Animal Ethics Committee Procedure



1 Purpose

To establish the institutional responsibilities and associated University of Southern Queensland Animal Ethics Committee (UniSQ AEC) administrative processes for activities conducted under the Australian code for the care and use of animals for scientific purposes 8th Edition 2013, at the University.

2 Scope

This procedure applies to the administrative processes pertaining to the conduct of the UniSQ AEC relating to the care and use of Animals for Scientific Purposes at the University.

3 Procedure Overview

This procedure establishes the responsibilities and processes for UniSQ AEC practices, as well as seeking, managing and revoking ethics approvals and amendments to approvals granted by the UniSQ AEC.

4 Procedures

4.1 UniSQ AEC Membership Categories

4.1.1 UniSQ AEC Chair

The University will appoint a chairperson of the UniSQ AEC.

The UniSQ AEC Chair will:

- hold a senior position at the University;
- be independent of the care and use of Animals for Scientific Purposes;
- be appointed in addition to Category A to D members;
- hold and/or possess any other qualification, experience, skill or ability as required by the University, Australian code for the care and use of animals for scientific purposes 8th Edition 2013, or the Regulator.

4.1.2 Deputy UniSQ AEC Chair

The University may appoint at least one Deputy UniSQ AEC Chair to the UniSQ AEC.

The Deputy UniSQ AEC Chair will:

- hold a current Category A to D membership role within the UniSQ AEC; and
- undertake the duties of the UniSQ AEC Chair, as directed.

4.1.3 UniSQ AEC Executive

The UniSQ AEC will have an Executive consisting of the following members:

- UniSQ AEC Chair;
- Category A member (optional);
- At least one member from either Category C or Category D.

The UniSQ AEC Executive may invite people with specific expertise to provide advice, as required.

4.1.4 Category A member

The University will appoint at least one person as a Category A member to the UniSQ AEC.

A Category A member will:

- hold qualifications in veterinary science that are recognised for registration as a veterinary surgeon in Australia;
- possess experience relevant to the University's activities, or the ability to acquire relevant knowledge; and
- hold and/or possess any other qualification, experience, skill or ability as required by the University, Australian code for the care and use of animals for scientific purposes 8th Edition 2013, or the Regulator.

4.1.5 Category B member

The University will appoint at least one person as a Category B member to the UniSQ AEC.

A Category B member will:

- hold higher degree in research qualifications (or equivalent experience) in a field related to the care and use of Animals for Scientific Purposes; and
- possess substantial and recent experience in the care and use of Animals for Scientific Purposes; and
- hold and/or possess any other qualification, experience, skill or ability as required by the University, Australian code for the care and use of animals for scientific purposes 8th Edition 2013, or the Regulator.

4.1.6 Category C member

The University will appoint at least one person as a Category C member to the UniSQ AEC.

A Category C member will:

- demonstrate commitment to, and experience in, furthering the welfare of Animals;
- hold active membership of, and endorsement by, an Animal welfare organisation (where possible);
- not be an Employee of, or otherwise associated with the University;
- not currently be involved in the care and use of Animals for Scientific Purposes; and
- hold and/or possess any other qualification, experience, skill or ability as required by the University, Australian code for the care and use of animals for scientific purposes 8th Edition 2013, or the Regulator.

4.1.7 Category D member

The University will appoint at least one person as a Category D member to the UniSQ AEC.

The Category D member will:

- not be an Employee of, or otherwise associated with the University;
- have never been involved in the use of Animals in scientific or teaching activities, either in their employment or beyond their undergraduate education;
- be viewed by the wider community as bringing a completely independent view to the UniSQ AEC:

- not fit the requirements of any other category; and
- hold and/or possess any other qualification, experience, skill or ability as required by the University, Australian code for the care and use of animals for scientific purposes 8th Edition 2013, or the Regulator.

4.1.8 UniSQ AEC Executive Officer

The University may appoint at least one person as the UniSQ AEC Executive Officer.

The UniSQ AEC Executive Officer will:

- normally hold a senior position in the Office of Research, Research Integrity and Ethics Team;
- hold and/or possess any other qualification, experience skill or ability as required by the University, Australian code for the care and use of animals for scientific purposes 8th Edition 2013, or the Regulator; and
- not be a voting member of the UniSQ AEC.

4.1.9 Animal Carer member

The University may appoint at least one person as an Animal Carer member to the UniSQ AEC.

An Animal Carer member will:

- hold responsibility for the routine care of Animals within the University; and
- hold and/or possess any other qualification, experience skill or ability as required by the University, Australian code for the care and use of animals for scientific purposes 8th Edition 2013, or the Regulator.

4.1.10 Committee Services Officer

The University will provide appropriate resources for a Committee Services Officer to assist the UniSQ AEC to carry out their responsibilities under Australian code for the care and use of animals for scientific purposes 8th Edition 2013.

4.1.11 Additional members

The University may appoint additional members with appropriate skills and/or experience to

assist the UniSQ AEC to function effectively, as required.

The UniSQ AEC may also invite people with specific expertise to provide advice, as required.

4.2 UniSQ AEC Chair and UniSQ AEC member responsibilities

The UniSQ AEC Chair is responsible for:

- impartially guiding the operation of the UniSQ AEC and the UniSQ AEC Executive;
- resolving conflicts of interest related to the business of the UniSQ AEC; and
- representing the UniSQ AEC in any negotiations with the University management.

