

Medical Records for Animals Used in Research, Teaching, and Testing: Public Statement from the American College of Laboratory Animal Medicine

ACLAM Medical Records Committee: Karl Field (Chair), Michele Bailey, Larry L. Foresman, Robert L. Harris, Sherri L. Motzel, Richard A. Rockar, Gaye Ruble, and Mark A. Suckow

Abstract

Medical records are considered to be a key element of a program of adequate veterinary care for animals used in research, teaching, and testing. However, prior to the release of the public statement on medical records by the American College of Laboratory Animal Medicine (ACLAM), the guidance that was available on the form and content of medical records used for the research setting was not consistent and, in some cases, was considered to be too rigid. To address this concern, ACLAM convened an ad hoc Medical Records Committee and charged the Committee with the task of developing a medical record guideline that was based on both professional judgment and performance standards. The Committee provided ACLAM with a guidance document titled *Public Statements: Medical Records for Animals Used in Research, Teaching, and Testing*, which was approved by ACLAM in late 2004. The ACLAM public statement on medical records provides guidance on the definition and content of medical records, and clearly identifies the Attending Veterinarian as the individual who is charged with authority and responsibility for oversight of the institution's medical records program. The document offers latitude to institutions in the precise form and process used for medical records but identifies typical information to be included in such records. As a result, the ACLAM public statement on medical records provides practical yet flexible guidelines to assure that documentation of animal health is performed in research, teaching, and testing situations.

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Executive Summary

Diplomates of the American College of Laboratory Animal Medicine (ACLAM¹) have long recognized that the medical record is one of the hallmarks of a program of adequate veterinary care (Gaertner 2003). Although the value of a medical record is widely recognized, a comprehensive guidance document written specifically for the use of medical records in the research, teaching, and testing environment was not readily available to the biomedical research community. A proposal was made by the Animal and Plant Health Inspection Service (APHIS¹) in 2003 to institute regulations relevant to medical records for animals used in teaching, testing, and research (APHIS 2003). The proposed regulation was considered by ACLAM and others to be prescriptive rather than based on performance standards because it did not differentiate between spontaneous and induced medical disease and the expectations were unclear, making them difficult to apply (Gaertner 2003; Hanley 2003). Therefore, in early 2004, ACLAM formed an ad hoc Medical Records Committee and charged it with the following task: develop guidelines for medical records applicable to the research setting that (1) allow for the use of performance standards and avoid overly rigid engineering standards; and (2) are not so prescriptive that they undermine the veterinarian's use of professional judgment.

The Medical Records Committee, under the guidance of the ACLAM Government Regulatory Affairs Committee (GRAC¹), produced a document titled *Public Statement: Medical Records for Animals Used in Research, Teaching and Testing* (ACLAM 2004). The GRAC provided guidance to the Medical Records Committee so that the final document would accomplish the following:

¹Abbreviations used in this article: ACLAM, American College of Laboratory Animal Medicine; APHIS, Animal and Plant Health Inspection Service; BOD, Board of Directors; GRAC, Government Regulatory Affairs Committee; IACUC, institutional animal care and use committee; USDA, US Department of Agriculture.

1. endorse professional judgment and performance standards, both of which promote a higher level of care than strict engineering standards, without being overly burdensome;
2. establish clear authority over the medical record program (i.e., Attending Veterinarian and IACUC oversight);
3. differentiate between the medical record requirements for spontaneous medical conditions versus those that were induced (animal models); and
4. provide guidance on the type of record that was outside the scope of this document.

The Committee developed a draft public statement, which was reviewed by the ACLAM Board of Directors (BOD¹). During development of the public statement, the Committee addressed a number of complex issues. For example,

1. It was very challenging to write a “one size fits all” guidance document. The public statement was carefully worded to ensure that it provided nonprescriptive guidance on defining what constitutes a medical record, who decides when the record is needed, how the records are maintained, and what is included in the record.
2. The Attending Veterinarian must have the authority to establish and oversee a medical records program, and the institution must support that authority.
3. Documentation of experimentally induced disease (animal model) is a research record and is not necessarily a part of the medical record. The course of the disease development is part of an experimental protocol that is reviewed and approved by an institutional animal care and use committee (IACUC¹), and the details of that disease are recorded in the research notes. Although this type of information may be part of a research record, it must be readily available for review by the veterinary staff, as well as appropriate for internal (e.g., IACUC) or external (e.g., US Department of Agriculture [USDA¹]) oversight uses.
4. A breeding record is not necessarily a medical record, although it may contain useful information regarding the animal’s welfare.
5. A reference to the research use of the animal should be included in the medical record.
6. Use of an electronic signature was addressed, as was the need for hand-written records that are “legible to someone other than the writer.”

