

## IACUC GUIDANCE ON PI RECORDKEEPING FOR ANIMAL RESEARCH

### INTRODUCTION

This document is provided to assist the animal investigator in determining the appropriate and necessary record-keeping for animals in research, as mandated by federal and university laws, regulations, and policies. Record-keeping is addressed in several existing policies and regulations, which are summarized in this reference document.

In addition, the IACUC requires certain monitoring and record-keeping for animals that experience severe or prolonged pain or impairment as a result of a study procedure which is not specifically covered by an established policy. At the time of protocol review the IACUC will ask the investigator to include the monitoring and record-keeping schedule in the protocol.

### LIST OF RECORDS REQUIRED IN VARIOUS IACUC POLICIES

- Breeding Colony records
- Anesthesia Records
- Intra-operative Surgery Records
- Post-operative Surgery Records
- Food and Water Restriction Records
- Neoplasia Records
- Post-procedural records as described in the approved protocol
- Record Retention

### EXCERPTS FROM IACUC POLICIES:

#### IACUC Anesthesia Policy 34

Peri-anesthetic records (pre, during and post) must be maintained for non-rodent mammals. (Section IV. 8.)

#### IACUC Rodent, Bird, Amphibian, Bird, Fish Surgery Policy 35

**SURGICAL AND POST-SURGICAL MONITORING AND DOCUMENTATION.** A surgical monitoring record must be maintained. Post-surgical health observations must be made and documented for a minimum of five consecutive days following the surgery, including weekends and holidays. If problems arise post-operatively, the animal must be observed daily until the problems are resolved. If instrumentation is internalized, observations and documentation must continue weekly beyond the first 5 days until removal of the instrument or final disposition of the animal. If the instrumentation is exteriorized (e.g., catheters), observations and documentation must be done daily until removal of the instrument or final

disposition of the animal. Records must be kept in the animal holding area, and must be readily and independently accessible to an inspector. (Item 8)

#### **IACUC Non-rodent Mammal (Large Animal) Surgery Policy 7**

**MONITORING DURING ANESTHESIA.** An anesthetic record is required and must include observations from the induction of anesthesia to extubation and return of the animal to its home cage or enclosure. For anesthesia periods over 30 minutes, use of an external heat source to maintain body temperature is required and must be described in the Animal Use Protocol. (Section IV. 7.)

**POST-SURGICAL MONITORING AND DOCUMENTATION.** Post-operative observations of animal health must be documented on an approved Post-Surgical Progress Notes form. Records must be kept in the animal holding area and must be readily and independently accessible to an inspector.

Health observations must be documented at least daily:

- until suture or staple removal and adequate healing of the surgical site or at least five days following the surgery, whichever occurs latest.
- for any procedure that involves exposed instruments, catheters, bandages, etc. until removal of these items and adequate healing of the associated sites has occurred.
- for animals that exhibit signs of pain, distress, discomfort or other health complications until resolved.

Health observations must be documented at least weekly:

- after adequate healing has occurred. (Section IV. 10.)

#### **IACUC Experimental Neoplasia Policy 9**

**Record keeping:** Tumor monitoring data sheets must be kept within the housing room until the death of the animal. Records must contain all pertinent information, including the protocol number, the name of the person monitoring the animals, identification of the animals, date of monitoring sessions, and any treatments given to the animals. Baseline and weekly weights must be recorded; more frequent weighing may be indicated with some models. (Item 5)

#### **IACUC Deviation from Standard Feeding and Watering Policy 37**

Animals undergoing food and/or water restriction must be identified with cage-side records. Records must include each of the following:

- a. the approved restriction schedule
- b. the time/date and amount, if applicable, of latest feeding/watering
- c. documentation that approved monitoring was conducted
- d. contact information for responsible personnel (including phone contact) (Item 4)

### **IACUC Rodent Breeding Colony Policy 6**

Labs must keep records of all the animals born in the colony and the number of animals born must be reported monthly at <https://iacuc.ucsd.edu/OnlineForms/MainMenu.aspx>. Reports must be submitted even if the number of animals born is "0".

### **RECORD RETENTION**

The UC Office of the President requires that research records must be retained for the duration of the activity and for an additional 3 years [http://ucop.edu/research-graduate-studies/files/research/policies/documents/retention\\_disposition\\_reqs.pdf](http://ucop.edu/research-graduate-studies/files/research/policies/documents/retention_disposition_reqs.pdf)

### **EXCERPTS FROM OTHER DOCUMENTS GOVERNING ANIMAL RESEARCH AT UCSD:**

#### **USDA Policy 3 Veterinary Care**

Appropriate post-operative records should be maintained in accordance with professionally accepted veterinary procedures regardless of the location of the animal.

#### **The Guide for the Care and Use of Laboratory Animals**

##### *Food or Water Restriction (Page 31)*

The animals should be closely monitored to ensure that food and fluid intake meets their nutritional needs. Body weights should be recorded at least weekly and more often for animals requiring greater restrictions. Written records should be maintained for each animal to document daily food and fluid consumption, hydration status, and any behavioral and clinical changes used as criteria for temporary or permanent removal of an animal from a protocol.

##### *Recordkeeping (Page 75)*

Records containing basic descriptive information are essential for management of colonies of large long-lived animals and should be maintained for each animal. These records often include species, animal identifier, sire and/or dam identifier, sex, birth or acquisition date, source, exit date, and final disposition. Such animal records are essential for genetic management and historical assessments of colonies. Records of rearing and housing histories, mating histories, and behavioral profiles are useful for the management of many species, especially nonhuman primates. Relevant recorded information should be provided when animals are transferred between institutions.

