



IACUC SOP:	TAMU-S-014	Title:	Procedure for Conducting IACUC Business in the Event of a Pandemic or Other Significant Emergency
------------	-------------------	--------	----------------------------------------------------------------------------------------------------------

	Location	Effective Date	Review By
	College Station/Dallas/Galveston/Kingsville	11/01/2023	10/31/2026
	Houston	12/01/2023	10/31/2026

1. PURPOSE

- 1.1. To outline options provided in the PHS Policy to utilize in the event of a pandemic or other significant emergency, that may not be used during the typical operation of the animal care and use program.
- 1.2. To describe procedures for conducting IACUC business during pandemics and other emergencies.

2. SCOPE

- 2.1. Applies to unforeseen events that may limit or impede the ability of the IACUC to conduct business.

3. RESPONSIBILITY

- 3.1. It is the responsibility of Texas A&M University to adhere to provisions of the Animal Welfare Regulations, PHS Policy, the Guide for the Care and Use of Animals, and the commitments detailed in Animal Welfare Assurance(s) with OLAW. This includes advance planning for conditions that could arise as a result of a human pandemic (e.g., influenza) or outbreaks of novel infections (e.g., coronavirus disease 2019) or other emergency or disaster that could jeopardize the health and wellbeing of animals because of a lack of personnel to care for the animals and/or to conduct IACUC official business.
- 3.2. It is the responsibility of the **IACUC** to:
 - 3.2.1. Remain properly constituted
 - 3.2.2. Ensure that quorum is achieved to conduct official business at a convened meeting
 - 3.2.3. Ensure that triennial protocol review occurs and if on-going protocols expire without IACUC review, that no further activities with live animals occur
 - 3.2.4. Ensure that a minimum of two convened meetings of a quorum of the IACUC occur semiannually
 - 3.2.5. Ensure that facility and research location inspection occur semiannually as outlined in regulation
 - 3.2.6. Ensure that animal concerns are addressed
- 3.3. The **AWO Staff** is responsible for maintaining a current membership record; training members; monitoring the committee membership to evaluate compliance with federal requirements; and notifying the Institutional Official of the need to appoint members in order to maintain compliance with regulations.

4. DEFINITIONS AND/OR ACRONYMS

- 4.1. **Ag Guide:** Guide for the Care and Use of Agricultural Animals in Research and Teaching. Primary reference document for meeting the needs and requirements of agricultural animals utilized in research and teaching.
- 4.2. **Alternate Member:** An IACUC member who acts as a substitute for a full voting member when the voting member is unavailable to act in an official IACUC capacity. The alternate member must represent the same membership category as the member replaced and is expected to vote their conscience rather than represent the position of the member they are replacing. An alternate may only replace one voting member at a time. Alternate Members are non-voting and do not contribute to quorum unless they are substituting for a voting member. Alternate members when substituting for a voting member perform the same duties, and must meet the same expectations, as the voting member they are replacing.
- 4.3. **Animal Concern:** Concern related to the care and use of animals at Texas A&M University. May be expressed verbally or in writing by a participant in the animal program, member of the institution, or general member of the public; and may be submitted anonymously or through a third-party hotline. May require reporting to federal regulators and/or accrediting body.

