MEETING THE INFORMATION REQUIREMENTS OF THE ANIMAL WELFARE ACT

Presented by the USDA, NAL, Animal Welfare Information Center (AWIC)

Ed Note: The Duke Medical Center Library & Archives and the Office of Animal Welfare Assurance (OAWA) are excited to bring you the following training opportunity. It is free for Duke researchers & staff!

The regulations of the Animal Welfare Act (AWA) require investigators provide the Institutional Animal Care and Use Committees (IACUC) with documentation demonstrating that alternatives to procedures that may cause more than momentary pain or distress to the animals have been considered and that activities do not unnecessarily duplicate previous experiments.

This workshop, facilitated by National Agricultural Library AWIC staff (from Beltsville, Maryland), will provide an opportunity to review the Animal Welfare Act requirement for your research, discuss the definition and examples of alternatives and complete hands-on literature search exercises.

This is a 2-part workshop including a 2 hour lecture and 1.5 hour hands-on training.

The Lecture Session will be offered on Tuesday September 16th from 10:00 am – 12:00 pm in Hock Plaza Ground Floor Conference Center.

The Hands-on Sessions are offered several times:
⇒ Tuesday September 16th from 1:00 -2:30 pm at the Medical Center Library, Rm 104
⇒ Tuesday September 16th from 3:00 -4:30 pm at the Medical Center Library, Rm 104
⇒ Wednesday September 17th from 1:30-3:00 pm at the Medical Center Library, Rm 104
⇒ Thursday September 18th from 9:00 – 10:30 am at Bostock, Rm 023

You should attend both the lecture and hands-on sessions. Registration is required (but it is free). Please visit the Library’s Classes Calendar to register at:

http://mclibrary.duke.edu/training-and-consulting/upcoming-classes

USDA / AAALAC ANNUAL REPORT

It is (almost) that time of year when the humidity starts to fall, the days begin to cool, and … OAWA starts collecting information on animal use numbers. Fall is about to arrive!

In accordance with the public law known as the Animal Welfare Act, Duke University is required to submit an annual report to the United States Department of Agriculture for all regulated species used in research, testing, teaching, or exhibition. This report requires each animal used be placed in the appropriate use category (categories defined by the federal agencies).

And so no one of us have to go through this painful exercise twice each year, information on animal numbers to be reported to our accreditation activity, the Association for the Assessment and Accreditation of Laboratory Animal Care, International (AAALAC, i.), are collected at the same time.

Mark your calendar now, and be looking for an email in early October where each research laboratory will verify the numbers of animals used for the period 1 October 2013 through 30 September 2014. That is the federal fiscal year and the basis for the counting period.

In preparation for that message, you may start to review your use numbers for this period and consider which category they should be placed.
⇒ Category C: No pain or distress
⇒ Category D: Anesthetics, analgesics, sedatives used to prevent pain or distress.
⇒ Category E: Some unalleviated pain or distress was experienced by the animals.

Please email Dr. Anna Hampton or call 919.668.6721 for answers to your questions.

For clarification of category assignments, visit the policy on “Categories of Potential Pain or Potential Distress.” There is a good chart in the appendix to help distinguish specific activities!

Wishing you a successful research month,
THE BASICS OF RUNNING A PI MANAGED HOUSING FACILITY

If your lab has been approved as a PI managed facility, you should know that there are specific requirements for working in and maintaining these areas. Here are some highlights. PI Managed Housing Facilities require:

- Initial IACUC approval followed by annual re-approval through inspection by site team.
- Contact person assigned for each lab/facility that is approved.
- Twenty-four hour temperature and humidity monitoring.
- Accurate and complete record keeping.
- Training for all lab staff involved in the animal care.

Daily Husbandry Procedures:

- Animal observations (required by federal guidelines).
- Environmental monitoring (temperature – humidity – air flow).
- Provide food and water (check daily to ensure quality).
- Cleaning of the housing area (sweep – mop – disinfect).
- Check live traps (if used) for escaped or feral rodents at least daily!
- Document all daily husbandry procedures.
- Housing approved for longer periods may require cage changing, weekly cleaning.
- Monthly requirements include sanitizing of the room, equipment (caging), feed and bedding containers, etc.
- Report animal health issues and emergencies to the ‘On-Call’ DLAR veterinarian (970.9410).

