



The ACC Connection

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WELCOME to the tenth 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 tenth issue is designed to help you become familiar with your responsibilities as laboratory animal researchers. The University of Connecticut Health Center and the Animal Care Committee are committed to the humane care and use of laboratory animals and we require compliance with all federal laws, state laws, and institutional policies which govern the use of laboratory animals.

The Federal Laws, Regulations, and Guidelines

Animal Welfare Act and Animal Welfare Act Regulations (AWA / AWARs)- This law governs the use of USDA-regulated species (simply stated as all warm-blooded vertebrate animals with the exception of birds and mice and rats bred for research purposes and farm animals used for food and fiber production). The USDA has also generated a list of Animal Care Policies (currently, there are 31 approved policies) that must be adhered to as well. If you use regulated species, you should be familiar with these laws and policies. If you need a copy of the Act and Regulations and/or the Animal Care Policies, please contact the ACC office at ooacc@uchc.edu.

PHS Policy and Health Research Extensions Act- This law governs the use of all vertebrate animals; there are no exceptions. This includes cold-blooded as well as warm-blooded animals. PHS Policy has also incorporated the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training. If you work with PHS-funded animals, you should be familiar with these laws and policies. If you need a copy of the PHS Policy, please contact the ACC office at ooacc@uchc.edu.

NIH Guidelines for Research Involving Recombinant DNA Molecules- This federal guideline governs the use of rDNA in research- including that which is used in animals. Compliance with the NIH Guidelines is mandatory; failure to adhere to it can result in suspension or termination of NIH funding for this type of research or lead to a requirement for prior NIH approval of any or all rDNA projects at the institution.

AVMA Panel on Euthanasia Guidelines- Though not technically a law, the AWA / AWARs, PHS Policy, and our PHS Assurance require that all methods of euthanasia of laboratory animals comply with this guideline from the American Veterinary Medical Association. A copy of the document can be found on the ACC website at <http://clacc.uchc.edu/ACC/AllLaws.htm>. Exemptions from this guideline require the prior review and approval by the Animal Care Committee.

Guide for the Care and Use of Laboratory Animals- Though not technically a law, the AWA / AWARs, PHS Policy, ACC Policy, and our PHS assurance require that all work performed with laboratory animals comply with the guidelines presented in *The Guide*. Copies of *The Guide* can be requested from the ACC office in either book or CD-ROM form; contact the ACC office at ooacc@uchc.edu.

Institutional Policies

UCHC Policies:

The Health Center has institutional policies which govern the use of laboratory animals.

Policy 2002-41, effective April 10, 2002, "Review and Approval of Research Involving Animal Subjects" can be found at the following website: http://www.policies.uchc.edu/policies/policy_2002_41.pdf.

Policy 2005-13, effective September 28, 2005, "Occupational Health Surveillance Program for Principal Investigators (PI), Researchers, Technicians, Center for Laboratory Animal Care (CLAC) Staff, and Students Utilizing Animals in Research or Education Programs" can be found at http://www.policies.uhc.edu/policies/policy_2005_13.pdf.

PHS Institutional Assurance- The University of Connecticut Health Center has a "contract" with the Public Health Service which details the procedures in place to assure PHS (via the Office for Laboratory Animal Welfare- OLAW) that we comply with the regulations set forth in PHS Policy. This document is called "University of Connecticut Health Center Assurance of Compliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals". This document must be complied with in order for the Health Center to have the ability to use PHS funds. Our PHS assurance number is A3471-01 and the effective dates for this assurance are 4/10/06 – 4/30/10. If you wish to view our PHS assurance, it is on the ACC website: http://clacc.uhc.edu/ACC/Animal_Care_Committee.htm.

ACC Policies:

The Animal Care Committee has policies which govern the use of laboratory animals. Currently, there are 31 approved policies which researchers must comply with in order to use laboratory animals. A list of approved policies can be found on the ACC website: <http://clacc.uhc.edu/ACC/Policies/AllPolicies.htm>. As an animal user, it is your responsibility to have current knowledge of the policies. Review the website. New policies are also listed in each edition of the **ACC Connection**.

