RECENT UPDATES TO THE ANIMAL USE APPLICATION PROCESS
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The Office of Animal Welfare Assurance is responsible for assuring that laboratory animal use at Duke is performed in compliance with Public Health Service (PHS) policy, U.S. Department of Agriculture Animal Welfare Regulations, the Association for Assessment and Accreditation of Laboratory Animal Care and Use International (AAALAC) standards and Duke’s institutional policies. We are continually enhancing our Animal Use Application (protocol form) and review process to reflect current changes in policy in accordance with guidance from the Office of Laboratory Animal Welfare (OLAW) at the National Institutes of Health (NIH). Our overarching goal is to facilitate research at Duke and ensure appropriate funding. Here are a few suggestions which may help you receive more rapid approvals for protocols/amendments, and decrease risk of non-compliance.

The New “Guide”: The long-awaited 8th edition of the “Guide for the Care and Use of Laboratory Animals” was recently published. This was the first revision since 1996. This publication is the main resource used by AAALAC to assess animal programs. The new “Guide” is currently under review at Duke and across the laboratory animal research community. Stay tuned for updates!

Download the Updated Protocol Form: One method that the IACUC uses to maintain compliance and stay current with rules and regulations is to enhance the protocol and amendment forms to capture new required information. To ensure that your application is complete, you should download the most recent version of the protocol form from our website at http://vetmed.duhs.duke.edu/index_of_new_protocol.htm, each time that you write a new protocol or an amendment.

Literature Search for Alternatives to Painful Procedures (Section B3): The “Guide” and the Animal Welfare Regulations both require that investigators consider and search for alternatives to proposed animal procedures that may result in pain and distress. Possible alternatives may include less invasive procedures, alternate species, isolated organ preparation, cell or tissue culture or computer models and simulations. The IACUC is required to review the investigator’s literature search.

To this end, we’ve made some changes in Section B3 which require that the potentially painful procedures be specified. In addition to other relevant terms, the word “alternative(s)” is now required as a search term.

USDA Categories of Use: What procedures define animal “use?” It’s been our historical practice at Duke, and many other institutions, to consider sample collection for genotype evaluation and identification methods (toe clipping, ear notching) as routine breeding husbandry (USDA Category B). However, in accordance with recent OLAW guidance, we are expanding our definition of animal “use” to include these procedures. Therefore, when considering the distribution of animals across USDA categories, any animal that undergoes genotyping or invasive identification procedures should be considered in Category C (Non-painful procedures) or D (Procedures using anesthesia/analgesia), as appropriate.

Counting Embryos and/or Pre-weaning Animals: It is the intent of applicable laws and regulations that all animals be “covered” by an IACUC-approved protocol. Although there is no specific requirement for how these animals are tracked, there is an indirect requirement to document their numbers and use. In the past, the total animal number of animals the IACUC approved did not reflect the disposition of neonates. This will include those used for experimentation, transferred to another protocol, or euthanized either as embryos or prior to weaning. OLAW guidance says that these animals must now be counted. However, the numbers of mice used or euthanized as embryos or prior to weaning generated should be counted separately from any that are weaned for use in experiments. This is necessary since the animal tracking system used by the Division of Laboratory Animal Resources (DLAR) is not currently set up to track rodents prior to weaning. To accommodate these considerations, we’re implementing some changes in Sections Q (Breeding Colony) and Section B8 (Animal Numbers) to capture the required information more accurately. If embryos or preweaning neonates are to be generated on your protocol, the total number expected should be listed in Section Q (Breeding), in the box labeled “Expected Offspring.” The portion of that total which will be euthanized before weaning should be included in Section B8 under “Animals euthanized as embryos or prior to weaning” divided according to the appropriate Category of Use. Section Q will also ask for a more detailed explanation of the disposition of neonates. This will include those used for experimentation, transferred to another protocol, or euthanized since they are unneeded or of the wrong genotype. If you need assistance completing the new forms, please contact me at debbie.vanderford@duke.edu.
2010 Training Re-Cap: PI and Research Staff Training

For those of you who participate in these events, thank you! If you haven’t been able to participate, here’s some of what you missed in 2010.

