



# ANIMAL TRACKS



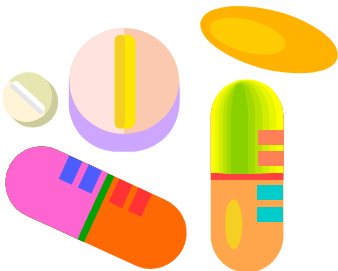
A newsletter for the Duke research community

November 2007

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

## Controlled Substance Use in the Animal Program at Duke

A few months ago, a program manager from the North Carolina Drug Enforcement Agency (DEA) and an agent of the federal Drug Enforcement Agency visited the Duke campus to review the controlled substance management system for animal use. Their review was broad and included controlled substance central storage and distribution (in DLAR and the hospital pharmacy), local laboratory (PI) storage, procurement processes, and auditing mechanisms of controlled substances. The agents reported that while there were no citations at that time, the present system of controlled drugs use and management required significant enhancement. The agents were emphatic in their conclusion that Duke's dispensing and recording practices required enhanced modification. The required modifications included increased licensure of investigators, enhanced record keeping and tracking, and



establishment of a robust internal auditing program. The agents stated that these items were not negotiable, but would grant time to develop our own policy instead of imposing the state and federal agencies potentially more restrictive 'solutions.'

Faced with this challenge, the IACUC established a Sub-Committee to work with the institution's Compliance Office and develop an acceptable controlled substance process for the animal program that maximizes local controls while maintaining researcher flexibility. As part of the process, the Sub-Committee has requested and received expert counsel from pharmacists at human pharmacies, a veterinary pharmacist from the NCSU veterinary college, and a local veterinary practitioner. The Duke IACUC has been consulted a number of times and has recommended modifications to the draft document. At present, the Sub-Committee's proposal is receiving review by the state controlled substances office and campus compliance and legal activities.

A 'Brown Bag Seminar' has been scheduled for November 12th in the Duke North Central Core Lecture Hall (Room 2002). This room is above the main entrance to Duke Hospital North. A member of each laboratory using, or expecting to use, controlled substances for animal research, testing, or teaching, is invited to attend. We are planning on distributing copies of the final policy, the necessary DEA applications for licensing, and template forms you may consider adopting for use within the laboratory for controlled substance management.

As an aside, these same DEA reviews and required program changes have occurred at many of our sister research institutions across the country. This is not a Duke specific challenge, but rather a nation-wide initiative by the DEA.

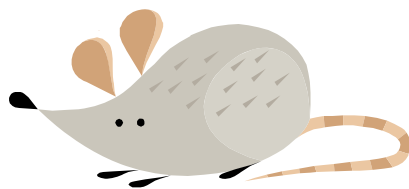
I am certain this message will present angst and anxiety for some in our research community. Our pledge is simple, to partner with the Duke research staff, working to achieve the necessary regulatory protections that assures continued animal use while maintaining a practical and flexible system of controlled substance use in animal based research.

Best wishes for a safe and productive research week,

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## Why Register Transgenic Rodents?



Researchers may be quite surprised when animal protocols involving transgenic animals are returned “conditional approval” upon registration of their work with the Duke Institutional Biosafety Committee. This requirement is based on the institution’s compliance with the National Institutes of Health Recombinant DNA (NIH rDNA) Guidelines: <http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>.

### *What is the definition of transgenic rodents in the NIH rDNA Guidelines?*

The Guidelines describe such work as “the generation of rodents in which the animal's genome has been altered by stable introduction of recombinant DNA, or DNA derived therefrom, into the germ-line (transgenic rodents)”. Note that this would not cover the “breeding” of germ-lines already established, unless other rDNA work is performed during the research with these animals.

In fact, the Guidelines also state, “The purchase or transfer of transgenic rodents for experiments that require BL1 containment (See Appendix GIII-M, *Footnotes and References of Appendix G*) are exempt from the *NIH Guidelines*.”

### *What do the NIH rDNA Guidelines require regarding transgenic rodents?*

“Routine” creation of transgenics requires Institutional Biosafety Committee (IBC) *registration* at the time the work is initiated. The IBC reviews and approves the protocol, but IBC *approval* is not required before the work starts. The NIH cautions researchers to carefully evaluate the creation of certain types of transgenic experiments that might lead to “creation of novel mechanisms or increased transmission of a recombinant pathogen or production of undesirable traits in the host animal.” Under such circumstances, increased containment may be required by the IBC.

