

WILDLIFE ETHICS COMMITTEE

Adverse events reporting policy

Notifying animal ethics committees of **unexpected adverse events** is a requirement of the Australian code for the care and use of animals for scientific purposes 8th edition (2013) updated 2021 (the Code). By sharing this information, findings can be used as a basis for developing prevention strategies that improve animal welfare and research outcomes (refinement).

Projects approved by the South Australian Wildlife Ethics Committee (WEC) require that this reporting is carried out using the WEC Adverse Event Form, as soon as reasonably possible following the event. Reports should be submitted via the [Executive Officer \(EO\) mailbox](#).

What is an unexpected adverse event?

According to 'the code' an adverse event refers to any event that has a negative impact on the wellbeing of an animal. An unexpected adverse event means an event that is not foreseen and approved in the original proposal.

The South Australian WEC define **unexpected adverse events** as:

An event occurring as a result of the project that has a negative impact on the wellbeing of an animal and was not foreseen and approved in the original proposal.

In order to be considered 'foreseen and approved' the perceived risk and extent of risk must have been outlined in the application, including a mitigation and response protocol.

The researcher may consider the event "normal", but if it has not been taken into consideration by the Committee when assessing the welfare impact, benefit, and justification of the activity then it must be reported.

Examples of reportable events

The Code states that 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 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 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.

Here are some specific wildlife related examples of reportable adverse events:

- Deaths of animals not described in the proposal e.g. animal found dead a week after surgery to implant a transmitter.
- Complications not described in the proposal e.g. animals develop abscesses under an adhesive bandage used to attach a transmitter.
- More deaths or complications occur than described in the proposal e.g. incidental trap death greater than the predicted percentage.
- Field emergencies that do or may compromise animal welfare or the success of the activity e.g. wild fire or flash flooding prevents researchers from accessing the trapping site to make the scheduled checks.
- Facilities or management practices result in problems for the animals e.g. birds show signs of getting sore feet due to the type of flooring in a holding enclosure.
- The procedures are having a greater negative welfare impact than described and approved e.g. animals are behaving abnormally or appear to be in more distress than expected following fitting of a radio-transmitter.

The collection of voucher specimens that have been approved in the original project should be included in the annual reporting but are not considered unexpected and do not require an adverse event report.

If a study animal dies from natural causes unrelated to the research activities, this event should be included in the annual reporting but indicate that it is not an adverse event.

Actions required

All adverse events whether unexpected or not should put the animals welfare first. Prior to submitting an adverse event report researchers should act promptly to deal with any welfare interventions that are required such as emergency treatment, consultation with a veterinarian or humane killing of an animal in accordance with the projects WEC approval.

Researchers are advised to refer to the **flowchart** at the end of this policy to clarify expected response to any adverse event.

How soon should WEC be notified?

Reports should be made 'promptly', preferably on the day of the event but not exceeding 7 days. Details should be supplied via the Adverse Event Report Form. If some specific details are not yet available, i.e. necropsy report, this can be noted on the form and resubmitted once it has been added.

Who should notify the WEC?

Anyone with responsibility for the research animals should notify the Committee about events that have occurred, or that may impact on animals they are using. Reporting is not limited to the Primary Researcher, however it may be appropriate for this person to submit reports on behalf of all personnel involved in the project. If any person, whether a member of the public or a research participant has concerns regarding the care or treatment of any research animal or the conduct of a project they may report the matter to the Committee.

Necropsy

A necropsy is the examination and dissection of the dead body of an animal in order to determine cause of death. Where the cause of death is not known or obvious, a necropsy should be performed whenever possible. Consider preserving the carcass (whether necropsied or not) and offering it to the SA Museum or other appropriate institution, as it may yield useful information.

Performing a necropsy

In accordance with the Code, a necropsy should be performed by a person with appropriate qualifications and/or experience. Normally this would be a veterinarian and/or veterinary pathologist. In some wildlife scenarios, when a vet is not available, it may be appropriate for an experienced researcher to provide notes and photographs outlining expected cause of death/injury.

How do I avoid making many reports for things that happen as a normal part of studying animals?

A report is not required if the Committee knows that the event may happen and the event has happened as expected and approved. If a researcher has explained in their application the type and extent of events that they expect will occur, and if the events happen as expected and are acted on as proposed, such events do not have to be reported as adverse events. These events and details outlining the actions taken should be included in the annual and/or final reports. Check with the Executive Officer.

Example of when an event report is NOT required:

- Expected deaths of animals as described and approved in the proposal e.g. a researcher studying Yellow-footed Antechinus (Marsupial Mouse) in the wild has outlined that they expect 100% of the males to die in their first year shortly after mating as this is the natural life-cycle for this species.
- Two skinks died in pitfalls traps due to obvious ant bite, but after mitigation as outlined in the application for this risk, there were no further deaths and the % deaths remained under the predicated % of captures.

What will happen once I have made a report?

