

PURDUE UNIVERSITY

**Assurance of Compliance with Public Health Service  
(PHS) Policy on Humane Care and Use  
of Laboratory Animals**

Purdue University, hereinafter referred to as institution, hereby gives assurance that it will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, hereinafter referred to as PHS Policy.

**I. Applicability**

This Assurance is applicable to all research, research training, experimentation, and biological testing and related activities, hereinafter referred to as activities, involving live, vertebrate animals supported by the Public Health Service (PHS) and conducted at this institution, or at another institution as a consequence of the sub-granting or subcontracting of a PHS-conducted or supported activity by this institution. "Institution" includes the following branches and major components of Purdue University: West Lafayette Campus (including all outlying farms), Calumet Campus, North Central Campus, and Indiana University-Purdue University at Ft. Wayne. The USDA registration number for the institution is 32-R-0007.

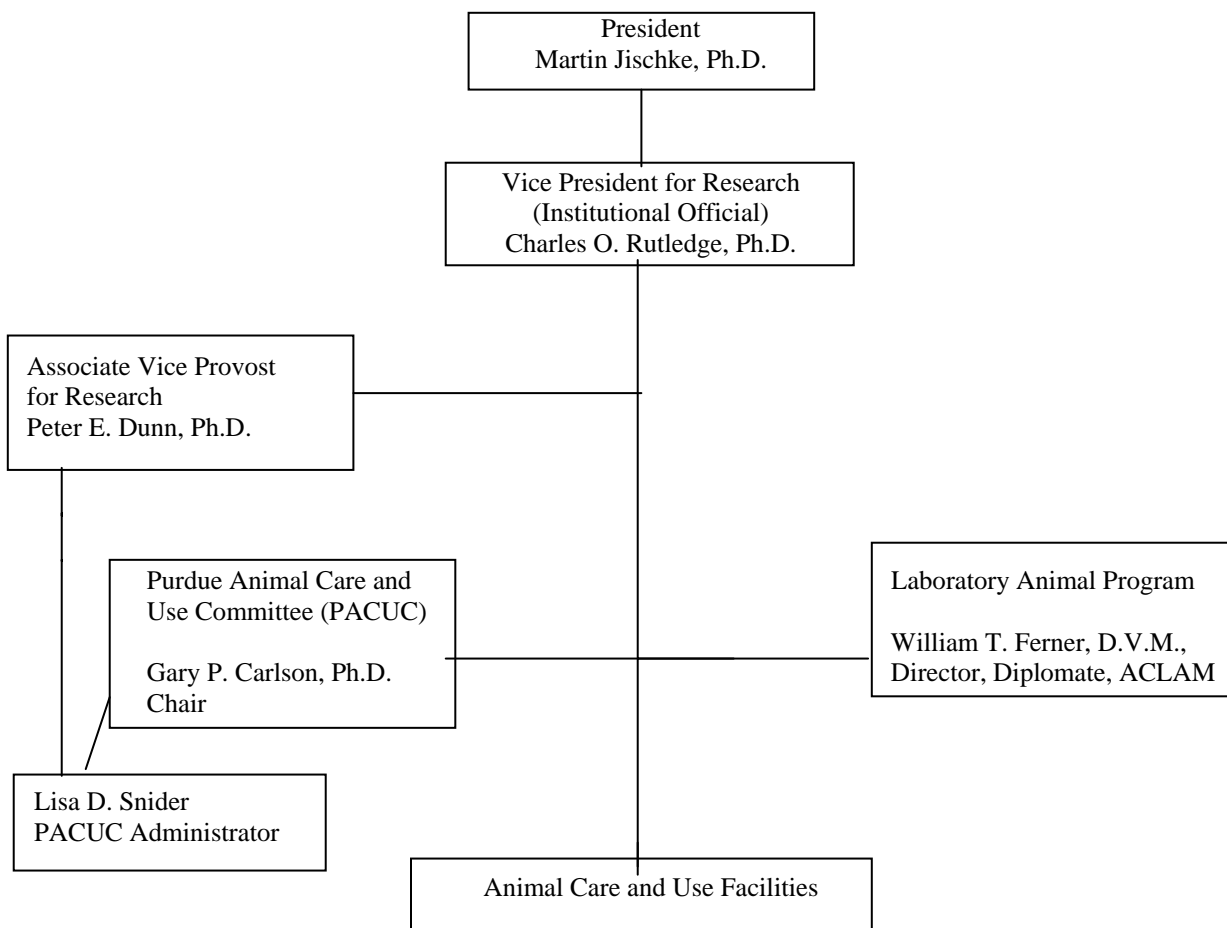
**II. Institutional Policy**

- A. This institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.
- B. This institution is guided by the, "Public Health Service Policy on Humane Care and Use of Laboratory Animals."
- C. This institution has established and will maintain a program for activities involving animals in accordance with the Guide for the Care and Use of Laboratory Animals (Guide) and the Guide for the Care and Use of Agricultural Animals Used in Agricultural Research and Teaching (Ag Guide).
- D. This institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this institution will make a reasonable effort to ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance as well as all other applicable laws and regulations pertaining to animal care and use.
- E. This institution will oversee the animal care and use procedures in all research, testing, and teaching activities that utilize University animals. University animals are vertebrate animals that are housed, cared for and used in any of Purdue University's

schools, departments, or other units and are used or intended for use in teaching, testing, or research. Vertebrate animals used in research, testing, or teaching that is not funded by PHS are subject to the same program of oversight, based on the same procedures and standards, as are the PHS-supported activities to which this Assurance applies.

**III. Institutional Program for Animal Care and Use**

A. The lines of authority and responsibility for administering the program and ensuring compliance with this policy are:



B. The qualifications, authority, and percent of time contributed by veterinarians who will participate in the program are:

William T. Ferner, D.V.M.

Graduate of the Ohio State University College of Veterinary Medicine.  
 Diplomate, American College of Laboratory Animal Medicine.  
 21 years training and experience in laboratory animal medicine.  
 Director, Laboratory Animal Program (LAP) and Attending Veterinarian, Office of

the Vice Provost for Research.

100% University appointment. Delegated program responsibility for activities involving animals at the institute with respect to implementation of the Policy and recommendations in the Guide.

Peggy O'Neil, M.S., D.V.M.

Laboratory animal veterinarian at Purdue since December 2001.

Received the D.V.M. degree from the University of California-Davis in 1986 and the M.S. degree in microbiology from the University of Missouri-Kansas City in 1976.

100% University Appointment. Delegated program responsibility for activities involving animals at the institute with respect to implementation of the Policy and recommendations in the Guide.

