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STANDARD OPERATING PROCEDURE

Medical Record Keeping Requirements – Large Animals

Approval(s):

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Director, DLAR	Date
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Chair, IACUC	Date
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Executive Director, IACUC	Date

- A. PURPOSE. This SOP defines institutional standards required at the University of Pittsburgh in the maintenance of medical records for “large animals”, including most species covered by the Animal Welfare Act (AWA) – (see Part C – Applicability).
- B. BACKGROUND. United States Department of Agriculture (USDA) and Public Health Service (PHS) regulatory policies as specified in the AWA and the Guide for the Care and Use of Laboratory Animals, require the documentation of information associated with the procurement, identification, investigative manipulation and medical maintenance of animals used within registered Biomedical Research Facilities. Additional conventions and practices have been recommended by oversight and accrediting bodies such as the Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC International). Furthermore, the American College of Laboratory Animal Medicine (ACLAM) has issued a 2005 Policy Statement defining Medical Records for Research Animals. This SOP meets or exceeds the guidelines and standards set by the above-mentioned bodies. Some aspects of medical record keeping requirements at this institution have already been described in the University of Pittsburgh Policy “Guidelines for Surgery - Large and Small Animals” Section VI-A – (revised 2/04). This SOP will expand on those requirements
- C. APPLICABILITY. The requirements specified in this SOP for the maintenance of medical records apply to all non-rodent, AWA-covered species, including rabbits, cats, dogs, nonhuman primates, pigs, horses and large & small ruminants.

Medical record keeping requirements for guinea pigs, gerbils, hamsters and other rodent species covered under the AWA, as well as bred for research rats & mice are described in the University of Pittsburgh SOP – *Medical Record Keeping Requirements – Rodents.*

- D. RESONSIBILITIES. The task of maintaining medical records on all large animals falls on both the Division of Laboratory Animal Resources (DLAR) and the Principal Investigator (or his/her designees) on whose Institutional Animal Care and Use Committee (IACUC) protocol the animals are listed. Both are responsible for the complete and timely entry of information required (see Section E) in their respective records.

The successful management of medical records will require the ongoing exchange of information between the investigative staff and DLAR. Both are charged by the IACUC to communicate in a fashion such that satisfactory documentation of all required information is achieved.

Oversight: The IACUC, through semi-annual program review and the Research Conduct and Compliance Office (RCCO), via random or “for cause” protocol audits will monitor compliance with standards set forth in this SOP. Additional medical records oversight and review is expected from regular USDA site visits, as well as from the Office of Laboratory Animal Welfare (OLAW), AAALAC and other regulatory and accreditation bodies.

- E. PROCEDURES.

1) DLAR Maintained Medical Records:

The DLAR Veterinary Service unit will maintain individual, separate (vs. batch) records for all species covered in this SOP. Such records should contain the following information:

- a) Animal identification #
- b) Source & date of arrival
- c) Any federal or state mandated certificates received with the animal (or copies thereof)
- d) Documentation of completion of quarantine requirements (e.g. physical examination, empirical entry treatments, immunizations, diagnostic screening & testing, etc.) - based on species specific approved protocols
- e) Documentation of further veterinary assessment, treatment, progress, etc. related to either spontaneously occurring disease, standard medical maintenance or research-related issues
- f) Documentation of DLAR monitored weight records, as well as any other physical measurement parameters required
- g) *Documentation of research manipulation that is invasive and/or requires a general anesthetic event (via a completed copy of a Post Procedural Form – PPF)
- h) *Documentation of the administration of chemical, biological or radiation hazards

(via a completed copy of a Post Procedural Form – PPF)

- i) *Anesthetic records for general anesthesia events (via a completed copy of an Anesthetic Form)
- j) *Copies of treatment records related to investigator administered post-operative analgesics, antibiotics & other indicated post-op Rx or records reflecting investigator administered Rx as directed by the DLAR veterinary staff (via a completed copy of a Treatment/Observation Form)
- k) Copies of e-mail communications with investigators reporting health issues, permission for treatment, etc.
- l) Copies of completed and approved Transfer Form requests associated with animal movement
- m) Documentation of all treatments prescribed and/or administered by the DLAR staff
- n) *Documentation of euthanasia (via a completed copy of a Post Procedural Form – PPF)

* - information should be provided to the DLAR by the investigative group

It is the responsibility of the investigative group to submit required information in a timely and unsolicited fashion. Standard forms for anesthetic monitoring, post-procedural care, treatment/observation and transfer are available on line at www.iacuc.pitt.edu - under the Forms section, click on Critical DLAR Forms

The method of providing such documentation to the DLAR may vary and can include direct or fax transfer of hard copy records or e-mail transmission of documents. The most effective and efficient method of information exchange should be determined on a site-by-site basis through discussions between the assigned veterinary service staff and investigative group.

In individual cases in which protocol-specified study end-point parameters (such as body weight loss, hematologic and/or clinical chemistry values, etc.) are in question, investigators are required to provide such information to the DLAR for inclusion in their medical records.

It is recommended, but not required that investigators provide the DLAR with the results of any routine laboratory testing performed, notification of experimental drugs/substances administered, other non-invasive manipulations performed and any additional information which may relate to the health and well being of the animal. Awareness of the total medical use history can greatly facilitate the ability of the veterinary staff to monitor animals and provide quality health care.

Investigators are also encouraged to mark or label cages, or otherwise provide suitable information at the room level, such that DLAR veterinary service and animal care personnel are made visually aware of animals that have undergone surgery, received hazardous agent administration or had other research manipulation that would warrant more aggressive monitoring and observation. The methods of identifying such

animals should be determined and agreed upon jointly by investigative and DLAR staffs on a facility-by-facility basis.

2) Investigator Maintained Medical Records:

The Principal Investigator (or his/her designees) is required to maintain information on their animals as specified below. Such documentation may be entered in batch form, although in general, keeping individual animal records is encouraged. This information may be integrated with research data recorded and as such, the format in which it is maintained may vary significantly from lab to lab. Non-proprietary information must be made available on request for IACUC, Compliance or DLAR veterinary review and the IACUC reserves the right to mandate changes in record keeping methodologies it does not feel are sufficiently accurate, comprehensive or otherwise suitable.

Investigator medical records should contain the following information:

- a) Animal Identification
- b) Documentation of all research manipulation (and associated animal monitoring) e.g.– surgical, anesthetic, behavioral testing, chemical, biological or radiation hazard administration, etc.
- c) Documentation of all drugs and substances administered – research and therapeutic
- d) Weight measurements – when required and indicated as a part of protocol prescribed research monitoring
- e) Lab results – especially those indicated as a part of protocol prescribed research monitoring
- f) General observations and clinical comments – especially relating to manipulation creating pain and distress
- g) Documentation of euthanasia

Questions concerning standards in the maintenance of investigative medical records or about the transfer of information related to research manipulation for inclusion into the DLAR medical records should be directed to veterinary service site team representatives at the facility in which the animals are housed.