Administrative Procedures:

- Ensure that cage cards are current and correctly reflect the protocol, species, etc.
- Each lab must submit an SOP describing care practices to the OAWA.
- An Adverse Event Mitigation Plan outlining disaster response and names of responsible individuals must be provided to OAWA.
- Maintain all records and have them available for site team inspections.
- Have lab SOPs and protocol documents available/accessible for all lab staff.
- Contact the OAWA about any changes to the approved procedures, location, etc. and submit appropriate amendment documents.
- Notify DLAR monthly to update animal census (if animals are not ordered through DLAR; such as weaned

SANITATION & DISINFECTION UPDATE

The Duke University Hospital system has converted to using Sani-Cloth® Germicidal Disposable Wipes by PDI for environmental surface cleaning and disinfecting. Any use of Duke North or Duke South, or any location where human clinical care is provided will require the use of these products for sanitation / disinfection after an animal activity.

But what does this mean for DLAR facilities or PI-Managed facilities? Actually not much. DLAR reviews and approved appropriate disinfectants and sanitizing agents for use in animal environments. It is true that human and animal viruses, bacteria, etc. are very similar—if they weren’t similar, then we would not be using animal models for human disease research! But there are on occasion sufficient differences that there can be a good reason for selecting different disinfectant agents.

So ….. When in an animal care facility, follow the DLAR guidance. When in a human care facility, following the DUHS Infection Control guidance!

QUADSPEAKE4

Ever wondered how to talk about animal research? If so, QuadSpeake4 can help. QuadSpeake4 is a rapid response communications curriculum for biomedical research professionals. It will provide you with professional strategies and training for talking about animal research in the classroom, in social settings, internally with colleagues and with the media.

QuadSpeake4 includes:

- A tactical plan for K-12 communications and presentations
- A strategic plan with talking points for discussing animal research in social settings
- An interactive strategic plan for internal communications
- A tactical plan for rapid response communications with the media
- A "Media Training 101" DVD

The full curriculum is available for purchase for $79.00. Please contact FBR at info@fbresearch.org to order.

Do you know people who wonder if animal research saves lives? Send them to this YouTube link for a video regarding:

⇒ Animal Research Saves Human Lives
⇒ Animal Research Saves Animal Lives
In order to approve a protocol that involves the use of animals, the IACUC must review the proposed care and use of animals and determine that federal criteria have been met. PHS requires that the project be conducted in accordance with the PHS Policy, the AWA, the Guide, the institution’s Assurance, and all other applicable federal statutes and regulations related to animals. The project should also comply with all institutional policies.

The institution is required to assure animals are used according to the manner and under humane expectations of animal care & use. The Duke standardized protocol application form assists our investigators with providing the information necessary to ensure compliance. Additionally, while there is no explicit requirement for the IACUC to do a side-by-side comparison of the information contained in the IACUC protocol review form and the information submitted to PHS, it is imperative that the protocol that the IACUC approves is consistent with the information submitted to PHS. At Duke, the IACUC and the OAWA perform concordance reviews to assure congruency between the grant and the protocol.

Investigators should note that if the IACUC requires changes to the protocol that are not reflected in the grant application, then the PHS funding component must be notified in the follow-up certification of IACUC approval. Duke is required to provide PHS with the date of IACUC approval. There is no provision for providing a contingent approval date; the date provided must signify full approval by the IACUC.

In most cases, the PHS allows a 60-day grace period following the receipt deadline date during which the investigator may secure IACUC approval; otherwise, the application cannot be peer reviewed. If the IACUC review occurs subsequent to the grant submission, then a letter verifying IACUC approval, and stating any modifications required by the IACUC, must be submitted to the funding agency. This grace period is nonexistent for some non-federally funded projects and investigators are required to submit evidence of IACUC approval coincident with the grant or contract submission.

