



# The ACC Connection

\* 2007 Special Edition \*

**WELCOME** to this special edition of the **ACC Connection**, a normally bi-monthly newsletter designed to help researchers with questions regarding animal research at the University of Connecticut Health Center. This special edition is to inform animal users about animal research compliance and the new post approval monitoring program approved by the Animal Care Committee.

There have been a lot of discussions recently about compliance- but what exactly is it? The Merriam-Webster Dictionary defines compliance as: **com-pliance**, Function: *noun*: conformity in fulfilling official requirements; this means adhering to the laws, regulations, and policies which govern laboratory animal research. A previous edition of the **ACC Connection** (Vol. 2(1) Jan 2006) archived on the website has delineated what those laws, regulations, and policies are.

It is also important to realize what agencies or organizations regulate laboratory animal research here at the Health Center- there are agencies we must report to regarding our animal use. It is vital that the Health Center maintain all accreditation that we currently have as well as maintain compliance with all regulatory agencies.

## Outside Agencies Involved with Laboratory Animal Oversight

### United States Department of Agriculture- Animal and Plant Health Inspection Service (USDA-APHIS)

The USDA-APHIS is a department which regulates laboratory animal use in regulated species and activities. The Health Center has been assigned a Veterinary Medical Officer (VMO) who works for APHIS. This individual inspects the Health Center a **minimum of once per year**. The inspection includes a visual inspection of the CLAC facility where all USDA-regulated species are housed, inspection of animal receipt records, inspection of animal health records, and may include an inspection of individual laboratories where USDA-regulated species are used.

After the inspection is complete, the VMO will generally ask to see a list of all protocols in which USDA-regulated species are used. Once this list is reviewed, the VMO will ask to see specific protocols off of that list. These protocols, and all related information, is given to the VMO who will review the animal care and use protocol, any amendments that have been approved on the protocols, and any other documentation related to these protocols (e.g., surgical notes, monitoring sheets, etc.).

The VMO will also review IACUC minutes and semi-annual inspection reports which have been submitted to the Institutional Official. The VMO may request any other document or report for review. It is against federal law to not cooperate or to interfere with the activities of a VMO. The VMO will be checking to see that all animal use at the Health Center is in compliance with the Animal Welfare Act (AWA), the Animal Welfare Act Regulations (AWARs), and the Animal Care Policies (ACPs) administered by the USDA-APHIS.

### The Office for Laboratory Animal Welfare (OLAW)- National Institutes of Health

OLAW is a department within the NIH that has oversight of all laboratory animal research which is supported by PHS funds. The Health Center's PHS Assurance with OLAW states that all animal work done at the Health Center will conform to the PHS Policy on Humane Care and Use of Laboratory Animals and the Health Research Extensions Act of 1985. It is important to realize that compliance with these regulations is **guaranteed by the institution**. OLAW will do random inspections; generally, they do about 10 inspections per year. OLAW considers self-reporting of deficiencies by the assured institution to OLAW to be appropriate. Certain activities required by PHS Policy and/or the HREA of 1985 (such as semi-annual laboratory inspections) must be completed, and appropriate reports must be filed.

Therefore, it is essential to self-report instances of non-compliance with PHS Policy to OLAW when it occurs and in a timely manner. OLAW has policies on reporting to them which can be found on the ACC website or on the OLAW website at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html>. OLAW mandates that the following situations require a report: a) any serious or continuing non-compliance with PHS Policy; b) any serious deviation from the

provisions of the *Guide for the Care and Use of Laboratory Animals (Guide)*; and c) any suspension of an activity by the IACUC. The following are types of situations which require prompt reporting to OLAW:

- conditions that jeopardize the health or well-being of animals;
- conduct of animal-related activities without appropriate IACUC review and approval;
- conduct of official IACUC business requiring a quorum in the absence of a quorum;
- failure to correct deficiencies identified during the semiannual evaluation in a timely manner; and
- IACUC suspension or other institutional intervention that results in the temporary or permanent interruption of an activity due to noncompliance with the Policy, Animal Welfare Act, the *Guide*, or the institution's Animal Welfare Assurance.

