

Purdue Animal Care and Use Committee

HANDBOOK

Lisa D. Snider, CPIA
IACUC Administrator
ldsnider@purdue.edu
(765) 494-7206

PACUC Handbook

Organization and Function of the PACUC

1. Mission Statement

The Purdue Animal Care and Use Committee (PACUC) exists to facilitate the performance of productive scientific and scholarly endeavors involving vertebrate animals. The PACUC accomplishes this by ensuring that all animal programs, procedures, and facilities at Purdue University adhere to the policies, recommendations, guidelines, and regulations of the United States Department of Agriculture (USDA) and the United States Public Health Service (USPHS) in accordance with the Animal Welfare Act and Purdue's Animal Welfare Assurance.

2. Role of the PACUC in Purdue University's Program of Animal Care and Use

The Institutional Official (IO) is the person who is "authorized legally to commit on behalf of the research facility" that all standards and requirements of the Animal Welfare Act will be met. The Associate Vice President for Research serves as the Institutional Official at Purdue University. The PACUC advises the Institutional Official about all matters related to the care and use of vertebrate animals in research, teaching, and testing at Purdue University. Although the PACUC advises and reports to the Institutional Official, the IO may not overturn decisions made by the PACUC to disapprove or suspend animal activities.

The Laboratory Animal Program (LAP) serves the University by assisting the PACUC in carrying out its mission. The LAP is distinct organizationally from the PACUC, with special responsibilities such as assuring the provision of satisfactory veterinary care and overseeing animal husbandry and the performance of certain aspects of animal use (e.g., pain relief, aseptic surgery). However, other activities of the LAP and PACUC overlap (See Table 1). Functional integration is also indicated by the fact that the position of Attending Veterinarian on the PACUC is held by the Director of the LAP. Other members of the LAP staff may also be named as voting or non-voting members of the PACUC.

3. Responsibilities of the PACUC and the LAP

The major functions of the PACUC and the LAP are presented in Table 1. As shown in the table, review of animal care and use protocols is a distinct function of the PACUC, whereas the provision of veterinary care is exclusively the responsibility of the LAP. Many other programmatic duties are complementary. For example, the PACUC is primarily responsible for assuring that animal care and use activities are performed in accordance with approved protocols. In addition, the PACUC provides training that will enable research and animal care personnel to maintain and document regulatory compliance. The LAP assures that animal housing, environments, and husbandry practices are consistent with federal policies. In addition, the LAP provides training necessary to assure that procedures approved by the PACUC are performed properly. Facilities inspections and reports of concern involve integration of PACUC and LAP functions. Whereas PACUC identifies and documents that deficiencies have been corrected in a timely manner; the LAP also identifies facility deficiencies. In addition, reports of concerns to the PACUC result, as needed, in actions by

the LAP to assess and remove threats to animal well-being. Furthermore, the LAP will assure that corrective plans endorsed by the PACUC are implemented satisfactorily.

TABLE 1: Responsibilities of the PACUC and LAP

PACUC	LAP
Protocol Review	Veterinary Care
Monitor Animal Care and Use Care and Use is Consistent With Approved Protocol	Monitor Animal Care and Use Care and Use is Consistent With Regulatory Standards
Facilities Inspections Identify Problems and Specify Corrective Actions, Document Completion of Corrective Actions	Facilities Inspections Identify Problems and Specify Corrective Actions.
Training Regulatory Compliance Requirements of the PACUC	Training Animal Care (e.g., husbandry) Animal Use (e.g., Aseptic Technique, Analgesia, etc.)
Reports of Concerns Review Nature of Concern Specify any Corrective Action Needed	Reports of Concerns Identify and Remove Threats to Animals
Occupational Health and Safety Advise PIs and other personnel about potential risks to personnel and necessary precautions	Animal Health and Well Being Monitor Health Status of Purdue Colonies Document Health of Incoming Animals
*Neither list is exhaustive.	

