



ANIMAL TRACKS



A newsletter for the Duke research community

September 2009

<http://vetmed.duhs.duke.edu>

AAALAC PREPARATION ITEMS

Accreditation visits are no mystery. Most negative findings are fairly common between institutions and over time. Being fore warned about these common findings is useful information as we finalize our preparation for our Site Visit/ Below are a few suggestions which will help with a stellar report for your laboratory or animal holding are:

- ◆ Current validation (calibration) for anesthesia vaporizers and other devices (options are annual OR the manufacturer's recommendations, if not annual)
- ◆ Annual validation of fume hoods & BSCs.
- ◆ Expired drugs so marked and separated from drugs that are within date.
- ◆ Controlled substances are secured behind TWO locks.
- ◆ List of "approved persons" to access controlled substances on the inside of the cabinet.
- ◆ Daily room checklist indicated as "no animals" for periods when animals are not kept in PI managed spaces (leave nothing blank!).
- ◆ Cage cards (with appropriate info) are required for all animals kept in a lab >12 hours.
- ◆ No housing of different species in the same room without IACUC approval.
- ◆ Animal welfare reporting procedures posted in lab.
- ◆ A copy of, or web access to, the Guide for the Care and Use of Laboratory Animals.
- ◆ Emergency Veterinary Contact procedures posted in the lab.

Wishing you a safe and productive research month,

Upcoming Dates & Deadlines

September 3	Amendment Meeting
September 7	Amendment Deadline
September 8	New Protocol Deadline
September 17	Amendment Meeting
September 21	Amendment Deadline

Deadlines are 5 PM on the date listed!

TIPS ON WRITING YOUR NIH GRANT INVOLVING ANIMALS

There shouldn't be a mystery what information the NIH requires when submitting an NIH grant application involving animals. The required information is specific and detailed, but it is not always intuitive and considering 'government-speak' is not always clear. Let's look at a few helpful tips on writing grants where animal work is included.

Information concerning animal use should be provided in administrative pages within the SF424 (R&R)-based application as well as in the separate Vertebrate Animal section of your grant submission.

The Research and Related "Other Project Information" page, located after the biosketches and before the abstract in the assembled application, requires you to answer 2 specific questions regarding animal use:

Question 1: Are vertebrate animals used? This is usually very simple to answer, but questions can arise as in the cases described below..

- ◆ **Use of animal tissue only:** 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 Vertebrate Animal section to validate the coding as "no vertebrate animals." However, if vertebrate animals are manipulated prior to euthanasia or obtained specifically for tissue harvest as part of the proposed research, then this must be classified as "use of vertebrate animals".
- ◆ **Antibody generation:** Antibodies that are available for purchase "off the shelf" and are not generated specifically for your research do not constitute use of vertebrate animals. However, the generation of custom antibodies must be classified as "use of live vertebrate animals."

(See NIH Grant Tips for Animal Grants ... Page 5)

This is true even if you are having the antisera prepared by a commercial vendor rather than doing the work yourself.

If you have questions about whether your use of animal tissues or animal-derived products constitutes the use of vertebrate animals for the purposes of your grant application, please contact the Office of Animal Welfare Assurance at 919.668.6720.

Question 2: Is the IACUC review pending? NIH will not release any funds until proof has been received that the proposed research has been reviewed and approved by the IACUC of the institution that is receiving the funds. In most cases this question will be answered “Yes”, since such review is done in a “just in time” fashion when the grant has been recommended for funding. If your grant application has previously been reviewed and approved by the IACUC, then the approval date is inserted in this section. Note that a “No” answer to this question may potentially slow down the progression of your grant through the internal Duke approval process, protocol coverage of all animal procedures described in the grant must be verified prior to its release by the Grants office.

NIH also requires the inclusion of an Animal Welfare Assurance Number, sometimes also referred to as a Public Health service (PHS) Assurance Number. This information (A3195-01) is automatically inserted by grants.duke. For non-PHS grant applications, a FUNDING AGENCY STATEMENT that includes all relevant regulatory information can be obtained by emailing Duke’s Office of Animal Welfare Assurance (OAWA) at IACUC@DUKE.EDU.

