re non-completion of annual report: Memo_outstanding annual report_Heath
40a	Example outcomes to researcher: 21777 Table for responses
40b	Example outcomes to researcher: Outcome of committee consideration - not yet approved
40c	Example outcomes to researcher: Outcome of committee consideration - not yet approved
41	AEC_Confidentiality_Agreement

	Induction Package for New AEC members containing the following documents:
42	<ul style="list-style-type: none"> • Animal Ethics Committee Application Form Guideline.pdf • Animal Ethics Committee Complaints and Grievance Policy and Procedure.pdf • Animal Ethics Committee Monitoring Policy and Procedure.pdf • Animal Ethics Committee Operating Policy and Procedure.pdf • Animal Ethics Committee Terms of Reference.pdf • ANZCCART_aec-induction-package2018-9-1.pdf • Code-care-use-animals-ea28.pdf
43	Process for notifying changes to the AEC membership.docx
	Other Documents
44a	Organisational Chart - Ethics Team.pdf
44b	Organisational Chart - Research.pdf
45	Producer consent form: Producer consent template autodrafter
46	Signed Agreement between CQU and Scientific Auditing Services Pty. Ltd.pdf
47	Completed Document List for Desktop Review.docx

ACRONYMS AND ABBREVIATIONS USED IN THIS REPORT

TABLE 8: List of acronyms and abbreviations that may be found in review report CQU29082019

Acronym / Abbreviation	Meaning
3Rs	The Principles of Replacement, Reduction and Refinement
AEC	Animal Ethics Committee
AEF	Animal Ethics Framework
AFM	Animal Facility Manager
AWO	Animal Welfare Officer
c	Clause
CQIRP	Central Queensland Innovation Research Precinct
CQU	Central Queensland University
DVRC	Deputy Vice-Chancellor of Research
ERP	External Review Panel
ECO	Ethics Coordinator
EO	Ethics Officer
NHMRC	National Health and Medical Research Council
NSW	New South Wales
ORE	Office of Research Ethics
QLD	Queensland
SOPs	Standard Operating Procedures
SRPs	Standard Research Procedures
the Act	<i>Animal Care and Protection Act 2001</i>
the Code	<i>Australian code for the care and use of animals for scientific purposes 8th Edition 2013</i>
TOR	Terms of Reference

List of Tables

TABLE 8: List of Tables

Page	Table
D12	Table 1: Section 2 - Chapter 2.1 Review Findings Identified as Areas Highlighted for Review by the Institution.
D20	Table 2: Section 2 - Chapter 2.2 Review Findings Identified as Areas Highlighted for Review by the Institution.
D25	Table 3: Section 2 - Chapter 2.3 Review Findings Identified as Areas Highlighted for Review by the Institution.
D29	Table 4: Section 2 - Chapter 2.4 Review Findings Identified as Areas Highlighted for Review by the Institution.
D34 - D38	Table 5 - Review of the Animal Ethics Research (RA) and Teaching (TA) Applications (Documents 15a & 15b)
D40	Table 6: Section 2 - Chapter 2.7 Review Findings Identified as Areas Highlighted for Review by the Institution.
E1 - E12	Table 7: Summary of Review Findings, Recommendations and Comments Arising From the Review Findings in Part D
G1	Table 8: List of Acronyms and Abbreviations That May Be Found in Review Report CQU29082019
H1	Table 9: List of Tables