

Unexpected Adverse Event (Animal) Procedure



1 Purpose

To establish the administrative process and responsibilities for the following in managing Unexpected Adverse Events (Animal) that have a negative impact on Animal Wellbeing for Animals cared for or used for Scientific Purposes by:

- the University;
- Principal Investigator;
- Animal Carer;
- UniSQ Animal Facility Manager;
- University of Southern Queensland Animal Ethics Committee (UniSQ AEC);
- Researchers; and
- others.

2 Scope

This procedure applies to all Unexpected Adverse Events (Animal) which occur in the care or use of Animals for Scientific Purposes with ethical approval granted by the UniSQ AEC.

3 Procedure Overview

This procedure establishes responsibilities and administrative processes in managing Unexpected Adverse Events (Animal) that have a negative impact on Animal Wellbeing for Animals cared for or used for Scientific Purposes by the University.

4 Procedures

4.1 Unexpected Adverse Event (Animal)

An Unexpected Adverse Event (Animal) may arise from various causes. Examples of Unexpected Adverse Events (Animal) include but not limited to:

- the death of an Animal, or group of Animals, that was not expected (e.g. during surgery or anesthesia, or after a procedure or treatment);
- adverse effects following a procedure or treatment that were not expected;
- adverse effects in a larger number of Animals than predicted during the planning of the project or activity, based on the number of Animals actually used, not the number approved for the study;
- a greater level of Animal pain or distress than was predicted during the planning of the project or activity; and
- power failures, inclement weather, emergency situations, or other factors external to the project or activity that have a negative impact on Animal Wellbeing.

Prompt action must be taken in response to Unexpected Adverse Events (Animal) and emergencies. This includes, but is not limited to:

- alleviation of Animal pain and distress;
- treatment, following veterinarian review and advice;
- if necessary, Animals being humanely killed by a competent person, without delay.

The Animal Wellbeing must take precedence over an individual Animal reaching the planned endpoint of a project or activity, or the continuation or completion of the project or activity.

4.2 Responsibilities

Researchers involved in any aspect of the care and use of Animals for Scientific Purposes must be aware of and accept their responsibilities, and act in accordance with the Australian code for the care and use of animals for scientific purposes 8th Edition 2013.

An Animal must not to be left in pain or distress. A decision on the whether an Animal experiencing pain and distress receives treatment or is euthanised must be made promptly.

An Animal experiencing pain and distress that cannot be immediately alleviated, or that is observed to have clinical scores above those permitted in the UniSQ AEC approved protocol, must be euthanised by the method outlined in the UniSQ AEC project approval without delay.

An Animal that is observed to be within the approved clinical score ranges permitted in the UniSQ AEC project approval are to be attended to immediately to minimise existing pain and distress and avoid further pain and distress. If treatment is required, veterinary care should be requested through following the UniSQ AEC Standard Work Procedure *EX001 Request for*

veterinary care to be provided for approved AEC project animals.

The University, Principal Investigators, Animal Carers, and the UniSQ Animal Facility Manager have specific responsibilities as provided below.

4.2.1 University responsibilities

The University will promote compliance with the Australian code for the care and use of animals for scientific purposes 8th Edition 2013 by ensuring that:

- guidelines for Animal care and use are developed in consultation with the UniSQ AEC, approved by the UniSQ AEC, and implemented and promoted within the University;
- clear lines of responsibility, communication, and accountability, including a person who is responsible for Animal Wellbeing at any given time is clearly identified so that appropriate actions can be promptly taken in response to an Unexpected Adverse Event (Animal);
- documentation is developed (in consultation with the UniSQ AEC) for the follow-up review of an approved project or activity at scheduled times, and when circumstances trigger additional follow-up review, including unexpected Adverse Events.

4.2.2 Principal Investigator responsibilities

Principal Investigators will identify known and potential causes of adverse impact on Animal Wellbeing and will take into consideration both unintended and unforeseen consequences both in the design of their experimental protocol and procedures and as a continuous Animal Wellbeing improvement process and practice, including but not limited to:

- taking steps to avoid or minimise adverse impacts, including setting intervention points and humane endpoints and monitoring Animals;
- reviewing the effectiveness of strategies to support and safeguard Animal Wellbeing on a regular basis;
- implementing changes to strategies to ensure the ongoing support and safeguarding of Animal Wellbeing;
- ensuring that all relevant persons are aware of and accept their responsibilities regarding Animal Wellbeing;
- monitoring and assessing Animal Wellbeing on an ongoing basis.

