

**DHA COMPONENT OVERSIGHT OFFICE
ANIMAL CARE AND USE REVIEW OFFICE (ACURO)**

ACURO Reporting Policy

Applicability: This Policy applies to all institutions conducting Department of Defense (DoD) (supported (extramural) or conducted (intramural)) Research, Development, Testing, and Evaluation (RDT&E) or Training with animals that fall under the Defense Health Agency (DHA) Component Animal Oversight Office, Animal Care and Use Review Office (ACURO).

Purpose: To inform institutions of the ACURO reporting requirements. This document serves as a guide for institutions to develop local policies and procedures to ensure ACURO's reporting requirements are satisfied. It is ACURO's responsibility to have awareness of activities occurring within these animal care and use programs that may impact research or training. Reporting these issues is a regulatory requirement and demonstrates a culture of compliance from the institute.

References:

1. DoDI 3216.01, "Use of Animals in DoD Conducted and Supported Research and Training," March 20, 2019.
2. DHA-MSR 6025.02, "The Care and Use of Animals in DoD Research, Development, Test, and Evaluation (RDT&E) or Training Programs," September 1, 2022.

Definitions and Clarifications:

1. **Significant Deficiency:** A deficiency that, in the judgement of the Institutional Animal Care and Use Committee (IACUC) and the Institutional Official (IO), is or may be a threat to the health or safety of animals.
2. **Noncompliance:** Any activity not in accordance with federal, state, or host nation laws, DoD regulations, and/or institutional policies regarding animal care and use.
3. **Adverse event:** An incident that leads to unintended injury or illness, unrelieved pain or distress, or death of an animal. These may 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.
4. **Suspension:** An approved activity that is suspended by the IACUC or institute for any reason.

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5. Substantiated Animal Welfare Concern: A report received via the institution's whistleblower process regarding concerns involving, but not limited to, animal welfare or conduct of study procedures. The report has been evaluated and deemed to be a legitimate concern that *is* subject to investigation by the IACUC.

Procedures:

1. WHAT MUST be reported to ACURO:

- a. All IACUC reports of:
 - i. significant deficiencies
 - ii. incidents of noncompliance
 - iii. adverse events
 - iv. protocol suspensions
 - v. substantiated animal welfare concerns
 - vi. any additional issues that are reported to Office of Laboratory Animal Welfare (OLAW), United States Department of Agriculture (USDA), AAALAC international, or comparable international authorities

- b. Other items to be reported:
 - i. a change in AAALAC, International accreditation status, including probation
 - ii. inactivation of your OLAW Assurance for reasons other than funding
 - iii. notification of being under USDA investigation or equivalent international authority
 - iv. FOIAs involving DoD work
 - v. taskers or requests for information involving the animal care and use program
 - vi. socially sensitive matters involving the animal care and use program

2. WHEN to report to ACURO:

- a. All reportable items must be sent to ACURO **within 5 business days** of the event. In the case of animal welfare concerns, reporting is expected after the concern is substantiated.

3. HOW to report to ACURO:

- a. Reports should be emailed to usarmy.detrick.medcom-usamrmc.other.acuro@health.mil

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- b. The email subject line should indicate a reportable event, i.e. (Adverse Event)

- c. Information to include in your report:
 - i. A brief description of the event to include species, incident date, ACURO protocol number
 - ii. Whether the incident will be reported to other agencies

ACURO reporting responsibilities to the Office of the Under Secretary of Defense for Research and Engineering (OUSD(R&E)): ACURO will notify within 5 business days of any of the following:

- 1. Reports of significant deficiencies
- 2. Reports of noncompliance with this issuance and its references that results in animal pain, distress, or death
- 3. Reports of change in an institution's AAALAC international accreditation status
- 4. Reports of adverse events to outside agencies
- 5. Reports of socially sensitive matters

Questions: Please contact the ACURO Office Manager by email: usarmy.detrick.medcom-usamrmc.other.acuro@health.mil or phone: (301) 619-6694.