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	IACUC SOP:	1 AIVIU-5-001	Hitle:	Document Management

Location	Effective Date	Review By
College Station/Dallas/Galveston/Kingsville	10/20/2022	09/30/2025
Houston	11/01/2022	09/30/2025

1. PURPOSE

1.1. To standardize both the management of IACUC issued Guidance and SOP documents and retention of IACUC documents and records.

2. RESPONSIBILITY

- 2.1. The IACUC Chair is responsible for appointing members to perform DMR.
- 2.2. **IACUC Members** are responsible for reviewing Guidance and SOP documents as a part of a convened quorum of the members of the IACUC (FCR), or as a designated reviewer(s) as appointed by the IACUC Chair (DMR).
- 2.3. The **AWO Staff** is responsible for assisting the IACUC with the revision of documents, maintenance of documents including disposal, and performing distribution to the research community and committee, as applicable. The AWO Staff will make documents available to inspectors and site visitors upon request.

3. DEFINITIONS AND/OR ACRONYMS

- 3.1. Active record: An active record is one which is not inactive or defined as a non-record.
- 3.2. AWO: TAMU Animal Welfare Office. Supports the IACUC administratively.
- 3.3. **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.
- 3.4. **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.
- 3.5. **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.
- 3.6. **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.
- 3.7. **IACUC Chair:** Chair of the IACUC appointed by the Institutional Official.
- 3.8. **Inactive Record:** A record that is no longer required to carry out the administrative or procedural function for which it was prepared, but must be kept for administrative, fiscal, legal, or historical purposes in accordance with the approved retention schedule.
- 3.9. Non-record: Non-records include documents prepared solely for convenience, such as copies of original documents, notes or preliminary drafts not circulated for comment; correspondence seeking guidance or information on IACUC policies or procedures that are not related to an active protocol; documents received or prepared for non-IACUC business.
- 3.10. **Record:** A record is any information which has administrative, fiscal, or legal value and is used in conducting the official business of the IACUC. Records include paper files, electronic files, or other documentary materials, regardless of physical form or characteristics. Electronic files include computer files, databases, and e-mail.
- 3.11. **Retention**: The length of time a record must be kept before it can be destroyed, otherwise disposed of, or permanently archived.
- 3.12. **SOP:** Standard Operating Procedure. SOP documents are developed by the IACUC to provide procedural standards for the activities performed by the committee.
- 3.13. **TAMU:** Texas A&M University.
- 3.14. **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.

4. PROCEDURE

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4.1. All records received or prepared during the normal course of IACUC business are the property of TAMU. The IACUC is responsible for ensuring that records associated with their activities are managed in accordance with institutional policies and in compliance with applicable federal and state laws.

4.2. IACUC Guidance and SOP Document Development

- 4.2.1. Guidance and SOP documents are developed as needed by the IACUC and are reviewed and approved by FCR or DMR, if no member calls for FCR.
 - 4.2.1.1. Note: Full committee review may be performed by distribution of documents to all members of the committee and soliciting feedback by an established date. The document will be approved when the deadline for comment has passed, and no additional modifications are received.
- 4.2.2. Document content relating to a specific animal program will only be reviewed by the IACUC providing oversight of that program.
- 4.2.3. Once approved, documents will be reviewed at no more than three-year intervals by FCR or DMR, if no member calls for FCR.
 - 4.2.3.1. AWO staff may administratively update formatting, correct grammar and typographical errors, update web addresses, make corrections to outdated Reference section data, and add location-specific definitions and contact information for individual centrally managed vivaria without additional review.
- 4.2.4. Documents will be distributed as appropriate to the audience.