Lee Matthews, D.V.M. -

Laboratory animal veterinarian at Purdue since July 2005.

100% University Appointment. Delegated program responsibility for activities involving animals at the institute with respect to implementation of the Policy and recommendations in the Guide.

In addition, some outlying farms utilize the services of private veterinary clinics. The responsibility of overseeing veterinary care, however, still rests with the Attending Veterinarian and the LAP veterinary staff.

It should also be noted that in the School of Veterinary Medicine, there will be many researchers/instructors with D.V.M. degrees who will provide clinical/medical care to their research subjects. In addition, veterinary care for large/farm research animals at the Animal Sciences Research and Education Center (ASREC) is for the most part provided by the School of Veterinary Medicine clinicians. Again, assuring that care is provided rests with the Attending Veterinarian and the LAP veterinary staff.

The Director, LAP, as the Attending Veterinarian of record for Purdue University and as per the Federal Animal Welfare Act, has final authority and responsibility to insure that campus programs of veterinary care are adequate.

Purdue University provides the Attending Veterinarian the authority to oversee the adequacy of all aspects of animal care on the Purdue campus and the authority to ensure that adequate veterinary care and adequate pre- & post- procedural or surgical care, in accordance with current established veterinary medical and nursing practices, is provided at all times.

This authority is exercised in the following manner:

While the responsibility for providing clinical care may be delegated to another

veterinarian, the Attending Veterinarian remains responsible for the care provided to all research, teaching, and testing animals at Purdue University. The Attending Veterinarian retains, at all times, the authority to immediately access the medical records of non-client, research, testing, and teaching animals to assess the care given.

Adequate veterinary care consists of appropriate methods to: prevent disease; survey, diagnose, treat, and control disease; manage protocol-associated disease, disability, or other sequel; provide anesthesia and analgesia; perform surgery and provide post-surgical care; assess animal well-being; and perform euthanasia.

Methods of disease prevention, diagnosis, and therapy will be those currently accepted in veterinary practice.

All animals must be observed on a daily basis in order to assess their health and well-being (e.g., monitor for signs of illness, injury, or abnormal behavior). More frequent observations might be warranted, such as during postoperative recovery or when animals are ill or have a physical impairment.

The daily observation of animals is regularly performed by someone other than the Attending Veterinarian (e.g., animal care staff, research staff or by a person trained to recognize such signs), but these individuals must provide direct and frequent communication to the Attending Veterinarian such that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the Attending Veterinarian. The Purdue University LAP veterinary staff is assigned the responsibility of assuring that corrective measures are provided once identified. Use of a Clinical Activity reporting system is used to facilitate notification of the Attending Veterinarian of animal abnormalities for all animals on the Purdue campus except those maintained at the Animal Sciences Research and Education Center (ASREC) Farms. Veterinary clinical care for ASREC animals is provided by the Purdue University School of Veterinary Medicine, Department of Veterinary Clinical Sciences.

