



# The ACC Connection

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**WELCOME** to the second edition of the **ACC Connection**, a quarterly newsletter designed to help researchers with questions regarding animal research at the University of Connecticut Health Center. Our third issue is designed to help you become familiar with the maze of regulatory requirements which govern the use of animals in research. These regulatory requirements are evolving and one objective of this newsletter is to serve as a vehicle to keep you informed of those changes and the measures that we must collectively take to be compliant with current regulations. The Health Center is required to ensure that animal use conforms to a multitude of state and federal regulations which include compliance with the Animal Welfare Act in accordance with the Animal Welfare Regulations (9 CFR, 1985), the Public Health Service Policy on Humane Care and Use of Laboratory Animals (2002), and the recommendations promulgated by the *Guide for the Care and Use of Laboratory Animals*.

Researchers may have noticed recently that protocols which were approved 3 years ago may not be approved today. This is due, in part, to changing regulatory requirements or enhanced federal oversight of those regulations as demonstrated by the following. In October of 2005, the Office of the Inspector General (OIG) issued a report about the USDA-Animal and Plant Health Inspection Service (APHIS) and its oversight of research laboratories which affects us here at the Health Center. The OIG concluded that IACUCs are not effectively monitoring the research at their institutions (finding #4 of the report); the most frequent violation being inadequate search for alternatives in the animal care and use protocol application. This "search for alternatives" finding has become a target inspection point for APHIS inspectors; consequently, the IACUC here at the Health Center must enforce this requirement more stringently than has been done in the past.

The ACC has a new application form instituted in March of 2005 which requires more information than the previous protocol application. Much of this is in a check-box or table form to try and help the investigators with filling out the protocol and identifying pertinent information. The additional information requested helps the IACUC understand what the protocol entails and ensures compliance with institutional, state, and federal regulations. If investigators need any assistance in filling out the form, they can go to the website (<http://clacc.uhc.edu>) and download the document entitled "Animal Care and Use Application Instructions" or contact the ACC coordinator. The ACC is charged with upholding the standards set forth in the regulations. The ACC members, institutional veterinarians, and the ACC coordinator are valuable resources in helping you prepare your protocols.

## The Animal Welfare Act

**Its Introduction-** The Animal Welfare Act (AWA) was first introduced in 1966 as the Laboratory Animal Welfare Act partly as a response to animal welfare groups. It has had numerous revisions over the years, the most important amendment being in 1986 which introduced the requirements for exercise for dogs; requirements for the psychological well-being of non-human primates; requirements for pain alleviation; justification requirements for multiple major survival surgeries.

**Covered Species-** You are required to abide by the Animal Welfare Act if you use a "covered species". Here at the Health Center, this includes warm-blooded vertebrate animals with the exception of mice of the genus *Mus* and rats of the genus *Rattus* bred for research purposes and birds.

**Responsibilities of the PI under the AWA-** PIs are required to submit a protocol to the ACC and have all procedures they intend to perform on animals approved by the ACC prior to their performance on an animal. The PI is required to provide an acceptable, written justification to the ACC for areas of non-compliance within the animal welfare act. This would include the mandate to utilize procedures that will avoid or minimize discomfort, distress, and pain to the animals; requirement that animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure; the requirement that the

animals' living conditions will be appropriate to their species and contribute to their health and comfort; the requirement that no animal will be used in more than one major operative procedure from which it is allowed to recover. The PI must provide written assurance that the activities do not unnecessarily duplicate previous experiments. The PI (and all personnel) must be trained in the procedures that they are going to perform. Methods of euthanasia used will be consistent with the recommendations of the AVMA Panel on Euthanasia.

[What are some things I actually have to know under the AWA-](#) There are a lot of things you should know that are required under the AWA:

1. If you are planning to perform any procedures that have the potential to cause pain or distress to your animals, **you must consult with a veterinarian while in the planning stages of your protocol:** not when you submit the protocol, not when you start to use your protocol, but when you are *planning* what to do.
2. If you are performing any procedures that have the potential to cause more than momentary pain or distress to the animals (what we term a "D" or "E" level procedure), you must perform a search for alternatives to pain or distress for each painful/distressful procedure you are planning to perform. In addition, if you are doing an "E" level procedure (you cannot give pain-relieving procedures to the animals) you have to write a justification in order to be able to do that. The justification must incorporate the concepts of Replacement, Reduction, and Refinement as defined in the protocol application form.
3. If your search for alternatives is accomplished by a literature search, that search must include, in the protocol: the search strategy used, the date of the search, the years searched, and **must** include at least 2 databases.
4. If you are going to house your animals under conditions other than what is standard and outlined in the AWA, you have to provide written justification.

## PHS Policy on the Humane Care and Use of Laboratory Animals

[Its Introduction-](#) The first PHS Policy was passed in 1979. Like the AWA, it has been amended on various occasions, most recently in 2002.

[Covered Species-](#) You are required to abide by PHS policy if you receive PHS funding and use any live, vertebrate animal in research, research training, experimentation, or biological testing or related purposes.

