



IACUC SOP:	TAMU-S-017	Title:	Review and Approval of Collaborative and Contracted Animal Activities		
		Location	Effective Date	Review By	
IACUC 1	(College Station/Dallas/Galveston/Kingsville)		10/20/2022	07/31/2023	
		IACUC 2	(Houston)	10/01/2022	07/31/2023

1. PURPOSE

- 1.1. To describe the process for TAMU IACUC oversight of animal activities that are performed under the oversight of an external IACUC

2. SCOPE

- 2.1. This SOP applies to:
 - 2.1.1. TAMU supported animal activities occurring at a location(s) under the oversight of an external IACUC (“outbound collaboration”), that are:
 - 2.1.1.1. Performed by TAMU faculty, staff, or students as a function of employment or completion of a degree (as applicable); and/or
 - 2.1.1.2. Funded through a TAMU contract, subaward, subcontract, fee for service, or other financial mechanism; or
 - 2.1.1.3. Related to the purchase or procurement of custom antibodies and surgically modified animals; or
 - 2.1.1.4. A function of an unfunded collaboration between TAMU and an external entity for which the TAMU IACUC desires an agreement or MOU; and where
 - 2.1.1.5. Another document that outlines IACUC oversight responsibilities between the two entities as defined in the *Guide* does not exist at the time of IACUC review (e.g.: Intrasystem Agreement, Interagency Agreement, etc.).
 - 2.1.2. Animal activities which occur under the dual oversight of the TAMU IACUC and Texas A&M AgriLife IACUC (“AgriLife IACUC”)
 - 2.1.3. Collaborative agreements and MOUs initiated by an external entity for animal activities occurring at a location(s) under the oversight of the TAMU IACUC (“inbound collaboration”)
- 2.2. TAMU supported animal activity performed at a location not under the oversight of an external IACUC remains the responsibility of the TAMU IACUC, including third party locations such as veterinary clinics and other commercial entities.

3. RESPONSIBILITY

- 3.1. The **IACUC Chair** (or designee) and **AV** (or designee) are responsible for reviewing outbound collaborative agreements such as MOUs, and dual oversight AgriLife IACUC AUPs on behalf of the IACUC.
- 3.2. The **AWO Director** has delegated authority to sign MOUs and IACUC cooperative agreements on behalf of the IO.

4. DEFINITIONS AND/OR ACRONYMS

- 4.1. **Amendment:** Significant change to on-going animal activity or research project as described in an approved
- 4.2. **Animal Activity:** For the purposes of this document, research, teaching or testing with live vertebrate animals
- 4.3. **AUP:** Animal Use Protocol. Document submitted by the PI indicating the housing and procedures involving animals.
- 4.4. **AV:** Attending Veterinarian. Individual designated by Texas A&M University to fulfil the regulatory role of AV. May also describe veterinary staff who report directly to, and have delegated authority from, the AV.
- 4.5. **AWO:** Animal Welfare Office. Supports the IACUC administratively.
- 4.6. **Dual Oversight:** For the purposes of this document, animal activity described in a single animal use protocol which falls under the oversight of both the TAMU IACUC and Texas A&M AgriLife IACUC.

- 4.7. **External AUP:** Abbreviated animal use protocol for a study or project with live vertebrate animals conducted at a location under the oversight of an external IACUC.
- 4.8. **External IACUC:** For the purposes of this document, non-TAMU IACUC.
- 4.9. **Guidance:** Guidance documents are developed by the IACUC to provide procedural standards to the research community on the topics identified. Animal care and use program participants are expected to adhere to the standards described unless an exception has been requested and approved by the IACUC.
- 4.10. **(The) Guide:** The Guide for the Care and Use of Laboratory Animals. Primary reference document for meeting the needs and requirements of animals used in biomedical research. The PHS Policy requires institutions to use the Guide as a basis for developing and implementing an institutional program for activities involving animals.
- 4.11. **HHS:** U.S. Department of Health & Human Services. Includes various agencies and offices, including the NIH ([see list](#)).
- 4.12. **IACUC:** Institutional Animal Care and Use Committee. Institutional body responsible for ensuring adherence to federal regulation and institutional policy relating to the care and use of animals in teaching, testing and research. Appointed by the Institutional Official.
- 4.13. **IACUC Chair:** Chair of the IACUC appointed by the Institutional Official.
- 4.14. **IO:** Institutional Official. Individual within the University with the administrative and operational authority to commit institutional resources to ensure that the animal care and use program will comply with the requirements of federal regulation.
- 4.15. **MOU:** Memorandum of Understanding. A formal written understanding between two IACUCs that addresses responsibilities for animal care and use, ownership, and IACUC review and oversight for collaborative activity involving research, teaching or testing with live vertebrate animals.
- 4.16. **NASA:** National Aeronautics and Space Administration
- 4.17. **NSF:** National Science Foundation
- 4.18. **OLAW:** Office of Laboratory Animal Welfare. Provides guidance and interpretation of the Public Health Service (PHS) Policy on the Humane Care and Use of Laboratory Animals (Policy) for PHS-funded research and monitors compliance with the Policy by Assured Institutions.
- 4.19. **PHS:** Public Health Service. Federal agency under the United States Department of Health and Human Services responsible for oversight of the PHS Policy.
- 4.20. **Reciprocal AUP:** For the purposes of this document, animal use protocol, or amendment to an animal use protocol, reviewed and approved by the Texas A&M AgriLife IACUC where activities with live animals are performed in Brazos and/or Burleson counties or other location as defined within the current Intrasystem Agreement.
- 4.21. **SOP:** Standard Operating Procedure. SOP documents are developed by the IACUC to provide procedural standards for the activities performed by the committee.
- 4.22. **TAMU:** Texas A&M University
- 4.23. **TAMUS:** Texas A&M University System
- 4.24. **USDA:** United States Department of Agriculture. USDA Animal Care, a unit under the Animal and Plant Health Inspection Service, administers the Animal Welfare Act (AWA) and associated Animal Welfare Act Regulations (AWAR).
- 4.25. **USDA Regulated:** Species or activities which fall under the AWA/AWAR.