Investigator Assurances

Every animal care and use protocol has a list of investigator assurances which the PI signs. When you submit the animal care and use protocol, make sure that you are familiar with these assurances- it is section 19 of the protocol. The following is a list of the assurances the PI makes every time he / she submits an animal care and use protocol:

Humane care and use- "I hereby certify that the foregoing information is complete and correct and that professionally acceptable, ethical, and humane standards governing the care, treatment, and use of animals will be followed."

Animal distress- "I assure that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research and that appropriate anesthetic, analgesic, and tranquilizing drugs will be used to relieve all unnecessary pain and distress for the subject animals during teaching, research, testing, and post-operative care."

Duplication of research- "I hereby certify that these studies do not unnecessarily duplicate previous experiments."

Personnel training- "I assure that personnel conducting procedures on the animals being maintained or studied are appropriately qualified and trained in these procedures prior to using live animals".

Compliance with laws- "I assure that I am familiar with and will comply with all the pertinent institutional, state, and federal laws, rules, and policies."

Cooperation- "I agree to cooperate with the ACC and the veterinarian in their supervision of these laws, rules, and policies."

Modifications to protocol- "I assure that any changes in protocol procedures or personnel will be submitted to and approved by the ACC prior to implementation."

Occupational health- "I assure that any individual working on this project has access to this protocol and are enrolled in this institution's Occupational Health and Safety Program."

Adverse events notification- "I assure that I will notify the ACC coordinator regarding any unexpected study result(s) that impact the animals; this will include any unanticipated pain and/or distress, morbidity, and mortality."

Protocol availability- "I assure that a copy of the approved protocol will be posted in a place where all individuals working on the protocol have access to it."

Grant proposal- "I assure that the procedures described in the grant proposal are consistent with those outlined in the protocol application."

Researcher Responsibilities- Where to Begin

Step One- Make sure that you are familiar with the federal laws governing laboratory animal use. The Animal Welfare Act and PHS Policy are two of concern, but the laws don't stop there. If you use endangered species in your research, you need to be familiar with the **Endangered Species Act** (<http://ipl.unm.edu/cwl/fedbook/esa.html>). If you are using wild-caught birds, you must know your responsibilities as a Principal Investigator in the **Migratory Bird Treaty Act** (<http://www.fws.gov/migratorybirds/intrnltr/mbta/mbtintro.html>). If you are unsure what regulations apply to the research you are doing, please contact the ACC office for assistance in this matter.

Step Two- Make sure you are familiar with any state laws governing laboratory animal use. In the State of Connecticut, there are few laws; the ones that are in force deal with laboratory dogs and their transport. If you use laboratory dogs, you need to be familiar with these laws.

Step Three- Make sure you are familiar with the institutional policies listed above. Go to the URLs and **read** the policies. You are ensuring that you are familiar with the policies; it makes sense to be so.

Step Four- Make sure that you are familiar with the ACC policies. Go to the website and **read** each policy. Make sure that your work is being done in compliance with these policies.

Step Five- Read your protocol! Quite often, we find non-compliance with research protocols simply because people weren't sure what was in the protocol- they "thought they were doing it right." Each animal care and use protocol must be stored in a place where everyone who uses that protocol has access to it. Don't rely on a co-worker telling you what the protocol says, read it yourself. Be familiar with the procedures outlined in the protocol and make sure you are following them. If a researcher discovers a better way to perform a procedure, and there needs to be a change in the protocol, a modification must be submitted and approved by the ACC before the new procedure is adopted by the laboratory. If a PI has new personnel starting in the laboratory or, conversely, if individuals have left the laboratory, the PI needs to give this information to the ACC coordinator by email to ooacc@uchc.edu.

Step Six- cooperate with the ACC in its efforts to enforce compliance with federal, state, and institutional policies. When your laboratory inspection is scheduled, honor that time commitment (rarely longer than 15 minutes). If it is discovered that there were deficiencies in the laboratory inspection, make sure that you make the changes that are required. If a compliance review is required of your protocol, cooperate with the review process.