4. Structure of the PACUC

All members, voting and non-voting, are appointed to PACUC by the Institutional Official of the University. The term of appointment will typically be three years, but may be determined to be another amount of time. Recommendations for appointment are made based on the specific areas of expertise needed by the PACUC and, in the case of voting members, is also based on meeting legal requirements (see below). According to USDA 9 CFR Subchapter A, Subpart A, sec. 2.31, an Institutional Animal Care and Use Committee (IACUC) should be “qualified through the experience and expertise of its members to assess the research facility’s animal program, facilities, and procedures.”

- a. **Voting members.** The PACUC will be composed of no less than five members. Only voting members are counted with respect to determining the existence of a quorum at PACUC meetings. The composition of the voting membership must comply with federal rules. Per those rules, one voting member must be a doctor of veterinary medicine, who is certified, or has training and experience, in laboratory animal science or medicine. As Attending Veterinarian, this person has authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use at Purdue University. In addition, at least one member must be a practicing scientist experienced in research involving vertebrate animals. At least one member must be a nonscientist who does not use animals for research, teaching, or testing. Finally, at least one member must not be affiliated with Purdue

University or be a member of the immediate family of anyone who is affiliated with Purdue. This nonaffiliated member should represent the interests of the general public in regards to the care and use of animals and must not be a user of vertebrate animals. Finally, one of the voting members of the PACUC must be designated as the Chairperson. All of these members are appointed by the Institutional Official of the University.

The responsibilities of voting members of the PACUC include: (a) Review all protocols and amendments that have been forwarded for evaluation by the PACUC and determine whether full committee review or designated member review is appropriate. (b) Attend PACUC meetings. (c) Participate at least annually (often semi-annually) in inspections of animal facilities that are conducted by PACUC. (d) Participate in the semi-annual review of the PACUC.

- b. Non-voting Members: The responsibilities of the non-voting members of the PACUC will differ depending on the unit, department, or animal facility that they represent. Non-voting members that are directly affiliated with academic departments or research areas *may* have the following duties: (a) advise the PACUC about protocols and amendments that are related to their specific areas of expertise or that have been submitted by researchers from their departmental/research units. (b) Attend PACUC meetings when matters (typically protocols or amendments) related to their expertise or from their departmental/research units will be discussed. (c) Participate no more than semi-annually in inspections of animal facilities that are conducted by PACUC.

Non-voting members affiliated with animal facilities will have no responsibility with respect to protocol review (i.e., they will not perform protocol review). Non-voting members affiliated with animal facilities will have the following responsibilities: (a) The person would be a non-voting member [a non-voting member attends monthly PACUC meetings, and is free to discuss all issues brought before the committee, but does not vote on motions put to the committee]. (b) The person would serve a 2-year term and then be off the committee so that another animal care staff member can rotate on. (c) Participate no more than semi-annually in inspections of animal facilities that are conducted by PACUC. (d) The person could serve on one of the established subcommittees if asked by the subcommittee chair [facilities or education subcommittee], see C below.

Members from Radiological and Environmental Management (REM), Facilities Planning & Construction (FP&C), and animal care personnel will advise the PACUC about aspects of protocols and other issues relevant to animal care and use (e.g., physical facilities, occupational health and safety, biohazards) that are the concern of their specific unit. They will be asked to participate in facilities inspections. These non-voting members are not required to attend PACUC meetings unless matters related to their areas of expertise are scheduled to be considered at the meeting.

- c. Standing Subcommittees: The PACUC has two standing subcommittees. The Facilities subcommittee advises the Chair of the PACUC about actions that are needed to ensure that all animal care and use facilities are in compliance with regulatory standards. To accomplish this objective, the Facilities subcommittee represents the PACUC in the planning and approval of new animal facilities and in the purchase and utilization of new equipment by animal facilities at Purdue University. The Facilities subcommittee also helps develop and approve plans to modify or renovate existing facilities throughout the University.

The Educational subcommittee helps the PACUC ensure and document that all personnel involved with animal care and use are appropriately qualified to perform their assigned duties. As part of their purview, the Educational subcommittee advises the PACUC on the development and implementation of animal care and use training programs in accordance with federal regulations.

