Researcher Annual Training

Beginning in January 2010, individuals listed on an approved animal protocol (PIs and research staff) must complete ‘Annual Refresher Training’ (ART) as part of the approval of a protocol’s Annual Progress Report approval process.

ART may be completed as early in the new calendar year as you choose, and is only required once per calendar year (Jan to Dec), but must be completed prior to approval of an Annual Progress Report. Regardless of the number of approved protocols, ART is only required once each calendar year.

ART does not replace or revisit the initial training (Animal Handler’s 1 & 2) required of new research personnel. ART focuses on compliance trends in the Duke animal program and highlights those where we have had more concerns or where the IACUC believes additional attention is warranted.

ART was designed by the IACUC as a means of educating to prevent serious non-compliances while providing practical and brief updates to changing in federal guidance and reminders of institutional obligations for assuring compliant animal care and use.

ART is brief, and shouldn’t take more than 45 minutes to complete. There are two methods to accomplish ART:

♦ OPTION A: Completing the web module; or
♦ OPTION B: Attending a Brown Bag Seminar where the topic is ‘Annual Refresher Training.’

The Web version includes a brief quiz; the Brown Bag will not have a quiz. Instructions for completing the web module version are included on page ___ of this issue of Animal Tracks and are also on the Animal Program Website on the ‘TRAINING’ page. The Brown Bag Seminar schedule is also included in this issue of Animal Tracks, and may also be found on the Animal Program Website ‘TRAINING’ page.

Wishing you safe and successful research outcomes,

Tips for Writing NIH Grant
(Vertebrate Animal Section <VAS>)

There shouldn’t be a mystery in what information the NIH is seeking when reviewing your VAS of your grant submission. Below is a brief review of the issue and items of interest to the NIH reviewers. This discussion is borrowed heavily from the NIH’s Checklist for VAS review, and modified to reflect the Duke research perspective (http://grants.nih.gov/grants/olaw/VASchecklist.pdf).

Performance site(s): You should specify Duke as the performance site. If Duke is not where animal work will be performed, collaborative performance site must be identified. If more than one performance site is planned, include description of animal care and use for each site. If you are sub-contracting to a researcher at an institution which lacks a PHS Assurance, an Assurance must be negotiated prior to transfer of funds from Duke to the sub-contracting institution. Our institution’s policy is to collaborate only with PHS Assured institutions when using federal funds. Exceptions to this Duke policy may be considered in special circumstances. The process of negotiating an Assurance is initiated by the NIH grants management staff. If you are sub-contracting for work at a foreign performance site, then Duke must confirm the foreign performance site has a Foreign Assurance with the PHS; and you must provide verification of approval of the animal care and use protocol by Duke’s IACUC, certifying to NIH that the activity as conducted at the foreign performance site is acceptable to the grantee.

See Page 5 ... NIH Grant Submission Tips
Dear Labby: I am confused about the requirements for doing rodent and avian surgery. I hear the rules are not the same as for sheep or primate surgery.

Dr. Stitches

Dear Dr. Stitches:

It is true that the federal requirements for rodent versus primate surgery are different, but the central theme remains the same—aspects technique and successful outcomes. The Duke IACUC published a policy earlier this year describing the expectations for mouse, rat, and avian surgery. The policy is of the animal program website (POLICIES link), but we can review the components of the policy as:

The Surgical Area:
- Any dedicated space in a laboratory appropriately managed to minimize contamination from other activities in the room.
- No other activities can be performed in this same area while surgery is being performed.
- Sufficient space for patient preparation and patient recovery must be provided.

Surgical Instruments:
- Sterile instruments are required.
- Instruments must be initially autoclaved or gas sterilized.
- Surgical instruments can be re-used for multiple animals on the same day.
- Between animals, the tips of the instruments should be placed into a glass/ceramic bead sterilizer or other IACUC approved method.

Surgeon preparation (required):
- Hand scrubbing and rinsing of all hand surfaces
- Sterile gloves
- A face mask
- Head cover

Patient Prep:
- Clipping of fur over the patient’s surgical site
- Preparation of surgical site using a 3 layered scrub-rinse process.
- Surgical draping of the disinfected area is required. The IACUC suggests use of adhesive plastic food wrap (e.g. Press-n-Seal is the only currently available product), pulled from a clean roll and applied across the surgical field and surrounding area. The incision can be made directly through the plastic wrap and into the skin.

Dear Labby: My protocol is about to lapse due to circumstances beyond our control. It has taken us a long time to breed and develop our animals for research. Is there any way we can keep from euthanizing our animals?

