IACUC SOP:	**TAMU-S-002**	Title:	**IACUC Submission Review Mechanisms**

Location	Effective Date	Review By
College Station/Dallas/Galveston/Kingsville	10/20/2022	07/31/2023
Houston	12/27/2021	07/31/2023

1. PURPOSE

1.1. To describe the mechanisms for IACUC review and approval of submissions such as reportable event forms, AUPs, modifications to AUPs, and pilot study updates.

2. SCOPE

2.1. This SOP applies to submissions reviewed by either DMR or FCR, and modifications reviewed by VVC (VVC)

3. RESPONSIBILITY

3.1. **IACUC Members** are responsible for:

3.1.1. Reviewing notices sent by AWO staff regarding incoming submissions and indicating if the member desires the submission to be reviewed by FCR.

3.1.2. Reviewing protocols, amendments, and reportable event forms (as applicable) as a part of a convened quorum of the members of the IACUC (FCR), or as a designated reviewer as appointed by the IACUC Chair (DMR).

3.2. The **IACUC Chair** is responsible for appointing members to perform DMR. The **IACUC Vice-Chair** may perform the duties of the Chair as described in TAMU-S-006 when conflicts of interest arise or the Chair is unavailable.

3.3. The **IACUC Chair** and **Attending Veterinarian** are responsible for reviewing initial Unanticipated or Adverse Event Reports submitted to the IACUC. This responsibility may be delegated to an appropriate designee as described in TAMU-S-006.

3.4. The **AWO Staff** is responsible for distributing a description of incoming submissions to the IACUC, soliciting the chair appointment of a designated member to perform the review, routing submissions for review (DMR, PR, VR) or consultation (VVC), tallying votes during full committee review, notifying the PI of veterinary or IACUC reviewer/committee decisions, and maintaining records pertaining to the specific method of review for a given submission, and the outcome of that review.

3.5. The **CMP Veterinary Staff** under the authority of the Attending Veterinarian, or **Attending Veterinarian for Dallas and Houston programs**, is responsible for performing a review of any protocol or amendment which includes procedures which may cause more than momentary or slight pain or distress. Additionally, VVC is performed by CMP and ARU Veterinary staff.

4. DEFINITIONS AND/OR ACRONYMS

4.1. **Ad hoc reviewer:** Individual from a compliance unit (BOHP, CRRC, IBC, EHS) who verifies that submissions meet the unit's standards.

4.2. **Amendment**: Significant change to on-going animal activity or research project as described in an approved protocol.

4.3. **AUP:** Animal Use Protocol. Document submitted by the PI indicating the housing and research procedures involving animals.

4.4. **AV:** Attending Veterinarian. Individual designated by Texas A&M University to fulfill the regulatory role of AV. May also describe veterinary staff who report directly, and have delegated authority from, the AV.

4.5. AWO: Animal Welfare Office. Supports the IACUC administratively.

4.6. BOHP: Biosafety Occupational Health Program. Provides occupational health services to personnel at risk of exposure to animals or infectious biohazards in the course of their participation in IBC or IACUC permitted research, teaching or diagnostic activities.