### *How do you register the creation of transgenics with the Duke IBC?*

Researchers should simply fill out the rDNA registration form located on the OESO website: <http://www.safety.duke.edu/LabSafety/DNA.asp>,

provide all the information requested on the form, and e-mail to the address at the top of the form. The Biological Safety Division of OESO will register the work, assign the protocol an IBC registration number, and take it to the IBC for review and approval.

### *Questions?*

Contact the Biological Safety Office (684-8822 or via e-mail at [biosafety@mc.duke.edu](mailto:biosafety@mc.duke.edu)). For more information on rDNA or viral vector registrations, Duke IBC information, or links to resources such as the NIH rDNA Guidelines, visit the website listed above for registration forms.

-Debra L. Hunt, DrPH, CBSP  
Director, Biological Safety  
Assistant Clinical Professor  
Duke University/Duke University Health Systems

## Stem Cell Website

If you are interested in learning more about stem cells, visit this website developed by the Biology Teachers Association of New Jersey (BTANJ).

<http://www.stemcellresources.org>



## Upcoming Dates & Deadlines

November 8	Significant Change Meeting
November 15	New Protocol Meeting
November 26	New Protocol Deadline Amendment Deadline
December 6	Significant Change Meeting
December 13	New Protocol Meeting
December 19	Amendment Deadline

*Deadlines are 5 PM on the date listed! No exceptions!*

## Grant Writing for Tight Times

—excerpted from *Science Careers*  
(*Science Online*), July 27, 2007



For scientists seeking money for their research, it may not be the worst of times, but it certainly is not the best of times. Approval rates for grant applications have dropped markedly in the past few years, making grant writing an even more vital skill. For example, in FY06 NIH funded 1 in 5 competitive grant applications. Just five years earlier, nearly one-third (32.1%) of NIH grant applications were funded. For new grant applications at NIH, in 2006 only about 1 in 6 (16.7%) were funded compared to 27.1% five years earlier. Last fiscal year, NSF funded about 1 in 5 research grant applications, according to the agency's most recent budget submission. Five years earlier, the overall funding rate (covering research and other grants) was 31%. Over this five-year period, the number of research grants funded by NSF has barely grown, from 6,220 in 2001 to 6,635 in 2006. So today's prospective investigators have little margin for error when requesting funds for research. In **The NIH R01 Tool Kit** (<http://tinyurl.com/33vg3u>), the Science Careers Editors provide new and experienced grant writers with tips on preparing grant applications for NIH's main research funding vehicle, the R01. This article updates one of our most visited pages, first written in 2001, to reflect new procedures for electronic grant applications and what we've learned over the last six years. The tool kit offers pragmatic advice for improving your chances with the NIH committee, called a study section, that reviews your proposal.

Lynnette Madsen, a program director at NSF, offers **A Guide to NSF Success** (<http://tinyurl.com/2vverd>). Madsen's work brings her into direct contact with both grant applicants and reviewers, and she offers ideas such as, "One or two notable efforts often come across stronger than myriad small, unrelated, and unconnected activities. In broader impacts, as in the other aspects of your proposal, make clear what is new and how it can be distinguished from your existing efforts and those of others. Back up your ideas with, as appropriate, an outline of your track record, references to literature—there is significant literature in this area, and you should be aware of it just as you are for your research activities—letters of support, and so on. The key factor to keep in mind is what impact the intended activity or activities will have."

## Animal Welfare Information Center (AWIC)

The **Animal Welfare Information Center (AWIC)** is mandated by the Animal Welfare Act (AWA) to provide information for improved animal care and use in research, testing, teaching, and exhibition.

The website, located at <http://awic.nal.usda.gov>, contains information on a variety of subjects including: research animals, farm animals, zoo, circus and marine animals, companion animals, government and professional resources, alternatives, literature searching and databases, pain and distress, and humane endpoints and euthanasia.

The research animal resources section provides resources about laboratory animals used in biomedical research including legislation, publications, training, meetings, and organizations.

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### IACUC Training: Basics and Challenges May 8, 2008

**GlaxoSmithKline  
Research Triangle Park, NC**

*Sponsored by North Carolina Association for Biomedical  
Research and the Research Triangle Branch of AALAS*

The Basics and Challenges IACUC Training Course is both a didactic and highly interactive course that addresses the most important and fundamental knowledge that IACUCs must assimilate in order to perform their charges. Expert faculty presents four modules covering the evolution of the regulation of animal research and the IACUC, IACUC functions, semi-annual evaluations and protocol review. The course also presents simple to complex customized scenarios (case studies) that address issues faced by IACUCs and give multiple opportunities to ask questions. While the emphasis is on the training of IACUC members, the modules and scenarios are such that IACUC support staff, investigators, veterinary staff and animal care personnel, as well as others affiliated directly or indirectly with the IACUC and/or affected by the animal welfare laws, regulations and policy should benefit as well.

