Reminder On The Need For IACUC Approval Prior To Peer Review

Release Date: December 6, 2000

NOTICE: OD-01-008

National Institutes of Health

On May 1, 2000, the NIH announced that beginning with applications submitted for the January 2001 Council round, IRB approval is no longer required prior to NIH peer review of an application that involves human participants. This change in policy is intended to provide flexibility at the institutional level to reduce the workload burdens that many IRBs are currently facing, while still ensuring full protection of participants in human studies.

At this time, however, there is no change in the NIH policy for submission of IACUC approval when animal studies are involved. IACUC approval is still required of all such applications either when the application is submitted, or within 60 days thereafter; otherwise, the application cannot be peer reviewed. Applicants are reminded that if IACUC approval does not accompany the application, they should wait until notified of the scientific review group assignment and then forward the documentation to the designated Scientific Review Administrator.

Because of the different bases for IRB and IACUC review requirements, rulemaking would be required to allow similar flexibility for IACUC review. Over the next year, the NIH will closely monitor implementation of the revised policy on the timing of IRB approval. If as expected, this change in policy continues to provide the necessary safeguards but with enhanced institutional flexibility, the NIH will consider proceeding with rulemaking to permit similar flexibility in the timing of IACUC approvals.
Compliance with PACUC Policies

It is important that individuals using animals in research, teaching or testing comply with PACUC policies. The PACUC utilizes regulations promulgated by the USDA and Public Health Service (PHS) when making a determination if a project is or is not in compliance with federal standards and as such PACUC policy.

The following is one of the more serious and, unfortunately, not uncommon reasons for noncompliance. A means to prevent such noncompliance is provided.

Approved Procedures

It is extremely important that investigators follow all the procedures as described in their written Application to Use Vertebrate Animals in Research, Teaching or Testing (PACUC Form 1) and as approved by the PACUC. This includes: the experimental manipulations to be performed on the animal(s) (section 7.1 and 9.1 of the form); the described monitoring procedures for pain or distress and procedures for alleviation of such pain or distress (sections 10.3 and 11.3 of the form); and the endpoints to be used to relieve suffering (section 10.4 of the form). The USDA and PHS consider any deviation from the written procedures to be a major infraction and as such require the PACUC to take immediate action to correct any protocol violation. At a minimum, this includes not allowing the deviation to continue.

All personnel listed in the protocol should read and fully understand all the commitments made in the written form prior to starting work. Many protocol violations appear to be the result of investigators or their authorized staff not following or being aware of the details in the approved form. It is important that all personnel listed in a protocol read and fully understand the approved procedures prior to beginning any studies with animals.

Please make sure that all staff members involved in the study are thoroughly familiar with the details of the form and that they follow the procedures exactly as described.

If modifications to written procedures have been approved by the PACUC, then all listed personnel must be fully informed of these modifications to be certain that studies with animals are conducted in accordance with current authorized procedures. Correspondence between the PACUC and investigator leading to final approval should also be reviewed if not incorporated into the written application form.
Please review your written application form, modifications and correspondence with the PACUC to be certain that the currently approved procedures are followed in any research involving animals.

As a reminder, before implementing any changes in any aspect of the PACUC approved protocol, including the addition of new personnel, you must submit a written amendment to the PACUC (PACUC Form 1A) and obtain PACUC approval. As a minimum, ten working days should be allowed for your amendment to be approved. Verification of approval from the PACUC should be obtained prior to instituting the change.

As always, you are encouraged to contact the PACUC office (494-7206) for consultation should you have questions on procedures and policies or require assistance to ensure compliance.

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Reporting Concerns Regarding the Care and Use of Vertebrate Animals

What should be reported to the Purdue Animal Care and Use Committee (PACUC)/Laboratory Animal Program (LAP)? Anything that poses a risk to the health and safety of animals at Purdue University that is not corrected to your satisfaction should be reported to the PACUC/LAP office. Some potential problem areas could be: untreated pain and discomfort, unsatisfactory living conditions, problems with the physical facilities that could pose risks to animals, problems in the conduct of animal research (i.e., procedures conducted outside of approved protocols or significant changes to protocols without prior approval), and inadequate training of or unsatisfactory performance by animal care and research personnel.

