

## ERM Animal Unexpected Events Subform guidance

### Introduction

This document is a guide to completing the Animal Ethics Unexpected Events subform in QUT's Ethics Research Manager (ERM). Its purpose is to help you understand each question, and therefore to help you consider and explain what happened to the animals during the adverse event, how you cared for the animals when the event occurred, and what changes (if any) you will make to your project to minimise the risk of the event happening again.

### About the form

To generate the form in ERM, first select the project you are reporting on. Then in the left hand column click 'create subform', select 'unexpected events form' from the drop down list, then click 'create'.

The unexpected events subform is a dynamic document, and questions may appear or disappear depending upon how you have responded to a previous question. As such, the numbering adjacent to each question may not always seem to be consecutive.

It is important for you to remember the composition of the ethics committee when completing the form. **Your answers should be written in lay language, primarily for an interested, intelligent person without a scientific background, not for a specialist.** You should clearly describe what happened to the animals and what was done to ensure their well-being. Your responses should also consider the 3Rs (Replacement, Reduction and Refinement) where required.

Documents can be uploaded to the form in most standard formats (e.g. word, excel, pdf, jpeg, mp4 etc). The form does not support hyperlinks. NOTE: the maximum total upload size for the whole project is 10GB. Therefore, if you need to include large files (particularly videos), it is recommended you enter the web address for a file sharing system into one of the text fields.

Once you have answered all the questions you can choose to perform a 'completeness check' to identify any sections in the form you may have missed. Most questions on the form are compulsory, however it is possible to write 'not applicable' in response to a question if appropriate.

The form automatically saves each time you select 'next' to move between sections. You can also 'save' your form as you go if you're not able to complete it at once, or if you want your project collaborators to review your responses prior to submission.

## What happens next?

When you've completed the form, sign the declaration and select 'submit' to send the form to the Animal Ethics Advisory Team.

Once submitted, your unexpected event subform will initially be assessed by the Animal Welfare and Ethics Coordinator (AWEC) then sent to the University Animal Ethics Committee (UAEC) for review. You will receive an email notification if the AWEC or the UAEC have any additional questions about the unexpected event, if any further action is required, or if the event is considered closed/resolved.

## Additional resources

It is recommended that you review the following guidelines (also referenced in this document) before preparing your report:

- [The Australian Code for the care and use of animals for scientific purposes](#)
- [Best practice methodology in the use of animals for scientific purposes](#)
- [PREPARE: guidelines for planning animal research and testing](#)
- [Improving Bioscience Research Reporting: The ARRIVE Guidelines for Reporting Animal Research](#)

## Guidance by question

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### Details

<b>1. Does this event relate to a human ethics or animal ethics project?</b> <ul style="list-style-type: none"> <li>• Human</li> <li>• Animal</li> </ul>	<p><i>This question helps decide the type of form, and therefore which sections of the form you will be asked to complete.</i></p> <p>Select 'animal'</p>
<b>2. Details of the person reporting the unexpected event.</b>	<p>Provide your name and best phone and email contact details</p>
<b>3. Are you the Chief Investigator?</b> <ul style="list-style-type: none"> <li>• Yes</li> <li>• No</li> </ul>	<p><i>If you select 'no' question 3.1 will appear.</i></p>
<b>3.1 Chief Investigator details</b>	<p>Provide the name, phone and email details for the project Chief Investigator</p>

### Event Summary

<b>4. Date the event occurred</b>	<p>Select the date the incident occurred from the calendar</p>
<b>5. Location of the event</b>	<p>You should provide specific details of where the incident occurred e.g. building location, room number, cage number</p>
<b>6. Briefly summarise the event using lay language</b>	<p>Your response should include the following:</p> <ul style="list-style-type: none"> <li>• The number and description of the animal(s) involved (species, strain, animal identification number and the experimental group the animal(s) belonged to)</li> <li>• the personnel in attendance/involved</li> <li>• a description of what was happening at the time of the adverse event</li> </ul> <p>If the animal was found dead, describe the nature in which it was found:</p> <ul style="list-style-type: none"> <li>• Was there any evidence in the area associated with the event (e.g. signs of struggle, blood in the area, damage to the housing)?</li> <li>• Could you estimate how long the animal was dead by the stage of rigor mortis?</li> </ul>