- 4.4. **Animal Facility:** Centralized vertebrate animal housing location managed by a Core Support unit. Includes vehicles owned by the facility used for live animal transport.
- 4.5. **Animal Study Area:** Location outside of a central animal facility where activities with live animals occur, inclusive of classroom spaces.
- 4.6. **AWO:** Animal Welfare Office. Supports the IACUC administratively.
- 4.7. **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.
- 4.8. **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.
- 4.9. **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.
- 4.10. **IACUC Chair:** Chair of the IACUC appointed by the IO.
- 4.11. **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.
- 4.12. **Member:** Committee member appointed to the IACUC by the Institutional Official, who may serve as either a voting or alternate member.
- 4.13. **Noncompliance:** Accidental or intentional failure to comply with state and federal regulations, System policies or regulations, University rules or procedures, IACUC guidance, or the requirements to conduct research, teaching or testing using animals; including adherence to the approved animal use protocol. **Serious noncompliance** has a negative impact on the welfare of an animal and/or is in direct violation of a federal standard regulating animal activities, including provisions of the Occupational Health and Safety Program, and may require reporting to federal regulators, funding agencies and accrediting bodies. (Also see Federal Notice NOT-OD-05-034 for examples of situations that constitute reportable noncompliance under the PHS Policy.)
- 4.14. **Non-scientific member:** Member whose primary concerns are in a nonscientific area.
- 4.15. **Non-voting member:** Member appointed in the “alternate” role who is participating in IACUC functions without contributing to a quorum or voting.
- 4.16. **OLAW:** National Institutes of Health Office of Laboratory Animal Welfare. OLAW provides guidance and interpretation of the Public Health Service Policy on Humane Care and Use of Laboratory Animals (Policy), and monitors compliance with the Policy by Assured institutions to ensure the humane care and use of animals in PHS-supported activities.
- 4.17. **PHS:** Public Health Service. Federal agency under the United States Department of Health and Human Services responsible for oversight of the PHS Policy.
- 4.18. **PHS Assurance:** PHS Welfare Assurance. Document executed by OLAW which describes the institution’s compliance with PHS Policy; and is required to receive direct or indirect PHS funds through a grant or contract award.
- 4.19. **PI:** Principal Investigator. The individual who has ultimate administrative and programmatic responsibility for the design, execution, and management of a project utilizing vertebrate animals.
- 4.20. **PPE:** Personnel Protective Equipment
- 4.21. **Quorum:** Majority of the total number of voting members of the IACUC. The minimum number of members of the committee that must be present to conduct full committee review as defined in regulation. Members with a conflict of interest (real or perceived) do not contribute to the quorum for that vote.
- 4.22. **Satellite Location:** PI managed building, room, area, enclosure, or other containment where animals are housed or held outside of the primary housing location for over 12 hours (USDA regulated species) or 24 hours (non-USDA regulated species).
- 4.23. **Social Distancing:** The deliberate increasing of the physical space between people to avoid spreading illness.



- 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.
- 4.26. **VMO:** Veterinary Medical Officer with the United States Department of Agriculture
- 4.27. **Voting Member:** Member contributing to the quorum on an official vote.

5. PROCEDURE

5.1. IACUC Meetings

5.1.1. Note:

- 5.1.1.1. See TAMU-S-008 for more information on IACUC meeting management.
- 5.1.1.2. See TAMU-S-011 for more information on semiannual program review.
- 5.1.2. The number of IACUC meetings may be reduced to as few as one every six months, the minimum allowed by the Guide for the Care and Use of Animals and Animal Welfare Regulations.
- 5.1.3. In order to conduct the following a convened meeting with a quorum of the voting members present must occur:
 - 5.1.3.1. Suspension of a protocol
 - 5.1.3.2. Full committee review of protocols and amendments
- 5.1.4. While optimal, there is no requirement to conduct the semiannual review of programs at a convened meeting with a quorum present
- 5.1.5. The IACUC may institute alternatives to face-to-face meetings such as teleconference or video conferencing (OLAW NOT-OD-06-052)

5.1.6. Recommendations:

- 5.1.6.1. Continue to find ways to correct problems without suspending protocols
- 5.1.6.2. Allow for Designated Member Review of **all** protocols if external situations comprise the ability to convene a meeting of a quorum. See below, section 5.2.8.
- 5.1.6.3. Assemble as many members as possible to conduct the semiannual review of programs, a minimum of two is required. See below for inspections, section 5.4.
- 5.1.6.4. Approve/accept semiannual report to the IO via electronic means such as secure file sharing (e.g.: Filex; Google Share Drive, Microsoft Teams), email, and/or fax. A majority of the members must electronically sign the report to the IO and can do so via secure document routing software (e.g.: Adobe Sign), secure file sharing (e.g.: Filex; Google Share Drive, Microsoft Teams), email or fax. Secure mechanisms are the preferable option over other options listed.
- 5.1.6.5. Encourage members to participate via web conference options (e.g.: Zoom) or teleconference

5.2. Protocol and Amendment Review

- 5.2.1. Note: See TAMU-S-002 for a description of the DMR and FCR process.
- 5.2.2. The only federal requirement for the full committee to review a protocol/amendment is when an IACUC member specifically requests full committee review of a given protocol. See PHS Policy IV.C.2 and AWR 2.31.d.2.
- 5.2.3. Depending on the committee, the IACUC may require certain protocols and amendments to be reviewed by the full committee.
- 5.2.4. Full committee review (FCR) can only occur at a convened meeting with a quorum of voting members present.
- 5.2.5. Chair (or designee) must appoint Designated Member Reviewers.
- 5.2.6. Every protocol covered by the Institutional Animal Welfare Assurance and/or Animal Welfare Registration must have a complete review every three years.

