Five Day Notification and Other Requirements for Dosing Animals With Hazardous Agents

If you dose animals with toxic chemicals or biohazardous agents, you must follow the safety precautions outlined in the SOP for Handling Animals Dosed with Toxic Chemicals and animal use section of the BSL 2 SOP, respectively. Both of these SOPs require that the Operations Manager of the animal facility be notified at least 5 days prior to dosing animals with hazardous agents. You can refer to your protocol’s approval form from OESO for clarification on which agents these are. Please send a completed copy of the animal handling SOP to the facility manager, along with an MSDS of the agent (for chemicals). You can only initiate work once you have received confirmation that your notification has been received. These SOPs also require that cage cards and door signs be used to notify researchers and animal handlers of the hazardous agent the animals were dosed with, along with listing any additional precautions they should take when entering the room, changing the cages and/or manipulating the animals.

For additional information please contact OESO.

A Commitment to Animal Well-being

All members of the Duke University animal care & use program are obliged to prevent unnecessary pain or suffering in animals owned or used in Duke University animals. All Duke employees, staff, and visitors are charged to provide immediate first aid as would be necessary in such situations, and to report situations of animal distress or unnecessary pain or suffering. Use the Duke University Adverse Event Form to submit the report.

Remember: Anyone having knowledge of animal distress or abuse and not reporting it, is also culpable for the adverse conditions. Animal care & use is a privilege, not a right. Collectively we can protect that privilege!

NIH Announces Adoption of the New Guide; OLAW Updates and Issues 29 New FAQs

The National Institutes of Health (NIH) has announced that has adopted the 8th Edition of the Guide for the Care and Use of Laboratory Animals. The NIH’s Office of Laboratory Animal Welfare (OLAW) has developed Position Statements in response to the new Guide. The Position Statements clarify the ways in which NIH expect institutions to implement the 8th Edition of The Guide by addressing the following concerns: cost of implementing the 8th Edition of the Guide; animal housing specifications; use of non-pharmaceutical-grade compounds; food and fluid restrictions; and multiple surgical procedures.

According to the NOH/OLAW, “effective January 1, 2012, institutions that receive Public Health Service (PHS) support for animal activities must base their animal care and use programs on the 8th Edition of The Guide and must complete at least one semi-annual program review and facilities inspection using the 8th Edition of the Guide by December 31, 2012.”

OLAW has also updated 23 FAQs and issued 6 new ones. Updated and new FAQs fall under the sections related to Applicability of PHS Policy, IACUC Composition, Functions and Authority, Protocol Review, Program Review and Inspection of Facilities, Animal Use and Management and Institutional Responsibilities.

The Duke IACUC began a program-wide review last January 2011, when the draft version of the new Guide was released. While not completely finished with its assessment, the IACUC has determined that because of our proactive approach to research program management, the Duke program is in a very good position relative to the new requirements. There may be some protocol question shifts or potentially a few new questions that are required in response to the OLAW, but most researchers will see little to no changes in their processes and activities.

Wishing you a good research month,
Foundation for Biomedical Research

The latest statistics from the FBR polls on Public Support for Biomedical Research

Each month, the Foundation for Biomedical Research (FBR) asks polling questions to get a sense of how our society believes animals should be used and provided care. This month, the FBR revisited the "Mouse Under your Kitchen Sink" question that was asked in 2009: "Which of the following best describes what you would do if you found mice under your kitchen sink?"

In 2009, FBR asked that question BEFORE they asked about using animals in research. Back then, 87% of respondents said "trap and kill the mouse" while only 54% supported using purpose-bred rodents in labs.

In this most recent poll, FBR asked the "Mouse Under your Kitchen Sink" question AFTER they asked the animals in research question. Here are the results:

* 75% of all respondents said "trap, poison and kill the mice."
* 20.5% said "catch them and release them outside"
* 4.5% were undecided

DEMOGRAPHIC SPLITS BY GENDER

* Men - 79.7% say "trap, poison and kill the mice."
* Women - 71% say "trap, poison and kill the mice."

