

**University of Texas at Austin
 Institutional Animal Care and Use Committee**

IACUC Informational Document # 8.3

TITLE	Investigator Resources and Information Regarding DOD Animal Use Compliance Committees		
Date of Last Revision		Version	1.0

Per IACUC Procedure # 8.2, the Department of Defense (DOD) uses a two-step/dual approval process for work involving animals. This informational document will guide investigators through the process of submitting to a DOD animal use compliance office (e.g. ACURO, AF/SGE-C) and will provide information for what to expect after approval from the DOD animal use compliance office.

8.3.0 NEW Animal Use Projects and DOD Grants

Before submitting to a DOD compliance office, an animal use protocol describing the work on the DOD grant must first be approved by the UT Austin IACUC.

Investigators should attach the grant application to the protocol and list the funding in the eProtocol form under “Funding – Other” with the source “Funding Pending (DOD)”. This will help UT parties avoid charging the account if the DOD compliance office has not approved the animal work, which would be noncompliant with funding stipulations.

Once the UT Austin IACUC approves the animal use protocol, the investigator must make a submission to the appropriate DOD compliance office. As a courtesy, ORSC staff can review the documentation prior to submission for administrative accuracies; however, these are not ORSC forms and the investigator is responsible for completion and submission of these documents. The following documentation must be emailed to the appropriate DOD compliance office (cc IACUC@austin.utexas.edu on the email):

1. IACUC approved version of each animal use protocol that will support the DOD funded study;
 - Create a PDF of your protocol by clicking “Print View” within your eProtocol protocol form.
 - If the IACUC protocol is only partially funded by the DOD grant, highlight the portions of the protocol that will be sponsored by the DOD.
2. IACUC approval letter;
 - Approval letter(s) can be downloaded within your eProtocol protocol form under “Event History.”
3. Any approved amendments to aforementioned protocols that affect the DOD funded study as well as documentation of IACUC approval of those amendments;

4. Completed Animal Use Appendix for each protocol (see “References” section below for links); and
 - UT Austin template language for administrative questions in the appendix can be found here: <https://research.utexas.edu/ors/animal-research/documents-materials-and-forms/>.
5. Signed PI Assurance (last page of appendix).

After receiving the submission, the DOD reviewer may send the investigator questions about the protocol or submission. It is the investigator’s responsibility to respond to these inquiries. ORSC staff may assist with responding to administrative or institutional-related questions by investigator’s request. ORSC staff will send these responses directly to the investigator to be incorporated in the investigator’s overall response to the DOD compliance office.

A letter and/or email indicating approval will be provided to the investigator once the DOD compliance office approves the submission. At this point, the investigator must submit an amendment to the IACUC protocol in eProtocol to relocate the DOD grant information under “Funding – Sponsored Projects” and attach the DOD compliance office approval letter/email to the protocol. **This step is crucial to ensuring ORSC staff are aware of the DOD compliance office’s approval and that they should submit future amendments to the DOD compliance office on the investigator’s behalf.**

8.3.1 AMENDMENTS to DOD Funded Animal Use Protocols

When an IACUC approves significant changes/major modifications to the DOD-funded portion of a protocol subject to ACURO oversight, ACURO must review and approve the changes before they can be implemented. Non-significant changes do not require DOD compliance office review and approval prior to implementation. Refer to the “ACURO Guidance for Submission of Changes to DOD-Supported Animal Care and Use Protocols” for details about what changes are considered to be significant or non-significant.

ORSC has implemented a procedure to support investigators in the management of their DOD funded protocols. When a researcher amends their DOD-funded animal use protocol, they will receive a notification from ORSC staff that they are not allowed to implement the change until the DOD has issued a secondary approval. ORSC will submit the amended protocol to the DOD on behalf of the investigator. Any previously approved non-significant changes will also be forwarded to the DOD compliance office at that time. The DOD will review the change and issue their own approval letter. The time to receive notification of secondary approval depends upon the complexity of the amendment.

Similar to new protocol ACURO review, the DOD reviewer may send the investigator questions about the protocol or submission. It is the investigator’s responsibility to respond to these inquiries. ORSC staff may assist with responding to administrative or institutional-related questions by

investigator's request. ORSC staff will send these responses directly to the investigator to be incorporated in the investigator's overall response to the DOD compliance office.

8.3.2 ANNUAL REVIEWS of DOD Funded Animal Use Protocols

Per DOD Instruction 3216.01, only those protocols that involve animals regulated by the USDA are required to conduct annual review. DOD funded protocols that involve unregulated species are not required to have annual review.

Annual reviews for animal use protocols that contain USDA-regulated species will be forwarded by ORSC staff to the DOD compliance office for review. Annual reviews for animal use protocols that do NOT contain USDA-regulated species will only be forwarded to the DOD compliance office for review if a significant change was made to the protocol at the time of annual review. See 8.3.1 AMENDMENTS to DOD Funded Animal Use Protocols for submission and review procedures.

8.3.3 NONCOMPLIANCE and/or ADVERSE EVENTS on DOD Funded Animal Use Protocols

DOD compliance offices require that institutions report any significant deficiencies, noncompliance, socially sensitive matters, adverse events, or protocol suspensions that occurred on a DOD-sponsored animal use protocol (refer to "ACURO Institutional Notifications to the Animal Care and Use Review Office"). ORSC staff will report the aforementioned occurrences to the DOD compliance office on behalf of the investigator. The investigator must cooperate with the reporting requirement by providing necessary details as requested.

8.3.4 THIRD-YEAR RESUBMISSIONS (DE NOVO) of DOD Funded Animal Use Protocols

Third-year resubmissions (de novo protocols) are treated equal to new protocols. Investigators should follow the instructions under 8.3.0 NEW Animal Use Projects and DOD Grants for submitting third-year resubmissions to the DOD compliance office for review.

References and Supporting Links

ACURO Guidance for Submission of Changes to DOD-Supported Animal Care and Use Protocols:
https://mrdc.amedd.army.mil/index.cfm/collaborate/research_protections/acuro

ACURO Institutional Notifications to the Animal Care and Use Review Office:
https://mrdc.amedd.army.mil/index.cfm/collaborate/research_protections/acuro

DOD Instruction 3216.01 - Use of Animals in DOD Conducted and Supported Research and Training: <https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321601p.pdf>

US Army Animal Care and Use Review Office (ACURO):
https://mrdc.amedd.army.mil/index.cfm/collaborate/research_protections/acuro

ACURO Appendix:

https://mrdc.amedd.army.mil/index.cfm/collaborate/research_protections/acuro/animal_appendix

US Air Force Medical Service Animal Use Program:

<https://www.airforcemedicine.af.mil/Organizations/AF-Research-Oversight-Compliance/Animal-Use-Program/>

AFM/SGE-C Appendix: <https://www.airforcemedicine.af.mil/Organizations/AF-Research-Oversight-Compliance/Animal-Use-Program/Appendix/>