

**Colorado State University Veterinary Medical Center  
Client Consent Form Guidelines-2009**

- 1 All studies using client-owned or student-owned animals in the Colorado State University Veterinary Medical Center (CSU-VMC) must have a client consent form approved by Dr. Hendrickson when the Institutional Animal Care and Use Form A-100 is submitted for consideration (<http://web.research.colostate.edu/ricro/acuc/documents/A-100.doc>).
- 2 The following are some of the key points that should be included in the Client Consent Form when submitted to Dr. Hendrickson for approval.
  - A Study description in layman's terms
  - B Description of samples being collected
  - C Description of any risk for the patient
  - D Description of potential benefits for the patient or owner
  - E Description of liability
  - F Description of how problems will be resolved if occur, including the financial responsibilities of the owner or investigator
  - G Dates and signatures
- 3 Please send your Client Consent form to Dr. Hendrickson ([dean.hendrickson@Colostate.edu](mailto:dean.hendrickson@Colostate.edu)) by email attachment as a Word Document by the first Tuesday of the month you are planning your IACUC submission (The IACUC deadline is the second Tuesday of the month). If you do not get your client consent form to Dr. Hendrickson by the first Tuesday of the month, there is no guarantee that it will be reviewed in time for IACUC submission.
- 4 The following Appendices are examples of previously approved Client Consent Forms that you can use as templates.
- 5 Please contact Dr. Laura Martin at IACUC ([laura.martin@Research.ColoState.edu](mailto:laura.martin@Research.ColoState.edu)) or Dr. Hendrickson if you have questions.

**APPENDIX ONE-APPROVED CLIENT CONSENT FORM**

**PET OWNER CONSENT  
CSU Fever Study**

Study Number \_\_\_\_\_ Veterinarian \_\_\_\_\_

Owner's Name \_\_\_\_\_ Cat's Name \_\_\_\_\_

**Overview of the study**

Your cat has a fever that may be caused by a blood infection that can be associated with fleas or ticks. Your veterinarian is prescribing one of two antibiotics (doxycycline or orbifloxacin) that have previously been shown to be effective for the treatment of the infections. The primary objective of the study is to determine which antibiotic protocol is most likely to totally eliminate the infection, lessening the likelihood of recurrence of the fever. Thus, we are requesting that you return for 2 recheck appointments to make sure the infection is cured.

**Is there any danger to my cat?**

The volume of blood required for the tests is the same quantity used for other routine tests and so there is no additional risk to your cat. Both antibiotics are commonly used in cats and generally are not associated with significant side-effects when used at the doses we will be studying. Use of any antibiotic can result in loss of appetite or diarrhea. Antibiotic pills can get stuck in the esophagus of cats and cause irritation and rarely scarring and so it is very important to give water after pilling or to coat the pills in butter before pilling. Your veterinarian will teach you how to do this during the office call. Rarely, one of the antibiotics (orbifloxacin) has been associated with blindness but this is extremely unlikely with the doses used in this study.

**What are the benefits to my cat?**

Your veterinarian believes that your cat has an infection and one of these two antibiotics was indicated, independent of this study. The study is providing a large number of tests to evaluate for the likely causes. By joining the study, you will be saving approximately \$500 in blood test charges and antibiotic costs.

**What am I agreeing to do by joining this study?**

As the owner or agent of the owner, your signature below indicates the following:

- A. Your approval for the inclusion of the named cat in this clinical trial.
- B. That the nature and purpose of this treatment, as well as the risks involved, have been explained to you verbally.



## **APPENDIX TWO-APPROVED CLIENT CONSENT FORM**

### **STEREOTACTIC RADIATION THERAPY FOR CATS WITH PITUITARY TUMORS**

#### Client Information Sheet

We greatly appreciate your interest in our clinical investigation employing stereotactic radiation therapy as a new treatment option for feline patients diagnosed with pituitary tumors. Your clinician will discuss with you disease characteristics as well as treatment options available to you. This handout will provide you with information concerning the purpose of this study as well as client and patient responsibilities.

Acromegaly (excessive growth hormone) and pituitary-dependent hyperadrenocorticism (excessive secretion of hormones from the adrenal glands) are endocrine diseases in the cat that result from a tumor located in the pituitary gland. Both conditions, although rare, cause significant clinical disease in our older cat population. Medical management and treatment is frequently frustrating and often associated with considerable complications. Surgical options are frequently limited and also present considerable risk. Stereotactic radiation therapy is a novel treatment option for these patients, which allows the “removal” of the tumor without surgery. Compared with full course radiation therapy, stereotactic radiation therapy requires far fewer treatments and much less anesthesia. This is particularly crucial to these patients as they typically present in a fragile state of health.

The purpose of this study is to determine the best protocol to eliminate the pituitary tumor, to document the effects of stereotactic radiation therapy on pituitary function, and to monitor the resolution of endocrine disease after stereotactic radiation therapy. We will perform several endocrine tests upon entry to the study and then again at regular intervals after the stereotactic radiation therapy. Long-term follow-up appointments will be required, as patients will be maintained on endocrine therapy as deemed necessary by monitoring hormone levels.

