



The ACC Connection

Volume 4, no. 4, JULY / AUG 2008

WELCOME to the 15th edition of the **ACC Connection**, a bi-monthly newsletter designed to help researchers with questions regarding animal research at the University of Connecticut Health Center. Our 15th issue is designed to help animal researchers understand what they need to know or do in order to use laboratory animals here at the Health Center. We will also present some helpful resources for laboratory animal users.

The Health Center's Animal Care Committee (ACC) is committed to the humane care and use of laboratory animals. To ensure that laboratory animals receive humane care and use or treatment in accordance with the highest ethical standards, laws, regulations, and policies governing animal research, it is imperative that this material be presented to all individuals who use laboratory animals. It is the responsibility of Principal Investigators and all laboratory animal users to know what is required to use animals at the Health Center.

Animal Training

Federal laws require that **ALL** individuals who use animals be trained in the biology of the species and the procedures that they are performing. This requirement is stated in both the Health Research Extension Act of 1985 (the statutory mandate for PHS Policy) and the Animal Welfare Act and Regulations. It is also institutional policy. All new animal users must attend an initial animal users training course. This is a 3-hour lecture which is given once per month by members of the ACC, CLAC, and ORS. To sign up- and enrollment is required to attend- the individual must contact the ACC Office at ooacc@uchc.edu.

Renewal animal training is done on-line via CITI training. The ACC office sends notification to those individuals who are in need of training with the course they need to complete and the date by which it must be completed. The minimum requirement is one course per year. The website contains information on how to use CITI Training website (<http://clacc.uchc.edu/Training/Onlinetraining.htm>). Please refer to the ACC policy which covers animal training on the website: <http://clacc.uchc.edu/ACC/Policies/AllPolicies.htm>. A previous edition of the **ACC Connection** has detailed the training program [4(1) Jan/Feb 2008] and is archived on the ACC website. Please sign up **NOT** how CITI will ask you to, but how we ask you to. Failure to do this will result in your doing a lot more training than what will be asked of you. **This cannot be emphasized enough.**

Enrollment in the Occupational Health Surveillance Program

All animal users must enroll in the occupational health surveillance program. Please take the time to review the occupational health website (<http://clacc.uchc.edu/ACC/OccHealthandSafetywithAnimals.htm>). This site provides information regarding the risks associated with working with laboratory animals, the description of the occupational health surveillance program, and information on how to enroll in this program. Federal law (PHS Policy) and institutional policy (http://www.policies.uchc.edu/policies/policy_2005_13.pdf) require the mandatory enrollment of all animal user personnel. It is up to the individual to decide whether or not they wish to **participate** in the program. A previous edition of the **ACC Connection** [4(2) May/June 2007] details the OHS program and is archived on the ACC website. To summarize, enrollment requires each individual to completely fill out a Mandatory Annual Certificate of Enrollment (MACE) form (which is a 2-page, carbonless copy form), sign it, and send the top (white) page to EHS and the bottom (yellow) page to the ACC office. You are not considered enrolled in the OHS program until the ACC office receives the yellow copy of the MACE enrollment form.

ACC Approved Policies

The Animal Care Committee has a number of policies (current total is 34) which govern the use of laboratory animals here at the Health Center. It is the responsibility of the PI to ensure that they, along with all laboratory animal user personnel, are familiar with the ACC policies. Everyone who uses laboratory animals is expected to comply with the ACC policies. Failure to do so may lead to the revocation of an individual's ability to use laboratory animals. You can find all the policies on the website: <http://clacc.uchc.edu/ACC/Policies/AllPolicies.htm>.

Be Familiar with the Federal Regulations Which Govern Animal Use

It is absolutely imperative that PIs, along with their laboratory staff, are cognizant of the regulations which govern animal use at the Health Center. This would include: Animal Welfare Act, Animal Welfare Regulations, USDA Animal Care Policies, the Health Research Extension Act of 1985, PHS Policy on Humane Care and Use of Laboratory Animals, and the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training. If applicable, researchers should also be aware of the mandates set forth in the Migratory Bird Act and the Endangered Species Act.