Step Seven- comply with the requirements for occupational health surveillance enrollment and animal user training. **Federal law** mandates that animal users must be enrolled in a medical surveillance program and that all individuals who use laboratory animals must be appropriately trained. The ACC has tried to balance researcher needs and preferences with the requirements of the laws and make the application of these laws as "non-intrusive" as possible; however, researcher preferences will not outweigh the need for compliance with applicable laws.

Step Eight- when forms are sent to the PI to fill out and are to be returned to the ACC office, please ensure that this is done. **All protocols need an annual review by the ACC-** all PIs will receive annual review forms twice during the lifetime of the protocol. **All animal care and use protocols are valid for 3 years from date of approval.** PIs will be given a letter notifying them that their protocol will expire approximately 4 months before the expiration date— this letter will detail when the renewal protocol must be submitted to the ACC office. By responding to these notifications, you do a lot to ensure compliance.

Step Nine- become familiar with the information available to you. Read the **ACC Connection** when it is sent out or go to the website for links to all copies of the newsletter. Browse the website and look at the policies, education materials, and web resources that are supplied there. There is a lot of information available to animal researchers on the website- it is the responsibility of the researchers to look at it.

Frequently Asked Questions

We have an ACC which is supposed to make sure that we are compliant with the laws. Why should I deal with this?

The Animal Care Committee at the Health Center does, indeed, work hard to make sure that the institution is compliant with federal, state, and institutional laws, regulations, and policies governing the use of laboratory animals. However, there are approximately 140 principal investigators and a further 600 individuals who use laboratory animals at the Health Center and approximately 325 active protocols. Try as we might to make sure everyone is trained according to policy and enrolled in the occupational health surveillance program, there are bound to be those who "slip through the cracks". Compliance with the laws and policies require **everyone's** help.

How does the ACC help me comply with all these regulations?

The ACC office will notify all animal users when they need animal use training. The office will also notify all animal users when they need to initially enroll in the occupational medical surveillance program and when the yearly renewals are required. The office will let a PI know the following: when the protocol is approved, when any modification to a protocol is approved, when a protocol will be expiring (typically 2 notifications- one 4 months prior and one 2 months prior to the expiration date), and when a protocol has been terminated. The office will schedule the laboratory inspections and let the PI know approximately 1 month prior to the scheduled date and time of the inspection. The office has copies of laws and policies which are available to the researchers. The ACC office maintains a website (http://clacc.uchc.edu/ACC/Animal_Care_Committee.htm) that has numerous resources to researchers.

Enrolling in occupational health /medical surveillance and doing the animal training is so tedious. Why do it?

Enrollment of all personnel who use animals in an occupational health / medical surveillance program is a requirement of PHS Policy. Adequate animal training is a requirement of the Animal Welfare Act and PHS Policy. There is no getting around the fact that this needs to be done. Enrollment in occupational health requires that all research personnel contact Employee Health Service. All yearly renewals are done by mail. Animal training is required by law for all animal users and yearly renewal training is performed on-line.

Upcoming Training, September 2007 – October 2007

New Animal Users Initial Basic Core Training

Monday, September 17	9:00 am – 12:00 pm	Building 20 conference room
Monday, October 22	9:00 am – 12:00 pm	Building 20 conference room

New Institutional, State, or Federal Regulations

Institutional

New animal care and use application form	August, 2007	To download the new form, go to the website at: http://clacc.uchc.edu/ACC/SubmittingProtocols.htm
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State

None

Federal

2007 AVMA Guidelines on Euthanasia	July, 2007	To see the new guidelines, go to the website at: http://clacc.uchc.edu/ACC/2007AVMAEuthanasia.pdf
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Next Issue: Grants and Animal Protocols

CONTACTS

ACC Coordinator / Research Compliance Monitor
ACC Chair
Director, Center for Laboratory Animal Care (CLAC)
AVP for Research Administration / Institutional Official
Animal Facility Supervisor
Biological Safety Officer

Alison D. Pohl, MS, MT, rLATg	x4129
Joseph Lorenzo, MD	x8199
Peter Autenried, DVM, Ph.D.	x2248
Leonard Paplauskas	x3173
Sara Fraize, rLAT	x4075
Ronald G. Wallace, Ph.D., CIH	x3781