Note: You can view the entire text of this publication online at http://grants.nih.gov/grants/olaw/GuideBook.pdf
IACUC DATES & DEADLINES

NOTE: THE FALL DATES OF IACUC ACTIVITY ARE AFFECTED BY THE THANKSGIVING AND CHRISTMAS HOLIDAYS.

September 18  Amendment Meeting
September 25  Amendment Deadline
September 25  New Protocol Meeting
October 2    Amendment Meeting
October 6    Amendment Deadline
October 6    New Protocol Deadline
October 16   Amendment Meeting
October 23   New Protocol Meeting
October 27   New Protocol Deadline
November 3   Amendment Deadline
November 13   Amendment Meeting
November 17   New Protocol Deadline
November 20   New Protocol Meeting
December 1   Amendment Deadline
December 9   Amendment Meeting
December 11  New Protocol Meeting
December 23  Amendment Deadline

THINGS TO REMEMBER

* Travel Plans This Fall? Check the training status of lab staff before they leave for a trip. Out of date training is the #1 reason amendments are delayed!

* Unanticipated deaths of research animals? All non-mouse, non-rat animals that die unexpectedly should have a complete necropsy performed to assure compliance with the USDA regulations on animal care. Contact DLAR to arrange for a necropsy.

Reporting Adverse Animal Conditions

If you observe an animal in distress, as a member of the Duke animal care program you are obligated to report the distress immediately! You are encouraged to take actions to prevent any further distress to the animal if you can. To report adverse animal conditions, contact the Duke Animal Welfare Hotline (919.684.3535) or Email the Duke IACUC at IACUC@duke.edu. Duke University will not tolerate any misuse or neglect of animals.

The identity of any person making a report is always kept confidential. Individuals making reports are protected against reprisals. For more information, go to http://vetmed.duke.edu/AnimalWelfareHotline.html. This site includes anonymous reporting options.

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

Some animal use activities require approval by both the Duke IACUC and the Duke IBC.

Activities that require IBC approval include recombinant DNA use, Select Agent use, work conducted at Biosafety Level 3 containment, and/or other types of biosafety review.

If you need IBC approval for animal use activities it is important to remember that IBC approval should be obtained prior to or in the same month as your IACUC approval. This will not only aide in the IACUC review process, but it will not stifle your IACUC approval.

To help facilitate this duel approval process, the IBC typically holds meetings on a monthly basis 1 week prior to the IACUC meeting. For more information on the IBC please visit their website at http://www.safety.duke.edu/BioSafety/ibc.htm. The IBC deadline and meeting schedule can be found HERE.

NEW SOURCE FOR BUPRENORPHINE EXTENDED RELEASE

Buprenorphine has been widely used for three decades in companion animals and laboratory research animals. Because of its potent analgesic effects, it has been used to alleviate moderate to severe postsurgical and post-procedure pain.

Animalgesics Labs has released Animalgesics® for Mice is a new product, manufactured under pharmaceutical grade manufacturing conditions per the FDA’s Current Good Manufacturing Procedures (CGMPs). These procedures assure the identity, strength, quality, and purity of our drug.

The NIH requires the use of pharmaceutic grade products in research animals, if pharmaceutic grade products exist. See the Duke Policy on USE OF NON-PHARMACEUTICAL GRADE SUBSTANCES IN LABORATORY ANIMALS for more information regarding options and requirements of animal use products.
GUIDELINES FOR POSTOPERATIVE SUPPORTIVE CARE

MAINTENANCE OF BODY TEMP

Because the ratio of body surface area to body mass is greater in small animals than larger ones, thermal support is often critical to the successful recovery of rodents from anesthesia. Hypothermia can lead to decreases in metabolism of anesthetic drugs and urinary excretion of such drugs with resulting prolongation of the anesthesia period. Particularly in rats and mice, body heat may be dissipated from the tail/soles of the feet/ears with resultant significant decreases in the core and surface body temperatures. Methods to minimize heat loss to the external environment (during surgery and post-surgical recovery of rodents) include:

- increasing the ambient temperature of the surgical room/procedure room.
- placement of a thermal blanket (such as a recirculating warm water heating pad) between the animal and heat-absorbing surfaces.
- careful and controlled use of incandescent or heat lamps during surgery and post-surgical recovery.
- maximization of organ exposure from body cavities during surgery.
- post-surgical recovery of the animal on a warming blanket or within a temperature-supported cage (such as a human infant incubator).
- administration of warmed (not hot) subcutaneous or intraperitoneal fluids intra- and/or postoperatively.
- post-surgical recovery on bedding to provide thermal insulation.

