ANIMAL HANDLER III 
(Annual Refresher Training)

The ‘Annual Refresher Training’ (also called AH III) has been created, IACUC approved, and posted to the OESO website. All Duke animal protocol participants must complete the AH III training in January of each year.

Go to your OESO training page to log in (http://www.safety.duke.edu/Training/) to complete the web training for 2013.

AH III Training completion is required for all protocol participants before approval of a new protocol or amendments to existing protocols. No need to wait, go on-line and complete it today.

CONGRUENCY REVIEWS

Congruency reviews, is a comparison between the grant (submitted to the funding agency) and the protocol (reviewed by the IACUC), are required prior to:
- Release of grant funds by the funding agency; and
- Initiation of collaborative animal work between institutions.

Congruency reviews are performed by the OAWA or IACUC and generally require 5-7 business days to complete. Why so long? To be congruent, every animal activity described in the grant, even those in years 4 or 5 and activities performed by others, must be IACUC approved before the congruency letter can be generated.

You can facilitate the congruency review by providing an electronic copy of your grant when you submit your protocol to IACUC@duke.edu. If your grant is approved out-of—cycle with your protocol, a congruency review can still be performed.

The secret? PLAN AHEAD! If you think you MAY need a congruency review, request it up front, because these reviews cannot be rushed!

PROTOCOL TEMPLATES

The NIH’s acceptance of the new Guide for the Care & Use of Laboratory Animals as the core reference document for animal care & use management has created several wrinkles, although most are minor. The NIH’s implementation the new Guide at the federal level has required modifications within our institutional program, and specifically as it involves the animal protocol template. For example, there are new sections (‘B12: Use of Pharmaceutical Grade Chemicals and Substances’ and ‘B13: Photography / Video Images of Research Animals and Tissues’). There are also subtle changes to existing sections (‘C1: Housing Arrangements’).

Researchers must assure they are using the current version of the Duke protocol template. How do you know what is the latest version? The version on the animal program website is always the current version. Some researchers download a copy of the template to keep on their hard drive, and that is fine, but always confirm you have the latest version by comparing your document version with that on the website. The key is in the footer of page 1 of the template. It will read: ‘Version 2012 10 <or the current version number>’

The IACUC must review all proposals for animal use based upon current regulatory obligations and expectations.

The IACUC generally grants a grace period for researcher currently writing a new protocol when the version changes, but as of today, the current version is 2012 11 (November) and the grace period will expire with the January IACUC meeting!

Amendment forms changes much less frequently, so also check to see if you are using the current Amendment Form version.

The safest approach? Always download the version on the animal program website—it is always a current version.
The Duke animal program recognizes that minors and non-employees may have justifiable reasons for working with animals at Duke, including education as a prospective scientist or collaborative activities with educational or other organizations. To provide a safe and healthful work environment, while also recognizing the sensitivity of the animal’s environmental needs, the Duke IACUC has approved a policy for minors and non-employees regarding handling of animals or tissues.

- An individual who has reached their 14th birthday (Minor 14) may observe animal care and animal use, but may not handle any animals, animal tissues, or research agents or products.
- An individual who has reached their 16th birthday (Minor 16) may handle animals (other than non-human primates or livestock), animal tissues, research agents or products, but may not handle any hazardous agents or materials having hazardous potential.
- An individual who has reached their 18th birthday (Adult) may perform any IACUC-approved activity.

In all cases, persons must be listed on the approved protocol as a protocol participant (Section A-3).

OESO clearance is also required for all cases. The sponsor and/or supervisor must submit and receive approval for the work using the “Workplace Safety Statement for Minors and Non-Employees” policy. The supervisor must provide OESO with:

- Primary Mentor / Sponsor(s): (Supervisor and Primary Investigator Name(s), if applicable
- Location of Work: (Department, Building, Room Number(s))
- Describe expected duties: List the biological material and chemicals.