UniSQ AEC members are individually responsible for:

- deciding, in their own judgement, whether an application or any other matter under consideration of the UniSQ AEC is ethically acceptable; and
- deciding, in their own judgement, whether an application or any other matter under consideration of the UniSQ AEC meets the requirements of Australian code for the care and use of animals for scientific purposes 8th Edition 2013.

The UniSQ AEC Chair and all UniSQ AEC members must also:

- be familiar with Australian code for the care and use of animals for scientific purposes 8th Edition 2013, and any other policies and guidelines relevant to the business of the UniSQ AEC;
- provide their opinion on the ethical acceptability of applications or any other matter under consideration of the UniSQ AEC;
- declare any interest that could influence the objectivity of their decision making prior to any deliberation of the UniSQ AEC; and
- maintain confidentiality regarding the content of applications and any other matter under consideration of the UniSQ AEC in accordance with the UniSQ AEC Confidentiality Agreement.

The UniSQ AEC Executive Officer is responsible for:

- providing guidance and advice to the UniSQ AEC on legislative and University policy and procedural matters that may affect the operations of the UniSQ AEC; and
- managing the UniSQ AEC expression of interest process for appointment to the Deputy UniSQ AEC Chair and UniSQ AEC Executive roles within the committee.

4.3 Appointment of UniSQ AEC Chair and UniSQ AEC members

4.3.1 Authority to appoint UniSQ AEC Chair and UniSQ AEC members to the UniSQ AEC

The Chair of the UniSQ AEC (UniSQ AEC Chair) is appointed by the Deputy Vice-Chancellor (Research and Innovation) as the University's Responsible Officer.

The power to appoint to all other positions on the UniSQ AEC has been delegated by the Deputy Vice-Chancellor (Research and Innovation) to the UniSQ AEC Chair.

If there is no UniSQ AEC Chair, appointment of members to the UniSQ AEC will be by the Deputy Vice-Chancellor (Research and Innovation).

All nominations must also be approved by the Regulator prior to appointment by the University.

4.3.2 Expressions of interest for membership of the UniSQ AEC

The UniSQ AEC will accept expressions of interest from suitably qualified individuals at any time. The UniSQ AEC may also wish to actively seek expressions of interest as required.

Applicants are required to submit to the University an expression of interest to join the UniSQ AEC that contains an appropriate level of information, including evidence of their qualifications, relevant interests and experience and a curriculum vitae. All expressions of interest must be submitted in writing (email accepted).

4.3.3 Processing of expressions of interest

Completed expressions of interest will be submitted to the Office of Research, via the UniSQ AEC Committee Services Officer. The UniSQ AEC Committee Services Officer will:

- acknowledge receipt of all expressions of interest in writing;
- undertake an initial assessment of an applicant's suitability against the specified membership categories (refer Section 4.1);
- provide applicants with general information about the UniSQ AEC, membership category criteria, and the committee's planned meeting schedule; and

request an applicant to confirm if they wish to progress their expression of interest.

4.3.4 Assessment of suitability

The UniSQ AEC Committee Services Officer will collate the expression of interest documentation provided by the applicant and forward it to the UniSQ AEC Chair, or Deputy Vice-Chancellor (Research and Innovation), as appropriate, for consideration and advice as to suitability for the proposed membership category and appointment to the UniSQ AEC.

An applicant may be invited to meet with the UniSQ AEC Chair or the Deputy Vice-Chancellor (Research and Innovation), as appropriate, to:

- provide an opportunity for both parties to meet and discuss the vacancy;
- ascertain the motivations of the applicant in applying for the role;
- further confirm the applicant's suitability for the role.

It will be decided by the UniSQ AEC Chair or the Deputy Vice-Chancellor (Research and Innovation), as appropriate, if:

- an applicant is deemed suitable for appointment to a particular membership category of the UniSQ AEC;
- the UniSQ AEC membership category can be filled by an applicant, and in what order if more than one applicant has expressed their interest, and is deemed appropriate for appointment; and
- the UniSQ AEC membership category cannot be filled and new expressions of interest are to be sought.

The UniSQ AEC Committee Services Officer will:

- request that the suitable applicant complete and return documentation required by the Regulator for UniSQ AEC member nomination;
- forward completed member nomination documentation to the Regulator; and
- confirm with the applicant the Regulator's Decision on their nomination.

If a member nomination is not approved by the Regulator, the UniSQ AEC Committee Services

Officer will:

- liaise with the Regulator to enquire if a nomination in a different membership category would be accepted;
- liaise with the UniSQ AEC Chair to confirm the Regulator's advice;
- liaise with the applicant to ascertain if they wish to be re-nominated in a different member category and progress re-nomination as appropriate.

Upon receipt of approval of an applicant's nomination from the Regulator, the UniSQ AEC Committee Services Officer will:

- prepare a letter of appointment;
- forward the appointment letter to the UniSQ AEC Chair or the Deputy Vice-Chancellor (Research and Innovation), as appropriate, for signature;
- provide to the applicant:
 - a signed appointment letter;
 - UniSQ AEC Terms of Reference;
 - UniSQ AEC Confidentiality Agreement; and
 - any other relevant documentation.

It is the responsibility of a new UniSQ AEC member to complete, sign and return all required appointment documentation prior to attendance at a UniSQ AEC scheduled meeting.

A new UniSQ AEC member must attend UniSQ AEC member induction training within three months of accepting an appointment to the UniSQ AEC and preferably prior to attendance at a UniSQ AEC scheduled meeting.

Upon receipt of the signed appointment letter, the new UniSQ AEC member is appointed to the vacant position.

