Guidelines on Medical Records for Investigative Personnel

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1. Purpose
To define the components of a medical record that are the responsibility of the investigative personnel, and to describe the procedures for generating, maintaining, and storing them.

2. Responsibility
   a. Animal health contacts are responsible for:
      i. Generating and maintaining all required records.
      ii. Maintaining the records in the appropriate location and for the appropriate amount of time as described in this document.
      iii. Submitting records to ULAM as described in this document.
      iv. Making records available within four working hours on request of the veterinary staff or institutional or regulatory inspectors. (UCUCA, ULAM, AAALAC, etc.).
      v. Other members of investigative personnel may perform some of the above duties under the direction of the animal health contact.
   b. The Principal Investigator is responsible for:
      i. Maintaining and submitting records of disposition for dogs and cats per the UM Disposition Records for Dogs and Cats Procedures.
   c. Animal care technicians are responsible for:
      i. Pulling surgical records for animals not covered by the Animal Welfare Act from drop boxes in animal rooms and submitting them to husbandry supervisors
   d. Animal husbandry supervisors are responsible for:
      i. Filing pulled surgical records once per month
   e. Veterinary staff are responsible for:
      i. Generating and maintaining all aspects of the permanent health record that are not the responsibility of investigative personnel as outlined in Procedures for Veterinary Medical Records and the Animal Care Identification and Communication Procedures.
      ii. Veterinary staff are available on request for instructing and assisting investigative personnel in developing record keeping procedures that comply with the minimum standards in this document.
   f. Veterinary technicians are responsible for:
      i. Receiving and reviewing medical record components generated by investigative personnel as described in this document.
      ii. Storage and disposition of medical records as outlined in Procedures for Veterinary Medical Records.

3. Definitions
   a. Types and Components of Records:
      i. Permanent medical record: A file identified by the patient’s ULAM clinical number that contains all health or surgical records generated for an animal including:
         1. Records generated by the veterinary staff during management of clinical conditions.
            a. The ULAM Standard Operating Procedures for Veterinary Medical Records provides a detailed definition and discussion of permanent medical records for use by ULAM personnel.
         2. Records generated by investigative personnel:
            a. Health/group health records
            b. Surgical/anesthetic/sedation records
            c. Post-surgical monitoring records
            d. Other records that detail the health history of an animal
      ii. Health/group health record: A record maintained by investigative personnel detailing the care and management (treatments, monitoring, etc.) of a health condition that is performed by the laboratory personnel under the direction of the ULAM veterinary staff. A single record can be used for multiple animals (a group health record) if:
         1. All animals are being treated/monitored in the same way and for the same condition, and
         2. The animals are housed together in one cage and share a single clinical number.
         3. Components of a health/group health record include:
b. Clinical observations/monitoring
   i. Drug
   ii. Dose
   iii. Route
   iv. Time/frequency given

d. Date and initial all entries

iii. Surgical/anesthetic/sedation record: A record maintained by investigative personnel that includes:

1. The surgery or procedure performed
2. The date performed
3. Anesthetic agent administered, including route, dose, and time/frequency
4. Any other drugs given (e.g. analgesics, antibiotics, reversal agents, etc.), including route, dose, and frequency
5. Anesthetic monitoring parameters (e.g. temperature, pulse, respiration, blood pressure, etc.)
6. Specific requirements for surgical records can be found in these ULAM documents:
   a. Guidelines on the Performance of Surgery in Rodents
   b. Guidelines on the Performance of Surgery in Non-Rodent Mammals
   c. Anesthesia and Sedation Monitoring Guidelines

iv. Post-operative record: A record maintained by investigative personnel that includes:

1. The surgery or procedure and the date it was performed
2. Notation of (at least) daily monitoring for the duration of the post-operative monitoring period as defined in the ULAM rodent or non-rodent mammal surgical guidelines, or as described in the animal use protocol.
3. Any drugs given, including the route, dose, volume and frequency.
4. For animal use protocols that state analgesia will be given "as needed," personnel MUST note that an animal is not painful/no longer needs analgesics BEFORE analgesics are discontinued.
   a. The presence or absence of pain MUST be noted each day for the duration of the post-operative monitoring period.
5. The surgical/anesthetic/sedation record and the post-operative record may be combined and kept on a single sheet of paper if preferred.
6. Specific requirements for post-operative monitoring records can be found in these ULAM documents:
   a. Guidelines on the Performance of Surgery in Rodents
   b. Guidelines on the Performance of Surgery in Non-Rodent Mammals

v. Tumor monitoring records: A record maintained by investigative personnel that includes the dates and observation codes for animals with experimentally induced tumors.

