



Address: 245 Duck Pond Drive, Blacksburg, VA 24061  
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## Clinical Research Project Client Consent Form

### **Study Title: Diagnostic utility of a feline optimized TSH assay for the diagnosis of feline hyperthyroidism**

**Principal Investigator:** Dr. Stefanie DeMonaco, DVM, MS, DACVIM; assistant professor at VMCVM

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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 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:**

Feline hyperthyroidism is the most common endocrine disease in older cats. Diagnosis is made by measuring serum thyroid hormone levels. When a diagnosis cannot be made by thyroid hormone levels alone, another hormone (TSH) is measured. Currently, feline TSH is measured using a canine TSH (cTSH) assay. The cTSH assay unfortunately cannot distinguish between cats with normal TSH levels and those with abnormally low TSH levels. This limits cTSH use in diagnosing hyperthyroidism in cats. A TSH assay that can differentiate between low and normal values has the ability to enhance the diagnosis of hyperthyroidism. A feline optimized TSH (fTSH) assay has become recently available, and preliminary data shows that it can differentiate between cats with normal TSH and those with low TSH.

The objective of our study is to determine the accuracy of fTSH for diagnosis of hyperthyroidism in cats. We also will compare fTSH vs cTSH concentrations in hyperthyroid cats, cats with normal thyroid function with illness, and healthy cats.

#### **Study Design/Procedures:**

Three groups of cats will be enrolled in this study: hyperthyroid cats, healthy cats, and cats with normal thyroid function who have underlying illnesses.

Inclusion criteria entails unremarkable blood work (CBC and Chemistry, except for abnormalities typical of hyperthyroid cats in the hyperthyroid cat group). All cats will have a blood sample collected, and T4, cTSH and fTSH will be measured.

All hyperthyroid cats will have a thyroid scan called scintigraphy performed as a part of radioiodine treatment and this scan will be used to confirm hyperthyroidism. Healthy cats and cats with non-thyroidal illness will not have thyroid scan performed.

Healthy cats and cats with non-thyroidal illness will return to the Veterinary Teaching Hospital to have a blood draw to measure T4 and TSH again at approximately 3 months after enrollment to confirm that they continue to have normal thyroid function.

Exclusion criteria includes cats with a history of recent anesthesia (within 48 hrs) or cats receiving medications known to alter thyroid hormone concentrations in dogs and people, like steroids or NSAIDs.

**Risks and Benefits:**

Risks of enrolling in this study are very low. Moreover, the procedures described below will in most cases already be performed on the patient as part of routine clinical care. This means that participating in this study will not add any additional risk for those cats.

- Blood draw: Risks are minimal and usually benign. Hematomas at site of sampling is the main complication.

Study-related bloodwork and exams will be provided at no cost to participating cats. The results of this study will also contribute to the progress of veterinary medicine science.

**Study Costs and Compensation:**

All costs associated with T4, cTSH, and fTSH testing are paid for by the research project.

**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 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

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(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.**

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:

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