Once Animals have been allocated from a UniSQ Animal Facility to a UniSQ AEC approved

project, the Principal Investigator is responsible for:

- day-to-day monitoring of Animal Wellbeing;
- monitoring records to verify that Animal Wellbeing has been monitored;
- notifying the UniSQ AEC of any Unexpected Adverse Events (Animal) that have (or may) impact on Animal Wellbeing of any Animal under their care; and
- nominating a suitably qualified and experienced person responsible for handling, monitoring and reporting of Unexpected Adverse Events (Animal) in their absence. Such nominations must be made in writing to the UniSQ AEC, via the Office of Research, be accepted by the person nominated, and approved by the UniSQ AEC prior to being implemented.

Principal Investigators must promote compliance with the Australian code for the care and use of animals for scientific purposes 8th Edition 2013 by:

- taking steps at all times to safeguard Animal Wellbeing by avoiding or minimising known or potential causes of harm, including pain and distress, to Animals;
- taking prompt action, including alleviating pain and distress; and
- promptly notifying the UniSQ AEC, in response to Unexpected Adverse Events (Animal) and emergencies, in accordance with this procedure.

Alleviating unanticipated Animal pain and distress must take precedence over an individual Animal reaching the planned endpoint of the project, or the continuation or completion of the project. If necessary, Animals must be humanely killed without delay.

4.2.3 Animal Carer responsibilities

Animal Carers must promote compliance with the Australian code for the care and use of animals for scientific purposes 8th Edition 2013 by undertaking all of the following:

- Take prompt actions based on the monitoring and assessment of Animal Wellbeing and in response to Unexpected Adverse Events (Animal) and emergencies, in accordance with procedures approved by the UniSQ AEC.
- Liaise with Principal Investigators, including promptly advising the Principal Investigator of actions taken and the reasons for emergency intervention. If an emergency welfare intervention is considered necessary for an Animal allocated to a project (e.g. treatment or humane killing of an Animal), Animal Carers must take reasonable steps to first

contact the Principal Investigator of the project. However, the Animal Wellbeing must be the priority at all times and may necessitate immediate intervention.

- Seek veterinary treatment and advice, as outlined in the UniSQ AEC approved protocol, and in accordance with UniSQ AEC Standard Work Procedure *EX001 Request for veterinary care to be provided for approved AEC project animals*.
- Undertake emergency welfare intervention (treatment or humane killing of an Animal), as required.
- Promptly notify the UniSQ AEC, via the Principal Investigator, in response to Unexpected Adverse Events (Animal) and emergencies, in accordance with this procedure.
- Maintain sufficient records of the monitoring of Animal Wellbeing to enable the UniSQ AEC to verify that adequate monitoring has occurred, and allow review and critical investigation of the cause(s) of and responses to Unexpected Adverse Events (Animal) as a basis for future prevention strategies.

4.2.4 UniSQ Animal Facility Manager responsibilities

Prior to the allocation of Animals from a UniSQ Animal Facility to a project with UniSQ AEC approval, the UniSQ Animal Facility Manager is responsible for:

- day-to-day monitoring of Animal Wellbeing;
- monitoring records to verify that Animal Wellbeing has been adequately monitored.

When Animals which are in the care of the UniSQ Animal Facility Manager are ill or injured, or show unexpected abnormalities, the UniSQ Animal Facility Manager must:

- ensure provision of prompt diagnosis and treatment under direct veterinary supervision and control;
- ensure appropriate actions in response to any subsequent report from the veterinarian on problems that may require changes to the management and/or care of the Animals under the care of the UniSQ Animal Facility Manager; and
- for Animals that die unexpectedly, ensure that University policies and procedures and AEC procedures are followed regarding the conduct of a necropsy by a competent person and access to diagnostic services when samples are collected for ancillary testing.

The UniSQ Animal Facility Manager must ensure that prompt and regular reports are provided to the UniSQ AEC as follows:

- monthly reports of UniSQ Animal Facility activity, including accurate reflection of current stock levels, breeding activity, UniSQ Animal Facility operating matters (e.g. licensing, biosecurity, facility and/or equipment maintenance), and any other matter deemed relevant to the ongoing effective operation of a UniSQ Animal Facility;
- prompt notification of Unexpected Adverse Events (Animal) relating to Animals for which the UniSQ Animal Facility Manager is responsible; and
- any other reports requested by the UniSQ AEC.

The UniSQ Animal Facility Manager, Animal Carers and Principal Investigators will promptly communicate any of Unexpected Adverse Events (Animal) and/or actions (intended or otherwise) to the appropriate people who have responsibility for the animals impacted by the of Unexpected Adverse Events (Animal).

