



IACUC Guidance:	<b>TAMU-G-033</b>	Title:	<b>Guidelines for the Use of Holding Protocols and SOPs</b>	
	Location	Effective Date	Review By	
	<b>College Station/Dallas/Galveston/Kingsville</b>	05/01/2024	04/30/2027	
	<b>Houston</b>	06/01/2024	04/30/2027	

**1. PURPOSE**

- 1.1. To guide the use of holding protocols and holding SOPs for unexpected circumstances that may arise necessitating the transfer of responsibility of animal care from the PI to the AV, or AV designee.

**2. SCOPE**

- 2.1. Transfer of animals to an IACUC-approved Holding Protocol or an existing IACUC-approved Holding SOP may be necessary for circumstances including, but not limited to:
  - 2.1.1. Unexpected PI acquisitions,
  - 2.1.2. Pending protocol approval for a new PI,
  - 2.1.3. Pending protocol approval due to delays in the renewal process,
  - 2.1.4. Breeding or maintenance of a rare genotype left over from a completed project.
- 2.2. Animals may also be transferred to an IACUC-approved Holding Protocol/SOP as determined by the IACUC, as a result of an investigator found to be in noncompliance with federal regulations or institutional rules.

**3. RESPONSIBILITY**

- 3.1. The **PI**, or designee is responsible for:
  - 3.1.1. Filing AUPs in a timely manner or notifying the IACUC when animals are remaining on a protocol that is about to expire and there are no plans for renewal.
  - 3.1.2. Obtaining permission from the AV, or responsible party prior to placement of animals onto the IACUC-approved Holding Protocol/SOP
  - 3.1.3. Completion of the Animal Transfer Form or other transfer request mechanism used by the Core Support unit.
  - 3.1.4. Discontinuation of data collection from animals on a Holding Protocol/SOP
  - 3.1.5. Payment of service and per diem fees to ARU/CMP/PAR/PRF; however, these cannot be drawn from federally funded grants.
- 3.2. The **AV**, or designee is responsible for:
  - 3.2.1. Assuming the role of PI for all animals on the Holding Protocol/SOP
  - 3.2.2. Authorizing any clinical treatment of animals on the Holding Protocol/SOP
  - 3.2.3. Authorizing the release of animals from the Holding Protocol/SOP to the investigator when he/she has an IACUC-approved AUP.
  - 3.2.4. Authorizing the transfer or shipment of animals from the Holding Protocol/SOP to another TAMU investigator or outside institution
- 3.3. The **IACUC** is responsible for:
  - 3.3.1. Review and approval of documents pertaining to animal research, which may include but is not limited to holding SOPs.
  - 3.3.2. Determining if animals on an approved protocol must be transferred to a Holding Protocol/SOP as a result of investigator noncompliance.
- 3.4. **ARU/CMP/PAR/PRF** or **Core Support** unit is responsible for:
  - 3.4.1. Ensuring the Holding Protocol/SOP describes the species which will be held.
  - 3.4.2. Identifying animals/cages on a Holding Protocol/SOP
  - 3.4.3. Establishing service fees and per diem fees for animals on a Holding Protocol/SOP
  - 3.4.4. Maintaining animals in a condition suitable for further studies
  - 3.4.5. Restricting PI and research personnel access to animals housed under a Holding Protocol/SOP



- 3.5. **AWO staff** are responsible for notifying the AV and Core Support manager (if applicable) when animals are to be transferred to the Holding Protocol/SOP for IACUC related causes.

