Procedure for Managing & Reporting Unexpected Adverse Events Involving Animals Used in Research & Teaching

Scope
This procedure applies to all ANU research or teaching activities that involve the use of animals. It applies only to unexpected adverse events, not events detailed and approved within a current animal ethics protocol. Reporting of unexpected adverse events **IN A TIMELY MANNER IS MANDATORY IN ORDER TO ENSURE** timely investigation and provision of veterinary support to prevent further occurrences and improve animal welfare outcomes. Reporting is critical to identifying where improvements can be made, positively contributing to the continuation of the research. There is an expectation that reasonable care and due diligence will be undertaken at all times where research involves the use of animals.

Subject
When is an unexpected adverse event report required?
When there is an event that has, or may have a negative impact on the wellbeing of animals that was not foreseen in the approved protocol.

Some examples of situations the ANU Animal Experimentation Ethics Committee (AEEC) & the legislation define as unexpected adverse events include:

- More deaths or complications than described in the approved protocol, e.g. 10% of animals die following surgery when a 5% fatality rate was expected and justified in the proposal;
- Deaths of animals not described in the proposal, e.g. one mouse found dead the day after surgery;
- Complications not described in the protocol, e.g. one or more animals have allergic reactions to a treatment; the type of anaesthetic doesn't provide adequate pain relief analgesia or restraint; animals die during or after anaesthesia; animals develop abscesses at the surgical or treatment site;
- Facility or equipment failure compromising or possibly compromising animal welfare or the success of the activity, e.g. power loss to a facility means ventilated mouse cages don't receive fresh air, therefore mice may suffer from build-up of ammonia; inability to irradiate animals on a particular day means that this critical part of the activity is not undertaken when animals are the right age, so there may be no justification to continue using these animals;
Animal wellbeing is compromised due to a deficiency in routine husbandry practices, such as the provision of suitable food, water, bedding and housing conditions; for further definitions see page 5.

If there is any uncertainty around whether an event should be reported then advice should be obtained from the ANU Veterinarian on 6125 1130 immediately (this phone is monitored out of office hours).

**When is an unexpected adverse event report NOT required?**
An unexpected adverse event report is not required if the event happened as detailed in the approved AEEC protocol.

Users of animals for scientific purposes should have provided details of the type and frequency of possible adverse events in their proposal to the AEEC. If the events happen as expected (as approved and outlined in the proposal), they do not have to be reported separately, unless additional reporting is a condition of AEEC approval.

**Procedure for Managing & Reporting Unexpected Adverse Events**

**The formula is Act, Inform and Report (AIR):**

1. **ACT:** Determine and remove obvious hazards while responding to the immediate needs of sick or at-risk animals. Alleviate immediate unexpected pain and distress in the animal. **The immediate welfare of the animals is paramount.**

2. **INFORM:** Reporting of unexpected adverse events is mandatory, not voluntary.
   (i) As soon as practically possible contact the veterinarian as timely treatment, autopsies, testing or further risk minimisation strategies may be required. The ANU has a veterinarian on-call for emergencies 24/7. The Emergency veterinary assistance number 6125 1130 (x51130). This number is diverted to the mobile phone of the vet on call. Samples **must not** be taken from the animal until you have spoken to the veterinarian and the vet has established next actions.
   (ii) Contact the Principal Investigator.
   (iii) Contact the animal facility manager (where relevant).
3. **REPORT:** All unexpected adverse events need to be reported to the AEEC and will require the completion of an Unexpected Adverse Form to be submitted to animal.ethics@anu.edu.au. Reports must be received by the AEEC within 72 hours; investigators working in remote locations must submit a written report to the AEEC within 10 days.

**Responsibilities of Investigators, Facility Managers & Animal Carers**

**Investigators must:**
- Immediately alleviate unanticipated pain and distress in their research animals. This may require immediate euthanasia even if the planned endpoint has not been reached;
- As soon as practically possible contact the ANU Veterinarian on call via the emergency number 6125 1130 (x51130). This number is diverted to the mobile phone of the vet on call (available 24/7);
- Promptly advise the facility manager (where appropriate)
- Promptly notify the AEEC by completing the unexpected adverse event form;
- For any animals that die unexpectedly, ensure that an autopsy is performed by a veterinarian or suitably qualified person as directed by a veterinarian, results must be recorded. Carcasses must be stored in accordance with veterinary instruction. Carcasses must not be disposed of until approval is given by the veterinarian.