4.3.5 Appointment to UniSQ AEC Deputy Chair or UniSQ AEC Executive

The University may appoint currently serving UniSQ AEC members to the role of UniSQ AEC Deputy Chair and the UniSQ AEC Executive, normally for a period of 12 months. This period is to allow all members an opportunity to gain skill and experience in committee management through contribution to the UniSQ AEC.

A UniSQ AEC member may submit an expression of interest for more than one role.

Currently serving UniSQ AEC members in the role of AEC Deputy Chair of the UniSQ AEC Executive will be required to resubmit an expression of interest, when requested, if they wish to be reconsidered to continue in the role.

If more than one expression of interest is received for each role, preference may be afforded to those members who are yet to serve in such a role, as determined by the UniSQ AEC Executive Officer, in consultation with the UniSQ AEC Chair.

The call for expressions of interest and subsequent appointment to the UniSQ AEC Deputy Chair and UniSQ AEC Executive roles will be managed by the UniSQ AEC Executive Officer on an annual basis.

The UniSQ AEC Executive Officer will:

- call for expressions of interest from current UniSQ AEC members who meet the role criteria;
- collate responses;
- determine, in consultation with the UniSQ AEC Chair, suitability of a member for the vacant role;
- confirm the Decision outcome with all UniSQ AEC members who submitted an expression of interest;
- progress an appointment letter for the specified role for the successful member; and
- undertake specific role training, as required.

4.3.6 Duration of appointment

The standard terms of appointment to the UniSQ AEC are:

- UniSQ AEC Chair three years;
- UniSQ AEC Deputy Chair 12 months;
- UniSQ AEC Executive member 12 months;
- UniSQ AEC member (Category A to D) three years;
- UniSQ Animal Carer member three years;

- UniSQ AEC Executive Officer as determined by the University;
- Other UniSQ AEC members as determined by the requirement for expertise, but no longer than three years.

4.3.7 UniSQ AEC member re-appointment

Existing members of the UniSQ AEC may be re-appointed. When the term of an existing member is approaching expiry, the UniSQ AEC Committee Services Officer will confirm if the member wishes to continue in their position. If the member wishes to continue, the UniSQ AEC Committee Services Officer will:

- in conjunction with the UniSQ AEC Chair, assess the suitability of the member for reappointment and seek endorsement of the UniSQ AEC Chair of the UniSQ AEC or the Deputy Vice-Chancellor (Research and Innovation), as appropriate, for the member to be re-appointed; and
- prepare and forward re-appointment documentation to the UniSQ AEC member; and
- notify the Regulator of the re-appointment period.

If a UniSQ AEC member wishes to accept the re-appointment, they will sign and return all required documentation to the UniSQ AEC Committee Services Officer.

If a UniSQ AEC member does not wish to continue, or the continuation is not endorsed by the UniSQ AEC Chair or the Deputy Vice-Chancellor (Research and Innovation) as appropriate, or the Regulator, the position will be declared vacant.

4.3.8 UniSQ AEC member retirement or resignation

If a member of the UniSQ AEC wishes to retire or resign from their position, notification must be provided to the UniSQ AEC Chair or Deputy Vice-Chancellor (Research and Innovation), as appropriate, in writing via the UniSQ AEC Committee Services Officer, providing as much notice as possible.

The retiring or resigning member will be:

- invited to attend an exit interview with the UniSQ AEC Chair, UniSQ Executive Officer or the Deputy Vice-Chancellor (Research and Innovation), as appropriate;
- required to return any loaned University equipment; and
- required to return to the University, or arrange for the confidential destruction of, any UniSQ AEC documentation, in accordance with the University's Records Governance

Management Policy and Procedure.

The UniSQ AEC Committee Services Officer will:

- confirm their retirement or resignation with the Regulator;
- prepare a letter acknowledging the member's notice of retirement/resignation and extending thanks from the University for their service on the UniSQ AEC; and
- receipt any loaned equipment.

4.3.9 UniSQ AEC member suspension or revocation

Membership of UniSQ AEC may be suspended or revoked by the UniSQ AEC Chair or the Deputy Vice-Chancellor (Research and Innovation), as appropriate, if:

- a member is subject to a Research Conduct Complaint; and/or
- a member has failed to uphold their duties in accordance with their letter of appointment, the UniSQ AEC Terms of Reference, Australian code for the care and use of animals for scientific purposes 8th Edition 2013, and/or the University's Research Code of Conduct Policy and pursuant policies and procedures.

Notification of the suspension or revocation of UniSQ AEC membership will be made in writing.

The suspended or revoked UniSQ AEC member:

- may be invited to attend an interview with the UniSQ AEC Chair, UniSQ AEC Executive Officer, or the Deputy Vice-Chancellor (Research and Innovation) as appropriate;
- will be required to return any loaned University equipment; and
- will be required to return to the University, or arrange for the confidential destruction of, any UniSQ AEC documentation, in accordance with the University's Records Governance Management Policy and Procedure.

The UniSQ AEC Committee Services Officer will:

 prepare a notice of suspension or revocation of membership from the UniSQ AEC for the signature of the UniSQ AEC Chair, or Deputy Vice-Chancellor (Research and Innovation), as appropriate;

- confirm the member's suspension or revocation of UniSQ AEC membership with the Regulator; and
- · receipt any loaned equipment.

4.4 General meeting protocols

The UniSQ AEC Committee Services Officer will circulate UniSQ AEC meeting papers to UniSQ AEC members, ensuring that sufficient time is allowed for the UniSQ AEC members to appropriately review and provide feedback prior to the UniSQ AEC meetings.

