XI. Consent Forms and Questionnaires

Consent form

Clinical Research Project
Client Consent Form

Study Title: Immunosignature Differentiation of Feline Alimentary Lymphoma and Inflammatory Bowel Disease
Principal Investigator: Kurt Zimmerman
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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 entirely 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:
Cats are plagued by a variety chronic gastrointestinal (GI) disorders, such as IBD and lymphoma. Unfortunately many of these disorders have very similar symptoms, like loss of appetite, weight loss, vomiting, and diarrhea. A trial-and-error approach with dietary changes, antibiotics, or anti-inflammatory medications is helpful in relieving symptoms in some patients. However, a large number of cats fail to respond to this palliative approach. In these non-responders, endoscopic stomach and intestinal biopsies are often necessary to determine the underlying cause and optimize treatment. This more invasive approach is associated with greater cost both in risk of medical complications for the cat and financially for the owner. Since treatment and outcome is different for IBD and lymphoma, it would be helpful to have a noninvasive test that could identify these two diseases and avoid the associated costs of a biopsy procedure. This study seeks to develop such a test. The unique pattern of blood proteins present in these patients will be determined using protein microarray. We hope the unique pattern for the two disorders can then be used to provide a safer, faster, and more reliable means for diagnosing the causes of GI disease in cats.

Study Design/Procedures:
Eligibility: Patients must be over 6 months of age with chronic upper GI disease of 3 or more weeks. Prior screening for liver and renal disease (CBC and chemistry) required. Patients must have upper GI biopsies (endoscopic or full-thickness) indicating a diagnosis of lymphoma or IBD to be eligible for this study. Research blood and fecal samples will be collected at time of GI biopsy and held while awaiting biopsy results to determine study eligibility. The protein chip analysis will only be run for those animals with a lymphoma or IBD diagnosis. The study will be conducted under an approved animal care (IACUC) protocol.
Immunosignature Differentiation of Lymphoma and Inflammatory Bowel Disease; Zimmerman

Risks and Benefits:
There are no significant risks associated with participation in this study. Only cats with chronic GI disease already undergoing biopsy as part of their planned diagnostic work up will be eligible for participation. A non-invasive blood sample is the only additional study associated testing required.

Study Costs and Compensation:
There is $280 compensation for cases with a biopsy diagnosis of IBD or lymphoma paid to client or veterinarian for cases external to VMCVM. Within the VMCVM, account credit or client payment are options.

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 file; only researchers will have access to the records.

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.

Statement of Consent:
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 __________(pets name).

Owner or Agent Signature: ______________________________________ Date: ________

Attending Clinician Signature: ______________________________________ Date: ________

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 Veterinary Teaching Hospital Board.

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

Dr. Terry Swecker
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.