



ANIMAL TRACKS



A newsletter for the Duke research community

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<http://www.duhs.duke.edu>

Managing An IACUC Semi-Annual Laboratory Inspection

In January the Duke IACUC will begin the next round of IACUC Semi-Annual inspections. This inspection process is required by the federal laws and policies for animal care and use programs, and must be completed every 6 months. Sometimes these visits can be distressing for the research team, but the IACUC Semi-Annual inspection should be viewed as a collegial opportunity to share the strong evidences of good performance of animal care and use within your laboratory, and also an opportunity to receive important program information in a clear and non-threatening manner. This visit is not intended to be one sided.

While having visitors in the research laboratory can be an anxious experience, if your research team is prepared for the IACUC's review, the outcome will be successful and relatively painless. The goal of this article is to provide a general overview of the IACUC Semi-Annual inspection process and to offer a suggested plan for preparation of this visits. When your IACUC visitors are in your laboratory, please ask questions concerning unclear or confusing processes of the animal program. Open communication benefits the entire university community and supports successful research outcomes for you and our institution.

PROCESS: The Duke University IACUC uses a Sub-Committee of 2 or 3 of its membership to perform these inspections. These Sub-Committee inspectors are not just IACUC members, but are also Duke researchers. They have an obligation to perform a thorough review of the areas where animal care or animal use occurs, but will perform this duty in a collegial and informative manner.

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FIRST STEP: Recognize that the IACUC inspectors are looking for 'evidence of good performance,' or to say it another way, the inspectors are seeking to confirm excellent animal care and humane animal use. Your laboratory can assist the Sub-Committee by explaining clearly, the humane care postures used by your laboratory.

WHAT IF? On occasion, the IACUC Sub-Committee may observe sub-optimal procedures or practices. When this occurs, the problems noted will be handled in a collegial manner. Whether the problem is minor or significant, the same focus still applies - determine the cause of the problem, correct the immediate problem, and establish a mechanism that will discourage a repeat occurrence of the problem. Most of the time, the Sub-Committee will discuss the concerns with your laboratory representative prior to leaving the area. You can begin thinking about how you should address the problem.

The federally mandated IACUC Semi-Annual review process can be a friendly and useful exercise, especially if your laboratory staff are prepared for the review.

FOR MORE INFORMATION: If you would like a self-inspection checklist, contact the Office of Animal Welfare Assurance.

Third Time is the Charm

The Duke IACUC Whistleblower policy has recently been updated.

The updated policy is printed on blue paper and should replace any yellow or green copies that you may have.

Distribution of the most recent whistleblower policies began in November. If you have an approved animal housing area in your lab and you have not yet received a BLUE copy for display, please contact Sonia at sonia.doss@duke.edu

Guidelines for Endpoints in Animal Study Proposals

Humane Endpoints: Experimental studies may involve procedures that cause clinical symptoms or morbidity in animals. According to federal guidance, the IACUC must consider the selection of the most appropriate endpoint(s) during the review of the protocol. This requires careful consideration of the scientific requirements of the study, the expected and possible adverse effects the animals may experience (pain, distress, illness, etc.), the most likely time course and progression of those adverse effects, and the earliest most predictive indicators of present or impending adverse effects. The effective use of humane endpoints requires that properly qualified individuals perform both general and study-specific observations of the research animals at appropriate time points. Optimally, studies are terminated when animals begin to exhibit clinical signs of disease. Humane endpoints should be selected that are compatible with meeting the research objectives. Such endpoints are preferable to death or moribundity since they minimize pain and distress. Efforts must be made to minimize pain and distress experienced by animals used in research.

Understanding Morbidity: The moribund condition is defined as a clinically irreversible condition leading inevitably to death. Animal proposals that include morbidity or animal procedures that have the potential to cause adverse sequella should address the following:

Criteria that monitor the **development of morbidity**, starting from a normal animal and proceeding to a sub-optimal condition could include changes in:

- Body weight,
- Skin and hair,
- Clarity in the eyes,
- Discharges from the nose or mouth,
- Changes in respiration, urine production, fecal production,
- Changes in locomotion style and speed,
- Measurable clinical signs,
- Unprovoked behavior and response to external stimuli.

Criteria that **define the maximal morbidity**, and may constitute a humane endpoint include, but are not limited to:

- Rapid weight loss.
- Diarrhea, if debilitating.
- Progressive dermatitis.
- Rough hair coat, hunched posture, lethargy or persistent recumbency.
- Coughing, labored breathing, nasal discharge.
- Jaundice and/or anemia.
- Neurological signs.
- Bleeding from any orifice.
- Self-induced trauma.
- Any condition interfering with eating or drinking (e.g. difficulty with ambulation).
- Excessive or prolonged hyperthermia or hypothermia.