For registration information, visit the web at [http://www.ncabr.org/conferences/iacuc/iacuc\\_registration\\_form.doc](http://www.ncabr.org/conferences/iacuc/iacuc_registration_form.doc)

## The Duke Animal Program Matching Game (acronyms and terms)

<b>A. IACUC</b>	1. The in-house process of assuring what the IACUC approved and what is being performed in the laboratory are consistent.
<b>B. Protocol</b>	2. The campus office that establishes safety policy, hosts the IBC, provides safety training, and performs safety audits.
<b>C. OAWA</b>	3. An approved animal use application describing in detail the planned animal use activities.
<b>D. DLAR</b>	4. A decision document provided by the IACUC that establishes the foundation for animal care and use operations on campus.
<b>E. OESO</b>	5. The campus agency that assures the health and well being of humans working with or around animals and animal tissues.
<b>F. EOHW</b>	6. The organization that supports the needs of the IACUC, facilitates the researcher's submission of animal use applications, and audits performance of animal use protocols
<b>G. Clearance</b>	7. The unit that prescribes, manages, and oversees daily animal care in the institution's vivaria, and assists researchers with surgery, anesthesia, recovery or treatment of sick or injured animals.
<b>H. AALAS LL</b>	8. A 'best practice' or 'suggestion' on how to perform a specific procedure or plan.
<b>I. PAM</b>	9. The web training modules provided by subscription through the Duke animal program for the research community. The modules feature technique and procedure training on most research species.
<b>J. Policy</b>	10. The 'final notice' that Occupational & Environmental Safety Office <u>AND</u> the Employee Occupational Health & Wellness have confirmed the proposed work can be safely performed on the Duke campus. This is not a protocol approval.
<b>K. Guideline</b>	11. A Duke institutional level committee charged under federal law with review of research proposals, monitoring of on-going animal activities, approval (or termination) of research on campus.
<b>L. Amendment</b>	12. A change in the original protocol that may include personnel, procedures, monitoring, or outcome assessments.

Answers: A, 11, B, 4, C, 6, D, 7, E, 2, F, 5, G, 10, H, 9, I, 1, J, 3, K, 8, L, 12

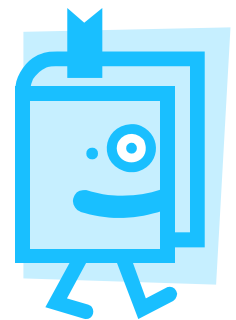
### Mandatory Use of New Protocol Form

The Duke IACUC has completed a 3 year project to develop a new protocol form for animal care and use applications at Duke. **The IACUC has determined that this new form must be used for all new protocols received after October 9, 2007.**

To learn more about this new form, visit our website at [http://vetmed.duhs.duke.edu/index\\_of\\_new\\_protocol.htm](http://vetmed.duhs.duke.edu/index_of_new_protocol.htm)

If you need help with completing the new form or if you have questions about the new template, call the OAWA at 668-6720 or email Ron Banks at [ron.banks@duke.edu](mailto:ron.banks@duke.edu)

### Are you missing a previous edition of the electronic newsletter, Animal Tracks?



We have begun to archive the previous editions on our website at [http://vetmed.duhs.duke.edu/index\\_of\\_training.htm](http://vetmed.duhs.duke.edu/index_of_training.htm)

We do our best to send the newsletter to all persons approved as animal handlers on IACUC approved protocols as well so others in the Duke research community who request to be on the mailing list. If you don't regularly receive this informative newsletter, send an email to [sonia.doss@duke.edu](mailto:sonia.doss@duke.edu) to be added to the list.

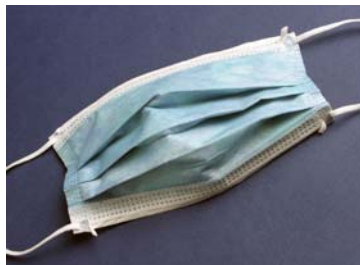
## Confused About Respirator Use?

You're not alone. Let's try to dispel the confusion. Here are a few frequently asked questions and answers:

### Q: Is there a difference between a “mask” and a “respirator”?

A: It depends on what is being called a “mask” – a surgical mask, a nuisance dust mask, or a respirator.

