PURDUE UNIVERSITY COLLEGE OF VETERINARY MEDICINE **Research Consent Form**	**Patient Label**

Ablation-Induced Immune Remodeling in Canine Lymphoma.

Clinical Investigators: Nick Dervisis, DVM, PhD, DACVIM (Oncology)

Purpose of Study:
Multicentric lymphoma (LSA) is a common cancer affecting the blood and lymphatic systems in dogs. Although CHOP-based chemotherapy is the current standard of care, it usually provides only temporary relief, with frequent relapses. This study explores a new approach using High-Intensity Focused Ultrasound (HIFU) to target and treat affected lymph nodes in dogs newly diagnosed with intermediate- to large-cell lymphoma.

HIFU is a non-invasive method that uses focused sound waves to heat and destroy tissue. This process can release tumor proteins and signals that may activate the dog's immune system.

We believe HIFU is safe and may trigger immune responses that improve outcomes for dogs with lymphoma. Results from this study may also help us understand how similar treatments might work in other species.

Eligibility:
Before enrolling in this study, your dog will need standard tests to confirm a lymphoma diagnosis and determine if they qualify for the study. These include:

1. ***Physical Exam***: A full examination of your dog.
2. ***Lab Work***: Blood will be drawn (about 6 ml, or one teaspoon) from the jugular vein, and urine (5 ml) will be collected by free catch. These are routine methods used at Purdue Veterinary Hospital.
3. ***Staging Tests***: Chest X-rays and abdominal ultrasound will assess if the cancer has spread. If needed, fine needle samples will be taken from organs for confirmation.
4. ***Lymph Node Analysis***: Cytology and biopsy will confirm the diagnosis.
5. ***Advanced Testing***: Flow cytometry and PARR (clonality testing) will be done on a lymph node.

To qualify, your dog must have intermediate- or large-cell lymphoma, be less than stage V (five), have no other life-threatening illness, and have relatively normal organ function. Additionally, your dog should not have received chemotherapy or corticosteroids in the last 3 and 2 weeks, respectively. You will be informed of all standard treatment options before

enrolling.

Procedures:
If your dog qualifies, they will undergo the following:

- **Pre-treatment Biopsy:** A sample will be taken from a lymph node on the side opposite the one to be treated.
- **Blood Collection:** About 10 ml (2 teaspoons) will be drawn for research (for immune and extracellular vesicle profiling).
- **HIFU Treatment:** The affected lymph node will be treated with HIFU under sedation. The haircoat over the treated lymph node will be removed with a combination of clippers and Nair cream.
- **Post-treatment Follow-up:** A biopsy of the treated and opposite side lymph node, and blood sample will be collected 5–7 days after HIFU.

After these steps, your dog will begin standard CHOP-based chemotherapy (UW-25 protocol) at our hospital.

Follow-up
Your dog will need to return for chemotherapy visits based on the UW-25 protocol schedule. ***After completing chemotherapy, we ask that you bring your dog for monthly check-ups for at least 6 months or until the lymphoma returns.*** Please notify the oncology team of any changes in your pet's health during this time.

Associated Risks:
We are testing a new approach to treating cancer. While many procedures used in this study are standard, HIFU is experimental and not part of regular care.

Possible side effects of HIFU may include:

- Skin irritation at the treatment site
- Swelling or inflammation of the treated lymph node
- Discomfort at the tumor site
- Systemic inflammation
- Abscess formation
- In rare cases, death

Diagnostic procedures may cause minor complications like bruising, inflammation, or infection. Sedation carries small risks, including adverse reactions and, rarely, death. We will take all precautions to minimize these risks and monitor your pet closely during and after sedation.

Chemotherapy is **not** experimental but may cause:

- Vomiting, diarrhea, or loss of appetite
- Decreased blood cell counts (red blood cell, white blood cell, platelets)
- Bleeding or bladder inflammation (specific to cyclophosphamide)
- Heart failure (specific to doxorubicin in some breeds)

We will monitor your dog carefully and use preventive strategies to manage side effects.

Compensation:
Once consent is given, the study will pay for:

- ***100% of the HIFU-related visit costs***, including sedation, blood and tissue samples, HIFU treatment, and management of related side effects.
- ***Up to $4,000 toward the cost of CHOP chemotherapy***. Note: The total cost of the full chemotherapy protocol ranges between $6,000–$8,000, depending on dog size and need for sedation or management of complications.
- ***The study does not cover medical complications related to chemotherapy***.
- ***The study will also cover the cost of the first six monthly recheck appointments*** after chemotherapy ends.

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.

Questions about this project may be directed at Dr. Nick Dervisis:
Email: ndervisi@purdue.edu
Phone: 765-494-1107

I understand that my decision to allow my animal to participate in this study is entirely voluntary. I am free to withdraw my animal from this study at any time without compromising the quality of care provided to my animal. I understand that if I chose to withdraw my animal from the study, that there may or may not be the opportunity to re-enroll my animal.

I also understand that there may be other reasons why my animal could be withdrawn from the study. If my animal's health worsens, it may not be safe for him/her to remain in the study. For example, some treatments are only safe when the overall health of an animal is good and major organs are functioning normally. I have been informed that the veterinarians attending to my animal will discuss with me any concerns that could arise regarding my animal's continued participation. I also understand that if I am unable to follow the study protocol in regards to giving medications, returning my animal for evaluation, or other items in the protocol, that my animal may need to be withdrawn from the study. Furthermore, I am aware that some studies may be stopped earlier than planned. I have also been informed that the information gained from the study, regardless of how long my animal or other animals participate, will be used in an attempt to make progress to improve the outlook for other animals, as well as my animal. I recognize it is very important, and I have provided all information which is relevant and which is requested regarding my animal's medical history.

I acknowledge that I have read and understand this consent form, and all my questions have been answered to my satisfaction. I have been assured that all personal identifying information will be kept confidential. I understand that results of this study may be shared, published, or used for educational instruction. This is important in improving veterinary care for animals. I also authorize the release of all data, including, but not limited to, medical data, photographs and videotapes.

I am aware that this study has been reviewed and approved by the Institutional Animal Care and Use Committee of Purdue University.

As a volunteer, I give my informed consent to the Purdue University Veterinary Hospital to enroll my animal in this study, according to the explanations and conditions presented in this document. I agree to hold harmless the Board of Trustees of The Trustees of Purdue University, the Purdue University Veterinary Hospital, and its officers, employees, agents and assigns from any and all liability, claims and actions that may arise from participation in this study.

☐ I have received a copy of this Consent form.

_____
Printed Name: Owner (or authorized agent)

_____ _____
Signature Owner (or authorized agent) Date

_____
Printed Name: Witness

_____ _____
Witness Signature Date

(Original to Medical Records; IACUC or VCSC Approval #: IPROTO202500000150