VIRGINIA-MARYLAND
COLLEGE OF VETERINARY MEDICINE
ANIMAL CANCER CARE
AND RESEARCH CENTER
VIRGINIA TECH

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# Clinical Research Project
# Client Consent Form

**Study Title:** High Intensity Focused Ultrasound ablation as single modality treatment for canine subcutaneous tumors.

**Principal Investigator:** Nick Dervisis, DVM, PhD, DACVIM (Oncology)
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One of the missions of the Animal Cancer Care & Research Center (ACCRC) at 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:**

Soft Tissue Sarcomas are a common form of cancer in dogs. They can invade tissues that are vital to normal function and surgical removal can be impossible without amputation or radiation therapy. In some cases, a tumor may be surgically resectable, but it could still recur at the surgical site or in a distant site like lymph node or lung.

One attractive option for such cases is tumor ablation. We propose using high-intensity focused ultrasound (HIFU) to kill tumor cells and release antigens from tumors, potentially stimulating the patient's anti-tumor immune response. We hope to find out if HIFU application will result in both tumor cell death and immunologic activation in dogs. To determine if the treatment is effective, we are recruiting dogs with **Soft Tissue Sarcomas** who will undergo HIFU treatment as the sole treatment modality.

The application of this experimental therapy has the potential to directly enhance the quality of life of dogs diagnosed with the disease and partially defray the cost of treatment. At the same time, the results of our efforts may lead to improved treatment options for human cancer patients.

**Study Design/Procedures:**

If you agree to participate in this study we will perform the following procedures:

**Pretreatment evaluation**

Before beginning treatment your dog will undergo the following:

1. **Complete physical exam**
2. **Lab work:** We will obtain blood samples from your pet, if no recent bloodwork is not available, for a complete blood count and chemistry profile. Six mls (about 1 teaspoon) of blood will be collected from a vein in your pet's neck, which is the easiest access point. We will also collect 5 mls of urine via free catch. These are the standard methods for obtaining blood at the ACCRC. This will be performed before your pet's treatment.
3. **Fine needle aspirate of the tumor:** A tumor fine needle aspirate and cytology will be obtained for diagnostic purposes. If your veterinarian has already performed this test, you may not need to repeat it at the ACCRC.
4. **Chest radiographs:** Chest radiographs will be performed to exclude any signs of cancer spread to lungs. This is the minimum standard for checking for cancer spread in dogs. If you have radiographs from your veterinarian, they may be acceptable and you may not need to repeat them at the ACCRC.

**Treatment**

The treatment will require a CT scan and two (2) anesthetic procedures. If your dog meets the study criteria (a neoplastic tumor under the skin that is amenable to HIFU treatment and expected survival over 4 weeks without treatment), your dog will be scheduled for a CT scan and a surgical biopsy under general anesthesia. This includes removing a small sample of the tumor to determine its specific type. Subsequently, your dog will be scheduled for the HIFU treatment.

HIFU treatment will be performed on a day that will be scheduled (Day 0). HIFU will be applied to the tumor under general anesthesia. During the procedure, blood samples (3 samples of 3mls each) will be taken for research purposes. Your dog will be recovered from the procedure and will be released to your care (outpatient procedure).

For the HIFU treatment, hair will be clipped over the tumor as is standard for any ultrasound in dogs. The actual treatment will be tailored to the individual tumor of each dog, and be delivered under general anesthesia in a series of bursts of sound will be focused on the tumor to raise its temperature (approximately 56 degrees Celsius or 132 degrees Fahrenheit) with the goal of killing the cells deep in the tumor through unbroken skin surface. The HIFU treatment is expected to take 30 minutes to an hour.

**Follow-up**
Your pet will need to return to the ACCRC at **1 week** (7 days) after the HIFU treatment for a recheck exam. At this visit, your pet will have a physical exam, a blood sample taken for research purposes (3mls) and additional diagnostics if indicated. We ask that you keep the clinical oncology service and investigators informed on the status of your pet's health.

Your pet will need to return to the ACCRC **every 3 months** for physical exam, chest radiographs, and additional diagnostics if indicated. These recheck visits will be repeated for a minimum of 18 months since the HIFU treatment, or until the tumor grows back, whichever comes first.

**Risks and Benefits:**
We are trying to develop a new, non-invasive, more effective and safe therapy against cancer. In addition, the study will cover the cost of the CT, biopsy, the cost of the HIFU treatment, and the cost of the planned recheck visits.

Some of the procedures performed in this study are routine clinical procedures. **The HIFU therapy is experimental and not part of the standard treatment.** Based on our pilot study of HIFU in dogs with cancer, the sort term side effects included small areas of skin burn at the treatment site. These skin burns were not painful and did not require treatment. Long term Side effects are currently unknown and may potentially include tumor inflammation, tumor-site discomfort, systemic inflammation, and risk for infection at the treated site.

Although unexpected, there could be problems with the diagnostic procedures (lab-work, staging, biopsy). These problems can be due to inflammation or infection and may result in bruising at the collection site. Additionally, all animals going under general anesthesia are in risk of adverse effects that may result even in death. We will try to minimize all these risks by taking extensive steps to prevent contamination of the biopsy site, and monitor continuously the vital functions of your pet when under general anesthesia and during the recovery period.

**Study Costs and Compensation:**
Once informed consent is obtained, the study will cover the expenses for the CT, tumor biopsy and histopathology, the HIFU treatment, and the cost of the scheduled recheck visits.

A financial incentive of $1,000 will be available to you as a credit in your account with ACCRC, after the completion of the study protocol. This will be available when either 18 months passed from the HIFU treatment, or the tumor grew back at the treated site. This incentive will only be available if you adhere to all the required visits.

You are responsible for any other clinical fees associated with medical complications of the HIFU therapy or other medical problems.

**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 locked 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 _____ .

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.

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

**ACCRC Interim Director:**
Dr Joanne Tuohy
540-526-2300
jltuohy@vt.edu

**Virginia Tech's Institutional Animal Care and Use Committee (IACUC) Post Approval Monitor:**
540-231-7678
iacucpam@vt.edu

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