Policies/Guidelines/Standard Operating Procedures of the PACUC

Please see the following website for the approved policies, guidelines, and standard operating procedures of the PACUC: www.purdue.edu/animals. \

Review of Animal Care and Use Protocols and Amendments

Applications for approval of new protocols and for approval to make significant modifications to previously approved protocols (see Appendix) 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 4-6 weeks for the review process to be completed. The major steps for reviewing protocol applications are depicted in Diagram 1.

- a. Protocol submission: The protocol application is submitted electronically via the Coeus system to the PACUC. The PACUC Secretary assigns the application to the entire PACUC via the Coeus system for review. The PACUC has three (3) working days to communicate via the Coeus system if any member wishes the protocol to be reviewed by full committee review (FCR). If communication is not received, the protocol will be reviewed via the Designated Member Review (DMR) process.
- b. Designated Member Review (DMR) of protocol applications (Outcome #1): Review is conducted via the Coeus system by the Chair (or designee) and a LAP veterinarian. The responsibility for the third review is divided among the remaining members of the PACUC, with different members performing this function on a monthly basis. This review has one of three potential outcomes.
 1. *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 and are received in approval-ready form.
 2. *Consider comments before recommending approval on a designated basis*. Reviewers may ask for additional information before determining whether a protocol application can be approved. The questions or comments of reviewers will be summarized in a question memo that is prepared by the PACUC Administrative Assistant (or designee) and forwarded to the PI or to his or her designate via Coeus. Further consideration of the protocol application will be suspended until a response to the question memo is returned. The response is sent to the DMR's for review and to determine whether the protocol is ready for approval via DMR.
 3. *Recommendation for review at a meeting of the full PACUC*. If an IACUC member performing DMR recommends full committee review (even after the full PACUC recommended DMR), the protocol application will be reviewed

at a meeting of the full PACUC. 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.

➤ The PACUC Administrative Assistant (or designee) forwards all questions and comments of the reviewers to the PI *unless the PACUC Administrator consults with the reviewer about withdrawing a question or comment*. The Administrator would consider withdrawing a question or comment only under a very limited set of circumstances. One circumstance would be if the issue raised by the reviewer seemed to already be addressed adequately within the protocol application. Another circumstance would be if a question or comment posed by the reviewer seemed to instruct the PI to perform a practice or procedure that is unsatisfactory or that is less satisfactory than the practice or procedure proposed by the PI. It is hoped that through discussion, the reviewer and the Administrator would either agree to withdraw or to rephrase the question or comment. If such an agreement cannot be reached, the Administrator (in consultation with the Chair) retains the right to withdraw the question. However, in this situation, the protocol will automatically be scheduled for review by the full PACUC.

c. Procedures for Full Committee Review (FCR) [Outcome #2]: The PACUC meets once per month on a 12-month basis unless there is no business to discuss. Under special circumstances, the PACUC may meet more often than once per month. 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 protocols 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. At the conclusion of the discussion, a motion is formulated concerning the action the committee will take on the protocol. The members of the PACUC are then asked to vote on that motion. The PACUC may vote to adopt any one of the following categories of action:

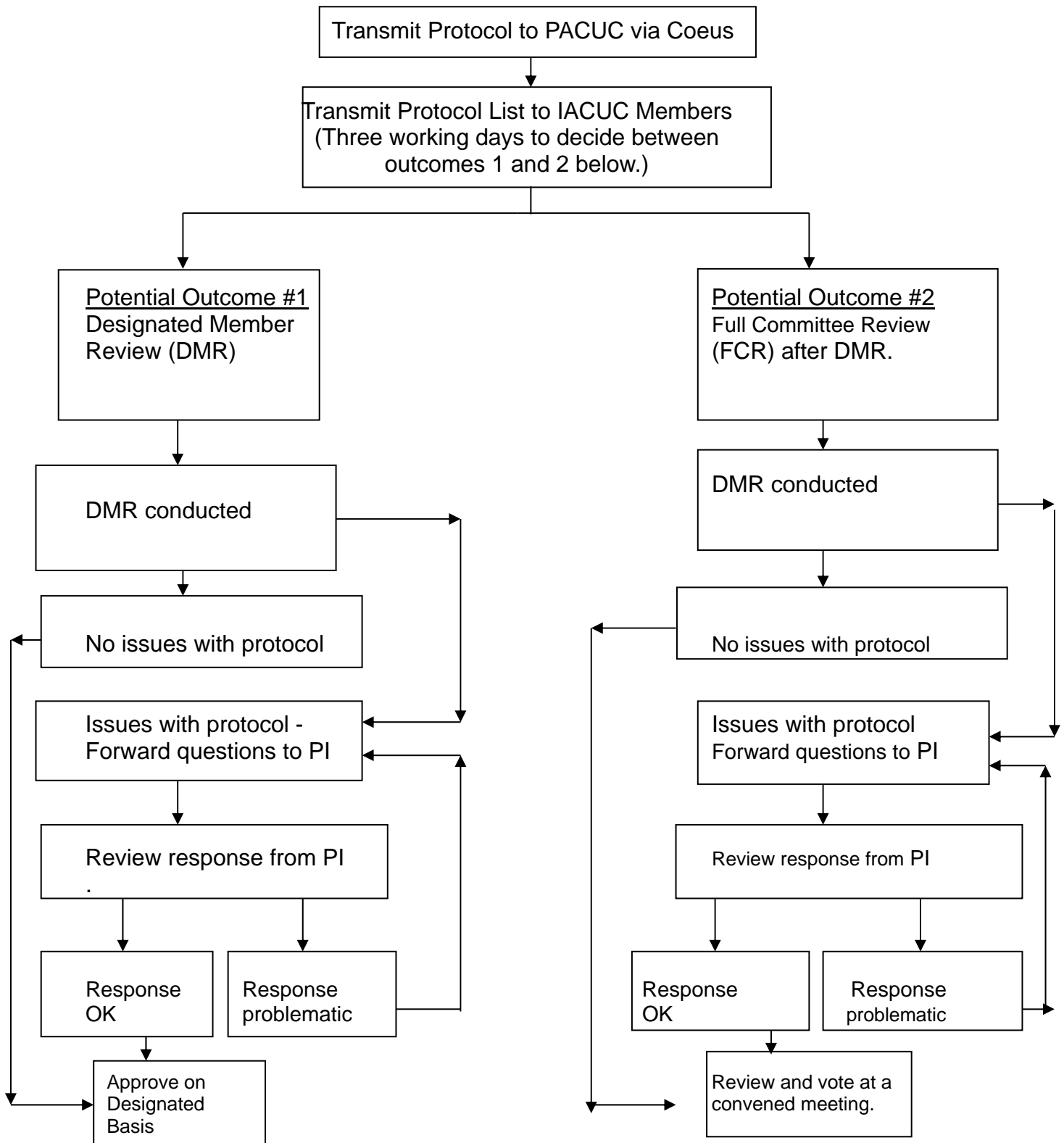
1. *Approval*: A protocol will be approved only when the PACUC considers that all significant points and potential concerns have been addressed satisfactorily by the PI. Granting approval means that the PI has permission to conduct the project that was described, with the number of animals that were indicated, in the protocol, or in other communications from the PI that were considered by the members of the PACUC. The Committee may instruct the 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.
2. *Withhold approval pending modifications*: This action will be taken when the PACUC deems that specific aspects of the protocol may be problematic and require further explanation, justification, documentation, or information. The

Administrator (or designee) will attempt to communicate, as clearly as possible, these problematic areas to the PI. The Chair (or designee) and a LAP veterinarian (appointed designated member review) will review the response of the PI to this communication. This procedure is in agreement with the PACUC-approved Policy on DMR review after FCR review. Approval to conduct the activity described in the protocol will be withheld until the response of the PI has been judged to satisfy the conditions set forth previously by the committee. If the two PACUC members (designated member 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 two PACUC members 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 PACUC Administrator. No further review by the Chair, LAP veterinarians, or other PACUC members is required.