It is also important to monitor the animal’s internal body temperature, at regular intervals, during the surgical and post-surgical recovery period. Digital rectal thermometers or infrared thermometers are good choices.

Normal Body Temperatures:

- Mouse: 98.8-99.3 F (37.2-37 C)
- Rat: 99.4 F (37.5 C)
- Hamster: 97.1-99.5 F (36.2-37.5 C)
- Guinea Pig: 98.9-103.1 F (37.2-39.5 C)

Note: The Animal Tracks (Volume 2014, #6, Page 5) had a discussion regarding various heating pad type devices that may be used for rodents.

OCULAR CARE

Rodents are frequently anesthetized with anesthetic drugs which inhibit blinking and associated ocular lubrication. This lack of blinking results in drying of corneal and decreases the risk of postoperative corneal ulceration. Regaining of the blink reflex often does not occur until some time during the anesthesia recovery period.

ALWAYS lubricate the cornea using an appropriate lubricating ointment (e.g., Lacrilube®) administered as soon as the animal is under general anesthesia with repeat application administered during the postoperative period until spontaneous blinking is resumed. Generally a non-antibiotic ointment is preferred.

FLUID SUPPORT

Volume deficits can be estimated by comparing pre-surgical body weight and post-surgical/post-anesthesia recovery body weight of an individual animal. Regular, frequent weighing of animals can be used to assess both nutritional and fluid intake deficits during the longer-term postoperative recovery period. Decrease in skin turgor/skin elasticity (which is best assessed by “tenting” the skin over the dorsal lumbar area and evaluating how quickly it returns to its normal position) corresponds to mild to moderate (10%-20%) dehydration.

Volume deficits can be corrected by the subcutaneous or intraperitoneal injection of warmed saline, warmed lactated Ringer’s solution, or other warmed balanced replacement fluids. The selected route replacement fluids are administered needs to consider the rate of absorption from the specific site. If fluids cannot be administered intravenously, the intraperitoneal route provides the most rapid absorption into the vascular system.

If significant blood loss has occurred, blood transfusions can be administered (usually via the lateral tail vein or jugular vein). With transfusions into inbred and F1 hybrid rodent strains, as well as naive animals, blood typing is usually not needed and transfusion reactions seldom occur.

Animals that do not have normal daily water consumption within 24 hours of recovery from anesthesia must have the estimated water intake deficit administered orally (i.e., maybe oral gavage), or parentrally on a daily basis, until normal intake has resumed. Animals that do not exhibit normal intake of water will not have corresponding normal intake of solid food.

Total Blood Volume:

- Mouse: 5.85 ml/100 gm body weight
- Rat: 57.5-69.9 ml/100 gm body weight
- Hamster: 65-80 ml/kg body weight
- Guinea Pig: 69-75 mg/kg body weight

Normal Daily Water Consumption:

- Mouse: 15 ml/100 gm body weight
- Rat: 7-10 ml/100 gm body weight
- Hamster: 7-12 ml/100 gm body weight
- Guinea Pig: 10 mg/100 gm body weight

Remember: If these items are not written in your protocol, contact a DLAR veterinarian to help build an appropriate treatment plan.

MANAGEMENT OF INFECTIONS

The routine use of postoperative antibiotics is not recommended in lieu of strict adherence to aseptic surgical techniques. If there is a concern that necessary asepsis has been compromised during the surgery/procedure, the investigator should consult with the Duke veterinarian staff concerning what appropriate broad-spectrum antibiotics are available for administration to rodents.