PACUC News

"PACUC Orientation Program for New Personnel"

The annual orientation program for new faculty, staff, and students, who will be using animals in research, teaching, and/or testing, will be held on Wednesday, September 6 and again on Thursday, September 7. This orientation program is MANDATORY for any personnel hired after October 1, 1999 through the present. This program presented by staff of the Purdue Animal Care and Use Committee and the Laboratory Animal Program is designed to introduce you to the Purdue system for maintaining regulatory compliance with federal and university guidelines and ensuring humane care and use of laboratory animals.

The program on September 6 and 7 is in STEW 202 and is from 1:30-4:00 p.m. A memo describing the program with a registration form will be mailed to all department heads in mid-August for copying and distribution to their new employees or new personnel in relevant areas may e-mail Lisa Snider at ldsnider@purdue.edu to sign up to attend one of the programs.

"Fall PACUC Meeting Dates"

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<th>Meeting Date</th>
<th>Deadline Date for Protocol Submission</th>
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<td>September 20</td>
<td>Aug. 30, 5:00 p.m.</td>
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<td>October 18</td>
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Quick Review of Compliance

It is extremely important, and the responsibility of the Principal Investigator (PI), to **update protocol information** when there is any change in the project regarding animal utilization. It is also important to remember it is the responsibility of the PI to **provide project oversight** and to assure that others associated with the project adhere to the approved protocol.

In instances where the investigative staff has assumed responsibility for some (e.g., feeding) or all aspects of daily animal care, it is important to remember that **each animal must be observed and cared for daily**, seven days a week, 365 days a year. This **care should be documented**.

Purdue University operates its animal care and use program according to the policies of the Public Health Service (PHS) and the requirements of the Animal Welfare Act. This includes submitting an assurance to the PHS, indicating the program's compliance with all PHS policies.

Individuals who utilize animals in research, education, or testing at Purdue must be aware of and comply with the Purdue University's program for humane care and use of animals. Failure to comply places the assurance at risk, thus jeopardizing the privilege of using any animals at Purdue.

Examples of noncompliance include, but are not limited to:

- Failure to have an active PACUC approval number for an activity involving animals. This may include continuing an activity past its scheduled termination date.

- Housing animals in facilities not approved by the PACUC.

- Use of animal procedures that have not been approved by the PACUC.

- Acquiring, maintaining, or using animals in numbers greater than those approved.

- Inadequate or improper care or housing of animals.
Examples of some (but not all) significant changes to approved protocols can be found below:

- Changes in the overall objectives of the approved studies.
- Changes from non-survival to survival surgery or vice-versa.
- Changes that increase the pain or discomfort experienced by animals (e.g., increased restraint, restrictions on food or water intake, exposure to noxious or hazardous stimuli or materials).
- Changes in the anesthetic agent(s) or dose(s) or the method(s) of administering of anesthetic agents.
- Changes in the use of analgesics.
- Changes in the use of sedatives or tranquilizing drugs.
- Changes in the method of euthanasia.
- Changes in the species used.
- Increases in the number of procedures performed on an animal.
- Modifications to a surgical procedure.
- Changes in the duration of a procedure that is performed on an animal (e.g., chronic rather than acute procedures or vice-versa, length of a behavioral test session).
- Changes in the housing or husbandry of animals.
- Changes in the personnel involved with the project (see Section 13a below).
- Changes in the frequency of procedures (e.g., blood sampling, drug administration, tissue biopsy, exposure to stimuli, number of repeated behavioral tests).
- Changes in the invasiveness of a procedure (e.g., utilized a catheter rather than a needle to obtain fluid samples, injected rather than administered an oral form of a drug).

