

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

Definition of an unanticipated or adverse event: Any event that specificity and severity are not accurately reflected in the protocol-related documents that result in unexpected animal welfare issues (death, disease, distress).

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

1.	Provide a description (include dates and details) of the adverse event or unanticipated outcome/problem:
2.	Provide a description of how this event or unanticipated outcome/problem was managed:
3.	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:

It is the University of Houston's 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.

Adverse events affecting USDA regulated species need a separate report per affected animal

Please email this form immediately to the IACUC: IACUC@uh.edu