In addition to adequate veterinary care, the Attending Veterinarian has the authority to ensure the provision of and to oversee the adequacy of all other aspects of animal care and use on the Purdue campus. These other aspects include animal husbandry and nutrition, sanitation practices, zoonosis control, and hazard containment. This oversight includes the authority to access all animals at all times for evaluation of their health and well-being. Visits to animal housing, study and surgery areas are routinely scheduled by the LAP veterinary staff in order to assess the adequacy of veterinary care and other aspects of animal care associated with the use of research and teaching animals.

The Attending Veterinarian also has the responsibility of providing guidance to principal investigators and other research personnel involved in the care and use

of animals regarding handling, immobilization, anesthesia, analgesia, tranquilization, and euthanasia in order to ensure that humane needs are met and are compatible with scientific requirements.

C. This institution has established an Institutional Animal Care and Use Committee (IACUC), which is qualified through the experience and expertise of its members to oversee the institution's animal program, facilities, and procedures. This IACUC, hereinafter referred to as the Purdue Animal Care and Use Committee (PACUC), consists of at least five members, and its membership meets the compositional requirements set forth in the PHS Policy at IV.A.3.b. Attachment #1 is a list of the names, position titles, earned degrees, and other credentials of the PACUC chairperson and members.

D. The PACUC will:

1. **Review at least once every six months the institution's program for humane care and use of animals, using the Guides as a basis for evaluation.** The Chair of the PACUC reviews the results of facilities inspections, the minutes of PACUC meetings, the reports of the subcommittees, and all correspondence, both from within and outside the University that is related to program operations. The Chair also reviews the program of veterinary care with the Director of the LAP. In addition, the PACUC Administrator provides the Chair with information about the number and status of new protocols, amendments to previously approved protocols, and re-reviews of protocols (e.g., triennial applications) that were considered by the PACUC during the six-month reporting period. At the conclusion of this process, the PACUC Administrator prepares a draft report for review and comment by the members of the PACUC. This report covers PACUC membership, structure and operations, program facility use and development, training and educational activities, veterinary care, and the results of semi-annual facilities inspections, among other items. The report also identifies specifically any departures from the provisions of the *Guides* or from the *Public Health Service Policy on the Humane Care and Use of Laboratory Animals*, distinguishes minor deficiencies from significant deficiencies, and states the reasons for each significant departure. In addition, the results of semiannual facilities inspections with correction dates for all deficiencies and reasonable plans of corrective action are included as part of the report. PACUC utilizes the PHS Semi-Annual Checklist at a convened meeting as an additional step to review all aspects of the animal care and use program. Furthermore, facilities that are accredited by AAALAC-I or other outside accrediting bodies are identified as are any changes in accreditation status. Each PACUC member receives a copy of this report approximately one week before the monthly PACUC meetings that are held in January and July each year. Following review and approval at those meetings, a final report is prepared and forwarded to the Institutional Official. The PACUC has direct access to the Institutional Official and to the Associate Vice Provost for Research, who is responsible for compliance at

Purdue. Thus, the PACUC is able, at any time, to inform and make recommendations about any aspects of the program for animal care and use, facilities, or personnel training to the Institutional Official and the Associate Vice Provost for Research.

2. **Inspect at least once every six months all of the institution's animal facilities (including satellite facilities) using the Guides as a basis for evaluation.** The PACUC Administrator heads inspection teams (whenever possible) that are comprised of at least two additional members of the PACUC (one of which is a LAP veterinarian). 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 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 facilities planning are also asked to participate in facilities inspections at least once per year. 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/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. The leader of the inspection team will then provide an informal, verbal preliminary report of the results of the inspection to the facility supervisor. 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.

3. **Review concerns involving the care and use of animals at the institution.** The following policies and procedures are used by the PACUC to help address reports of regulatory noncompliance or other animal welfare concerns. *The goal of these policies is to permanently correct 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 concerns via conversations or written messages to other PACUC members, or to the Institutional Official (i.e., the Vice Provost 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 that is the subject of 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 they may have already 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. 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 possible. The PACUC Chair will ask the Director of the LAP to begin, within 24-hrs, a preliminary review of the concerns reported.
  2. 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 principal investigator (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.