### **The Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC) International**

AAALAC International is a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs. More than 700 companies, universities, hospitals, government agencies, and other research institutions in 28 countries have earned AAALAC accreditation, demonstrating their commitment to responsible animal care and use. These institutions **volunteer** to participate in AAALAC's program in addition to complying with the local, state, and federal laws that regulate animal research.

The AAALAC International accreditation program evaluates organizations that use animals in research, teaching, or testing. Those that meet or exceed AAALAC standards are awarded accreditation. The accreditation process includes an extensive **internal** review conducted by the institution applying for accreditation. During this review, the institution creates a comprehensive document called a "Program Description" which describes all aspects of the animal care and use program (policies, animal housing and management, veterinary care, and facilities). The Program Description is then submitted to AAALAC.

Next, AAALAC evaluators (members of AAALAC's Council on Accreditation) review the Program Description and conduct their own comprehensive on-site assessment. The site visitors' report is then reviewed by the entire Council on Accreditation and accreditation status is determined. Any deficiencies found are outlined in a letter and the institution is given a period of time to correct them. Once the deficiencies are corrected, accreditation is awarded. The entire process is **completely confidential**. After an institution earns accreditation, it must be re-evaluated every three years in order to maintain its accredited status. Accreditation benefits an institution and the animals in its care in many ways including making it easier for the institution to apply for PHS funding.

### **Office of Biotechnology Activities (OBA)- National Institutes of Health**

OBA is the agency within the NIH that has oversight for all use of recombinant DNA. It has a variety of responsibilities including monitoring scientific progress in human genetics research, manage the operation of the RAC, developing and implementing NIH policies and procedures for the safe conduct of rDNA activities and human gene transfer, and reviewing and approving experiments involving the cloning of genes encoding for toxin molecules that are lethal for vertebrates at an LD50 of  $\leq 100$  ng/kg- just to name a few. As a condition of funding by NIH, all work with rDNA must comply with the *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)*. For more information specific to rDNA use, please get a copy of the **ACC Connection**, Vol. 2, no.4, October 2006.

## **UHC Post-Approval Monitoring Program**

During its February 2007 meeting the, the ACC approved a policy on post procedure monitoring.

**Purpose:** The Animal Care Committee (ACC) recognizes that ensuring compliance with approved animal care and use protocols is an important aspect of a laboratory animal program. The purpose of a post approval monitoring (PAM) program is to work with investigators to facilitate their animal research and to be proactive in identifying potential problems in their compliance with active ACC protocols.

**Action:**

1. All PAM will be under the supervision of the ACC and will be performed by a designated Compliance Liaison Officer (CLO).
2. Review of approved protocols will be conducted at a rate of up to four per month.
3. All active animal care and use protocols are eligible for PAM review. Criteria which may increase the frequency of PAM protocol review include:
  - Animal use in pain categories D or E
  - Significant personnel changes