The UniSQ AEC Committee Services Officer, in liaison with the UniSQ AEC Chair, will confirm that each UniSQ AEC meeting is quorate prior to the commencement of the meeting. A UniSQ AEC meeting will be deemed quorate if it will have at least one member for each of Categories A, B, C, and D, and that the members within Categories C and D represent at least one-third of those members that will be in attendance. If the meeting is not quorate, the meeting will be rescheduled or cancelled, with all tabled items referred to the next available scheduled meeting.

UniSQ AEC Meetings are scheduled in accordance with the University Meeting Schedule. The UniSQ AEC may determine that additional or extra meetings are scheduled, as required.

4.5 Animal ethics approval requirements

All care and use of Animals for Scientific Purposes at the University require ethics approval. This includes use of Animals for Scientific Purposes in collaborative teaching and/or research with other organisations and/or individuals.

All activities that involve the care and use of Animals for Scientific Purposes are:

- subject to ethical review; and
- may only commence after approval has been granted in accordance with this procedure;
 and
- must be conducted in accordance with the approval; and
- must cease if the approval is suspended, withdrawn or expired; and
- must seek approval to amend an existing approval prior to implementing any revisions to the approved protocol.

University Researchers commencing or amending an activity involving the care or use of

Animals for Scientific Purposes, without prior written approval in accordance with this procedure, may be subject to criminal prosecution under the *Animal Care and Protection Act 2001* as well as civil liability and penalty in accordance with the University's policies on misconduct.

Where an Animal is not classified as an Animal under Australian code for the care and use of animals for scientific purposes 8th Edition 2013, the University has the authority to determine if an ethics approval is required. In such situations the Ethics Coordinator must be contacted to arrange for a determination as to whether the University will require an ethics approval prior to undertaking a project.

Should any changes need to be made to an approved protocol, an Animal Ethics Amendment Request Form must be submitted, reviewed by the UniSQ AEC, and approved by the UniSQ AEC before the changes may be implemented.

4.6 Applications involving more than one institution and/or Animal Ethics Committee

The University recognises that a significant amount of research involving the care and use of Animals for Scientific Purposes is conducted in collaboration with other organisations, or through other organisations. Where these organisations have an Animal Ethics Committee, some form of review will be undertaken by all organisations. Therefore, for clarity and in order to reduce duplication of effort should an application be received that involves more than one institution and/or Animal Ethics Committee, the Principal Investigator of the project will develop and submit a proposal to the UniSQ AEC for approval procedures to ensure that agreement has been reached from all collaborating parties on the following:

- all parties are aware of and can meet their respective responsibilities under Australian code for the care and use of animals for scientific purposes 8th Edition 2013;
- a project or activity does not commence before each Animal Ethics Committee, or its delegate, provides ethical approval;
- that each Animal Ethics Committee will be responsible for approval and monitoring of Animal care and use at the institution for which it acts;
- the responsible Animal Ethics Committees are aware of all aspects of the proposed use of Animals, and consider the cumulative effects on the Wellbeing of the Animals involved;
- the responsible Animal Ethics Committees can inspect the Animals at all phases of the project or activity, including any transport of Animals between sites;
- Animals will receive appropriate care in all phases of the project, including any transport of Animals between sites; and

 communication procedures are established between all Animal Ethics Committees and all investigators.

The Principal Investigator of a project will also ensure:

- Research Conduct Complaints are managed in accordance with the Research Code of Conduct: Management of Potential Breaches Procedure;
- Unexpected Adverse Events (Animal) will be managed in accordance with the University's Unexpected Adverse Event (Animal) Procedure and will be communicated to the collaborating institution's Animal Ethics Committee as outlined in the ethics approval conditions;
- milestone reports (including progress and final reports) and UniSQ AEC review outcomes on submitted milestone reports will be forwarded to the collaborating institution's Animal Ethics Committee, as required by that institution's ethics approval conditions; and
- any other required reporting to collaborating institutions is undertaken in accordance with the collaborating institution's requirements.

4.7 Applications involving work outside of Australia

Applications involving work in other countries that will be conducted by UniSQ Researchers will be accepted for consideration for approval if it can be demonstrated by the Principal Investigator that:

- the activity or project will comply with Australian code for the care and use of animals for scientific purposes 8th Edition 2013, and will not breach relevant local legislation;
- the activity or project is not being carried out in another country as a means of avoiding compliance with Australian code for the care and use of animals for scientific purposes 8th Edition 2013;
- Animal care and use can be properly monitored. The UniSQ AEC may choose to appoint a delegate to act on its behalf in such matters;
- the UniSQ AEC has been provided with adequate information on local compliance requirements and how these will be met; and
- any approval granted by an Animal Ethics Committee in another country may be accepted by the UniSQ AEC if it can be demonstrated that the outcomes would be the equivalent of those expected through application of Australian code for the care and use of animals for scientific purposes 8th Edition 2013.

4.8 Making an application

Applications for the care and use Animals for Scientific Purposes are to be made using the most current version of the appropriate application form.

The most recent version of the application form must be sourced from the UniSQ Animal Ethics website.

Complete applications, including all relevant supporting documentation are to be submitted electronically to email: ethics@usq.edu.au. Please note that unless complete applications, including all relevant supporting document are submitted, the application will not be progressed to the UniSQ AEC for review.

The Ethics Coordinator may provide advice and information about the ethics approval process, however the Ethics Coordinator is unable to assist with or provide specific advice on the preparation or content of applications.

An applicant may use the UniSQ AEC Standard Work Procedures as part of their application for ethical review.

4.9 Receipt of application

Upon receiving an application, the Ethics Coordinator or nominee will record the application in the relevant University system and acknowledge receipt of the application.

