

Informed consent for participating shelters, rescues, and fosters participating in Lesley's Place Program for homeless dogs with mammary tumors.

Purpose of the program: Lesley's place offers mammary tumor care to homeless dogs with mammary tumors that otherwise would not have access to treatments. The purpose of this program is to provide care for dogs with mammary tumors/breast cancer and advance clinical and basic research to benefit both dogs and women with breast cancer. This care is provided free of charge to shelters and rescues and is funded through the non-profit organization Lesley's Place. Privately owned dogs even though they might have been adopted from shelters are not eligible to participate in this program.

This program has a dual purpose: 1) to provide clinical care to dogs with mammary tumors and 2) through this care advancing knowledge and contributing to research by utilizing tumor tissues, blood samples and clinical data to support research on breast cancer in both women and dogs.

What is involved/eligibility/treatment:

First steps: Prior to enrollment the dogs will be screened by the shelters for eligibility to participate in this program. All of the following criteria must be fulfilled in order to be evaluated at the hospital for staging

- 1) have one tumor of at least 3 cm in diameter.
- 2) have completed the minimum sets of vaccines including Rabies vaccines
- 3) have no history of people-directed aggression
- 4) quarantined outside a larger shelter for at least 2 weeks prior to screening visit at hospital (infectious diseases)
- 5) have identified foster to provide home care after surgery
- 6) have no signs of active upper airways infection and be in general good health with no serious concurrent illness.
- 7) signed the informed consent describing the benefits and responsibilities associated with participation, including a commitment to return for follow-up.

Next steps: Dogs that pass the first screening questions will be evaluated at the hospital and undergo presurgical staging which includes physical exam and tumor measurements, thoracic radiographs, and blood work. Dogs with no evidence of distant metastasis and no serious concurrent illness identified by the blood work will undergo surgery. The surgery involves complete removal of all palpable mammary tumors. This surgery may be staged in 2 separate procedures in dogs with multiple mammary tumors in both chains. Intact dogs will undergo ovariohysterectomy as part of the surgery. In addition, blood samples will be collected for hormone panel analysis at the time of surgery. All tumors will be evaluated by a board-certified pathologist with expertise in mammary tumor pathology. The tumor ER status will also be determined and used to determine the potential clinical benefit from using an aromatase inhibitor after surgery in dogs with high-risk tumors. This will be offered at no cost to dogs with ER positive high-risk tumors if the respective shelters, rescues or adoptive owners are interested in pursuing further treatment. The data regarding the tumor's hormone receptor status and serum hormone levels will also be used for research purposes. Tumor tissues will be collected and processed for research purposes.

Last steps: Dogs with histopathological confirmation of malignant mammary tumors will be enrolled in the program and required to return for follow-up exams. Dogs with benign tumors will be discharged from the

program and not required to return for follow-up exams. However, dogs with malignant tumors have a risk for developing distant metastasis after surgery and therefore need to be followed by regular exams and thoracic radiographs. In addition, blood for the serum hormone levels will also be collected at these visits.

Follow-up exams: Dogs enrolled in this program are required to return to the hospital every 4 months the first year after surgery and every 6 months the second year. These follow-up visits are similar to what would have been recommended to privately owned dogs with malignant mammary tumors. Regular follow-up visits will not be required after 2 years, but we do ask that the fosters/owners provide follow-up data on their dogs and let us know when the dogs die and the cause of death. These follow-ups are crucial for the health of the dogs and for the research we perform. It is therefore imperative that the shelters and fosters that provide care to these dogs commit to these requirements.

Risks and benefits: There are no specific risks associated with this study apart from those risks associated with the standard of care for dogs undergoing staging tests, anesthesia, and surgery for removal of mammary tumors and spaying.

Risks of general anesthesia include adverse reactions to anesthesia drugs which can result in either temporary or permanent damage to organs such as the liver and kidney. Severe reactions are rare but can be life threatening. Risks associated with surgery include infection, incision dehiscence (break down and opening of the incisions), and postoperative pain and discomfort. These complications will be treated according to standard of care, including antibiotics, pain medication, and additional surgical management as indicated.

The benefits associated with participating in this study include access to standard of care for their mammary tumors and the potential for longer and better-quality survival because of it. This treatment may also increase the dogs' likelihood of finding permanent homes. Other benefits: The results from this study and the associated research may improve our understanding of tumor development in dogs. This in turn can help our understanding of tumor development in humans. Better understanding of tumor development might lead to new and improved cancer treatments in the future.

Cost: All cost associated with enrollment and treatment for mammary tumors through this program is free of charge to the shelters, rescues, and fosters. This includes Blood work, thoracic radiographs, anesthesia, surgery, post-surgical care and post-surgical complications. The shelters and fosters will be responsible for any costs associated with diagnosing and treating any other diseases than mammary tumors this dog may develop while she is in your care. Notably, the program does not offer chemotherapy in high risk patients after surgery. However, we can refer cases to a medical oncologist if this is something the shelters/fosters want to pursue.

Responsibility of participating shelters, rescues and fosters/adoptive owners:

By enrolling your shelter dogs into this program you agree to the terms and responsibility described in this informed consent, including abiding by the follow-up requirements, the use of clinical data, tumor tissue and blood for research purposes and notifying new fosters about this dog's participation in this program.

Case name _____ Study number _____ Shelter/Rescue
Name _____

Shelter/Rescue agent: print name _____ signature _____
date _____

Phone number _____ Email _____

Person obtaining consent: : print name _____ signature _____
date _____