TITLE: IACUC Records Management

PURPOSE: To ensure that IACUC records are maintained, stored and disposed of in accordance with all appropriate regulations.

REVIEW/REVISIONS: The IACUC will review and revise this SOP as needed.

DATE OF LAST REVISION: 01/12/2015

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

PROCEDURES:

These procedures outline the management of IACUC records with the aims of:

- Complying with AWAR, PHS Policy, federal and state law and University policy regarding records management and retention
- Identifying and protecting permanent records
- Efficiently managing the costs and optimizing the storage space associated with record retention
- Ensuring the timely disposal of inactive records

Active records:

Active records are maintained and stored in the IACUC Office or on secure, remote computer hardware, and consist of:

- IACUC records associated with proposed activities involving animals and proposed significant changes in activities involving animals, including correspondence, protocol forms, amendments or other records
  - A protocol is approved for a three year period, which is defined as the life of the activity
- IACUC meeting minutes, including records of attendance, activities and deliberations
- Semi-annual IACUC evaluations, including minority views, forwarded to the Institutional Official
- PHS Assurance approved by OLAW
- Records of accrediting body determinations (e.g., AAALAC)

Active records must be maintained for the duration of the approval period or activity. After this time, records become inactive.

Inactive records:

Inactive records are placed in labeled archival boxes and stored at the University Records Center. These records remain under the control of the IACUC and are available to authorized OLAW, USDA or funding agency representatives, as needed. Inactive records are scheduled for disposal three years after their storage date, with the following proviso:

- There is no audit, current or anticipated investigation, or pending legal action or proceeding that would prohibit the disposal of the record

GLP records:

GLP records are maintained and stored in the IACUC Office or on secure, remote computer hardware, and consist of:

- All records associated with an approved GLP protocol, including correspondence, protocol forms, amendments or other records
A GLP protocol is approved for a three year period, which is defined as the life of the activity.

GLP records are maintained for the duration of the approval period. At the end of the approval period, GLP records are transferred to the Quality Assurance Officer or designee for appropriate retention and eventual disposal.

**Permanent records:**
Permanent records are maintained and stored in the IACUC Office or on secure, remote computer hardware, and consist of:

- Personnel training and certification records

Permanent records are retained indefinitely, with the following provisos:

- Electronic permanent records may be transferred to different formats or databases, so long as the original information is retained
- Personnel records may be deleted, if the individual is no longer a student or employee of the University of Arizona

**Non-records:**
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.

**Disposal of records:**
Records must be destroyed or deleted using methods which do not permit recovery and future use of the information.

- Paper records must be shredded or disposed of through an approved document disposal service
- Electronic records must be destroyed or deleted through thorough multiple overwrites, or physical destruction of drives or electronic storage media to ensure proper destruction
- The information on hard disks from outdated computers or other hardware scheduled to be discarded must be similarly be destroyed or deleted

**DEFINITIONS:**

- **Active record:** An active record is one which is not inactive or defined as a non-record. Permanent and GLP records are also active records.
- **GLP record:** A record that is associated with a Good Laboratory Practices (GLP) protocol.
- **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.
- **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.
- **Permanent Record:** A permanent record is one required to ensure the continuity of IACUC-related activities.
- **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.
- **Retention:** The length of time a record must be kept before it can be destroyed, otherwise disposed of, or permanently archived.
JUSTIFICATION:

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

AWAR §2.35a, §2.35f and PHS Policy IV,E describe the record retention requirements for IACUCs.

21 CFR §58.195a-b, d-e, g-h describe the record retention requirements for GLP studies.