5. PROCEDURE

A. General

- 5.1. All TAMU supported animal activity must be reviewed and approved by an appropriately constituted IACUC, whether the animals are housed in TAMU facilities or at an external location under the oversight of another

IACUC. This review may be performed by either the TAMU IACUC or the external institution's IACUC, with the TAMU IACUC making the final decision as to which option is appropriate and as defined below.

B. Outbound Collaborations/MOUs for Animal Activities under the Oversight of an External IACUC (other than the AgriLife IACUC)

- 5.2. When TAMU supported animal activity is to be performed at an external institution and that institution's IACUC has reviewed and approved the AUP, the TAMU IACUC accepts the review by the external board. Proof of approval by the external IACUC must be received prior to TAMU signature of the MOU.
- 5.3. The IACUC recommends that animal ownership be relinquished when activities occur under the oversight of an external IACUC.
- 5.4. A MOU is instituted between TAMU and the external institution to establish IACUC oversight responsibilities. See TAMU-F-029 and TAMU-F-029a.
- 5.5. AWO staff may assist the IACUC in the negotiation of terms with the external institution and completion of the MOU document.
- 5.6. As applicable, the external institution must have an Animal Welfare Assurance with OLAW for activities supported by the HHS, NASA or NSF, and be registered with the USDA for regulated species prior to completion of the MOU.
- 5.7. The drafted MOU (as an attachment to an External AUP) along with a brief description of the scope of work to be performed at the other institution is reviewed by the Chair and AV, or their designees, who will ensure that both the performance of the activity at the external institution and the terms of the MOU are acceptable.
 - 5.7.1. The IACUC Chair and AV (or their designees) may request modification of the terms of the MOU, approve the MOU/External AUP, or send the MOU to the IACUC for full committee review as described in TAMU-S-002, including written notification to the PI if the external performance site/MOU is rejected by the IACUC.
- 5.8. The MOU form is signed by the AWO Director, AVP/RCO or IO upon approval by both institutions and a copy of the fully signed MOU is maintained by the AWO.
- 5.9. Approval and expiration of the External AUP (or similar) will be congruent with the dates granted by the external entity.
- 5.10. The IACUC is responsible for investigation and reporting activities as outlined in the individual executed MOU and as per IACUC SOP (see TAMU-S-012 and TAMU-S-015).
- 5.11. Continuing review of the applicability of the collaboration will be performed by the IACUC Chair and AV (or designees) upon renewal of the external protocol for continuing projects.

C. Inbound Collaborations/MOUs for Animal Activities under Oversight of the TAMU IACUC

- 5.12. An MOU between an external institution and TAMU may be initiated at the discretion of the external institution for collaborations where animal activities occur at TAMU on behalf of the external institution; however, the TAMU IACUC remains responsible for review and approval of those animal activities occurring at a location for which the TAMU IACUC has oversight.
- 5.13. AWO staff may assist the IACUC in the negotiation of terms with the external institution and completion of the draft MOU document.
- 5.14. The drafted MOU is attached to the applicable TAMU AUP or amendment application and reviewed as described in TAMU-S-002, TAMU-S-003, TAMU-S-004 and/or TAMU-S-005, as applicable. Review must be complete prior to finalization of the MOU.
- 5.15. The MOU form is signed by the AWO Director, AVP/RCO or IO upon approval by both institutions and a copy of the fully signed MOU is maintained by the AWO.
- 5.16. The TAMU IACUC is responsible for investigation and reporting activities as outlined in the individual executed MOU and as per IACUC SOP (see TAMU-S-012 and TAMU-S-015).