NOTE: Minors and Non-employees cannot work with or be exposed to human blood or body fluids or other potentially infectious material to include primary human cells. Certain hazardous chemicals and radiologicals are also restricted.

For more information, visit the Animal Program Website Policy Page; select ‘Minors & Non-Employees Working with Duke Animals.’

Duke animals must be protected from distress associated with non-routine visitation or photography/video lights. Even minor distress such as unfamiliar persons/smells, may affect research outcomes and animal well-being. Access to Duke-owned animals is strictly controlled and visitors are approved on a case-by-case basis.

All visitation/photography must follow the DLAR Biosafety Flow Patterns which protects animals from disease and enhances animal well-being, animal welfare, and research outcomes.

- **Duke researchers** may visit any facility for which they have need or purpose (e.g., approved protocol, collaboration, or serving an oversight role).

- **Compliance Liaisons / Regulatory Inspectors** may audit/inspect animal care activities at any time.

- **Visiting Faculty, Scientists, or Prospective Employees** shall be escorted at all times while in the animal areas. No contact with animals is permitted, unless the individual is listed in Section A-3 of a Duke approved protocol (which also requires clearance of the OESO and the EOHW).

- **The General Public (includes family members and friends)** are encouraged to visit the Duke Lemur Center. The Lemur Center does not generally permit handling of their animals, except as would be directed and approved by DLC supervisory staff.

- **When media** wish to visit animal care areas, they must be escorted by a Duke employee having the approved access to the specific animal space. No direct contact with any animal is authorized. Additionally, media require:
  - Clearance by the Director, DLAR (or designee) for photography/video. The Lemur Center staff provide Lemur Center clearance.
  - Clearance by the Duke Office of Communication.

For more information, see the full policy on the Animal Program Website Policy Page; select ‘Visitation, Observations, or Photography of Duke-Owned Animals.’
**Academy of Surgical Research Certification Programs**

Proper training of personnel involved in research activities is being emphasized more than ever, especially with the USDA declaring this the "Age of Enforcement". The Academy of Surgical Research offers certifications which can be used to document the training of your personnel involved in studies utilizing anesthesia and surgery (as required in Section 4 Veterinary Care of the Guide).

The Academy offers three certifications:

- Surgical Research Anesthetist (SRA),
- Surgical Research Technician (SRT), and
- Surgical Research Specialist (SRS).

For each certification, the applicant must meet set criteria, and submit a case log along with two narratives. If accepted, they then must pass a comprehensive exam. Once certified, individuals must submit CEUs every other year to maintain their certification. Please refer to the enclosed brochure for details regarding specific requirements for each certification.

The Academy of Surgical Research holds an annual meeting at rotating sites in the fall, usually October. We provide hands on training through various wet labs, as well as traditional seminars and keynote presentations. Please visit the ASR Website for information on next year's meeting and further information on our certifications. You may also contact the ASR Certification Committee with questions.

Sincerely,

Lisa Johnson, BA, SRS, LATg
Chairperson Certification Committee
Academy of Surgical Research

**Foundation or Biomedical Research Seeking Articles:**

The Foundation is looking for previously published and cleared stories with high resolution photos that deal with basic or applied research featuring animal models and are written for a general consumer audience. These can be new articles or "evergreen" articles published within the last few years.

The Foundation provides your institution with full attribution including bylines and photo credits. They DO NOT edit the stories, but rather they are inserted "as is" with your permission. You can see a PDF copy of a recent issue at image below for an idea of the types of stories we are looking for:

The most recent issue of the magazine featured reprinted articles from Virginia Tech, University of North Carolina, Dartmouth College, Oklahoma State University, and the National Center for Research Resources, just to name a few!

These articles can come from corporate magazines, alumni magazines, medical school magazines, or vet school magazines, for example.