**Animal facility managers must:**
- Immediately contact relevant investigators;
- Immediately contact the ANU veterinarian;
- Provide prompt diagnosis and treatment under direct veterinary supervision for any animals that are ill or injured or showed unexpected abnormalities;
- When an animal dies unexpectedly, or is euthanased due to unforeseen complications, an autopsy should be performed by a veterinarian or a person with appropriate qualifications and/or experience as directed by a veterinarian, the AEEC must be notified promptly. Carcasses must be stored in accordance with veterinary instruction and must not be disposed of until approval is given by the veterinarian;
- Liaise with investigators about any unexpected adverse events;
- Promptly notify the AEEC of unexpected adverse events relating to animals for which they are responsible
Animal carers must:

- Take reasonable steps to first contact the responsible investigator. However, the welfare of the animal must be the priority at all times and may necessitate immediate intervention including euthanasia;
- Contact the facility manager or the University Vet;
- Contact the investigator, if not already done, and advise them of the actions taken and why they were taken;
- For any animals that die unexpectedly, an autopsy should be performed by a veterinarian or suitably qualified person as directed by a veterinarian, results must be recorded. Carcasses must be stored in accordance with veterinary instruction and must not be disposed of until approval is given by the veterinarian.

AEEC Responsibilities & Processes

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

All adverse events involving the use of animals as part of ANU research and teaching activities must be reported to the AEEC. Reports are received by Research Services at animal.ethics@anu.edu.au and are immediately passed on to the AEEC and ANU Veterinarian electronically. Research Services will send an acknowledgement of receipt on behalf of the AEEC to the person lodging the report. Depending on the seriousness or urgency of the event the AEEC, in consultation with the University veterinarian, may undertake one or more of the following:

- Require that the project cease until the matter has been investigated further;
- Request further information from the principal investigator or other staff involved;
- Request immediate veterinary intervention if this has not already occurred;
- Request that the ANU veterinarian or nominated person visit a specific animal holding facility or site to make an assessment;
- Defer the matter to the next scheduled meeting;
- Call a special meeting to discuss the event.
The AEEC will provide a written response to the project supervisor outlining any further action required. AEEC instructions must be followed.

**Veterinary Responsibilities & Involvement**

In most cases the University Vet or a nominated delegate will investigate the event and any action taken. The aim of the investigation is to determine the cause of the unexpected adverse event. The project supervisor and relevant staff must cooperate with the vet during this investigation.

The University Vet or a nominated delegate will determine if further veterinary or clinical intervention is required; if the project should be suspended pending the results of further investigations or if any other action should be taken to protect the welfare of the animals involved.

The University Vet or nominated delegate has the authority to take samples from other animals if required to determine the cause of the unexpected adverse event.

The University Vet or nominated delegate will provide an update on the progress of the investigation of the unexpected adverse event(s) to the AEEC.

**Definitions**

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<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tr>
<td>Adverse event</td>
<td>Any event that has a negative impact on the wellbeing of an animal.</td>
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<tr>
<td>Unexpected adverse event</td>
<td>An event that may have a negative impact on the wellbeing of any 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:</td>
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<td>• death of an animal, or group of animals, that was not expected (e.g. during surgery or anaesthesia, or after a procedure or treatment);</td>
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<td>• adverse effects following a procedure or treatment that were not foreshadowed in the approved project;</td>
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<td>• the sudden death of any animal under an approved animal ethics protocol;</td>
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<td>• adverse effects in a larger number of animals than predicted</td>
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The Deputy Vice-Chancellor (Research) is responsible for the development, compliance monitoring and review of this policy and any associated schedules, procedures and guidelines.
Implementation Officer

The Director, Research Services is responsible for the implementation of this policy in accordance with the scope outlined above.

Relevant Legislation & Guidelines

*Australian Code for the care and use of animals for scientific purposes (2013)*


*Australian Code for the Responsible Conduct of Research (2007)*


*ANU Code of Research Conduct*


*ACT Animal Welfare Act 1992*