Training Trenches

“Brown Bag Sessions”

Brown Bags will be on Tuesdays. Information on upcoming Brown Bag Sessions can be found on our website www.purdue.edu/animals under the Training link.


“Training Opportunity for Faculty”

Staff of the Purdue Animal Care and Use Committee, the Laboratory Animal Program, and guest speakers will be conducting a training session on “How to Write an Approval-ready Animal Use Protocol.” on April 7 and again on April 11. The April 7 session will be from 9:30-11:00 in STEW 218A and the April 11 session will be from 1:30-3:00 in STEW 310. This training opportunity is being offered on two separate occasions with the hope that we are able to attract a large audience. The room on April 7 holds 42 people and the room on April 11 can accommodate 84. Please reserve your space by contacting Susan Cutter, Training Coordinator, or Lisa Snider, PACUC Administrator, scutter@purdue.edu or ldsnider@purdue.edu.

The training session will be directed toward faculty, not graduate and post-doctoral students. These students will be welcome but we ask that they not be sent in place of a faculty member.
Additional information on this training session will be sent to faculty via a listserv in the near future. Please look for this important e-mail in the next couple of weeks.

**PACUC Policies**

From time to time, we like to remind you of PACUC Policies or just how things work in the PACUC office in general. It has been awhile since we have published our animal use protocol review process so we thought we would refresh your memory in this edition of the PACUC Newsletter. Please contact Lisa Snider if you have any questions on the information provided below.

"Protocol Review Process"

Applications for approval of new protocols and for approval to make significant modifications to previously approved protocols (Amendments) must be completed by the principal investigator and submitted to the PACUC for review and approval prior to initiation of those activities. PIs should allow 2-4 weeks for the review process to be completed.

a. Protocol submission: Principal Investigators should initiate this process by submitting a copy of their protocol application to their PACUC representative (if their area has one). The PACUC representative will advise the PI about problematic areas or points of confusion that could be clarified prior to review by the PACUC. Following the completion of any revisions that are needed, the PI should submit the protocol application to the Secretary of the PACUC. The Secretary logs the protocol by date, and assigns the protocol a reference number. The Secretary then makes three copies of the application in preparation for pre-review.

b. Pre-review of protocol applications: Pre-review is conducted by the Chair of the PACUC (or his/her designee) and a LAP veterinarian. The responsibility for the third pre-review is divided among the remaining members of the PACUC, with different members performing this function on a monthly basis. Pre-review has one of three potential outcomes.

*Recommendation for approval on a designated basis.* This outcome is reserved for protocols that do not raise questions about animal care and use or about regulatory compliance on the part of the pre-reviewers. If all pre-reviewers recommend that the protocol be considered for approval on a designated basis, the PACUC Administrator prepares a Protocol Summary Information (PSI) form. The PSI form is a brief description of the protocol including the title, the name of the PI, the PI’s departmental affiliation, the species and number of animals that will be used, and a summary of the objectives and procedures to be used under cover of the protocol. The PSI form is forwarded to all members of the PACUC, who have five (5) working
days to request additional information or to forward the protocol application for consideration at the next scheduled meeting of PACUC. If this 5-day period elapses without a response from any member of the PACUC, the protocol application will be approved on a designated basis.

Consider comments before recommending approval on a designated basis. Pre-reviewers may ask for additional information before determining whether a protocol application should be considered for designated review or review at a meeting of the full committee. The questions or comments of the pre-reviewers will be summarized in a question memo that is prepared by the PACUC Administrator and forwarded to the PI. Further consideration of the protocol application will be suspended until a response to the question memo is returned to the Administrator. The Chair (or his/her designee), in consultation with the LAP veterinarian that served as a pre-reviewer, evaluates the response and determines whether or not forwarding the protocol for designated review is warranted. If designated review is deemed appropriate, a PSI form is prepared and forwarded to each member of the committee as described above. If review at a meeting of the full PACUC is warranted, a copy of the protocol and of the PI’s responses to the question memo will be forwarded to each PACUC member at least one week before the next scheduled meeting of the full committee.

