

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 endeavor, 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)
Reports of Concerns Review Nature of Concern Specify any Corrective Action Needed	Reports of Concerns Identify and Remove Threats to Animals Oversee Implementation of Corrective Actions
Occupational Health and Safety Advise PIs 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 laboratory 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) initial screening of protocols and amendments (i.e., prior to transmission to PACUC) that have been submitted by investigators from their departmental or research unit. (b) Review all protocols and amendments that have been forwarded for evaluation by the full PACUC. (c) Attend PACUC meetings. (d) Review descriptions of projects that have been forwarded for designated approval. (e) Participate at least once annually in pre-review of protocols and amendments that have been transmitted to PACUC. (f) Participate once annually in post-full Committee review of protocols and amendments for which approval was withheld pending satisfaction of conditions. (g) Participate at least annually (often semi-annually) in inspections of animal facilities that are conducted by 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) initial screening of protocols and amendments (i.e., prior to transmission to PACUC) that have been submitted by investigators from their departmental or research unit. (b) Review and 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. (c) Attend PACUC meetings when matters (typically protocols or amendments) related to their expertise or from their departmental/research units will be discussed. (d) Review descriptions of projects that have been forwarded for designated approval. (e) Participate no more than annually in pre-review of protocols and amendments that have been transmitted to PACUC. (f) 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 would serve on one of the established subcommittees [facilities or education subcommittee], see C below.

Members from Radiological and Environmental Management (REM), Facilities Planning & Construction (FP&C), and the Office of Research Administration (ORA) 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 insure 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 insure 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 of the PACUC

1. Eligibility Requirements for Submission of Animal Care and Use Protocols

- a. Who is eligible to submit a protocol application to the PACUC?
1. All faculty and other University personnel who meet the eligibility requirements set forth by Sponsored Program Services to apply for extramural research funds.
 2. Personnel who are authorized to direct research projects as part of their affiliation with USDA/ARS.
 3. All faculty or other University personnel with administrative responsibility for courses offered by Purdue University or who are in charge of other teaching activities (e.g., workshops, exhibits, extension services, demonstrations) that involve the care and use of animals.

2. Criteria for Determining Projects that Require Review by the PACUC

- a. Protocols must be submitted for all projects using nonhuman, vertebrate, animals for the purposes of research, teaching, or testing that meet any one of the following criteria:
1. The animals are owned by Purdue University.

2. The animals are housed for more than 12 hours at facilities owned by Purdue University.
 3. The project is supported by funds that are administered by Purdue University.
 4. The project is directed by an employee of Purdue University.
- b. Types of animal use that do not require review by the PACUC
1. Projects involving the use of only invertebrate animals.
 2. Projects using only cadavers, animal tissues, fluids, internal organs, eggs, embryos, fetuses or other animal products that have been obtained from one of the following:
 - a. A standard commercial source (e.g., Carolina Biological Supply, Harlan Company)
 - b. Another institution (e.g., a university or a commercial laboratory) whose program of animal care and use has been documented to be in strict accordance with all applicable federal regulations.
 - c. As a by-product of another project that has been approved by the PACUC. A by-product of another project is an animal product that is not produced directly, as part of that project, for use in research, teaching, or testing.
 3. Non-intrusive observation for purposes of research or teaching which involves only the observation of animals without manipulating or altering the animal or its environment or interfering in any way with the ability of animals to engage in normal behavior or biological functions.
 4. Projects involving animals that are dead, as long as death was not caused to meet, in whole or part, the objectives of the project. For example, studies involving analysis of museum specimens or collection of data from animals found dead in the field do not require approval of the PACUC.

3. 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.

