



COLLEGE OF VETERINARY MEDICINE  
DEPARTMENT OF CLINICAL SCIENCES

## CLIENT INFORMED CONSENT FORM

### Title: Use of pre- and intra-operative lymphoscintigraphy to more accurately stage canine oral neoplasia

1. **Why is the study being performed?**  
This study is being performed to determine if the lymph nodes that drain tumors in the mouth can be more accurately identified with the use of lymphoscintigraphy. Lymphoscintigraphy is a minimally invasive procedure that involves injection (for this study, into or next to the tumor) of a very small amount of a radioactive material (radionuclide) that can then be traced as it flows inside the body by using a special camera (gamma camera). Additionally, it will be studied that if, by analyzing these nodes, can the spread of cancer (metastasis) to lymph nodes be more accurately determined; the result of which may change recommendations for additional treatment and prognosis of your pet. Up to 20 animals will be able to be included in the study.
2. **Which animals / patients can participate in the study?**  
Any dog may be considered a candidate for this study if they have a malignant tumor in the mouth (diagnosed by microscopic examination) with a plan to have it surgically removed, with the exceptions listed below.
3. **Why might my animal NOT be able to participate in the study?**  
Patients will not be able to participate in this study if they have had previous surgery of the mouth including removal of the entire tumor, or past significant reconstruction (e.g. for a fractured jaw). This does not include patients who have had previous dental cleanings, uncomplicated tooth extraction or a small sample of tumor taken for biopsy (these patients are still eligible candidates). Patients will also be unable to participate if they are pregnant, nursing, or unable to undergo general anesthesia.
4. **What will be happening to my animal if we participate in the study?**  
If your pet enrolls in this study, two lymphoscintigraphy scans will be performed before surgery, as well as standard procedures for staging (evaluation for spread of the cancer) and overall health status that may be recommended by the Oncology and/or Surgery Service (e.g. blood work, chest x-rays, CT scan). The lymphoscintigraphy scans are performed under sedation to limit anxiety and movement of your pet during the procedure (up to 3 hours). For the first scan, a small amount of a radionuclide will be injected either 1) into or 2) next to the tumor, and the gamma camera will be used to identify which lymph nodes are receiving drainage from that site. After imaging, the sedation will be reversed and your pet will remain in hospital overnight. On the next day, a single image will be taken to see how much radioactive signal remains from the previous injection. There is a small chance that there will be too much signal to properly perform the second scan, in which case, it will be postponed for one additional day. When possible, a second scan will be performed with the injection into the location (into or next to the tumor) not given on the first scan to determine if there is a different drainage pattern between the two injection sites. After the second scan, aspirate (obtaining cells with a small needle) of the mandibular lymph node as part of routine staging will be performed, and your pet will then go to surgery for removal of the tumor. In addition, the lymph node(s) identified by lymphoscintigraphy will be removed with the assistance of a handheld gamma probe, which will help target the exact location of the nodes, enabling a smaller incision to access them, as well as to make sure that all potentially involved nodes are removed. After surgery, your pet will recover in hospital as routine for oral tumor surgery. Visitation will not be allowed between the two scans if your pet has higher radiation emissions; this may be up to 24 hours after the first scan, however visitation may be allowed sooner if lower levels of radiation emission are detected. Visitation will not be allowed immediately after the second scan as your pet will be going directly to surgery. After surgery, in-hospital visitation will be at the discretion of the surgeon.
5. **Are there any benefits from the study for my animal?**  
It is possible that additional information will be gained regarding the specific disease status of your pet relating to lymph node metastasis, and this information may guide decisions regarding recommendations for more or less follow-up treatment, as well as potentially changing the offered prognosis.



