Protocol Post-approval Monitoring Policy

An important part of Purdue University’s program for the care and use of animals used in research, teaching, or testing, is the meaningful monitoring of the protocols that have been approved by the PACUC. The protocol post-approval monitoring policy has been developed to contribute to this important oversight requirement. The protocol post-approval monitoring process will involve laboratory/site visits to observe animal procedures being performed, evaluate record keeping, and discuss approved activities.

Protocol post-approval monitoring process and procedures

Protocol post-approval monitoring visits may be announced or unannounced. Post-approval monitoring will occur approximately two times per year for active protocols (or more if deemed necessary by the PACUC or to relevant laboratories in which protocol deviations have occurred), but no less than once per year. Post-approval monitoring visits will be conducted by one of the laboratory animal veterinarians (LAV) and the PACUC Administrator in the immediate future.

The approved protocols will be prioritized to determine the frequency and order of monitoring, based on the potential for pain and distress, significant personnel changes, and current activity of protocols. Problems or deficiencies noted on these visits will be corrected at the time the deficiency is noted and further training/education provided, if needed. A summary of these visits, and actions taken to correct the deficiency, will be reported to the PACUC by the LAV or PACUC Administrator at the next monthly meeting.

Post-approval monitoring will be conducted using the Protocol Post-Approval Monitoring Form and a database will be utilized to aid in the prioritizing of protocols.
Starting within the next several months, principal investigators may be contacted by the PACUC office to schedule a time to meet and discuss their approved protocol(s). Your co-operation with this process will be greatly appreciated.

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**Controlled Drug Acquisition**

According to Purdue University Policy, “narcotics and other substances falling under the Controlled Drug Regulations and intended for use in classrooms or laboratories (other than those for the School of Veterinary Medicine) must be requested against a specific federal registration and permit. All individuals employing such drugs for teaching and research must be registered with the Drug Enforcement Administration and the Indiana Board of Pharmacy.”¹ This policy therefore states that principal investigators needing to administer controlled substances, such as specific DEA scheduled anesthetics and analgesics or other controlled drugs to teaching and research animals, must acquire their own individual DEA license. Veterinary Teaching Hospital (VTH) clinicians administering controlled drugs to client-owned patients of the Small and Large Animal Clinics do not need to apply for an individual DEA license as these drugs can be obtained from the VTH Pharmacy for clinical purposes. SVM faculty, who are also VTH clinicians, administering controlled drugs to their teaching or research animals must use their own DEA license to acquire the items through the VTH Pharmacy. Commonly used DEA scheduled drugs would include pentobarbital, ketamine, butorphanol, and buprenorphine.

In order to comply with this Purdue University policy, the Laboratory Animal Program Veterinarians will no longer be providing prescriptions for controlled drugs used for research and teaching animals. The Veterinary School Pharmacy has provided the information needed (see the end of this Newsletter) to apply for a license with the Drug Enforcement Administration. There is no cost to the investigator if they are a non-DVM and if the application is approved through Purdue University. Persons with a DVM license and who are applying through Purdue will be expected to pay the State of Indiana fee (approximately $30.00).

To give all impacted individuals time to go through the application process, the Laboratory Animal Program veterinary staff with DEA licenses will continue to provide prescriptions for usual amounts of controlled drug anesthetics and analgesics for research and teaching animals housed on the West Lafayette Campus until June 1, 2004. After this time, all principal investigators needing controlled substances for teaching and research animals will need their own DEA license to acquire scheduled drugs.

1. Purdue University Faculty and Staff Handbook 2003-2004 p. 90.

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**LAP Audio CD Library**

The Laboratory Animal Program maintains a collection of materials useful to animal researchers at Purdue University. Staff attendees at the 2003 Annual Meeting of the American Association of Laboratory Animal Science recommended purchase of a number of audio recordings of pertinent
lectures from this meeting. The CD’s have arrived and are available for checkout and review by animal users at Purdue. If you are interested in listening to any of these CD’s please stop by the PACUC/LAP offices at VAHF and check them out.

