

<b>Title: Record Keeping for Regulated Animals at Oklahoma State University</b>	Policy No. <b>IACUC-013</b>
	Effective Date: <b>2/09/15</b>

## 1. Reference(s):

USDA Animal and Plant Health Inspection Service (APHIS) Animal Care Policy Manual, Policy #3, “Veterinary Care”.

USDA Animal and Plant Health Inspection Service (APHIS) Animal Welfare Inspection Guide, Chapter 7: “Research Facility Inspection – IACUC requirements and Protocols”, Section 7-47: “Records”.

*Medical Records for Animals Used in Research, Teaching and Testing: Public Statement from the American College of Laboratory Animal Medicine.* American College of Laboratory Animal Medicine, 2007.

National Research Council. *Guide for the Care and Use of Laboratory Animals: Eighth Edition.* Washington, D.C., Academic Press, 2011.

Federation of Animal Science Societies. *Guide for the Care and Use of Agricultural Animals in Research and Teaching:* Third Edition. Champaign, IL. 2010

\* IACUC – Institutional Animal Care and Use Committee, USDA – United States Department of Agriculture, AAALAC – Association for the Assessment and Accreditation of Laboratory Animal Care International, OLAW – Office of Laboratory Animal Welfare

**2. Policy:** Oversight of animal-related research and teaching activities, both at the internal (IACUC)\* and external (OLAW, USDA, AAALAC)\* level, emphasizes the need for proper documentation of care for regulated animals. Detailed records are the primary means of documenting individual/herd health as well as compliance with IACUC-approved protocols. For this reason, Oklahoma State University’s Institutional Animal Care and Use Committee (IACUC) created this policy to help investigators, instructors, staff, and students understand the expectations for record keeping.

**2.1. Veterinary Medical Records** – The USDA (policy #3), the *Guide for the Care and Use of Laboratory Animals*, and the *Guide for the Care and Use of Agricultural Animals in Research and Teaching* state the necessity for maintaining veterinary medical records. Information within the medical record should be sufficiently comprehensive to demonstrate the delivery of adequate health care.

**2.1.1.** Medical records are typically maintained by veterinarians and their staff; however a number of individuals may make entries (e.g., veterinary staff, husbandry staff, research staff, trained students). For those regulated animals under the care of Animal Resources (AR), the AR veterinary staff would be responsible for these

records. However, all veterinarians providing medical care to regulated animals need to maintain adequate medical records (e.g., OSU Veterinary Teaching Hospital, ambulatory vet services). The provision of veterinary care must then be coordinated with the University Attending Veterinarian in a timely fashion (e.g., email, phone, direct communication). The University Attending Veterinarian must be informed of issues affecting any regulated animal's health, behavior, and well-being.

**2.1.2.** Individual medical records should be kept for all non-rodent mammalian species. Group records may be acceptable (most often, but not limited to rodents, birds, amphibians, reptiles, and fishes) when groups of animals all have similar diagnoses, procedures, or treatments. Any animal or subgroup of animals diagnosed, treated, or managed differently from the rest should have its own record. Group records may also be appropriate for routine husbandry, preventative health care and other minor procedures.

**2.1.3.** Medical records should be current, legible, dated, and indicate the originator of entry (e.g., initials, signature, electronic signature). Any format is acceptable as long as all appropriate information is included (see 2.1.4).

**2.1.4.** Medical records should include but are not limited to the following:

- Animal or group identification (may include PI name, Animal Care and Use Protocol (ACUP) reference number, species, identification number)
- Descriptions of any illness, injury, distress, and/or behavioral abnormalities and the resolution of the noted problem
- Differential, Suspected, or Confirmed diagnosis as appropriate
- Dates, details, and results (if appropriate) of all observations, examinations, diagnostics, tests, and other such procedures
- Dates and other details regarding all treatments including the name, dose, route, frequency, and duration of treatment (a “check off” system may be appropriate here)
- Details for re-evaluation if necessary
- Description of any surgical procedures (if applicable) as well as appropriate pre-, peri-, or post-operative care (includes anesthetic monitoring)
- Any actions taken to alleviate pain and distress (pharmacological and non-pharmacological interventions)
- Documentation of euthanasia or other disposition
- Necropsy findings (if applicable)
- Any preventative/routine health procedures as appropriate for species (e.g., vaccination, examination, diagnostics)

**2.2. Research Records (protocol-related)** – Research records encompass all aspects of the IACUC-approved protocol involving animal-related work (e.g., procedures, manipulations, treatments) and animal health or condition. Detailed research records are necessary to ensure demonstrable compliance with IACUC-approved activities to internal/external auditors (e.g., IACUC, Post-Approval Monitoring, AAALAC, USDA). These records also confirm the scientific merit of the work and aid in reproducibility of experiments and procedures.

**2.2.1.** Research records are typically maintained by the investigator(s) and their staff (e.g., lab manager, post-doctoral, graduate and undergraduate students). The extent of detail required to document research records varies based on the nature of the work and procedures/manipulations performed.