Vertebrate Animal Section Section 12 (SF-424 R&R): If you indicated that Vertebrate Animals are involved in your project, five key points must be addressed in this section. In addition, when research involving vertebrate animals will take place at collaborating site(s) or other performance site(s), this information must be provided before discussing the five points.

Performance site: If Duke is not the only site where animal work will be performed, the additional performance sites (e.g. collaborative or field sites) must also be identified. A description of animal care and use for each site should be included in your discussion of the 5 key points described below. If you are sub-contracting to a researcher at an institution that 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 that 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. This certifies to NIH that the activity as conducted at the foreign performance site is acceptable to the grantee institution.

Key Point 1. Provide a detailed description of the proposed use of the animals in the work outlined in the Research Design and Methods section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work. Remember that your IACUC protocol requires that you list the exact animal numbers proposed. So you either already have this information or will need to calculate it to submit a new protocol or amend an existing protocol to cover your proposed studies.

Key Point 2: Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.

- ◆ 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.
- ◆ 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?

Key Point 3. Provide information on the veterinary care of the animals involved.

The availability of veterinary care is an important item for grant reviewers and must be described for each performance site. Noting that DLAR's veterinarians who assure daily animal care are board certified will strengthen your application. Grant reviewers will appreciate the statement that animal monitoring and observation by veterinary or animal care staff occurs daily at Duke. 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 (at least weekly communication is recommended). You should clearly note the training of personnel handling animals; particular attention to this issue is required for research involving NHP.

Key Point 4. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.

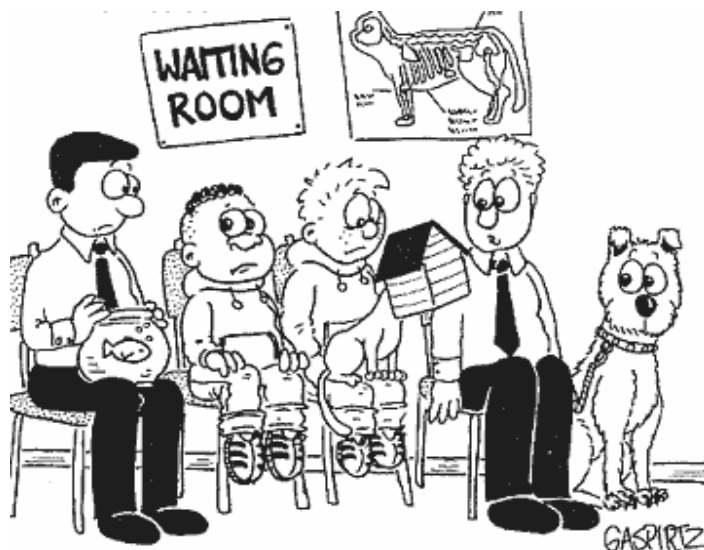
This section should include a description of the specific measures and circumstances when tranquilizers, analgesics, and anesthetics will be used. This is a critical review point of

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 pre-emptive 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.

Key Point 5. Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If not, present a justification for not following the recommendations.

Methods approved in the AVMA Guidelines for Euthanasia are described on the animal program website, <http://vetmed.duhs.duke.edu>. For each method chosen, you should justify why this method is preferred for your studies. For 'routine' euthanasia, either a barbiturate overdose (or CO₂ asphyxiation followed by bilateral thoracotomy for mice and rats) is the best option. At all times, your method of euthanasia must be consistent with recommendations of the AVMA Guidelines on Euthanasia or an exception must be approved by the IACUC.

(Continued on the Next Page, Column 1)



Concordance Letters: Once your grant has been recommended for funding, you will need to obtain a concordance letter stating that your grant is concordant with your animal protocol before the funds can be released to Duke. To receive this letter, the entire grant proposal (send the whole application as available from the NIH Commons web site; you can delete the biosketches and budget pages if you wish) must be forwarded to OAWA for review with your protocol.

