July 2012

IACUC Newsflash

THE UNIVERSITY OF PITTSBURGH

LEADER IN EDUCATION • PIONEER IN RESEARCH • PARTNER IN REGIONAL DEVELOPMENT

| Institutional Animal Care and Use Committee | University of Pittsburgh

In this Issue:

- **Refreshed:**
  iacuc.pitt.edu has been updated. See whats new!
- **ARO update:**
  Get the latest news on the University's online protocol managment system.
- **Compliance Q&A:**
  You asked, we answer.
- **Reminders & Updates:**
  Important information for the investigative community.

Dear Research Community,

The Spring Semi-Annual Review of our program has concluded, and I would like to thank you all for your time and candidness during our visits. It is encouraging to see the high level of involvement you have all taken with the SAR process. As we move forward, I am confident that the IACUC and investigators here at Pitt will continue to work effectively together to conduct cutting edge research and to promote excellence in animal care. On our end, we have completed the transition to the Online Protocol Management System, Animal Research Online (ARO) which has decreased review time for your protocols and allows for easy online access at any time. We have also redesigned our web site (www.iacuc.pitt.edu) to make it more organized and user-friendly.

Please take some time to explore our new website and check back often to see updates to our program. As always, I invite you to contact me with any comments or questions you may have. Keep in mind that our goal is to assist you in your research endeavors, so that your animal based work can be completed in a manner compliant with federal, state, and institutional policies. If, at any point during your research, you have a question regarding these policies, do not hesitate to contact the IACUC office! We can offer you answers to your questions, training for you and your staff, and information related to all facets of your animal-based research.

Lastly, I want to thank you for your continued hard work and dedication to research. It is your work that has helped keep our University in the spotlight as an internationally recognized center of excellence.

Very Best,

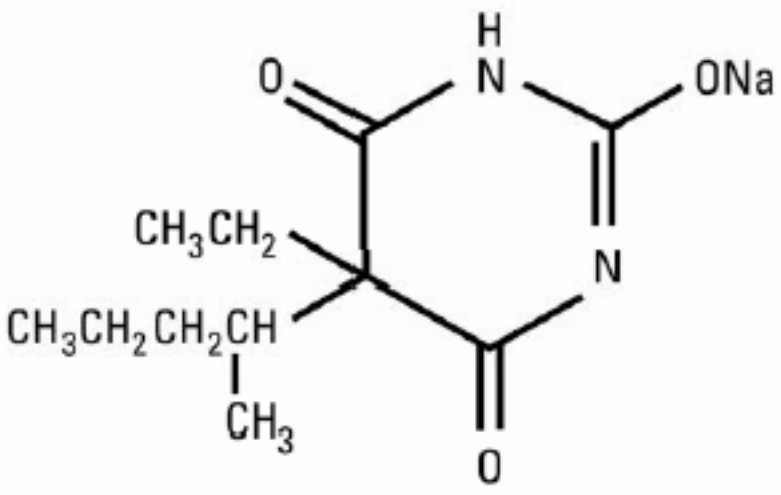
Dr. Denise Capozzi

Sodium Pentobarbital for Injection is Again Available Commercially

Last September, investigators were apprised that the manufacturer of Nembutal (sodium pentobarbital for injection) limited the distribution of the drug to hospitals, and authorized its use solely for the treatment of epilepsy. As of December 22, 2011, Nembutal was sold to Oak Pharmaceuticals, which is again offering the drug for veterinary purposes. Nembutal can again be purchased through Butler-Schein, the supplier that University of Pittsburgh investigators must use to obtain controlled substances, in both 20 ml and 50 ml bottles. Consequently, Butler-Schein should be the supplier for future orders of Nembutal.

Should an investigator require a custom formulation of Nembutal that is not commercially available, use of Hieber's Compounding Pharmacy may be permitted. In such a case, an investigator must obtain a prescription in order for the drug to be compounded by Hieber's pharmacy.

Please note that Nembutal is a schedule II controlled substance, and must be obtained, stored, dispensed, and administered in accordance with the University's controlled substance guidelines (see: http://www.rcco.pitt.edu/ControlledDrugs/). Further information about Nembutal can be obtained from: http://akorn.com/prod_detail.php?ndc=67386-501-52 .



Compliance Question & Answer

Policy (specifically that which involves animals in research) is dynamic, complex, and often controversial. As always, we encourage dialogue between our offices and our investigators so that, as a community, we can remain in compliance.

During the past six months, many of you have come forward with excellent questions. Of these, we've chosen the most relevant, and provided them here, along with the answers.

