

# INSTITUTIONAL NOTIFICATIONS TO THE ANIMAL CARE AND USE REVIEW OFFICE

February 2020

Institutions conducting DoD-supported or conducted Research, Development, Testing, and Evaluation (RDT&E) or Training with animals must inform the US Army Medical Research and Development Command (USAMRDC) Animal Care and Use Review Office (ACURO) in a timely manner of any of the following for DoD-supported or conducted work RDT&E or training: significant deficiencies, noncompliance, change in AAALAC, International accreditation status, socially sensitive matters, adverse events, protocol suspensions. This document provides guidance on when and how to submit notifications to ACURO.

## 1. Definitions and Clarifications:

- a. **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.
- b. **Noncompliance:** Any activity not in accordance with federal, DoD, and/or Institutional policies regarding animal care and use.
- c. **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.
- d. **Protocol suspension:** An approved activity that is suspended by the IACUC or Institute for any reason.

## 2. Procedures:

- a. All IACUC-substantiated/confirmed significant deficiencies, noncompliance, change in AAALAC, International accreditation status, socially sensitive matters, adverse events, 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, or comparable international authorities.
- 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.

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- c. When an AAALAC International accredited organization has a change in accreditation status, the institution 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](mailto: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](mailto:usarmy.detrick.medcomusamrmc.other.acuro@mail.mil) or phone: (301) 619-6694.