4.10 Initial assessment and classification of application

Within 15 University Business Days of receiving the application, the Ethics Coordinator or nominee will:

- undertake an initial assessment of the ethics application; or
- provide a timeframe to the applicant/s in which the initial assessment of the ethics application will be undertaken.

Initial assessment of the application will determine:

- if a complete application has been submitted, that all parts of the application form have been satisfactorily completed and all relevant supporting documentation provided;
- the classification of the application of an amendment application (i.e. 'minor' or 'major' amendment) if applicable using the Animal Ethics Minor and Major Amendment Classification Guide;

the relevant review and Decision making authority.

4.11 Decision making authority

The UniSQ AEC is the Decision making authority for:

- applications for ethics approvals for the care and use of Animals for Scientific Purposes;
- major amendments to existing approvals for the care and use of Animals for Scientific Purposes granted by the UniSQ AEC;
- UniSQ AEC Standard Working Procedures (for live Animals);
- suspending and revoking existing approvals granted by the UniSQ AEC;
- acceptability of reports submitted on Unexpected Adverse Events (Animal), milestone reports (including progress and final reports); annual usage of Animal statistics; and any other report requested by the UniSQ AEC;
- administrative review and ratification of collaborative research projects that have been subject to a full review and approval by a non-Australian Animal Ethics Committee; and
- all other activities related to the care and use of Animals for Scientific Purposes at the University.

The UniSQ AEC may delegate the Decision making authority to the UniSQ AEC Executive (if members are available) for:

- minor amendments to existing UniSQ AEC approved projects;
- minor amendments to existing UniSQ AEC Standard Work Procedures;
- administrative review and ratification of collaborative research projects that have been subject to a full review and have received approval from a duly registered Australian Animal Ethics Committee;
- final review and approval of delegated applications, standard work procedures, amendment requests and any other matters that have been subject to a full review and have received conditional approval from the UniSQ AEC.

The UniSQ AEC may delegate the Decision making authority to the UniSQ AEC Chair for:

 minor amendments to existing UniSQ AEC approved projects, where the only change is for an investigator/s to join and/or leave a research project with appropriate evidence.

Matters for consideration and Decision by the UniSQ AEC or the approved delegate are known as Items Under Review.

The UniSQ AEC may delegate the Decision making authority to the UniSQ AEC Chair (if available), for:

final review and approval of delegated applications, UniSQ AEC Standard Work
Procedures, amendment requests and any other matter that has been subject to a full
review and has received conditional approval from the UniSQ AEC.

Usually, the delegation of the Decision making authority to the UniSQ AEC Chair occurs when the revisions required are considered by the UniSQ AEC to be sufficiently minor and do not require further scientific or Animal Wellbeing considerations to be reviewed.

4.12 Confidentiality

All persons involved in receipting and consideration of Items Under Review must maintain confidentiality regarding the content of applications and any deliberations to the greatest extent possible at all times.

The University recognises that in some instances, advice will be required to be sought from persons and/or organisations external to the Office of Research or the UniSQ AEC in order to progress an application. In such instances, only the information required in order to obtain the advice will be disclosed, in as non-identifiable manner as possible.

Persons and/or organisations from whom the advice is sought will be bound by the same requirements of confidentiality as all persons involved in considering applications. Prior to seeking any such external advice, the UniSQ AEC Executive Officer or the UniSQ AEC Chair will inform the person and/or organisation from whom the advice is sought, of the University's confidentiality requirements, and seek written agreement using the Confidential Provision of Advice Form before formally seeking advice.

4.13 Conflicts of Interest

All persons involved in receipting and consideration of Items Under Review must declare any conflicts of interest that could influence the objectivity of their Decision making. Such conflicts of interest should be declared to either:

UniSQ AEC Executive Officer; and/or

The UniSQ AEC Chair.

The UniSQ AEC Chair, in consultation with the Manager (Research Integrity and Ethics), will put in place appropriate measures to manage any conflicts of interest in accordance with University policy.

4.14 Consideration by the UniSQ AEC

The UniSQ AEC will consider Items Under Review in accordance with its terms of reference.

The UniSQ AEC will make a judgement as to whether a proposed use of Animals is ethically acceptable and is based on the information contained in the application and supporting documentation as to whether the:

- principles of the Animal Wellbeing and Ethics Policy and Australian code for the care and use of animals for scientific purposes 8th Edition 2013 are demonstrated; and
- potential effects on the Wellbeing of the Animals involved is justified by the potential benefits.

Further information may be obtained through discussion/s with the applicant/s and advice sought from experts as required.

In some instances, the UniSQ AEC may request a face-to-face meeting with an applicant/s to attempt to resolve any issues. Any such invitations will be issued by the UniSQ AEC Chair, via the UniSQ AEC Committee Services Officer.

4.15 Decision

After consideration of Items Under Review by the UniSQ AEC or the approved delegate, one of the following Decisions will be reached:

- approval;
- · conditional approval; or
- non-approval.

4.16 Resubmission of items

4.16.1 Conditionally approved items

Items Under Review which were conditionally approved at the time of initial Decision may be resubmitted for consideration to the relevant delegate.

The applicant is required to address and/or defend the UniSQ AEC feedback received in relation to the initial Decision prior to re-submission. Should this not occur, the UniSQ AEC Chair may choose not to accept the re-submission.

In such instances, applicants may be invited to meet with the relevant delegate/s to provide a defence of the application.

4.16.2 Non-approved items

Items Under Review which were not approved at the time of initial Decision may be re-submitted for consideration at a future meeting of the UniSQ AEC.

