KETAMINE RECALL!

On December 22, 2009, the U.S. Food and Drug Administration (FDA) announced a nationwide voluntary recall of ketamine hydrochloride injectable (100mg/ml, 10 ml vials) manufactured by Teva Animal Health, Inc. Not all Teva products are affected by the recall. Teva Animal Health also manufactures ketamine hydrochloride products for other companies. These products are sold under various brand names and can include the following:

- Ketamine Hydrochloride Injection, USP (AmTech Group, Inc.)
- KetaThesia (Butler)
- VetaKet (Lloyd Laboratories)
- Ketaject (Phoenix)
- Keta-Sthetic (RXV)
- VEDCO (KetaVed)
- Fort Dodge/Pfizer (Ketaset)

Teva Animal Health is not the only manufacturer of ketamine hydrochloride in the U.S. and not all products sold under the above-listed names listed are affected. Therefore, regardless of the brand name on the product, look at the lot number on all ketamine hydrochloride (100 mg/ml in 10 ml vials) products.

- If the lot number is 6 numeric digits, the product is NOT part of the recall;
- If the lot number is 7 numeric digits, the product should be returned
- If the lot number starts with "5401", regardless of the number of digits or the presence of letters in the lot code, the product should be returned.

To return the recalled product:
- If purchased from DLAR: return to DLAR
- If purchased from another supplier: contact the supplier for the specific return process.

If you believe your research has been compromised by the use of these products, please contact the IACUC for options to increase your animal numbers for repeat procedures.

DR. JAMES REYNOLDS IS DEPARTING THE DUKE IACUC

It is with sadness that the animal program was recently advised by Dr. James Reynolds that he has accepted an offer to continue his research initiatives at another institution, and therefore must resign his position as IACUC Chairman for the Duke animal care & use program. Dr. Reynolds has served as the institution’s IACUC Chairman for the past 4 years, and during this time has led the institution’s animal care & use program in several significant initiatives. Below are a few of the programmatic enhancements for which Dr. Reynolds played a pivotal role as IACUC Chairman:

- Successful accreditation reviews by AAALAC international in 2006 and 2009. These two site visits remain the ‘cleanest’ of all accreditation reviews of the Duke animal program since the initial accreditation review in 1976.
- Numerous successful outcomes of unannounced USDA inspections
- Development of the PI Managed Animal Holding Facility registration process.
- Development of our nationally recognized Compliance Liaison Program—a program which continues to be modeled by other institutions.

This list could continue, but suffice it to say, Dr. Reynolds’ contribution to the health and vitality of the Duke animal care & use program has been pivotal and will continue far past his departure from campus. His leadership, collegial interactions, friendship, and programmatic support will be missed. We wish him well in his future endeavors.

You can send your personal note of thanks to James at reyo010@mc.duke.edu.

New IACUC Chair Sought

See Page 2 for responsibilities, qualifications, and application procedures.
NEW IACUC CHAIR SOUGHT

With the anticipated departure from Duke of James Reynolds, Ph.D., current Chair of the Duke Institutional Animal Care and Use Committee (IACUC), the School of Medicine is seeking a new Chair of the IACUC.

The Duke Institutional Animal Care and Use Committee (IACUC) oversees all animal-based research, training and teaching activities conducted at Duke University and conducted by Duke faculty members at other institutions or in the field. The Chair’s primary responsibility is to ensure that all animal use activities are conducted in compliance with the United States Department of Agriculture (USDA) Animal Welfare Act, Public Health Service (PHS) Policies, The Guide for the Care and Use of Laboratory Animals, Duke University animal use policies, and IACUC-approved animal care or use protocols.

This responsibility is met through a combination of protocol, amendment, and annual renewal reviews, semiannual programmatic reviews, and oversight of investigations into incidents of potential protocol noncompliance and potential animal welfare concerns. The IACUC Chair works closely with (but is independent of) Duke’s Office of Animal Welfare Assurance (OAWA) and Duke’s Division of Laboratory Animal Resources (DLAR). The Chair reports directly to the Vice Dean for Research and is accountable to the Institutional Official (Dean Nancy Andrews).

