Compliance Review

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 must be documented daily.**

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, teaching, or testing at Purdue must be aware of and comply with Purdue University’s program for humane care and use of animals. Failure to comply places our 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 a PACUC approval number for an activity involving animals. This may include continuing an activity past its scheduled expiration date (protocols are approved for 3 years only - no exceptions or extensions).
- 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.

• Carrying out procedures on animals in rooms that have not been approved by PACUC.

• 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 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.

• 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).

Please make sure you are doing your part to keep Purdue in compliance with the Animal Welfare Act and the PHS Assurance document.

Lisa Snider
PACUC Administrator

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Animal Use Qualification Form

Documentation of Personnel Qualifications. It is the strong belief of PACUC that personnel involved with animal care and use at Purdue University are highly qualified to perform their designated duties.

The skills and techniques employed for animal use and care at Purdue University are as diverse as the variety of species with which those abilities are used. To evaluate the qualifications of the personnel involved with animal care and use at Purdue, the PACUC relies on the expertise of the Principal Investigators (PI) and Animal Facility Supervisors.

All personnel who have contact with animals that
are used for research, teaching, or testing purposes, must fill out the Animal Use Qualification Form (http://www.purdue.edu/research/vpr/rschadmi n/rschoversight/animals/forms.shtml). The PI must review each form that is submitted by personnel who are listed on his/her protocol or amendment. The PI will certify that each person possesses the credentials that he or she has indicated on the form. If training is provided, records should be maintained by the PI. Principal Investigators must also complete a qualification form to document their own credentials. Each PI may certify the accuracy of his or her own qualifications. All animal care personnel involved with the care and housing of animals used under cover of approved or submitted protocols must also submit a completed Animal Use Qualification Form to their facility supervisors for approval. Facility supervisors must also complete a qualification form to document their own credentials.

As a reminder to those who have already submitted a qualification form to the PACUC office, please remember to update the form if you learn a new technique or work with new species. It is imperative that these forms remain current. Questions regarding Animal Use Qualification Forms should be directed to Sheila Light, PACUC Secretary, at 49163 or lap@purdue.edu.

Lisa Snider
PACUC Administrator

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Explaining PACUC’s 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. Please always use the most updated version of the Protocol which can be found on our website, www.purdue.edu/animals, and not a version that has been saved on your computer.

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 in 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**
• Justification of the species and the number requested
• Consideration of non-animal, less invasive, or less painful alternative procedures, and the use of species phylogenetically lower than the species that is proposed for use.
• Nature 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
• Justification for multiple survival surgeries
• 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

I 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.

Lisa Snider
PACUC Administrator

New and Triennial Protocol Applications

The PACUC office has been receiving a significant number of protocol applications (new and triennial re-writes) recently that do not have the signatures of the principal investigator and department head on the last page.

Please remember to obtain these signatures prior to mailing the application to the PACUC office. We cannot process the application until such time that the signature page is complete.

Thank you for your attention to this.

Lisa Snider
PACUC Administrator

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Upcoming 2008 PACUC Meetings

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<thead>
<tr>
<th>Meeting Date</th>
<th>Deadline Date for Protocol Submission</th>
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<td>May 21</td>
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<td>July 16</td>
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