<p><b>7. Please indicate what immediate actions were taken to minimise any impact on the wellbeing of the animal(s) involved e.g. veterinary assistance; withdrawal of the animal from the activity; euthanasia; necropsy</b></p>	<p>Explain what you did next. Describe the steps you took at the time of the event to promptly minimise any pain or distress the animal(s) may have been experiencing.</p>
<p><b>8. What subsequent actions have been taken to minimise the event repeating?</b></p>	<p>List the changes (if any) will you be making to the project, the environment, equipment, associated procedures, medications, training of personnel, selection criteria for animals etc. to reduce the chances of a similar event occurring in the future.</p> <p>If you propose to make changes to the project you will also need to submit a variation request in ERM and update the application accordingly. Any changes to the project need to be approved by the UAEC before they are implemented.</p>
<p><b>9. Please provide a description of the current situation regarding the care and welfare of the animal(s) involved.</b></p>	<p>Your response could consider the following:</p> <ul style="list-style-type: none"> <li>• If the animal(s) involved in the event is still alive what is its current health status?</li> <li>• What is the status of the remainder of the animals in the project?</li> <li>• Is the project (or part of the project) still proceeding or has it been put on hold while modifications are made or further investigations are undertaken?</li> <li>• Can any data from the animal involved in the event still be of use in the project?</li> </ul>
<p><b>9.1 Are you requesting replacement animals as a result of this adverse event?</b></p> <ul style="list-style-type: none"> <li>• Yes</li> <li>• No</li> </ul>	<p><i>If you select 'yes' question 9.2 will appear.</i></p>
<p><b>9.2 Provide details of how many additional animals you require, which experimental group they will belong to, and justify why the extra animals are required (particularly if a drop-out rate was already anticipated in the study).</b></p>	<p>Explain why any additional animals are necessary for the project. Simply stating that it is to replace the lost animal(s) is not adequate.</p> <p>Statistical projections/power calculations often make allowances for some degree of outlying data or loss of data. If your project had already allowed for a drop-out rate, describe why any additional animals were not considered part of that drop-out rate.</p>
<p><b>10. Please outline any health, safety, environmental, legal, ethical and/or other issues that have arisen due to the event or incident.</b></p>	<p>Consider some of the following examples:</p> <ul style="list-style-type: none"> <li>• Are any there any associated health and safety concerns? e.g. zoonotic diseases, injuries to personnel that occurred, or could be prevented in future, as part of the event</li> <li>• Is a notifiable disease suspected?</li> </ul>

- Could the event impact the environment? e.g. death of an endangered species, escape of a declared pest species
- If this is a collaborative project do the other institutions need to be advised?
- Does the funding/grant body need to be advised of the event?
- Does the adverse event cause any potential risk of legal or reputational damage to the University?

## Necropsy

### 12. Has/will a necropsy been performed?

- Yes
- No

*If you select 'yes' questions 13 and 13.1 will appear.  
If you select 'no' question 14 will appear.*

When an animal dies unexpectedly or is euthanised prior to the completion of the project due to unforeseen or adverse circumstances, a necropsy should be performed by a competent person (Code 3.1.25)

### 13. Please specify the experience and the qualifications of the person(s) who has/will perform the necropsy.

You should provide the name, any relevant qualifications and species specific experience of the person conducting the necropsy.  
This person must be competent at performing a necropsy and have a good understanding of the anatomy of the species so they can detect any clinically relevant changes.

#### 13.1 If completed, please attach a copy of the necropsy report.

The necropsy report must include the date/time of when the necropsy was performed, and specific identification details for the animal. The report should discuss the different body areas including: external appearance (skin, coat, orifices), musculoskeletal system, urogenital system, digestive system, respiratory system, cardiovascular system. The amount of detail provided on each body system should depend on its relevance to the adverse event.

It is not always possible to determine a cause of death, but the report should discuss the potential causes of the event. It may also be helpful to include references where appropriate.

If you wish to provide any videos or other large files it is preferable to type in the web address to a file sharing system (e.g. Onedrive).

### 14. Provide a justification why a necropsy will not be performed

Some possible examples of why a necropsy wasn't suitable include:

- the animal was already decomposing so a necropsy would not provide worthwhile information
- the whole animal was retained to be used as a species voucher specimen

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- the location of the animal meant a necropsy was not appropriate
  - the cause of death could be determined definitively without a necropsy
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### Unexpected Event details

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**14. Please upload any supporting documents here.**

Supporting documents can include the animal passport, cage cards, any monitoring sheets, test results, pathology reports, X-rays or images etc. relevant to the event.  
There is no need to attach the necropsy report here a second time.  
If you wish to provide any videos or other large files it is preferable to type in the web address to a file sharing system (e.g. Onedrive)

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### Declaration

Enter your name as an electronic signature. Once you have signed the declaration you should select 'submit' to send the form to the animal ethics team for review.

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