**Animal Research Violations Discovered At The University Of Connecticut**

As an example of the jeopardy in which an institution can find itself, the following is an excerpt from the May 18, 2000 Hartford Courant:

"Federal inspectors in animal research laboratories at the University of Connecticut (UConn) have found chronic problems that university officials fear could jeopardize all of UConn's animal research. The United States Department of Agriculture (USDA) has cited UConn for violations of the Animal Welfare Act at two of their animal research laboratories. The problems found included inadequate animal care, outdated drugs and poor building maintenance. Examples of inadequate animal care included:
The death of five rabbits which may have resulted from high temperatures due to the failure of an air-conditioning system or from irregular feeding and watering

Pigs housed outdoors with insufficient shade and water

Surgery performed by a researcher without authorization and without recording the use of pain-relieving drugs

A spokesman for the USDA indicated that UConn has been cited several times in the past for failure to comply with the federal Animal Welfare Act. For example, in 1998, UConn was fined $4,500 when inspectors found that a veterinarian did not have proper control over the health and well being of animals. The USDA has not yet determined what the penalties will be for these most recent violations."

**Animal Numbers for Approved Protocols**

In order to comply with USDA and PHS directives, the Laboratory Animal Program (LAP) monitors the number of animals acquired and used under each protocol. This activity is performed to ensure that the number used does not exceed the number approved. The term "used" means the number of animals ordered for or assigned to a protocol.

The LAP attempts to notify the principal investigator when use is approaching the number approved. Should you receive a notice from the LAP regarding your animal numbers and have a question regarding its content or should you have any questions regarding the animal tracking procedure, contact the LAP office at 49163.

**Written Narrative for Alternatives**

On June 21, 2000, the USDA published a revised policy pertaining to the consideration of alternatives to painful/distressful procedures.

The Animal Welfare Act (AWA) regulations require principal investigators to consider alternatives to procedures that may cause more than momentary or slight pain or distress to the animals and provide a written narrative of the methods used and sources consulted to determine the availability of alternatives, including refinements, reductions, and replacements.

Alternatives or alternative methods are generally regarded as those that incorporate some aspect of replacement, reduction, or refinement of animal use in pursuit of the minimization of animal pain and distress consistent with the goals of the research. These include methods that use non-animal systems or lower animal species to partially or fully
replace animals (for example, the use of an in vitro or insect model to replace a mammalian model), methods that reduce the number of animals to the minimum required to obtain scientifically valid data, and methods that refine animal use by lessening or eliminating pain or distress and, thereby, enhancing animal well-being.

A fundamental goal of the AWA and the accompanying regulations is the minimization of animal pain and distress via the consideration of alternatives and alternative methods. Toward this end, the regulations state that any proposed animal activity, or significant changes to an ongoing animal activity, must include:

- A rationale for involving animals, the appropriateness of the species, and the number of animals to be used;
- A description of procedures or methods designed to assure that discomfort and pain to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research, and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals;
- A written narrative description of the methods and sources used to consider alternatives to procedures that may cause more than momentary or slight pain or distress to the animals; and
- A written assurance that the activities do not unnecessarily duplicate previous experiments.

The USDA believes that the performance of a database search remains the most effective and efficient method for demonstrating compliance with the requirement to consider alternatives to painful/distressful procedures. However, in some circumstances (as in highly specialized fields of study), conferences, colloquia, subject expert consultants, or other sources may provide relevant and up-to-date information regarding alternatives in lieu of, or in addition to, a database search. When other sources are the primary means of considering alternatives, the Institutional Animal Care and Use Committee (IACUC), i.e. the PACUC and the inspecting USDA Veterinary Medical Officer should closely scrutinize the results. Sufficient documentation, such as the consultant's name and qualifications and the date and content of the consult, should be provided to the IACUC to demonstrate the expert's knowledge of the availability of alternatives in the specific field of study. For example, an immunologist cited as a subject expert may or may not possess expertise concerning alternatives to in vivo antibody production.

When a database search is the primary means of meeting this requirement, the narrative must, at a minimum, include:
The names of the databases searched;

- The date the search was performed;

- The period covered by the search; and

- The key words and/or the search strategy used.