The Executive officer will consult promptly with the Executive Committee of the WEC. If the Executive Committee are satisfied that the researcher has taken the appropriate measures to avoid a recurrence of the situation, then no further action is required and the report is presented to the WEC at the next scheduled meeting. If the WEC decides that urgent or further investigation is required, contact will be made with the researchers and, where applicable, staff from the relevant institution (i.e. Department for Environment and Water/SA Museum/ ZoosSA). Following an investigation, a project may be allowed to continue with or without modification or may be suspended pending further review if necessary.

Responsibilities

Position	Responsibility
WEC executive officer	Present procedure to WEC for review biennially.
WEC members	Review procedure biennially.
WEC members	Use procedure in day to day responsibilities on committee.
WEC researchers	Use procedure in approved projects.
WEC Chair	Ownership of procedure.

Associated Documents and References

[*Australian code for the care and use of animals for scientific purposes \(8th edition 2013\)*](#)

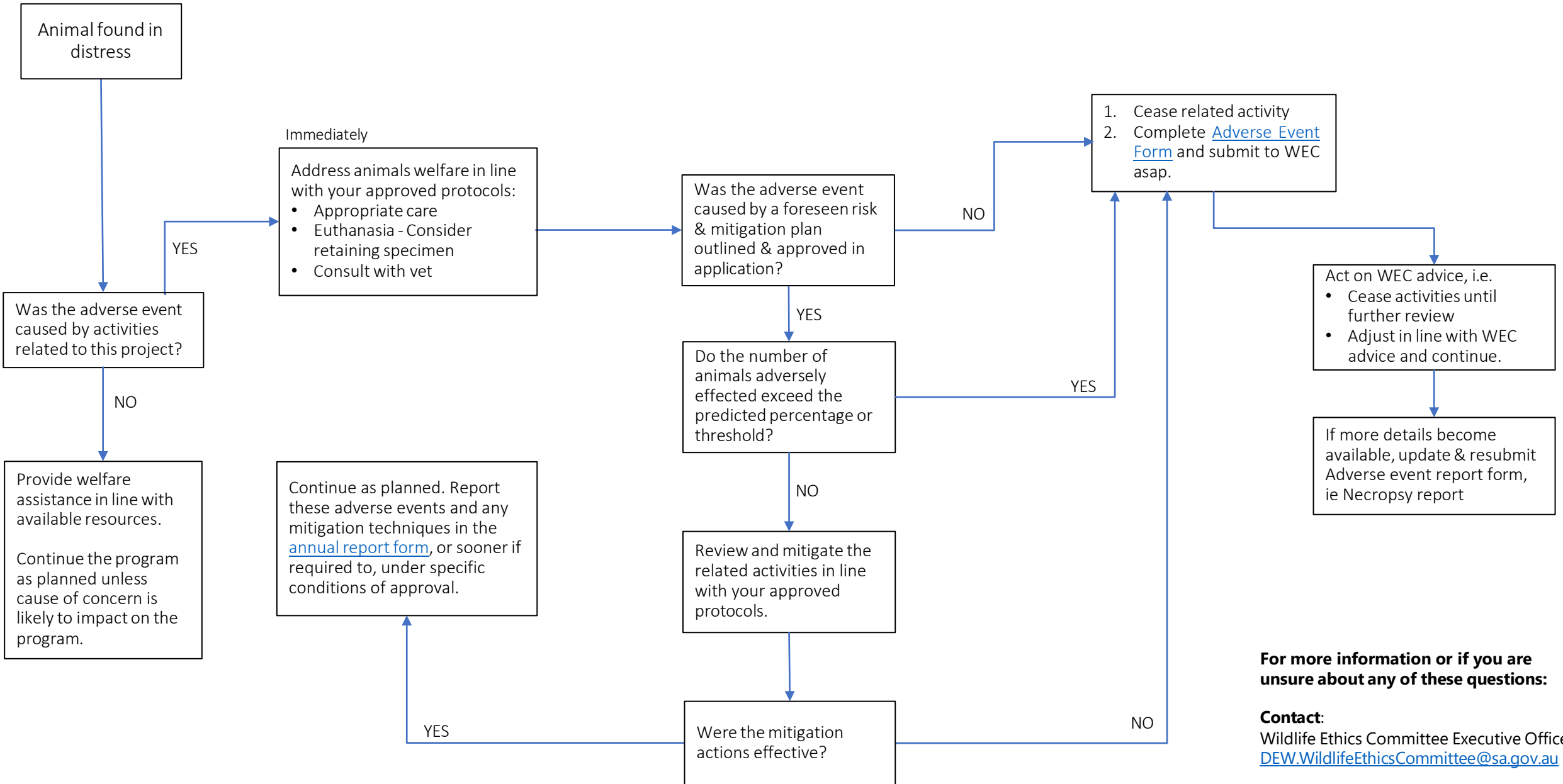
Contact

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Approved by	Wildlife Ethics Committee	Date Approved	10 th October 2024
Responsible Unit	Science and Information Branch	Review Date	January 2026
Keywords		Version	2

Wildlife Animal ethics Committee – Adverse Event Flowchart

Oct 2024



For more information or if you are unsure about any of these questions:

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