5.2.7. All modifications and amendments must be reviewed and approved by the IACUC before changes can be implemented for on-going activities.

5.2.8. Procedure During Emergency:

5.2.8.1. Suspend requirement for automatic FCR as described in TAMU-S-002 to allow for Designated Member Review of **all** protocols during the period of an emergency.

5.2.8.2. Authorize the AWO Director to appoint Designated Member Reviewers if both the Chair and Vice Chair(s) are unavailable for an extended period.

5.3. Approval Dates

5.3.1. IACUCs have flexibility to develop a system that functions well for their institution, provided that the approval date occurs within a reasonable period of time after review and approval [see AWR 2.31(d), PHS Policy IV.C.]. For example, the IACUC may designate an approval date as the last working day of the month in which the proposal was reviewed, allowing time to make minor corrections or confirm other activities which may affect the approval (e.g., safety committee review, research staff training). See OLAW NOT-OD-11-053 and NOT-OD-23-152.

5.4. Semiannual Inspection of Facilities

5.4.1. Note: See TAMU-S-010 for a description of the semiannual inspection process

5.4.2. Animal facilities in which USDA regulated species are housed, as well as animal study areas where animals are maintained for more than 12 hours, must be inspected twice a year, 6 months apart. Inspections must be performed by at least two members of the IACUC, however inspectors can be deployed to perform inspections as determined by the IACUC.

5.4.3. Animal facilities in which animals under the Animal Welfare Assurance are housed, vehicles owned by the facility used for animal transport, as well as animal study areas where animals are maintained for more than 24 hours, must be inspected twice a year, 6 months apart. Qualified ad hoc consultants can conduct the inspections.

5.4.3.1. Does not include inspection of personal vehicles. See TAMU-G-016.

5.4.4. Animal facilities and study areas in which animals under the Animal Welfare Assurance are used in surgical procedures must be inspected twice a year, 6 months apart. Qualified, ad hoc consultants can conduct the inspections.

5.4.5. Animal facilities in which agricultural animals used for agricultural activities are housed, as well as animal study areas, must be inspected twice a year to the standards of the Ag Guide. While not backed by federal regulation, the Ag Guide must be followed for agricultural animals used for agricultural research, teaching and testing as per TAMUS policy 15.99.07.

5.4.6. Pre-Crisis Planning:

5.4.6.1. Train veterinary technicians or other appropriate staff members in the animal care and use program to conduct facility inspections properly and have them assist with inspections as qualified ad hoc consultants.

5.4.7. Procedure During Emergency

5.4.7.1. The timing of facility inspections may extend 30 days beyond the six-month interval from the last review if there is no forward drift of the date from year to year.

5.4.7.1.1. If any impacted location is unable to undergo inspection as indicated in 5.4.7.1 and is covered under the institutional Animal Welfare Assurance, the IO will request a waiver for the performance of semiannual inspections from OLAW. While it is not required to request a waiver from the USDA, documentation of the extent of the suspension must be maintained, and provided to the VMO upon request.

5.4.7.2. This includes using any qualified individual as ad hoc consultants. For areas housing non-USDA regulated species, the IACUC may use as few as one qualified individual to conduct the

inspections. The IACUC still remains responsible for the evaluation and report to the Institutional Official.

- 5.4.7.3. Inspections may be conducted utilizing live feed video conferencing, when in-person inspections are not feasible.
- 5.4.7.4. Suspension of inspection of non-satellite PI locations as long as surgery is not performed in that location.
- 5.4.7.5. Suspension of initial inspection for non-housing locations.
- 5.4.7.6. Social distancing and personal protective equipment will be employed as necessary to reduce disease transmission between participants:
 - 5.4.7.6.1. Participants will wear PPE as required by the institution or individual location
 - 5.4.7.6.2. The number of participants will be reduced where possible to ensure adequate social distancing
 - 5.4.7.6.3. Whenever possible, inspectors will utilize separate vehicles to travel between locations and/or perform inspections
 - 5.4.7.6.4. If inspectors must ride in the same vehicle, guidance from the institution will be followed. In the absence of institutional standards, appropriate PPE must be worn and vehicle surfaces disinfected as appropriate.