- ◆ Before you request a concordance letter, you should review your own grant to make sure that the animal procedures described are in fact covered in your protocol. If not, these procedures can be added to your protocol via the standard amendment process.
- ◆ It is the policy of the IACUC that a concordance letter can be issued once an amendment that describes any non-concordant procedures has been submitted. However, the procedures covered by that amendment cannot be performed until the amendment has received full approval by the IACUC.
- ◆ If a Duke grant includes animal funds, but the animal activity will be performed at another campus (sub-recipient grantee), a Duke IACUC approved protocol is still required! A concordance letter will not be issued against a protocol at another campus. Concordance letters will only be provided for Duke IACUC approved protocols.

For further information, you can consult NIH's Checklist for Vertebrate Animal Section review (<http://grants.nih.gov/grants/olaw/VASchecklist.pdf>).

UPCOMING TRAINING OPPORTUNITIES

The Duke ACUP is pleased to provide the following training opportunities for all staff involved in the care and use of animals.

Friday September 11, 2009: 12:00 to 1:00 PM
Brown Bag Seminar: **Mouse Methodologies**
Hock Plaza Auditorium, Room 0001

Friday September 17, 2009: 12:00 to 1:00 PM
Brown Bag Seminar: **Preparing Your Lab For The AAALAC Site Visit** Duke North; Room 2002

Friday September 18, 2009: 1:00 to 2:30 PM
Hands-on Workshop: **Mouse Methodologies Workshop**
(NOTE: Requires prior attendance to Sept 11 Seminar)
Surgical Pavilion, DLAR, Room

Thursday October 1, 2009: 12:00 to 1:00 PM
Brown Bag seminar: **Preparing Your Lab For The AAALAC Site Visit** Hock Plaza Auditorium, Room 0001

The Pro-Test Petition

We're almost there - Help us to reach our immediate aim of getting 10,000 people to sign onto a statement of principles in support of live-saving biomedical research. Go to <http://raisingvoices.net> and sign onto the Petition yourself - or if you have already done so, please forward this message to friends, family and colleagues asking that they join you in standing up for science!

The Pro-Test Petition makes the point that the once-silent majority of Americans that supports the necessary and humane use of animals in biomedical research will be silent no more; that we will no longer tolerate violence, intimidation and terrorist actions directed against those who conduct this critical research; that we stand united in support of science.

Americans for Medical Progress, UCLA Pro-Test and Speaking of Research launched the Pro-Test Petition at April's historic UCLA Pro-Test rally in which 800 citizens marched to show solidarity with scientists and against violence by animal rights militants. Several prominent organizations have already promoted the Pro-Test Petition to their membership, including the Federation of American Societies for Experimental Biology (FASEB), Society for Neuroscience (SfN), American Physiological Society (APS), the American College of Neuropsychopharmacology (ACNP), and the American Society of Primatologists (APS).

Here's the Pro-Test Petition and its statement of beliefs:

The Pro-Test Petition

We the undersigned believe:

1. That animal research has contributed and continues to contribute to major advances in the length and quality of our lives. It remains vital to understanding basic biological processes and for the development of new treatments and therapies such as antibiotics, vaccines, organ transplants, and cancer medicines.
2. That animal research is morally justifiable provided animal welfare remains a high priority and no valid non-animal alternatives are available.
3. That violence, intimidation and harassment of scientists and others involved in animal research is neither a legitimate means of protest, nor morally justified.

- 4 To sign the petition, visit <http://raisingvoices.net>.



Duke ACUP's Brown Bag Seminar

Friday, September 17th, 2009

Noon – 1 p.m.

Duke North Conference Room 2002

John Norton, DVM, PhD, Director, DLAR
University Veterinarian
Will be presenting:

“AAALAC is coming to Duke”

The Association for Assessment and Accreditation of Laboratory Animal Care International, AAALAC, will be coming to Duke in October to perform our triennial site visit. This site visit is necessary to maintain our accreditation. The following topics will be covered:

- What is AAALAC?
- Why is it important for Duke to be accredited?
- What does this mean for your research?