##### *Aquatic Animal Recordkeeping (Pages 87-88)*

Adequate recordkeeping is necessary in aquatic system management. In general, the same standards used for terrestrial animals apply to aquatic and semiaquatic species, although modifications may be necessary to account for species or system variations.

Although many aquatic animals are maintained using group (vs. individual) identification, detailed animal records are still necessary. Animal information that may routinely be captured, particularly in biomedical research with fish, includes species; genetic information (parental stock identification, genetic composition); stock source; stock numbers in system; tank identification; system life support information; breeding; deaths; illnesses; animal transfers within and out of the facility; and fertilization/hatching information. Records should be kept concerning feeding information (e.g., food offered, acceptance), non-expired food supplies to ensure sustenance of nutritional profile, and any live cultures. Records of water quality testing for system and source water and maintenance activities of the life support system components are important for tracking and ensuring water quality. The exact water quality parameters tested and testing frequency should be clearly established and will vary with such factors as the type of life support system, animals, and research, as discussed under Water Quality.

*Medical Management (Page 114)*

Recurrent or significant problems involving experimental animal health should be communicated to the IACUC, and all treatments and outcomes should be documented

*Postoperative Care (Pages 119-120)*

An important component of postsurgical care is observation of the animal and intervention as necessary during recovery from anesthesia and surgery ... The intensity of monitoring will vary with the species and the procedure and may be greater during the immediate anesthetic recovery period. During this period, animals should be in a clean, dry, and comfortable area where they can be observed frequently by trained personnel. Particular attention should be given to thermoregulation, cardiovascular and respiratory function, electrolyte and fluid balance, and management of postoperative pain or discomfort... Appropriate medical records should also be maintained.

*Anesthetics and Analgesics (Page 122)*

Agents that provide anesthesia and analgesia must be used before their expiration dates and should be acquired, stored, their use recorded, and disposed of legally and safely.

**EXCERPTS FROM IACUC BEST-PRACTICES DOCUMENTS:**

**IACUC Best Practices for recordkeeping during and after anesthetic and/or surgery procedures on USDA-covered species (hamsters, gerbils, rabbits, dogs, cats, primates, sheep, pigs, cows, etc)**

- Entries should be initialed or signed by the person who made the observation or administered the treatment. Each entry must be traceable to the person who recorded or performed it.
- The date and time of the entry should be recorded. Entries must be chronological and reference a specific time.
- Entries should be made proximately to the time of the observation or treatment. Write it down as it happens.
- These records must be kept for three years after the study is completed and readily available for inspection by regulatory personnel. This is a regulatory requirement by the USDA, AALAC, and most granting agencies.

- Drug treatments must be recorded so that a total dose is recorded or can be calculated, e.g. either recorded in total mg, or a volume plus a concentration. For example: 0.2 mg acepromazine, OR .0.1 ml acepromazine (2 mg/ml)
- During anesthesia and anesthetic recovery, physiologic parameters must be observed and recorded frequently. At a minimum a heart rate and respiratory rate should be checked every 15 minutes for a stable animal in a short procedure. Other observations should be made as warranted: body temperature, color of mucous membranes, etc. depending on the type and length of the procedure. Close monitoring is required. *Regulatory bodies assume that "if it wasn't recorded, it didn't happen"*.
- The end of the monitoring period must be noted and signed by the person who made this determination, whether due to recovery or euthanasia. It must be clear that the animal was closely monitored as long as necessary.
- Recorded observations should include descriptive language, rather than only state a conclusion. Descriptive phrases include "active, no lameness noted", "all food consumed, normal feces present", "incision is intact", "swelling extends 1 cm from wound margins, no discharge noted", "attitude alert", "bight, alert, responsive". Inadequate phrases (without supporting descriptions) include "normal," "comfortable", "OK".
- Health observations must be documented at least daily for at least five days following the surgery or until suture removal and adequate healing of the surgical site, whichever occurs latest.
- Health observations must be documented at least daily for any procedure that involves exposed instrumentation, catheterization, bandage etc., until removal of the apparatus and adequate healing of the associated sites has occurred.
- Health observations must be documented at least daily for animals that exhibit signs of pain, distress, discomfort or other health complications until resolved.
- Health observations must be documented at least weekly after adequate healing has occurred.
- Daily post-surgical observations should include at least the following:
  - Observation of the comfort level of the animal. This can be evaluated by activity, mental attitude, elimination, food consumption, etc.
  - A specific check of the surgical wounds. Is there any discharge, redness, or swelling? Is the incision intact?
  - If any catheters or devices are in place, describe the condition of the device and record any procedures performed such as cleaning the skin exit site or flushing a catheter to keep it patent.
  - Any procedure-specific observations related to potential or unexpected complications such as organ failure, infection, ischemia, etc.

<b>IACUC Best Practices for Maintenance of Guillotines used for Euthanasia</b>
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...Guillotines should be sharpened a minimum of every 12 months or more often as needed.  
A log book should be maintained and available to inspectors....

<b>Forms available on IACUC web site</b>
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**Forms**

FORM [Rodent Group Post-Surgical Form](#)

FORM [Large Animal Daily Observations Form](#)

FORM [Long Term Rodent Post-Op Monitoring Log](#)

FORM [Post-Anesthetic Recovery Record](#)

FORM [Daily Progress Notes Form](#)

FORM [Laboratory Checklist](#)

FORM [Food and Water Restriction Log](#)

REF [Guillotine Use and Maintenance Log](#)