THIS IS IMPORTANT: When you realize that 75% of all Americans (and 71% of women) are willing to kill a mouse that invades their house, but only 55% of all Americans (and only 42.6% of women) support the use of mice who are cared for, enriched and nourished in research labs...then you start to see where public messaging has potential.

FBR believes it is possible to MOVE THE NEEDLE with another 19.6% of all Americans and 28.4% of all women if we start to tell our stories.

This is the key to understanding why FBR does radio, TV, billboards, magazines and books. It is impossible to change the attitudes of the hard core opposition... but the belief is we can reach an additional 20%! And we should.

Public Support Hits 55.4% for November

Zogby polled 2,175 adults (10/28 - 10/31) which included 1,047 men and 1,112 women. 55.4% of those polled supported the use of animals in research while 19.1% were opposed. 15.5% were undecided. The MOE (margin of error) was 2.1%.

DEMOGRAPHIC SPLITS - REGION
Most Support - 57.6% in the Great Lakes Region
Most Opposition - 32% in the West

DEMOGRAPHIC SPLITS - POLITICAL PARTY
Most Support - 71.2% among Republicans
Most Opposition - 38.9% among Democrats

DEMOGRAPHIC SPLITS - GENDER
Men - 69.3% support
Women - 42.6% support

~ IACUC Tip Sheet ~

Reporting Adverse Animal Conditions

Question: Who is responsible for the condition of Duke owned animals? Answer: All of us!!

If you observe an animal in distress, as a member of the Duke animal care program you are obligated to report the distress immediately! You are encouraged to take actions to prevent any further distress to the animal if you can. To report adverse animal conditions, contact the Duke Animal Welfare Hotline (919.684.3535) or Email the Duke IACUC at IACUC@duke.edu

Duke University will not tolerate any misuse or neglect of animals.

Laura Hale, MD, Ph.D.
Chair, Institutional Animal Care & Use Committee
919.668.6720
IACUC@duke.edu

John Norton, D.V.M., Ph.D.
Director, Division of Laboratory Animal Resources
919.684.4204
john.norton@duke.edu

Ron Banks, D.V.M.
Director, Office of Animal Welfare Assurance
919.684.4744
ron.banks@duke.edu
Civil Rights Group Exposes Violence Proponent Camille Marino
(Americans for Medical Progress)

The Southern Poverty Law Center, a well-respected and influential civil rights organization that tracks and exposes extremist movements throughout the United States, has turned its attention to the hate group Negotiation Is Over and its organizer, Camille Marino.

Writing on the SPLC's HateWatch blog, reporter Leah Nelson yesterday vividly described the threats, graphic images and threats posted by Marino on the Negotiation Is Over website. She called it "a one-stop shop for animal liberationists" that included information on picking locks, making flash bombs and hacking. SPLC describes Negotiation Is Over as "the brainchild of Camille Marino, a 47-year-old former investment banking professional who for the past three years has devoted her life to radical animal rights activism."

The article is an absolute must-read for those who are concerned by the growing violence of animal rights militants, and it will prove to be a lasting resource for other journalists investigating the tactics used to oppose animal based research. Read it on the SPLC site here and consider leaving a comment to stand against the hatred Marino espouses.

Longtime Marino target UCLA Professor David Jentsch, founder of Pro-Test for Science and a Director of AMP, told HateWatch, "One of the things that's been distinctive in her website and her movement is you see this commiseration, this coming together of a group of people across the country that are the most hateful and the most willing to be blatant about their sort of lust for violence...She creates a permissive environment by being a model, then she provides the information. Here's the person, here's the email, send it. She becomes this vehicle for almost unbelievable animosity and hatred."