The Animal Welfare Information Center (AWIC) is an information service of the National Agricultural Library specifically established to provide information about alternatives. AWIC offers expertise in formulation of the search strategy and selection of key words and databases, access to unique databases, on- and off-site training of institute personnel in conducting effective alternatives searches, and is able to perform no-cost or low-cost electronic database searches. AWIC can be contacted at (301) 504-6212, via E-mail at awic@nal.usda.gov, or via its web site at http://www.nal.usda.gov/awic. Other excellent resources for assistance with alternative searches are available and may be equally acceptable.

Regardless of the alternatives sources(s) used, the written narrative should include adequate information for the PACUC to assess that a reasonable and good faith effort was made to determine the availability of alternatives or alternative methods. If a database search or other source identifies a bona fide alternative method (one that could be used to accomplish the goals of the animal use proposal), the written narrative should justify why this alternative was not used.

When a proposal is modified during its performance, significant changes are subject to prior review by the PACUC, including the review of the implications of those changes concerning the availability of alternatives. Although additional attempts to identify alternatives or alternative methods are not required at the time of each annual review of the animal protocol, regulations require the principal investigator to reconsider alternatives at least once every 3 years, consistent with the triennial review requirements of the Public Health Service Policy.

**USDA Seeks Comments On Animal Pain And Distress**

The USDA is considering changes to the Animal Welfare regulations to promote the humane treatment of animals used in research, testing, and teaching and to improve the quality of information reported to Congress concerning animal pain and distress.

In the regulations, a "painful procedure" is defined as any procedure that would reasonably be expected to cause more than slight or momentary pain or distress in a
The USDA is considering adding a definition for the term "distress." Although this term is used throughout the Animal Welfare regulations, it is not defined. The addition of such a definition would clarify what regulatory agencies consider to be "distress" and could help assist research facilities to recognize and minimize distress in animals in accordance with the Animal Welfare Act (AWA).

The USDA is also considering replacing or modifying the system used to classify animal pain and distress. Professional standards regarding the recognition and relief of animal pain and distress have changed significantly since the USDA established its classification system. Some biomedical research professionals and animal welfare advocates believe the classification system is outdated and inadequate.

For example, the current system does not include a means to report:

- An assessment of the relative intensity or duration of pain or distress either observed in the animal or anticipated to be experienced by the animal;
- An assessment of the anticipated or observed efficacy of the pain- or distress-relieving agent provided to animals undergoing a painful or distressful procedure;
- A distinction between procedures causing animal pain and procedures causing animal distress;
- Animals that were prevented from experiencing pain or distress by the appropriate and effective use of pain- or distress-relieving methods or procedures (e.g., well-anesthetized animals that undergo terminal surgery) or through the appropriate and effective use of pain- or distress-relieving methods or procedures other than anesthetic, analgesic, or tranquilizing agents;
- Animals that experience pain or distress without having been used in a procedure (e.g., illness in animals that have been genetically altered to develop disease).

A different categorization system could produce data that more accurately depict the nature of animal pain or distress and provide a better tool to measure efforts made to minimize animal pain and distress at research facilities.

The USDA is soliciting public comments on the changes being considered and will consider all comments received by September 8, 2000.

The USDA is particularly interested in comments addressing the following five questions:
Would adding a definition for distress to the regulations help institutions using animals for research, testing, or teaching better recognize, minimize, and report animal distress?

If a definition for distress is added to the regulations, what key elements should be included in that definition?

What are the benefits and limitations of the current pain and distress classification system?

Should the current animal pain and distress classification system be modified or replaced? If so, what specific modifications or alternate classification systems should be considered?

Should animal pain and distress be prospectively or retrospectively reported?

Complete details can be viewed at http://www.aphis.usda.gov/ac/acpain

**URL's for Other Sites of Interest**


Want to see what the United States Humane Society is proposing as a classification scheme for pain and distress in lab animals: Check: [http://www.hsus.org/programs/research/usda_proposed_scale.html.html](http://www.hsus.org/programs/research/usda_proposed_scale.html.html)