



IACUC SOP:	TAMU-S-009	Title:	AUP Review Criteria
------------	-------------------	--------	----------------------------

Location	Effective Date	Review By
College Station/Dallas/Galveston/Kingsville	07/01/2024	06/30/2027
Houston	11/01/2021	09/20/2024

1. PURPOSE

- 1.1. To describe the review criteria for IACUC protocols that use vertebrate animal subjects. The criteria are based on the principles of scientific conduct and guidelines established by the PHS, USDA, the Guide, the AWA/AWAR. Criteria unique to TAMU institutional guidelines and policies may also apply.

2. SCOPE

- 2.1. This SOP applies to the performance of AUP and amendment submission review by IACUC members.
- 2.2. PI and ad-hoc reviewer responsibility described for purposes of clarification only.

3. RESPONSIBILITY

- 3.1. The **PI** is responsible for submitting an Animal Use Protocol that provides accurate information regarding proposed animal activities including external sources of funding, conduct of activities, use of hazardous chemicals or biohazards associated with animal use, and including a plan to mitigate risk to personnel.
- 3.2. **IACUC Members** are responsible for conducting an unbiased review of protocols using criteria established by federal and institutional regulations, policies, and recommendations 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).
- 3.3. The **IACUC Chair** is responsible for appointing members to perform DMR.
- 3.4. The **AWO Staff** is responsible for: notifying the IACUC of incoming submissions; soliciting the chair appointment of a designated member to perform the review; routing submissions for review (DMR, PR, VR) or consultation (VVC); assigning ad hoc reviewers as applicable; tallying votes during full committee review; notifying the PI of veterinary or IACUC reviewer/committee decisions; maintaining records pertaining to the specific method of review for a given submission and the outcome of that review.
- 3.5. **Ad-Hoc Reviewers** are responsible for conducting a review of animal activities using criteria established by their compliance units.
- 3.6. **Veterinary Staff** under the authority of the Attending Veterinarian, are 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 an institutional compliance unit (BOHP, CRRC, Biosafety Program/IBC, HRPP/IRB, EHS/RSC, etc.) 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 animal use 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 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, provides administrative support to the IACUC.
- 4.6. **Biohazard:** Material containing: a) biological agents that may cause disease in humans, animals, or plants; b) recombinant or synthetic nucleic acid molecules including transgenic plant and animals; c) human and non-human primate blood, tissue, cells and cell lines; d) toxins of biological origin; e) any material requiring a CDC license or a USDA permit.

~~4.7. **Biosafety Program:** Supports the IBC administratively.~~



- 4.8. **(Office of) Biosafety:** Supports the Institutional Biosafety Committee (IBC) administratively.
- 4.9. **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.
- 4.10. **CDC:** U.S. Centers for Disease Control and Prevention
- 4.11. Centrally administered support service for animal research and teaching programs at Texas A&M University:
 - 4.11.1. **ARU:** Animal Resource Unit supports the School of Dentistry vivarium
 - 4.11.2. **CMP:** Comparative Medicine Program supports the Texas A&M College Station campus
 - 4.11.3. **PAR:** Program for Animal Resources supports the Institute of Biosciences and Technology vivarium
 - 4.11.4. **PRF:** Pharmaceutical Research Facility supports the Kingsville Pharmaceutical Science Facility vivarium
 - 4.11.5. **Sea Life:** The Sea Life Facility supports the Galveston campus
- 4.12. **Chemical Hazard:** Substance that has properties with the potential to do harm to human or animal health, the environment, or capable of damaging property.
- 4.13. **CRRC:** Clinical Research Review Committee, provides institutional oversight for clinical research and teaching involving client-owned animals.
- 4.14. **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 TAMU-S-002.
- ~~4.15. **EHS:** Environmental Health and Safety Department, provides services that promote a healthy and safe environment for faculty, staff, students and visitors and promotes work practices that protect the environment.~~
- 4.16. **FCR:** Full committee review. Review and formal vote performed by a convened quorum of the members of the IACUC as described in TAMU-S-002.
- 4.17. **Hazard:** Any source of potential damage, harm or adverse effects to a person or property/environment such as chemicals, biological materials, radioactive materials, radiation-generating devices, or dangerous equipment.
- 4.18. **HRPP:** Human Research Protection Program. Supports the Institutional Review Board (IRB) administratively.
- 4.19. **Human Subject:** Generally means an individual who becomes a participant in a research study; or an individual's identifiable data or biospecimen used for research.
- 4.20. **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.
- 4.21. **IACUC Chair:** Chair of the IACUC appointed by the Institutional Official.
- 4.22. **IBC:** Institutional Biosafety Committee. Institutional body responsible for the review and oversight of research, teaching, and testing activities utilizing biohazardous materials and Dual Use Research of Concern. Appointed by the Institutional Official.
- ~~4.23. **IBC:** Institutional Biosafety Committee, appointed by the Institutional Official and tasked to provide review and oversight of research, teaching, and testing activities utilizing biohazards.~~
- 4.24. **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.
- 4.25. **IRB:** Institutional Review Board, appointed by the Institutional Official and tasked to provide review and oversight of research involving human subjects.
- 4.26. **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.
- 4.27. **Paralytic:** Medication that causes extreme muscle relaxation resulting in the inability to move. Also known as a neuromuscular-blocking drug (NMB).