3. *Deferral/Table*: 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 until the information needed by the committee is available.
4. *Disapproval*: The PACUC may vote to disapprove a protocol application. To appeal a decision to disapprove, the PI must present the PACUC with pertinent 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 Protocol Review Process (briefly)



Information that Must be Evaluated as Part of the Review Process.

The USPHS and the USDA 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
- 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

Procedures for Making Changes to Approved Protocols

Requests for changes may take the form of an amendment to an approved protocol or a request for an animal supplement to an approved protocol. Requests for amendments and animal supplements are subject to DMR or FCR, as described previously for new protocol applications.

Amendments to approved protocols. Amendments are submitted to the PACUC via the Coeus system. It will be reviewed as described above for protocols. If the PACUC recommends the amendment be reviewed by the full committee review process, it will be reviewed as described above for protocols.

Per federal regulations, approval by the PACUC is required prior to the implementation of any “significant” changes to a protocol. The PACUC uses the following list as a guide to determine what types of changes should be considered significant. Rather than being exhaustive, this list is used to indicate the general range of changes that should be considered for approval by the PACUC.

- Changes/additions of personnel.
- 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 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 as an oral form of a drug).

Re-review of Approved Protocols

All protocols are approved by PACUC for a period of three (3) years. However, both the USDA and the USPHS have requirements pertaining to the continuing review of previously approved activities involving the care and use of animals. According to the USDA, the PACUC is required to conduct “continuing reviews” of activities covered by approved protocols at intervals “not less than annually.” The PHS policy requires a “complete review” of previously approved activities “at least once every three years.” To meet these requirements, the PACUC has developed policies and procedures for conducting re-reviews of approved protocols.

- a. Annual Review of Approved Protocols. This review requires that PIs submit information about personnel changes, the number of animals used, the health status of animals, and about unexpected complications or difficulties that may have occurred during the previous 12-month period of approval. The PIs have been informed that significant changes from their originally approved protocols must be approved by the PACUC *before* they can be implemented. About a month before the anniversary of each protocol (excluding those protocols that are scheduled for more extensive triennial resubmission and review), the PI will be sent a reminder directing him or her to provide this information. The Annual Review process is the same as for protocol review described above.
- b. Triennial resubmission and review of previously approved protocols. Protocols are approved by the PACUC for a period of three years. To continue a project beyond this three-year approval period, the PI must submit a complete protocol application that is subject to the same review and approval process as is a new application (see above). The PI is notified 120 days prior to the protocol expiring that a re-written protocol is needed. The PI should forward the triennial resubmission of his or her protocol application not less than 6 weeks prior to the expiration of the current protocol. The triennial resubmission will retain the same identification number as the original protocol.

Procedures for Conducting Semi-annual Facilities Inspections

To remain in compliance with USPHS and USDA policies, the PACUC must inspect all facilities involved with animal care and use at least once every six (6) months. The purpose of these inspections is to:

- Ensure that each facility is in compliance with all applicable animal care and use policies, guidelines, and regulations
- Educate animal care and research personnel about these policies and regulations
- Prepare animal care personnel for visits by outside inspectors (e.g., USDA).

Format of semi-annual facilities inspections. The PACUC Administrator leads inspection teams (whenever possible) that are comprised of at least one member of the PACUC (two members are required if inspecting USDA covered species). There could be an occasion when the Administrator is not able to participate in an inspection (e.g., illness, out-of-town, etc.). If this occasion should occur, the Lab Animal Program veterinarian assigned to the inspection would take the lead. Each voting member of the PACUC is assigned to participate in inspections of different animal facilities on the West Lafayette and regional campuses. Non-voting members of the PACUC from the West Lafayette campus who are researchers or are involved with the program of occupational health and safety or animal care are also asked to participate in facilities inspections at least once per year. The PACUC members are assigned to the inspections of particular facilities by the PACUC Administrator, based on their availability and/or area of expertise. The Fort Wayne representatives do participate in facilities inspections on the West Lafayette campus.