The IACUC will require a **plan for monitoring** the animals both before and after a change in any of the above aspects. The plan should include provisions of care (as appropriate), and

potentially increasing frequency of monitoring (to detect declining health), as appropriate. Monitoring or clinical care on weekends and holidays may require involvement of the investigative staff to supplement that provided by the animal care and veterinary staff.

Clear **identification of personnel responsible** for evaluation of developing morbidity is also necessary. Checklists or score sheets may be helpful in ensuring appropriate observations are made, consistently interpreted, and properly documented.



MEDICAL RECORDS OF RESEARCH ANIMALS

The Animal Welfare Act (AWA) and the “Guide for the Care and Use of Laboratory Animals” (Guide) specifically address the use and content of medical records. The Duke Institutional Animal Care and Use Committee (IACUC) and Division of Laboratory Animal Resources (DLAR) provide the following guidance, based on The Guide and USDA Policy #3.

1. Any individual performing an observation, procedure, manipulation, surgery, treatment, medication, or any other care assessment must document his or her activities and observations in the designated animal record.
2. All notations must be initialed and dated.
 - A. Rodents, birds, and cold-blooded species: Detailed records may be kept in an investigator’s laboratory notebook. However, to aid DLAR veterinary staff or regulatory agencies, a brief description of the procedure and the date performed should be noted directly on the animal’s cage card (i.e. OVX 11/07/06 would mean an ovari-hysterectomy was performed on the animal on 11/07/06). This practice would help avoid confusion when animals are showing anticipated or protocol approved clinical signs (i.e. an animal that is recovering from anesthesia may look like it has minor paresis or other minimal neurological deficits when in fact is it simply post-procedure anticipated movement).
 - B. Non rodent species: The records are maintained by DLAR or the Duke Lemur Center, in the proximity to the animal’s housing area (hard copy or electronic). These records are official individual animal records for higher order species. Regulatory agencies will reference those DLAR records for any questions concerning animal care or health status. Records generated by the principal investigator (PI) outside of the ‘official’ medical record should be submitted to DLAR within 48 hours. Copies from principal investigators (PI) are acceptable to be placed in the official animal record.

For more details, please see the animal program web site at <http://vetmed.duhs.duke.edu/> Select the link for policies and review the one titled ‘Medical Record Keeping.’

Q & A

Is an IACUC approved protocol always required where animals are used for research, teaching, or product safety evaluation?

An IACUC protocol is required if one of the following conditions exists :

- ⇒ The species used for research, teaching, or testing is a vertebrate species, or if invertebrates are being housed with vertebrate species, or
- ⇒ The research, teaching, or product safety evaluation is supported by the PHS, or
- ⇒ The activity will be performed at an institution with an Animal Welfare, Assurance that commits the institution to comply with the PHS Policy, or
- ⇒ The institution is receiving support for animal research, teaching, or testing from an agency that requires compliance with PHS Policy (e.g., the National Science Foundation), or
- ⇒ The institution has a policy that requires a protocol for faculty or staff that use animals or animal tissues.

It might be easier to define when a protocol is not required. Examples that do not require a protocol include:

- ⇒ Tissues or fixed specimens that are obtained from a biological supply house; or
- ⇒ Eggs (e.g. chicken) that have no potential for hatching (e.g. study prior to 1 week before hatching), or
- ⇒ Tissues (e.g. chicken legs for surgery practice) obtained from a grocery store, or
- ⇒ Work that is done off Duke campus, without Duke resources or grant funds that are managed by Duke (except the participation of Duke faculty or staff), and for which Duke will not be noted as having any responsibility or oversight.

Upcoming Events

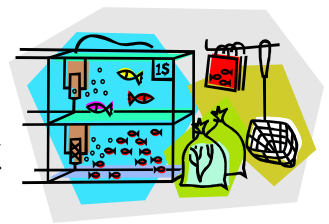
November 27	New protocol deadline
November 27	SC deadline
December 7	SC meeting
December 14	IACUC meeting
December 26	SC deadline
January 4	SC meeting
January 8	New protocol deadline
January 8	SC deadline

SC= Significant change



Do zoological gardens and aquariums fall under the jurisdiction of the USDA? NIH? AAALAC?

Yes. Zoos and some aquariums (e.g., those that maintain USDA regulated species) could be defined as exhibitors under the Animal Welfare Regulations and would therefore comply with all regulations governing exhibitors. If federal funds were used to maintain the animals, then the facility would have to adhere to certain animal care practices as required by that funding agency. For example, support for animals from an agency of the Public Health Service (PHS), such as the NIH, are obligated to abide by PHS policy. Support for animals from other federal or private funding agencies (e.g., the National Science Foundation, Morris Animal Foundation, etc.) may require adherence to the PHS Policy as a condition of receiving their support. AAALAC accreditation is voluntary, but is often considered desirable.