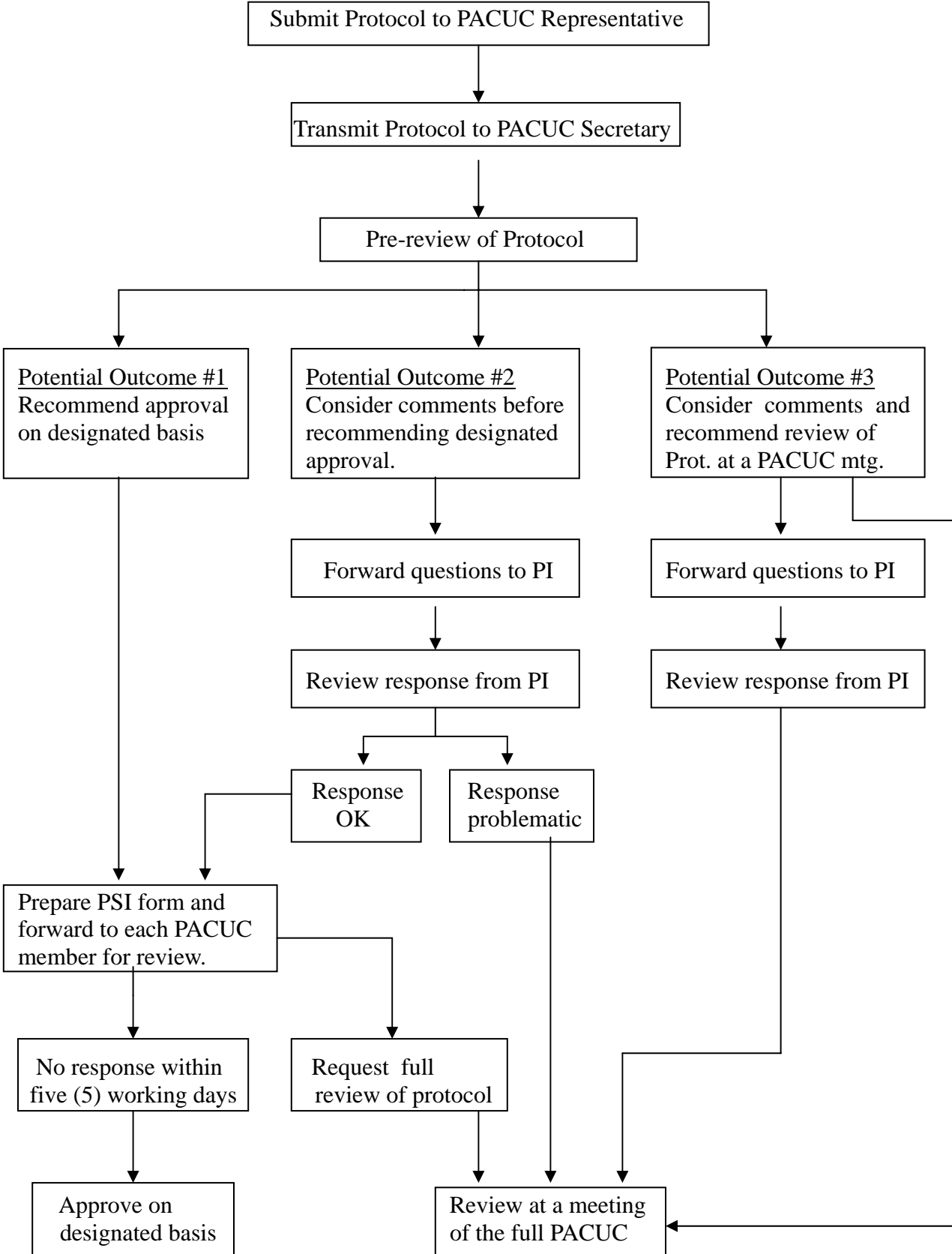
- a. Protocol submission: Principal Investigators should initiate this process by submitting a copy of their protocol application to their PACUC representative (if their area has one). The PACUC representative will advise the PI about problematic areas or points of confusion that could be clarified prior to review by the PACUC. Following the completion of any revisions that are needed, the PACUC representative submits 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.

1. 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.
2. 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 or to his or her designate. Further consideration of the protocol application will be suspended until a response to the question memo is returned to the Chair. 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.
3. 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.

The PACUC Administrator will forward all questions and comments of the pre-reviewers to the PI *unless the PACUC Administrator consults with the pre-reviewer about withdrawing a question or comment.* The PACUC 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 pre-reviewer seemed to already be addressed adequately within the protocol application. Another circumstance would be if a question or comment posed by the pre-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 pre-reviewer and the PACUC Administrator would either agree to withdraw or to rephrase the question or comment. If such an agreement cannot be reached, the protocol will automatically be scheduled for review by the full PACUC for a decision on whether or not the question should be asked.