How do you report concerns to the PACUC/LAP? You may phone our office at 47206, send a note (PACUC/SCCD), or e-mail to: Lisa Snider, Administrative Assistant, ldsnider@purdue.edu; William Ferner, Director and Attending Veterinarian, ferner@purdue.edu; Raymond Galinsky, PACUC Chair, galinsky@purdue.edu. Please supply the following information: What is the nature of your concern (be as specific as you can be)? What facility is the subject of your concern? Is animal health and safety at immediate risk? All reports will be held in strict confidence and may be made anonymously.

What will happen after your concerns have been reported? PACUC or LAP will begin an
investigation of your concerns within 24 hours. Some potential actions that could occur include: a visit to the facility, removal of conditions that pose risks to the welfare of animals, review of the rules and regulations with the parties involved, and the provision of training in animal care practices and procedures. The goal of the PACUC and the LAP is to permanently correct any unsatisfactory situation as quickly as possible – not to penalize or impose sanctions.

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**Updating Qualification Forms**

In an effort to be proactive with the USDA, the LAP/PACUC office is implementing a new policy to keep your qualification forms updated. Keeping your qualification form current is required because the USDA Veterinary Medical Officer assigned to Purdue checks these forms frequently while doing animal facility inspections on campus. A copy of your form will be sent to you asking that you review it and make modifications as appropriate. All forms should be returned to Sheila Light, the LAP secretary (LAP/SCCD). If you do not have any updates, the form should still be returned to Ms. Light with a note indicating this.

If you have any questions concerning this matter, please contact Ms. Light at sjlight@purdue.edu or 49163.

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**New Guidelines for Animal Euthanasia**

The long-awaited 2000 Report of the AVMA Panel on Euthanasia was published in the March 1, 2001 issue of the *Journal of the American Veterinary Medical Association*. Highlights of the changes in the new report are:

1. **Ether** – Ether is now considered a "conditionally acceptable" inhalant agent for euthanasia and should be used only in carefully controlled situations in compliance with state and federal regulations.
2. **Carbon dioxide** – Compressed CO₂ gas in cylinders are the only recommended sources of carbon dioxide for euthanasia; other methods such as from dry ice, fire extinguishers or other chemical means are unacceptable.
3. **Barbiturates** – Intracardiac injection may only be used if the animal is heavily sedated, unconscious or anesthetized.
4. **Chloral hydrate** – Chloral hydrate is conditionally acceptable for euthanasia of large animals only when administered intravenously and only after sedation.
5. **Blow to the head** – A blow to the head can be a humane method of euthanasia.
for neonatal animals with thin craniums, such as young pigs, when properly performed.

6. **Gunshot** – A properly placed gunshot to the head can cause immediate insensibility and humane death, but should only be performed by highly skilled personnel in jurisdictions that allow for legal firearm use. A gunshot to the heart or neck does not immediately render animals unconscious and thus is not considered to meet the panel’s definition of euthanasia.

7. **Thoracic compression** – Thoracic compression has been added to the list of conditionally acceptable methods to euthanatize small- to medium-sized free-ranging birds when alternate techniques are not practical.

8. **Wildlife species** – The issue of euthanasia of wildlife species is covered in much greater detail, with suggested doses of various agents also included in the report.

The report is the result of extensive deliberations by a panel comprised not only of veterinarians representing various animal species specialties, but also representatives of the research and wildlife management community. As stated in the "Guide for the Care and Use of Laboratory Animals" (NRC, National Academy Press, Washington, D.C. 1996) and the "Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching" (FASS, Savoy, IL 1999), the AVMA Report is used as a guide in assuring that humane methods of euthanasia are used for all animals under PACUC protocol at Purdue University. A copy of the report can be obtained by contacting the PACUC office (SCC-D), or it can be downloaded from the Internet at: [http://www.avma.org/resources/euthanasia.pdf](http://www.avma.org/resources/euthanasia.pdf).