4.7. **Category E**: USDA pain categorization in which animals experience more than momentary pain and distress that cannot be relieved for study-related reasons.
4.8. Centrally administered support service for animal research and teaching programs at Texas A&M University:
  4.8.1. **ARU**: Animal Resource Unit supports the College of Dentistry
  4.8.2. **CMP**: Comparative Medicine Program supports Texas A&M Campus
  4.8.3. **PAR**: Program for Animal Resources supports Institute of Biosciences and Technology
  4.8.4. **PRF**: Pharmaceutical Research Facility supports Kingsville Pharmaceutical Science Facilities
4.9. **CRRC:** Clinical Research Review Committee. Provides institutional oversight for clinical research and teaching involving client-owned animals.
4.10. **DMR:** Designated member review. Review performed by qualified IACUC member(s) appointed by the IACUC Chair to serve as the designated reviewer(s) as described in this SOP.
4.11. **EHS:** Environmental Health and Safety Department.
4.12. **FCR:** Full committee review. Review and formal vote performed by a convened quorum of the members of the IACUC as described in this SOP.
4.13. **Freund's Adjuvant:** A solution of antigen emulsified in mineral oil which stimulates an immune response when injected into animals.
4.14. **GLP:** Good Laboratory Practices.
4.15. **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.
4.16. **IACUC Chair:** Chair of the IACUC appointed by the IO.
4.17. **IBC:** Institutional Biosafety Committee. Appointed by the IO and tasked to provide review and oversight of research, teaching, and testing activities utilizing biohazards.
4.18. **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.
4.19. **IRB:** Institutional Review Board. Appointed by the IO and tasked to provide review and oversight of research, teaching, and testing activities utilizing human subjects.
4.20. **iRIS:** Web-based compliance submission system
4.21. **LPS:** Lipopolysaccharide, an endotoxin used to induce an immune response and often used in vaccine adjuvants.
4.22. **Momentary pain and distress:** Activity defined by the USDA as a slight or otherwise routine procedure such as injection, tattooing, blood sampling which would not require the use of pain-relieving drugs.
4.23. **Paralytic:** Medication that causes extreme muscle relaxation resulting in the inability to move. Also known as a neuromuscular-blocking drug.
4.24. **PI:** Principal Investigator. The individual who has ultimate administrative and programmatic responsibility for the design, execution, and management of a project utilizing vertebrate animals.
4.25. **Pilot Study:** A small-scale test of the methods and procedures to be used on a larger scale.
4.26. **PR:** Primary Review. Pre-review performed by a qualified IACUC member(s) prior to review by FCR. Reviewer may be appointed by the IACUC Chair.
4.27. **Submission:** Report of adverse or unanticipated event or potential noncompliance (reportable event form), new or de novo protocol (AUP), personnel change request (PCR) or amendment to an approved protocol (including VVC requests and pilot study updates).
4.28. **Unanticipated or Adverse Event**: Any happening that is not consistent with routine expected outcomes that results in any unforeseen animal welfare *issue* that impacts the health or safety of animals (unintended injury

or illness, unrelieved pain or distress, death). May require reporting to federal regulators and accrediting bodies.

4.29. **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).

4.30. **USDA Regulated:** Species or activities which fall under the AWA/AWAR.

4.31. **VR:** Veterinary review. Review performed by Attending Veterinarian or his/her designee, also a qualified veterinarian associated with the animal program.

4.32. **VVC:** Veterinary Verification and Consultation. Process by which the AV or designee confirms adherence to approved IACUC SOPs or Guidance documents. Does not apply to Houston animal program.

5. PROCEDURE

5.1. Notes:

5.1.1. VVC eligibility and parameters are as described in TAMU-S-003 and TAMU-S-004

5.1.2. Reportable Event Forms are reviewed as described in TAMU-S-012 (PI self-report of potential noncompliance) and TAMU-S-015 (unanticipated or adverse events)

5.1.3. Triennial continuing review is performed as described in TAMU-S-013

5.1.4. AUP review criteria is described in TAMU-S-009

5.1.5. Pilot study updates are submitted in iRIS and may or may not include modifications to the AUP beyond the pilot study outcome report required in TAMU-G-030

5.2. Veterinary Verification and Consultation

5.2.1. **Notes:** Does not apply to Houston program.

5.2.2. Protocol modifications must meet the description in TAMU-S-003 to be eligible for VVC.

5.2.3. Initial request through AWO:

5.2.3.1. Written requests received by the AWO (e.g: email, iRIS amendments eligible for VVC) are routed to a CMP/ARU veterinarian, who can choose to:

5.2.3.1.1. Verify the change verbally or in writing to AWO staff

5.2.3.1.1.1. AWO staff or CMP veterinarian will notify the submitter that they can implement the change immediately

5.2.3.1.1.2. AWO staff will administratively update the AUP in iRIS to reflect VVC modification

5.2.3.1.2. Request modification prior to verification verbally or in writing to AWO staff

5.2.3.1.2.1. Required modifications are conveyed to the PI in writing and are incorporated into the AUP after final verification by the veterinarian

