



Policy 370

Reporting Adverse Events

Responsible Official:	Research Administration
Administering Division/Department:	Research Compliance and Regulatory Affairs / IACUC
Effective Date:	12/01/2010
Last Revision Date:	06/15/2022

370.1 Policy

The IACUC is under a federal mandate to monitor all research activities related to animal use. To assist the IACUC in fulfilling this requirement, all suspected Adverse Events (AE) should be reported in a timely manner. This includes a verbal or email report of the adverse event to the IACUC within 72 hours followed by a written report within 10 business days. Reporting of potential AEs can be made to an Emory veterinarian, the IACUC office, or anonymously via the Emory Trust Line (see Policy 306 Whistleblower). An optional report form is available as Appendix 1.

370.2 Definitions

Adverse Event (AE) is the 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.

370.3 Examples of events that are required to be reported as AEs

370.3.1 Animal mortality or morbidity in excess of that described in the approved IACUC protocol

370.3.2 Unforeseen events that lead to the harm of the animal(s) or that cause obvious distress not described and approved in the protocol.

370.4 Examples of events that are not required to be reported as AEs

370.4.1 Injury/illness unrelated to approved procedures and being treated by the clinical veterinarians

370.4.2 Death, illness or morbidity of animals described as expected in the approved IACUC protocol

370.5 Applicability

This policy applies to all research-related animal use under the jurisdiction of Emory's IACUC.



370.6 Contact Information

370.6.1 Anonymous Concerns: Emory Trust Line

Phone: 1-888-550-8850

Online: <http://www.mycompliancereport.com/EmoryTrustlineOnline>

370.6.2 Animal Facilities

- **Emory NPRC DAR Main Office** Phone: 404-727-7721
- **EU-DAR Main Office** Phone: 404-727-7423

Appendix list

Appendix 1 Adverse Event Report Form

Contact Information

Subject	Contact	Phone	Email
Clarification of Policy	Office of Research Compliance and Regulatory Affairs - IACUC	404-712-0734	iacuc@emory.edu

Revision History

- Version Published on: 06/23/2022
- Revisions: 06/05/2019



Appendix 1 Adverse Event Report Form


Please fill in all known information

Protocol Number:	PI Name:
Grant # or Funding Information:	Location of Adverse Event:
Species:	Cage or Animal Identification Code:
Date of Finding:	Time of Finding:
Nature of Event – Please describe what happened: (additional space is provided on the next page)	
Person Reporting Event: (not required if reporting anonymously)	Report Submitted to: <input type="radio"/> IACUC Office <input type="radio"/> EU-DAR Facility Veterinarian <input type="radio"/> Emory NPRC Facility Veterinarian
Date of Report:	IACUC Use Only - Case Number:



Nature of Event: continue description here

A large, empty rectangular box with a black border, intended for the user to provide a detailed description of the event.

To submit this report, click on the  at the top left hand corner, next to the Printer icon, on the Adobe Acrobat tool and type the email address of the recipient/s