5.5. Appointment and Training of IACUC Members

- 5.5.1. Appointment of members, including non-scientific members and alternates will continue according to TAMU-S-006, with the following **recommendations**:
 - 5.5.1.1. Formal Orientation conducted by the AWO staff and/or experienced IACUC members can be accomplished via audio/video conferencing.
 - 5.5.1.2. On-site inspection training conducted by AWO staff or experienced IACUC member during a regularly scheduled inspection may be substituted for inspection training conducted via audio/video conferencing.

5.6. Investigation of Animal Concerns and Potential Noncompliance

- 5.6.1. Investigation of animals concerns and potential noncompliance will continue as according to TAMU-S-012, with the following **recommendations**:
 - 5.6.1.1. Use of virtual technology (e.g.: Zoom) in place of face-to-face meetings
 - 5.6.1.2. Reliance upon the AV (or designee) for any required in-person observation of animals

6. REFERENCES, MATERIALS, AND/OR ADDITIONAL INFORMATION

6.1. References:

- 6.1.1. [Flexibilities for Assured Institutions for Activities of Institutional Animal Care and Use Committees \(IACUCs\) Due to COVID-19](#), NOT-OD-20-088, 2020: Information on flexibilities in the PHS Policy that are applicable to implementing a pandemic plan for animal care and use programs.
- 6.1.2. Office of Extramural Research Guidance Regarding Administrative IACUC Issues and Efforts to Reduce Regulatory Burden: [NOT-OD-01-017](#).
- 6.1.3. Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals: [NOT-OD-06-052](#).
- 6.1.4. Guidance to Reduce Regulatory Burden for IACUC Administration Regarding Alternate Members and Approval Dates: [NOT-OD-11-053](#).
- 6.1.5. [Streamlining IACUC Review for Animal Activities](#), NOT-OD-23-152: Request for Information (RFI) on Flexibilities for Streamlining IACUC Review of Protocols and Significant Changes.
- 6.1.6. Guide for the Care and Use of Laboratory Animals. 8th edition. Washington (DC): National Academies Press (US); 2011.

6.2. Resources:



- 6.2.1. [AVMA Guidelines for the Depopulation of Animals](#), 2019 (PDF), suggestions for members of the veterinary profession to make good decisions that support animal welfare within the constraints of an emergency event.
- 6.2.2. [TAMU Emergency Operations Plans](#)
- 6.3. For information about coronavirus disease 2019 (COVID-19), see:
 - 6.3.1. <https://www.cdc.gov/coronavirus/2019-ncov/index.html>
 - 6.3.2. <https://www.who.int/emergencies/diseases/novel-coronavirus-2019>
 - 6.3.3. <https://medlineplus.gov/coronavirusinfections.html>
- 6.4. IACUC/AWO Referenced Documents: (requires TAMU NetID authentication)
 - 6.4.1. TAMU-G-016 Transporting Animals on Texas A&M Campuses
 - 6.4.2. TAMU-S-002 Mechanisms of IACUC Review, Veterinary Consultation and Confirmation
 - 6.4.3. TAMU-S-006 Composition, Appointment, Responsibilities, and Training of the IACUC
 - 6.4.4. TAMU-S-008 IACUC Meeting Management
 - 6.4.5. TAMU-S-010 Semiannual Facility Inspections and IACUC Oversight of Animal Use Locations
 - 6.4.6. TAMU-S-011 Semiannual Review Programmatic Review
 - 6.4.7. TAMU-S-012 Review and Investigation of Animal Welfare Concerns and Potential Noncompliance
 - 6.4.8. TAMU-O-037 Inspection Expectations & Procedure Overview During COVID-19 Pandemic

7. HISTORY

Effective Date	Version #	Description
01/04/2021	000	College Station/Galveston: New Document
01/04/2021	001	Houston/Kingsville: New Document
01/19/2021	002	Dallas: New Document
12/27/2021	003	Houston/Kingsville: Revised; 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	004	Dallas: Revised; 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	005	College Station/Galveston: Revised; 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	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.
11/01/2023	008	College Station/Dallas/Galveston/Kingsville: Renewal; updated definitions and resources, minor clarification in procedures and changes in how the Animal Welfare Assurance and USDA registration are referenced, addition of animal concern/noncompliance investigation. Reviewed and approved via TEAMs.
12/01/2023	009	Houston: Renewal; updated definitions and resources, minor clarification in procedures and changes in how the Animal Welfare Assurance and USDA registration are referenced, addition of animal concern/noncompliance investigation. Reviewed and approved via TEAMs.