- 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.
  - 3. The Director will provide the Chair with a report of the results of the preliminary investigation as soon as possible.
  - 4. The Chair and the Director will assess the extent to which the allegations made in the original complaint have been substantiated or disconfirmed. As part of this assessment, the Director will advise the Chair 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 and/or the Director, 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 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 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.
  3. The Chair may call an emergency meeting of the PACUC to consider 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.
      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

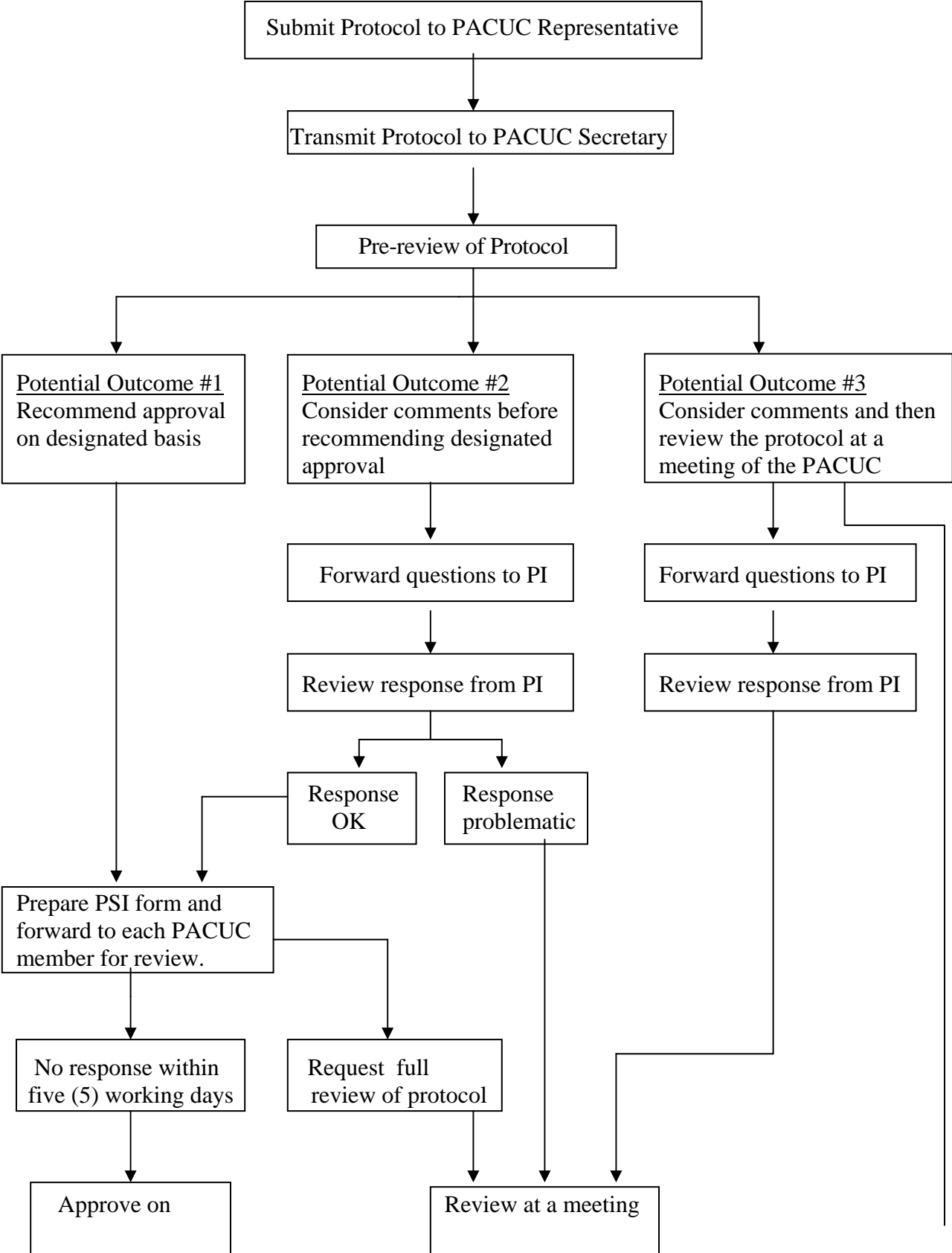
pertaining to the concerns that have been reported.

- b. ask the Director 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 assume control of the 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.
4. **Serious concerns involving animals will be reported promptly to OLAW through the Institutional Official.**
  5. **Make written recommendations to the Vice Provost for Research regarding any aspect of the institution's animal program, facilities, or personnel training.** This will usually be accomplished in writing as part of the semi-annual program review. Additional communication during the periods that intervene between semi-annual reviews will take the form of meetings with or memoranda to the Vice Provost for Research or the Associate Vice Provost for Research regarding specific topics related to program operations.
  6. **Review and approve, require modifications in (to secure approval) or withhold approval of those activities related to the care and use of**

**animals as set forth in the PHS Policy at IV.C.** Applications for approval of new protocols and for approval to make significant modifications to previously approved protocols must be completed by the principal investigator and submitted to the PACUC for review and approval prior to initiation of those activities.

