Clinical Research Project
Client Consent Form

Study Title: Lactoferrin as a Biomarker for the Diagnosis and Monitoring of Inflammatory Bowel Disease and Intestinal Lymphoma in Dogs: Kurt Zimmerman 540.231.3692; KLZ@VT.EDU

One of the missions of the Virginia-Maryland College of Veterinary Medicine (VMCVM) 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:
Gastrointestinal (GI) related disorders account for nearly 30% of the cases in dogs presenting to primary care veterinary practices. Canine idiopathic inflammatory bowel disease (IBD) and alimentary lymphoma (ALA) account for many of these cases. Exact figures for the prevalence of canine IBD are difficult to come by. However, in a retrospective review of 319 dogs seen for chronic GI disease at the VA-MD College of Veterinary Medicine, 60% were diagnosed with IBD. In dogs, lymphoma develops at the rate of 13-30 cases per 100,000 individuals. ALA represents 8-10% of these cases. Clinical signs such as anorexia, weight loss, vomiting, and diarrhea can be very similar with both of these conditions. Unfortunately, treatment and long-term prognosis varies between IBD and ALA. Upper GI endoscopic biopsy is the most common test used to distinguish between these two conditions. However, this method has limitations: in some cases it is histologically difficult to distinguishing between ALA and IBD, the endoscopic biopsy sample size and quality may be inadequate for a diagnosis, and GI lymphoma may be located at site not biopsied. Some of these limitations can be overcome by more invasive surgery, but at greater financial cost and patient risk. What is needed is a reliable, easily, non-invasive method for distinguishing between ALA and IBD. This proposal examines if fecal and serum lactoferrin can distinguish between normal, ALA, and IBD in dogs.

Study Design/Procedures:
Eligibility: Patients must over 10 lbs. and 6 months of age with chronic upper or mixed bowel disease of more than 3 weeks. Prior screening for liver and renal disease by blood work (CBC and chemistry) are required. Patients must have upper GI biopsies (endoscopic or full-thickness) indicating a diagnosis of lymphoma or IBD to be eligible for this study. Note: as of 11/1/17 we only need cases of confirmed GI Lymphoma. IBD cases are no longer eligible.

Procedures: Research blood and fecal samples will be collected at time of GI biopsy and held while awaiting biopsy results to determine study eligibility. For those dogs with a diagnosis of lymphoma, additional fecal samples must be submitted at 30 and 60 days following biopsy.

Risks and Benefits:
There are no significant risks associated with participation in this study. Your participation and associated findings from this study will remain anonymous.
Study Costs and Compensation:
There is $635 compensation paid after all samples and paperwork have been submitted. Payment can be made 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 __________________ (pet’s 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)

2/2/2017