Diagram 1: The Protocol Review Process



4. 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

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 should 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.

5. 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

6. Procedures for Making Changes to Approved Protocols

Significant changes to an approved protocol require additional review by the PACUC. Requests for changes may take the form of an amendment to an approved protocol, a request for an animal supplement to an approved protocol, or a request for an animal transfer. Requests for amendments and animal supplements are subject to pre-review, expedited approval and full review at a meeting of the PACUC, as described previously for new protocol applications.

- a. Amendments to approved protocols. Amendments are submitted to the Secretary of the PACUC on the PACUC Form 1A, “Request for an amendment to an approved protocol” (see Appendix A). This form and a copy of the currently active approved protocol are forwarded to the pre-reviewers. If the pre-reviewers recommend the amendment for approval on a designated basis, a copy of the amendment form will be forwarded to all PACUC members. The PACUC members have five (5) days to recommend full review at a meeting of the PACUC or the amendment request will be approved on a designated basis.

Each of the items listed below is considered by the PACUC to represent a “significant” change in animal care and use. Per federal regulations, written approval by the PACUC is required prior to the implementation of any of these changes. This is not intended to be an exhaustive list of the changes that require an approved amendment. Rather, the list should be used to indicate the general range of changes that would be considered “significant.”

- 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 or the site the experimentation will take place in.
 - Changes in the personnel involved with the project (see Section 15 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).
- b. Request for animal supplement. PIs may ask for approval to use additional animals of the same species as those covered by an approved protocol by submitting the PACUC Form 6, “Request for Animal Supplement” (see Appendix A). This form enables PIs to request the use of a larger number of the same species as those approved on their original protocol. The form requires the PI to provide a brief justification for the request. These requests are submitted to the Secretary of the PACUC, who prepares them for pre-review by three members of the PACUC.
- c. Request for animal transfer. Researchers may ask to transfer animals purchased under cover of one protocol to another approved protocol. This has the desirable effect of reducing the total number of animals used. Animals to be transferred should be in good health and should not have been involved in studies that exposed them to pathogens or toxins. Animals that have received survival surgery under their original protocol may not be transferred to a protocol that will subject them to a second survival surgery. Requests should be submitted on a PACUC Form 9, “Animal Transfer” (see Appendix A). The form requires the PI to specify the number of animals that are being transferred, the species of the animals, the number of the current protocol which authorizes their use, the number of the approved protocol to which transfer is being requested, and a description of how the animals have been used. Requests are submitted directly to the Secretary of the PACUC, who forwards them for evaluation by the Chair (or his/her designee) and two Laboratory Animal Veterinarians.

7. 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 re-review of approved protocols.* This policy 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 form directing him or her to provide this information. The information provided on this form is reviewed by the Chair of the PACUC (or his/her designee), by a Laboratory Animal Veterinarian, and by one other member of the PACUC. PACUC members are assigned to participate in this review on a rotating basis as was described for protocol pre-review. Questions or concerns raised by the reviewers are forwarded, in writing, to the PI. Annual renewal of the protocol will be withheld until the Chair of the PACUC (or his/her designee) has evaluated the PI’s responses to these questions or concerns as satisfactory. To aid in making this evaluation, the Chair (or his/her designee) will consult, as needed, with the other reviewers or other members of the PACUC. In addition, any of the three reviewers may request that renewal be considered and voted on at a meeting of the full PACUC.
- 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. The Secretary of the PACUC will notify the PI about 90 days before the three-year anniversary date (i.e., the expiration date) of his or her approved protocol application. 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.

