

College of Veterinary Medicine Policy on Using Privately-Owned Animals for Research, Teaching and Engagement

Preamble

Discovery efforts in the Purdue University College of Veterinary Medicine (PVM) are aimed at improving the health and well-being of animals and people. The College recognizes the potential benefit of research using privately-owned animals with or without pre-existing medical conditions. In contrast to purpose-bred animals, privately-owned animals may closely represent the actual pet animal population in terms of genetic background and environmental exposure. In addition, while PVM researchers make every effort to adopt out purpose-bred animals at the end of an experiment, this is not always possible, necessitating euthanasia. This can sometimes be avoided by the use of privately-owned animals. The PVM permits the use of privately-owned animals on a case-by-case basis. This policy provides the background and procedures by which the veterinary college will consider approval of requests for the use of privately-owned animals.

Definition

Privately-owned animals are defined as those animals which remain the property of the owners who maintain responsibility for their upkeep, housing, and transportation on a long term basis. Privately-owned animals may belong either to clients or to volunteers such as students, staff, or community members.

Scope of Policy: Non-Therapeutic Procedures for Research, Teaching and/or Engagement Purposes

Privately-owned animals that are patients at the Purdue University Veterinary Teaching Hospital (VTH) and who are receiving required therapeutic treatments where any teaching activity which occurs is incidental to the treatment are not covered by this policy. However, if the same procedure or treatment is performed on a privately-owned animal when it would not otherwise have been, then that animal is regarded as being used for research, teaching or engagement; this policy is intended to cover all such non-therapeutic uses. This policy therefore covers any non-therapeutic treatment by PVM employees involving privately-owned animals, even if these animals do not actually come onto Purdue property.

Approval process

College of Veterinary Medicine faculty and staff members who want to use privately-owned animals for teaching, research, engagement or testing, need to have approval from the Veterinary Clinical Studies Committee (VCSC). The VCSC will determine if the proposed study requires PACUC approval. A study can be exempt from PACUC

approval if the following conditions are met:

1. There must be a valid, current veterinarian-client-patient relationship (VCPR).
2. Animals are undergoing standard-of-care treatment that is not influenced by their involvement in a clinical study.

PACUC approval is needed for research involving privately-owned animals if there is not a VCPR; if any substances are administered for the purpose of research, testing, or experimentation; if a procedure is performed that is unrelated to improving the animal's well-being; or if a novel or publically unavailable substance is given.

In order to apply for PACUC exemption, investigators should submit a VCSC application (appendix 1) and a client consent form (appendix 2) to the VCSC for evaluation. If the committee agrees that the proposed study meets the guidelines, no further action is required. If the committee determines that PACUC approval is required, the principal investigator will be told that a full protocol application must be submitted to PACUC and approved before the research can be initiated. The VCSC will provide written notification and comments on its decisions to the investigator to be included with the protocol application to PACUC, with a copy sent to the office of the Associate Dean for Research. Protocol applications for studies with university-owned animals do not require VCSC approval and should be submitted directly to PACUC.

Veterinary Clinical Studies Committee

The Veterinary Clinical Studies Committee (VCSC) in the PVM will evaluate the use of privately-owned animals for teaching and/or research purposes. The VCSC will determine if the proposed studies require full PACUC approval. The VCSC will focus on proper consent forms for both teaching and research, paying particular attention to the adequacy of owner education information and protection of the owner's and animal's interest in the form. The VCSC will also assess the adequacy of the study design. The application should specifically address the risk to the animal(s), the pain and/or stress that the procedure(s) may cause, and how these will be minimized.

The PVM Associate Dean for Research will appoint the membership of the VCSC and provide oversight of VCSC activities. Membership will include the Director of Clinical Trials Group (VCSC chair), the VTH Director (or designee), and at least two other PVM faculty members. When the proposed procedures utilize samples or animals submitted to the Animal Disease Diagnostic Laboratory (ADDL) for laboratory analysis or necropsy, the Director of the ADDL (or designee) will serve as a member. VCSC meetings will be scheduled as needed. At least one member of the VCSC must also be a member of the PACUC committee.

Informed Consent

The American Veterinary Medical Association (AVMA) policy on informed consent in context of practice states:

“Informed consent letter protects the public by ensuring that veterinarians provide sufficient information in a manner so that clients may reach appropriate decisions regarding the care of their animals.”

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“Veterinarians, to the best of their ability, should inform the client or authorized agent, in a manner that would be understood by a reasonable person, of the diagnostic and treatment options, risk assessment, and prognosis, and should provide the client or authorized agent with an estimate of the charges for veterinary services to be rendered. The client or authorized agent should indicate that the information is understood and consents to the recommended treatment or procedure.

