MONTANA STATE UNIVERSITY
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)

GUIDANCE ON PROMPT REPORTING OF UNANTICIPATED ADVERSE EVENTS

The IACUC Unanticipated Adverse Event Form must be completed for reporting any adverse or unanticipated event affecting animals used in research, testing or teaching.

Principal Investigators should seek assistance from the Attending Veterinarian when adverse events occur. S/he can assist in assessing the situation, seeking resolutions, and helping with the report. Consultation with the Attending Veterinarian **MUST** occur when pain or distress is beyond the level anticipated in the protocol description or when interventional control (such as administration of analgesics) is not possible.

Definition of an unanticipated or adverse event: Any event not consistent with routine expected outcomes that results in unexpected animal welfare issues (death, disease, distress).

Examples of events that MUST be reported include, but are not limited to the following:

- Animal death or illness from spontaneous disease not related to activities approved on a protocol.
- Unexpected animal death or injuries related to approved animal activities (e.g., allergic reactions, broken limbs, complications during or recovering from surgery, sudden death). Unexpected death includes an increased number of deaths over what was stated in the approved protocol.
- Death, disease or distress due to equipment failure or natural disaster.

The Adverse Event Form should be completed and submitted to the IACUC within 24 hours of observing the event.

Email a copy of the report to the IACUC Program Manager,

Adverse events affecting USDA regulated species require a separate report for each affected animal.

Questions regarding the use of this form should be directed to the IACUC Chair, or the IACUC Program Manager.

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UNANTICIPATED ADVERSE EVENT FORM

For use in reporting any event not consistent with routine expected outcomes that results in unexpected animal welfare issues (death, disease, distress).

PROTOCOL # ___ **BUILDING & ROOM #**

PROTOCOL TITLE:

PRINCIPAL INVESTIGATOR:

Investigator's Name **Investigator's Signature** **Date**

Description of the Unanticipated Problem or Adverse Event			
Date of Event/ Problem:		**Date Identified:**	
Species of Animal		**Number of animals involved**	
Location of Event:			
Outcome	☐ Treated/Recovered ☐ Treated/Euthanized ☐ Fatal		
Was the Attending 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
Does this event require a change to the protocol? If yes, please submit a modification to the protocol.			☐ Yes ☐ No

1.	**Provide a description (include dates and details) of the adverse event, or unanticipated problem:**

2.	Provide a description of how this adverse event, or unanticipated problem was managed:

3.	**Provide a description of the corrective actions taken to ensure that this type of adverse event, or unanticipated problem does not occur in the future:**

It is Montana State University policy that the procurement, housing, care, and use of animals should conform to the Guide for the Care and Use of Laboratory Animals and other relevant federal or state policies and procedures. The policy applies to all research and teaching involving the use of laboratory animals whether funded from external or internal sources. Submit to the IACUC_Program Manager, and/or Office of Research Compliance