

Virginia Polytechnic Institute and State University Veterinary Teaching Hospital Address: 245 Duck Pond Dr., Blacksburg, Virginia 24061-0443 Phone: 540-231-4621 | Fax: 540-231-9354



Clinical Research Project Client Consent Form

Study Title: Evaluation of incidence of incomplete margins after incisional scar revision Study Contact: Dr. Joanne Tuohy, Assistant Professor, Surgical Oncology. Phone: 540-231-4621, email: jltuohy@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 animal in a clinical research study. Your participation is voluntary, and you may withdraw your animal from the study at any time by notifying the Principal Investigator. There is no penalty if you choose not to participate.

Study Purpose:

Typically, when a cancerous mass is surgically removed, the surgeon will send the tissue for laboratory analysis to see if the cancer was completely removed. Surgeons attempt to obtain "clean margins," which provides an indication that they didn't leave cancer cells behind that could grow back later. If laboratory analysis shows incomplete tumor removal, surgical revision of the incision is a treatment option, with the goal of achieving complete removal of the cancer cells.

There is currently no standardization of histologic evaluation techniques in veterinary medicine that is strongly supported by research. This study will use a comprehensive histologic evaluation technique to thoroughly assess the resected tissue and provide detailed information about whether any microscopic tumor cells were observed within the resected tissue. We aim to use these data to establish standardized histologic evaluations to improve veterinary cancer management. This information can help inform follow-up treatment or monitoring recommendations.

Study Procedures:

Surgically resected tissue from revised incisions for previously resected soft tissue sarcomas, mast cell tumors, and other dermal / subcutaneous tumors will be submitted to the ViTALS laboratory for a comprehensive histopathologic evaluation. The results of the histopathologic evaluation will be conveyed to the owner by the primary clinician, as part of standard-of-care. Owners who participate in the study will be contacted by members of the Oncology service at 3-month intervals for 24 months to ask whether there is tumor regrowth in the surgery site.

Risks and Benefits:

There are no risks associated with participation in the study as the tumor specimen is evaluated following removal. The tumor will undergo thorough assessment of margins which will help us determine if there is residual tumor. In addition, participation will help us better understand if this technique could be of benefit in cancer treatment in the future.

Study Costs and Compensation:

There are no costs to you for your pet to participate in the study. The costs of the comprehensive margin evaluation are being covered by the study. However, the owner will be responsible for all other non-study related costs associated with the assessment, diagnosis, and/or treatment of the participating animal.

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.

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, Veterinary Teaching Hospital Virginia-Maryland College of Veterinary Medicine Address: 245 Duck Pond Dr., Blacksburg, Virginia 24061-0443 Phone: 540-231-4621

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