“Documentation of verbal or written informed consent and the client's understanding is recommended.”

Any use of privately-owned animals for research, testing, and teaching should include an informed consent form, which will be reviewed by the VCSC and the VTH Administrative Office. In the consent form, a clear statement of who is responsible for unexpected costs, such as expenses due to unexpected illnesses, should be included. The signed consent form is a part of the animal's medical record and a permanent copy of the form must remain in the medical record for patients and in the investigator's files. A template for a client-consent form is included (Appendix 2).

Appendix 1

Veterinary Clinical Studies Committee
APPLICATION TO USE PRIVATELY-OWNED ANIMALS
IN CLINICAL RESEARCH

Principal Investigator/Project Director:

Protocol Title:

VCSC Number:

1. Justification for Animal Use and Species

- 1.1 How was it determined that alternatives (e.g., less painful/distressful animal procedures, use of phylogenetically lower species or non-animal procedures) could not be substituted (i.e., why live animals must be used)? **"Alternatives" refers to methods, models, and approaches that result in the reduction of the number of animals used, that incorporate refinements of procedures which result in the lessening of pain or distress to animals, or that provide for the replacement of animals with non-whole animal systems or the replacement of one animal species with another, particularly if the substituted species is non-mammalian or invertebrate. There must be a written narrative description of the methods and sources which were consulted to determine the availability of alternatives (reduction, refinements, replacement).**

<http://ntp.niehs.nih.gov/pubhealth/evalatm/index.html>
<http://ntp.niehs.nih.gov/pubhealth/evalatm/iccvam/index.html>

- 1.2 Briefly state the objective(s), including the rationale for using vertebrate animals. Use terminology that can be understood by someone with minimal knowledge of the specific scientific area.

- 1.3 Indicate the scientific rationale for the number of animals to be used. How did you determine the number of animals required? Your explanation should include the numbers per group, number of groups, power analysis used, number of animals needed for training, etc.

1.4 Enter the following information for all applicable protocol locations:

	Animal Housing*	Animal Procedure Area(s)*	Surgery(if applicable)
Building			
Room No.(s)			

*

1.5 Are **ONLY** pharmaceutical grade drugs or chemicals used for this protocol? YES__ NO__ N/A__
If non-pharmaceutical grade drugs are used, the study does not qualify for Veterinary Clinical Studies Committee approval and a full PACUC application should be submitted.

2 Personnel Training Qualifications and Conflict of Interest Disclosure

2.1 **Personnel Qualifications.** List the names of all individuals (including yourself as project director) who will be conducting the procedures on animals. If no qualification number has been issued, please refer to the PACUC website for information on how to complete an Animal Use Qualification Form (<http://www.purdue.edu/research/research-compliance/regulatory/care-use-of-animals/qualification-training.php>). **PERSONNEL LISTED IN THIS SECTION MUST MATCH THE PERSONNEL LISTED IN THE INVESTIGATORS/STUDY PERSONNEL TAB IN COEUS WHENEVER POSSIBLE.**

Name	Qualification Number	Specific Procedures Each Person Will Perform (e.g., surgery, injections, blood collection, euthanasia, etc.) PLEASE DO NOT LIST JOB TITLES

2.2 **Conflict of Interest and/or Financial Conflict Interest.** An individual financial conflict of interest in the context of research with animal subjects may occur when a specific PACUC protocol is used in research projects that are related to, or may impact, the business scope and activities of companies/entities where Investigators/Researchers/Personnel using that protocol may have a Significant Financial Interest (i.e., an outside income from the company that exceeds \$5,000 and/or ownership interest in such outside entity).

Do you, or any other personnel listed on this protocol, have any financial interests and/or real or potential conflicts of interest related to this study? YES ___* NO ___

*If you responded YES, please choose the situation that best describes the disclosure and management status of any and all financial interests/conflicts of interest related to this PACUC protocol:

A. ___ I, and/or study personnel, have already disclosed relevant financial interests and/or conflicts of interest to Purdue officials in the Office of the Executive Vice President for Research and Partnerships (EVPRP) and all identified conflicts of interest are managed.

B. _____ I, and/or study personnel, are in the process of disclosing financial interests and/or managing conflicts of interest related to this protocol and/or have filed relevant Reportable Outside Activity Form(s) with the Office of the Vice President for Ethics and Compliance.

Guidance to Investigators: If B was chosen, please complete your Research Related Significant Financial Interest Disclosure (at <https://webapps.ecn.purdue.edu/VPR/PDD>) and/or your relevant Reportable Outside Activity Form (<https://webapps.ecn.purdue.edu/VPEC/OAD>), at your earliest convenience (if you have not done so already).

