Institutional Animal Care and Use Committee (IACUC)

Record Keeping Guidelines for USDA-Regulated Species

Date of IACUC Review and Approval: October 6, 2017

I. Purpose: Brown University’s Institutional Animal Care and Use Committee (IACUC) has developed the following guideline to help research investigators understand the best practices for medical recordkeeping when working with USDA-covered species. The United States Department of Agriculture (USDA) and Public Health Service (PHS) emphasize proper documentation of animal care and use.

II. Guidelines: This guideline offers direction on the following topics:
- General Recordkeeping Requirements
- Clinical Records
- Procedure Records
- Final Disposition Records

III. General Record Keeping Requirements:
1. Individual records (e.g., binders, tinbacks) are typically used for USDA-covered species upon their arrival to the facility. Grouped records for more than one animal may be acceptable for certain species. Please consult with a AC veterinarian to determine what type of records are appropriate for the species selected for a particular project.
2. Dates and times (including AM/PM) of all time-sensitive observations (i.e., evaluations, post-operative observations), treatments (i.e., pain medication, antibiotics, experimental drugs) and/or procedures (i.e., imaging, biopsy, blood draw) must be recorded.
   a. All entries must be legible, made in ink, and initialed by the individual making the entry.
   b. Any deletions or corrections to the record must consist of making a single line through the entry and initialing and dating next to the line.
3. Clinical records should be kept in the vicinity of the animals. Records must be readily accessible for the AC veterinarian and authorized inspectors when requested.
4. The USDA requires that records be maintained for a 3-year time period after the final disposition of the animal(s) or the completion of the activity.
5. If an animal(s) is transferred to another facility location or another protocol (once you have obtained approval from Animal Care and the IACUC), this should be noted in the clinical record. A copy of the appropriate documentation (e.g., transfer form) should accompany the animal(s) record.
IV. **Clinical Records:**

The following information should be included in the clinical record.

1. Date of arrival at Brown, Principal Investigator (PI) name and IACUC protocol number.
2. Vendor or originating source of animal and accompanying health forms.
3. Species, identification number and cage card/barn/stall number.
4. Pertinent history and description of any abnormalities.
5. Date of release from quarantine, if applicable.
6. Dates of routine preventative care (e.g., vaccinations, nail clipping, teeth cleaning, etc).
7. Diagnostic laboratory services that are performed and copies of results (e.g., serology, parasitology, hematology).
8. Record of veterinary care to include assessment of the animal’s condition and progress seen over the duration of the treatment/observation period (i.e., dosages, routes and frequency of administration of any drugs/medications).
9. Resolution of health problems (e.g., return to a normal clinical state, euthanasia).
10. Necropsy findings, if applicable.

V. **Procedure Records:**

It is essential that the procedure (i.e., surgery, imaging) and all post-procedural care adhere to what is described in the related approved IACUC protocol. As the medical records are the primary method of assessing procedural and animal care compliance with the protocol, accurate and detailed records must be kept. Generally there are three documents used to record procedures.

1. Procedure Report (at a minimum):
   a. Date of procedure.
   b. PI name and IACUC protocol number.
   c. Species and identification number.
   d. Names of all participating personnel (i.e., surgeons and anesthetists).
   e. Detailed description of the procedure.
   f. Any deviations from the procedure, as approved in the protocol, due to emergency or unforeseen circumstances must be documented and explained.

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

3. Postoperative/procedure Monitoring (at a minimum):
   a. PI name and IACUC protocol number.
   b. Species and identification number.
   c. Date and time of postoperative observations (include AM/PM).
   d. Initials of individuals conducting the observations/care.
   e. Condition of the animal should be evaluated. Any abnormalities in clinical condition or behavior (differing from a normal, healthy, awake animal) must be noted in the clinical record and reported to an Animal Care veterinarian.
      i. Mentation (i.e., bright, quiet, dull).
      ii. Vital signs (i.e., temperature, heart rate, respiratory rate, appetite, gastrointestinal and bladder function).

      Pain assessments should be performed, 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 the AC veterinarian.
      iii. Appearance of surgical sites (i.e. signs of adverse reactions or potential infection)
   f. Any analgesics, antibiotics/microbials, and all other drugs administered, including dose, route, and time provided. Time intervals for administering medications must be strictly adhered to per the approved protocol.

VI. **Final Disposition Record**:
The final disposition of the animal should be recorded in the animal’s record. In the case of an unexpected death or unexpected euthanasia (i.e., euthanasia prior to expected research endpoint) an AC veterinarian and the IACUC should be notified in a timely fashion.

Necropsies may be performed in order to collect tissue as per protocol or in cases of unexplained or unexpected outcomes.

VII. **References:**
   USDA Animal and Plant Health Inspection Animal Care Policy Manual, Policy #3, “Veterinary Care”.