Q: *I understand the USDA and OLAW's requirement for Semi-Annual Review (SAR) but how should I prepare?*

A: The IACUC expects researchers at the University of Pittsburgh to maintain compliance with federal, state, and institutional regulations continuously throughout the year, and often will make unannounced visits in addition to the spring and fall SAR.

While reviewers are trained to look at your entire program to assure compliance, some questions that everyone listed on your protocol should be prepared to answer are:

1. What type of work you are approved for?
2. Where are current copies of your protocols, and are they accessible to everyone listed on them?
3 Where specifically in your lab (bench, hood) is your animal work done?
4. Do you have any controlled substances described in your protocol? If so, where are they stored and what security is in place? Where are your logbooks?
5. Where are your animals housed? Do you know who the veterinarian/ vet tech is for that site?
6. How do you transport your animals from the animal facility to your laboratory?
7. Are all your animal-related reagents and supplies in date? What mechanisms are in place to ensure expired items are identified and disposed of?
8. Is the IACUC required signage posted? Is it visible and up to date?

In addition, remember that these reviews work best when the dialog is two-way. Use these visits as an opportunity to ask questions and seek advice.

Q: *I have been questioned about clinical records related to my small animal research study. What are my responsibilities?*

A: The maintenance of specific medical records on bred for research rats and mice is not mandated by the United States Department of Agriculture (USDA) under the Animal Welfare Act, nor is it required by the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals or the National Research Council's (NRC) Guide for the Care and Use of Laboratory Animals. However, the latter document, in conjunction with previous NRC reports does emphasize the importance of accurate recording of the strains, sub-strains, and/or specific genetic backgrounds (via standard nomenclature) of animals used in research projects.

In order to assure a satisfactory level of humane care and meet current standards in the field of laboratory animal science and expectations of oversight and accrediting bodies such as the Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC International), it is necessary to maintain a basic level of record-keeping requirements for these species. Furthermore, the American College of Laboratory Animal Medicine (ACLAM), in a 2004 Policy Statement on Medical Records for Research Animals, recommended the maintenance of (group) health records for rodents.

Our policy specifically outlines who is responsible for record keeping, what records must be kept, where records should be maintained, and who should have access to records.
If you have not done so recently, please review the full policy on our website at:

https://www.iacuc2.pitt.edu/sop/restricted/MedRecordKeepingRodents.doc

Reminders

Animal Welfare is Everyone's Responsibility.
While the DLAR has been charged with caring for all research animals in their facilities, it is still important to do your part to assure their welfare.

- Every time you remove a housing unit, assure that the adequate food, water, and ventilation are available once it is returned to the rack, and before leaving the room.
- If you see someone or something that looks out of place, notify the RCCO and DLAR immediately.
- Always follow your approved IACUC protocol exactly, and do not deviate from what is written. If a clinical procedure must be performed which is not on your protocol, such as an emergency surgery, contact the University Vet Services before taking any action.

All proposed changes to an IACUC protocol, including personnel additions and room changes, must be requested via a modification request.

With new residents, interns, and graduate students coming in for summer rotations who may wish to work with animal models under your approved IACUC protocol, it is imperative that you submit a modification to add them to your protocol and gain approval BEFORE they begin their work.

Also, it is very important that the IACUC office has an up-to-date list of your active animal use areas. New or retired procedure rooms and use areas must be brought to the IACUC's attention via a protocol modification.

Tips

- **Breeding SOP violations**

The IACUC recognizes the importance of rodent breeding colonies to biomedical research at the University of Pittsburgh. It is also recognized that effective colony management is essential to ensure animal welfare is protected. Working with the DLAR, the IACUC tracks and cites instances of non-compliance with the University's breeding SOP and sanctions repeat offenders. Time spent developing a good management system at the start of your breeding will pay dividends as your program expands. If you have questions with setting up your management system, speak with your site supervisor or contact the IACUC office at IACUC@pitt.edu

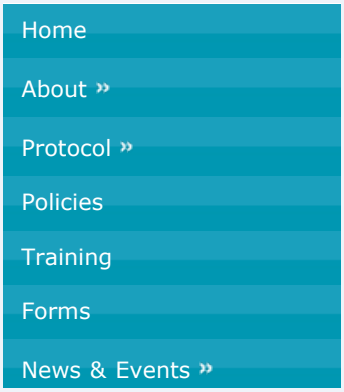
Updates

New NIH requirements necessitate a change in the IACUC's grant review policy.
NIH has recently changed its "just in time" (JIT) procedures, which must be completed in order for funding to be released for an NIH grant. The announcement can be found at:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-101.html .

