The ‘Annual Refresher Training’ (also called AH III) has been IACUC-approved and will be hosted on the OESO Safety Training website (http://www.safety.duke.edu), and will be available early in January 2015. The DUE DATE for completion of the 2015 AH III module is 30 January 2015.

Every protocol participant are required to complete this ‘refresher training’ module, but before you plan tons of time sit for excruciating boring web training, here’s a couple of reminders on what AH III is designed to do. AH III is:

⇒ Only 10 pages (or screens) long.
⇒ Focused upon the more significant or more commonly occurring issues in 2014.
⇒ A good reminder on our obligations for animal use.
⇒ Meets the NIH & USDA expectations for ongoing training.
⇒ Not even long enough to finish a cup of coffee, an Almond Joy, or a stick of celery!

You’ll get a tickler from the server sometime around mid-January as a reminder, but no need to wait. Got 15 minutes? Go on-line to the OESO training web and complete the annual refresher web training.

Wishing you a successful research month!

Biomedical research, testing, and teaching programs involving animals often require controlled substances for prevention of pain or distress. Controlled substances are used to produce anesthesia, analgesia, tranquilization, sedation, hypnosis, euthanasia, or as a means to study the actions of specified drug regimens. Controlled substances have the potential for misuse. Accordingly, the federal agencies (DEA) and state offices (DHHS) require individuals using controlled substances to obtain both state and federal registrations, and to abide by the guidance describing licensing, storage, distribution, use, and disposal of controlled substances.

Registration for use of controlled substances is an individual obligation – there is no statutory requirement for institutional management of controlled substance registration. Even so, Duke University has an interest in the health and well-being of its animals and regulatory compliance of its researchers, employees, faculty, and staff. Therefore, the Duke Office of Animal Welfare Assurance (OAWA) will assist controlled substance registrants by providing guidance and oversight, which will help assure compliance with all federal regulations, state rules, and institutional requirements.

OAWA has established procedures for local use of controlled substances in animals under Duke approved research protocols. These procedures apply to those situations where controlled substances are being used for animal anesthesia, analgesia, euthanasia, restraint, or experimentation under the auspices of the Duke University animal care & use program. All controlled substance use must be in accordance with the IACUC-approved protocol, or under accepted clinical veterinary guidelines as prescribed by a Duke veterinarian.

For more information, visit the Duke Animal Program Webpage ‘Controlled Substance Procedures.’
MINORS AND/OR NON-EMPLOYEES WORKING WITH ANIMALS

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.'

VISITATION, ANIMAL OBSERVATIONS, OR PHOTOGRAPHY OF DUKE-OWNED 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.'
ADOPTION OF RETIRED RESEARCH ANIMALS

When animals are no longer appropriate for use in research or teaching, they may be available for adoption as pets. But before you get a great idea to have your own lemur or monkey, these species are not candidates for adoption (but you can adopt a lemur through the Adopt-A-Lemur program at the DLC … still can’t take it home). For the other animals, several conditions must be met before adoption is approved. For example, you must:

⇒ Agree not to use the animal as a food source (yes, it has happened),
⇒ Agree to care for the animal in a manner generally accepted as appropriate for a pet of the species,
⇒ Agree with DLAR’s assessment of the animal’s health at the time of transfer (yes, all adopted pets will receive a first-class Duke veterinary clinical and behavioral review prior to release!)

Since these animals were purchased for use in a funded research protocol, the animal must also:

• Not be actively involved in an IACUC-approved animal protocol at the time of the disposition through adoption request.
• Not be eligible for transfer to an existing or new IACUC-approved protocol (i.e. there is no need for the animal in the Duke program).
• Not have any signs of compromised health, either natural or experimentally derived, that would impair its ability to thrive.

What kind of clinical care is provided for the adoptees? All rodents receive a complete physical examination to confirm there is no current evidence of disease. Rabbit, dogs, or cats will be neutered, vaccinated, and have a complete physical examination noting there is no current evidence of disease. Other species may be neutered and vaccination (if it is customary for those provisions in a pet of that species), and have a complete physical examination noting there is no current evidence of disease.

A nominal charge may be assessed for neutering a prospective pet - this fee is for disposable materials only; there is no charge for professional time or equipment use. And there is no charge for the adoption process.

While Duke does not advertise available adoptees, you can talk with DLAR about adopting one of your research animals. And as expected, there will be forms to sign including a liability form, a transfer of ownership form, and a medical agreement form. The adoption will be reported to the IACUC, and all decisions rest with the Director, DLAR.

Does to get any better? Well, actually it does! You get to have a life-long friend who was a hero as a research animal and helped push back the boundaries of ignorance! Pretty cool!
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/tutorialUindex.htm While the tutorial differs from 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 inter-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

Review of Grants and Contracts Submitted to PHS
(Adapted from the Institutional Animal Care and Use Committee Guidebook)

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.

As a PHS Assured institution, Duke University 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
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