The SPLC spoke extensively to Marino, and many of her venomous comments are included in the article. Interestingly, after finishing the interview and being provided with a transcript of her comments, which she approved, Marino contacted the reporter in an attempt to withdraw her consent to be quoted on "a blog filled with the most contemptible groups of racists, bigots, madmen and hate-mongers...groups that I despise." HateWatch turned down Marino's request, citing the widely accepted journalistic practice that once an on-the-record interview is conducted, permission cannot be withdrawn.

As was reported by AMP earlier, Marino's nefarious tactic of targeting life science students in college and grad school is the topic of an article in the current Security Management magazine.

The Speaking of Research site has already posted a strong commentary based on the Southern Poverty Law Center article, "Putting Animal Rights Extremists on the Hate Map," linking Marino with radical Steve Best, a Professor of Philosophy at the University of Texas El Paso, who regularly spews his hate speech on the Negotiation Is Over website. The Speaking of Research post signs off with an optimistic note:

"Of course there are many who do not need to be told that animal rights extremist groups like Negotiation is Over and the Animal Liberation Front are hate groups. The University of Florida student newspaper 'The Independent Florida Alligator' recently published an editorial strongly condemning the harassment of students and scientists by extremists, indicating that any students who may be targeted by extremists will find a lot of support among their fellow students, and in California the neighbors of scientists targeted by extremists have made their support for their harassed neighbors very clear."

We've also seen the success of the Pro-Test movement in Oxford a few years ago, when students, scientists and members of the public joined to express their support for animal research, and delivered a decisive blow to the campaigns of harassment, intimidation and violence then being waged by animal rights hate groups in the UK.

"Extremism and hate can be defeated, and the first step in doing so is to recognize it for what it is, and we applaud the SPLC for once again doing so."
Federal Government Funding for FY 2012 Extended by CR

The Department of Health and Human Services (HHS), including the National Institutes of Health (NIH), is operating under a Continuing Resolution (CR) signed by President Obama on November 19, 2011. This CR, also known as the “Mini-bus,” continues government operations through December 16, 2011 at the FY 2011 level minus 1.5 percent.

Last week NIH posted a notice stating, "Until FY 2012 appropriations are enacted, NIH will issue non-competing research grant awards at a level below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level). This is consistent with our practice during the CRs of FY 2006—2011. Upward adjustments to awarded levels will be considered after our FY 2012 appropriations are enacted but NIH expects institutions to monitor their expenditures carefully during this period."

The Mini-bus also includes funding for the Departments of Agriculture, Commerce, Justice, Transportation and Housing and Urban Development as well as support for various federal science programs. During the House Rules Committee’s Nov. 16 consideration of the package, House Appropriations Chair Harold Rogers (R,KY) outlined his plans to consider the remaining nine appropriations bills in an omnibus package prior to the end of the calendar year.

PCRM Raises Concern about Rats and Mice – 'The Other 99%'

You just knew it was going to happen, and it has. The Physicians Committee for Responsible Medicine (PCRM), President Neal Barnard chose to devote his latest blog entry to rats and mice used in research. He concludes,

“As we work to end invasive experiments on great apes, heartbreaking cardiovascular experiments on dogs, and medical training on pigs, goats, cats, and ferrets, it is important to remember that millions of intelligent mice and rats are also needlessly suffering. They are a forgotten 99 percent.”

In an article published in Comparative Medicine (2009 Feb;59(1):60-71), rats were evaluated for the effectiveness of Buprenorphine in a postoperative pain model (paw incision) in rats. The authors assessed acute postoperative pain relief, rebound hyperalgesia, and the long-term effects of postoperative opioid treatment on subsequent opioid exposure. Pain sensitivity to noxious and nonnoxious mechanical stimuli at the site of injury (primary pain) was assessed at 1, 4, 24, and 72 hours after surgery. Pain sensitivity at a site distal to the injury (secondary pain) was assessed at 24 and 72 hours after surgery. Rats were tested for their sensitivity to the analgesic and locomotor effects of morphine 9 to 10 days after surgery.