D. AgriLife IACUC/TAMU IACUC Dual Oversight and Reciprocal Review

- 5.17. To be eligible for this process, a copy of the Reciprocal AUP that describes animal activity occurring at a location under the oversight of the TAMU IACUC, along with verification of AgriLife IACUC approval, must be provided to initiate TAMU IACUC review.
 - 5.17.1. Note: AUPs with USDA regulated species, or which require an Animal Welfare Assurance with OLAW, are ineligible for reciprocal review.
- 5.18. All IACUC members are provided access to incoming Reciprocal AUPs and are given an opportunity to call for FCR as described in TAMU-S-002.
- 5.19. In absence of a call for FCR, the Reciprocal AUP (as a Study Miscellaneous Form or similar) is reviewed by the Chair and AV, or their designees, who will confirm that the performance of the activity as approved by the AgriLife IACUC falls within standards established by the TAMU IACUC (via IACUC Guidance and/or SOP).
 - 5.19.1. The IACUC Chair and AV (or their designees) may approve the Reciprocal AUP or send the Reciprocal AUP to the IACUC for full committee review as described in TAMU-S-002, including written notification to the PI if approval of the Reciprocal AUP is rejected by the IACUC and must be resubmitted as a TAMU AUP application.
- 5.20. TAMU IACUC approval and expiration will be congruent with the dates granted by the AgriLife IACUC.
- 5.21. Oversight by the TAMU IACUC and AV remain unaltered for locations which fall under the oversight of the TAMU IACUC (as defined in the applicable Intrasytem Agreement).
- 5.22. Continuing review of the applicability of the collaboration will be performed by the IACUC Chair and AV (or designees) upon renewal of the external protocol for continuing projects.

E. Procurement of Custom Antibodies and Surgically Modified Animals

- 5.23. The purchase of antibodies for use in live vertebrate animals produced by a contract company for general sale (e.g.: off-the-shelf or stock item) does not require additional review and approval by the TAMU IACUC beyond a general description provided by the PI within the AUP.
- 5.24. The purchase or acquisition of surgically modified animals (e.g.: surgery conducted in response to a specific, custom request by the investigator) or custom antibodies (e.g.: produced using antigen(s) provided by or at the request of the investigator) by a contract company requires IACUC review and approval:
 - 5.24.1. The PI must include a general description of the custom activity performed within the TAMU AUP.
 - 5.24.2. Proof of external IACUC review and approval for the activity must be attached to the AUP.
 - 5.24.3. As applicable, the contract company must have an Animal Welfare Assurance with OLAW for activities supported by the HHS, PHS, or NASA, and be registered with the USDA for regulated species prior to approval of the TAMU AUP.

F. AAALAC Considerations (for the Accredited Portion of the TAMU Animal Care and Use Program)

- 5.25. For TAMU-owned animals housed at an external entity that is AAALAC accredited:
 - 5.25.1. Confirmation of AAALAC accreditation is required prior to housing animals at the external location.
- 5.26. For TAMU-owned animals housed at an external entity that is not AAALAC accredited:
 - 5.26.1. Prior approval must be granted by the Division of Research due to the additional costs incurred by the inclusion of the location in the TAMU Accreditation.
 - 5.26.2. A site visit of the external facility must be performed by the AV (or designee), a subcommittee of the IACUC, and/or AWO staff prior to housing animals at the external location.
 - 5.26.3. The external site must be described in the TAMU AAALAC program description and included in the AAALAC site visit.

6. REFERENCES, MATERIALS, AND/OR ADDITIONAL INFORMATION

- 6.1. References:
 - 6.1.1. TAMUS Rule [15.99.07 Use of Vertebrate Animals](#)
 - 6.1.2. Intrasytem Agreements between TAMU and various TAMUS entities (contact AWO for current list)
 - 6.1.3. OLAW



- 6.1.3.1. *Guide for the Care and Use of Laboratory Animals*, Chapter 2 [Collaborations](#)
- 6.1.3.2. FAQ A.2. [Does the PHS Policy apply to the production of custom antibodies or to the purchase of surgically modified animals?](#)
- 6.1.3.3. FAQ D.8. [When institutions collaborate, or when the performance site is not the awardee institution, which IACUC is responsible for review of the research activity?](#)
- 6.2. [IACUC/AWO Referenced Documents](#): (requires TAMU NetID authentication)
 - 6.2.1. TAMU-F-029 FDP IACUC Memorandum of Understanding (MOU)
 - 6.2.2. TAMU-F-029a FDP IACUC Memorandum of Understanding (MOU) Guidance
 - 6.2.3. TAMU-S-002 Submission Review Mechanisms
 - 6.2.4. TAMU-S-003 Significant and Minor Changes to Approved Animal Activities
 - 6.2.5. TAMU-S-004 Veterinary Verification and Consultation
 - 6.2.6. TAMU-S-005 Change to Approved Protocols by Administrative Review
 - 6.2.7. TAMU-S-012 Review and Investigation of Animal Welfare Concerns and Potential Noncompliance
 - 6.2.8. TAMU-S-015 Review of Unanticipated or Adverse Event Reports

7. HISTORY

Effective Date	Version #	Description
08/18/2022	000	IACUC 1: New document
10/01/2022	001	IACUC 2: New document; Reviewed and approved via e-mail
10/20/2022	002	IACUC 1: Merging of Kingsville animal care and use program with College Station/Dallas/Galveston.