#### **4. DEFINITIONS AND/OR ACRONYMS**

- 4.1. **AUP:** Animal Use Protocol. Document submitted by the PI indicating the housing and procedures involving animals.
- 4.2. **AWO:** Animal Welfare Office. Supports the IACUC administratively.
- 4.3. **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.
- 4.4. Centrally administered support service for animal research and teaching programs at Texas A&M University:
  - 4.4.1. **ARU:** Animal Resource Unit supports the College of Dentistry vivarium
  - 4.4.2. **CMP:** Comparative Medicine Program supports the Texas A&M College Station campus
  - 4.4.3. **PAR:** Program for Animal Resources supports the Institute of Biosciences and Technology vivarium
  - 4.4.4. **PRF:** Pharmaceutical Research Facility supports the Kingsville Pharmaceutical Science Facility vivarium
  - 4.4.5. **Sea Life:** The Sea Life Facility supports the Galveston campus
- 4.5. **Core Support:** Individuals performing professional activities such as husbandry or technical services as a function of a dedicated service organization.
- 4.6. **Holding SOP:** Standard Operating Procedure for temporary housing and routine care of animals not approved under an IACUC-approved protocol. Designates an individual with primary responsibility for the animals. Must be entered into iRIS as a protocol/SOP for IACUC review and approval.
- 4.7. **Holding Protocol:** IACUC-approved protocol for temporary housing and routine care of animals under the responsibility of the AV.
- 4.8. **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.
- 4.9. **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.
- 4.10. **iRIS:** Web-based compliance submission system
- 4.11. **SRS:** Sponsored Research Services. Consortium of research administrators supporting Texas A&M University System Members throughout the grant/award process.

#### **5. GUIDELINES OR PROCEDURE**

##### **5.1. Criteria for Holding Protocol/SOP Use**

- 5.1.1. Use of a Holding Protocol/SOP is intended to be temporary.
- 5.1.2. Situations which might be covered under this protocol include:
  - 5.1.2.1. Animals on a protocol under investigation for potential issues of noncompliance where the welfare or well-being of the animals is in question and after IACUC suspension of activity.
  - 5.1.2.2. Expired or terminated protocol where animals are still present.
  - 5.1.2.3. New investigators in the process of submitting a protocol for review and approval by the IACUC that require the transfer/housing of animals immediately at Texas A&M University.
  - 5.1.2.4. Investigators that are leaving and do not have the necessary approvals for animal transfer to their new institution.
- 5.1.3. The IACUC approved Holding Protocol/SOP must describe the species which will be held.

##### **5.2. Procedure for Holding Protocol/SOP Use**

###### **5.2.1. Expired/Suspended protocols**

- 5.2.1.1. The AWO will notify the Principal Investigator, IACUC Chair (expired AUPs), Attending Veterinarian, and non-ARU/CMP/PAR/PRF Core Support unit Director/Manager (if applicable) that animals on a protocol will be moved to the Holding Protocol/SOP.
- 5.2.1.2. Any animals remaining at the time of AUP expiration are automatically considered to be affiliated with the appropriate Holding Protocol/SOP, with the facility designated transfer process to be completed no later than **1 business week** after the date of expiration.
- 5.2.1.3. Core Support units will identify cage cards/racks/rooms/pens etc. under the protocol/SOP, transfer cages and animals to the Holding Protocol/SOP and notify the PI that animals may not be used in any way, only maintained.
- 5.2.1.4. Maintenance may include the provision of special diets, medicines, and clinical treatment necessary to maintain the animals in a condition suitable for further studies. However, no data collection, teaching or testing in conjunction with the research described in the protocol, or otherwise, may be conducted.
- 5.2.1.5. No access to animals by PI or study participants may occur without approval by the office of the AV or non-ARU/CMP/PAR/PRF Core Support unit Director/Manager (as applicable); exclusive of suspension of an activity, protocol, or personnel by the IACUC, IO or AV.
- 5.2.1.6. No access to animals may be granted without prior IACUC approval when animals have been transferred as a result of suspension of an activity, protocol, or personnel.
- 5.2.1.7. Animals may not be transferred from the holding protocol without prior IACUC approval when animals have been transferred as a result of suspension of an activity, protocol or personnel.
- 5.2.1.8. Continuation of research activities beyond the protocol expiration is a violation of both the Animal Welfare Regulations (AWRs) and the PHS Policy on Humane Care and Use of Laboratory Animals (PHS Policy).
- 5.2.1.9. Breeding colonies may be maintained by the discretion of Core Support unit management; including the establishment of new breeding pairs, trios or harems.

