The IACUC Connection

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WELCOME to the 36th edition of the ***IACUC Connection***, a quarterly newsletter designed to help researchers with questions regarding animal research at UConn Health. We thought we would celebrate the 50th anniversary of the first passage of the Animal Welfare Act in 1966 so our 36th issue is revisiting 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. UConn Health 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, 2013), the Public Health Service Policy on Humane Care and Use of Laboratory Animals (2015), and the recommendations promulgated by the *Guide for the Care and Use of Laboratory Animals* (2011).

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 November of 2014, 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; 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 UConn Health must enforce this requirement more stringently than has been done in the past.

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 (1970, 1976, 1985, 1990, 2002, 2005, and 2013), the most important amendment being in 1985 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 IACUC and have all procedures they intend to perform on animals approved by the IACUC prior to their performance on an animal. The PI is required to provide an acceptable, written justification to the IACUC 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 *2013 AVMA Euthanasia Guidelines*.

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 (1975, 1985, 2002 and, most recently in 2015). The most important revision was in 1985 which set the standard that we use today regarding PHS assurances, mandatory IACUCs and protocol review, and incorporation of the Health Research Extension Act of 1985 and the US Government Principles.

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 *2013 AVMA Euthanasia Guidelines* 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 1985 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 IACUC-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 IACUC. This will be checked by the IACUC office. If you are using procedures ***which have not been approved*** by the IACUC, the grant should be "pending" on the routing slip for the vertebrate animal section.
3. If your protocol has expired (that is, it has passed the 3-year expiration date), you may not use your experimental animals until your renewal protocol has been approved by the IACUC. 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 UConn Health 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 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 IACUC approval letter). ***Please note*** that all grants are compared with the IACUC 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 IACUC 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 IACUC 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 IACUC approval?
No. The IACUC may not extend the three-year approval by any means other than an IACUC review and approval using the established procedures. When IACUC 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 to the Office for Laboratory Animal Welfare (OLAW).

Do the requirements of PHS Policy apply exclusively to activities that are supported to PHS?
No. Our current 2013 PHS Assurance of Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals 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.

Upcoming Training, April 2016 – June 2016

Animal Users Training

Monday, April 11	9:00 am – 12:30 pm	Low Learning Center
Monday, May 9	9:00 am – 12:30 pm	Low Learning Center
Tuesday, May 31	1:00 pm – 4:30 pm	OPVR Conference Room L-5053*
Monday, June 20	9:00 am – 12:30 pm	Low Learning Center

* This training date and time is for summer students ONLY

PLEASE NOTE: Individuals who wish to attend training must complete a registration form and submit it to the IACUC office. Forms and instructions are located on the web at http://iacuc.uchc.edu/training/initialtraining.html.

PLEASE NOTE: All individuals working at the UCH starting 9/1/13 or later must complete animal training documentation. The document can be found on the web at http://iacuc.uchc.edu/documents/protocols/training_records_form.docx. We will be copying this information, or asking that they be sent to the IACUC office, when we perform semi-annual inspections in June and December.

New Institutional, State, or Federal Regulations

Institutional
Please review all of our IACUC policies. They are located on the web at http://acc.uchc.edu/policies/index.html. All animal users are responsible for knowing and complying with all IACUC approved policies. You should also be aware of required institutional policies. They are located on the web at http://www.policies.uchc.edu/.

State
None

Federal
None

Important Reminders to Principal Investigators

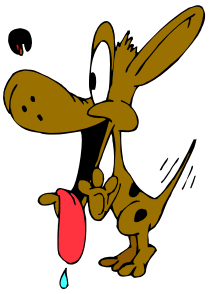
- When an individual leaves your laboratory, and is no longer an active animal user, you **must** contact the IACUC Office (ooacc@uchc.edu) with this information.

- If any unexpected morbidity and/or mortality occurs in any experimental animal, you **must** contact the IACUC office (ooacc@uchc.edu) with this information.

- Always remember to list ***ALL*** transgenic and gene targeted animals and their origin in your animal care and use protocols. If you have any questions regarding transgenic or gene-targeted animals, please contact the IACUC office (ooacc@uchc.edu) or the Biosafety Officer (rwallace@adp.uchc.edu) for help.

- When your laboratory location has moved, you must modify your IACUC protocol to reflect the correct room locations.

- If you have any cares, concerns, or questions, please contact the IACUC office at ooacc@uchc.edu or at x3429.



Next Issue: Surprise!

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