Animal Tracks: Ten (10) issues of the research community newsletter “Animal Tracks” were published in 2010. Back copies are available on the animal program website at: http://vetmed.duhs.duke.edu/index_of_training.htm

Web Training Through AALAS: Four hundred fifty (450) Duke researchers had an account on the AALAS Learning Library! This resource, available free-of-charge to staff or employees of Duke, has almost every web training course for animal care and use that you might need! Contact Bill Wade (w.wade@duke.edu) if you would like to enroll in this extensive and cost free on-line training opportunity.

Brown Bag Seminars: Eighteen (18) Brown Bag Seminars were hosted for Duke research staff during 2010. Topics included Protocol Development, FBR Grand Rounds, JAX labs, Charles River labs and many more. In 2010, 724 staff members participated in one or more of these Brown Bag sessions.

Thanks again for your participation this past year. We look forward to seeing you again.

REMINDER ON ANNUAL REFRESHER TRAINING: The Duke IACUC requires annual training for PIs and research staff. The 2011 edition of the Annual Refresher Training (ART) has been posted on the OESO web site. ART is required prior to 1 April of each year. Failing to complete ART by April will delay processing of protocols or amendments. To check your status please go to www.safety.duke.edu

AALAS Issues Position Statement on Animal Rights Terrorists

Memphis, TN - The American association for Laboratory Animal Science (AALAS) has released a position statement condemning threats and harassments made to those who work with animals in research. Following is AALAS’s response:

The American Association for Laboratory Animal Science (AALAS) is dedicated to advancing responsible laboratory animal care and use for the scientific and medical benefit of both people and animals. AALAS and its members willingly join with other groups and individuals concerned about animal welfare to publicly condemn any violence, threats, and harassment to, and intimidation of individuals and businesses involved in the research process. AALAS believes that ethical and humane conduct of animal-based research has contributed, and will continue to contribute, to the advancement of science and medicine. Acts of terrorism do not result in improvements in animal welfare. Progress comes only from thoughtful discussion and scientific assessment of alternative methods that refine the animal research process—efforts that AALAS itself fosters through educational and scientific programs. Terrorism in the name of “animal rights” jeopardizes the lives of people and animals—in the present by the violence itself, and in the future by hindering the progress of ethical animal-based research designed to find cures and treatments for diseases that affect humans and animals. The AALAS memberships extends heartfelt support to our scientific colleagues and their families who have been affected by threats and acts of violence.

SPRING SEMIANNUAL SITE VISIT SCHEDULE SET

The semiannual site visit schedule for Spring 2011 is listed below. Please make a note on your calendars for your facility.

- FEB 3 2011: LSRC—SANDS
- FEB 10, 2011: GSRB2
- MAR 3, 2011: JONES—ENG (TEER)—RP 2/3/4—GSRB2 ANNEX, GSRB1
- MAR 10, 2011: Marine Lab—Museum of Life and Science
- MAR 17, 2011: CARL—EYE CENTER—DLAR FARM—INDY PARK
- MAR 31, 2011: CCIF
- APR 7, 2011: FOSTER ST.—BIO SCI—FEL—FRENCH FAMILY SCI
- APR 14, 2011: DUKE NORTH/SOUTH—GHRB—CIEMAS
- APR 21, 2011: VIVARIUM—MSRB
- MAY 5, 2011: LEMUR CENTER—ECOTOX FACILITY

If you have any questions please contact Bill Wade at 668.6722 or w.wade@duke.edu

R.A.C.C. program under way.

The first Research Animal Coordinator Certification (RACC) program class began on Monday, November 8, 2010. There are currently four classes enrolled and a total of 25 students. Classes meet each week in Hock Plaza and will run until August 2011. The curriculum is designed to prepare participants for a greater role in managing all protocol and research related activities. The course consists of both didactic and web based training modules. If you are interested in participating in this program please contact Bill Wade 668.6722 or w.wade@duke.edu
The Academy of Surgical Research was founded in 1982 with a mission to:

- Encourage, foster, promote and advance professional and academic standards, education, research and development in the arts and sciences of experimental surgery.
- Encourage the advancement of the field of surgery in all aspects, including research, education and critical promotion of research products for clinical applications.
- Promote humane use and treatment of experimental animals and support the use of alternatives when possible.