The item is to be re-worked to take into account the feedback received in relation to the initial Decision prior to re-submission. Should this not occur, the UniSQ AEC Chair may choose not to accept the re-submission.

In such instances applicants may be invited to attend a meeting with the UniSQ AEC or the UniSQ AEC Executive, as appropriate, to provide a defence of the application.

4.17 Duration of UniSQ AEC approvals

All UniSQ AEC approvals granted for the care and use of Animals for Scientific Purposes will be for a specific duration, up to a maximum of three years.

Approvals for the care and use of Animals for Teaching Activities should be in place prior to the commencement of the Study Period. Therefore, it is recommended that applications for teaching activities are submitted to the UniSQ AEC for review and approval a minimum of six months prior to the commencement of the Study Period in which the activities are anticipated to be undertaken.

4.18 Communication of Decision

Communication of the Decision about an Item Under Review will be communicated to the applicant/s within 20 University Business Days of either:

- a meeting of the UniSQ AEC where the Item Under Review was tabled; or
- consideration by the UniSQ AEC Executive or UniSQ AEC Chair, as appropriate.

Communication of the Decision will occur in writing.

4.19 Appeals of UniSQ AEC Decisions

Appeals about Decisions of the UniSQ AEC may only be made on the basis of procedural irregularity.

Appeals are to be made in writing to the Deputy Vice-Chancellor (Research and Innovation).

4.20 Failure to uphold the conditions of a UniSQ AEC approval

Failure to uphold the conditions of a UniSQ AEC approval must be reported as soon as practicable to the Manager (Research Integrity and Ethics) for consideration, in accordance with the Research Code of Conduct: Management of Potential Breaches Procedure.

4.21 Non-compliance with a UniSQ AEC approval

Non-compliance with UniSQ AEC ethical approval must be reported to the Manager (Research Integrity and Ethics) for consideration, in accordance with the Research Code of Conduct: Management of Potential Breaches Procedure.

4.22 Revocation or suspension of a UniSQ AEC approval

The UniSQ AEC Chair has the power to suspend or revoke an approval for the use of Animals for Scientific Purposes in the event of allegations of:

- failure to uphold the conditions of a UniSQ AEC approval; and/or
- non-compliance with a UniSQ AEC approval; and/or
- Complaint about the conduct of research in relation to UniSQ AEC Chair.

Should the Manager (Research Integrity and Ethics) find that there has been a failure to uphold the requirements of the UniSQ AEC approval, or there is a substantiated Complaint in relation to the conduct of research in relation to a UniSQ AEC approval, the Manager (Research Integrity and Ethics) may recommend revocation or suspension of the UniSQ AEC approval to the UniSQ AEC Chair.

The UniSQ AEC Executive Officer will inform the Deputy Vice-Chancellor (Research and Innovation) of any such suspension or revocation of a UniSQ AEC approval. The Deputy Vice-Chancellor (Research and Innovation) may notify the Regulator of any such suspension or revocation of a UniSQ AEC approval, as required.

Any revocation or suspension of a UniSQ AEC approval must be reported by the UniSQ AEC Chair to the UniSQ AEC at the next scheduled UniSQ AEC meeting.

4.23 Amendment to an existing UniSQ AEC approval

Additional approval must be sought from and granted by the UniSQ AEC prior to implementing any proposed change to the way in which an Animal is cared for or used for Scientific Purposes which varies from that which was originally approved by the UniSQ AEC.

To seek an amendment to an existing UniSQ AEC approval for the care and use of Animals for Scientific Purposes, the Principal Investigator is responsible for submission of an amendment application in accordance with Section 4.8 of this procedure.

4.24 Project review and reporting

Regular reviews of existing UniSQ AEC approvals for the care and use of Animals for Scientific Purposes will be undertaken when:

- there is a proposal to amend an approved project or activity; and/or
- there is an Unexpected Adverse Event (Animal); and/or
- undertaking a project or activity review as part of an annual progress report;
- an approved project or activity has been discontinued.

The Principal Investigator must notify the UniSQ AEC if any of the above-listed circumstances arise, warranting review of an existing approval for the care and use of Animals for Scientific Purposes in accordance with the Unexpected Adverse Event (Animal) Procedure.

Upon conclusion of the review, one of the following Decisions will be reached:

- the ethics approval is to be continued;
- the ethics approval is to be suspended;
- the ethics approval is to be modified; or
- the ethics approval is to be discontinued.

Principal Investigators must provide to the UniSQ AEC via the UniSQ AEC Committee Services Officer:

 an annual report on the project or activity for which ethical approval for the care or use of Animals for Scientific Purposes was granted;

- an Annual Animal Use Statistic Report;
- a final report to the outcomes of the project or activity for which ethical approval for the care or use of Animals for Scientific Purposes was granted;
- reports on the creation and maintenance of any genetically modified Animals;
- notification of an Unexpected Adverse Event (Animal) in accordance with the Unexpected Adverse Event (Animal) Procedure; and
- any other reports as requested by the UniSQ AEC and other relevant University committees such as the Institutional Biosafety Committee.

4.25 Site Inspections

4.25.1 On-site Inspections

The UniSQ AEC will ensure annual inspections of all UniSQ Animal Facilities used for the care and use of Animals for Scientific Purposes are undertaken.

4.25.2 Remote site inspections

The UniSQ AEC will determine the appropriate delegation and timelines for inspections of research undertaken remotely at the time of the UniSQ AEC approval. This will be communicated to the Principle Investigator. Appropriate reporting methods will be determined by the UniSQ AEC and will form part of the reporting requirements for the UniSQ AEC approved project.