1. Detailed information on tumor monitoring can be found in:
   a. Guidelines and SOP on Tumor Monitoring

vi. Food and/or water restriction records: A record maintained by investigative personnel that includes:

1. Daily food and/or fluid volume consumed
2. Hydration status
3. Appearance and general affect
4. Experimental performance
5. Routine body weights
6. Refer to the Guidelines on Experimental Food or Water Restriction or Manipulation in Laboratory Animals

vii. Experimentally induced disease/research record: A record that may be maintained by investigative personnel that may include:

1. Animal identification information
2. Date and type of procedure performed/compounds administered
3. Routine observations as defined by the protocol
4. Adverse or unexpected consequences
5. Date of euthanasia or termination of study

viii. Breeding Record: A record that may be maintained by investigative personnel that may include:

1. Animal identification
2. Genotype
3. Sire and dam
4. Breeding partners
5. Outcome of breeding attempts

ix. Record of disposition: A record of the death, euthanasia, transfer, sale, adoption, or donation of an animal.

x. Records from vendor: Health information/medical history that arrives with the animal. This is incorporated into the animal's permanent medical record.

b. Required records: Those records that must be maintained by investigative personnel:

i. Health/group health records are required if the laboratory personnel are performing any part of the monitoring and care of a non-research-related clinical condition under the direction of the veterinary staff.

ii. Surgical/anesthetic/sedation records are required for all animals undergoing those procedures.

iii. Post-operative monitoring records are required for all animals undergoing survival surgery.

iv. Tumor monitoring records must be maintained as described in the animal use protocol for all animals with experimentally induced tumors

v. Food and water restriction records are required for all animals undergoing such restriction as per the animal use protocol and the Guidelines on Experimental Food or Water Restriction or Manipulation in Laboratory Animals.

vi. Records of disposition are required for all cats and dogs.

c. Recommended records: Those records that are not mandated (unless described in the protocol). However, generating and maintaining these records is highly recommended.

i. Experimentally induced disease/research records
ii. Breeding records

d. Animal health contact: The person(s) listed as such on the animal use protocol and the cage card.

e. Clinical number: A unique identifying number assigned by the ULAM veterinary staff used to centralize information into complete medical records in a retrievable form. Clinical numbers may be assigned to an individual animal or a group of animals depending on the circumstance.

i. This number can be found handwritten on the cage card of all large animals. Rodents are not given a clinical number until/unless they are reported for a clinical concern.

ii. It is typically of the format: \text{00X#\#\#}

   1. \text{00} is the last two digits of the year the animal was received.
   2. \text{###} is a unique identifier for that animal.

f. Active case: Those involving animals currently being treated and/or monitored for a clinical condition, or an experimental condition (e.g. tumor burden, food and water restriction, etc).

i. A clinical condition is resolved by the veterinary staff.

ii. The animal is euthanized or un-enrolled from study.

iii. The animal is transferred to another laboratory or institution.

h. Disposition: The sale, transfer, donation, adoption, death, or euthanasia of an animal.

4. Procedures

a. Generating Records

i. Investigative personnel must generate physical, required records as described above.

ii. ULAM provides the following forms for use by investigative personnel (see Appendices at the end of this document):

   1. Rodent Surgery and Post-Operative Record (Notebook and Cage Card Sizes). See Appendices A and B.

      a. For examples of how the above records should be filled out see Appendix C.

      b. Pre-printed cage card-sized templates are available from ULAM on request

   2. Non-rodent Mammal Anesthesia Monitoring Form. See Appendix D.

   3. Post-operative Medical Record Form for Non-rodent Mammals. See Appendix E.

   iii. Investigative personnel may create records templates to fit their preferences and needs. Regardless of the format, records must contain the same minimum information as described above (definitions) and in the ULAM templates.

b. Maintaining Records

i. The minimum information required is listed for each type of record in the Definitions section.