- 4.28. **Physical Hazard:** An agent, factor or circumstance that can cause harm with or without contact. Physical hazards can be classified as a type of occupational or [environmental hazard](#) and can include [ergonomic hazards](#), [radiation](#), heat and cold stress, [vibration](#) hazards, and [noise](#) hazards. [Engineering controls](#) are often used to mitigate physical hazards.
- 4.29. **PI:** Principal Investigator. The individual who has ultimate administrative and programmatic responsibility for the design, execution, and management of a project utilizing vertebrate animals.
- 4.30. **PPE:** Personnel Protective Equipment
- 4.31. **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.
- 4.32. **Radiological Hazard:** Substance, material, or device that is radioactive or produces radiation with the potential to do harm to human or animal health. Examples include radioisotopes and medical imaging techniques such as x-ray, computed tomography (CT), positron emission tomography (PET), and magnetic resonance imaging (MRI).
- 4.33. **RSC:** Radiation Safety Committee
- 4.34. **Submission:** Report of adverse or unanticipated event or potential noncompliance (reportable event form), new or de novo protocol (AUP), ~~annual continuing review form~~, personnel change request (PCR) or amendment to an approved protocol (including VVC request and pilot study updates).
- 4.35. **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).
- 4.36. **USDA Regulated:** Species or activities which fall under the AWA/AWAR.
- 4.37. **VR:** Veterinary review. Review performed by Attending Veterinarian or his/her designee, also a qualified veterinarian associated with the animal program.
- 4.38. **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. GUIDELINES OR PROCEDURE

- 5.1. **Minimum criteria for IACUC review and approval of animal activities.** A protocol review checklist is available for IACUC members (TAMU-C-008).
 - 5.1.1. Procedures involving animals will avoid or minimize pain or distress to the animals;
 - 5.1.2. PI must consider using alternatives to procedures that might cause pain or distress to animals. Further, the investigator must provide a written narrative discussing why alternatives can or cannot be used. The narrative must also include a list of the databases searched, the search strategy (including scientifically relevant terminology), and/or any other sources consulted;
 - 5.1.3. PI must provide written assurance that the proposed activities are not unnecessarily duplicative;
 - 5.1.4. If painful or distressful procedures are unavoidable
 - 5.1.4.1. The procedures must be performed with appropriate anesthesia, analgesia, or sedatives, unless withholding them can be scientifically justified;
 - 5.1.4.2. Involve a veterinarian in the planning (review by a veterinarian on the IACUC after the protocol has been submitted is not acceptable; the veterinarian should be consulted before the protocol is submitted.);
 - 5.1.4.3. Never use paralytics without anesthesia;
 - 5.1.5. Animals that experience severe or chronic pain that cannot be relieved will be euthanized at the end of the experiment or, if appropriate, during the experiment;
 - 5.1.6. The animals' living conditions must be appropriate for the species(s) and must contribute to their health and comfort;

- 5.1.7. Any medical care required by the animals will be provided by a qualified veterinarian, i.e. a veterinarian trained in laboratory animal medicine;
- 5.1.8. People that will be performing any procedures on animals will be qualified and trained to perform the procedures;
- 5.1.9. Any procedures that involve surgery will include appropriate pre- and post-operative care.
 - 5.1.9.1. All survival surgeries must use aseptic technique including the use of sterile gloves and masks.
 - 5.1.9.2. Operative procedures that penetrate or expose a body cavity or procedures that result in permanent impairment of physical or physiological functions (major procedures) must be performed in a dedicated surgical facility that is maintained in aseptic condition.
 - 5.1.9.3. Rodents are exempted from this requirement. Minor surgical procedures must be performed aseptically but do not require a dedicated site;
- 5.1.10. Use of an animal in more than one major operative procedure, from which it is allowed to recover, is prohibited unless it can be justified scientifically, or is necessary for the health of the animal;
- 5.1.11. Use of professionally recognized methods of euthanasia unless a different method can be scientifically justified. The guidelines developed by the American Veterinary Medical Association are generally recognized as the currently accepted standard;
- 5.1.12. Identification of the species to be used and the number of animals requested;
- 5.1.13. The scientific rationale for using animals, and the reasons for using the requested species and the number of animals;
- 5.1.14. A complete description of the procedures involving animals; and
- 5.1.15. A complete description of the methods that will be used to minimize pain and discomfort to that which is unavoidable and necessary to the collection of scientifically valuable data.
- 5.1.16. All participants in animal activities are enrolled in the Biosafety Occupational Health Program (BOHP) and have completed all IACUC-required training.
- 5.2. **Ad-hoc Review and Approval**
 - 5.2.1. All applicable external/ad-hoc reviews as described in TAMU-S-002 must be complete prior to final IACUC approval.
 - 5.2.2. Ad-hoc reviewers will provide comments and stipulations as needed and review PI revision or response.
 - 5.2.3. The IACUC cannot overturn the stipulations or decisions of other compliance units or committees, however all required modifications must be reviewed and approved by the IACUC.
- 5.3. **Environmental Health and Safety**
 - 5.3.1. General and Physical Safety
 - 5.3.1.1. EHS staff is assigned to review all new AUPs for safety hazards.
 - 5.3.2. Chemical and physical hazards
 - 5.3.2.1. The use of chemical and physical hazards must be reviewed and approved by EHS prior to AUP approval. EHS shall have the final determination of classification of an activity, chemical, substance, or material as "hazardous."
 - 5.3.3. Radiological hazards
 - 5.3.3.1. The use of radiological hazards in animals must be approved through the Radiological Safety Office (RSO), a division of EHS, prior to protocol approval. EHS reviewers will consult with RSO regarding use of radiological hazards.
- 5.4. **Biosafety Occupational Health Program**
 - 5.4.1. All participants in animal activities must be enrolled in BOHP.
 - 5.4.2. BOHP staff will be assigned to review all submissions involving personnel and will verify enrollment of each participant.
- 5.5. **Biosafety Program/IBC**