AALAS October 2003

1. Michael D. Hayre Memorial Lecture: Pain Assessment and Alleviation-Telling It Like It Is

2. 21st Century Advocacy: Why, When, and How To Engage Research Critics

3. Advanced Pain Medicine For The Laboratory Animal (2 CD’s)

4. NCRR Animal Improvement Project Funding Opportunities (2 CD’s)

5. Functional Observational Battery: Uses in Toxicology and Model Pheno-typing

6. Environmental Enrichment; Tips for Starting or Expanding a Program

7. Research in Pain Relief – An ACLAM Foundation Initiative (2 CD’s)

8. The Roles and Responsibilities of the IO, IACUC and AV: The AAALAC International Perspective (2 CD’s)

9. Training and Compliance: Experi-ences from the Trenches (4CD’s)

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AAALAC-I Accreditation

The Laboratory Animal Program (LAP) and the PACUC, at the request of the Office of the Vice Provost for Research (VPR), are in the process of performing a review of Purdue’s animal care and use program. The intent is to obtain accreditation by the Association for the Assessment and Accreditation of Laboratory Animal Care) – International (AAALAC-I). AAALAC-I accreditation fits with the overall Strategic Plan of the University that emphasizes pre-eminence in research taking Purdue University to the next level, advancing quality in all areas, and peer recognition. The majority of Purdue’s peer and Big10 institutions are AAALAC-I accredited.

While the process began early in 2003, activities to date have primarily involved the LAP, PACUC, and School/Departmental animal care personnel spending considerable time and effort in gathering information. In applying for accreditation, the institution is required to submit a detailed description of the animal care and use program for all units. This entails conducting an extensive internal review. In the review process, a list of items in need of attention has been prepared and continues to be updated as the review proceeds. Items include physical facility needs and programmatic issues. Some items will require the LAP and PACUC to work with individual Schools and Departments as well as individual investigators who use animal models, and certain actions will be required prior to obtaining accreditation.

Units included in this endeavor include: Animal Sciences, ASREC (Beef, Dairy, Poultry, Sheep, Swine), Agriculture Extension Sites, Biology, Biomedical Engineering, Foods & Nutrition, Forestry and Natural Resources (Aquaculture and Wildlife Animal Care Facility), Psychology, and Veterinary Medicine. Two Purdue University units are
Currently accredited: Pharmacy and the Fort Wayne Campus.

In addition to there being certain facility and equipment needs, achieving accreditation may require some animal care operating procedure modifications in certain Schools and Departments. A school/department specific list outlining some of these needs has been prepared and provided to animal facility managers/supervisors.

As some individuals may be unfamiliar with AAALAC-I, pertinent points regarding accreditation are listed:

- Established in 1965, AAALAC-I is a private nonprofit organization that promotes the humane treatment of animals in science through a voluntary accreditation program. More than 650 companies, universities, hospitals, government agencies and other research institutions have voluntarily earned AAALAC-I accreditation, demonstrating their commitment to responsible animal care and use. Thirty-one percent of accredited institutions are universities.

- AAALAC-I does not have its own set of standards. AAALAC-I accredited institutions must adhere strictly to applicable local and national regulations. AAALAC-I uses the current edition of The Guide for the Care and Use of Laboratory Animals (NRC 1996) as its primary standard for evaluating animal care facilities and programs. AAALAC-I accreditation demonstrates that not only does the institution meet the minimums required by law, but it is going the extra step to achieve excellence in animal care and use.

- For animals in an agricultural setting, AAALAC-I takes the position that the housing and care for farm animals should meet the standards that prevail on a high-quality, well-managed farm. AAALAC-I recognizes The Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching (FASS 1999) as a reference resource for individual farm animal species.

- Compliance with the standards of the Guides is not an option for Purdue. Our Public Health Service (PHS) assurance states Purdue will comply with the Guides.

- AAALAC-I accreditation enhances regulatory compliance. As already noted, accreditation entails an in depth self-evaluation. In addition to reviewing this internal report, AAALAC-I conducts a comprehensive on-site peer assessment (which is repeated every three years). Accreditation provides credibility to the program in the eyes of regulatory agencies and the public.

- AAALAC-I accreditation is viewed as a symbol of quality. AAALAC-I accreditation shows that an institution is serious about setting, achieving, and maintaining high standards for animal use. In addition, accreditation promotes scientific validity as reliable research results depend on healthy animals and superior animal care.

Feel free to contact the PACUC or LAP if you have any questions regarding this effort.