ADVERSE EVENT NOTIFICATION

**Purpose:** Both the PHS Policy (IV.C.5) and USDA Animal Welfare Regulations [9 CFR 2.31(d)(5)] require IACUC continued review of previously approved protocols. The IACUC, as a part of post-approval monitoring, requires investigators to notify the IACUC and Veterinary Resources (VR) of any adverse events (AE) or unexpected outcomes to animals during the course of a project.

**Applicability:** This policy applies to all research-related animal use under the oversight of the UMB IACUC.

**Definition of an adverse event**: *Any occurrence of an unforeseen event that negatively impacts the welfare of research animal(s), involving pain, distress, and/or death of the animal. By definition, AEs are not identified as potential risks or outcomes in the approved IACUC protocol.*

**The following form should be used for:**

1. Any adverse event affecting an USDA regulated species. A separate form must be submitted per animal.
2. Any adverse event affecting >10% of laboratory mice or rats or cold-blooded vertebrates. Batch reporting is acceptable. *(Note: A 10% loss of animals could be considered a potential recurring event requiring re-evaluation and/or refinement of a process / procedure*).

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**Examples of events that are required to be reported as AEs:**

* Animal mortality or morbidity in excess of that described in the approved IACUC protocol.
* Unforeseen events that lead to the harm of the animal(s) or that cause obvious pain or distress not justified and approved in the protocol.
* Conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals or personnel ([grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html)).

**Examples of events that are NOT required to be reported as AEs:**

* Injury / illness unrelated to IACUC approved procedures and being evaluated / treated by the Veterinary Resources (VR) clinical staff.
* Death or morbidity of animals described as expected in the approved IACUC protocol

**Timeframe for reporting:**

The first priority is to protect animal health and welfare. The PI or their staff should immediately contact a VR Attending Veterinarian (6-3540 or call after hours 443-835-9841) and/or VR Facility Management (6-3547 or 6-1601) regarding the adverse event.

The IACUC must be notified of the event within 24 hours and a completed Adverse Event Notification form should be submitted by email within 1-3 days to the IACUC

([iacuc@som.umaryland.edu](mailto:iacuc@som.umaryland.edu)) and cc’d to Veterinary Resources ([tcoksaygan@som.umaryland.edu](mailto:tcoksaygan@som.umaryland.edu)).

*If you have any questions regarding the use of this form, please contact the Office of Animal Welfare Assurance (OAWA) (6-7859 / 8470 or* [*iacuc@som.umaryland.edu*](mailto:iacuc@som.umaryland.edu)*).*

\*\*ADVERSE EVENT NOTIFICATION FORM\*\*

**Date:** Click here to enter a date.

**Principal Investigator:** Click here to enter text. **IACUC Protocol No.:** Click here to enter text.

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

**Title of Project:** Click here to enter text.

**Adverse Event**: *Any occurrence of an unforeseen event that negatively impacts the welfare of research animal(s), involving pain, distress, and/or death of the animal. By definition, AEs are not identified as potential risks or outcomes in the approved IACUC protocol.*

**ADVERSE EVENT/UNANTICIPATED PROBLEM DESCRIPTION**

Date of Event/Injury: Click here to enter a date.

Location of Event: Click here to enter text.

Outcome:  Treated/Recovered  Treated/Euthanized  Fatal

Was a Veterinary Resources Veterinarian consulted?  Yes  No

Is this event related to the research?  Related  Possibly Related  Not Related

Is the possibility of this event noted in the current approved protocol?  Yes  No

1. Please provide a description (include dates and details) of the adverse event/unanticipated problem:

Click here to enter text.

1. Please provide a description of how this event/problem was managed:

Click here to enter text.

1. Please provide a description of the corrective actions taken to ensure that this type of event/problem does not occur in the future:

Click here to enter text.

**Changes necessitated by adverse event**

Does this adverse event require a change to the protocol?  Yes  No

*If yes, please attach an* [*IACUC Protocol Amendment Form*](https://www.umaryland.edu/oawa/forms) *with this report.*

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Signature of Principal Investigator