Semi-annual facilities inspections are conducted according to the following format. The facility supervisor or designee will accompany the inspection team (whenever possible) during their visit and deficiencies will be pointed out and discussed with the facility supervisor as they are identified. At the conclusion of the inspection, the team members briefly discuss any deficiencies found. A formal report of the results of the inspection will be prepared by the PACUC Administrator and forwarded to the facilities supervisor on a timely basis. That report will identify deficiencies as minor or significant and will specify plans of corrective action that note the date by which each item listed should be corrected. All deficiencies must be remedied by the correction dates specified in the report, unless a prior request for an extension of the correction date has been received and approved by the PACUC Administrator.

Constructing New Facilities or Modifying Existing Facilities for Animal Care and Use

All plans to build new animal housing, food storage, and surgical facilities or that alter the function (e.g., species housed), use, or floor plan of existing facilities, should be submitted to the PACUC for review by the Facilities subcommittee. The purpose of this review is to insure that the plans for new construction and for remodeling older facilities conform to all applicable regulations before construction begins. In addition, the Facilities subcommittee of the PACUC must confirm that all newly constructed or remodeled facilities comply with all applicable regulations prior to the time when the facilities are put in use for animal housing, care, research or teaching activities.

Documenting the Qualifications of Personnel to Participate in Animal Care and Use Activities

All personnel that use animals for research, teaching, or testing, or who care for animals used for these purposes, must electronically submit an Animal Use Qualification form. Each PI must review each form that is submitted by the personnel who are listed on his or her active protocols. The PI will certify that each staff member possesses the credentials that he or she has indicated on the form. PIs must also complete a qualification form to document their own credentials. Each PI will certify the accuracy of his or her own qualification form. Where additional training is needed, the LAP/PACUC office may be contacted.

All personnel involved with the care and housing of animals used under cover of approved or submitted protocols (e.g., caretakers, veterinary technicians, technologists, etc.) must also electronically submit a completed Animal Use Qualification form. The supervisors will review each form and will certify the accuracy of the information provided. Facility supervisors are also required to complete a qualification form. Each facility supervisor will certify the accuracy of his or her own form.

Personnel who are being trained to perform animal care and use duties under the direct supervision of a qualified instructor are not required to submit an Animal Use Qualification form to receive training. However, documentation of qualifications is needed before the trainee will be authorized to engage in any animal care and use activity independently (i.e., without direct supervision by another qualified person). Personnel performing duties independently must be added to the protocol via an Amendment Form.

Participation in the University's Occupational Health and Safety Program

All personnel who have contact with animals as part of their employment at Purdue are eligible to participate in the University's animal exposure occupational health and safety program. Participation includes eligibility for pre-placement and regularly scheduled medical examinations, and dependent on risk, vaccinations, allergy testing, and training in the safe handling and disposal of hazardous materials. It is the responsibility of PIs and Animal Facility Supervisors to evaluate risks and provide appropriate safety training that is needed to protect the personnel who work under their direction from those risks. Assistance in risk assessment is also available from PACUC. Furthermore, job-related injuries or illnesses should be reported to the Purdue University Student Health Center, and the PI or supervisor should be informed immediately.

Undergraduate students *who are listed on an approved protocol*, but do not receive a paycheck from Purdue, are eligible to receive an occupational health exam as described above.

Mandatory Orientation Meetings for New Personnel

The PACUC conducts mandatory orientation meetings for all new personnel that are involved with animal care and use activities at Purdue University. Attendees will be informed about the functions and operations of the PACUC and the LAP, about U.S. government principles for the care and utilization of animals used in testing, research, and training, about the university program for occupational health and safety, and about

how to report concerns about the care and use of animals at the University. Authorization to engage in animal care and use activities will not be approved for personnel who fail to attend an orientation program.