Triennial resubmissions that have not been received in the PACUC office by their expiration date will be deactivated. When a protocol is deactivated, the PACUC will notify the Vice President for Research that the activities covered by the protocol are no longer authorized. The LAP will also check on the disposition of any remaining animals that have been cared for and used, or not used, under cover of the deactivated protocol. At the discretion of the LAP Director, animals that are no longer approved for use may be euthanized or, if appropriate, transferred to a different approved protocol. If a triennial application is under review but not yet approved, continued housing and care of the animals beyond

the expiration date of the protocol, must be justified as a means of avoiding the waste of research animals or of reducing the need to use additional animals in the future. This justification will be evaluated by the Chair of the PACUC, the Director of the LAP, and a third member of the PACUC. The identity of the third PACUC member will change on a monthly basis. Except for the provision of adequate housing and care, the use of animals for purposes of research, teaching, or testing is prohibited during the period between expiration of the original protocol and approval of the triennial resubmission by the PACUC.

8. Special Authorizations

Under special circumstances, limited authorization to engage in animal care and use activities may be granted prior to receiving approval via the expedited review or via review at a meeting of the full PACUC. Such special authorizations can be granted only when they are judged by the Chair of the PACUC *and* the Attending Veterinarian to promote animal well-being. For example, emergency situations (e.g., equipment failures) that require animals to be moved to locations not listed on a protocol may be authorized prior to approval by the full PACUC, if waiting to obtain that approval would put animal welfare at risk. A special authorization may also be granted if failure to take that action could render meaningless the data collected from animals that are currently on study, or could increase the number of animals required to meet the objectives of an approved protocol. Special authorizations may not be granted when such action may increase risks to animal health and well being, or when time permits the review by the full PACUC. The PACUC will be informed about all cases where special authorization has been granted.

9. Policy on the shipment of additional animals from a vendor

If it is the policy of a vendor to ship additional animals with the amount that was ordered, up to a 10% overage of rats, mice, baby chicks, and fish is approved for use without an Animal Supplement having to be filed and approved with PACUC.

10. Policies on Conflict of Interest

Conflict of interest is defined as a person having direct involvement in a study or facility. The following policies have been adopted by the PACUC to eliminate conflicts of interest:

- a. Members are prohibited from conducting pre-reviews of protocols, amendments, or annual and triennial reviews with which they are in conflict.
- b. Members are not allowed to contribute to the quorum that is necessary for committee action pertaining to protocols (including annual reviews and triennial resubmissions) or amendments with which they are in conflict.
- c. Members are prohibited from making or seconding motions pertaining to protocols or amendments with which they are in conflict.
- d. Members are prohibited from voting on motions pertaining to protocols or amendments with which they are in conflict.
- e. Members are required to absent themselves from PACUC meetings during discussions of protocols and amendments with which they are in conflict.

Members may be asked to return temporarily to the meeting for the purpose of answering questions posed by the Committee.

- f. In addition to policies pertaining to protocol review, a PACUC member will not be assigned to an inspection team that is responsible for inspecting that PACUC member's own facility.

11. 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:

- Insure 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).

In accordance with Purdue University's Animal Welfare Assurance, each inspection is conducted by at least three (3) PACUC members.

- a. Scheduling and assigning PACUC members to facilities inspections. For each facility, no more than 6 months elapses between each PACUC inspection. Each voting member of the PACUC is assigned to participate in inspections of different animal facilities on the West Lafayette and regional campuses. The PACUC Administrator coordinates the inspection teams. The PACUC members, other than the Attending Veterinarian, are assigned to the inspections of particular facilities by the PACUC Administrator based on their availability and on their areas of expertise. 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 can also be asked to participate in facility inspections.
- b. Format of semi-annual facilities inspections. Prior to the beginning of the inspection, the PACUC Administrator reviews the report from the last inspection of the facility. The facility supervisor may accompany the inspection team during their visit. It is PACUC policy that inspection teams must follow appropriate laboratory procedures to prevent interference with the conduct of approved research. Deficiencies will be pointed out and discussed with the facility supervisor, if present, as the team identifies them. At the conclusion of the inspection, the team members will meet briefly to prepare an exit debriefing. The members will discuss the findings of the inspection and will decide whether the deficiencies that were observed should be classified as minor or significant. Per federal regulations, significant deficiencies involving projects that are funded by the PHS must be reported promptly to the Office for Laboratory Animal Welfare (OLAW). This report will usually be filed by the Institutional Official. The team will also consider how each deficiency might be corrected and will select a date by which each correction should be completed. The leader of the inspection team will then provide an informal preliminary report of the results of the inspection to the facility supervisor. The goals of this debriefing are to insure that the perceptions of the inspection team are accurate and that the correction dates selected for each deficiency are realistic. The debriefing also enables personnel at the facility to begin corrective action prior to receiving the formal written inspection report. A formal report of the results of the inspection that