In general, press releases, journal articles, or stories with a great deal of technical jargon are not a good match for this publication. Articles that have already appeared in your quarterly magazine, alumni magazine or staff newsletter are a good match. They should be about 1,000-1,500 words long, and written for a general audience. Stories showing how animal research has helped children, wildlife, or pets are especially valuable.

Not suitable: Press releases and scientific journal articles.

Please check with your Communications/PR staff and see if you have any suitable articles that can be submitted. The submission deadline for our Winter issue is Monday, December 3rd. Each issue is packaged with a different special bonus, sometimes a DVD, sometimes a poster or other educational program.

Please submit your articles to Michael Stebbins at info@fbresearch.org. If you have any questions, please feel free to call us at 202-457-0654. Advertising opportunities also available.

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**Safeguarding animal welfare is the responsibility of every Duke Animal Program participant!**

**REPORT ANIMAL HEALTH EMERGENCIES** to DLAR using the Veterinary Pager (24 hrs/day): 919-970-9410

**REPORT ANIMAL WELFARE CONCERNS** to the OAWA via the Animal Welfare Hotline: 919-684-3535 or to the IACUC at iacuc@duke.edu

The identity of any person making a report is always kept confidential. Reporting individuals are protected against reprisals.
WHAT INVESTIGATORS NEED TO KNOW ABOUT THE USE OF ANIMALS
(From the NIH Web)

Principal investigators are responsible for the scientific and technical aspects of a grant award and must ensure compliance with Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals when using live, vertebrate animals. PHS Policy incorporates U.S. Government Principles, the Guide for the Care and Use of Laboratory Animals, and the Report of the American Veterinary Medical Association (AVMA) Panel on Euthanasia. Vertebrate animals include traditional laboratory animals, farm animals, wildlife, and aquatic animals. Animal use encompasses research, teaching, or testing. Generation of custom antibodies is considered an activity involving vertebrate animals.

Who Must Comply With the PHS Policy? The PHS Policy on Humane Care and Use of Laboratory Animals applies to extramural and intramural activities supported by any PHS agency, including the National Institutes of Health (NIH), the Food and Drug Administration, and the Centers for Disease Control and Prevention. All funding mechanisms, including research and training grants, cooperative agreements, and contracts, conducted at domestic and foreign institutions, are covered by the Policy.

What Is the IACUCs Task? Institutional Animal Care and Use Committees (IACUCs) are local institutional committees with federally mandated oversight responsibilities, including:

• Reviewing animal-use protocols;
• Reviewing significant changes to protocols;
• Evaluating institutional compliance with PHS Policy, U.S. Department of Agriculture (USDA) Animal Welfare Regulations, and institutional policies;
• Monitoring institutional animal care and use programs, including inspecting animal facilities;
• Reviewing concerns about animal care or use;
• Reporting noncompliance and suspensions to the Office of Laboratory Animal Welfare (OLAW)

Institutional and Investigator Responsibilities: The NIH has certain specific and detailed expectations of Duke and each Investigator holding a federally funded grant. These expectations include:

• Describing proposed use of animals in grant applications.
• Obtaining IACUC approval prior to using animals and prior to implementing significant changes.
• Ensuring research is conducted in accord with the protocol.
• Complying with institutional policies and procedures.
• Addressing significant changes to the use of animals in progress reports.
• Addressing changes in the use of animals that may be a potential change in scope of the grant.

How to Write an Application Involving Research Animals: New investigators, or post docs wishing to learn, can complete the on-line tutorial at the NIH website listed as: http://www.niaid.nih.gov/ncn/clinical/researchanimals/tutoriaUindex.htm While the tutorial differs form the Duke protocol template, the concepts and procedures are applicable to the Duke template.

Applying for Funding: The proposed involvement of vertebrate animals is evaluated as part of the agency peer review process. In addition to providing IACUC approval status, applicants must address five points in the Research Plan of the grant application:

1. A detailed description of the proposed use of the animals, including species, strains, ages, sex, and numbers.
2. Justification of the use of animals, choice of species, and numbers to be used.
3. Information on the veterinary care of the animals.
4. A description of the procedures for ensuring humane treatment (i.e., minimization of discomfort, distress, pain, and injury).
5. The method of euthanasia, the reasons for its selection, and consistency with the AVMA Euthanasia Report.