And most importantly...

- How to prepare your laboratory for the site visit.

It is important that as many people as possible from the laboratories attend, so that we all have a better understanding of what the expectations are and why they are important to your research as well as the accreditation of the Institution.

Please visit AAALAC's website for more information:

<http://www.aaalac.org/>

The session will be held in **Duke North**, Room 2002, located on the lower level above the main hospital entrance lobby

NO FOOD OR BEVERAGES ARE AUTHORIZED IN THIS ROOM

Please plan on arriving prior to noon in order to get refreshments, sign in, and be seated.

This session will count for 1 CEU of AALAS In-house Training Credit



Duke Animal Care & Use Program Brown Bag Seminar

Friday September 11, 2009

Noon – 1 p.m.

Hock Plaza Auditorium, Room 0001

Bill Wade, LVT, RLATG
Compliance Liaison for Education &
Training, OAWA

Will be presenting:

MOUSE METHODOLOGY

During this seminar we will review some common practices and methodologies used for the mouse model. Topics will include occupational hazards, restraint and handling, sex/age determination, animal ID, blood collection injection techniques, oral gavage, euthanasia. This seminar will offer a good basic overview for new research staff or a refresher for anyone interested.

****NOTE:** In order to sign up for the Mouse Methodology Workshop on September 18, 2009, you must attend this seminar.

The presentation will be on **Friday September 11th, 2009 from noon to 1 p.m.**

The session will be held in the Hock Plaza Auditorium, located at 2424 Erwin Road across from Research Dr. From the main lobby (level 3) take the elevator to the Ground Floor (G) turn left and the auditorium will be ahead on your right.

Attendees are encouraged to bring a lunch. OAWA will provide drinks and desserts.

Please plan on arriving prior to noon in order to get refreshments, sign in, and be seated.

This session will count for 1 CEU of AALAS In-house Training Credit



Duke ACUP's Mouse Methodology Workshop

Friday September 18th, 2009

1:00 – 2:30 PM

Surgical Pavilion, DLAR, Room 1205

Michelle Calkins, LVT, RLATG

Amy McArdle, CVT, RLATG

Corrine Smolinski, RVT, RLAT

Lisa Colvin, RLAT

****MOUSE METHODOLOGY WORKSHOP****

This workshop will offer research staff the opportunity to receive training on common practices and procedures used in the mouse model. To include:

- Handling and Restraint
- Common blood withdrawal techniques
- Oral dosing
- Common injection techniques
- Euthanasia

This workshop is ideally suited for new research staff but will also offer a good refresher for those interested.

****NOTE:** The workshop will be limited to 12 participants. Participants in the workshop must have also attended the [BBS on September 11th](#) to qualify.

Please contact Michelle Calkins directly to sign up (681.1831 or michelle.calkins@duke.edu)

The workshop will be on **Friday, September 18th, 2009** from 1 – 2:30 p.m.

The session will be held in room **1205 in the DLAR Surgical Pavilion**. Please come to the Vivarium main entrance to meet DLAR staff and then proceed to the lab area.



Duke ACUP's Brown Bag Seminar

Thursday, October 1st, 2009

Noon – 1 p.m.

Hock Plaza Auditorium Room 0001

Ron Banks, DVM, Director of OAWA
Will be presenting:

“AAALAC is coming to Duke”

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- How to prepare your laboratory for the site visit.

It is important that as many people as possible from the laboratories attend, so that we all have a better understanding of what the expectations are and why they are important to your research as well as the accreditation of the Institution.

Please visit AAALAC's website for more information:

<http://www.aaalac.org/>

The session will be held in **the Hock Plaza Auditorium**, Room 0001, located on the lower level. From the lobby take the elevator **down** to level G. Go left and the auditorium will be down the hall on the right.

Attendees are encouraged to bring a lunch.

OAWA will provide drinks and desserts.

Please plan on arriving prior to noon in order to get refreshments, sign in, and be seated.

This session will count for 1 CEU of AALAS In-house Training Credit