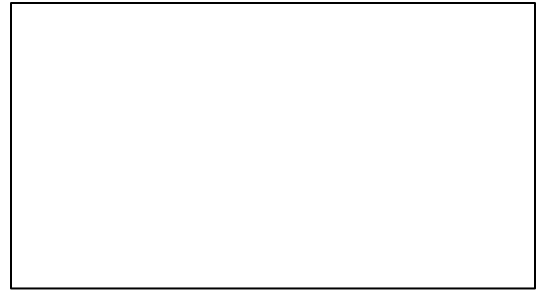




Virginia Polytechnic Institute and State University
Veterinary Teaching Hospital
Address: 245 Duck Pond Dr., Blacksburg, Virginia 24061-0443
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Clinical Research Project Client Consent Form

Study Title: Histotripsy as a novel limb salvage treatment and immunotherapy for osteosarcoma
Study Contact: Joanne Tuohy, DVM, PhD, DACVS Assistant Professor, Small Animal Surgery
Phone: 540-526-2300 | Email: jtuohy@vt.edu

One of the missions of the Virginia-Maryland College of Veterinary Medicine is to create, disseminate and apply medical knowledge through discovery, learning, and engagement. You are invited to participate in this mission by enrolling your pet in a clinical research study. Your participation is voluntary, and you may withdraw your pet from the study at any time by notifying the Principal Investigator. There is no penalty if you choose not to participate.

Study Purpose:

Histotripsy is a potential novel treatment for canine osteosarcoma that can destroy tissue without radiation or heat. In order to obtain information on the effects of histotripsy treatment on osteosarcoma, we are looking to enroll dogs with appendicular osteosarcoma that are going to undergo limb amputation as standard-of-care therapy.

Study Procedures:

Dogs with appendicular osteosarcoma will undergo histotripsy of the tumor 1 to 5 days prior to limb amputation to determine if this novel treatment might provide an effective option for dogs with this type of cancer. Tumor samples will be obtained after limb amputation and evaluated by a pathologist at Virginia Tech to provide a diagnosis. Results from this evaluation will be provided to you. This is routine procedure for evaluating suspected osteosarcoma tumors. We will be collecting blood samples from your pet 2 weeks after amputation, at 1 month after completion of chemotherapy, then at 6, 9, 12 months after amputation.

Risks and Benefits:

We have utilized histotripsy to treat excised osteosarcoma from dogs with no side effects, hence we do not anticipate significant risks associated with using histotripsy to treat osteosarcoma. The standard recommended treatment of your dog will not be affected by participation in this study. Histopathological diagnosis of your dog's tumor will be provided to you by Virginia Tech Laboratory Services at no cost. Studies like this represent the future of medicine and are needed to improve the diagnosis and treatment of disease.

Study Costs and Compensation:

There are no costs to you for your dog to participate in the study. Histopathological diagnosis of your dog's tumor will be provided to you at no cost. Up to \$2,000 of the cost of surgical limb amputation will be covered by the study. A financial credit of \$200 will be applied to all owners who complete the scheduled rechecks for 1 year.

Confidentiality:

The data collected in the course of this study are confidential. In any publication or presentation of the study data, we will not include information that would make it possible to identify a research participant. Research records will be kept in a secure location; only researchers will have access to the records. Data resulting from the study will become the property of Virginia Tech.

Statement of Consent:

In giving my consent by signing this form, I acknowledge that I have been informed of the purpose and nature of this study and its associated procedures, as well as any possible side effects.

I have read and understood the above information. I have been given the opportunity to ask questions and receive answers, and I consent to participate in the study. I further certify that I am the owner (or duly authorized agent of the owner) of _____.

(Animal's name)

Owner or Agent Signature: _____ Date: _____

Owner or Agent Printed Name: _____

Attending Clinician Signature: _____ Date: _____

Attending Clinician Printed Name: _____

Please don't hesitate to contact us if you have any questions or concerns about this study.

If you have any questions or concerns regarding the study and would like to talk to someone other than the researchers, please contact:

Hospital Director,
Animal Cancer Care and Research Center
Virginia-Maryland College of Veterinary Medicine
Address: 4 Riverside Circle, Roanoke, VA 24016
Phone: 540-526-2300

You will be given a copy of this form to keep for your records.