

# Client Consent Form

## Canine Gastrointestinal Permeability Assessment Using Commercially Available Lactulose Solution: A Pilot Study

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**I. Study Purpose** Healthy gastrointestinal barrier function is important in preventing access of microbes and other noxious substances from entering the bloodstream, while also allowing nutrient absorption and prevention of nutrient loss. Increased gastrointestinal permeability is a feature of many disease states, including protein-losing enteropathy, to which certain breeds including Soft Coated Wheaten Terriers (SCWTs) are predisposed. At present, there is no in-clinic test available to assess gastrointestinal barrier function and permeability. Our primary goal with this study is to evaluate whether a readily available sugar solution can be used for this purpose, and to provide blood samples to aid in the development of an in-clinic diagnostic device.

**1. Study design** The study will compare blood levels of orally administered sugars between three groups: healthy SCWTs, SCWTs with protein-losing enteropathy, and a control group of healthy age-matched control dogs. Screening tests performed include a physical examination, complete blood count (CBC), and chemistry panel. Participating owners will also be asked to provide a fecal sample from their dog at the time of screening for fecal occult blood testing.

**II. Study Eligibility** Your dog is eligible to participate in this study if he /she is between 3 and 8 years of age, weighs between 10 and 40 kg, **and** is (a) a healthy SCWT; (b) a SCWT with a diagnosis of protein-losing enteropathy; or (c) a healthy dog of any other breed meeting the age and weight requirements.

**1. Commitment** By enrolling your dog to participate in this study, you agree:

- i) To present your dog to the veterinarian for initial screening tests involving taking a blood sample for CBC, serum chemistry, and blood amino acid analysis.
- ii) To present your dog for the gastrointestinal assessment visit. Your dog must be fasted for 16 hours prior to administration of the Alicam® video capsule endoscope, which will be performed at this appointment. Between 2 and 4 hours later, your dog will be offered a sugar solution to drink. Following this, a maximum of 5 blood samples will be drawn over a period of no more than 4 hours in order to assess sugar absorption levels. Your dog will be fasted for a total of 8 hours following Alicam® capsule administration.
- iii) To monitor your dog's feces for the next week and return the video capsule endoscope in the sample kit provided. The video capsule endoscope generally passes in the feces in approximately 1-2 days but can take up to a week to pass.

**2. Exclusion** To be enrolled, your dog may not have a history of chronic GI disease > 3 weeks (including vomiting, diarrhea, blood in stool, or decrease in appetite) or a history or biochemical evidence of liver, kidney, or GI diseases, and must weigh at least 10 kg (22 lbs) and less than 40 kg (88 lb). Gastric acid suppressants (e.g. omeprazole (Prilosec)), famotidine (Pepcid), non-steroidal inflammatory drugs are prohibited 21 days prior and during the monitoring period.

**3. Voluntary Participation** The participation in this study is voluntary and withdrawal from the study is permitted at any time requested without repercussion.

**III. Compensation** This study will pay for:

1. Screening health lab work: complete blood count (CBC), chemistry panel, fecal occult blood, amino acid

- analysis
- 2. Alicam® video capsule endoscopy
- 3. You will receive \$150 gift card at the completion of your dog's appointment for oral sugar solution administration and blood sampling and an additional \$50 gift card when you return the video capsule endoscope.

**IV. Potential Risks**

This study has been reviewed by the North Carolina State University Institutional Animal Care and Use Committee (NCSU - IACUC).

1. Blood will be collected via a vein in the neck or leg via needle stick or by placement of a temporary catheter to facilitate collection of multiple samples. Blood sampling is usually well tolerated by dogs and causes only momentary discomfort and stress related to restraint. Complications from blood draw are uncommon, but may include bruising or collapse (vagal episode). Rarely, blood draw from the neck may result in temporary nerve damage (Horner's Syndrome).

2. A video capsule endoscope will be orally administered to your dog following a 16 hour fast. We will ask you to fast your dog for an additional 8 hours. The capsules are designed to acquire images of your dog's GI tract and pass in the feces causing no harm to the dog. The capsule may be retained in your dog's stomach for longer than 24 hours but is not expected to cause your dog complications even with prolonged retention.

**Confidentiality** Information from this study may be used in a published media and/or used for educational purposes but patient and owner names will remain confidential.

**Contact Information** Dr. Katie Tolbert, [mktolbe2@ncsu.edu](mailto:mktolbe2@ncsu.edu)

**AUTHORIZATION:**

I, (\_\_\_\_\_), the owner of (\_\_\_\_\_) acknowledge that I have read the above consent form and authorize study participation. The study has been explained to me and I have been given the opportunity to ask questions. I understand and accept the risks associated with the study. To my knowledge my dog is eligible for participation.

\_\_\_\_\_  
*Owner Signature* *Date*

\_\_\_\_\_  
*Investigator Signature* *Date*

PATIENT HOSPITAL NUMBER \_\_\_\_\_