



## **Institutional Animal Care and Use Committee (IACUC): Standard Operating Procedure (SOP) for Recordkeeping Guidelines in USDA-Regulated Species**

### **1.0 Standard Operating Procedure (SOP) Purpose**

The purpose of this SOP is to ensure Principal Investigators (PIs) understand and implement best practices for medical recordkeeping when working with United States Department of Agriculture (USDA)-covered species.

### **2.0 SOP**

Medical/clinical records are required for USDA-covered species. Individual medical/clinical records (e.g., binders, tinbacks) are typically used for USDA-covered species upon each animal's arrival to the facility. Grouped records for more than one animal may be acceptable for certain species. If the PI is uncertain, the PI must consult with a Center for Animal Resources and Education (CARE) veterinarian to determine what type of records are appropriate for the species selected for a particular project.

Dates and times (including AM/PM) of all time-sensitive observations (e.g., evaluations, post-operative observations), treatments (e.g., pain medication, antibiotics, experimental drugs) and/or procedures (e.g., imaging, biopsy, blood draw) must be recorded by a member of the research team or CARE team if applicable.

All entries must be legible, made in black or blue ink, and initialed by the individual making the entry. If an authorized individual wishes to make a deletion or correction to the record, the individual must make a single line through the entry and initial and date next to the line. Medical/Clinical records must be kept in the vicinity of the corresponding animal(s). Records must be readily accessible to the CARE veterinarians, Animal Research Compliance (ARC) program staff, and authorized inspectors upon request.

The USDA requires that records be maintained for three years after the final disposition of the animal(s) or the completion of the activity. If an animal(s) is transferred to another facility location or another protocol, this should be noted in the clinical/medical record. A copy of the appropriate documentation (e.g., transfer form) should accompany the relevant record.

#### **2.1 Clinical Records**

The following information must be included in the clinical record:

- Date of animal's arrival at Brown, PI name and IACUC protocol number.
- Vendor or originating source of animal and accompanying health forms.
- Species, identification number and cage card/barn/stall number.
- Pertinent history and description of any abnormalities.
- Date of release from quarantine, if applicable.
- Dates of routine preventative care (e.g., vaccinations, nail clipping, teeth cleaning).

- Diagnostic laboratory services performed and copies of results (e.g., serology, parasitology, hematology).
- Record of veterinary care, including assessment of the animal's condition and progress over the duration of the treatment/observation period (e.g., dosages, routes and frequency of administration of any drugs/medications).
- Resolution of health problems (e.g., return to a normal clinical state, euthanasia).
- Necropsy findings, if applicable.

## **2.2 Documents Used to Record Procedures**

It is essential that procedures (e.g., surgery, imaging) and all post-procedural care adhere to the related IACUC-approved animal use protocol. As the medical/clinical records are the primary method of assessing procedural and animal care compliance with the protocol, accurate and detailed records must be kept by all individuals who are filling out records. Generally three documents are used to record procedures, detailed below.

### **2.2.1 Procedure Report**

The procedure report must include, at a minimum:

- Date of procedure.
- PI name and IACUC protocol number.
- Species and identification number.
- Names of all participating personnel (e.g., surgeons and anesthetists).
- Detailed description of the procedure.
- Documentation and explanation of any deviations from the procedure, as approved in the protocol, due to emergency or unforeseen circumstances.

### **2.2.2 Anesthesia Report**

The anesthesia report must include, at a minimum:

- PI name and IACUC protocol number.
- Species and identification number.
- Date and location of procedure.
- General procedures conducted, including but not limited to, number of intubation attempts, beginning and end of the procedure, and time of extubation.
- Significant procedural events and time of occurrence (e.g., primary incisions, vessel ligation, start of cardiopulmonary bypass, drilling sites for craniotomy).
- Any complications, including the time of occurrence and any interventions.
- Analgesics, anesthetics, antibiotics, and all other drugs administered, including dose, route, and time provided.
- Vital signs, including pulse and respiratory rate, recorded with appropriate frequency (generally every 5 - 10 minutes).
  - The body temperature must be documented at least every 15 minutes. Other monitoring techniques (e.g., blood pressure, pulse oximetry, ECG) must be performed at similar intervals.

### **2.2.3 Postoperative/Procedure Monitoring Report**

Postoperative/Procedure monitoring reports must include, at a minimum:

- PI name and IACUC protocol number.
- Species and identification number.
- Date and time of postoperative observations (including AM/PM).
- Initials of individuals conducting the observations/care.
- Condition of the animal<sup>1</sup>,
- Mentation (e.g., bright, quiet, dull).
- Vital signs (e.g., temperature, heart rate, respiratory rate, appetite, gastrointestinal and bladder function).
- Pain assessments<sup>2</sup>,
- Description of the appearance of surgical sites (e.g., signs of adverse reactions or potential infection).
- Analgesics, antibiotics/microbials, and all other drugs administered, including dose, route, and time provided<sup>3</sup>.

### 2.2.4 Final Disposition Records

The final disposition of the animal must be recorded in the animal's medical/clinical record. In the case of an unexpected death or unexpected euthanasia (i.e., euthanasia prior to expected research endpoint), a CARE veterinarian and the IACUC must be notified promptly by a member of the lab. Necropsies may be performed in order to collect tissue in accordance with the relevant protocol or in cases of unexplained or unexpected outcomes.

### 3.0 Definitions: N/A

### 4.0 Responsibilities

All individuals to whom this SOP applies are responsible for becoming familiar with and following this SOP. University supervisors are responsible for promoting the understanding of this SOP and for taking appropriate steps to help ensure compliance with it.

### 5.0 Related Information

The following information compliments and supplements this document. The information is intended to help explain this SOP and is not an all-inclusive list of policies, procedures, laws and requirements.

#### 5.1 Related University Policies: N/A

#### 5.2 Related SOPs: N/A

#### 5.3 Related Forms: N/A

#### 5.4 Frequently Asked Questions (FAQs): N/A

#### 5.5 Other Related Information: References:

- 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.

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<sup>1</sup> including any abnormalities in clinical condition or behavior (differing from a normal, healthy, awake animal)

<sup>2</sup> at a minimum, with each scheduled administration of analgesics. A negative pain assessment (i.e., pain-free state) must be observed and documented prior to discontinuing analgesic administration. Departure from protocol-approved analgesia regimens should be communicated to a CARE veterinarian.

<sup>3</sup> Time intervals for administering medications must be strictly adhered to per the approved protocol.

- USDA Animal and Plant Health Inspection Animal Care Policy Manual, Policy #3, “Veterinary Care.”

## **6.0 SOP Owner and Contact(s)**

**6.1 SOP Owner:** Vice President for Research

**6.2 SOP Approved by:** Vice President for Research

**6.3 Subject Matter Contact:** Brown University Animal Research Compliance (ARC)

- Telephone: 401-863-3050
- Email: IACUC@Brown.edu

## **7.0 SOP History**

**7.1 SOP Issue Date:** October 6, 2017

**7.2 SOP Effective Date:** October 6, 2023

**7.3 SOP Update/Review Summary:** SOP Reviewed at October 6, 2023 IACUC meeting.

- This SOP is not new; it was converted to the University’s new SOP template and re-reviewed by the IACUC at its convened meeting on October 2, 2020.
- IACUC Recordkeeping Guidelines for USDA-Regulated Species, Date of IACUC Review and Approval: October 6, 2017 as a policy. Reviewed and updated on October 2, 2020 to align with University SOP template.