After several revisions of the document, a final draft of the public statement was approved by the ACLAM BOD. This document was distributed to more than 700 ACLAM board-certified laboratory animal medicine veterinarians for comment. All comments were reviewed and addressed by the committee, a final version was presented to and approved by the BOD, and the public statement was released in October 2004.

As noted in the conclusion of the ACLAM public statement on medical records (ACLAM 2004), “Medical records for animals used in research, teaching and testing are a core component of adequate veterinary care. They should document information associated with management of clinical disease, diagnostic and therapeutic procedures performed, and preventive medical procedures. The methods by which medical records are developed and maintained should be determined by the institution, with the guidance and professional judgment of the Attending Veterinarian. Application of performance standards within the medical record program allows the veterinarian to effectively employ professional judgment, ensuring that the animal receives the highest level of care available.”

The following text is a copy of the ACLAM public statement on medical records, with references added in brackets.

ACLAM PUBLIC STATEMENTS: Medical Records for Animals Used in Research, Teaching and Testing²

Introduction

The guidelines summarized below were prepared by the American College of Laboratory Animal Medicine (ACLAM) to assist research facilities in their efforts to establish and maintain animal health medical records (medical records). The professional guidance of the Attending Veterinarian or his/her designee in the development and oversight of a medical records program is essential in the application of these guidelines by an institution [FASS 1999]. Application of performance standards within the medical record program allows the veterinarian to effectively employ professional judgment, ensuring that the animal receives the highest level of care available. The Attending Veterinarian must receive institutional support through the IACUC, Institutional Official, or other means, to assure compliance with the development and effective application of these guidelines for the medical records program.

This document provides guidelines for maintenance of clinical data for animals used in research, teaching and testing. Because of the potential volume of data generated in these settings, there is a risk that critical information may be diluted. For this reason, the precise mechanism chosen to summarize clinical data into a medical record is not prescribed. Each institution must establish its own standards of performance [Haskins and Eisele 1997]. The ACLAM recognizes that varied approaches can be used to achieve the

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desired outcome of providing the highest quality of care available.

ACLAM Position on Medical Records Content and Scope

Establishing and maintaining appropriate medical records is a core component of adequate veterinary care [AVMA 2002; Gaertner 2003]. Medical records provide documentation of the care given, and communicate that information to other professionals [APHIS 2000; CFR 2003; Osborne 1983]. Medical record information may be retained in a medical record and/or research record, depending on how the institution wishes to run its program.

The institution, under the guidance of the Attending Veterinarian, should determine the method(s) by which medical records are maintained. Medical records may take many forms [Haskins and Eisele 1997] and have several components, such as written records, computerized records, sentinel animal reports, clinical pathology reports, quality assurance reports, cage cards, and animal disposition reports. These components can be included in the medical and/or research record, or can be linked and available. The method of record keeping should be designed to fit the specific needs of each program of veterinary care.

Oversight of the medical records must fall under the direction of the Attending Veterinarian or his/her designee and the IACUC. Individuals typically responsible for making notations in medical records include veterinary staff (veterinarians and/or veterinary technicians), animal husbandry staff (animal care staff, managers, supervisors), and research staff (e.g., principal investigators, study directors and/or research technicians).

The ACLAM recognizes that many research animals, particularly rodents, can be obtained and maintained in a state of good health, without the necessity of a medical record being created. When medical records for such animals are indicated, group records may be acceptable and may be more efficient than individual records [FASS 1999]. Individual medical records should be maintained for animals that receive regular individual health evaluations, as deemed appropriate by the institution [Suckow and Doerning 2000].

When a medical record is created, the information should be recorded so that the care and course of treatment for animals can be reconstructed, if necessary [Lees 1981]. The medical record should also contain a sufficient amount of detail to determine the research use of the animal. However, clinical notations related to a disease that is experimentally induced in animals do not necessarily need to be maintained in the medical record. Rather, it may be appropriate for this information to be retained within research records, but the information must be readily available for review by the veterinary staff, as well as for appropriate internal (e.g., IACUC) or external (e.g., USDA) oversight uses.