Buprenorphine dosed at 0.05 mg/kg and given subcutaneously was found to be the most effective of the tested agents. This dose induced analgesia during the acute postoperative period and the longest period of pain relief, and it did not induce long-term changes in opioid sensitivity in 2 functional measures of the opioid system.

A lower dose of Buprenorphine (0.01 mg/kg SC) did not meet the criterion for analgesia.

A higher dose of Buprenorphine (0.1 mg/kg SC) was less effective in pain relief at later recovery periods and induced a long-lasting opioid tolerance, indicating greater neural adaptations (long-term effects on opioid sensitivity).

Upcoming Dates & Deadlines

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2012
A CHECKLIST FOR SUBMITTING ANIMAL USE APPLICATIONS
(Obtaining approval to work with animals at Duke)

GETTING STARTED:

♦ VISIT THE DUKE ANIMAL PROGRAM WEB SITE at: http://vetmed.duhs.duke.edu/
  ♦ Familiarize yourself with this web site. This is the principle source for animal program forms, policies, guidelines, directions for training, or process procedures used in the Duke animal care and use program.
  ♦ For more specific protocol development guidance click on the link at the left titled “Protocol Development.” You may access the protocol template from this page, or by using the next step.
  ♦ The protocol template may be found on the page (http://vetmed.duhs.duke.edu/index_of_new_protocol.htm).
    ♦ Review the protocol template instructions.
    ♦ Download the appropriate version on the template for your animal protocol (most researchers select ‘Option A’).
  ♦ Visit the ‘IACUC Meeting Deadlines’ web page to confirm the review and approval schedule that best meets your needs (http://vetmed.duhs.duke.edu/index_of_iacuc_meeting_deadlines.htm). While most protocols are approved at the first IACUC meeting, you should plan on a 2 month approval process, just to be safe.

♦ OBTAIN YOUR DUKE ‘NetID’ AND ‘Password’: While the animal program site is freely accessible, you will need your NetID and Password for certain steps toward protocol approval. NetID and Passwords are automatically created when you initiate a relationship with Duke (e.g. grad students’ fees are paid at the registrar; faculty position acceptance letter has been received by Duke HR). If you have problems or don’t know your NetID or Password, call the Office of Information Technology (OIT) at 919.684.2200.

♦ COMPLETE THE HEALTH REVIEW: The form for ‘Health Review for Animal Handlers’ is located at: https://www.hr.duke.edu/secure/eohw/animal.php. Once submitted, the assessment usually takes a few days, but may take longer if EOHW (Employee Health) determines additional medical assessment or immunizations are necessary prior to working with animals, animal tissues, or animal byproducts.

♦ COMPLETE THE BASIC WEB TRAINING FOR ANIMAL USERS: Visit the OESO (safety office) web site at: http://www.safety.duke.edu/. Select the link on the left ‘On-line Training.’ Enter your NetID and Password. Select ‘Courses Available On-Line.’ All animal users must complete Animal Handlers I and Animal Handlers II. If you are working with rodents and will use CO2 for euthanasia, you must also complete ‘CO2 Euthanasia of Rodents.’ You may complete any of the other courses you feel are appropriate for your lab procedures. The IACUC, OESO, or EOHW may require specified web courses (e.g. biosafety work may require completion of the biosafety web module) during the protocol review.

♦ FACILITY ORIENTATION: Access to animal vivaria requires an approved protocol and Facility Orientation. Contact Peg Hogan, RLATG, CMAR (ph: 919.684.3885) or Email hogan012@mc.duke.edu for scheduling.

PROTOCOL PRE-REVIEW: To assist researchers with protocol development, the Office of Animal Welfare Assurance (OAWA) provides a pre-review service. Just complete your application for animal use as best you can, and Email it to IACUC@DUKE.EDU. An OAWA veterinarian (Dr. Banks, Sharp, or Vanderford) will review your application and offer suggestions for improvement, in the hopes of achieving IACUC approval on the first review. This pre-review is not required, but it is the program default process and strongly encouraged to maximize an approval.