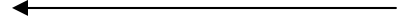
- a. Protocol submission: Principal Investigators are advised to initiate the protocol review process by submitting a copy of their protocol application to a PACUC member that is familiar with their research or teaching objectives. The PACUC representative will advise the PI about problematic areas or points of confusion that could be clarified prior to review by the PACUC. Following the completion of any revisions that are needed, the protocol application is submitted to the Secretary of the PACUC. The Secretary (or designee) 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. The major steps for reviewing protocol applications are depicted in Diagram 2.

Diagram 2: The Protocol Review Process



designated basis

of the full PACUC



- b. Pre-review of protocol applications: Pre-review is conducted by the Chair (or designee) and a LAP veterinarian. The responsibility for the third review is divided (by the PACUC Administrator) 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 (or designee) 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 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 request that the protocol application be forwarded to the full committee 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.
  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 (or designee) 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. The Chair (or 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 (or designee) 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 forwards 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 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 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 Review at Meetings of the Full PACUC: The PACUC meets once per month on a 12-month basis. 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 matters 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, 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), 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 judged to satisfy the conditions set forth previously by the committee. If the three PACUC members 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 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. *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.

4. *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 until the information needed by the committee is available.
5. *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.

7. **Review and approve, require modifications in (to secure approval) or withhold approval of proposed significant changes regarding the use of animals in ongoing activities as set forth in the PHS Policy at IV.C.** 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 pre-review, designated 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.

Per federal regulations, written 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 in the overall objectives of the approved studies.
  - Changes from non-survival to survival surgery or vice-versa.
  - Changes that increase the pain or discomfort experienced by animals (e.g., increased restraint, restrictions on food or water intake, exposure to noxious or hazardous stimuli or materials).
  - Changes in the anesthetic agent(s) or dose(s) or the method(s) of administering of anesthetic agents.
  - Changes in the use of analgesics.
  - Changes in the use of sedatives or tranquilizing drugs.
  - Changes in the method of euthanasia.
  - Changes in the species used.
  - Increases in the number of procedures performed on an animal.
- 
- Modifications to a surgical procedure.
  - Changes in the duration of a procedure that is performed on an animal (e.g., chronic rather than acute procedures or vice-versa, length of a behavioral test session).
  - Changes in the housing or husbandry of animals.
  - Changes in the personnel involved with the project (see item “c” in this section 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 as an oral form of a drug).
- b. Request for animal supplement. Approval to use additional animals of the same species as those covered by an approved protocol may be obtained by submitting the PACUC Form 6, “Request for Animal Supplement” (see Appendix A). 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 as was described previously.
- c. 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. 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 a formal

amendment would be requested.

- d. Special authorizations provided by the Chair and Veterinary Staff. Under special circumstances, limited authorization to engage in animal care and use activities may be granted prior to receiving approval via the designated 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 *and/or* the Director 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 (e.g., change in analgesia or anesthesia, need for a replacement animal). 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.

8. **Notify investigators and the institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure PACUC approval as set forth in the PHS Policy at IV.C.4.** For each of the actions listed above and listed below, the PACUC Administrator (or designee) will communicate to the PI the decision of the PACUC, and will elucidate, as determined by the PACUC, any information or modifications that would be required to obtain approval or renewal. In cases where the unanimous vote of PACUC is for disapproval, the 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 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. The PACUC Administrator records all decisions regarding protocol review in the meeting minutes. Copies of the minutes from all PACUC meetings are sent to the Vice Provost for Research, who is also the IO. In addition, the Associate Vice Provost for Research participates in the review process for all protocols in his capacity as an ad hoc member of the PACUC. The Associate Vice Provost for Research also meets with the IO each week to review issues related to university research administration.

9. **Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with PHS Policy IV.C. 1-4, at least once every three years.**
  - 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 (see Appendix A) directing him or her to provide this information. The information provided on this form is reviewed by the Chair (or 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 (or designee) has evaluated the PI's responses to these questions or concerns as satisfactory. To aid in making this evaluation, the Chair (or 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.
  