Anticipated responsibilities of the Chair are dependent upon the candidate’s qualifications/interests and final percent effort to be dedicated to the position, but are expected to include the following:

1) Protocol Review:
   ◆ Collaborate with the OAWA and DLAR veterinarians to conduct pre-reviews of new protocols to be considered by the IACUC at its monthly full committee meeting.
   ◆ Serve as the Designated Member Reviewer for all new protocols not approved at the monthly meeting and interact closely with Principal Investigators (PIs) to ensure all concerns identified during the full committee review are resolved.
   ◆ Serve as the principal Designated Member Reviewer for all protocol amendments reviewed outside the monthly full committee meetings.
   ◆ Collaborate with the OAWA veterinarian to conduct pre-reviews of amendments reviewed by the significant change sub-committee process.
   ◆ Review annual renewals and progress reports for all active protocols.

2) Programmatic Oversight:
   ◆ Chair the monthly full committee meeting and lead discussion on business items, compliance concerns, and proposed animal use (protocols).
   ◆ Assist in the preparation of all official communications that result from IACUC actions (minutes, protocol results, enforcement activities, etc).

3) Compliance Oversight and Enforcement:
   ◆ Chair the semi-annual programmatic meeting and prepare resultant reports evaluating all aspects of the Duke animal use program.
   ◆ Participate in and chair, as needed, IACUC sub-committee activities.
   ◆ Chair one of the two significant change subcommittee meetings run each month. Review all significant change amendments being considered by the subcommittee.
   ◆ Chair, oversee and/or participate in any called IACUC subcommittee investigation.
   ◆ Assist in the preparation and submission of all regulatory communications (USDA and PHS annual reports, reports on protocol deviations and animal welfare concerns, AAALAC programmatic description, etc).
   ◆ Participate as needed during regulatory inspections and accreditation site visits of the Duke animal program.
   ◆ Participate as needed in the inspection of new and existing animal use facilities.
   ◆ Provide guidance to PIs and research staff on procedural and animal use activities.
   ◆ Direct the activities of the Duke IACUC Vice Chair.
   ◆ Oversee and conduct as needed concordance reviews certifying procedures detailed in the grant application have been approved by the Duke IACUC.

Qualifications:
   ◆ The ideal candidate will have significant animal-based research experience, be detail-oriented, and possess excellent written and verbal communication as well as organizational skills.
   ◆ Candidates should hold a terminal graduate degree (PhD, MD, DVM, DSc, etc).
   ◆ Previous experience on the Duke IACUC, while not absolutely required (given appropriate IACUC experience elsewhere), is preferred.

Salary coverage will be commensurate with percent effort dedicated to the position. Interested individuals should contact Sally Kornbluth, Ph.D.: kornb001@mc.duke.edu.
SPRING 2010 IAUCUC SEMIANNUAL SITE VISITS

The Spring 2010 session of the IACUC semiannual site visits will begin in January. PIs and lab staff will be notified individually for their areas as the site visit draws closer. Please contact OAWA if you have any questions about how to prepare for this event. Dr. Banks will also present a Brown Bag Seminar on how to prepare for the site visit (please see upcoming training opportunities below).

We encourage you to check your lab areas for some of the following commonly observed items:

- Is protocol information readily available to all lab staff?
- Is emergency contact information and animal welfare reporting procedures posted?
- Are anesthesia machines, hoods and other equipment inspected/calibrated and current?
- Do lab staff have access to the Guide for the Care and Use of Laboratory Animals?
- Are all drugs correctly labeled and stored and is appropriate documentation readily available?

Your laboratory may consider sending one more members to a Brown Bag Seminar titled ‘IACUC Site Visit Prep’ for the most up-to-date information for planning a successful inspection.

NOTIFICATION OF HAZARDOUS WORK IN ANIMAL CARE AREAS

When animal research involves the use of hazardous agents, it is imperative animal care staff are notified of potential risks and how to work safely when such risks are present.