5.2.3.1.3. Notify the AWO staff that the VVC must be converted to an amendment

5.2.3.1.3.1. AWO staff or CMP veterinarian will notify the submitter that the change cannot be verified by veterinary staff and that an amendment to the protocol must be reviewed and approved by the IACUC for the change to take affect

5.2.3.1.4. AWO staff will route the amendment for FCR/DMR as described below

5.2.4. Initial request through veterinary staff:

5.2.4.1. PIs or protocol staff may discuss changes directly with CMP/ARU veterinary staff (e.g: in person, on the phone or via email), who can choose to:

5.2.4.1.1. Verify the change and notify both the requester and the AWO staff that the change may be implemented immediately

5.2.4.1.1.1. Verification may occur verbally or via email

5.2.4.1.1.2. AWO staff will administratively update the AUP in iRIS to reflect the VVC modification based on the information provided by the veterinarian
5.2.4.1.2. Request modification verbally or in writing to PI or protocol staff prior to verification
5.2.4.1.3. Notify the requestor verbally or in writing that the change cannot be verified by veterinary staff and that an amendment to the protocol must be reviewed and approved by the IACUC for the change to take affect

5.3. Veterinary Review

5.3.1. Protocols and amendments with USDA regulated species or activities are routed to a CMP/ARU/PAR/PRF veterinarian for review of procedures which may cause more than momentary or slight pain or distress prior to DMR or FCR.
5.3.1.1. All VR modifications are conveyed to the PI in writing and are incorporated into the final document prior to IACUC review.
5.3.2. Protocols and amendments without USDA regulated species or activities are routed to a CMP/ARU/PAR/PRF veterinarian/AV for review of procedures which may cause more than momentary or slight pain or distress simultaneous to IACUC review.
5.3.2.1. All VR modifications are conveyed to the PI in writing and are incorporated into the final document prior to approval by the IACUC.
5.3.3. Adverse/unanticipated event reports (reportable event forms) and pilot study updates are routed to a CMP/ARU/PAR/PRF veterinarian for review simultaneous to IACUC review.
5.3.3.1. All VR modifications are conveyed to the PI in writing and are incorporated into the final document prior to approval by the IACUC.

5.4. Designated Member Review

5.4.1. All members are provided with access to incoming submissions and are given an opportunity to call for FCR (reportable event form, AUP, 5 days; Amendment, pilot study update, 2 days).
5.4.2. DMR is performed in absence of a call for FCR.
5.4.2.1. For College Station/Galveston: Submissions (AUP, amendment) containing the following activities are assigned to two DMRs by default:
5.4.2.1.1. Multiple major survival surgery on the same animal
5.4.2.1.2. Unrelieved pain and distress (“category E” activities; AUP); or additional unrelieved pain and distress (amendment)
5.4.2.1.3. Use of paralytics
5.4.2.1.4. Use of Freund’s Adjuvant or LPS
5.4.3. The DMR may result in the following, with notification to the PI in writing:
5.4.3.1. Approval of the submission
5.4.3.1.1. For adverse/unanticipated event reports (reportable event forms) and pilot study updates without AUP modifications this means the report is accepted as submitted
5.4.3.2. Requirement for modification to secure approval of the submission
5.4.3.2.1. For adverse/unanticipated event reports (reportable event forms) and pilot study updates without AUP modification this means additional information is required.
5.4.3.3. Referral to the full committee for review of the submission
5.4.3.4. Categorization of an adverse/unanticipated event report (reportable event form) as not meeting the threshold to be considered “adverse” or “unanticipated” based on the definition above and as described in TAMU-G-015.
5.4.4. When the submission is assigned to more than one designated reviewer:
5.4.4.1. The reviewers receive identical versions of the submission

5.4.4.2. Each reviewer is aware of modifications requested by the other reviewer(s) and agrees to the modifications made to the submission before final approval
5.4.4.3. The reviewers communicate so that they are unanimous in the final review decision.