4.3. Records Retention

4.3.1. Active Records

- 4.3.1.1. Active records are maintained and stored in the AWO or on secure, remote computer hardware, and consist of:
 - 4.3.1.1.1 IACUC records associated with proposed activities involving animals and proposed significant changes in activities involving animals, including documentation of veterinary consultation and IACUC review, the protocol document with IACUC approved revisions, and addenda related to the protocol document as required by the IACUC
 - 4.3.1.1.1. A protocol is approved for a three-year period, which is defined as the life of the activity
 - 4.3.1.1.1.2. A protocol may be set to the "Closed" status in iRIS by AWO staff prior to the scheduled expiration date when requested by the PI, the PI's designee or the PI's Department Head (or higher).
 - 4.3.1.1.2. IACUC meeting minutes, including records of attendance, activities, and deliberations
 - 4.3.1.1.3. Semi-annual IACUC evaluations, including minority views, forwarded to the Institutional Official
 - 4.3.1.1.4. Approved PHS Assurance
 - 4.3.1.1.5. Records of accrediting body determinations (e.g., AAALAC)
 - 4.3.1.1.6. Annual Reports issued to federal agencies (e.g., OLAW, USDA)
 - 4.3.1.1.7. IACUC membership lists
 - 4.3.1.1.8. IACUC Guidance and SOP documents
 - 4.3.1.1.9. Other documents deemed necessary for the function of either the IACUC or the office
- 4.3.1.2. Active records must be maintained for the duration of the approval period or activity. After this time, records become inactive.

4.3.2. Inactive Paper Records

4.3.2.1. Inactive paper records are retained in the AWO or are placed in labeled archival boxes and stored in TAMU archives. These records remain under the control of the IACUC and are available to authorized OLAW, USDA, or funding agency representatives, as needed.

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- 4.3.2.2. Inactive records are scheduled for disposal three years after their storage date, with the following proviso:
 - 4.3.2.2.1. There is no audit, current or anticipated investigation, or pending legal action or proceeding that would prohibit the disposal of the record

4.3.3. Inactive Electronic Records

- 4.3.3.1. Inactive electronic records, exclusive of protocol records, are scheduled for deletion three years after their inactivation date.
- 4.3.3.2. Protocol records are indicated in the electronic protocol management system as inactive at the conclusion of the three-year approval period, or sooner.
- 4.3.3.3. Records may be electronically archived three years after inactivation, with the following proviso:4.3.3.3.1. There is no audit, current or anticipated investigation, or pending legal action or proceeding that would prohibit the disposal or archiving (electronic) of the record

4.3.4. Non-Records

4.3.4.1. Non-records should be deleted or destroyed promptly, unless there is an administrative or other reason to retain the information. There is no retention schedule associated with non-records.

4.3.5. Disposal of Records

- 4.3.5.1. Records must be destroyed or deleted using methods which do not permit recovery and future use of the information.
 - 4.3.5.1.1. Paper records must be shredded or disposed of through an approved document disposal service
 - 4.3.5.1.2. Electronic records must be deleted permanently or removed from the record management system through vendor-authorized mechanisms for archiving.
 - 4.3.5.1.3. The information on hard disks from outdated computers or other hardware scheduled to be discarded must be destroyed or deleted

5. REFERENCES, MATERIALS, AND/OR ADDITIONAL INFORMATION

- 5.1. AWAR §2.35a, §2.35f and PHS Policy IV,E describe the record retention requirements for IACUCs.
- 5.2. TAMUS Retention Schedule
- 5.3. TAMU-S-002 IACUC Submission Review Mechanisms

6. HISTORY

Effective Date	Version #	Description	
03/21/2019	000	College Station/Galveston: New document; replaced AWAP 102 (never approved)	
09/23/2019	001	Houston/Kingsville: New document; replaced IBT-100	
11/19/2019	002	Dallas: New document; replaced CD-100	
01/16/2020	003	College Station/Galveston: Document modified to clarify potential mechanisms of FCR; review of document content related to individual programs; administrative modification of data contained in the Definitions and Reference sections related to the addition of centrally administered vivaria; early closure of AUPs	
01/21/2020	004	Dallas: Document modified to clarify potential mechanisms of FCR; review of document content related to individual programs; administrative modification of data contained in the Definitions and Reference sections related to the addition of centrally administered vivaria; early closure of AUPs	
01/27/2020	005	Houston/Kingsville: Document modified to clarify potential mechanisms of FCR; review of document content related to individual programs; administrative modification of data	



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		contained in the Definitions and Reference sections related to the addition of centrally administered vivaria; early closure of AUPs. Replaced IBT-S-001.
03/24/2022	006	College Station/Dallas/Galveston: Merging of Dallas animal care and use program with College Station/Galveston
10/01/2022	007	College Station/Dallas/Galveston: Renewal; updated definitions, removal of reference to areas of individual IACUC oversight
10/20/2022	008	College Station/Dallas/Galveston/Kingsville: Merging of Kingsville animal care and use program with College Station/Dallas/Galveston.
11/01/2022	009	Houston: Renewal; updated definitions, removal of reference to areas of individual IACUC oversight. Reviewed and approved via email.