**2.2.2.** Individual research records should be kept for all non-rodent mammalian species. Group records may be acceptable (most often, but not limited to rodents, birds, amphibians, and reptiles) when groups of animals all have similar diagnoses, procedures, or treatments. Any animal or subgroup of animals diagnosed, treated, or managed differently from the rest should have its own record. Group research records may be appropriate for routine and other minor procedures/manipulations.

**2.2.3.** Research records should be current, legible, dated, and indicate the originator of entry (e.g., initials, signature, electronic signature). Any format (e.g., lab notebook, field journal, electronic, cage cards) is acceptable as long as all appropriate information is included (see 2.2.4). Templates, anesthetic monitoring charts, and post-operative monitoring forms that are specific to an investigator's work may be helpful to keep organized, detailed records. Animal Resources can help researchers, staff and students develop protocol-specific forms.

**2.2.4.** Research records should include, but are not limited to, the following:

- Animal or group identification (may include PI name, ACUP reference number, species, identification number, experimental treatment)
- Date and description of all procedures/manipulations
  - Time (AM/PM) should be included for all time-sensitive observations (e.g., evaluations, post-operative monitoring), treatments (e.g., pain medication, antibiotics, experimental drugs), and/or procedures (e.g., imaging, blood draw, biopsy)
- All drugs, therapeutic agents, or other experimental agents administered as part of the study (e.g., name, dose, volume, and route)
- Description of any surgical procedures and identification of surgeon(s)
- Description of anesthesia or sedation
  - include any pre-, peri-, or post-operative monitoring as outlined in the IACUC-approved protocol
  - include a description of drug administration (i.e. name, dose, volume, route, and time)

- Any clinical observations as required per IACUC-approved protocol (e.g., experimentally-induced disease, post-operative monitoring)
- Any unexpected outcomes, morbidity and mortality. *All unexpected outcomes, morbidity and mortality should be reported to the University Attending Veterinarian (or designee) by the investigator, research staff, trained students, or veterinarian in a timely fashion.*
- Date and description of prolonged restraint
- Date and description of any food/water restriction
- Date and description of special diets administered and special feeding and/or watering requirements
- Controlled Drug Log/Inventory (if applicable)
- Animal numbers (census) utilized by the principal investigator and the number of animals approved by the IACUC per IACUC protocol (e.g., computer records, acquisition and disposition records, dead animal records, inventory cards)
- Documentation of euthanasia or other disposition (e.g., transferred to another ACUP, released at site of capture).

**2.3 Husbandry Records** – Both the *Guide for the Care and Use of Laboratory Animals* and the *Guide for the Care and Use of Agricultural Animals in Research and Testing* state the necessity for adequate husbandry programs that are appropriate for a particular species of animal. To meet these expectations, records should be kept by facilities overseeing regulated animals' care to ensure husbandry requirements are being carried out.

**2.3.1** Husbandry records should include but are not limited to the following:

- Animal Observations – Animals are typically observed daily by trained caretakers, however frequency may increase (e.g., post-operative, parturition) or decrease (maintained on range or pasture) depending on the circumstances of the facility. For those animals maintained on range or pasture, observations should be frequent enough to detect illness or injury in a timely fashion, recognize the need for emergency action, and ensure adequate availability of feed and water.
- Animal numbers (census) that indicate the number of animals approved by the IACUC and the number of animals housed by the facility (e.g., computer records, acquisition and disposition records, dead animal records, inventory cards)
- Provision of adequate housing and availability of feed and water
- Environmental sanitation procedures both at the level of the microenvironment (e.g., cage, pen, stall,) and macroenvironment (e.g., room, barn)

- Environmental parameters (if applicable) as appropriate for species (e.g., temperature, humidity, light, noise)
- Any maintenance, repairs, or unexpected facility issues. *All unexpected facility issues that may affect or impair animals housed within the facility should be reported to the University Attending Veterinarian (or designee) by the investigator, research staff, trained students, or veterinarian immediately.*

**2.4 Records Retention and Availability**– According to the USDA APHIS *Animal Welfare Inspection Guide*, all records and reports **must** be [2.35(f)]:

- Maintained and held for:
  - A minimum of 3 years from the date
    - That an animal is disposed of, or euthanized
    - Of completion of the IACUC-approved protocol
    - Of completion of the IACUC-approved significant change to a protocol
  - Longer than 3 years if:
    - Necessary to comply with any applicable Federal, State, or local law
    - The research facility or project investigator is notified, in writing, that specified records must be retained pending completion of an investigation or proceeding
- Available for inspection and copying by:
  - Any Animal and Plant Health Inspection Service (APHIS) official
  - Any funding Federal agency representative
  - An IACUC member or personnel of the Office of University Research Compliance or Animal Resources

**3. Approval/Authentication:**

IACUC Chair Signature:	Date:	Attending Veterinarian Signature:	Date:
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