Recommendation for review at a meeting of the full PACUC. If any pre-reviewer recommends full committee review, the protocol application will be reviewed at a meeting of the full PACUC. A request made by any member of the PACUC for review at a meeting of the PACUC will be considered final and is not subject to modification by the Chair or any other person. Pre-reviewers, who recommend that a protocol application be reviewed at a meeting of the PACUC, may also request that additional information be obtained from the PI. In this case, the PACUC Administrator will prepare a question memo as described above. The protocol application, along with the response to the memo will be forwarded to each member of the PACUC at least one week prior to the meeting at which approval will be considered.

Full Committee Review of Protocols
The PACUC meets once per month on a 12-month basis. Under special circumstances, the PACUC may meet more often than once per month. Special meetings of the PACUC may be called at any time. Review of protocols at a meeting of the full PACUC can only begin if there is a quorum of the voting members of the PACUC present at the meeting. The Chair will also ask those present to indicate any potential conflicts of interest they may have pertaining to matters that are listed on the agenda for the meeting. If a quorum exists after any person who has a potential conflict of interest is excused,
consideration of a protocol can begin. The Chair asks if any voting member will move to consider approval of the protocol. Discussion of the protocol begins after a second to that motion has been obtained. At the conclusion of the discussion, the chair or another committee member may formulate a motion concerning the action the committee will take on the protocol. The PACUC may vote to adopt any one of the following categories of action:

a. **Approval**
   A protocol should be approved only when the PACUC considers that all significant points and potential concerns have been addressed satisfactorily by the PI. Granting approval means that the PI has permission to conduct the project that was described, with the number of animals that were indicated, in the protocol, or in communications from the PI that were considered by the members of the PACUC. The Committee may instruct the Chair or Administrator to communicate to the PI comments or remarks made during the discussion of the protocol. However, approval of the protocol is not conditional upon the response of the PI to this communication, nor is the PI required or expected to respond.

b. **Withhold approval pending modifications**
   This action should be taken when the PACUC deems that specific aspects of the protocol may be problematic and require further explanation, justification, documentation, or information. The Chair or Administrator will attempt to communicate, as clearly as possible, these problematic areas to the PI. The Chair (or his/her designee), a LAP veterinarian, and one other member of PACUC will review the response of the PI to this communication. These individuals may communicate further with the PI or any one of them may return the protocol along with the response of the PI to the full Committee. Approval to conduct the activity described in the protocol will be withheld until the response of the PI has been deemed to satisfy the conditions set forth previously by the committee. The three pre-reviewers of the protocol application will evaluate this response. If the three pre-reviewers agree that the response of the PI addresses satisfactorily the issues raised at the PACUC meeting, the protocol will be approved. In cases where consensus among the three pre-reviewers cannot be obtained, evaluation of the response and the decision to approve will be made, based on a majority vote at the next meeting of the full PACUC.

   Approval will also be withheld when the PACUC considers that all significant points and potential concerns have been addressed satisfactorily by the PI, but that, specific administrative details, such as signatures of responsible parties, phone numbers, and information about submission to
funding agencies are missing or need clarification. Approval will be granted when this type of information has been provided to the satisfaction of the Administrator. No further review by the Chair, LAP veterinarians, or other PACUC members is required.

c. **Limited Approval**

Limited approval may be granted when the PACUC is willing to approve certain uses of animals (e.g., some experiments, some procedures, some species, and some number of animals) but not all uses that are described in the protocol. For example, based on concerns about husbandry, investigator qualifications, or other issues, the PACUC may limit approval to only a specific subset of the species requested. In addition, approval for protocols that propose the use of novel or potentially problematic techniques may be limited to a smaller number of animals than requested until the procedures can be evaluated further. That is, approval could be limited to a subset of studies (e.g., one or two preliminary studies) that are proposed.

d. **Deferral**

The Committee may decide to defer action on or table a protocol until a later date. The reason for deferring action usually involves having insufficient information upon which to make a judgment about the protocol. A protocol may be deferred if the PI is unavailable to provide the necessary information or if a committee member with special expertise in areas covered by the protocol is absent from the meeting.

e. **Disapproval**

Under some circumstances, the PACUC may vote to disapprove a protocol application. Every attempt will be made to resolve the differences between the PI and the PACUC before a motion to disapprove is voted on. However, disapproval is a course of action in situations where the PI refuses, or is unable, to address concerns or modify problematic aspects of the protocol that were identified by the committee. Disapproval is also an option in cases where the investigator is unwilling or unable to provide evidence that he or she is qualified to conduct the proposed activities, or when special equipment or facilities needed to minimize the threat to health and safety of animals are not available.

