

Record Keeping for Animal Research: Experimental Procedures

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BACKGROUND

Written records are a standard form of documentation, which verify experimental procedures and protocol compliance. Records pertaining to the use of animals in research may be maintained in various formats and be situated in various locations, including a laboratory notebook, in an animal's individual animal record, on log sheets within animal rooms or lab space, or on housing cage cards. Researchers may have specific monitoring, assessments, or procedures detailed in their IACUC protocol that require documentation, such as behavioral assessments, assessments for endpoint criteria, weight monitoring and records of food/water consumption during caloric restrictions, etc. According to *The Guide for the Care and Use of Laboratory Animals*: "Basic demographic information and clinical histories enhance the value of individual animals for both breeding and research and should be readily accessible to investigators, veterinary staff, and animal care staff." *The Guide* also endorses the American College of Laboratory Animal Medicine's (ACLAM) "Guidelines for Adequate Veterinary Care" (ACLAM 1996). These guidelines include veterinary access to all animals and their medical records. The ACLAM later clarified some points about medical records in a document titled *Public Statement: Medical Records for Animals Used in Research, Teaching and Testing*. The clarification acknowledges that records of experimentally induced disease that are detailed in a reviewed and approved animal protocol may be part of the research record as opposed to the medical record, however they must be readily available for review by veterinary staff, as well as appropriate internal (IACUC) or external (OLAW) regulatory groups. Records may also be critical to fulfilling the mandate that the IACUC conduct effective post-approval monitoring of animal use protocols.

PURPOSE

There are many types of records pertaining to the use of animals in research that should be retained and be available for veterinary and IACUC review.

This document aims to assist animal users with the appropriate and necessary means of record keeping that is used to document and describe procedures performed using animals in research. Any records may be subject to assessment and verification by the IACUC. Therefore, it is important that records of animal procedures are readily available, and should be accurate, clear, current, and concise yet informative.

DEFINITION

Medical and experimental procedures include, but may not be limited to: injections, blood collection, drug administration, gavage, tail tipping for genotype, and surgery.

RELATED IACUC GUIDELINES/POLICES: the following provide further information on record keeping and/or reporting requirements:

- Adverse, Unexpected, or Unusual Event Reporting Form
- Surgical Management, Monitoring and Record Keeping
- Log Sheet Examples for Procedure or Surgery
- Health Monitoring: Record Keeping and Investigator Notification

GUIDELINES

1. All medical and experimental procedures must be recorded in individual animal records, or group records where appropriate. While detailed records may be contained in lab notebooks that are kept outside the housing or procedure rooms, medical and experimental procedures must also be recorded in the animal housing or procedure rooms in such a way that veterinarians, OLAC staff, or IACUC personnel would be able to match the records to the appropriate animals upon review.
2. Sufficient and explicit information about procedures performed on animals must be documented in a Procedure Log or similar document. The log or document should be kept in the appropriate animal housing room, or procedure room, and be easily accessible to OLAC staff and veterinarians.
3. Procedures and the date performed must be documented at the cage level, on the cage card or other notifying card. If details are too extensive to fit on the cage card, a brief description can be noted on the card, and further details can be provided in the Procedure Log.
 - a. Cage cards should indicate any hazardous chemicals, biohazardous materials, or human cells introduced into the animal.
 - b. Cage cards may also have a color-coded sticker, indicating or representing a procedure, as long as its color is meaningful and understood to the person viewing the card.
4. For all species, the necessary information on the Procedure Log or other appropriate document, should include:
 - a. Protocol number
 - b. Names of personnel responsible for the procedures performed with contact information (phone number and/or email address)
 - c. Description of the procedure performed

- d. Date procedure was performed
 - e. A complete description of the animal(s)
 - i. animal ID number or cage ID for groups
 - ii. species, strain
 - iii. cage location,
 - iv. treatment group, any other identifying information.
 - f. Pertinent details related to the procedure including drug or compound name, volume of collection or administration, route of administration or site of collection, dose, frequency, duration, and location on the body.
 - g. Notations on the animal observations related to the procedure including complications and corrective measures.
5. Any deviations from the approved protocol due to emergency need must be documented, explained, and reported to the IACUC. Permanent changes, including deviations made following an official veterinary consultation, require an amendment to the approved protocol.
 6. If there are unusual or abnormal observations of the animal noted by OLAC personnel or veterinarians, records of experimental manipulation or procedures (logs and cage card descriptions) should be obvious and legible to the person viewing the records, including what and when a procedure was done, and whom the contact person is, in case a concern needs to be addressed.
 7. Food and Fluid Regulation: Body weights must be recorded at least weekly or more frequently according to the approved protocol. Written records must 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. These records should also be readily available for review.