Components of a Medical Record

When institutional representatives determine that a medical record should be created, the record typically contains the following types of information [APHIS 2000; NRC 1996]:

1. Identification of the animal(s) or group(s),
2. Clinical information such as results of physical examination, the behavior of the animal, and notations regarding observed abnormalities, illnesses, and/or injuries,
3. Immunizations and other prophylactic treatments and procedures as appropriate for the species,
4. Documentation of diagnostic tests and interpretation,
5. Reference to the research intervention, where appropriate,
6. Treatment prescribed and provided, the clinical response, and follow up,
7. Surgery, anesthesia, analgesia and peri/post-operative care,
8. Control of pain and distress,
9. Documentation of euthanasia or other disposition,
10. Documentation of necropsy findings, if indicated.

Medical records should be written to define and reflect the current level of understanding of a health problem [FASS 1999]. The record should be refined as additional information is acquired, and communicate the medical logic and case progression [Chavis and Hutton 1998; Lees 1981].

Notations in the medical record should be made by individuals who have administered treatments, or made direct observations or evaluations of the animal(s) or their diagnostic results, or their designee. Individuals typically responsible for making notations in the record include veterinary staff (veterinarians and/or veterinary technicians), animal husbandry staff (animal care staff, managers, supervisors), and research staff (e.g., principal investigators, study directors and/or research technicians). All entries in the record should be dated, indicate the originator of the entry (e.g., initials, signature, and electronic signature) and be legible to someone other than the writer [CareFirst 2004].

Facilities may wish to consider establishing a list that summarizes the animal's medical history at a glance. This may be particularly valuable for animals that undergo a major survival surgery and/or are reassigned to another project. A copy of the medical record, or a pertinent summary of that animal's medical history, should follow the animal upon reassignment [APHIS 2000].

Types of Medical Records

A. Individual Health Records

Individual health records should be maintained for animals that receive regular individual health evaluations, as deemed appropriate by the institution [Haskins and Eisele

1997]. Examinations performed on the animal should be recorded; however, performance of routine preventive medical procedures on an entire group of animals may be recorded as a group record. Clinical records maintained on individual animals are used to document routine preventive care (e.g., physical examinations, vaccinations, dental prophylaxis), as well as spontaneous (non-induced) illnesses or injuries [NRC 1996]. These records should also document peri-surgical and peri-anesthetic care.

B. Group Health Records

Group health records may be appropriate for animals that are members of a larger cohort (e.g. a colony/school/flock/herd/room), as well as for animals that undergo periodic evaluation by means of examination of several representative individuals of the group [Haskins and Eisele 1997; Suckow and Doering 2000]. Documentation of peri-surgical and peri-anesthetic care may also be done as a group record.

C. Records of Sedation or Anesthesia and Peri-surgical/Peri-procedural Care for Survival and Terminal Procedures

Records of sedation and anesthesia (with or without surgery), and peri-surgical / peri-procedural care, document adequate veterinary care and the alleviation of pain and distress during the conduct of these procedures [Haskins and Eisele 1997], whether survival or terminal. Procedures of this nature should be documented in a medical record and/or research record, or can be linked and available to the record, as deemed appropriate by the institution.

The procedural documentation may contain:

1. Animal or group identification and the date of the procedure,
2. All drugs administered, including dose, route, time, and the ability to identify the person administering the drugs,
3. A description of the surgical procedure and identification of the surgeon(s),
4. Ongoing findings during monitoring,
5. Notation of any variations from the normal and expected events during the anesthetic and recovery periods, including the actions taken and the time performed, the animal's response to these actions, and the ability to identify the person performing these actions,
6. Assessment for pain and distress,
7. Actions taken to alleviate pain and distress, including non-pharmacologic interventions, and the response to these actions,
8. A notation defining the end of the monitoring period (euthanasia or functional recovery from the sedation or anesthesia), including the time, date, and the ability to identify the person performing this observation.

Other Types of Records

Experimentally induced disease/research records, and breeding records, are not necessarily a part of the medical record, but they may provide useful adjunctive information about the animal's welfare. The information in these records may be included as part of the medical record when deemed appropriate by the Attending Veterinarian.

A. Experimentally Induced Disease/Research Record

A distinction must be made between spontaneous disease (rare in young, microbiologically-defined research animals) and experimentally induced diseases. Clinical notations for disease which is experimentally induced in animals do not necessarily need to be recorded in the medical record. Rather, it may be appropriate for this information to be retained within the research records, which must then be readily available for review by the veterinary staff. If research data in a researcher's notebook or computerized database cannot be readily retrieved, then essential clinical data should be included within the medical record.

Research records can be maintained for an individual or a group of animals, and may take on many forms and have several components, such as a laboratory notebook, cage cards, or other suitable records. Such information may include: animal identification information (may be group ID); date and type of procedure performed/compound administered/etc; routine observations defined by the protocol; adverse or unexpected complications; and date of euthanasia or termination of study.