When someone says they are wearing a “mask” in an animal facility, they usually mean a **surgical mask**, which is NOT a respirator. Surgical masks fit more loosely than respirators and are only designed to protect the wearer against blood and body fluid splashes, not inhaling particles. They are primarily for infection control, to protect the animals or other people from what the wearer may shed or exhale (such as bacteria). “Masks” may also refer to **nuisance dust masks**, widely available at home improvement stores. These masks generally have a single strap, are not government-approved, and do not have any information printed on them. They will filter out large dust particles from activities such as mowing grass but are not designed to protect users from smaller, respirable particles. **Respirators**, on the other hand, are designed to protect the user from respirable air contaminants (such as chemical, biological, or radiological agents) and are tested and approved by NIOSH (National Institute for Occupational Safety and Health). Respirators include a variety of types such as Self-Contained Breathing Apparatus (SCBA), full face and half face cartridge respirators, and, more commonly used in animal facilities, N95 filtering facepieces and Powered Air Purifying Respirators (PAPRs). N95 respirators, frequently referred to as “masks”, can be distinguished from surgical and nuisance dust masks because they generally have two straps that go completely around the head and have information such as the NIOSH N95 approval printed on them.



Surgical mask



Nuisance dust mask



N95 Respirator



3M HEPA Airmate PAPR

### Q: I see both N95 respirators and PAPRs used in the animal facilities at Duke. What is the difference between them and what do they protect against?

A: The N95s offer 95% filter efficiency (at 0.3 micron size) against non-oil based particles, which include animal dander and zoonotic agents, the primary exposures of concern in our animal settings. Most N95 respirators are relatively inexpensive, disposable, and easy to obtain. The downside is that they can be itchy, get in the way of eyeglasses, and build up heat and moisture without an exhalation valve, making them uncomfortable if worn for extended periods of time. PAPRs with HEPA filters, such as the commonly used 3M HEPA Airmate, offer additional protection beyond the N95 respirator: 99.97% filter efficiency (at 0.3 microns), a higher protection factor (25 vs. 10 for an N95) due to the positive pressure under which they operate, and full face coverage to protect those whose animal allergies cause eye irritation. They usually offer more thermal comfort due to the cool air blowing across the wearer's face; however, they are expensive and require maintenance (e.g., battery charging, airflow check, filter replacement). It is important to note that both types of respirators **ONLY** offer protection against particulates. They are not effective against gases and vapors, which explains why you may still notice animal odors when wearing these respirators!

### Q: What are the requirements if I wear a respirator?

A: All respirator users at Duke, even voluntary users, must be included in Duke's Respiratory Protection Program (RPP) per OSHA. This is because OESO must ensure that you are using the correct type of respirator for the hazard(s) you are likely to encounter (and that you won't be harmed by using a respirator where you aren't required to do so). Required users must: 1) obtain medical clearance, 2) complete annual training, and 3) pass annual fit testing (not applicable for loose-fitting PAPRs). Voluntary users have the option of either: 1) completing a brief, one-time online training, or 2) submitting a receipt to OESO that you have received and read our brochure on voluntary respirator use.

If you want more information on respirator use, if you need to be added to the RPP, or if you want to check your compliance with the RPP (necessary for OESO's animal protocol clearance), please contact OESO's Occupational Hygiene and Safety division at 684-5996.



## OAWA's Brown Bag Seminar

Monday, November 12<sup>th</sup>, 2007

Noon – 1 p.m.

**Duke North Central Core Lecture Hall 2002**

*\* please note the room change to accommodate additional attendees\**

**Dr. Ron Banks**

**Director of the Office of Animal Welfare**

**Assurance will be presenting:**

# Controlled Substances Management in the Duke Animal Care Program: New Procedure Mandates from the state/federal DEA

The North Carolina Drug Enforcement Agency (DEA) and the federal DEA have encouraged enhancement of the institution's process of controlled substance management. A Sub-Committee of the IACUC has worked with researchers and compliance staff, and has obtained expert counsel from local pharmacies and veterinary practitioners to develop a process that meets the requirements of the DEA and provides sufficient protections for the institution and the research community.

A member of each laboratory using, or expecting to use, controlled substances for animal research, testing, or teaching, is invited to attend and learn how the process of controlled substance use for animals at Duke will change. Meeting attendees will receive:

- A copy of the final Duke policy,
- Necessary DEA applications for licensing,
- Template forms you may consider adopting within the laboratory,
- Suggestions on how to develop their local process.

The presentation will be on **November 12<sup>th</sup>, 2007** in the  
**Duke North Central Core Lecture Hall 2002.**

(located directly above the Duke Hospital entrance  
at the intersection of Fulton Road and Erwin Drive)

Attendees are encouraged to bring a lunch. OAWA will provide drinks and desserts. The session will begin promptly at noon. Please arrive early to sign-in and find a seat.