10. **Be authorized to suspend an activity involving animals as set forth in the PHS Policy at IV.C.6.d.** Suspension of an activity requires a majority vote obtained at a meeting of the PACUC where a quorum is present. When a decision to suspend an activity has been approved, a written statement that includes any minority opinions, will be prepared by the Chair of the PACUC (or designee) and will be made available to the IO with a request that the formal communication to the PI be made by the IO.
  - a. 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 Chair (or designee) will inform the IO. The IO will review the reasons for suspension and will provide a preliminary report to OLAW.

- b. In cases where the PACUC votes to suspend a previously approved activity following completion of an investigation, the Chair (or designee) will submit to the IO the reasons for the suspension and any recommendations that are made by the PACUC for corrective actions. The IO will use this information along with that obtained in discussions with the Chair and other relevant parties to determine corrective actions and to formulate a report with full explanation for OLAW.

- E. The individual(s) authorized by this institution to verify PACUC approval of those sections of protocol applications related to the care and use of animals are the Chairperson of the PACUC and the PACUC Administrator, respectively.

F. It is the policy of Purdue University to take every reasonable precaution to provide a work environment that is free from recognized hazards for its employees in accordance with the General Duty Clause of the Indiana Occupational Safety and Health Law (IC 22-8-1.1 Section 2). The Purdue University Biological Safety Manual provides information on work practices, procedures, and policies necessary to ensure the health and safety of individuals exposed to biohazardous agents in the workplace.

Purdue University has established an Institutional Biosafety Committee with the responsibility to promote safe and proper biohazard management at all Purdue University campuses and related facilities.

The Biological Safety Program applies to all personnel at Purdue University's West Lafayette campus and Regional campuses, University research farms and agricultural centers, and related facilities and operations engaged in the use of biohazardous agents.

The Occupational Health and Safety Program for Individuals with Animal Exposure is an important part of Purdue University's institutional animal care program. This program, operated through the Vice Provost for Research, the Laboratory Animal Program, and the Office of the Vice President for Physical Facilities, is designed to protect both Purdue personnel and animals. The following information is an introduction to the current Occupational Health and Safety Program for Individuals with Animal Exposure and provides information and training to individuals with animal exposure concerning the risks associated with that exposure. The requirements of the Occupational Health and Safety Program are based on guidelines in the NIH *Guide for the Care and Use of Laboratory Animals*.

The department responsible for monitoring the program is Radiological and Environmental Management (REM).

- i. All individuals at Purdue University who have exposure to animals are given the opportunity to participate or decline participation in the program. This includes exposure to animals by way of handling, feeding, cleaning, exposure to unfixed tissues, and exposure to animal wastes or bodily fluids.

Generally, this includes:

- Veterinary staff of the Laboratory Animal Program
- Animal caretakers
- Animal technicians
- And the following people having animal exposure:  
Principal investigators, students listed on approved PACUC protocols, laboratory personnel, maintenance personnel and custodial personnel. Awareness training is provided to maintenance and custodial personnel.

It is the responsibility of the department, principal investigators, and facility managers to identify individuals who meet these criteria. If a person feels he/she should be included in the program, they should consult with their supervisor, department head, REM, or the Laboratory Animal Program office.

Note: For students exposed to animals as part of their academic curriculum, PACUC is inquiring, as part of the annual protocol review process, what information the faculty member in charge of the course provides to students with regards to species-specific information on occupational health and safety, including but not limited to: allergies, zoonoses, potential hazards, workplace injuries, etc.

- ii. Participation in the Occupational Health and Safety Program for Individuals with Animal Exposure is provided at no cost to the individual participant. The participant is required to do the following:

- Read all the information pertaining to the program provided on the PACUC/LAP website.
- Complete the Participation/Declination Form and return it to the appropriate office.
- If a person chooses to participate in the program, a medical questionnaire form will be sent to them to fill out for evaluation and risk assessment based on the answers to those questions.
- If an individual chooses to decline participation in the program, he or she should fill out the Participation/Declination form and return it to the appropriate offices on either the West Lafayette Campus or the Fort Wayne Campus at the locations given above.

- Whether or not an individual participates in the program, all eligible persons must read all the information at <http://www.purdue.edu/research/vpr/compliance/animals/occhealth.shtml> concerning risks and hazards associated with animal exposure prior to declining participation.
- iii. On-the-job injuries and illness must be reported to the person's supervisor, who will assist them in getting to the Purdue University Health Center or other health care provider, if necessary.

