

INSTITUTIONAL NOTIFICATIONS TO THE ANIMAL CARE AND USE REVIEW
OFFICE
MAY 2019

Institutions conducting DoD-supported or conducted Research, Development, Testing, and Evaluation (RDT&E) or Training with animals must inform the Component Oversight Office, in a timely manner, of any significant deficiencies, noncompliance with DOD policy, and reports of adverse events regarding the DoD-supported or conducted activity. This document provides Animal Care and Use Review Office (ACURO) guidance for notifications.

1. Definitions and Clarifications:

- a. **Adverse event:** An incident that leads to unintended and substantial injury or illness, unrelieved pain or distress, or death of an animal. Adverse events include unforeseen, unanticipated, inappropriately addressed, or inappropriately alleviated sources of pain, distress, and/or death of an animal that were NOT identified (specifically or generally) as potential risk factors or potential adverse complications in the approved IACUC protocol or policy. Some adverse events may be expected in accordance with the animal care and use protocol. Those that occur at a higher frequency or severity than expected are reportable as outlined below.
- b. **Non-compliance:** An activity not in accordance with federal, DOD, and/or Institutional policies regarding animal care and use.
- c. **Significant Deficiency:** A deficiency that, in the judgement of the Institutional Animal Care and Use Committee (IACUC) and the institutional official, is or may be a threat to the health or safety of animals.
- d. **Protocol suspension:** An approved activity that is suspended by the IACUC or Institute for any reason.

2. Procedures:

- a. All IACUC-substantiated/confirmed adverse events, non-compliant activities, significant deficiencies, and protocol suspensions must be reported to ACURO within 5 business days. This includes any official reports to outside agencies, such as the Office of Laboratory Animal Welfare, United States Department of Agriculture, and comparable international authorities.

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- b. When an institution is notified by the USDA that it is under investigation, the institution must report the investigation to ACURO within 5 business days of initial notification.
 - c. When an AAALAC International accredited organization has a change in accreditation status, the institute must report the status change to ACURO within 5 business days.
 - d. Institutions will promptly notify ACURO of FOIA requests or other socially-sensitive matters (e.g. activist activities) concerning or potentially impacting DoD-conducted or supported protocols.
 - e. It is impractical to provide a comprehensive list all reportable events. Therefore, the Institution may call or e-mail ACURO to discuss specific incidents.
 - f. Preliminary reporting/discussion may occur by telephone.
 - g. E-mail notifications must be sent to usarmy.detrick.medcom-usamrmc.other.acuro@mail.mil. Include information in the subject line to identify the nature of the notification, e.g. "ADVERSE/REPORTABLE EVENT".
3. For questions regarding notifications, please contact the ACURO Office Manager by e-mail: usarmy.detrick.medcomusamrmc.other.acuro@mail.mil or phone: (301) 619-6694.