Failure to address these elements will result in the application being designated incomplete and is grounds for PHS to defer the application or may negatively affect the priority score.
Obtaining IACUC Review: IACUC approval is required prior to award except in rare circumstances. The use of animals as described in the protocol approved by the IACUC must be congruent with the description in a competing grant application. Any modification required by the IACUC that affects the content of the application must be submitted to the agency along with the IACUC approval date.

Receiving all Award: To receive an award the grantee organization and every performance site where animal work will be performed must have an Animal Welfare Assurance approved by OLAW. OLAW will contact an organization with specific instructions when an Assurance is required. An institutional Assurance is negotiated when the grantee does not have its own animal facilities and the animal work will be performed at an institution with an Assurance.

Working with a foreign (non-US) institution? Foreign institutions provide a Statement of Compliance with Standards for Humane Care and Use of Animals.

Past Award
IACUC approval is required at least every 3 years (annually if covered by USDA regulations). Significant changes in animal care and use are to be approved by the IACUC prior to implementation. Check with your IACUC to determine what constitutes a significant change. Conducting research in the absence of a valid IACUC approval or implementing a significant change without IACUC approval constitutes non-compliance.

Investigators also must be aware of and comply with additional institutional policies that may be more restrictive.

For additional information:
- http://www.nap.edu/readingroom/books/labrats

Note: You can view the entire text of this publication online at http://grants.nih.gov/grants/olaw/GuideBook.pdf
PROCEDURE FOR HANDLING FIRE ALARM ACTIVATION DURING ANESTHETIZED ANIMAL PROCEDURES

Working with the OESO, the Duke Animal Program has established a policy that described expectations during fire alarms. The Policy addresses humane and ethical concerns or leaving animals anesthetized during routine or un-complicated fire alarms, and includes appropriate human safety assurance.

The full text of the policy is available on the Animal Program Website.

These procedure should only be followed when the fire alarm is activated during an anesthetized animal research procedure. Research procedures on deceased animals or other animal components are not affected by this policy and those involved are REQUIRED TO LEAVE THE AREA IMMEDIATELY UPON FIRE ALARM ACTIVATION.

SCHEDULED FIRE DRILLS

The OESO Fire Safety Office will post notices of a scheduled fire drill at least 48 hours in advance stating the date and window of time the drill will occur. If an unavoidable conflict arises, the research personnel must notify the OESO Fire Safety office immediately. Our main office phone number will be posted on the notice. If no prior notification is given, the drill will be held, and ALL OCCUPANTS ARE REQUIRED TO EXIT THE BUILDING IMMEDIATELY!

FIRE ALARM ACTIVATIONS

In every animal surgical lab, there will be a poster permanently displayed in a visible location which lists a building contact person, an alternate contact person, and their mobile phone numbers. The designated contact persons for fire alarm evacuations will be determined by the department(s) upon the receipt of this policy. Alternates will also be determined. A list of contact persons and their cell phone numbers will be distributed to all animal procedural areas.

If the fire alarm is activated, the research personnel check the areas for signs for smoke, fire, toxins or other dangers. ONLY if they do not see any immediate signs of smoke, fire, or other hazards, they will immediately contact the department designated contact person in the building and state that they are remaining in the laboratory because they are performing an animal procedure on an anesthetized animal. If they decide to evacuate, they shall still notify the building contact of this as well. This ensures proper accountability.

If the research personnel and designee are remaining in the lab, the laboratory designee (if applicable) will continue to serve as a lookout person for signs for smoke, fire, or other hazards, and in charge of communications with the building contact person. If no others persons are in the lab to serve as a laboratory designee, the research personnel must watch for signs of changing conditions to the best of his/her ability.

