

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 - It is no longer valid when it is established but no regular visits occur afterwards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 UDSA, 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