4.2.5 UniSQ AEC responsibilities

The UniSQ AEC will ensure, on behalf of the University, compliance with the Australian code for the care and use of animals for scientific purposes 8th Edition 2013 by:

- taking appropriate action in response to Unexpected Adverse Events (Animal);
- ensuring that Animal Wellbeing is not compromised;
- ensuring the issue is addressed promptly;
- ensuring activities that have the potential to adversely affect Animal Wellbeing cease immediately; and
- referring any matters deemed relevant to the Deputy Vice-Chancellor (Research and Innovation), as the University's Responsible Officer.

Actions may include consulting with relevant persons, and where necessary, suspending or withdrawing approval for the project or activity.

4.3 Unexpected Adverse Event (Animal) Decision Tree

The University will have an Unexpected Adverse Event (Animal) Decision Tree. This Decision Tree will guide the course of action to be taken when handling an Unexpected Adverse Event (Animal).

The Unexpected Adverse Event (Animal) Decision Tree will be developed with input from persons with appropriate expertise and will be approved by the UniSQ AEC.

The an Unexpected Adverse Event (Animal) Decision Tree will be made available to all persons involved in the care and use of Animals for Scientific Purposes. All persons involved in the care and use of Animals for Scientific Purposes have a responsibility to familiarise themselves with the Unexpected Adverse Event (Animal) Decision Tree.

The Unexpected Adverse Event (Animal) Decision Tree will be reviewed by the UniSQ AEC annually and, additionally as required, if a weakness in the Decision Tree is identified in the handling of an Unexpected Adverse Event (Animal). The Unexpected Adverse Event (Animal) Decision Tree will be maintained by the Office of Research and made available to all Researchers.

4.4 Management of Unexpected Adverse Events (Animal)

4.4.1 Initial actions

The Researcher who discovers the Unexpected Adverse Event (Animal) is required to act, inform, and report as follows:

- Determine and remove obvious hazards if safe to do so.
- Respond to the immediate need of sick, or at-risk Animal.
- Inform the Principal Investigator and UniSQ Animal Facility Manager as soon as possible.
- Determine whether treatment and/or veterinary services are to be accessed, or the animal is to be humanely killed. Treatment must be undertaken in accordance with the UniSQ AEC approved protocol for the respective project, and UniSQ AEC Standard Work Procedure *EX001 Request for veterinary care to be provided for approved AEC project animals*. Humane killing of an Animal must be undertaken in accordance with the UniSQ AEC approved protocol for the respective project, and the corresponding UniSQ AEC Standard Work Procedure for euthanasia.
- If the Animal was found dead or has been humanely killed, determine whether a necropsy be performed by a competent person. Necropsy must be performed by a competent person and undertaken in accordance with the UniSQ AEC Standard Work Procedure *DP011 Small mammal: Investigation of morbidity or unexplained death*.
- Report the initial details of the Unexpected Adverse Event (Animal), via the Principal Investigator, to the UniSQ AEC, within 48 hours of the event occurring.

4.4.2 Initial report of Unexpected Adverse Event (Animal) to UniSQ AEC

The Researcher who discovers the Unexpected Adverse Event (Animal) is required to complete the Unexpected Adverse Event (Animal) Form as much as possible and forward it to the Principal Investigator, or the UniSQ Animal Facility Manager (whoever is responsible for the Animal at that point in time), as soon as practical after the event has occurred.

The Principal Investigator or the UniSQ Animal Facility Manager must provide an initial report of the Unexpected Adverse Event (Animal) to the UniSQ AEC, via the Research Integrity and Ethics Office (email: researchintegrity@usq.edu.au), and copy to the UniSQ Animal Welfare Officer (email: animalwelfareofficer@usq.edu.au), within 48 hours of the event occurring. Details of whether a necropsy is being undertaken should be disclosed, and any supporting information, documentation (such as copies of monitoring sheets of the animal) and images (digital pictures if available) should be submitted.

4.4.3 Review and refine processes

Following an Unexpected Adverse Event (Animal), the Principal Investigator must review the protocol and procedures that led up to the event to determine if the protocol and/or procedures require modification and/or refinement, investigators require further training, or further supervision of trainees is required to be implemented.

Notes of the review and any outcomes should be submitted with the final report of the Unexpected Adverse Event (Animal) Form.

Where the review requires a revision to an existing protocol or procedure, the Principal Investigator will submit an Amendment Application to the UniSQ AEC in accordance with the UniSQ AEC Committee Procedure. UniSQ AEC approval of the revision must be received prior to implementing any changes to the protocol.