For each of the actions listed above, the Chair or Administrator will communicate to the PI the decision of the PACUC, and will elucidate the information or modifications required to obtain approval. In cases where the unanimous vote of PACUC is for disapproval, the Chair or Administrator will inform the PI of this decision in a memo that also describes the Committee's reason for taking this action. If the vote for disapproval was not unanimous, the Chair or
Administrator will inform the PI of the Committee’s decision. In addition, one PACUC member will be designated by the Committee to describe the majority opinion with respect to the vote for disapproval and another member will be designated to provide the PI with the minority view pertaining to that action. A PI will have one opportunity to appeal the decision to disapprove. To appeal, the PI must present the PACUC with evidence or expert opinions in addition to those that were available when the decision to disapprove was made. This presentation shall be made by the PI, in writing or in person, at a regular meeting of the PACUC where a quorum of the voting members is present. The intention to appeal must be announced no less than ten (10) days prior to the PACUC meeting where the option to appeal will be executed.

The Public Health Service and the United States Department of Agriculture include each of the following topics among those that should be considered as part of the preparation and review of animal care and use protocols.

- Rationale and purpose of the proposed use of animals
- Training and experience of personnel with the procedures to be used
- Housing and husbandry requirements
- Appropriate use of sedation, analgesia, and anesthesia
- Unnecessary duplication of experimentation
- Are multiple survival surgeries planned and justified?
- Criteria and process for intervening to reduce stress or discomfort of animals
- Plans for post-procedural care
- Method of euthanasia or other dispositions of animals
- Safety of the working environment for personnel

We hope that this article has helped answer some questions you may have had regarding the protocol review process and the types of information that must be considered as part of the review process.

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The Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC)

“Status of Purdue’s Accreditation”

The last update regarding the AAALAC accreditation effort was provided in the December 2004 PACUC Newsletter. In the latest correspondence from AAALAC to Purdue (December 2005), they noted that Purdue’s response for most items identified as concerns during the accreditation visit had been adequate. However, Purdue remains Provisionally
Accredited pending the resolution of two items. The first remaining item will entail implementation of a means for after-hour temperature and power monitoring of each animal room on campus. The second item entails relocation of a procedure room. Correction of these two remaining issues is being pursued with an anticipated completion of Spring 2007. Once Full Accreditation is achieved, an announcement will be made.

AAALAC has just published a new resource to help investigators better understand the AAALAC accreditation process, its purpose, and its potential benefits to their work. Printed below is AAALAC’s “Information for Investigators.”

"Information for Investigators"

If you’re a researcher, you know that there are many regulations and requirements surrounding the use of animals in research. So at first glance, it may seem that participating in AAALAC’s voluntary accreditation program is perhaps unnecessary—or just one more hurdle standing between you and your work.

We’ve created this section to address these concerns, and provide you with some information on the purpose and value of AAALAC International accreditation. Please share this resource with your colleagues. If you have specific questions regarding AAALAC accreditation at your institution, you may contact us anytime at accredit@aaalac.org.

Why AAALAC International is different?

AAALAC is not a regulatory agency. We are a voluntary, peer-review accreditation program. Our site visitors are not inspectors—they are evaluators, there to provide a collegial review to verify that your institution is meeting AAALAC International standards. The entire process is completely confidential and not subject to FOIA (the Freedom of Information Act). Our goal is to work with the scientific community to promote high quality animal care and good science.

How AAALAC benefits your work.

Eliminating variables. As you well know, reliable research results depend on eliminating extraneous variables. AAALAC accreditation helps to minimize the "animal variable" by encouraging your institution to maintain consistent, high standards for animal care and use. The accreditation process engages scientists, veterinarians, managers and administrators in an independent, rigorous assessment of your institution’s animal care and use program. This helps ensure that the animals you use in your studies are healthy, well cared for, and free from undue stress—all of which translates into better, more consistent research outcomes.