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**Training Update**

Last year Purdue purchased a number of audiovisual materials to assist in training animal research and husbandry personnel. (See the list published in this past edition of the PACUC Newsletter, Vol. 15, No. 1, April 2000.) This material is available for general checkout in the John W. Hicks Undergraduate Library and is being widely used. However, the LAP/PACUC office has received many requests for training on more specific techniques.

The following web sites address many of the training issues discussed during this past year.

**Regulatory**

NIH Guide  http://www.nap.edu/readingroom/books/labrats/

APHIS Animal Care  http://www.aphis.usda.gov/ac/


International Conference on Humane End-points  http://www.lal.org.uk/pdf.htm

GLP/GMP OSHA Training (pay site)  www.sciencelearning.com

Audiovisual Alternatives to Animal Use  http://oslovet.veths.no/NORINA/

International Animal Shipping Regulations  http://www.aphis.usda.gov/guidance/regulations/animal/international/

**Husbandry**

Sterilants and High Level Disinfectants  http://www.fda.gov/cdrh/ode/germlab.html


**Dog/cat**

Univ of Pennsylvania Computer Learning  http://cal.vet.upenn.edu/

Diagnostic/therapeutic techniques  http://www.vetmed.wsu.edu/courses_samdx/

**Laboratory Animals**

Essentials for Animal Research  http://www.unmc.edu/Education/Animal/ess_idex.htm

Lab Animal Welfare Training Exchange  http://www.lawte.org/
UT Austin Technical Assistance http://www.utexas.edu/research/arc

UC Davis Lab Animal Autotutorials http://clueless.ucdavis.edu/autotoot.html currently not available

Univ Arizona Autotutorials http://www.ahsc.arizona.edu/uac/train.shtml

Univ Iowa Autotutorials http://www.uiowa.edu/~vpr/research/animal/educ-res.htm

Mouse Anesthesia http://www.lal.org.uk/mouse.htm

Rodent Surgery http://www.oprs.ucla.edu/animal/rsrg.htm

Aseptic Transgenic Surgery http://oacu.od.nih.gov/ppt_slides/


Saphenous Vein Blood Collection http://www.uib.no/vivariet/mou_blood/Blood_coll_mice_.html

**Wildlife**

Mammals http://www.mammalsociety.org/committees/commanimalcareuse/98acucguidelines.PDF

Herpetology http://www.xmission.com/~gastown/herpmed/

**Other Resources**

Animal Image database http://www.vetmed.wsu.edu/imagedb/

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**Animal Tracking**

In order to comply with USDA and USPHS directives, the LAP has been tracking the number of animals acquired under each protocol to ensure that the number of animals used does not exceed the number approved for use by the PACUC. The term "used" means the number of animals ordered or assigned to a protocol, including animals
transferred from other protocols.

Each PACUC approved protocol is tracked on a yearly basis, starting on the original approval date of the protocol. Tracking is done individually for each year that a protocol is active. For example, on the anniversary date of each protocol’s approval, the tracking begins anew and investigators are permitted to use the full allotment of animals for the next year period until the total number of animals described for the study has been used.

As a courtesy, the LAP has been sending letters to notify investigators when they have used 75 percent of their approved number of animals for a given protocol. Investigators can then determine whether an Animal Supplement Form (Form 6) must be submitted for approval to the PACUC. Should investigators reach their limit of usable animals for a given protocol, an Animal Supplement Form must be approved by the PACUC before additional animals can be used during the current tracking year.

If you have questions regarding this procedure, please contact Larry Miloscio at perrin@purdue.edu or 62886.

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Summer 2001 PACUC Meeting Dates

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Please contact Lisa Snider (ldsnider@purdue.edu) if you have any questions regarding these dates. Thank you.

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