



SUBJECT: Recordkeeping Requirements for Research Personnel	Effective Date: 1/25/2019	Policy Number: 10.4.5	
	Supersedes: 2/26/2016	Page 1	Of 6
	Responsible Authorities: Primary Investigator Institutional Animal Care and Use Committee Director, Comparative Medicine		

I. Background

The United States Department of Agriculture (USDA) and Public Health Service (PHS) emphasize proper documentation of animal care and use. Written records are a standard form of documentation which verify experimental procedures and protocol compliance. As part of an effective animal care and use program, research personnel working with animals must develop and maintain accurate study records. The *Guide for the Care and Use of Laboratory Animals* states that adequate recordkeeping is necessary for management of both colonies of terrestrial species and systems of aquatic species. Adequate records are considered critical for documenting animal well-being as well as tracking animal care and use at an institution.

II. Purpose

To assist research personnel in determining the appropriate and necessary record-keeping for animals in research, as mandated by federal laws and/or institutional, regulations, and policies. Recordkeeping is addressed in several existing policies and regulations, which are summarized in this reference document. In addition, the IACUC requires certain monitoring and recordkeeping for animals that experience severe or prolonged pain or impairment as a result of a study procedure which might not be specifically covered by an established policy.

III. General Statement

Regulatory and accrediting agencies expect proper documentation of animal care and use as a means for the institution to ensure compliance with research protocols and clinical care procedures including but not limited to information on acquisition of animals, experimental use, adequate pre- and post-procedural care, appropriate husbandry and veterinary care, final disposition and adequate training of personnel working with animals. The extent of records maintained varies based on the nature of the particular research study.

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IV. Policy

- A. It is the responsibility of the research personnel to maintain adequate records that reflect experimental procedures performed on animals, observations of animal well-being (e.g. post-procedure monitoring and humane endpoints) and final disposition of animals. In addition, training provided to personnel working with animals must be documented. Principal Investigators (PI) must also keep track of animal numbers by IACUC protocol. For USDA covered species, PIs must track animal numbers by pain category. Various forms of written documentation can be employed such as lab notebooks, electronic computer records and specific forms as required by particular IACUC policies.
- B. Researchers who are approved for maintaining animals in a Satellite Facility must keep additional documentation, e.g. in a weekly/monthly spreadsheet, including daily health checks of all animals present under their care, feeding and watering data, cleaning and sanitizing schedules, initial and changing census, sick or dead animals found, measurements of environmental data such as temperature and humidity. Water testing data and system life support information must be kept for all aquatic systems housing aquatic species.
- C. A variety of records must be maintained by Comparative Medicine (CM) including but not limited to daily health checks, sanitizing and sterilizing schedules, individual health and population health surveillance records. The Attending Veterinarian is responsible for development and implementation of appropriate recordkeeping within CM and description of best practices in particular SOP(s).
- D. Comparative Medicine must keep acquisition records for animals ordered through CM and track animal numbers against approved animal numbers in specific IACUC protocol(s) for all animals utilized in FAU's Animal Care and Use Program.
- E. PIs who perform their research in PI managed satellite facilities or in the field have to keep track of the animal numbers used. Research Integrity will request numbers of wild caught animals housed in satellite facilities or utilized in field research from relevant research staff semi-annually or more often if necessary.
- F. Any transfer of animals between facilities and/or protocols must be requested through the CM database (i.e. VSATS) for animal number tracking purposes. If animals have been used in prior research the IACUC is required to review such request to determine whether using that particular animal(s) in another research study is appropriate based on animal welfare considerations. The IACUC delegates this authority to the Attending Veterinarian (AV). If an animal is experimentally naïve the animal numbers of the prior IACUC protocol will be credited.
- G. Animals must be identified in a manner consistent with regulatory and accreditation requirements.
- H. As the Guide states, medical records are a key element of the veterinary care program and are considered critical for documenting animal well-being. It is a shared responsibility of the PI and the veterinary staff to maintain accurate medical records. The Attending Veterinarian and/or her designee must be

involved in establishing, reviewing, and overseeing medical and animal use records program-wide.

- I. Breeding records should be kept as applicable and contain basic descriptive information essential for management of colonies such as species, animal identification(s), sire and/or dam identifier, sex, birth or acquisition date, source, and final disposition.
- J. Any records maintained in FAU's Animal Care and Use Program **are considered legal documents**. Therefore, entries into recording documents must be
 1. In chronological order
 2. Logical to a reviewer not involved in the specific study
 3. Legible
 4. Made in ink
 5. Corrected or deleted if necessary with a single line followed by initialing and dating next to the line.
- K. Clinical records should be kept in close proximity to the animals for the time being relevant for veterinary care (e.g. post-operative care records for 2 weeks) and thereafter must be readily accessible for the veterinarian(s) if kept in the research laboratory.
- L. All animal related records must be readily available to authorized inspectors such as IACUC site visitors and inspectors of regulatory or accreditation agencies.
- M. Animal research related records must be retained for the duration of the research or teaching activity and for an additional three (3) years following expiration and/or closure of the protocol.

V. Definitions

Animal records are any written documentation associated with animal models in research and teaching.

Satellite Animal Housing Facility is the term that refers to any location where animals are housed outside the CM-managed Centralized Facilities for more than 12 hours. Housing does not include areas where experimental procedures are performed; these areas must be identified in the IACUC approved protocol.

Animal transfer is any new allocation of animal(s) to a different housing area, a different IACUC protocol of the same PI or a different IACUC protocol of another PI independent of whether an animal is still experimentally naïve.