To help accomplish this mission, the Academy created the Surgical Research Specialist (SRS) certification. Starting in 2006, the Academy expanded the certification program to include the Surgical Research Technician (SRT) and Surgical Research Anesthetist (SRA).

**Levels of Certification**

- **Surgical Research Specialist (SRS):** The SRS certification is based upon the demonstration of knowledge to perform basic aseptic survival surgery on animals.
- **Surgical Research Technician (SRT):** The SRT certification is oriented towards individuals who perform minor surgical procedures.
- **Surgical Research Anesthetist (SRA):** The SRA certification is oriented towards individuals working as anesthetists that also have responsibilities as part of the surgical team that include aseptic preparation and perioperative care for surgical patients.

**Requirements for Certification**

The candidates for SRS, SRT and SRA certification are required to maintain a log that lists in detail the procedures performed animal species, candidate’s role or responsibility and the outcome. For each certification level a log of at least 12 months must be kept, recorded and submitted as part of the application process. This surgical log also reinforces the importance of outcomes monitoring as a life-long responsibility of individuals performing aseptic survival surgery. In addition, each certification level requires validation of a candidate’s knowledge by passing a comprehensive exam. Each level of certification has specific case log and narratives requirements.

**Surgical Research Specialist (SRS)**

- **Case Log:** SRS candidates must have a minimum of 24 procedures of significant complexity. There must be at least two different procedures reflected in this total with the exception listed below and the applicant must have acted as the primary surgeon.
- **Narrative:** Narratives should comprehensively describe all aspects of the procedure and include the following minimums: drug regimens, anesthetic and analgesic regimen, animal preparation, post operative monitoring and pain assessment.

**Surgical Research Technician (SRT)**

- **Case Log:** SRT candidates must have a minimum of 12 survival aseptically procedures (minor or major surgical procedures).
- **Narrative:** Narratives should comprehensively describe all aspects of the procedure and include the following minimums: drug regimens, anesthetic and analgesic regimen, animal preparation, detailed description of surgical technique, acceptable survival surgical procedures, post operative monitoring and pain assessment.

**Surgical Research Anesthetist (SRA)**

- **Case Log:** SRA candidates must have 15 cases where they served as anesthetist. Acceptable cases must be longer than 30 minutes of surgical duration, have had the candidate present from induction through recovery and a minimum of monitoring to include heart rate, respiratory rate, body temperature and at least one of the following parameters: blood pressure, SaO2, Expiratory CO2, Inspiratory CO2. Rodents will require justification from the candidate to prevent inclusion of common “stick and leave” anesthetic regimens.

**NOTE:** As of 4/15/11, the CASE LOG requirement will increase to 30 cases, with no more than 15 involving the same species (for example, 15 cynos, 10 rabbits, and 5 beagles; or 15 or two species).
- **Narrative:** Narratives will include 2 anesthesia case reports reflected in the case log including a detailed description of actions taken and changes in the animal’s anesthesia state during a surgical procedure as well as the trends evidenced during the procedure and their likely causes.
If you’ve ever worked with rodents, one of the hardest procedures to perform reliably is endotracheal intubation. You’re either good at it or you’re intimidated by it. Practice does make perfect, but who has time for that?

One of our main problems is that after someone has been trained and becomes proficient in rat intubation, they may not need to perform this procedure for several months. Within that time, the person may lose proficiency and confidence at the technique. Other complications associated with intubation are:

- Technically challenging (time consuming and stressful)
- Tissue trauma can be caused to the larynx
- Post-intubation complications due to trauma (e.g. swelling)
- Length of intubation tube can vary from one rat to another or male to female

While on a quest to find a more reliable procedure I was given a golden nugget. The simple ventilation technique described below was shown to me by Farhad Forudi, a technologist from the Cleveland Clinic. The technique saves so much time and reduces the other potential complications of intubation!