**5.2.2. New/Leaving Investigators**

- 5.2.2.1. Investigators/Departments are responsible for all charges associated with maintaining animals on the holding protocol until they are approved for exportation, transfer to a different approved protocol, or the determination is made to euthanize the animals.
- 5.2.2.2. No access to animals by PI or research staff without approval by the office of the AV for ARU/CMP/PAR/PRF or Core Support unit Director/Manager, as applicable.

**5.3. Billing of Services Provided to Animals on Holding Protocol/SOP**

- 5.3.1. No use of sponsored funding for animal maintenance while on the holding protocol without explicit approval from granting agency. Approval must be coordinated through SRS.
- 5.3.2. The Office of Management and Budget Cost Principles and the NIH Grants Policy Statement do not permit charges to grant awards for the conduct of animal activities after IACUC approval has lapsed; such charges are a violation of the terms and conditions of the grant award and must be reported to the NIH Institute or Center supporting the award.
- 5.3.3. Animal housing per diem is still charged to the principal investigator's funding code while on the Animal Holding Protocol/SOP.

**6. EXCEPTIONS**

- 6.1. The PI of the Holding Protocol/SOP may request an exception to the above standards by describing the departure in the protocol/SOP
- 6.2. For programmatic exceptions, the facility director or manager may submit a request for the exception using TAMU-F-013

**7. REFERENCES, MATERIALS, AND/OR ADDITIONAL INFORMATION**



- 7.1. References:
  - 7.1.1. [Volume 41, No. 8. 2012](#). LabAnimal.com
- 7.2. Resources:
  - 7.2.1. [IACUC/AWO Referenced Documents](#): (requires TAMU NetID authentication)
    - 7.2.1.1. TAMU-F-013 Request for Programmatic Exception from Animal Welfare Standards
  - 7.2.2. SRS: <https://vpr.tamu.edu/division-units/sponsored-research-services>
  - 7.2.3. For more information about the use of available holding protocols/SOPs, please contact:
    - 7.2.3.1. CMP at 979-845-7433
    - 7.2.3.2. ARU: at (214) 828-8149
    - 7.2.3.3. PAR: at (713) 677-7471
    - 7.2.3.4. PRF: at (361) 221-0770
    - 7.2.3.5. Sea Life Facility: at (409) 740-4574

**8. HISTORY**

Effective Date	Version #	Description
08/03/2020	000	College Station/Galveston: New Document; reviewed and approved by email
10/01/2020	001	Houston/Kingsville: New format and updated Content; partially replaces IBT-220.01 reviewed and approved by email
10/20/2020	002	Dallas: New format and updated Content; partially replaces CD-220.01
02/01/2022	003	College Station/Galveston: Renewal; updated definitions and resources; added exceptions section; Reviewed and approved by email
03/01/2022	004	Houston/Kingsville: Renewal; updated definitions and resources; added exceptions section
03/24/2022	005	College Station/Dallas/Galveston: Merging of Dallas animal care and use program with College Station/Galveston
10/20/2022	006	College Station/Dallas/Galveston/Kingsville: Merging of Kingsville animal care and use program with College Station/Dallas/Galveston.
05/01/2024	007	College Station/Dallas/Galveston/Kingsville: Updated scope, responsibility, and definition sections; updated procedure to address placement of animals from expired AUPs onto holding AUP/SOP, clarification of procedures related to suspension. Reviewed and approved via TEAMS
06/01/2024	008	Houston: Updated scope, responsibility, and definition sections; updated procedure to address placement of animals from expired AUPs onto holding AUP/SOP, clarification of procedures related to suspension.