Mouse Momma

Dear Ms. Momma:

The animal program does not wish that any animal be euthanized needlessly. The good folks at DLAR have created an ‘Animal Holding Protocol’ which can be used in special circumstances, and may be useful for your situation. Eligibility for the holding protocol is determined on a case-by-case basis. Situations which may allow for use of the holding protocols include animals remaining when a protocol becomes inactive (such as an expiring protocol). Other used of the holding protocol include:

- New investigators coming to Duke that require immediate housing of their animals but do not have an approved Duke protocol presently;
- Investigators that are leaving Duke and donot have the necessary approvals for transfer to the new institution;
- Animals on a protocol under investigation for potential issues of non-compliance where the welfare or well-being of the animals is in question; or
- A non-compliance situation where the IACUC has taken the animals into receivership;

For more information, see the IACUC policy on the animal program website or call the DLAR @ 681-6792.
Description of animal use: A concise, but complete description, including sufficient information for evaluation of procedures is required to validate the appropriate use of animals.

No vertebrate animals: If animal tissue used in the study is obtained from other sources (e.g., tissue repository or from animals euthanized for an unrelated purpose), the application may be classified as "no vertebrate animals used." A statement indicating the source of the tissues is required in the VAS to validate the coding as "no vertebrate animals."

Tissue harvest / antibody generation: If animals are manipulated prior to euthanasia or obtained specifically for tissue harvest as part of the proposed research, this constitutes using animals and must be classified as "use of live vertebrate animals." Activities, such as the generation of custom antibodies, constitutes using live vertebrate animals and must be classified as "use of live vertebrate animals."

Animals to be used: Clearly describe / list the Species; Strain; Ages; Sex; and Estimated Number of animals to be used (remember the IACUC protocol requires exact animal numbers proposed). DO NOT grossly over-estimate your grant, because your IACUC protocol must account for the animal numbers listed on your grant.

Justification: Investigators must justify the use of animals in their research:
- The justification must indicate why alternatives to animals (e.g., computer models, cell culture) cannot be used, and should indicate the potential benefits and knowledge to be gained.
- Rationale for the choice of species must be provided. The rationale should indicate the advantages of the species chosen and why alternative species are not appropriate. In the case of non-human primates (NHP), thorough justification for the choice of species is required; comparison of the species chosen to other NHP species may be appropriate. The use of NHP should be noted during review.

Additional considerations:
- Estimates for the number of animals to be used should be as accurate as possible. Justification for the number of animals to be used should include considerations of animal availability, experimental success rate, inclusion of control groups and requirements to reach statistical significance.

Questions that the reviewer may ask (and therefore you should address in your application) include:
- Can the proposed research be conducted without animal experimentation?
- Does the proposed approach minimize the number of animals to be used, and do the methods minimize animal distress, discomfort and pain?
- Does the proposed research involve animal pain or distress? If so, are procedures to alleviate pain and distress described adequately, and are they justified by the anticipated advances in knowledge or health care?
- Is particular care taken to describe and justify research involving non-human primates (NHP) or companion animals (e.g., cats, dogs)?

Veterinary care (indicate for each performance site): The availability of veterinary care is an important item for grant reviewers. Noting DLAR’s board certified veterinarians who assure daily animal care will strengthen your application. Grant reviewers will also be concerned about the frequency of animal monitoring and observation by veterinary or animal care staff at Duke, which is daily. The granting agency will also wish to know how monitoring occurs. At Duke, animals are observed in their home cages and/or in the laboratory on a daily basis. It would be worthwhile to include that the OAWA monitors animals during IACUC process audits while animals are participating in behavioral or surgical procedures. Grant reviewers will require a brief discussion of the circumstances when veterinary staff will intervene and what steps will be taken. The response is that the IACUC approved protocol provides the basis for humane endpoints for all animal studies, and that the steps described in the protocol include intervention by clinical veterinary staff, removal of the animal from the experiment, or euthanasia if necessary. The mechanism and regularity of your laboratory’s communication with the Duke
♦ veterinary staff should be cited (recommended at least weekly communication). You should clearly note the training of personnel handling animals; particular attention to this issue is required for research involving NHP.