4.4.4 Completion of Unexpected Adverse Event (Animal) process

Following the review and refinement process, and receipt of a pathology report (if available), the Principal Investigator must complete all details on the Unexpected Adverse Event (Animal) Form, and submit it to the UniSQ AEC, via the Research Integrity and Ethics Office (email: researchintegrity@usq.edu.au), and copy to the UniSQ Animal Welfare Officer (email: animalwelfareofficer@usq.edu.au), within 20 University Business Days of the event occurring.

4.4.5 Review of Unexpected Adverse Event (Animal) by the UniSQ AEC

4.4.5.1 Initial notification

Upon initial notification of the Unexpected Adverse Event (Animal), normally by the Principal Investigator, the Office of Research, via the Manager Research Integrity and Ethics will review the details of the Adverse Event (Animal) and determine if:

- immediate action is to be undertaken, in consultation with the UniSQ AEC and/or the UniSQ Animal Welfare Officer;

- further review should be undertaken upon receipt of final notification and further reporting (e.g. pathology); or
- no further action is required.

4.4.5.2 Final notification

Upon final notification of the Unexpected Adverse Event (Animal), by the Principal Investigator, the Office of Research, via the Manager Research Integrity and Ethics will review the details of the Adverse Event (Animal) and:

- determine if immediate action is to be undertaken, in consultation with the UniSQ AEC and/or the UniSQ Animal Welfare Officer;
- seek further review from the UniSQ Animal Welfare Officer and/or other appropriately qualified individuals and/or organisations;
- refer, via relevant processes for refinement, replacement, and/or reduction alternatives if appropriate;
- determine and notify relevant persons and/or authorities;
- determine that no immediate action is to be undertaken and the Unexpected Adverse Event (Animal) be referred to the next available UniSQ AEC meeting.

4.4.5.3 Report to UniSQ AEC

A report of Unexpected Adverse Events (Animal) which have occurred recently (normally between UniSQ AEC meeting dates) will be prepared by the Office of Research and reported to the UniSQ AEC at each scheduled meeting in accordance with the UniSQ AEC meeting schedule.

A historical report of all Unexpected Adverse Events (Animal) that have occurred for each currently operating UniSQ AEC approved project will be prepared by the Office of Research and reported to the UniSQ AEC at each scheduled meeting in accordance with the UniSQ AEC meeting schedule.

4.5 Non-compliance

If it is either found or suspected that there is/has been non-compliance with any of the following conditions, ethical approval for the project may be suspended or revoked in accordance with the Animal Ethics Committee Procedure and the matter referred for investigation as a Research Conduct Complaint in accordance with the Research Code of Conduct: Management of Potential Breaches Procedure:

- ethical approval for the care and use of Animals for Scientific Purposes as granted by the UniSQ AEC; and/or
- the Research Code of Conduct Policy; and/or
- the Australian code for the care and use of animals for scientific purposes 8th Edition 2013.

The Deputy Vice-Chancellor (Research and Innovation) is responsible for responding promptly and effectively to the recommendations of the UniSQ AEC.

5 References

Australian Government. (2013). *Australian code for the care and use of animals for scientific purposes 8th Edition*. Canberra, ACT: Australian Government.

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	23/10/2015
Effective Date	23/10/2015
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 Records and Information Management Policy Research Code of Conduct Policy Work Health and Safety Policy
Related Procedures	Animal Ethics Committee Procedure Incident Management Procedure Research Code of Conduct: Management of Potential Breaches Procedure
Related forms, publications and websites	Amendment Application Animal Ethics Minor and Major Amendment Classification Guide Department of Agriculture and Fisheries - Animal welfare and ethics Unexpected Adverse Event (Animal) Form UniSQ AEC Standard Work Procedures
Definitions	Terms defined in the Definitions Dictionary Adverse Event (Animal) <p>An event that has a negative impact on the wellbeing of an Animal.</p> Animal <p>Any live non-human vertebrate (that is, fish, amphibians, reptiles, birds and mammals, encompassing domestic Animals, purpose-bred Animals, livestock, wildlife) and cephalopods.</p> Animal Carer <p>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.</p> 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.

[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.

[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.

[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 or 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.

[UniSQ Animal Facility Manager](#)

The person at the University responsible for the overall management of a UniSQ Animal Facility used for the breeding and holding of Animals.

Definitions that relate to this procedure only

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

	<p>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.</p> <p>Source: Adapted from the Australian code for the care and use of animals for scientific purposes 8th Edition 2013.</p>
Keywords	
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