COLLEGE OF VETERINARY MEDICINE  
DEPARTMENT OF CLINICAL SCIENCES

## CLIENT INFORMED CONSENT FORM

6. **Are there any risks or discomforts for my animal?**  
Potential risks or discomfort to your pet as a result of the lymphoscintigraphy scans or lymph node resection are minimal. Your pet will be under sedation or general anesthesia for these procedures so discomfort and stress are minimized. There are limited risks associated with sedation, however rare complications (including death) are possible. Post-operative discomfort from removal of lymph nodes is typically very minimal and well controlled with medication. There are no foreseeable risks associated with exposure to the radionuclide, given the extremely small doses that are administered (well within recommended safety guidelines for personal exposure). There are also no risks for secondary exposure to you or your family once your pet is discharged from hospital.
7. **Unforeseen adverse events**  
Although unlikely, possible incision complications standard for any surgical procedure exist with removal of lymph nodes, including infection, dehiscence (suture failure) or seroma (swelling at the surgical site). Even extensive removal of lymph nodes in this location has been previously documented in dogs with minimal to no post-operative complications. In the case of an adverse event following discharge, contact the clinician listed on the discharge instructions.
8. **Are there other treatment options other than participating in the study?**  
Participation in this study is entirely voluntary. It is possible to pursue any alternative level of diagnostic or therapeutic intervention as discussed with the Oncology and/or Surgery Service. The decision to elect NOT to participate in the study will not impact the quality of patient care or treatment while at Auburn University Veterinary Teaching Hospital.
9. **Owner responsibilities**  
No additional owner responsibilities exist (no follow-up appointments will be required as a result of participation in this study).
10. **Participant dismissal**  
At this time, there is no foreseen explanation that a participant may be dismissed from the study once enrolled. If such a situation were to arise, you would be notified of the reason and a full explanation given; likely the only explanation would relate to the well-being of your pet.
11. **Financial obligations of all parties**  
Study funds will pay for the lymphoscintigraphy scans and direct associated fees (radionuclide, radiology professional fees), as well as the day one sedation, 1-2 nights of hospitalization in general wards (between the two days of scanning), the formalin fixation to contain the lymph nodes, and supplemental histopathology fee for lymph node examination. All additional costs associated with the patient, including additional diagnostic tests (including lymph node cytology and tumor histopathology), treatment, or hospitalization, are the responsibility of the owner. The risk of adverse reactions or accidental injury relating directly from participation in this study is very low; in the event of reactions or injury, the decision regarding financial obligation will be made on an individual case basis as per standard hospital policy.
12. **Access to study information**  
Results of the study pertaining to your pet's clinical status or well-being (e.g. presence or absence of lymph node metastasis) will automatically be communicated with the owner once available; typically histopathology results are available within 7-10 days of submission.
13. **Confidentiality**  
Data obtained during this research including, but not limited to, results of lymphoscintigraphy, intra-operative pictures, histopathology and cytology, may be used for publication purposes, however any identifying details will be removed and data will be published anonymously.
14. **Contact persons regarding this study**  
Participants may contact any of these individuals with questions about this study.  
Dr. Harry Boothe (Principal Investigator): 334-844-4690, boothhw@auburn.edu



COLLEGE OF VETERINARY MEDICINE  
DEPARTMENT OF CLINICAL SCIENCES

**CLIENT INFORMED CONSENT FORM**

Dr. Kristin Kry (Co-investigator, attending veterinarian): 334-844-4690, klk0018@auburn.edu

15. **Hospital review contact person**

Participants with concerns about any research study at the AU College of Veterinary Medicine may also contact:

**Doug Allen, DVM, MS, DACVS.** Director, Veterinary Teaching Hospital. College of Veterinary Medicine, Auburn University. (334) 844-4690.

**Frank F. "Skip" Bartol, PhD.** Associate Dean of Research and Graduate Studies. College of Veterinary Medicine; Auburn University. (334) 844-3700.

16. **Owner acknowledgements:**

As legal owner of (or agent for) this animal, I understand and acknowledge the following:

- a. I am agreeing to participate in a research study at the AU College of Veterinary Medicine.
- b. I am free to withdraw my consent and to discontinue participation in the study at any time.
- c. The decision for my animal to participate in this study is mine alone and participation is voluntary.
- d. The decision to withdraw from the study or to disregard the recommendations of the veterinarians involved in the study, relieves the investigators of current and future obligations (both medical and financial) to the pet and/or owner covered by this study.
- e. Non-study treatment protocols have been discussed and I understand the relative benefits of those treatments.
- f. I am responsible for decisions and financial obligations related to treatment(s) sought or required for my animal at AU-VTH or at any other veterinary facility that are NOT specified in this document. This would include treatment for disease progression or for medical complications - related or unrelated to the study.
- g. If I withdraw my animal from the study, I may be responsible for medical, diagnostic and treatment costs incurred even if these were originally covered by the study.
- h. Any decision to discontinue participation in this study, whether to pursue other therapies or to have my animal euthanized, does not entitle me to any financial reimbursement for costs incurred during participation.
- i. I have discussed the procedures / benefits and risks of study participation and had the chance to have my questions about the study answered.

\_\_\_\_\_  
Owner signature

\_\_\_\_\_  
Date

17. **Investigator assurances**

- a. I have explained the study details and answered questions to the best of my ability.
- b. If the animal is a patient in the Auburn University Veterinary Teaching Hospital, I have discussed enrolling the patient into this study with the senior faculty member responsible for this patient's care.

\_\_\_\_\_  
Primary Investigator

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness

\_\_\_\_\_  
Date

This study has been reviewed and approved by the Clinical Research Review Committee of the College of Veterinary Medicine (CRRC) and the Auburn University Institutional Animal Care and Use Committee (IACUC).  
(Effective date – Feb 2010)