♦ Provisions to minimize distress, discomfort, pain and injury: Your grant should include a description of the specific measures and circumstances when tranquilizers, analgesics, anesthetics and antibiotics will be used. This is a critical review point of many grants, so a clear description of concisely what and when they will be used is vital! The grant application should also include care, monitoring or special housing following surgery or treatments (e.g. heat / cooling provisions, special feeds, modified housing, or other specific care provisions post-procedure). This is another place where clear indicators of humane endpoints to minimize pain and distress are important. You should specify that preemptive analgesia is employed (this is a Duke animal program policy) and that no animal will be left to suffer unalleviated pain or distress. A brief description of restraint devices is also necessary. For non-standard restraint devices, a more detailed discussion will be necessary.

♦ Euthanasia: The grant review is expecting a clear discussion of the method(s) for euthanasia. It is critical that you choose methods approved in the AVMA Guidelines for Euthanasia (a copy is available on the animal program website). For the method chosen, you should justify why this method is preferred. For ‘routine’ euthanasia, either a barbiturate overdose or CO2 followed by bilateral thoracotomoy is the best option. At all times, your method of euthanasia must be consistent with recommendations of the AVMA Guidelines on Euthanasia, or an approved except by the IACUC.

♦ Other VAS-related items:

♦ PHS Assurance Number: The reviewer will require Duke’s Assurance Number, which is A3195-01. The animal program publishes a FUNDING AGENCY STATEMENT which includes all relevant regulatory information, and which you may submit with your grant. You can obtain a copy by requesting a copy at the email IACUC@DUKE.EDU.

♦ IACUC Approval: While the grant will be reviewed without an IACUC approved protocol, no funds for animal work can be released until there is an IACUC approved protocol for ALL of the animal procedures described in the grant. If you do not have an IACUC approved protocol when submitting your grant, simply note ‘PENDING’ as the status of the IACUC approval. Whether you have an approved or pending IACUC application has not bearing on your grant application.

♦ AAALAC Accreditation: Although not required by the NIH, noting Duke’s AAALAC (Association for the Assessment and Accreditation of Laboratory Animal Care, International) accreditation may provide a worthy advantage during the review process. Since the NIH requires all grantee institutions be assured as a category I or II program (AAALAC accreditation is classified as category I), such designation will save you significant additional explanation in your grant submission.

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What The NIH Guide For the Care & Use of Animals Says about TRAINING

According to The NIH Guide, personnel caring for animals should be appropriately trained and the institution should provide for formal or on the job training to facilitate effective implementation of the program and humane care and use of animals. Personnel using or caring for animals should also participate regularly in continuing education activities relevant to their responsibilities. They are encouraged to be involved in local and national meetings of AALAS and other relevant professional organizations. Investigators, technical personnel, trainees and visiting investigators who perform animal anesthesia, surgery or other experimental manipulations must be qualified through training or experience to accomplish these task in a humane and scientifically acceptable manner. The Duke Animal Care and Use program offers many and varied training opportunities. For additional information on opportunities offered through DLAR and OAWA please contact either Michelle Calkins (681.1831/michelle.calkins@duke.edu) or Bill Wade (668.6722/w.wade@duke.edu)
North Carolina Association for Biomedical Research (NCABR)

Founded in 1989 by North Carolina’s leading bioscience research institutions (including Duke), the North Carolina Association for Biomedical Research (NCABR) is the only organization in the state dedicated to advancing all North Carolinians’ appreciation for the remarkable benefits of bioscience research and careers.

As a statewide nonprofit organization, NCABR’s members include academia, industry, government, hospitals, nonprofit research, voluntary health and other nonprofit organizations, as well as the general public. NCABR plays a leading role in North Carolina and the nation by providing objective, timely and authoritative advice and information to students and educators, representatives from government and the media, as well as members of the research community and the general public.

Since 1989, NCABR has launched innovative science education outreach programs and has designed a variety of bioscience education and career-related publications many of which are the first of their kind in the country and are now used nationally. NCABR’s ongoing efforts to promote public understanding of biomedical research were recognized in 1999 when Research America, a national nonprofit public education and advocacy alliance of 450 research organizations, honored NCABR with its prestigious national award for "An Organization that has Distinguished Itself By Its Advocacy" for bioscience research. NCABR received this award in a ceremony in the United States Senate along with NBC news anchor Katie Couric and former Oregon Senator and Governor Mark Hatfield.

To date, more than 2,000 North Carolina K-12 teachers have participated in NCABR’s science education programs and have designed a variety of bioscience education and career-related publications many of which are the first of their kind in the country and are now used nationally. NCABR’s ongoing efforts to promote public understanding of biomedical research were recognized in 1999 when Research America, a national nonprofit public education and advocacy alliance of 450 research organizations, honored NCABR with its prestigious national award for "An Organization that has Distinguished Itself By Its Advocacy" for bioscience research. NCABR received this award in a ceremony in the United States Senate along with NBC news anchor Katie Couric and former Oregon Senator and Governor Mark Hatfield.