   1. Date and initial all entries.
   2. Write legibly.
   3. Write drug names in full (e.g. buprenorphine, not "bup"); do not abbreviate.

c. Storing and Submitting Records

i. Active cases

   1. Health/group records: Must be maintained in the animal room until the case is resolved by the veterinary staff or the animal is euthanized.

      a. Records must be made available within four working hours on request of the veterinary staff or institutional or regulatory inspectors (UCUCA, AAALAC, etc.).

   2. Surgical/anesthetic/sedation record and post-operative records: Must be maintained in the animal room for the post-operative period as defined by the surgical guidelines.

      a. Records must be made available within four working hours on request of the veterinary staff or institutional or regulatory inspectors (UCUCA, AAALAC, etc.).

   3. Tumor monitoring: Must be maintained in the animal room as described in the Guidelines and SOP on Tumor Monitoring and the UM Policy on Surgical and Tumor Monitoring Records.

   4. Food and water restriction records: Must be maintained in close proximity to the animal (in the animal room is preferred) for the duration of restriction.

ii. Inactive cases:

   1. Rats (genus \textit{Rattus}) and mice (genus \textit{Mus}) bred specifically for research, as well as fish, reptiles and amphibians. These animals are not covered by the Animal Welfare Act.

      a. Once the surgical monitoring period is complete, investigative personnel clip records (or copies thereof) and place them into the drop box in the animal room. These records will be collected by husbandry personnel once per calendar month.

   2. All other mammals (covered by the Animal Welfare Act):

      a. Records \textbf{must be submitted to ULAM} for long term storage within one week of the final entry in the record (usually euthanasia, the end of post-surgical monitoring, the resolution of a clinical case, or transfer to another institution or laboratory).

      i. It is highly recommended to submit a copy of these documents.

      b. Confirm the record contains the following information before submitting to ULAM (Documents without this information will not be accepted):

         i. Protocol number
         ii. Principal investigator's last name
         iii. Animal's clinical number (if one has been assigned by ULAM personnel)

      c. Deposit completed records in the ATR/Records drop-boxes. These boxes are located:

         i. Outside the veterinary technicians’ offices in Med Sci II, BSRB, LSI, and NCRC
         ii. Outside break rooms in MSRB and BSRB
         iii. Contact the husbandry supervisor in your area for ATR drop-box locations in other buildings.
3. Disposition of dogs and cats:
   a. Records of disposition must be generated for all dogs and cats and must include:
      i. USDA identification number
      ii. Description of animal (species, breed, markings, sex, age)
      iii. Date and manner of disposition (euthanasia, transfer, etc.)
   b. Records must be stored for 3 years.
   c. Records must be made available within four working hours on request of the veterinary staff or institutional or regulatory inspectors. (USDA, UCUCA, AAALAC, etc.).
   d. Principal investigators leaving the University must forward their records to the UCUCA office for retention during the remainder of their 3-year UCUCA approval period.
   e. Promptly return tags from euthanized dogs and cats to the ULAM husbandry office.

5. Related Documents
   a. Guidelines on the Performance of Surgery in Rodents
   b. Guidelines on the Performance of Surgery in Non-Rodent Mammals
   c. Anesthesia and Sedation Monitoring Guidelines
   d. Guidelines and SOP on Tumor Monitoring
   e. UM Policy on Surgical and Tumor Monitoring Records
   f. Guidelines on Experimental Food or Water Restriction or Manipulation in Laboratory Animals
   g. UM Disposition Records for Dogs and Cats Procedures
   h. Procedures for Veterinary Medical Records
      i. Animal Care Identification and Communication Procedures

6. Appendices
   a. Appendix A: Rodent Surgery and Post-Operative Record (Notebook Size)
      • (Linked from Guidelines on the Performance of Surgery in Rodents)
   b. Appendix B: Rodent Surgery and Post-Operative Record (Cage Card)
      • (Linked from Guidelines on the Performance of Surgery in Rodents)
   c. Appendix C: Examples of Rodent Surgery and Post-Operative Records (Both Cage Card and Notebook Sizes)
      • (Linked from Guidelines on the Performance of Surgery in Rodents)
   d. Appendix D: Non-rodent Mammal Anesthesia Monitoring Form
      • (not available as of 5/3/17, will have a form available soon)
   e. Appendix E: Non-rodent Mammal Post-Operative Record Form
      • (Linked from Guidelines on the Performance of Surgery in Non-Rodent Mammals)
   f. Appendix F: UM Disposition Records for Dogs and Cats Procedures

7. References