



Clinical Research Project Client Consent Form

Study Title: Detection of circulating tumor DNA and microRNA in dogs and cats with lymphoma

Principal Investigator: Priscila B. S. Serpa

Address: 205 Duck Pond Dr., Blacksburg, VA 24061-0443

Phone: 540-231-0774, Email: pserpa@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:

A few techniques are available to diagnose lymphoma, the most common blood-related cancer in dogs and cats. However, these techniques may fail to provide a definitive diagnosis, or the collection of samples may not be possible because of tumor location, financial constraints, or the patient's clinical condition.

Small fragments of our genes (also called DNA) and other regulatory molecules (also called microRNA) usually are present in the blood in minimal amounts. Therefore, when an animal has cancer, both the DNA and microRNA of the cancerous cells will also circulate in the blood.

This study aims to perform whole-genome and microRNA sequencing in the tissues of dogs and cats diagnosed with lymphoma. Then, we will investigate whether these same DNA mutations and microRNA signatures will also be identified in the patient's blood. In the future, we plan to follow patients along their treatment and post-treatment phases to evaluate if these biomarkers will be associated with disease progression or remission during chemotherapy and whether they will predict the patient's outcome.

We hope that our study will improve the health care and wellbeing of small animals with cancer.

Study Design/Procedures:

For this study, we are seeking dogs and cats diagnosed with B-cell and T-cell lymphoma and healthy animals to serve as controls. For each patient, we will perform whole-genome and RNA sequencing of cancerous tissues. Then, we will evaluate whether the cancer's genetic material is also present in the blood plasma.

Aiming to cause minimal distress to enrolled animals, we intend to minimize the collection of extra samples as much as possible. Thus, we will use leftover samples collected for diagnostic purposes (i.e., smears obtained for initial cytologic evaluation and blood submitted for complete blood count) during regular clinical workup, not material collected for this study's sole purpose. The exception is the collection of additional biopsies (either by fine needle aspiration, core biopsies, or surgical procedures) to analyze the genetic material and confirm each lymphoma, additional blood samples in case the remaining plasma volume is less than 2 mL after blood work is completed, and in the case of the healthy controls.

Patients can be enrolled regardless of the decision to pursue treatment.

Risks and Benefits:

Today, dogs and cats diagnosed with lymphoma have a survival rate varying from a few days to a few years, depending on tumor type and location, and their overall health status. The diagnosis and prognosis may represent a clinical and pathological challenge. In addition, the diagnostic procedures can be invasive and costly.

For most patients, this study offers no additional risk for the animals enrolled. If additional material is collected, the risk is minimal given the minimally-invasive nature of fine-needle aspirates and blood sample collection that would be performed otherwise for diagnostic workup.

Other animals may benefit if our research leads to more precise and accurate diagnostic tools, improving clinical decision-making for dogs and cats with lymphoma.

Study Costs and Compensation:

The study may cover the costs of genetic and cellular analysis related to the cancer diagnosis.

The cost of any other tests or procedures considered standard of care in treating the animals' illness, including clinically necessary bloodwork, surgery, aftercare, and follow-up treatment, is not covered by the study and is the owner's responsibility.

Confidentiality:

The data collected in the course of this study is 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 access the records. Sponsors of this study will not have access to study data.

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: _____

Principal Investigator Signature: _____ Date: _____

Principal Investigator Printed Name: Priscila Serpa

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

The research and procedures have been reviewed and approved by the Virginia Tech Institutional Animal Care and Use Committee and the Virginia-Maryland College of Veterinary Medicine Clinical Research Review Committee.

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

Dr. William S. Swecker, Jr.
Hospital Director
Veterinary Teaching Hospital

Address: 245 Duck Pond Dr.,
Blacksburg, Virginia 24061-0443
Phone: 540.231.4621

OR

Dr. John H. Rossmeisl, Jr.
Hospital Director
Animal Cancer Care and Research Center
4 Riverside Circle
Roanoke, VA 24016
United States
Phone: 540.526.2300

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