5.5. **Full Committee Review**
5.5.1. Submissions (AUP, amendment) containing the following activities are automatically reviewed by FCR (by program):
5.5.1.1. Dallas
5.5.1.1.1. Submissions involving USDA covered species
5.5.1.1.1.1. Excludes amendments with no increase in pain or distress
5.5.1.2. Houston/Kingsville:
5.5.1.2.1. Submissions involving USDA covered species
5.5.1.2.1.1. Excludes amendments with no increase in pain or distress
5.5.2. The submission may be routed for PR prior to FCR. The reviewer may request clarification or modification to the submission, with notification to the PI in writing.
5.5.3. FCR may result in the following by majority vote of the convened quorum, with notification to the PI in writing:
5.5.3.1. Approval of the submission
5.5.3.2. Requirement for modification to secure approval of the submission
5.5.3.3. Withholding of approval with reason(s) for decision
5.5.3.3.1. Notes:
5.5.3.3.1.1. AUPs: The IO is notified in writing of all AUPs that are not granted approval by the IACUC.
5.5.3.3.1.2. Amendments: A disapproved amendment does not change the approval status of the AUP.
5.5.3.4. Categorization of an unanticipated or adverse event report (reportable event form) as not meeting the threshold to be considered “adverse” or “unanticipated” based on the definition above and as described in TAMU-G-015.
5.5.4. For submissions requiring modification to secure approval, review of the revised submission may occur by one of the following mechanisms:
5.5.4.1. FCR at a future meeting as requested by the membership
5.5.4.2. DMR subsequent to FCR by unanimous vote of the quorum of members present
5.5.5. Members with a conflict of interest are recused from the meeting and do not contribute to the quorum for that vote.
5.5.6. Members that abstain from voting do not contribute to the quorum for that vote.

5.6. Approval
5.6.1. The following must occur prior to finalization of IACUC approval (except as noted below):
5.6.1.1. Training and BOHP enrollment must be complete as described in TAMU-G-029 for the PI and protocol participants; and
5.6.1.2. Applicable external reviews by the CRRC, EHSD, and IBC must be complete, and all required modifications to the AUP reviewed and approved by the IACUC.
5.6.2. When an AUP or amendment is approved, animal activities including acquisition, housing and use, or modification of approved activities as described in the amendment may commence on the day of approval.

5.6.3. Exception: AUPs, which are ready for IACUC approval based on the outcome of DMR/FCR, except for completion of external review (CRRC, EHSD, IBC) requirements, may be approved in cases where significant delays in completion are anticipated and the AUP is sponsor funded.
5.6.3.1. This process is not considered a suspension by the IACUC of approved work, but rather an administrative hold while requirements are met.
5.6.3.2. Individual use of this exception must be authorized by the IACUC Chair, or IACUC Vice-Chair in cases of conflict of interest.
5.6.3.3. The AUP is approved and then immediately placed in an administrative on-hold status. An approval memo is generated which may be submitted to the funding agency.
5.6.3.4. Activities described in the AUP may not be performed until all requirements have been completed and the AUP status returned to "Approved".
5.6.3.5. The PI, protocol participants and housing facility (if applicable) are notified by AWO staff of the inability to use the AUP while in the administrative on-hold status.
5.6.3.6. The AWO staff will administratively execute an amendment to the AUP to finalize the external review process.
5.6.3.6.1. Modifications requested by the PI or required by the CRRC, EHSD, and IBC are reviewed and approved by the IACUC (DMR or FCR) before the AUP may be returned to Approved status. All steps outlined above for VR, DMR and FCR are performed as for PI initiated amendments.
5.6.3.6.2. The AUP is returned to the Approved status administratively by AWO staff when the outstanding requirements are complete and the amendment is approved. The PI, protocol participants and housing facility (if applicable) are notified when the status is updated.