VI. Accountability

The Principal Investigator (PI) will be responsible for:

- Appropriate recordkeeping concerning any animal related matters when using animal models in research or teaching.
- Communicating with the Attending Veterinarian and the IACUC on what kind of recordkeeping is required to observe animal welfare.

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- Describing all experimental procedures and circumstances leading to potential pain/distress in the animal care and use protocol. Requesting the review and approval of an amendment to the IACUC protocol prior to implementing changes.
- Tracking all animal numbers used by IACUC protocol and/or pain category as applicable.
- Assuring that personnel are appropriately trained and the training is documented in writing.

The IACUC will be responsible for:

- Reviewing and approving, requiring modifications in (to secure approval) or withholding approval of IACUC protocols and/or amendments, especially in the assessment of the appropriateness of the use of painful/distressful procedures, the measures to be implemented to alleviate pain/distress, proposed humane endpoints and level of recordkeeping necessary.
- Providing oversight for all animal procedures conducted including painful/distressful procedures and conditions.
- Assure that appropriate recordkeeping is followed by all animal care and use constituents to document animal well-being and track all animal care and use at the institution.
- Develop and direct an appropriate training program.

The Research Integrity office will be responsible for:

- Administrative support of the IACUC members to facilitate their regulatory function.
- Maintaining policy and assure regular review and update as necessary by the IACUC.
- Reviewing relevant animal related records and provide information to the IACUC for deliberation.

The Attending Veterinarian and the Office of Comparative Medicine (CM) will be responsible for:

- Veterinary review of IACUC protocol(s) and providing advice to PIs on appropriate study design concerning painful/distressful procedures and humane endpoints.
- Keeping track of animal numbers used for the entire animal care and use program.
- Development and implementation of appropriate recordkeeping within CM and description of best practices in particular SOP(s)

VII. Procedures

- A. During semi-annual site visits or post-approval monitoring sessions by the IACUC all animal related records must be presented to the IACUC members while visiting the research laboratory.
- B. Animal husbandry records must be presented by CM or the responsible PI at a satellite facility. These records must contain as a minimum:

1. Daily health checks including number of sick/dead animals found
 2. Daily census of animals
 3. Daily check of proper function of life support equipment
 4. Daily check of environmental parameters such as room temperature and humidity
 5. Feeding and watering (if applicable) schedule
 6. Sanitation of primary and secondary enclosures and equipment
 7. Regular water quality measurement for aquatic species
- C. Experimental records have to be available either in the animal housing facility or in the research laboratory and being presented by a senior lab member able to explain specifics if questions arise. At a minimum the following documentations need to be accessible if applicable to the current IACUC protocol(s) and the research lab:
1. Surgical, post-operative and/or post-procedural records
 2. Body weight monitoring records
 3. Food and fluid regulation records
 4. Scoring sheets and/or any other humane endpoint documentation as described in the IACUC protocol
 5. Administration of drugs and/or experimental compounds including name of agent, dose, volume, route, and frequency per approved protocol
 6. Breeding colony records
 7. Research personnel training records
- D. At a minimum, records should consist of the following:
1. Date and/or time of entry
 2. IACUC protocol number
 3. Animal ID or group ID
 4. Type of procedure performed either experimental or husbandry related
 5. Initial of person making the entry
- E. Animals housed in any animal facility either centralized CM or PI managed satellite facility must be identified. This can also be done as group ID at the cage or tank level. In general, this will be done through cage cards/tags labeled with the following at the minimum:
1. Name of the Principal Investigator
 2. IACUC protocol number
 3. Date of arrival or date of birth
 4. Source
 5. Species/strain
 6. Sex
 7. Weight or age
 8. A specific animal identifier if appropriate
- F. Entries related to unexpected health concerns should be made in the *Progress Notes*. *Progress notes* are available in each housing room and organized by PI and IACUC number in a room log book. Both CM personnel and research staff can provide notes related to the health of a particular animal. After the initial entry the veterinarian needs to be informed unless the

animal will be euthanized. It is important that with the closure of any clinical case a final entry indicates whether the health problem has been resolved or the animal was euthanized due to humane concerns.

- G. Table summarizing IACUC Policies requiring specific forms for monitoring and documentation:

IACUC POLICY	ASSOCIATED FORMS
10.4.3 Animal Procurement and Acclimation	Animal Order Form; Animal Transfer Form; Animal Import Request Form
10.4.4. Satellite Animal Housing Facilities	Satellite Facilities Application and Renewal Form; Satellite Facilities Procedures Description Form
10.4.6 Anesthesia, Surgeries and Analgesia	Rodent Group Anesthetic/Surgical Record; Rodent Individual Anesthetic/Surgical Record
10.4.5 Recordkeeping Requirements	Progress Notes
10.4.18 Controlled Substances & Prescription Drugs	Certification of Research Personnel Using Controlled Substances; Controlled Substance Record Usage Log
10.4.22 Researcher Training	Laboratory Training Documentation

VIII. Policy Renewal Date
1/25/2022

IX. References
Regulations, guidelines and policies are available on the IACUC web site at <http://www.fau.edu/research/research-integrity/iacuc-policies-and-procedures.php>

Specific Comparative Medicine's Standard Operating Procedures (SOPs) are also available at http://www.fau.edu/research/docs/policies/research-integrity/p01_policies_procedures.pdf

POLICY APPROVAL

Initiating Authority

Signature: _____

Date: _____

Name: Daniel C. Flynn, Ph.D., Vice President for Research

Executed signature pages are available in the Initiating Authority Office(s)