

## 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 their animal research, by compiling a list of the relevant sections from federal and university laws, regulations, and policies. Record-keeping is addressed in several existing policies and regulations as listed below.

Please refer to the full text of policies and regulations for context and reference (use the links from the chapter titles), regarding the details of monitoring and record keeping requirements.

In addition, investigators may have described additional monitoring or other processes that require documentation in their animal use protocols (e.g. regular checks during behavioral testing or regular weight monitoring). As the protocol represents a contract between the investigator and the IACUC, any such record keeping requirements will be subject to verification by IACUC Office staff, as are the policy-mandated records.

### LIST OF RECORDS REQUIRED IN VARIOUS IACUC POLICIES

- Record Retention
- 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

### EXCERPTS FROM IACUC POLICIES:

#### [Record Retention](#)

The UC Office of the President requires that research records be retained for the duration of the activity and for an additional 3 years after the protocol has ended as outlined in UCOP's Administrative Records Relating to Research: Retention and Disposition Requirements.

#### [Policy 34, Anesthesia](#)

10. For all non-rodent mammals, peri-anesthetic records (pre, during and post) must be maintained, even when surgery is not performed. At a minimum, the record must indicate the time the animal was examined, the person who examined the animal, any treatments or medications administered, any

abnormal findings, and (when applicable) the time of the recovery events, which are all listed on the Post Anesthetic Recovery Record.

11. For rodents, birds, fish, amphibians and reptiles, anesthesia records are only required for surgeries and may be kept as part of the surgical record.

#### **Policy 35, Surgery in Rodents, Birds, Reptiles, Amphibians and Fish**

6. **MONITORING DURING ANESTHESIA.** Animals must be monitored for basic physiologic function, which may include temperature, heart rate, respiratory rate, movement, mucous membrane color, etc. Animals must not be left unattended from the time of anesthetic induction until the animal is fully conscious, physiologically stable and able to maintain awake posture or positioning as appropriate for the species or until euthanized.

7. **ANALGESIA and POST-SURGICAL CARE.** Animals must receive adequate analgesia and post-surgical care as described in the applicable Animal Use Protocol. The Surgery in Rodents, Birds, Reptiles, Amphibians, and Fish Date: 2.20.2019 Page 3 of 7 post-surgical care must be performed by trained individuals.

8. **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.

Observations must be recorded contemporaneously; any exceptions to this must be clearly documented and justified. If any records are recreated or reproduced in any form, the original records must be maintained.

#### **Policy 7, Surgery in Non-Rodent Mammals**

**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.

**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.

Observations must be recorded contemporaneously; any exceptions to this must be clearly documented and justified. If any records are recreated or reproduced in any form, the original records must be maintained.

5. PRE-SURGICAL EVALUATION AND FASTING. Surgical staff must perform and document a pre-surgical health assessment of each animal. Withholding of food and/or water prior to surgery must be described in the applicable Animal Use Protocol.

6. ANESTHESIA. Animals must be properly anesthetized for all surgical procedures consistent with the Anesthesia Policy (Policy 34 and as described in the applicable Animal Use Protocol. Animals must not be left unattended from the time of anesthetic induction until the animal is fully conscious, physiologically stable and able to maintain awake posture or positioning as appropriate for the species. Animals must be monitored for basic physiologic function, which at minimum includes temperature, heart rate, respiratory rate, movement, and mucous membrane color, from the time of anesthetic induction until the animal is fully conscious, physiologically stable, able to maintain awake posture or positioning as appropriate for the species or until euthanized.

9. ANALGESIA and POST-SURGICAL CARE. Animals must receive adequate analgesia and post-surgical care as described in the applicable Animal Use Protocol. The post-surgical care of animals includes weekends and holidays, and must be performed by trained individuals. Observation of pain or distress beyond that anticipated and approved of in the Animal Use Protocol requires a veterinary staff consultation or euthanasia of the animal.

#### [Policy 9, Experimental Neoplasia](#)

**5) 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.

Observations must be recorded contemporaneously; any exceptions to this must be clearly documented and justified. If any records are recreated or reproduced in any form, the original records must be maintained.

#### [Policy 37, Deviation from Standard Feeding or Watering](#)

2 d.: During intervals of food and/or water restriction, affected cages must be identified with cage-side records. Records must include each of the following:

- i. the approved restriction schedule
- ii. the time/date and amount, if applicable, of latest feeding/watering
- iii. documentation that approved monitoring was conducted
- iv. contact information for responsible personnel (including phone contact)

#### **[Policy 6, Rodent Breeding Colonies](#)**

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/>. Reports must be submitted even if the number of animals born is "0".

#### **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.

#### **[The Guide for the Care and Use of Laboratory Animals](#) (*citations removed*)**

##### *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:**

#### **[Best Practices for recordkeeping during and after anesthetic and/or surgery procedures on USDA-covered species \(excludes mice, rats and birds\)](#)**

- 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.

#### **IACUC Best Practices for Maintenance of Guillotines used for Euthanasia**

...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>
--

FORM [Small Animal Post-Operative Monitoring Form](#) (PDF)

FORM [Small Animal Surgery Record](#) (PDF)

FORM [Large Animal Anesthesia Record](#) (PDF)

FORM [Large Animal Post-Anesthetic Recovery Record](#) (PDF)

FORM [Large Animal Daily Progress Notes Form](#) (PDF)

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

FORM [Food and Water Restriction Log](#) (PDF)

FORM [Sample Tumor Monitoring Form - Single Site](#) (PDF)

FORM [Sample Tumor Monitoring Form - Two Sites](#) (PDF)

FORM [Guillotine Use and Maintenance Log](#) (DOC)

*The forms above only serve as examples. They may be used by labs in their current form or modified as needed. Labs are free to generate their own forms, as long as all the requirements listed in this document are met.*