To date, more than 2,000 North Carolina K-12 teachers have participated in NCABR’s science education programs, more than a thousand North Carolinians have attended an NCABR public forum to debate biomedical research issues, and dozens of members of the North Carolina and national media have attended an NCABR science journalism program. For more information about our own biomedical research organization, visit their website at: http://www.ncabr.org/

AMERICANS FOR MEDICAL PROGRESS (AMP)

Americans for Medical Progress (AMP) protects society’s investment in research by nurturing public understanding of and support for the humane, necessary and valuable use of animals in medicine. Threats by animal rights extremists hurt medical progress. AMP provides accurate and incisive information to foster a balanced public debate on the animal research issue, ensuring that among the voices heard are those whose lives have been touched by research and those who work in the field. Through various specialty publications, outreach initiatives and the media, AMP informs the public of the facts of animal-based research. AMP also distributes timely and relevant news, information and analysis about animal rights extremism to the research community through its news service. For more information on AMP, visit their website at http://www.amprogress.org/site/c.jrLUK0PDLoF/b.913145/k.4502/Americans_for_Medical_Progress.htm

Foundation for Biomedical Research

The Foundation for Biomedical Research (FBR) provides free resources on their website http://fbresearch.org/education/index.htm

Brochures

- Facts vs Myths (pdf)
- Proud Achievements of Animal Research (pdf)
- The Importance of Being a Mouse (pdf)

Species Sheets

- Rats and Mice (pdf)
- Dogs and Cats (pdf)
- Non-Human Primates (pdf)
- Other Species (pdf)

Opinions About Animal Research From:

- Scientists
- Religions
- Organizations
- Opponents

Other Resources

- AIDS and Animal Research
- Facts About Animal Research
- Nobel Prizes
- Animal Research 101
Question: I have received an ‘approval from OESO for my protocol. Can’t I begin using animals? 

Answer: No. It is CRITICALLY IMPORTANT to recognize the while OESO, Employee Health, the IBC, and potentially other Offices on campus may be involved in review of certain animal use protocols, ONLY approval by the IACUC authorizes use of animals. Each animal use application or amendment is routinely submitted to OESO, Employee Health, and DLAR for review of the relevant sections. In some cases, OESO training, a safety audit, or maybe immunizations (from Employee Health) may be required before the IACUC can approve the animal use application or amendment. The notice you receive from OESO (or others) indicates that there are no problems from their perspective, however it IS NOT an approval to begin animal use activities. The easiest way to think about this is that the IACUC approval can only occur AFTER the various agencies or Offices have ‘cleared’ the protocol and the people.
WHY WAIT? AVOID DELAYS!
Protocol Process Updates: Obtaining OESO and EOHW Clearance for Animal Use Protocols & Amendments

There are two parallel processes at work with every protocol or amendment submission to the Institutional Animal Care & Use Committee (IACUC); but must be completed before the proposed work with animals can be accomplished. The IACUC must APPROVE the proposed activity, while Occupational Environmental Safety Office (OESO) and Employee Occupational Health and Wellness (EOHW) must CLEAR the proposed protocols and amendments. Often, the protocol will be approved by the IACUC many days prior to clearance being granted by OESO or EOHW. Usually the hold-up is with one individual listed on the protocol not completing the web training, or re-submitting a health questionnaire -- really very small but highly significant issues! Did you know you can obtain OESO and EOHW clearance prior to submitting the protocol document for review?

Principle Investigators and their research lab staff may complete the necessary requirements and confirm their protocol will be cleared quickly by completing (and updating annual requirements) via the on-line training (http://www.safety.duke.edu/) and the Health Review for Animal Handlers (https://www.hr.duke.edu/secure/eohw/animal.php).

OESO On-Line training modules:

All Duke Principle Investigators on animal protocols (whether handling animals or not) and all research associates handling animals must complete the on-line training modules Animal Handlers Part I and Animal Handler Part II located on the OESO web site. Log in with your Duke NetId and password. The On-Line training tab is located on the left hand side of the main page. To access the Animal Handlers courses click on Courses Available on Line. The two components are Regulations Impacting Animal Care and Use and Veterinary Care. There is a quiz for each module. Once completed the data is maintained by OESO and can be accessed by animal program staff during the protocol review process. These modules are required only once (no annual update on these modules).

EOHW clearance:

All research staff who will work with animal mod-