Work-related injuries must be reported to Radiological and Environmental Management within 48 hours on a First Report of Injury form available at <http://www.adpc.purdue.edu/HR/wc.htm>

- G. The total gross number of square feet in each animal facility, the species of animals housed therein and the average daily inventory, by species of animals in each facility, is presented in tabular form in Attachment #2.
- H. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use at Purdue is reviewed and evaluated by the Educational Subcommittee, which advises the PACUC and the LAP about program training needs and how best to meet them. A Training Coordinator has been hired to establish a comprehensive training program for the Institution. A summary of current training efforts is presented below:

A number of videotapes, auto tutorial slide sets, and reference materials on animal care and use are available on the Purdue University campus. These materials have been cataloged by the Educational Subcommittee of the PACUC and placed in a central library location. These acquisitions include the University of California at Davis Animal Handling Series of videotapes and the complete American College of Laboratory Animal Medicine Series II auto-tutorial sets. These materials are available at the central library facility and would be appropriate for use by technical or investigator staff for self or group study.

In addition, using the materials as noted above, LAP staff offers training sessions on a regular (i.e., usually monthly) basis. Using a "brown-bag" or other similar format, the training sessions attempt to accomplish four objectives:

- Supplement "on-the-job training" with an institution-sponsored discussion and training program that is specific to the animal care and use activity of each individual and to the species with which they work.
- Assist in ensuring that individuals caring for or using animals in teaching and/or research are qualified to do so, as required by the Animal Welfare Act and the Public Health Service Policy. The Guide notes that personnel using or caring for animals should participate regularly in continuing-education activities relevant to their responsibilities.

- Assist individuals that express an interest in advancement in the field of laboratory animal science in preparing for the certification examination(s) of the American Association for Laboratory Animal Science (AALAS).
- Facilitate discussion on various topics of animal care among the staff at Purdue.

The PACUC publishes a quarterly newsletter that is distributed to animal research personnel at all levels. The purpose of the newsletter is to disseminate information about program developments, matters of regulatory compliance, animal welfare, occupational health and safety, and items of general interest from the community of animal researchers both within and outside of Purdue University.

Through the Department of Veterinary Pathobiology, a formal course is taught that is designed primarily to prepare future investigators for judicious and proper use of research animals. It is available to graduate students of any university department who are using or plan to use vertebrate animals in research, teaching, or testing. The course is also open to junior veterinary students. Topics of lectures and discussions include the history of animal research; ethical thought related to research animal use; animal models and non-animal alternatives; biology, husbandry, and diseases of common laboratory animal species; hygiene and occupational health; perioperative care and aseptic surgery; anesthesia; analgesia; and euthanasia.

The PACUC views the protocol review process as an educational interaction with the investigator. Thus, the committee provides feedback from its deliberations relating to the number of animals required, alternative approaches that reduce the number of animals required, methods to minimize pain and distress, and other topics.

Training and consultation are also provided on a one-on-one basis to individuals by the Training Coordinator and/or LAP veterinary staff. This training and consultation ensure that research protocols and research techniques include up-to-date concepts in humane care and use of research animals. In addition, the LAP staff serves as a resource of material and educational services for researchers and students with questions or concerns regarding laboratory and teaching animals.

Each month the PACUC conducts mandatory orientation meetings for all new personnel that are involved with animal care and use activities at Purdue University. Attendees are informed of the functions and operations of the PACUC and the LAP; the U.S. government principles for the care and utilization of animals used in testing, research, and training; the university program for occupational health and safety; and how to report concerns about the care and use of animals at the University. Authorization to engage in animal care and use activities may be suspended for personnel who fail to attend an orientation meeting. This orientation session is also available on-line for those whose schedules do not allow them to attend the “live” session.

Several training modules are also offered on-line using the Laboratory Animal Training Association's (LATA) services. These modules are: (1) The Humane Care and Use of the Laboratory Rat and Mouse, (2) The Humane Care and Use of Laboratory Swine, (3) The Humane Care and Use of Laboratory Cats, and (4) Aseptic Surgery of Rodents. Completing these modules is a requirement for people who work with these species.

The Purdue Animal Care and Use Committee web site is accessible at the following address: <http://www.purdue.edu/animals>. This web site offers information on the protocol application, amendment form, animal supplement form, the occupational health program, the animal use qualification form, policies and guidelines of the PACUC and LAP, the PACUC Orientation Program, and several other areas of interest. The PACUC Handbook, which contains a detailed description of PACUC's functions and policies, is also available at the web site. Links to websites operated by OLAW, the Animal and Plant Health Inspection Service of the USDA, and AAALAC International, are also found at the PACUC Website. This institution's goal is to utilize the website as a place where researchers and other personnel can find information and links to information about current developments specific to their particular animal care and use activities. In addition, this institution uses the "ListServ" capabilities of the internet to communicate rapidly new information to personnel that have common animal care and use interests.

