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

ACURO Submission 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: As DHA's component oversight office, ACURO is required to conduct administrative reviews and approval of animal use protocols conducted or supported by the DoD. The purpose of the ACURO review is to conduct the Component level evaluation of proposed animal studies to ensure that DoD supported or conducted work is being performed in accordance with the standards outlined in DoD regulations.

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.
3. Onsite Compliance Inspection Guidance for DoD-Supported Research, Development, Testing, and Evaluation (RDT&E) Using Animals, Office of the Under Secretary of Defense for Research and Engineering (OUSDRE), 27 Aug 24
4. Guide for the Care and Use of Laboratory Animals, 8th edition, National Research Council, 2011 (Guide)

Procedures:

1. **DoD Supported Animal Studies (Extramural):**

    a. **DoD Requirements:** Before any funded animal work can begin, the ACURO office must conduct an administrative review of all DoD supported RDT&E involving animals and training to teach human medical or surgical care involving animals. This review must conclude with approval by a DoD veterinarian trained or experienced in laboratory animal medicine and science to ensure conformance with all applicable regulations, policies, and standards of veterinary care.

    b. **HOW to submit:** Before beginning funded animal studies, required documents must be submitted to ACURO for review and approval. These instructions apply to de novo protocol submissions as well.

        i. SUBMIT the documents below for processing to: usarmy.detrick.medcom-usamrmc.other.acuro@health.mil (PDF format is preferred). Alternatively, documents may be uploaded via Electronic Biomedical Research Application Portal) (eBRAP) (https://ebrap.org/eBRAP/public/index.htm).

            1. ACURO Animal Use Appendix
            2. IACUC Approved Protocol

3. Documentation of IACUC Approval (include expiration date)
4. Signed ACURO Protocol PI Assurances (the last page of the ACURO Appendix)

ii. All forms and instructions are available on the ACURO web page: https://mrdc.health.mil/index.cfm/collaborate/research_protections/acuro/protocol_submission

c. **CHANGES or other Lifecycle actions:** ACURO is also required to review and approve lifecycle actions including most amendments, de novo reviews and any reportable events. As stated above, this policy and its instructions apply to and are the same for de novo reviews. For more detailed instructions on amendments and reportable events see the ACURO Protocol Change Policy and the ACURO Reporting Policy available on ACURO's web page.

2. International DoD Supported Animal Studies (International Extramural):

a. **International submissions (Country and/or site approval):** International submissions involve several more steps, in addition to those outlined in Section 1, prior to submission, review, and approval.

i. **Country Accessibility**: DoD personnel must be able to safely enter the country to conduct a site visit. If the country where proposed animal work will take place is currently on the list of US countries of concern, and the awardee was not already notified by the funding agency, ACURO will notify the awardee and the funding agency via an email that we cannot approve work in a country that we are unable to enter, including for security reasons.[3] Additionally, ACURO will make case-by-case determinations using the State Department website (Travel Advisories).

ii. **Country laws and regulations comparability assessment:** Foreign countries laws and regulations pertaining to animal care and use vary, therefore an ACURO review to determine comparability of those laws and regulations to the US is required prior to any review or approval of animal work. The determination is referred to as the International Country Comparability Program Review (ICPR). If the country has been previously reviewed, then that review will be accepted, at the discretion of the ACURO Director.

iii. **Foreign Site level review:**

1. **Approved ICPR:** If the foreign country where the animal work is going to be taking place has been **approved** via an ICPR, ACURO will reach out to the award PI to begin the review and approval process. As part of that process, IACUC POCs will be contacted to ask several additional questions. For example, but not limited to:

a. What governing bodies within your country oversee animal care and use within the research environment?
b. What laws and regulations govern animal care and use within your country?
c. What documents are required by your country and IACUC to approve and conduct animal work?
d. How long is the approval period for a protocol?
e. A document must be provided to ACURO signed by the Institutional Official (individual responsible for making decisions on behalf of the institution) stating that the care and use of animals will be conducted in accordance with the standards of the current edition of the Guide for the Care and Use of Laboratory Animals, applicable Federal and DoD regulations and ACURO policies.

2. **AAALAC Accredited site:** If the foreign country where the work is being conducted **has not** been reviewed and approved via ICPR, but the site is AAALAC accredited, an individual site assessment will take place.

    a. The assessment will include asking the IACUC questions, as well as requesting documentation. For example, but not limited to:
        i. What govern bodies within your country oversee animal care and use within the research environment?
        ii. What laws and regulations govern animal care and use within your country?
        iii. What documents are required by your country and IACUC to approve and conduct animal work?
        iv. How long is the approval period for a protocol?

b. **DOD Requirements:** Once the country and site have been approved, the submission process to ACURO for review and approval of the animal research protocol may begin. Before any funded animal work can begin, the ACURO office must conduct an administrative review of all DoD supported RDT&E involving animals and training to teach human medical or surgical care involving animals. This review must conclude with approval by a DoD veterinarian trained or experienced in laboratory animal medicine and science to ensure conformance with all applicable regulations, policies, and standards of veterinary care.

c. **HOW to submit:** Before beginning funded animal studies, required documents must be submitted to ACURO for review and approval. These instructions apply to de novo protocol submissions as well.

    i. SUBMIT the documents below for processing to: usarmy.detrick.medcom-usamrmc.other.acuro@health.mil (PDF format is preferred). Alternatively,

documents may be uploaded via Electronic Biomedical Research Application Portal) (eBRAP) (https://ebrap.org/eBRAP/public/index.htm).

1. ACURO Animal Use Appendix
2. IACUC Approved Protocol
3. Documentation of IACUC Approval (include expiration date)
4. Signed ACURO Protocol PI Assurances (the last page of the ACURO Appendix)
5. ICPR form
6. Documents listed within the ICPR (i.e. additional required documents for protocol approval, permits, ethic committee approval)

ii. All forms and instructions are available on the ACURO web page: https://mrdc.health.mil/index.cfm/collaborate/research_protections/acuro/protocol_submission

d. **CHANGES or other Lifecycle actions:** ACURO is also required to review and approve lifecycle actions including most amendments, de novo reviews and any reportable events. As stated above, this policy and its instructions apply to and are the same for de novo reviews. For more detailed instructions on amendments and reportable events see the ACURO Protocol Change Policy and the ACURO Reporting Policy available on ACURO's web page.

3. DoD Conducted Animal Studies (Intramural):

a. **DoD Requirements:** All DHA laboratories must submit all RDT&E animal use protocols involving nonhuman primates, dogs, cats, or marine mammals and all training protocols using animals to teach human medical or surgical care to ACURO for administrative review and approval. ACURO approval is required prior to starting the animal work.

b. **HOW to submit:** Before beginning animal work, required documents must be submitted to ACURO for review and approval. These instructions apply to de novo protocol submissions as well.

i. SUBMIT the documents below for processing to usarmy.detrick.medcom-usamrmc.other.acuro@health.mil (PDF format is preferred)

1. IACUC Approved Protocol
2. Documentation of IACUC Approval (include expiration date)

c. **CHANGES or other Lifecycle actions:** ACURO is also required to review and approve lifecycle actions to these protocols, including major amendments, de novo reviews and any reportable events. As stated above, this policy and its instructions apply to and are the same for de novo reviews. For more detailed instructions on

amendments and reportable events see the ACURO Protocol Change Policy and Reporting Policy, available on ACURO's web page.

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