www.iacuc.pitt.edu

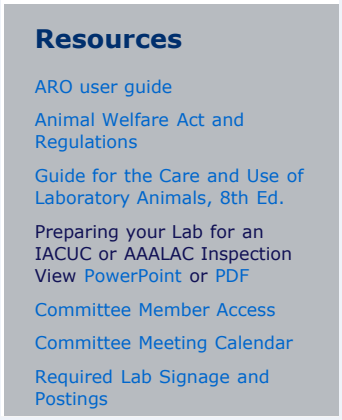
The IACUC website has been redesigned to provide a more user-friendly experience. Some features include:



The main navigation bar serves as your compass. It remains in place wherever you travel on the site and allows you to select a new destination. From here, you can:

Learn more about the IACUC, its roles and its functions
Find information on protocol reviews and compliance
Find institutional polices
Review the required training
Access pertinent IACUC forms
Catch up on recent news and events

The resources bar:



The resources bar gives you immediate access to important information. It remains in place wherever you travel on the site and allows you to quickly reference one of the featured guidance documents. Some current featured links include:

The ARO user guide. This document covers all aspects of the new online protocol management system.
The AWA, 9 CFR. This regulatory document outlines the United States laws regarding animal care and use.
The Guide. A primary reference document for any institution receiving NIH funding for any institution that is AAALAC accredited.

Featured news:

A prominent feature on the home page. Look back often for news and updates relevant to your animal research.

Reporting concerns:

One of the most important feature of the site. This button allows you to quickly and confidentially report concerns regarding animal welfare.

The Institutional Animal Care and Use Committee at the University of Pittsburgh investigates all concerns regarding the care, treatment, and use of animals for research or teaching at the University.

Update on ARO (Animal Research Online)

On January 1, 2012, we introduced ARO (http://www.aro.pitt.edu), our online protocol processing system. We appreciate the cooperation of the research community as initial implementation problems were identified and corrected. This message provides information regarding utilization of the ARO system, its impact on protocol processing times, improvements that have already been incorporated, and planned improvements for the coming year.

ARO Has Reduced Protocol Review Times

Over 325 IACUC protocols have now been submitted through ARO. One reason for implementing ARO was to automate a number of aspects of protocol processing, with the objective of minimizing administrative burden and reducing protocol review times. We are pleased to announce that this objective is being realized. The following table compares the average total review times for IACUC protocols during the first half of 2011 (when protocols were submitted as emailed documents) and ARO submissions during 2012. The review times include the cumulative time for the initial review and subsequent reviews after protocols were revised in response to reviewer questions. Now that IACUC reviewers and protocol review coordinators are familiarized with ARO, we are hopeful that review times will decrease even further in the future.

Type of Protocol	Protocols Submitted as Word Documents in 2011	Protocols Submitted through ARO
New Protocol	43 days	30 days
Modification	24 days	6 days

Improvements in ARO Since Implementation

No new system is ever perfect, and the ARO development team has listened to user feedback to identify potential improvements. We have already implemented "Modification Light" (MOD LITE), to facilitate common administrative changes to protocols, including:

- Personnel Changes
- Protocol Administrator or Editor Changes
- Title Changes

Continued

- Emergency Contact Changes

MOD LITE allows users to make these changes on one form, without having to subsequently edit a copy of the protocol. To use the MOD LITE function go to your protocol's home page, then click the "Create Mod-Lite" link under Activities.

Planned Improvements in ARO During 2012-2013

The ARO development team is committed to making the following improvements to ARO during the 2012-2013 academic year:

- Implementation of a "protocol copy" feature, which clones an approved ARO protocol such that it can be edited and submitted as a new protocol. We are hopeful that this feature will reduce administrative burden for investigators.
- Providing for the pre-population of some fields in the protocol, based on previous entries. This feature should eliminate the administrative burden of entering the same information more than once.
- Improvements in the reports that can be generated from ARO by IACUC and animal facility staff members, to facilitate administrative and compliance activities.
- Improvements in the ARO meeting management function, to optimize the use of the system for generating the agenda for IACUC meetings.

Investigators are welcome to submit suggestions for other improvements in ARO to the attention of the development team. To do so, please contact Michael Kessler in the IACUC Office (kesslermc@upmc.edu).

Reminder that IACUC Protocols Submitted Prior to the Implementation of ARO Can Be Transitioned to ARO

Annual renewals and modifications of existing protocols not originally entered into the ARO system must be submitted by emailing a Microsoft Word document to the IACUC office, as in previous years. However, it is not necessary to wait until the three-year expiration of a protocol before it is entered into ARO.

Investigators, if they wish, may enter their existing protocols into ARO before the three-year renewal, so they can benefit from the conveniences and time savings of the system. Note that such early three-year renewals will be subject to a standard review by the IACUC.