(Continued on the next Page)
PROTOCOL SUBMISSION:

- **SUBMISSION FOR IACUC REVIEW:** When ready, submit all applications for animal use to ICUC@DUKE.EDU. Once an application is submitted, DO NOT revise the document; only reply to the Emailed questions. Emails become part of the protocol file. A REVISED APPLICATION WILL REQUIRE RE-REVIEW AND MAY DELAY PROTOCOL APPROVAL!

- **ADMINISTRATIVE REVIEW:** You will receive a confirmation from one of OAWA’s Protocol Specialists that your protocol has been added to the IACUC’s agenda. The Protocol Specialist will also perform an ‘Administrative Review’ and may suggest enhancements (e.g. missing contact information, missing housing or procedure location, etc.). Please reply by Email with the information requested.

- **VETERINARY REVIEW:** All protocols receive a review by a Duke veterinarian prior to going to the IACUC. This review will include the entire protocol, but will focus on animal care, anesthesia, analgesia, and other animal care activities. The reviewer may identify specific concerns and offer suggestions to reconcile the concern. Please reply to the Email with the information requested. The pre-review and the veterinary review may occur at the same time, if both are performed by a veterinarian.

- **OESO / EOHW REVIEW:** All protocols and amendments are reviewed by OESO and EOHW to assure compliance with Duke requirements for a safe workplace. You will receive an Email notice from OESO/EOHW concerning any issues that require attention. Please do not delay in responding to OESO/EOHW. Animal protocols may be reviewed by the IACUC, but the protocol approval will not be granted until PROTOCOL CLEARANCE has been received from OESO and EOHW.

- **PRIMARY IACUC MEMBER REVIEWER:** A member of the IACUC will be assigned as the PRIMARY REVIEWER. A few days before the IACUC meeting you may receive an Email from the PRIMARY REVIEWER requesting clarification of certain points. Please reply to the Email with the information requested. The PRIMARY REVIEWER will be your advocate at the IACUC meeting.

- **NOTICE OF IACUC REVIEW:** Within 3 business days of the IACUC meeting you will be advised of the outcome of the Committee’s review. If approved, you will be given a protocol registry number and instructions on annual reporting of your animal use activity. If additional clarifications are required to secure approval, you will receive a point-by-point breakdown of necessary actions to secure approval.

PROTOCOL MAINTENANCE:

- **ANNUAL PROTOCOL REPORT:** A request for an annual report of your animal use activities will be sent via Email during the 10th month of the protocol. Please complete and return the annual report promptly, as IACUC approval is required by the 12 month anniversary, or the protocol may be suspended by the IACUC.

- **USDA REPORT:** The Duke animal program must report animal use to the USDA annually. A request for your animal numbers used will be sent via Email each fall. Please reply as soon as possible.

- **AMENDMENTS TO APPROVED ACTIVITY:** Any change of research direction, addition of new procedures or personnel, or changes in approved procedures must be IACUC approved prior to performing the changed activity. The Amendment form is available on the animal program website under ‘FORMS AND REPORTS.’ Depending upon the nature of the change, amendments may take between 3 and 14 business days for approval.

- **DE NOVO REVIEW:** According to NIH/PHS Policy, all protocols have a life cycle of 3 years. Projects continuing beyond 3 years must have a new protocol approved by the IACUC by the 36th month, or must be terminated. At the 33rd month of your protocol life cycle, OAWA will alert you by Email to submit a new protocol.

- **POST APPROVAL MONITORING:** Duke has an active program of Post Approval Monitoring (PAM). Compliance Liaisons will occasionally monitor animal procedures and confirm that the laboratory practices are as described in the approved protocol. Most laboratories will receive one visit per year, but depending upon the type of research, more monitoring sessions may be required. Researchers should view this process as partnering with the IACUC to assure program integrity. Deficiencies noted will be addressed quickly and in a collegial manner.