identifies deficiencies as minor or significant, that specifies a plan of corrective action, and that notes dates by which each item listed should be corrected, will be completed by the PACUC Administrator and forwarded to the facilities supervisor on a timely basis. The policy of the PACUC is to work with facility personnel to identify and permanently correct deficiencies as quickly as possible. Therefore, the relationship between the inspection team and the staff at the animal facility should always be constructive and should never be adversarial.

12. 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.

13. Policies for Addressing Reports of Concerns about Animal Care and Use

The cornerstone of self-regulation is the program for reviewing and resolving reports of concerns about animal care and use at the institution. The existence of such a program is federally mandated. Accordingly, a critical responsibility of the PACUC is to establish an environment where concerns about animals can be reported without penalty or fear of reprisal and a program that is capable of reviewing and resolving those concerns as fairly and as expeditiously as possible. The following policies and procedures were adopted by the PACUC to help address reports of regulatory noncompliance or other animal welfare concerns. *The goal of these policies is to correct permanently any unsatisfactory situation as quickly as possible--not to penalize or impose sanctions.*

a. Policies on Reporting concerns to the PACUC.

1. There are no restrictions on who can report concerns about animal care and use to the PACUC.
2. There will be no reprisals or threats of reprisals against those who report concerns.
3. Individuals may report concerns by phoning, writing or speaking directly with the Chair of the PACUC, the Director of the LAP or another LAP veterinarian, or the PACUC Administrator. It is also appropriate to transmit allegations via conversations or written messages to other PACUC members, or to the Institutional Official (i.e., the Vice President for Research).
4. Individuals reporting concerns will be asked to describe the nature of their concerns with as much detail as possible. Each report of concern should identify the facility or personnel that are the subject of the concern, specify the location within that facility of the animals that may be at risk, and when the actions that generated the concern took place. Persons reporting concerns may also be asked to evaluate the degree to which the risk to animals is immediate. In addition,

- these persons will be asked about any actions that may have already been taken to address the concerns and about the perceived outcome of those actions.
5. The confidentiality of those reporting incidences of noncompliance or misuse will be protected as much as possible. Anonymous reports will also be accepted.
- b. Policies on investigating concerns reported to the PACUC:
1. The information contained in the report of concerns should be relayed to the Chair of the PACUC as quickly as possible¹.
 2. The PACUC Chair will ask the Director of the LAP to begin, within 24-hrs, a preliminary review of the concerns reported.
 3. The purpose of the preliminary review is to evaluate the substance of the allegation and to assess quickly any potential risks to the health and welfare of the animals that are the subject of the concern. As part of the review, a LAP veterinarian may take one or more of the following steps:
 - a. visit the facility under review.
 - b. consult with or address questions to the PI or other personnel who may have information relevant to evaluating and resolving the concern.
 - c. take immediate action appropriate to removing threats to the health or well being of animals.
 1. This data-gathering phase of the review should be conducted with discretion appropriate to protect not only the person who reported the concern, but also any person or persons that are the subject of the report.
 4. The LAP Director will provide the PACUC Chair with a written report of the results of the preliminary investigation as soon as possible.
 5. The PACUC Chair and the Director of the LAP will assess the extent to which the allegations made in the original complaint have been substantiated or not confirmed. As part of this assessment, the Director of the LAP will advise the Chair of the PACUC about whether or not conditions exist that pose risks to the health or welfare of animals.
- c. Actions that can be taken to resolve concerns:
1. In cases where there is little or no threat to the health or well being of animals, the Chair of the PACUC and/or the Director of the LAP, may act to resolve the concern by reviewing the relevant rules and regulations with parties involved or by providing training in animal care practices and procedures to remove the basis of the concern. In addition, the Chair or LAP Director may ask the PI to voluntarily suspend animal care and use activities until completion of training or the satisfaction of other conditions has been documented. *The PACUC will be informed of any actions taken by the Chair and the Director of the LAP and will have the opportunity to recommend further action.*
 2. The Chair may ask the PI to suspend voluntarily further activities involving animals until the completion of a review of the concerns by the full PACUC.

