**Animal Research Ethics Committee (AREC)**

**UNEXPECTED ADVERSE EVENT REPORT**

**NOTE:** The Fiji National University Animal Research Ethics Committee reports on the unexpected adverse events based on “*The ANZCCART* [*Guidelines for the Use of Animals in Experiments and Research*](https://anzccart.adelaide.edu.au/system/files/media/documents/2019-07/aec-induction-package2018-9-1.pdf)” that has been stipulated in the CONSTITUTION OF THE FNU ANIMAL RESEARCH ETHICS COMMITTEE.

The *ANZCCART* [*Guidelines for the Use of Animals in Experiments and Research*](https://anzccart.adelaide.edu.au/system/files/media/documents/2019-07/aec-induction-package2018-9-1.pdf) defines an Adverse Event as; any event that has a negative impact on the wellbeing of an animal.

Itdefines an Unexpected Adverse Event as; 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
* adverse effects following a procedure or treatment that was 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, and not the number approved for the study
* a greater level of pain or distress than was predicated in the planning of the project or activity
* power failures, inclement weather, an emergency situation, or other factors external to the project or activity that have a negative impact on the welfare of the animals

Prompt action must be taken in response to unexpected adverse events and emergencies, including alleviation of pain and distress, in accordance with institutional and AREC policies and procedures. Alleviation of pain and distress of severity that was not anticipated in an approved project must take precedence over an individual animal reaching the planned endpoint of the project or activity, or the continuation or completion of the project or activity. If necessary, animals must be killed humanely without delay in accordance with *the ANZCCART* [*Guidelines for the Use of Animals in Experiments and Research*](https://anzccart.adelaide.edu.au/system/files/media/documents/2019-07/aec-induction-package2018-9-1.pdf).

When an animal dies unexpectedly or is humanely killed due to unforeseen complications, a necropsy should be performed by a competent person in accordance with *the ANZCCART* [*guidelines for the Use of Animals in Experiments and Research*](https://anzccart.adelaide.edu.au/system/files/media/documents/2019-07/aec-induction-package2018-9-1.pdf).

It is the policy of the Fiji National University’s (FNU) Animal Research Ethics Committee (AREC) that unexpected adverse events, including unexpected deaths, are reported to the AREC within 24 hours.

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| *Office use:* | **Report Number** |  | **Date Received** |  |  |

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| **UNEXPECTED ADVERSE EVENT REPORT** |

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| **Title of Project:** | Click here to enter text. |
| **Approval No.:** | **AREC** Click here to enter text. |
| **Principal Investigator:** | Click here to enter text. |
| **School:** | Click here to enter text. |
| **Telephone No.:** | Click here to enter text. |
| **Email Address:** | Click here to enter text. |
| **Date of expiry of the Approval:** |  |

1. **Species and Number of Animals that have died:**

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| **Species (and strain if appropriate)** | Click here to enter text. |
| **No. of animal (s) that died** | Click here to enter text. |
| **Sex of the animal (s)** | Click here to enter text. |
| **Identification No. (s)** | Click here to enter text. |
| **Age of the animal (s)** | Click here to enter text. |
| **Date of adverse event** | Click here to enter text. |
| **Location of animal(s) at time of the adverse event** | Click here to enter text. |
| **No. of animals in the treatment group the animal (s) belongs to** | Click here to enter text. |

**2. Fate of Any Progeny:**

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| Click here to enter text. |

**3. What were the circumstances surrounding the adverse event? Include details of the symptoms and/or signs exhibited by the animal, e.g. weight loss, diarrhea, vomiting, respiratory difficulty, collapse, abdominal swelling or other signs of injury or distress, or found dead.**

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| Click here to enter text. |
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**4. At what stage of the project did the event occur? What treatments/procedures had been performed on the particular animal(s) prior to the event? Include a timeline of events if relevant.**

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| Click here to enter text. |

**5. What action was taken when the event happened or was discovered? (e.g. animal euthanased, the vet called, pain relief was administered, and animal monitoring changed).**

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| Click here to enter text. |

**6. Was a necropsy performed?** ☐ **YES** ☐ **NO**

**If NO, explain why not.**

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| Click here to enter text. |

**If YES, advise who performed the necropsy, with contact details, and attach a copy of the necropsy report.**

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| |  |  | | --- | --- | | **Name:** Click here to enter text. |  | | **Organisation/Position:** Click here to enter text. |  | | **Address:** Click here to enter text. |  | | **Phone:** Click here to enter text. |  | | **Email Address:** Click here to enter text. |  | |

**7. What other investigations have taken place? (eg. histopathology, haematology, faecal tests, microbial culture).**

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| Click here to enter text. |

**8. Are other animals at risk?** ☐ **YES** ☐ **NO**

**If YES, what measures have been taken to minimize risk or to prevent reoccurrence of this risk?**

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| Click here to enter text. |

**9. Have there been any previous unexpected events in this protocol?**

**If YES, please provide the Report Number and the cause of death.**

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| Click here to enter text. |

**10. List and attach any supporting documentation (photos/references/pathology reports etc.)**

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| Click here to enter text. |

**11. Why/how do you think this event occurred?**

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| Click here to enter text. |

**12. What immediate and long-term actions are being taken to prevent a recurrence? (e.g. modification to procedures or experimental design, housing, monitoring or researcher/student training or supervision).**

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| Click here to enter text. |

**13. Is there any other information or comment you wish to provide in relation to this event?**

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| Click here to enter text. |

Signature of Principal Investigator:

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date:** Click here to enter text.

Thank you for submitting this form. A Report Number will be issued to you by the Ethics Office; please include this reference in your Progress/Final Report.