Record Keeping for USDA Covered Species

I. Purpose: The United States Department of Agriculture (USDA) and Public Health Service (PHS) require proper documentation of animal care and use to assess compliance with research protocols and clinical care procedures. The University of Pennsylvania’s IACUC has accepted the following guidelines for recordkeeping for investigators using USDA covered species. USDA covered species are any live or dead warm blooded animal used for research, teaching, or testing activities. This does not include birds, rats of the genus *Rattus*, and mice of the genus *Mus* bred for use in research, as well as farm animals used in production.

II. General Recordkeeping Requirements:
(See Clinical Health and Procedure Record example)

a. Individual record binders are maintained for animals that receive regular individual health evaluations (typically all non-rodent mammals; this includes rabbits). Group records may be acceptable for rodent species and others under some conditions. Please consult with a University Laboratory Animal Resources (ULAR) veterinarian to determine what type of record is appropriate for your purposes.

b. All entries must be legible, made in ink, and initialed by the individual making the entry.

c. Dates of all observations, treatments, and procedures must be recorded. Dates and times (including AM/PM) of all time-sensitive observations or treatments (post-operative evaluations, pain medication) must be recorded.

d. Any deletions from the record must consist of making a single line through the entry and initialing and dating next to the line.

e. Clinical records should be kept in the vicinity of the animals. Records must be readily accessible to the ULAR clinical care staff (CCS) and authorized inspectors.

f. For each animal used, a Final Disposition Report must be filed with ULAR. Any unexpected deaths and unexpected euthanasias must be reported to ULAR and IACUC in a timely fashion.

g. The USDA requires that all records be maintained for a 3 year period after the final disposition of the animal.

h. If an animal(s) is transferred to another location or protocol (once you have obtained approval from ULAR), this should be noted in the chart and all of the appropriate records should accompany the animal(s).

III. Protocol Related Recordkeeping:
a. It is essential that the procedure and all post-procedural care follows what is written in the approved IACUC protocol. As the records are the primary method of evaluating compliance with the protocol, accurate and detailed records must be kept.
b. Extent of records vary based on the nature of the procedure; however, at a minimum, records of the procedure must consist of:
   i. IACUC protocol number and principal investigator’s (PI) name
   ii. Animal species and identification number
   iii. Date of procedure
   iv. Procedure start and stop times
   v. Names of individuals participating
   vi. Pre-procedural health assessment (e.g. weight, temperature, attitude)
   vii. Detailed description of the procedure (see Surgical Record Sheet for template)
   viii. Any deviations from the procedure as approved in the protocol due to emergency need must be documented and explained
   ix. Anesthetics administered, including dose, route, and time provided
   x. Any drugs or supportive fluids given during procedure, including dose, route, and time provided
   xi. An anesthesia chart (see Anesthesia Chart Example) documenting:
       1. Vital signs, including pulse and respiratory rate, should be recorded frequently (generally every 5 minutes) to assure stability
       2. Drugs given - be sure to include dose and time
       3. General procedures - include intubation, beginning and end of surgery, extubation, etc.

c. At a minimum, records of post-procedural monitoring and care must consist of:
   i. IACUC protocol number and PI’s name
   ii. Animal identification number
   iii. Date and time of observations (includes AM/PM)
   iv. Initials of individuals conducting the observations/care
   v. General condition of the animal (e.g. pain assessment, condition of incision sites, etc)
   vi. Any analgesics, antibiotics, or other drugs administered, including dose, route, and time provided
   vii. Any abnormalities in condition or behavior (differing from a normal, healthy, awake animal) must be noted in the chart and followed up with the ULAR CCS in a timely fashion.
   viii. Post-operative record charts that conform to these guidelines can be obtained from ULAR (Immediate Postoperative Recovery Record, Postoperative Care During Periods of Analgesic Administration)

IV. Clinical Care Recordkeeping:
   a. Clinical care records are typically set up and maintained by the ULAR CCS; however, PIs and PI staff should be active participants in the clinical care process. They should review these records and discuss health status with the ULAR CCS to assess an individual animal’s suitability for their study procedures.
   b. At a minimum, clinical care records must consist of:
      i. Date of arrival at Penn
      ii. IACUC protocol number and PI’s name
      iii. Animal species and identification number
      iv. Pertinent history and description of any abnormalities
      v. Date of release from quarantine
vi. Routine preventative care (e.g. vaccinations, nail clipping, etc)

vii. Examination findings and results of diagnostic laboratory services that are performed to facilitate veterinary medical care that can include gross and microscopic pathology, clinical pathology, hematology, clinical chemistry, microbiology, serology and parasitology

viii. Tentative/provisional diagnosis

ix. Corrective measures (diagnostic and treatment plan) being taken as the result of a variation from normal health or behavior

x. Record of veterinary care given or directed to include assessment of the animal’s condition and progress seen over the duration of the treatment/observation period, and daily treatment provided as well as dosages, routes and frequency of administration of any drugs/medications

xi. Resolution of the problem (e.g. return to a normal state, euthanasia)

xii. Documentation of necropsy findings, if indicated.

V. Associated Documents:

a. Clinical Health and Procedure Record - provides an example of a completed clinical record that details animal care and use

b. Surgical Record Sheet - provides a template that may be used to document surgical procedure

c. Anesthesia Chart Example - provides an example of a completed chart that documents animal signs and treatments during procedure

d. Immediate Postoperative Recovery Record - provides a template that may be used to document animal care during immediate recovery period (period from extubation to recovery from anesthesia)

e. Postoperative Care During Periods of Analgesic Administration - provides a template that may be used to document animal care during post-operative period

f. Final Disposition Report - form provided in health record binders. This form must be completed upon routine and unexpected disposition of USDA covered animals

VI. References:

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