

DEFENSE HEALTH AGENCY (DHA) COMPONENT OVERSIGHT OFFICE ANIMAL CARE AND USE REVIEW OFFICE (ACURO)

ACURO Protocol Change Policy

Applicability: This Policy applies to all institutions conducting Department of Defense (DoD) (supported or conducted) Research, Development, Testing, and Evaluation (RDT&E) or Training with animals that fall under the DHA Component Animal Oversight Office, ACURO, directly or via Memoranda of Agreement.

Purpose: This policy provides guidance on what types of changes require review and approval by ACURO. As DHA's component oversight office, ACURO is required to conduct administrative reviews of animal use protocols conducted or supported by the DoD. ACURO is also required to review and approve life-cycle changes for those protocols subject to ACURO oversight.

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.

Procedures:

DoD Supported Animal Studies (Extramural):

1. When an Institutional Animal Care and Use Committee (IACUC) approves significant changes/major modifications (as determined by ACURO) to the DoD-funded portion of a protocol subject to ACURO oversight, ACURO must review and approve the changes before they can be implemented, except where otherwise indicated below.
 - a. Examples of changes that must be reviewed and approved by ACURO before they can be implemented (except as otherwise indicated in section 3) include:
 - i. Any change considered to be significant/major by your institution that impacts DoD-funded work
 - ii. Changes in duration, frequency, type, number, or any new procedures performed on an animal, to include any change from terminal to survival procedures
 - iii. Change in species
 - iv. Change in study objectives
 - v. Change in Principal Investigator
 - vi. Changes in anesthesia, analgesia, sedation, or tranquilization

DEFENSE HEALTH AGENCY (DHA) COMPONENT OVERSIGHT OFFICE ANIMAL CARE AND USE REVIEW OFFICE (ACURO)

- vii. Changes in experimental substances, any change in the compound, including increase in frequency of administration, dose, or route
- viii. Changes in euthanasia methods
- ix. Any increase of animal numbers
- x. Changes involving increased risk to personnel and/or animal safety (e.g. addition of hazardous agents)

2. The following changes **do NOT** require ACURO review and approval prior to implementation for DoD-funded work and do not need to be submitted to ACURO.

- a. Administrative changes, e.g. correction of grammatical and/or typographical errors, contact information, etc.
- b. Personnel changes, with exception of the Principal Investigator
- c. Change of strain
- d. Decrease in animal numbers
- e. Change in housing and/or animal use location
- f. Changing from a more invasive procedure to a less invasive one (e.g., collecting less blood, doing fewer injections, postmortem rather than pre-mortem sample collection)

3. Significant/major changes approved by Veterinary Verification & Consultation (VVC)

- a. If your institution reviews a significant change using the VVC process while adhering to all applicable OLAW guidance, including OLAW Notice NOT-OD-14-126 (Guidance on Significant Changes to Animal Activities), you may immediately implement the change and do NOT need to await receipt of ACURO approval.
- b. Provide the amendment submission and documentation of the veterinary consultation with IACUC notification to ACURO **no later than 5 business days after approval**.
- c. ACURO will review the submission and, if needed, may request additional information or copies of institutional policies related to the VVC process and the approved change.
- d. ACURO considers changes approved in accordance with the procedures outlined here to be in full compliance with DoD requirements.
- e. Any institution utilizing a VVC process that is NOT consistent with OLAW guidance, including OLAW NOT-OD-14-126, must receive ACURO approval prior to implementation of any significant protocol changes.

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

DoD Conducted Animal Studies (Intramural):

1. Significant changes (as defined by institutional policy) to DoD-conducted studies subject to ACURO review must be reviewed and approved by ACURO prior to implementation.
2. Significant changes approved via VVC by DoD laboratories are subject to ACURO review as described above in Section 3.

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