Ignorance of the laws governing the use of animals is not an excuse to not adhere to them. Violation of federal laws governing the use of laboratory animals is reportable to the NIH Office of Laboratory Animal Welfare (OLAW), the USDA, and your funding agency. It is in everyone's best interest **NOT** to allow this to happen. All applicable laws are accessible through the ACC website (<http://clacc.uchc.edu/ACC/AllLaws.htm>). Everyone who uses laboratory animals should review this information.

Write and Submit the Animal Care and Use Application and Modifications

All research involving the use of live, vertebrate animals **must be approved by the ACC prior to using the animals**. It is the responsibility of the PI to submit an animal care and use application to the ACC. The application forms can be found on the ACC website (<http://clacc.uchc.edu/ACC/SubmittingProtocols.htm>). Deadlines by which to submit forms for ACC meetings are also on the website (<http://clacc.uchc.edu/ACC/SubmittingProtocols.htm>). Failure to submit an application and receive ACC approval prior to starting animal work is a serious violation of federal law (AWA, PHS Policy) and is reportable to OLAW, the USDA, and your funding agency. It is in everyone's best interest **NOT** to allow this to happen.

It is also federally mandated that the ACC approve changes or modifications to approved animal care and use protocols. The ACC requires that all modifications to an approved protocol be submitted to, and approved by, the ACC **PRIOR** to the implementation of those changes. Failure to do this is a violation of federal law and is reportable to OLAW, the USDA, and your funding agency. Previous editions of the **ACC Connection** [1(1) Oct 2005; 3(4) July/Aug 2007] have detailed how the submission process is handled at the Health Center and are archived on the website.

Read the Ethics of Animal Use Webpage

Using animals in an ethical and responsible manner is expected at the Health Center. The issues of animals and ethics and the use of animals in biomedical research are topics important for all researchers and personnel who use animals. People should take some time to think about it. It is not the intent of the ACC to tell anyone how they should feel about these topics; however, it is important that information be available to the research and animal care community so that each individual can explore these topics.

Notify the ACC of any Unexpected Study Results that Impact Animals

The ACC needs to be informed if any animal work results in unexpected or unanticipated animal morbidity and/or mortality. This would include any unanticipated pain and distress to the animals. It is the PI's responsibility to inform the ACC of any events in a timely manner (defined as within 72 hours of discovery). Please review the policy on this topic which is available on the website (<http://clacc.uchc.edu/ACC/Policies/MorbidityMortality.htm>).

Read the *ACC Connection* Newsletters

New *ACC Connection* Newsletters are mailed to all PIs in January, March, May, July, September, and November. They are also posted on the ACC website (<http://clacc.uchc.edu/ACC/ACC%20Connection/ACC%20Connection.htm>). These documents contain a variety of information that is of a help to all animal users.

Read the Animal Users Training Handbook

Federal law is fairly clear on what training information must be provided to laboratory animal users. In most cases, there is not enough time to present everything during the initial animal users training class. Therefore, a training handbook (given out to everyone who attends the initial animal user training class) which covers a variety of topics is also located on the website (<http://clacc.uchc.edu/ACC/2008Handbook.pdf>). It is the responsibility of all animal users to be familiar with the information provided in this resource document. The ACC office also has copies of the handbook; contact the ACC office at ooacc@uchc.edu if you want one sent to you.