6. REFERENCES, MATERIALS, AND/OR ADDITIONAL INFORMATION

6.1. PHS Policy on Humane Care and Use of Laboratory Animals section IV.C
6.2. USDA Animal Welfare Regulations Part 2 Subpart C § 2.31.d.2
6.3. OLAW Notice NOT-OD-09-035 Guidance to IACUCs Regarding Use of Designated Member Review (DMR) for Animal Study Proposal Review Subsequent to Full Committee Review (FCR)
6.4. OLAW Notice NOT-OD-14-126 Guidance on Significant Changes to Animal Activities describes the types of animal activities where the IACUC has the authority to establish and approve internal policies/procedures for the review and approval of protocol amendments.
6.5. USDA agreement with NOT-OD-14-126: http://grants.nih.gov/grants/olaw/educational_resources.htm#a_08212014
6.6. *Guide for the Care and Use of Laboratory Animals*, Physical Restraint pp. 29-30
6.7. Contacts for centrally administered support service units:
6.7.1. ARU: (214) 828-8149
6.7.2. CMP: (979) 845-7433
6.7.3. PAR: (713) 677-7471
6.7.4. PRF: (361) 221-0770
6.8. AWO: (requires TAMU NetID authentication)
6.8.1. TAMU-G-015 Guidelines for Reporting Animal Concerns, Unanticipated or Adverse Events, and Potential Non-compliance
6.8.2. TAMU-G-030 Guidelines for Performance of Pilot Studies
6.8.3. TAMU-S-003 Significant and Minor Changes to Approved Animal Activities
6.8.4. TAMU-S-004 Veterinary Verification and Consultation
6.8.5. TAMU-S-009 AUP Review Criteria
6.8.6. TAMU-S-013 Continuing Review of Animal Use Protocols - Triennial

6.8.7. TAMU-S-015 Review of Unanticipated or Adverse Event Reports

7. HISTORY

Effective Date	Version #	Description
02/21/2019	000	College Station/Galveston: New document; replaced AWAP-303
08/26/2019	001	Houston/Kingsville: New document; replaced portions of IBT-106
11/21/2019	002	College Station/Galveston: Added adverse/unanticipated event reports, pilot study updates and auto FCR categories
12/16/2019	003	Houston/Kingsville: Added adverse/unanticipated event reports, pilot study updates and auto FCR categories; replaced IBT-S-002
12/17/2019	004	Dallas: New document; replaced CD-109 and portions of CD-106
01/16/2020	005	College Station/Galveston: Modifications to VVC procedure
01/21/2020	006	Dallas: Updates to allow VVC for Dallas; modifications to VVC procedure; addition of contact information for all centrally administered support service units
11/02/2020	007	College Station/Galveston: Expansion to address Event Report Forms and Annual Continuing Review Forms; removal of requirement for auto-FCR; expansion of section on the Approval process (Note: Changes in red already apply to College Station/Galveston)
12/01/2020	008	Houston/Kingsville: Expansion to address Event Report Forms and Annual Continuing Review Forms; updated requirement for auto-FCR; expansion of section on the Approval process (Note: Changes in red already apply to Houston/Kingsville)
12/15/2020	009	Dallas: Expansion to address Event Report Forms and Annual Continuing Review Forms; updated requirement for auto-FCR; expansion of section on the Approval process
12/27/2021	010	Houston/Kingsville: Removal of annual continuing review process with no modification to expiration date. Approved on 12/13/2021 with delayed start date to match final rule effective date.
12/27/2021	011	Dallas: Removal of annual continuing review process with no modification to expiration date. Approved on 12/14/2021 with delayed start date to match final rule effective date.
12/27/2021	012	College Station/Galveston: Removal of annual continuing review process with no modification to expiration date. Approved on 12/16/2021 with delayed start date to match final rule effective date.
03/24/2022	013	College Station/Dallas/Galveston: Merging of Dallas animal care and use program with College Station/Galveston
10/20/2022	014	College Station/Dallas/Galveston/Kingsville: Merging of Kingsville animal care and use program with College Station/Dallas/Galveston.