- Significant increases in protocol activity
  - The use of biohazards and/or carcinogens
  - The use of physical restraint
  - The use of food and/or water restrictions
4. A summary of the findings of PAM reviews during a given month will be reported to the ACC at its monthly meeting.
  5. The procedure for the performance of a PAM review will be as follows:
    - The CLO will notify a PI that his or her protocol has been selected for review approximately one week before the review will occur. At this time, the PI will receive a checklist for the review of items that will be addressed during the PAM review (different checklists will be devised with core elements to be addressed during all reviews and broad categories with special activities such as survival surgery).
    - All visits will be scheduled at the convenience of the PI and the senior research staff of the laboratory.
    - During the PAM review, the CLO will ask the PI and the laboratory staff that are present to describe their animal procedures verbally. These verbal reports will then be checked against the approved procedures in the protocol that is being reviewed. Specific attention will be paid to drugs administered, procedures performed, and all surgeries (survival and non-survival).
    - During the PAM review, the CLO will identify any inconsistencies between the verbal record of what the laboratory is actually doing with animals and the procedures that are described in the ACC approved protocol. If any inconsistencies are identified, the CLO will immediately ask the PI to address these either by discontinuing the procedure or, within 28 days, submitting a modification of the protocol to the ACC office. At this time, the PI can also ask questions of the CLO and seek clarification of any issues that might be raised during the PAM review.
  6. The PI and the senior research staff for the reviewed protocol are required to be present during a PAM review to facilitate the review.
  7. Issues that pose a significant threat to animal welfare will be referred immediately to the attending veterinarian for resolution and also to the ACC for further investigation.
  8. A written report of the monitoring results will be sent to the PI, ACC Chair, and Director, Office of Research Compliance.
  9. The PI will have 28 calendar days from the date of the initial PAM review to respond to the report if deficiencies are detected and corrective actions are recommended.
  10. The ACC chair (or designee) will review and approve the PI's responses. If the PI's responses are not acceptable, the ACC chair (or designee) will seek further revisions and the PI will have 14 additional days to respond.
  11. If the PI does not respond to the inspection findings of the CLO within the appropriate time frame as outlined above, the ACC will then decide on how to proceed.
  12. Investigators who disagree with PAM review results, recommendations, or corrective actions can appeal their concerns to the ACC.
  13. A copy of the final compliance monitoring report shall be kept with the protocol file.

If you have any questions regarding this new policy, please contact the ACC office or the Office of Research Compliance for information. Please note that the new post approval monitoring program is in addition to the semi-annual facility and laboratory inspections, not replacing the inspections.

# Frequently Asked Questions

## *What can happen with non-compliance with the AWA and AWARs?*

If the Health Center does not comply with the AWA and AWARs, it can be fined. If the non-compliance is continuing, it invites the Investigative Enforcement Service (IES) arm of USDA-APHIS to come to the Health Center and do an audit of the entire animal care and use program. It can result in the Health Center's USDA registration to be voided by USDA-APHIS. Please note that any instance of non-compliance with the AWA and AWARs is automatically considered to be a violation of PHS Policy as PHS Policy states that compliance with the AWA and AWARs is a requirement of PHS Policy.

## *What can happen with non-compliance of PHS Policy?*

Continuing non-compliance with PHS Policy (which, by definition, requires compliance with the AWA and AWARs) can result in many things: inspection visit by OLAW, loss of PHS assurance, and loss of federal funding for the Health Center. It may also result in an inspection visit by AAALAC International which can result in a loss of AAALAC accreditation.

## *What can happen with non-compliance of NIH Guidelines for rDNA work?*

Non-compliance with the [NIH Guidelines](#) 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 being performed at the Health Center. Compliance with the [NIH Guidelines](#) is critical to the safe conduct of research.

## *What are the most common items of non-compliance?*

The most common areas of non-compliance include: adding personnel to an approved protocol without ACC approval; not performing procedures described in the protocol (e.g., not giving analgesics when the protocol states analgesics will be given); performing work beyond the expiration date of the protocol; not reporting adverse events to the ACC; performing procedures that are not approved in the protocol; using expired drugs or materials; using non-pharmaceutical grade compounds without ACC approval; and failure to monitor animals post-procedurally as necessary to ensure well-being.

## *What can I, as a researcher using animals, do?*

Everyone can help to ensure compliance. If you are a PI, make sure that your protocol accurately reflects the procedures you are performing on the animals. If you need to modify your protocol, submit a modification request to the ACC and do not institute the change(s) until the modification request has been reviewed and approved. Read all protocols in which you are listed as an animal user. Everyone understands the necessity of complying with federal, state, and institutional laws, regulations, and policies. Most instances of non-compliance are "accidental"- the individuals involved did not realize that what was being done was non-compliant with the regulations. However, this is not an acceptable justification for non-compliance to any oversight agency. The more effort each individual expends in the area of ensuring compliance, the better it is for the institution.

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