4.26 Reporting on the activities of the UniSQ AEC

The UniSQ AEC reports to the University Research Committee and other committees as directed by the Deputy Vice-Chancellor (Research and Innovation) and as required by Australian code for the care and use of animals for scientific purposes 8th Edition 2013.

The UniSQ AEC Chair will meet with the Deputy Vice-Chancellor (Research and Innovation) on an annual basis to discuss the UniSQ AEC annual report prior to the submission of the annual report to the UniSQ Council. The meeting will focus on the effectiveness and consistency of the UniSQ AEC processes in relation to the requirements of Australian code for the care and use of animals for scientific purposes 8th Edition 2013.

Reporting occurs via submission of confirmed minutes of UniSQ AEC meetings.

The UniSQ AEC Executive reports to the UniSQ AEC on activities undertaken between meetings.

The UniSQ Chair reports to the UniSQ AEC on activities undertaken between meetings.

4.27 Independent external review

The University will ensure that an independent external review is conducted at least every four years to assess the University's compliance with Australian code for the care and use of animals for scientific purposes 8th Edition 2013, and to ensure the continued suitability, adequacy and effectiveness of its procedures to meet its responsibilities under the this code.

The independent external review will be conducted in accordance with Section 6 of Australian code for the care and use of animals for scientific purposes 8th Edition 2013.

4.28 Record keeping

The Office of Research will maintain:

- a register of all applications made for ethical approval for the care and use of Animals for Scientific Purposes at the University;
- the outcomes of all such applications and any deliberations related to those outcomes;
- the outcomes of any other Items Under Review and any deliberations related to those outcomes;
- minutes that record Decisions of the UniSQ AEC;
- minutes and all records relating to the operation of the UniSQ AEC; and
- records of inspections conducted by the UniSQ AEC.

These records may be made available to persons at the University responsible for the care of Animals, as required to undertake their work activities, via request in writing to the UniSQ AEC Executive Officer in accordance with the University's policies on record-keeping. Records will be maintained in accordance with the University's Records Governance Management Policy and Procedure.

4.29 Complaints

If a person is dissatisfied with the outcome of the Animal ethics approval processes, or the conduct of a member of the UniSQ AEC, or Employee of the Office of Research, a Complaint may be made in writing to the Deputy Vice-Chancellor (Research and Innovation) for investigation and resolution.

Complaints made by Students may be made in accordance with the Student Grievance

Resolution Procedure and will be referred to the Deputy Vice-Chancellor (Research and Innovation) for investigation and resolution.

Complaints about the conduct of a UniSQ AEC Member are to be made in writing to the Deputy Vice-Chancellor (Research and Innovation) for consideration and resolution in accordance with the University's policies on Complaints management.

4.30 Compliance

When research projects, research activities or functions of the AEC are in breach of Australian code for the care and use of animals for scientific purposes 8th Edition 2013 are detected, the AEC, and/or the Responsible Officer and in accordance with the appropriate Policy Instruments must ensure that:

- actions are taken to ensure that Animal wellbeing is not compromised, the issue is addressed promptly, and activities that have the potential to adversely affect Animal wellbeing cease immediately;
- actions are taken to address the issues in consultation with the person(s) involved;
- when considered necessary, such matters are referred to the institution for action;
- non-compliance receives appropriate follow-up.

5 References

Nil.

6 Schedules

This procedure must be read in conjunction with its subordinate schedules as provided in the table below.

7 Procedure Information

Accountable Officer	Deputy Vice-Chancellor (Research and Innovation)
Responsible Officer	Deputy Vice-Chancellor (Research and Innovation)
Policy Type	University Procedure
Policy Suite	Animal Wellbeing and Ethics Policy
Subordinate	

Schedules	
Approved Date	11/7/2016
Effective Date	11/7/2016
Review Date	23/10/2020
Relevant Legislation	Animal Care and Protection Act 2001
	Animal Care and Protection Regulation 2012
	Australian code for the care and use of animals for scientific purposes 8th Edition 2013
	Australian Code for the Responsible Conduct of Research
Policy Exceptions	Policy Exceptions Register
Related Policies	Code of Conduct Policy
	Collaborative Research Across Organisations (under development)
	Conflict of Interest Policy
	Records and Information Management Policy
	Research Code of Conduct Policy
	Student General Conduct Policy
	Student Grievance Resolution Policy
	Work Health and Safety Policy
Related Procedures	Biosafety Procedure
	Conflict of Interest Procedure
	Research Code of Conduct: Management of Potential Breaches Procedure
	Student Grievance Resolution Procedure
	Unexpected Adverse Event (Animal) Procedure
Related forms, publications and websites	Animal Ethics Minor and Major Amendment Classification Guide
	Animal Ethics Research Application Form
	Animal Ethics Teaching Application Form

Animal Ethics Amendment Request Form

Confidential Provision of Advice Form (available from ethics@usq.edu.au)

Department of Agriculture and Fisheries - Animal welfare and ethics

Feedback, Complaints and Appeals

University Meeting Schedule

UniSQ AEC Confidentiality Agreement (available from ethics@usq.edu.au)

UniSQ AEC Standard Work Procedures

Definitions

Terms defined in the Definitions Dictionary

AEC Major Amendment

An amendment classified as major by the UniSQ Animal Ethics Committee (AEC) in accordance with the University's Animal Ethics Amendment Classification Guidelines.

AEC Minor Amendment

An amendment classified as minor by the UniSQ Animal Ethics Committee (AEC) in accordance with the University's Animal Ethics Amendment Classification Guidelines.