Researchers must assure all required signage is properly affixed and notification of pending (or ongoing) hazardous work has occurred prior to working with the agent in an animal use area. The PI will prepare a Standard Operating Procedure (SOP) that outlines the safe work practices for the animal use area when hazardous agents are employed. Personal Protective Equipment (PPE) is required, appropriate to the species and the hazardous agent being used. Investigators must notify DLAR via written communication, preferably e-mail, at least 2 business days prior to the use of hazardous agents in animals. PIs should contact Dr. Randall Reynolds (randall.reynolds@duke.edu), Peg Hogan (hogan012@mc.duke.edu) or Dr. Francis Sun (francis.sun@duke.edu) for more information or prior to use of hazardous agents in research animals.

QUESTIONS, CONCERNS OR COMPLAINTS ABOUT THE CARE, USE AND/OR WELFARE OF RESEARCH ANIMALS?

Any individual who has concerns related to the use of animals in biomedical research at Duke University is encouraged to voice those concerns. Please contact the Duke Animal Welfare Hotline (919.684.3535) or E-Mail the Duke IACUC at IA-CUC@duke.edu

Duke University will not tolerate any misuse or neglect of animals nor will the institution accept reprisal against an individual who has come forward with concerns or allegations of wrong doing involving the care and use of animals.

Such reprisal is prohibited by federal law (USDA Regulations & the 9th Code of Federal Regulations).

Individuals who feel that action has been taken against them because they reported an apparent violation of animal care and use requirements, should present their case to one of the individuals listed below:

Laura Hale, MD, PhD
Vice-Chair
Institutional Animal Care and Use Committee
919.684.6720

Ron Banks, DVM
Director
Office of Animal Welfare Assurance
919.684.4744

John Norton, DVM, PhD
Director
Division of Laboratory Animal resources
919.684.4204

ANNUAL REFRESHER TRAINING (ART)

ART made be found at the OESO On-Line Learning Web Site. Go to http://safety.duke.edu. Click ‘ON-LINE TRAINING’ on the left margin, and select Annual Refresher Training.

There are Brown Bag seminars scheduled which can be attended in order to receive credit for the annual refresher training. Please see upcoming training events on Page 4.
RESEARCH ANNUAL TRAINING

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 ART is located on the OESO On-Line Learning Web Site. Go to http://safety.duke.edu. Click ‘ON-LINE TRAINING’ on the left margin, and select Annual Refresher Training. The Web version includes a brief quiz.

The BBS ART will be provided several times during the year. The February provision will be held in the Hock Plaza Auditorium (Basement Auditorium) on February 11. There is no quiz with this version, but attendees must ‘sign in’ and attend the full session (~ 50 minutes) to obtain ART credit.

UPCOMING ANIMAL PROGRAM TRAINING OPPORTUNITIES

| Brown Bag Seminar: PI Annual Training |
| January 15, 2010 |
| 12:00 to 1:00 PM |
| Hock Plaza Auditorium |

| Brown Bag Seminar: Rodent Aseptic Surgery |
| January 20, 2010 |
| 12:00 to 1:00 PM |
| Hock Plaza auditorium |

| Brown Bag Seminar: Mouse Nomenclature, Genetic Background Effects and the Importance of Genetic Stability; Colony Management and Breeding Strategies; and JAX Search Tools |
| February 8, 2010 |
| 12:00 to 1:00 PM |
| Hock Plaza auditorium |

| Brown Bag Seminar: Cre-lox Technology in Mouse Models of Disease Research; Mouse Models of Human Cancer; and Immunodeficient Mice in Cancer Research |
| February 10, 2010 |
| 12:00 to 1:00 PM |
| Hock Plaza auditorium |

| Brown Bag Seminar: PI Annual Training |
| February 11, 2010 |
| 12:00 to 1:00 PM |
| Hock Plaza Auditorium |

| Brown Bag Seminar: IACUC Site Visit Prep |
| February 17, 2010 |
| 12:00 to 1:00 PM |
| Jones Auditorium Room 143 |

AALAS LEARNING LIBRARY

All individuals with an active protocol have access to FREE web module training through the AALAS Learning Library training site.

If you or your lab staff are interested in obtaining a password for this research procedure and bio-methodology training, please contact Bill Wade @ 668.6722 or via e-mail at w.wade@duke.edu