#### **Patients-Who is eligible?**

Feline patients diagnosed with a pituitary tumor by CT or MRI, and demonstrating clinical signs of endocrine disease associated with the tumor, are eligible for this study. All patients must undergo a thorough diagnostic evaluation, which includes a complete blood count, serum chemistry profile, urinalysis, urine culture, abdominal ultrasound and thoracic radiographs. Patients demonstrating signs of heart disease will also undergo a cardiac evaluation which will include an echocardiogram. These tests will ensure that all patients can safely undergo anesthesia and stereotactic radiation therapy. Additional baseline endocrine testing will also be performed.

#### **The Study- What is involved?**

After initial diagnostic evaluation, patients will undergo anesthesia for a CT scan, to plan the radiation therapy. Stereotactic radiation therapy will involve either one or two periods of anesthesia, depending on tumor size and effectiveness of the treatment. Each anesthetic procedure will last approximately one hour, and following treatment, the patients will be placed in supervised recovery cages in the radiation therapy suite. During the radiation therapy, the radiation beam will be administered from 6-9 angles, ensuring that important normal tissues are avoided. Radiation administration will take 15-20 minutes and the patient and anesthesia monitors will be observed through closed circuit cameras.

Endocrine testing will be performed on weeks 2, 6, 12, 26 and 52 weeks following stereotactic radiation therapy. A CT scan will be performed one month following therapy. Patients will be evaluated by their referring veterinarian or the principal investigator weekly for the first month and then monthly for one year. This evaluation will include a thorough patient history and physical examination, with blood tests performed as needed to monitor any endocrine problems.

**The Risks-What should I expect?**

The study will require that your pet be anesthetized for the radiation therapy as well as the CT scans. Although anesthesia is very safe, there is always some associated risk. Your pet will be closely monitored by the attending clinician at all times during the course of the study. Feline patients with pituitary tumors present medical challenges due to the management of a variety of hormonal disturbances, and these conditions will be monitored and managed throughout the study. For example, insulin will be prescribed and the dose adjusted as the patient responds to the radiation therapy. Radiosurgical ablation of the pituitary tumor may result in hypothyroidism, hypocortisolemia, and temporary diabetes insipidus in the cats. All cats will receive long term therapy with thyroid hormone, steroid therapy and temporary therapy for diabetes insipidus.

**Financial Incentive-What will CSU do?**

The study will pay for endocrine testing that is required by the study (before radiation therapy, and at 2, 6, 12, 26, and 52 weeks after therapy) and the follow-up CT scan. Pet owners will also receive a \$1,000 credit toward their invoices at CSU for participation in the study. Expenses in excess of this \$1,000 credit are the responsibility of the pet owner. In addition, the study will not cover any emergencies, or pay for the management of unrelated medical conditions. Written estimates will be provided before any procedures are performed.

**Owner commitment-What do I do?**

The owner is responsible for making appointments with the oncology receptionist and keeping those appointments according to the study protocol. Study procedures and treatment will be performed over the course of two days. Owners will be responsible for scheduling follow-up evaluations through their primary care veterinarian or the principal investigator, weekly for the first month, then monthly for one year. The owners are responsible for administering medication that is prescribed by the primary clinician. A CT scan will be performed one month following the stereotactic radiation therapy, and will be paid for by the study.

**Any questions?**

Please do not hesitate to ask for additional information from your clinician or a member of our protocol team if you do not understand something about your pet's treatment or care.

Dr. Christie Anderson-Clinical Trial Intern: (970) 297-0305

Dr. Susan M. LaRue, DVM Ph.D: (970)297-0334

Dr. Katharine Lunn, BVMS, MS, PhD, MRCVS, DACVIM: (970) 297-4010

**CLIENT CONSENT FORM**  
**Stereotactic Radiation Therapy for Cats with Pituitary Tumors**

I, the undersigned, am the owner or authorized agent for the owner, and agree to enter my cat into the clinical trial investigating the use of stereotactic radiation therapy to ablate pituitary tumors in cats. The study design, objectives and procedures of the study have been clearly explained to me. I understand the risks of the procedures being conducted as part of this study.

Alternative treatment options have been discussed with me and I understand the relative benefits of those treatments.

Clients participating in this study will be given special financial incentives. Specifically, endocrine testing, a CT scan and \$1000 toward treatment costs will be covered by the study.

I give my permission to publish data generated from this study for the benefit of the scientific community. I understand that my pet will not be identified individually.

Following the discussion of the study protocol and after reading the above material, I voluntarily consent to enter my pet into this clinical trial. I agree to participate in this clinical study and will follow the instructions of the veterinarians as it applies to the protocol.

\_\_\_\_\_  
Signature of owner/agent

Date: \_\_\_\_\_

\_\_\_\_\_  
Witness

Date: \_\_\_\_\_