Once the animal is anesthetized, place a modified Foley catheter over the animal’s nose. Secure the thin rubber band behind the upper incisors (tape can be used as a substitute for a rubber band if the incisors are too small) and viola you’re animal is ventilated.

One of the complications we’ve encountered is ventilating the stomach along with the lungs. Steve McBrian, my co-worker and expert at this technique, will manipulate the head to insure the animal’s lungs are ventilated and not their stomach.

We use some of the following techniques if you encounter this problem:
- Straighten out the neck
- Pull the rubber band tighter
- Place a rolled gauze under the head/neck
- Turn down the ventilator volume
- Reposition the arms

Additional items you will need:
- Ventilator; I use a Harvard Small Animal Ventilator – Volume Controlled Single Animal
- Thin Rubber Band
- Tape
- 12Fr or 14Fr Bard Foley Catheter (123614A); trimmed to ~ 1”

Once you figure out all the little quirks it’s like riding a bike, no matter how long it’s been you can pick it right back up.
According to the Zogby International public opinion survey (November 29 – December 1), public support for the use of animals in biomedical research now stands at 60.1%. The same poll reported public support of 55.8% in October and 52.7% in September. The poll has a margin of error of 2.2% +/- . Here’s how ALL demographics from the latest poll break down:

**SUPPORT BY REGION**
- East: 43.20%
- South: 66.90%
- Midwest: 73.20%
- West: 51.40%

**SUPPORT BY POLITICAL PARTY**
- Dems: 50.90%
- Repubs: 67.30%
- Independents: 63.50%

**SUPPORT BY IDEOLOGY**
- Liberal: 52.30%
- Moderate: 58.30%
- Conservative: 68.10%

**SUPPORT BY RACE**
- White: 61.00%
- Hispanic: 60.80%
- AfrAmer: 53.60%
- Asian: 61.20%

**SUPPORT BY RELIGION**
- Catholic: 60.30%
- Protestant: 62.20%
- Jewish: 30.30%
- Other: 55.20%

**SUPPORT BY GENDER**
- Male: 69.20%
- Female: 51.60%

The message is clear. Barely over half, and in some cases very barely over half, of society supports the use of animals in research. There have been examples of unacceptable situations involving animals (the recent case just north of us at the testing lab with dogs), but at the end of the day … if these results slip to the lower side of 50, then the medical breakthroughs so many depend upon may not be possible. In 2011, make it a goal to communicate the value of animal based research, the wonderful care your animals receive and the need for continued research efforts!

Want to hold your animals in your laboratory for longer than 12 hours? Here are the requirements to have a PI Managed Housing Facility:

- PI Managed Housing is defined as those areas where animals are held or used for greater than 11 hours and 59 minutes (the 12 hour rule). IACUC approval for holding animals in the laboratory for 12 or more hours is a federal requirement.
- PI Managed Housing approval requires:
  - Step 1: IACUC approval of a scientific justification for holding the animals in the laboratory for 12 or more hours; and
  - Step 2: IACUC Subcommittee inspection and approval of the proposed housing site. Maximum census for the PI Managed Housing area is verified during the Subcommittee inspection.
  - Standard Operating Procedures (SOPs) for animal care, sanitation, daily observations, and general housekeeping.
  - An Adverse Event Plan (AEP) for the specific facility must be on file with the OAWA prior to approval for housing.

- In addition to the facility specific items, all research staff working in these areas must have completed Animal Handler’s I & II training on line as well as the modules on Husbandry and Veterinary Care for Investigator—Managed Rodent or Non-Rodent colonies. These modules are designed to familiarize PIs and their staff on health monitoring and reporting, daily record keeping and basic husbandry requirements.

If you work in a PI managed area and have questions or need assistance in making sure that you are in compliance please contact Bill Wade @ 668.6722 or w.wade@duke.edu

**Upcoming Dates & Deadlines**

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
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<tr>
<td>Feb 7</td>
<td>New Protocol Deadline</td>
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<td>Amendment Deadline</td>
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<td>Feb 21</td>
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<td>Amendment Deadline</td>
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<td>New Protocol Deadline</td>
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