Pets Used in Clinical Trials

The new PVM Clinical Studies Committee
Introduction

• The old Veterinary Clinical Research Panel has been revamped and reconstituted as the Veterinary Clinical Studies Committee

• Will review clinical research applications and approve those that fall within USDA guidelines as clinical trials

• Will continue to review PACUC protocol applications and client consent forms when privately-owned animals are used as was done previously
USDA, AVMA, and OLAW policy

• Allow use of veterinary patients in clinical research without requiring IACUC approval in certain specific instances
  • Must be client owned animals in clinical trials
  • Must have a valid veterinary-client-patient-relationship
• A pet that receives care pursuant to a valid VCPR and in accordance with a state veterinary practice act is not considered an animal used or intended to be used for research, testing, and experimentation.

• Such care includes but is not limited to routine vaccinations, surgery, and medical treatment

• Examples:
  • Comparing two methods of treatment or diagnosis
  • Any study that investigates tissues or substances after they have been collected in the course of routine veterinary care
  • Collecting a small additional amount of blood or other sample for investigation
VCPR

• VCPR ONLY exists when a veterinarian examines an animal in person, and the relationship is maintained by regular veterinary visits to monitor health
  • It CANNOT be established online, via email, or over the phone
  • It is no longer valid when it is established but no regular visits occur afterwards

• A VCPR may be maintained at the vet’s discretion between exams via phone or other consultations
PACUC approval

- Clinical studies that would still require full PACUC approval would include:
  
  Administration of a substance for the purpose of research, testing, or experimentation

  The performance of a procedure or provision of a substance unrelated to improving the animal’s well-being

  The administration of a novel or publically unavailable substance where the beneficial effects are unknown
VCSC Make-up

• Composed of veterinarians primarily involved in clinical practice, should work closely with the IACUC, and have at least one member who is a member of the IACUC to serve as a conduit between the two entities
Studies that you believe do not require full PACUC approval

• Submit copy of client consent form and **VCSC Application to use VTH Patients in a Clinical Trial** form to the clinical studies committee

• VCSC application shortened version for full protocol application (4 pages)
  • On PVM research webpage
  • Send back to Erin Lane (lane35@purdue.edu)
Clinical trials

• Application reviewed by VCSC committee
  • If they agree that it is a clinical trial as outlined by USDA, etc., researcher will be approved and will not have to do anything else
  • If they feel it requires full IACUC approval, researcher will be notified that a full application is required
Use of Privately-owned animals

• Animals that are not owned by Purdue, and are also not patients in the hospital are considered privately-owned
  • Volunteered by students or staff
• Because no valid VCPR, use of these animals must receive PACUC approval
• Submit PACUC application and client consent form to VCSC
  • How this has always been done
Use of Purdue-owned animals

• Submit application directly to PACUC