3 Requested Procedures

3.1 Please include a clear, concise, sequential description of the experimental design involving the use of animals that is easily understood.

3.2 Describe how the procedures that are requested in this application would change the management of an animal when compared to one with a similar condition that was not included in this study.

3.3 Describe post-discharge care and monitoring. Include follow up visits to the hospital and contact by telephone.

3.4 What complications specific to the proposed intervention can reasonably be anticipated? How will potential complications be detected, managed, and resolved? List the specific criteria that will be used to decide when to perform euthanasia prior to completion of the study or to otherwise relieve the suffering (e.g., refusal to eat, loss of body weight, tumor ulceration or total burden, health problems refractory to medical intervention, etc.).
<http://www.purdue.edu/research/vpr/rschadmin/rschoversight/animals/policies.php> Under Guidelines, “Humane Endpoints for Research and Teaching Animals.”

3.5 Describe where the client consent form will be secured and how patient information will be kept confidential

4 Humane Endpoints

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- 4.1 List the specific criteria that will be used to decide when to perform euthanasia prior to completion of the study or to otherwise relieve the suffering (e.g., refusal to eat, loss of body weight, tumor ulceration or total burden, health problems refractory to medical intervention, etc.).
<http://www.purdue.edu/research/research-compliance/regulatory/care-use-of-animals/docs/HumaneEndpointsforResearchandTeachingAnimals.pdf>. Under Guidelines, “Humane Endpoints for Research, Teaching, or Testing Animals.”

IMPORTANT: Please be certain to forward this protocol application along with a Research Consent Form (RCF – Appendix 2) to Erin Lane, lane35@purdue.edu

Appendix 2

<p style="text-align: center;">PURDUE UNIVERSITY</p> <p style="text-align: center;">COLLEGE OF VETERINARY MEDICINE</p> <p style="text-align: center;">Research Consent Form</p>	<p style="text-align: center;">Patient Label</p>
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(title of study or trial)

Clinical Investigators: _____

Purpose of Study:

Eligibility: To be eligible for participation in this study, (*state eligibility requirements*)

Procedures: *State them*

Associated Risks: *Need to clearly state the likely risks associated with procedures and treatments so that the client understands the risk they are assuming.*

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Compensation: *Specify any compensation to the owner, or credits the owner may receive.* The owner will be responsible for all other appropriate medical fees.

Incentives: *if applicable*

Questions about this project may be directed to _____, at 765-XXX-XXXX_____.

I understand that my decision to allow my animal to participate in this study is entirely voluntary. I am free to withdraw my animal from this study at any time without compromising the quality of care provided to my animal. I understand that if I chose to withdraw my animal from the study, that there may or may not be the opportunity to re-enroll my animal.

I also understand that there may be other reasons why my animal could be withdrawn from the study. If my animal's health worsens, it may not be safe for him/her to remain in the study. For example, some treatments are only safe when the overall health of an animal is good and major organs are functioning normally. I have been informed that the veterinarians attending to my animal will discuss with me any concerns that could arise regarding my animal's continued participation. I also understand that if I am unable to follow the study protocol in regards to giving medications, returning my animal for evaluation, or other items in the protocol, that my animal may need to be withdrawn from the study. Furthermore, I am aware that some studies may be stopped earlier than planned. I have also been informed that the information gained from the study, regardless of how long my animal or other animals participate, will be used in an attempt to make progress to improve the outlook for other animals, as well as my animal. I recognize it is very important, and I have provided all information which is relevant and which is requested regarding my animal's medical history.

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I acknowledge that I have read and understand this consent form, and all my questions have been answered to my satisfaction. I have been assured that all personal identifying information will be kept confidential. I understand that results of this study may be shared, published, or used for educational instruction. This is important in improving veterinary care for animals. I also authorize the release of all data, including, but not limited to, medical data, photographs and videotapes.

I am aware that this study has been reviewed and approved by the Purdue Animal Care and Use Committee of Purdue University.

As a volunteer, I give my informed consent to the Purdue University Veterinary Teaching Hospital to enroll my animal in this study, according to the explanations and conditions presented in this document. I agree to hold harmless the Board of Trustees of The Trustees of Purdue University, the Purdue University Veterinary Teaching Hospital, and its officers, employees, agents and assigns from any and all liability, claims and actions that may arise from participation in this study.

I have received a copy of this Consent form.

Printed Name: Owner (or authorized agent)

Signature Owner (or authorized agent)

Date

Printed Name: Witness

Witness Signature

Date

(Original to Medical Records; PACUC Approval # _____)