B. Breeding Records

Records for breeding animals may be maintained to document medical information relevant to reproduction. When maintained, these records can be included within the animal's medical record, or can be linked and available to the record. These records should allow the veterinary and/or research staff to identify the pedigree of the animal, when appropriate [NRC 1996]. Typically useful information includes the animal identification, genotype, sire and dam, animals with which the individual has been paired, and the outcome of each breeding attempt. Additional information which allows identification of the animal's breeding history and productivity may be included as needed [FASS 1999].

Conclusions

Medical records for animals used in research, teaching and testing are a core component of adequate veterinary care. They should document information associated with management of clinical disease, diagnostic and therapeutic pro-

cedures performed, and preventive medical procedures. The methods by which medical records are developed and maintained should be determined by the institution, with the guidance and professional judgment of the Attending Veterinarian. Application of performance standards within the medical record program allows the veterinarian to effectively employ professional judgment, ensuring that the animal receives the highest level of care available.

References

- ACLAM [American College of Laboratory Animal Medicine]. 2004. Public Statements: Medical records for animals used in research, teaching and testing. Available online (http://www.aclam.org/aclam_public.html ACLAM public statements).
- APHIS [Animal and Plant Health Inspection Service], US Department of Agriculture. 2000. Regulation of agricultural animals (Policy 3). In: Animal Care Resource Guide. Washington DC: USDA. Available online (<http://www.aphis.usda.gov/ac/polmanpdf.html>).
- APHIS [Animal and Plant Health Inspection Service], US Department of Agriculture. April 11, 2003. Docket No. 97-033-1: Animal Welfare; Medical Records. ACTION: Proposed rule. Available online (<http://www.aphis.usda.gov/ac/medicalrecords.html>).
- AVMA [American Veterinary Medical Association]. 2002. Principles of Veterinary Medical Ethics of the American Veterinary Medical Association. Section VII.A. Available online (<https://vetboard.glsuite.us/Renewal/Resources/Main/Principles%20of%20Veterinary%20Medical%20Ethics%20of%20the%20AVMA.doc>).
- CareFirst [CareFirst Blue Cross Blue Shield]. 2004. Medical Record Documentation Standards. Section 4. Available online (<http://www.carefirst.com/providers/html/MedicalRecord.html>).
- CFR [Code of Federal Regulations]. 2003, Title 9, Chapter 1, Subchapter A - Animal Welfare. US Department of Agriculture, Animal and Plant Health Inspection Service. Available online (<http://www.nal.usda.gov/awic/legislat/usdaleg1.htm>).
- Chavis SA, Hutton JI. 1998. The medical record. In: McCurnin DM, ed. Clinical Textbook for Veterinary Technicians. 4th ed. Philadelphia: W. B. Saunders. p 59-78.
- FASS [Federation of Animal Science Societies]. 1999. Guide for the Care and Use of Agricultural Animals Used in Agricultural Research and Teaching. 1st rev ed. Savoy IL: Federation of Animal Science Societies. p 20-25.
- Gaertner DJ. June 3, 2003. Letter to APHIS on proposed medical records rule making, Docket No. 97-033-1, Animal Welfare; Medical Records. Available online (http://www.aclam.org/aclam_public.html). ACLAM public statements.
- Hanley MF. June 9, 2003. Letter to APHIS RE: Animal Welfare, Medical Records, Docket No. 97-033-1, Animal Welfare; Medical Records.
- Haskins SC, Eisele PH. 1997. Postoperative support and intensive care. In: Kohn DF, Wixson SK, White WJ, Benson GJ, eds. Anesthesia and Analgesia in Laboratory Animals. New York: Academic Press. p 381-382.
- Lees GE. 1981. Symposium on physical diagnosis. History-taking and development of the examination record. In: Bistner SI, ed. The Veterinary Clinics of North America. Small Animal Practice. Vol. 11 / No. 2. Philadelphia: W. B. Saunders Co. p 441-452.
- NRC [National Research Council]. 1996. Guide for the Care and Use of Laboratory Animals. 7th ed. Washington DC: National Academy Press. p 46-47.
- Osborne CA. 1983. The problem-oriented medical system. In: Furumoto HH, ed. The Veterinary Clinics of North America. Small Animal Practice. Vol. 13 / No. 4. Philadelphia: W. B. Saunders Co. p 745-790.
- Suckow MA, Doerning BJ. 2000. Assessment of veterinary care. In: Silverman J, Suckow MA, Murthy S, eds. The IACUC Handbook. Boca Raton: CRC Press. p 460.