

**EAST TEXAS A&M UNIVERSITY  
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)**

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**GUIDANCE ON PROMPT REPORTING OF UNANTICIPATED  
PROBLEMS/PROTOCOL DEVIATIONS/ ADVERSE EVENTS**

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

**\*\*It is appropriate to seek assistance from a veterinarian when adverse events or protocol deviations occur. They 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 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 an AUP.
- Unexpected animal death or injuries related to approved animal activities (ie-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 due to equipment failure or natural disaster.
- Conduct of animal-related activities without appropriate IACUC review and approval (i.e.- implementing protocol amendments prior to obtaining approval)

**The Adverse Event Report should be completed and submitted to the IACUC within twenty-four (24) hours of observing the event.**

Email a copy of the report to: [researchcompliance@etamu.edu](mailto:researchcompliance@etamu.edu)

Questions regarding the use of this form should be directed to the IACUC chair or [researchcompliance@etamu.edu](mailto:researchcompliance@etamu.edu).

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**UNANTICIPATED PROBLEMS/PROTOCOL DEVIATIONS/ADVERSE EVENTS FORM**

For use in reporting unanticipated problems, protocol deviations, or adverse events associated with animals used in research, testing, or teaching

**PROTOCOL #** \_\_\_\_\_

**BUILDING & ROOM #** \_\_\_\_\_

**PROTOCOL TITLE:**

**PRINCIPAL INVESTIGATOR:**

\_\_\_\_\_  
Investigator's Name

\_\_\_\_\_  
Investigator's Signature

\_\_\_\_\_  
Date

Description of the Unanticipated Problem, Protocol Deviation, or Adverse Event			
<b>Date of Event/ Problem:</b>		<b>Date Identified:</b>	
<b>Species of Animal</b>		<b>Number of animals involved</b>	
<b>Location of Event:</b>			
<b>Outcome</b>	<input type="checkbox"/> Treated/Recovered <input type="checkbox"/> Treated/Euthanized <input type="checkbox"/> Fatal		
<b>Was a Veterinarian consulted?</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No		
<b>Is this event related to the research?</b>	<input type="checkbox"/> Related <input type="checkbox"/> Possibly Related <input type="checkbox"/> Not Related		
<b>Is the possibility of this event noted in the current approved protocol?</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No		
<b>Does this event require a change to the protocol? If yes, please submit an amendment with this report.</b>	<input type="checkbox"/> Yes <input type="checkbox"/> No		

<b>1.</b>	<b>Provide a description (include dates and details) of the adverse event or unanticipated outcome/problem:</b>
<b>2.</b>	<b>Provide a description of how this event or unanticipated outcome/problem was managed:</b>
<b>3.</b>	<b>Provide a description of the corrective actions taken to ensure that this type of event or unanticipated outcome/problem does not occur in the future:</b>

It is East Texas A&M 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.

**Please email this form immediately to the IACUC chair: [ResearchCompliance@etamu.edu](mailto:ResearchCompliance@etamu.edu)**