Animal

Any live non-human vertebrate (that is, fish, amphibians, reptiles, birds and mammals, encompassing domestic Animals, purpose-bred Animals, livestock, wildlife) and cephalopods.

Animal Carer

Any person involved in the care of Animals that are used for scientific purposes, including during their acquisition, transport, breeding, housing and husbandry. Defined as per Australian code for the care and use of animals for scientific purposes 8th Edition 2013.

Animal Ethics Committee (AEC)

A committee constituted in accordance with the terms of reference and membership laid down in Australian code for the care and use of animals for scientific purposes 8th Edition 2013.

Animal Wellbeing

An Animal is in a positive mental state and is able to achieve successful biological function, to have positive experiences, to express innate behaviours and to respond and cope with potentially adverse conditions. Animal Wellbeing may be assessed by physiological and behavioural measures of an Animal's physical and psychological health and by the Animal's capacity to cope with stressors and species-specific behaviours in response to social and environmental conditions.

Appeal

A formal, written request made by a Student or Employee to a higher authority to have a Decision overturned.

Complaint

A Complaint is an "expression of dissatisfaction made to or about the University, related to its products, services, staff or the handling of a complaint, where a response or resolution is explicitly or implicitly expected or legally required".

Decision

A determination made by an Employee, contractor or other authorised delegate in the course of their duties on behalf of the University.

Employee

A person employed by the University and whose conditions of employment are covered by the Enterprise Agreement and includes persons employed on a continuing, fixed term or casual basis. Employees also include senior Employees whose conditions of employment are covered by a written agreement or contract with the University.

Policy Instrument

A Policy Instrument refers to an instrument that is governed by the Policy framework. These include Policies, Procedures and Schedules.

Research Conduct Complaint

A Complaint about a potential breach of the University Research Code of Conduct and the Australian Code for the Responsible Conduct of Research occurs when a concern is raised or identified that one or

more Researchers have conducted research that is not in accordance with the principles and responsibilities outlined in those documents. All Research Conduct Complaints will be dealt with in accordance with the University's Managing and Investigating Potential Breaches of the Research Code of Conduct Procedure.

Research Purposes

Original investigation undertaken to gain knowledge, understanding and insight.

Researcher

Any person/s involved in Research Activities at, or on behalf of the University. This includes, but is not limited to Employees, Students, visiting scholars, research partners, research affiliates, holders of Honorary or Adjunct positions.

Responsible Officer

The person assigned by the Accountable Officer who is responsible for operationalising Policy Instruments.

Scientific Purposes

All activities conducted with the aim of acquiring, developing or demonstrating knowledge or techniques in all areas of science, including teaching, field trials, environmental studies, research (including the breeding of a new Animal line where the impact on Animal wellbeing is unknown or uncertain), diagnosis, product testing and the production of biological products.

<u>Semester</u>

A period of time during which instruction is provided, learning is undertaken and Assessment is carried out. There are three Semester periods during an Academic Year, known consecutively as Semester 1, Semester 2 and Semester 3.

Student

A person who is enrolled in a UniSQ Upskill Course or who is admitted to an Award Program or Non-Award Program offered by the University and is: currently enrolled in one or more Courses or study units; or not currently enrolled but is on an approved Leave of Absence or whose admission has not been cancelled.

Teaching Activity

Any action or group of actions undertaken with the aim of achieving a scientific purpose, where the scientific purpose is imparting or demonstrating knowledge or techniques to achieve an educational outcome in science, as specified in the relevant curriculum or competency requirements.

Unexpected Adverse Event (Animal)

An event that may have a negative impact on the wellbeing of Animals and was not foreshadowed in the approved project or activity. An unexpected adverse event may result from different causes, including but not limited to: death of an Animal, or group of Animals, that was not expected (e.g. during surgery or anaesthesia, or after a procedure or treatment); adverse effects following a procedure or treatment that were not expected; adverse effects in larger numbers of Animals than predicted during the planning of the project od activity, based on the number of Animals actually used, not the number approved for the study; a greater level of pain or distress than was predicted during the planning of the project or activity; power failures, inclement weather, emergency situations or other factors external to the project or activity that have a negative impact on the welfare of the Animals.

University

The term 'University' or 'UniSQ' means the University of Southern Queensland.

University Business Days

The days of Monday to Friday inclusive between 9am and 5pm Australian Eastern Standard Time (AEST), with the exclusion of gazetted Public Holidays for the relevant campus location, plus the closure of the University between 25 December and 1 January in the following year inclusive as specified in the Enterprise Agreement, as well as any closure of the University either at one or several campuses in accordance with a direction of the Crisis Management Team.

UniSQ Animal Facility

Any place where Animals approved by the UniSQ AEC for Scientific Purposes are kept, held or housed, including yards, paddocks, tanks, ponds, buildings, cages, pens and containers.

Definitions that relate to this procedure only

Items Under Review

Matters for consideration and Decision by the UniSQ AEC or the

	approved delegate.
	Principal Investigator
	The person appointed to the role of Principal Investigator as per the approved ethics application. This person may also be known as the chief or lead researcher or investigator. The Principal Investigator is the person who is responsible for the overall management and conduct of an individual project and for ensuring that clear lines or responsibility, communication and accountability regarding the care and use of Animals are identified and upheld.
	Source: Adapted from Australian code for the care and use of animals for scientific purposes 8th Edition 2013.
	Regulator
	The Department of Agriculture and Fisheries (Queensland).
Keywords	
Record No	14/1878PL