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*).

.

**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) and cc’d to Veterinary Resources (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**).*

\*\*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.*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Principal Investigator