



AUSTIN HEALTH AEC (2019) GUIDELINE FOR MANAGEMENT OF ADVERSE EVENTS

Approved Feb 2017
Revised May 2019

1. PURPOSE

This guideline is to ensure that adverse events involving animals or the BioResources Facility are dealt with in a timely, consistent and appropriate manner and animal welfare is safeguarded.

It is to ensure Austin Health compliance with *The Australian Code for the Care and Use of Animals for Scientific Purposes 8th Edition 2013* (the Code).

Relevant sections of the code are:

2.1.5 Institutions must promote compliance with the Code by:

(v) 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. Guidelines must include:

(d) actions required for unexpected adverse events and emergencies, including those that require welfare interventions such as the emergency treatment or humane killing of any animal, to ensure that adverse impacts on animal wellbeing are addressed rapidly. Such guidance should include timeframes for actions, prompt reporting to the AEC, liaison between animal carers and investigators, and circumstances when consultation with a veterinarian, the performance of a necropsy by a competent person, and access to diagnostic investigations are required

2.2.32 Institutions, in consultation with the AEC, must develop documentation for:

(i) application for AEC approval to commence a project or activity that addresses the governing principles of the Code (see Chapter 2.7)

(c) unexpected adverse events

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2.3.24 The AEC must take appropriate action in response to unexpected adverse events 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 (see Clause 2.1.5 [v] [d]). Actions may include consulting with relevant people and, where necessary, suspending or withdrawing approval for the project or activity.

2. **GENERAL**

There are two types of adverse events which require reporting to the AEC; an unexpected adverse event and an anticipated adverse event.

An **unexpected** adverse event is defined as an event that **was not** expected or anticipated within the approved AEC protocol that has, or has the potential to have, a negative impact on animal welfare.

These may include, but are not limited to:

- The death of an animal, or group of animals, that was not expected, or in greater numbers than expected (e.g. post-surgical or anaesthetic death) during the planning of the project;
- Adverse effects after a treatment or procedure that were not anticipated during the planning of the project;
- Adverse effects in a larger number of animals than was anticipated;
- A greater level of pain or distress to animals than was predicted during the planning of the project;
- An Adverse event that was expected but has occurred at a frequency or severity in excess of that forecast, and which impacts negatively on the wellbeing of the animal(s); or
- A facility failure or external event (e.g. power failure, inclement weather, emergency situation) that has or the potential to have a negative effect on animal welfare.

An **anticipated** adverse event is defined as an event that **was** expected or anticipated and described within the approved AEC protocol that has, or has the potential to have, a negative impact on animal welfare.

These may include, but are not limited to:

- A known percentage of loss expected in an animal model (e.g. 10% death is expected due to the characteristics of the animal model used);
- A known weight loss;
- A known clinical symptom; or
- Where death is an endpoint (please note, Ministerial approval is required in these cases).

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3. PREVENTION OF ADVERSE EVENTS

Not all adverse events can be predicted or prevented, however the risk of some events can be reduced by the following:

- Sound experimental design;
- Utilisation of pilot studies or designing studies with limited numbers of animals initially, particularly when new procedures or strains are required;
- Investigating and reporting potential impacts of the experiment on animal wellbeing. Reporting “near misses”;
- Inclusion of protocols and strategies within the experimental plan to minimise impacts on animal wellbeing;
- Utilisation of current best care practices in planning protocols;
- Informing and training staff in project design and to anticipate and respond to adverse events;
- Reporting in full adverse events when they do occur and determining if experimental design needs to be altered as a consequence; and
- The AEC holding a record of these reports and auditing in order to minimise repeat behaviours.

4. RESPONSE TO ADVERSE EVENTS

- Animal welfare **must** be addressed initially –first aid and/or analgesia including, if necessary, immediate humane euthanasia.
- Contact the PI or person or responsible person immediately if euthanasia is required. If these persons are not available then the BRF manager, AWO and BRF staff must address the immediate animal welfare issues, including humane euthanasia if required. **Animal welfare will always take precedence over experimental endpoint.**
- Once the immediate animal welfare issue has been resolved then assess risk to any other animals and address this as soon as possible.
- Complete animal monitoring records as soon as practical regarding the event- including the following:
 - Date, details of animal (species, strain, age, breed), protocol number, procedure and any medications given and brief summary of the procedures performed.
 - Details must also be entered on cage card and if an animal/s has been euthanased then it must be entered onto the room record sheet.
- If an animal has died, place the body in the fridge **NOT** the freezer to allow for post mortem examination.

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5. REPORTING OF AN UNEXPECTED ADVERSE EVENT

- Advise the BioResources Facility (BRF) staff as soon as possible. Ensure the BRF manager and AWO are also informed.
- Inform the Principal investigator and any others involved in the protocol.
- Inform the AEC within 24 hours (by email to the BRF manager, the AWO or the AEC Secretary is sufficient at this time point).
- Once the investigation into the event has been completed (this may take some weeks if pathology is required), complete an adverse event report form and forward this to the AEC secretary (aec.ethics@austin.org.au). This should be done within one calendar month of the adverse event.

The form is available on the Austin Health website at the following link:
http://www.austin.org.au/Animal_Ethics_Submissions/Existing_Projects/

6. REPORTING OF AN ANTICIPATED ADVERSE EVENT

- Events that may impact on animal wellbeing, but are described in the approved protocol as expected to occur in a particular proportion of the animals used in the project, should be reported in the Annual report for each reporting period (i.e. 1 Jan to 31 Dec), provided that the proportion of animals affected does **NOT** exceed that documented in the approved protocol. Where the proportion of animals affected, or the severity of the effects exceeds that documented in the approved protocol, the adverse event must be reported promptly via an Adverse Event Report as per the instructions under “Reporting of an Unexpected Adverse Event”.

7. INVESTIGATION OF THE ADVERSE EVENT

- A post mortem must be carried out by a competent person on any animal that dies due to an adverse event to ensure prevention of further animal loss and to address any human error that may have contributed to the event. Pathology may be required to be sent to a registered laboratory as part of the investigation.
- Collect data required to complete the adverse event report form from all involved, including the BRF staff.
- Identify possible causes and formulate a plan to ensure the risk of reoccurrence is reduced.
- Consult with BRF staff and/or AWO if required to reassess protocol.
- Include findings and recommendations on the adverse event report to the AEC.
- Inform relevant personnel and BRF staff of findings and any alterations to the protocol as a result of the investigation.
- If required, as a result of the investigation, submit an amendment to the AEC for the protocol.

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