Justify Exemptions to Standards

Frequently in research, there comes a time to balance the needs of the researcher and the need to follow federal or institutional laws and regulations. The ACC can be a valuable resource to investigators when they find themselves in this position. Regulations are “there for a reason”; namely, to ensure animal health and well-being. Exemptions to these standards require scientific and/or medical justification and ACC approval. ***Cost savings and/or research convenience are never adequate reasons for an exemption to regulatory standards.***

The process for justifying exemptions to standards starts with knowing what the standards are. These are primarily promulgated by *The Guide for the Care and Use of Laboratory Animals*, the *2007 AVMA Guidelines on Euthanasia*, and the Animal Welfare Regulations. All these documents can be viewed on the ACC website (<http://clacc.uchc.edu/ACC/AllLaws.htm>). Then, determine if you need an exemption from a standard. You will need to determine the ***scientific and/or medical reason(s)*** you need to do what it is you plan to do. For instance, why is it you need to keep your animals in your laboratory for more than 24 hours? Convenience to the research personnel would not be a good answer and would not be approved by the ACC; however, if you need to perform a blood draw every 8 hours throughout the night and over the weekend and monitor the animals’ biological responses- that may be an adequate justification for the animals needing to be in the laboratory.

The following are examples of situations which would require ACC approval for exemption to the standards: single housing of rodents, housing animals outside of the CLAC facility for more than 12 hours for USDA regulated species or more than 24 hours for all other species; multiple major survival surgery; food and/or fluid restriction more than what is usually done for pre-operative measures; prolonged restraint; non-standard caging (e.g., wire-bottom, metabolic, no bedding); physical methods of euthanasia without anesthesia or sedation (e.g., decapitation, cervical dislocation, perfusion); not providing standard enrichment to the animals; withholding psychological enrichment from nonhuman primates; and withholding exercise for laboratory dogs. This is not an exhaustive list, but some of the more common exemptions the ACC has dealt with in the past. Contact the ACC office to determine if you may require an exemption approval. Review the website at <http://clacc.uchc.edu/ACC/Frequently%20asked%20questions/Justifyingexemptions.htm>.

Frequently Asked Questions

Why can't I do on-line training for initial animal care and use training? It is so much more convenient.

On-line training is a great advantage for animal users- it lets individuals complete their training when it is convenient for them. However, initial training covers information quite specific to the Health Center- especially with regard to policies and procedures of the Health Center. It would be more difficult to accomplish this by relying only on CITI training for all our training needs.

Why do I have to report unusual and/or unexpected animal morbidity and/or mortality?

It is a condition for approval to use animals that the PI will report any adverse incidences involving those animals to the ACC. It is required by ACC policy (<http://clacc.uchc.edu/ACC/Policies/MorbidityMortality.htm>) in order to comply with federal regulations and laws. A Principal Investigator signs an assurance when submitting the animal care and use protocol application- one of these assurances is that they will report any instances of unusual and/or unexpected animal morbidity and/or mortality.

How much trouble can we get into if we don't follow federal laws regarding the use of laboratory animals?

The theoretical answer would be “unlimited”. Both the USDA and the NIH have the ability (and certainly have been known) to fine institutions for failure to follow federal laws governing animal research. It is uncommon, though not unheard of, for institutions to be fined millions of dollars for failure to care for laboratory animals and have research grants terminated because of this. The potential for monetary damage is real. Typically, initial instances of misuse of laboratory animals or non-compliance result in trying to remedy the problem in a timely manner (unless, of course, the problem is egregious).

Upcoming Training, July 2008 – August 2008

New Animal Users Initial Basic Core Training

Monday, July 21	9:00 am – 12:00 pm	Building 20 conference room
Monday, August 18	9:00 am – 12:00 pm	Building 20 conference room

New Institutional, State, or Federal Regulations

Institutional

None

State

None

Federal

Great Ape Protection Act

This bill was submitted to Congress in April and in May was submitted to the House of Representatives. This would end invasive research and testing on all chimpanzees in the United States.

2008 Farm Bill

May 22, 1008

The 2008 Farm Bill was enacted into law following presidential veto override votes in both the House and Senate. The law prohibits the use of live animals for marketing medical devices; increases fines under the AWA; and provides for enhanced protection of pets.



Next Issue: Common Protocol Submission Errors

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