Encouraging performance-based oversight. AAALAC’s standards are "performance-based," meaning we look at the larger picture of what is trying to be accomplished and the end result, as opposed to enforcing a series of narrow, unyielding "engineering" requirements. We look to see that your IACUC (Institutional Animal Care and Use Committee) is taking a similar approach when they review protocols. This gives
you an opportunity to explain and justify your methodology and anticipated outcomes, instead of being forced to follow prescribed approaches.

**Enhancing funding opportunities.** Many private biomedical organizations strongly recommend that grantees be supported by AAALAC-accredited animal programs. Government agencies also regard AAALAC accreditation as evidence of a commitment to excellence. Accreditation ensures private and public funding sources that animal use will be justified and humane, and can have a favorable impact on your proposal’s review.

The AAALAC process.

The accreditation process includes an extensive internal review during which a comprehensive document called a "Program Description" is created. The Program Description, which describes all aspects of animal care and use at your institution, is submitted to AAALAC.

Next, an AAALAC team visits your facilities. The site visit team is comprised of at least one member of AAALAC’s Council on Accreditation and one or more AAALAC ad hoc consultants, many of whom are bench scientists. During their review, the team assesses your program to verify that it’s upholding the principles outlined in the Guide for the Care and Use of Laboratory Animals and other appropriate reference resources. The team’s report, which includes commendations and recommendations, is then reviewed and deliberated on by AAALAC’s Council on Accreditation and your accreditation status is determined. If deficiencies are found, they are outlined in a letter and your institution is given a period of time to address them. After the deficiencies are corrected, accreditation is awarded. This entire process is completely confidential, allowing frank and open dialogue between your institution and AAALAC International.

*(A detailed description of the AAALAC process is posted at [www.aaalac.org/accreditation/index.cfm](http://www.aaalac.org/accreditation/index.cfm)*

**What you need to know about your institution’s animal program.**

The meaning of animal care and use "program." AAALAC evaluates your institution’s entire animal care and use program, which includes much more than just animal facilities and veterinary care. AAALAC defines a program as encompassing the following:

- **Institutional policies** (for things such as IACUC structure and procedures, occupational health and safety, as well as training of personnel)

- **Animal environment** (including housing and management)

- **Veterinary medical care** (including preventive medicine, surgery, pain management, euthanasia, procurement and transportation)

- **Physical plant** (including functional areas and surgery facilities)

*(Note: All of these program areas are covered in the Guide for the Care and Use of Laboratory Animals.)*

The Institutional Official. The "Institutional Official" (IO) is the person designated to have final administrative authority over the animal care and use program. This person must have the
authority to allocate institutional resources as needed and approve any changes recommended by the IACUC.

The IACUC. The "IACUC" (Institutional Animal Care and Use Committee) oversees the animal care and use program and reports to the Institutional Official on (at least) a semiannual basis. The IACUC is responsible for:

- Reviewing your institution’s program and inspecting facilities at least once every six months, and preparing reports for the Institutional Official.
- Recommending improvements for research facilities, the animal program, physical plant, or personnel training to your Institutional Official.
- Reviewing and (if necessary) investigating concerns involving laboratory animals.
- Reviewing and approving proposed research protocols that involve animals.
- Suspending (when justified) research, testing, or training procedures involving animals.
- Ensuring that the Animal Welfare Act, PHS Policy on Humane Care and Use of Laboratory Animals, and any other applicable regulations and standards (such as AAALAC) are met.

Note: Your IACUC may also have institution-specific policies or other requirements not otherwise specified in the Guide for the Care and Use of Laboratory Animals or in applicable animal welfare regulations.

The Attending Veterinarian. The Attending Veterinarian (AV) is responsible for overseeing the entire veterinary care program which, depending on the size of your institution, may include coordinating the work of several other veterinarians. The AV may be employed full-time, part-time, or as a consultant, and has sufficient authority to ensure adequate veterinary care for all of the animals used at your institution.

Training requirements. If you're going to be working with animals—for example, surgery or other experimental procedures—there are likely to be some training requirements you must meet. If you have not been informed of these requirements, ask the veterinarian who will be overseeing the animals in your study about them.

Regulations. For a quick overview of animal research regulations in the United States, visit [www.aaalac.org/resources/usregs.cfm](http://www.aaalac.org/resources/usregs.cfm). For inter-national regulations, visit [www.aaalac.org/resources/internationalregs.cfm](http://www.aaalac.org/resources/internationalregs.cfm).

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