¹ Of course, one exception to this procedure would be if the allegations involved the activities of the PACUC Chair or the Director of the LAP. If this were the case, the matter should be referred directly to the Institutional Official.

3. The Chair may call an emergency meeting of the PACUC to consider more serious problems that require immediate action. After hearing the report of concerns and the results of the preliminary review, a majority of a quorum of the voting members of the PACUC may vote to:
 - a. suspend, in full or in part, the activities covered by a previously approved protocol.²
 1. This action would be taken should the committee deem that results of the preliminary review provide sufficient evidence of serious noncompliance with federal regulations or University policies pertaining to the care and use of animals.
 2. The PI or his or her designated representative will be given prior notification of these actions. The PI will have the opportunity to explain or provide information about the circumstances pertaining to the concerns that have been reported.
 - b. ask the Director of the LAP to provide additional information regarding the concerns that have been reported.
 - c. appoint a subcommittee to investigate the situation further.
 - d. request that those against whom the complaint has been made have the opportunity to explain their actions before the full PACUC.
 - e. suspend, in full or in part, the activities covered by a previously approved protocol, *pending* the completion of further investigation.
 - f. provide the IO with recommendations pertaining to the imposition of additional sanctions on individuals who have been found responsible for serious or repeated violations.
 - g. withhold approval of new protocol applications or requests for amendments until the concern has been resolved.
 - h. request that the LAP veterinarian confiscate animals thereby removing them from threats to their health or welfare. In some cases, (e.g., where it is not possible to relieve conditions that harm or threaten to harm animals), the LAP veterinarian may be asked to euthanize animals.
 1. The PI or his or her designated representative should be given prior notification of these actions. The PI may avert these actions if he or she can substantiate, to the satisfaction of the Director of the LAP, that the conditions that posed risks to the animals have been removed permanently
- d. Requirements for reporting to USDA, OLAW, and the Institutional Official
 1. When all investigations have been completed, a report that includes any minority opinions will be made available to all parties involved, including the IO.
 2. In cases, where the PACUC votes to suspend in full or in part, an activity covered by a protocol pending the completion of an investigation, the IO (or his/her

² Note that suspension of any previously approved activity requires a majority vote of a quorum of the voting members of the PACUC. All members have the opportunity to present minority opinions.

designee) will forward a preliminary report to the OLAW. This is required only if the suspended activity is supported by PHS funds.

3. In cases where the PACUC votes to suspend a previously approved activity following completion of an investigation, the Chair of the PACUC will inform the Institutional Official. The Institutional Official will submit a complete report to the USDA, the OLAW (if the project is funded by PHS), and any federal agencies that may provide funds for the activity.

14. 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 fill out an Animal Use Qualification form. Each PI must review each form that is submitted by the research personnel who are listed on his or her active protocols or on any new protocol application or amendment submitted by the PI. The PI will certify that each research 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 submit a completed Animal Use Qualification form to their facility supervisors. 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.

a. Approval of personnel changes.

The PACUC requires that all personnel changes be pre-reviewed by the Laboratory Animal Program staff (by at least 2 veterinarians) and by the Chair of the PACUC (or by his/her designee). Changes or additions that are not considered to alter animal care and use significantly (e.g., addition of graduate students, replacement of a research assistant with an equally or better qualified person) will be approved immediately (i.e., will not go through the regular review process). If any of the pre-reviewers considers a change or addition to be significant (e.g., change in the PI or the replacement of a person with a highly specialized research skill), submission of the amendment will go through the regular review process.

15. Participation in the University's Occupational Health and Safety Program

All personnel (i.e., people who collect a paycheck) who have contact with animals as part of their employment at Purdue are eligible to participate in the University's 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 (by the staff of Radiological and Environmental Management [REM]) 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 REM. 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.

16. 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. This program is also available on-line at <http://www.purdue.edu/animals>. The on-line version may be substituted for attending the program in person.

NOTE: There may be additional policies/guidelines that have not been included in this handbook. These may be found on the PACUC website.