5.5.1. The use of biological hazards associated with animal use must be reviewed and approved by a reviewer from the Biosafety Program. Biosafety/IBC shall have the final determination of the classification of biohazard use and the need for an IBC permit.

5.6. Clinical Research Review Committee

5.6.1. Clinical research or teaching involving client-owned animals by CVM PIs requires a CRRC consent form and review by the CRRC.

5.6.2. Non-CVM use of client-owned animals will be reviewed by the IACUC (IACUC consent form attached to submission)

5.7. Human Research Protection Program/IRB

5.7.1. Animal research also involving human subjects must be reviewed and approved by a reviewer from the HRPP/IRB who shall have the final determination of the classification of human subjects and the need for an IRB permit.

6. REFERENCES, MATERIALS, AND/OR ADDITIONAL INFORMATION

- 6.1. [PHS Policy on Humane Care and Use of Laboratory Animals, section IV](#)
- 6.2. [USDA Animal Welfare Regulations Part 2 Subpart C § 2.31.d](#)
- 6.3. [Guide for the Care and Use of Laboratory Animals](#)
- 6.4. [Guide for the Care and Use of Agricultural Animals in Research and Teaching](#) (2020)
- 6.5. [AVMA Guidelines for the Euthanasia of Animals](#) (2020)
- 6.6. [TAMUS 15.99.07 Use of Vertebrate Animals](#)
- 6.7. [TAMU 15.99.07.M1 Use of Vertebrate Animals in Research, Teaching and Testing](#)
- 6.8. BOHP website <https://bohp.tamu.edu/>
- 6.9. EHS website <https://ehs.tamu.edu/>
- 6.10. GLP website <https://rcb.tamu.edu/quality-assurance/glp>
- 6.11. IBC website <https://rcb.tamu.edu/biohazards>
- 6.12. IRB website <https://rcb.tamu.edu/humansubjects>
- 6.13. [IACUC/AWO Referenced Documents: \(requires TAMU NetID authentication\)](#)
 - 6.13.1. TAMU-C-008 TAMU IACUC Review Checklist
 - 6.13.2. TAMU-S-002 IACUC Submission Review Mechanisms

7. HISTORY

Effective Date	Version #	Description
11/21/2019	000	College Station/Galveston: New document; replaced AWAP 302 & partially replaced AWAP 305
2/21/2020	001	Houston/Kingsville: New document
3/3/2020	001	Administrative update of location-specific Responsibilities and Definitions for centrally managed vivaria
3/17/2020	002	Dallas: New document
10/01/2021	003	College Station/Galveston: Renewal; updated definitions, changes for congruence with TAMU-S-002. Reviewed and approved via e-mail.
11/01/2021	004	Houston/Kingsville: Renewal; updated definitions, changes for congruence with TAMU-S-002. Reviewed and approved via e-mail.
11/16/2021	005	Dallas: Renewal; updated definitions, changes for congruence with TAMU-S-002
03/24/2022	006	College Station/Dallas/Galveston: Merging of Dallas animal care and use program with College Station/Galveston
10/20/2022	007	College Station/Dallas/Galveston/Kingsville: Merging of Kingsville animal care and use program with College Station/Dallas/Galveston.
07/01/2024	008	College Station/Dallas/Galveston/Kingsville: Renewal; updated definition and reference sections



(NOTE: items above in red have only been approved by the College Station/Dallas/ Galveston/Kingsville IACUC.)