[Responsibilities of the PI under PHS Policy-](#) The responsibilities of the PI under PHS policy are similar to those under the AWA. PIs are required to submit a protocol to the ACC and have all procedures they intend to perform on animals approved by the ACC prior to their performance on an animal. PIs are required to perform procedures which will avoid or minimize discomfort, distress, and pain to the animals and procedures that will cause more than momentary or slight pain or distress need to be performed with appropriate sedation, analgesia, or anesthesia unless the procedure is justified for scientific reasons, in writing, by the investigator. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly killed at the end of the procedure or, if appropriate, during the procedure. PIs will assure that they and their staff conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures. Methods of euthanasia used will be consistent with the recommendations of the AVMA Panel on Euthanasia unless a deviation is justified for scientific reasons in writing by the PI.

[US Government Principles-](#) The US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training were promulgated in 1985 by the Interagency Research Animal Committee and adopted by US Government agencies that either develop requirements for or sponsor procedures involving the use of vertebrate animals. They are incorporated into PHS policy in the 1986 revision of PHS Policy.

[What are some things I actually have to know under PHS Policy-](#) There are a few things you should be aware of as you perform your PHS supported activities:

1. Everyone who is listed on the protocol as an animal user must be enrolled in an occupational health / medical surveillance program.
2. When you submit an NIH / PHS supported grant, and reference an ACC-approved animal care and use protocol number, you are stating that all the animal procedures you describe in the grant have been given approval by the ACC. This will be checked by the ACC office. If you are using procedures **which have not been approved** by the ACC, the grant should be "pending" on the routing slip for the vertebrate animal section.
3. If your protocol has expired (that is, has past the 3-year expiration date), you may not use your experimental animals until your renewal protocol has been approved by the ACC. There may be **no exceptions** to this- it is against PHS Policy. Using the animals after the protocol has expired constitutes a serious violation and is reportable to the Office for Laboratory Animal Welfare (OLAW) and may subject the Health Center to fines.

## Frequently Asked Questions

### *Why do I need to know this (Why are you wasting my time)?*

As a PI, you are responsible for numerous things and regulatory burden happens to be one of them. The more you know of what the regulations say, the better you can write your protocol. You are more likely to stay in compliance with the regulations; after all, if you don't know what the regulations are, how can you be compliant with them?

### *With the "just-in-time" rule for PHS policy, I don't have to have an approved protocol to submit my grant. How does this actually work?*

The 2002 amendment to PHS policy made the "just-in-time" rule which basically says that you don't have to have an approved protocol when you submit your grant. If your grant is going to be funded, you will have to provide the funding agency with a verification of approval by the IACUC (our ACC) of "those components of the application or proposal related to the care and use of animals". Typically, you have 60 days to provide the approval verification (e.g., the ACC approval letter). **Please note** that all grants are compared with the ACC approved protocols to ensure that the procedures in the grants match the procedures outlined in the protocol. If there are discrepancies, the PI will be notified by the ACC office and the approval letter will not be issued until the discrepancy is resolved. Protocols take an average of 2 months to be approved by the ACC so this should be considered by the PI when notification by the granting agency is given.

### *If my protocol has reached its 3-year expiration date and my renewal protocol has not yet been approved, can I get an administrative extension of the ACC approval?*

No. The ACC may not extend the three-year approval by any means other than an ACC review and approval using the established procedures. When ACC approval expires, it is no longer valid. Continuation of animal activities beyond the expiration is a serious and reportable violation of PHS Policy and the Animal Welfare Act.

### *Do the requirements of PHS Policy apply exclusively to activities that are supported to PHS?*

No. Our PHS Assurance of Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, 2006, states that we will treat all animals as if they are covered under PHS Policy to avoid any perceptions of unequal treatment of any research laboratory animal housed and used at the Health Center.

### *Can I just cut and paste the vertebrate animal section from my grant application to the animal care and use application?*

No. You will notice on the new application form that cutting and pasting from a grant would be very difficult compared with the old application form. The vertebrate section of a grant does not go into enough detail which the protocol requires. It is strongly recommended that you do not cut and paste from your grant.

If you have questions you'd like to see answered in future issues, please send them to [pohl@uchc.edu](mailto:pohl@uchc.edu) and we will do our best to answer as many questions as possible.

## Upcoming Training, January 2006 – March 2006

### Animal Users Training

Monday, January 16, 2006	9:00 am – 12:00 pm	Building 20 conference room
Monday, February 20, 2006	9:00 am – 12:00 pm	Building 20 conference room
Monday, March 20, 2006	9:00 am – 12:00 pm	Building 20 conference room

## New Institutional, State, or Federal Regulations

**UCHC Policy #2005-13**    9/28/05    Occupational Health Surveillance Program for Principal Investigators (PI), Researchers, Technicians, Center for Laboratory Animal Care (CLAC) Staff, and Students Utilizing Animals in Research or Educational Programs. To view the policy, go to: [http://www.policies.uchc.edu/policies/policy\\_2005\\_13.pdf](http://www.policies.uchc.edu/policies/policy_2005_13.pdf)

**ACC Policy**    11/17/05    Utilizing Designated Member Review (DMR) for New Protocol Submissions. To view the policy, go to: <http://clacc.uchc.edu/ACC/Policies/AllPolicies.htm>



## Next Issue: The 3 R's- What you need to know

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