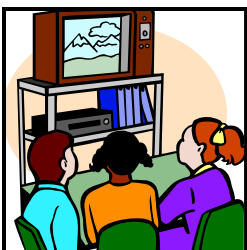
Are all animal use activities expected to adhere to the same research criteria as biomedical research institutions? What if the work is a field study involving observation only?

Strict observational studies conducted at zoos or in the field – no matter who is conducting them—are not covered by the USDA, but may be covered by the PHS Policy and accreditation guidelines through AAALAC. While the manner and methodology of animal utilization is significantly different between field studies and biomedical studies, the same central concerns and precepts for humane care and use apply. As such, a protocol is necessary in many cases — especially if Duke resources and funds are being used to support the field or zoo observations. The principal concerns of such a protocol will be general assurances of animal well being, and if necessary appropriate intervention to prevent animal distress, pain, or suffering. If a non-observational procedure (e.g. counting eggs in a nest, measuring individual sizes, etc) is performed on an animal for the purpose of obtaining data, then this activity is considered regulated research. The USDA has been working (since 1999) to more clearly define the context of behavioral and observation study oversight, but as now, a clear policy has not emerged.

**From the IACUC Handbook.

NCABR Releases New Video and Training Set

The North Carolina Association for Biomedical Research has released a superb video titled 'LIVING PROOF' and accompanying training materials. The video and training resources can be downloaded at http://www.ncabr.org/biomed/bio_resources/livingproof.html



The video features four survivors of life threatening diseases who have opened up their life and their story on how research using animals have provided them years of life that they would not have had otherwise. One of the highlighted personalities is Duke's own Dr. Dennis Rickman. This is a 'must-see' for all members of the Duke community. With the accompanying curriculum, this video becomes a wonderful training resource for science classes across the state.

New Form for Exemption To Policy

The Duke IACUC has released a new form for those who wish to apply for an Exemption to Policy for the care or use of animals at Duke. This form replaces about a dozen other forms. The IACUC hopes that consolidation of forms will eliminate the confusion of which form should be selected for which activities or procedures. You can download a copy of the new Exemption Form at http://vetmed.duhs.duke.edu/index_of_forms.htm Select the option 'Exemption Request to Policy.'

New Form for Housing Greater Than 12 Hours

In response to the recent AAALAC Site Visit, the Duke IACUC has clarified and enhanced the process for application to house animals outside of a central vivarium for greater than 12 hours. You can download a copy of the new Exemption Form at http://vetmed.duhs.duke.edu/index_of_forms.htm Select the option 'Housing Request OUTSIDE of a DLAR Managed Facility.'



USDA Annual Report

Duke is in the midst of the annual USDA animal numbers report. For those who have submitted their report to the OAWA, THANK YOU! For those who are still working in it ... YOU ARE LATE!

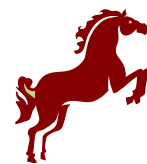
Seriously, if you have any question about this annual federal report, please contact Michelle Keys at michelle.keys@duke.edu

HorseFacts.org

HorseFacts.org is part of a public education program created by [Foundation for Biomedical Research](#) (FBR), in association with the [American Association of Equine Practitioners Foundation](#) (AAEPF). HorseFacts.org has been designed to promote public understanding, respect and support for the vital role that humane and responsible animal research plays in advancing equine health and medicine.

Animal extremists are opposed all research with animals - even though it advances veterinary medicine. Our program is designed to counteract the anti-research misinformation of the animal extremist movement. We seek to increase understanding about the importance of biomedical research to all animals, especially horses.

The Mane Facts about Horse Health



- Humans and horses share 95% of their D.N.A.
- Diagnostic tests for several common genetically determined diseases of the horse have been developed as a result of the Horse Genome Project. A wealth of information available from the sequencing of the horse genome, suggests that genetics will have an overriding influence on all aspects of equine research.
- Some of the most promising applications in biotechnology are in the field of animal health, in such areas as assisted reproduction, increased disease resistance, nano-based diagnostic and "smart" treatment delivery systems, new and improved vaccines and refined diagnostic techniques. Further research with lab animals is required before these promising advances are made available to veterinarians.
- While the average life span of a horse is 20-25 years, they often live well past that. The oldest recorded horse was "Old Billy," an English barge. He lived 62 years. One of our poster horses, "Gary," is 30. The retired Thoroughbred is still going strong.
- The horse is either the primary or secondary host of many infectious agents including: Equine Influenza Virus, Equine Herpes Viruses, African Horsesickness Virus, Eastern, Western, and Venezuelan Equine Encephalomyelitis Viruses, Vesicular Stomatitis Virus, Equine Arteritis Virus, Equine Infectious Anemia Virus, and Equine Morbillivirus (Hendra Virus).
- Immunology research plays an important role in equine health. Once a test is developed to identify the cause of an undesirable immune response, researchers can inform veterinarians about what treatments to administer and how long or how much of the treatment is needed.

See more facts about horses at HorseFacts.org