University of Louisville Institutional Animal Care and Use Committee Policies and Procedures

Individual Animal Records

Policy: Individual animal records must be maintained as outlined in this policy for animals covered by the United States Department of Agriculture (USDA) through the Animal Welfare Act (AWA). Group or colony records are generally acceptable for most rodents and other non-USDA regulated species, although individual medical records may be created to document veterinary care. PIs may create projector protocol-specific record components, such as procedure description templates, anesthetic monitoring charts, and post-operative monitoring forms that conform to the guidelines below in consultation with a Comparative Medicine (CMRU) veterinarian. Both CMRU and investigative staff are responsible for maintaining timely and complete animal records. All individual animal records must be maintained for at least 3 years after the final disposition of the animal.

Rationale: In accordance with federal regulations and standards, animal records must contain proper documentation of animal procurement, identification, experimental manipulation, medical care, and disposition as applicable. This policy ensure compliance with the AWA, Public Health Service (PHS) Policy, and the *Guide for the Care and Use of Laboratory Animals* to meet those provisions. Additionally, animal records must be readily available to allow for quick and accurate animal assessment for research purposes and overall wellbeing. Detailed animal health records are a primary method of documenting individual animal health and compliance with IACUC-approved *Proposals*.

Procedures, Guidelines, and Exceptions:

- 1. General Recordkeeping Requirements:
 - a. All entries must be legible, made in ink, and initialed by the individual making the entry.
 - b. Dates of all observations, treatments, and procedures must be recorded. Dates and times (including AM/PM or military time) of all time-sensitive observations or treatments (post-operative evaluations, pain medication) must be recorded.
 - c. Any corrections to, or deletions from, the record must consist of making a single line through the entry and initialing and dating next to the line.
 - d. Clinical records should be kept in the vicinity of the animals. All records must be readily accessible to the CMRU veterinary staff and authorized regulatory personnel.
 - e. Any unexpected deaths and unscheduled euthanasia must be documented in the record and be reported to CMRU veterinary staff and in a timely fashion. An CMRU veterinarian may need to perform a necropsy of the animal to fulfill USDA requirements and will make this determination.
 - f. Final disposition of the animal must be documented in the individual health record to include:
 - 1) Transfer to another protocol (once approval from CMRU has been obtained)
 - 2) Transfer to another research facility (once approval from CMRU has been obtained. Note that all appropriate records should accompany the animal(s)).
 - 3) Euthanasia to include:
 - a) Method of euthanasia.
 - b) Drug name, dose, and route of administration, if applicable.

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c) Method used to ensure death (e.g., absence of heart beat and respiration, vital organ removal, thoracotomy).

2. Protocol Related Recordkeeping:

- a. The extent of records varies based on the nature of the procedure; however, at a minimum, records of procedures must contain:
 - 1) IACUC protocol number and principal investigator's (PI) name.
 - 2) Animal species and identification number.
 - 3) Date of procedure.
 - 4) Procedure start and end times.
 - 5) Names of individuals performing the procedure(s) (e.g., surgeon, anesthetist).
 - 6) Pre-procedural health assessment (e.g., body weight, body temperature, attitude).
 - 7) Any withholding of food/diet or water/fluid.
 - 8) Detailed description of the procedure.
 - 9) Description and explanation of any deviations from the procedure as approved in the IACUC *Proposal* due to emergency need.
 - 10) All drugs, therapeutic agents, or experimental agents administered, including anesthetics and supportive fluids, including dose, route, volume, and time provided.
- b. For animals undergoing *anesthesia or sedation*, an anesthesia/sedation chart and recovery record must contain the following information.
 - 1) Vital signs monitored should include heart rate, respiratory rate, and body temperature, recorded at a frequency to ensure stability (at least every 10 minutes for USDA-regulated non-rodent species; at least every 15 minutes for rodents and all other species). Documents should record continued monitoring until the animal has recovered from anesthesia/sedation and until body temperature has reached at least 100°F.
 - 2) All drugs administered must be recorded, including dose, route, volume, and time.
 - 3) Records must chart general anesthetic procedures, including the following:
 - a) Times of intubation and extubation
 - b) Times surgery/procedures began and ended
 - c) Times that the animal was able to remain in sternal recumbency unassisted, move about their enclosure normally unassisted, and returned to its home cage, *etc*.
 - 4) Records must contain a description of emergency measures taken, including procedures, drugs (name of drug, dose, route of administration), *etc*.
 - 5) Clinical signs of pain and responses taken should be recorded.
- c. At a minimum, records of *post-procedural monitoring and care* must contain:
 - 1) Date and time of observations (including AM/PM or military time).
 - 2) Initials of individuals conducting the observations/care.
 - 3) General condition of the animal (e.g., pain assessment, condition of incision sites).
 - 4) Notes of all analgesics, antibiotics, or other drugs administered, including dose, route, and time provided.
 - 5) Date of suture/staple removal (generally 7-10 days post operatively), if applicable.
 - 6) Documentation of bandage/dressing changes, if applicable.
 - 7) Any abnormalities in condition or behavior (differing from a normal, healthy, awake animal), including confirmation that such abnormalities were forwarded to CMRU Veterinary Services in a timely fashion.

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- 3. Clinical Care Recordkeeping. At a minimum, clinical care records must contain:
 - a. Date of arrival.
 - b. IACUC protocol number and PI's name.
 - c. Animal species and identification number.
 - d. Pertinent history and description of any abnormalities.
 - e. Date of release from quarantine, if applicable.
 - f. Descriptions of routine preventative care (e.g., vaccinations, nail clipping, weighing)
 - g. Examination findings and results of diagnostic laboratory services that are performed to facilitate veterinary medical care, which may include gross and microscopic pathology, clinical pathology, hematology, clinical chemistry, microbiology, serology and parasitology.
 - h. Tentative/provisional diagnoses.
 - i. Corrective measures (diagnostic and treatment plan) taken as the result of a variation from normal health or behavior.
 - j. Records of veterinary care given or directed, including assessment of the animal's condition and progress over the duration of the treatment/observation period, and daily treatment provided as well as dosages, routes, volumes, and frequencies of administration of any drugs/medications.
 - k. Resolution of the problem (e.g., return to a normal state, euthanasia)
 - 1. Documentation of necropsy findings, if indicated.

References:

- 1. ACVA. 2009. Position Statement: Recommendations for Monitoring Anesthetized Veterinary Patients. https://acvaa.org/wp-content/uploads/2019/05/Small-Animal-Monitoring-Guidlines.pdf.
- 2. Field, K, M Bailey, LL Foresman, *et al.* 2007. Medical Records for Animals Used in Research, Teaching and Testing: Public Statement from the American College of Laboratory Animal Medicine. *ILAR Journal* 48 (1), 37-41.
- 3. National Research Council. 2011. *The Guide for the Care and Use of Laboratory Animals*: 8th Edition. Washington DC: National Academes Press.
- 4. USDA Animal and Plant Health Inspection Service. 2015. Animal Care Policy Manual, Policy #3, Veterinary Care.
- 5. USDA Animal and Plant Health Inspection Service. 2019. Animal Welfare Act and Animal Welfare Regulations, as amended.

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