Prior to beginning their participation on the PACUC, all new voting and non-voting members take part in an orientation meeting that is organized by the PACUC Administrator. At that meeting, new members receive copies of the Guide for the Care and Use of Laboratory Animals, the Guide for the Care and Use of Agricultural Animals used in Agricultural Research and Teaching, and a copy of USDA regulations contained in 9 CFR, Chapter 1. Each new member also receives a copy of the PACUC Handbook, a document that codifies and integrates the mission, policies and procedures of the PACUC. The Chair discusses and provides an overview of the contents and applicability of each of these documents. In addition, the Chair gives special attention to matters of maintaining confidentiality with regard to PACUC deliberations, the policy on conflict of interest, how to perform protocol reviews, and other topics.

The PACUC also provides continuing information and training to help PACUC members understand and evaluate the issues that are brought before the Committee. As one way of achieving that objective, a training session/retreat for PACUC members is held annually. In the past, department heads, deans, and other administrators at Purdue have also attended the retreat. In addition to a review of the mission and operations of the PACUC, the format of the retreat will typically include formal presentations by PACUC members or other knowledgeable parties at Purdue. Invited talks may also be given by people outside Purdue University who are recognized for their expertise on matters of current interest to the committee.

#### **IV. Institutional Status**

As specified in the PHS Policy at IV.A.2, as Category 2, all of this institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the PACUC and will be re-evaluated by the PACUC at least once every six months. The reports of the PACUC evaluation are submitted to the Vice Provost for Research; a copy of the most recent report is attached (Attachment #3). Each report contains a description of the nature and extent of this institution's adherence to the Guides. Any departures from the Guides are identified specifically and reasons for each departure are stated. Where program or facility deficiencies are noted, the report contains a reasonable and specific plan and schedule for correcting each deficiency. The report distinguishes significant deficiencies from minor deficiencies. Semi-annual reports of the PACUC evaluations submitted to the Institutional Official (the Vice Provost for Research) will also contain a reasonable and specific plan and schedule for correcting each deficiency and distinguish significant deficiencies from minor deficiencies. Semi-annual reports of PACUC evaluations will be maintained by this institution and made available to OLAW upon request.

Purdue University applied for campus-wide accreditation by AAALAC-I. The initial site visit was conducted in September 2004. Purdue has received formal communication from the AAALAC-I Council granting the university with provisional accreditation for the Colleges of Agriculture, Science, Engineering, Veterinary Medicine, Consumer and Family Sciences, and Liberal Arts and with deferred accreditation for the School of Pharmacy, Nursing, and Health Sciences.

#### **V. Record-keeping Requirements**

- A. This institution will maintain for at least three years:
  - 1. A copy of this Assurance and any modifications thereto, as approved by PHS.
  - 2. Minutes of PACUC meetings, including records of attendance, activities of the committee, and committee deliberations.
  - 3. Records of protocol applications and proposed significant changes in the care and use of animals and whether PACUC approval was given or withheld.
  - 4. Records of semi-annual PACUC reports and recommendations as forwarded to the Vice Provost for Research.
  - 5. Records of accrediting body determinations.
- B. This institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the PACUC for the duration of the activity and for an additional three years after completion of the activity.
- C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

## **VI. Reporting Requirements**

- A. At least once every 12 months, the PACUC, through the Institutional Official, will report in writing to the Office of Laboratory Animal Welfare (OLAW):
  - 1. Any change in the status of the institution (e.g., if the institution becomes accredited by AAALAC or AAALAC accreditation is revoked), any change in the description of the institution's program for animal care and use as described in this Assurance, or any changes in PACUC membership. If there are no changes to report, this institution will submit a letter to OLAW stating that there are no changes.
  - 2. Notification of the date that the PACUC conducted its semi-annual evaluations of the institution's program and facilities (including satellite facilities) and submitted the evaluations to the Vice Provost for Research.
- B. The PACUC, through the Institutional Official, will provide the OLAW promptly with a full explanation of the circumstances and actions taken with respect to:
  - 1. Any serious or continuing non-compliance with the PHS Policy.
  - 2. Any serious deviations from the provisions of the Guides.
  - 3. Any suspension of an activity by the PACUC.
- C. Reports filed under VI.A.2. and VI.B. above shall include any minority views filed by members of the PACUC.

**VII. Institutional Endorsement and PHS Approval**

A. Authorized Institutional Official

Name: Charles O. Rutledge, Ph.D.  
Title: Interim Vice Provost for Research  
Address: Purdue University  
610 Purdue Mall  
West Lafayette, IN 47907

Phone: (765) 494-6209

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

B. PHS Approving Official

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Phone: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

C. Effective Date of Assurance \_\_\_\_\_

D. Expiration Date of Assurance \_\_\_\_\_