The building contact person will notify responding units of the person(s) remaining in the laboratory and their exact location.

The building contact person will notify the research personnel or his/her designee immediately if conditions deteriorate and evacuation is necessary.

If evacuation is necessary, the research personnel and his/her designee will then take steps to safely and quickly euthanize the animal (e.g. perform a bilateral thoracotomy while anesthetized), if conditions allow, and evacuate the building immediately.

If the research personnel are alone when conducting the procedure, the research personnel shall notify the building contact person that the procedure is complete. Any alarms after this point will require prompt evacuation from the building for all occupants.

OESO HAS SEVERAL GUIDELINES FOR SOP DEVELOPMENT OF HAZARDOUS AGENT USE IN ANIMAL PROTOCOLS

OESO Biosafety Division has a great web site which assists with specific SOP development! For example:

- Guide for Developing an SOP for the use of Biohazards in Animals
- Guide for Developing SOP for the use of Hazardous Drugs
- SOP for the use of Toxic Chemicals in Animals
- Guidelines for the Safe Handling of Animals Exposed to LPS in Research
- Radiation Safety Animal Care and Use Protocol Wizard

You can reach the OESO Biosafety site at: http://www.safety.duke.edu/BioSafety/Animals.htm
A common compliance issue involves inappropriate animal housing density—either too much or too few. According to the 8th Edition of The Guide, animal should be provided with at least a certain living space to allow for normal postural adjustments and behavioral needs. The Duke Animal Program has rodent caging ranging from 67 - 75 square inches, so it is not as simple as saying 'x' is the required number of mice per cage in all situations.

When overcrowded conditions exist, the IACUC has established a series of steps to assure the well-being needs of the animal have been addressed while providing maximal flexibility for the research team in meeting their research objective.

As a general rule (and based on the space requirements identified in The Guide), no more than two adults may be in a cage when a litter is born. A litter includes any number of pups born to a single dam at the same parturition. In cases of extremely large litters, it may be helpful to divide the litters between two cages and foster half of the litter on to a nursing dam. It is not acceptable to add a nursing dam to a cage where there is a large litter. More than one litter and two adults per cage will require IACUC approval as an exemption (Section U: Exemption from Animal Welfare Standards). Any exemption must be marked on the designated cage card. If these conditions are exceeded, it may constitutes an ‘incident’ of animal overcrowding.

The expected ‘standard’ is for mouse pups to be weaned by 21 days of age. The weaning age may be extended if delayed weaning has been approved by the IACUC (or by DLAR veterinary staff for health concerns). In cases of approved delayed weaning, cages should be marked with date of weaning.

Breeding cages containing pups 22 days of age or older without IACUC approval are considered overcrowded, and may result in an IACUC reportable ‘incident.’

Generally, no more than one litter may be present in the cage at any given time. The IACUC does entertain exceptions for multiple litters if the strain exhibits ‘failure to thrive’ or is a ‘poor breeder.’

An incident of overcrowding must meet the following two (2) conditions:

1. A cage exhibiting excessive density has not been corrected by the PI within two business days of DLAR notification. Excessive density events resolved by the PI within two business days of notification by DLAR are not be counted as an incident; and

2. Any number of cages that occur within a 3 business day period of the first identified incident are considered a single incident. Subsequent unresolved overcrowding events are considered separate incidents if they occur >3 business days from the first identified and unresolved overcrowding incident. As an example, overcrowded cages identified on a Monday (calendar day 1), and Tuesday (calendar day 2). Neither are resolved within 2 business of DLAR notification. These are considered the same incident. Another example involves overcrowded cages are identified on Monday (calendar day 1) and Thursday (calendar day 4) of the same week. Neither are resolved within 2 business of DLAR notification. These are considered two separate incidents, and may be reportable to the IACUC for deliberation of formal corrective action.

For more animal density details, visit the Animal Program Website, Policy Page.