Your pet is being invited to participate in a research study and you are being asked to consider your pet’s involvement. Consenting to have your pet participation is voluntary. There will be no change in veterinary care or treatments available to your pet should you decide not to enroll your pet in the study.

What is the purpose of this research study and my pet’s involvement?
This experimental therapy will examine the ability of dogs to develop anti-tumor immune responses after vaccination. The vaccination will utilize a group of proteins, known as EGFR and HER2, that are overexpressed in a variety of human and dog tumors that are typically associated with more progressive disease and a worse outcome.

Studies in mice have shown both vaccines to be effective in reducing tumor growth by causing the body to make an abundance of antibodies, a specific type of protein, that attack and kill the tumor cells. The purpose of this study is to see if the vaccine has the same effect on the tumor in the dog. Your pet will receive two injections of the vaccine approximately 21 days apart. A small amount of blood will be collected at the time of the first vaccination and at the time of the 2nd vaccination and a final blood sample at day 40-50 after the start of the therapy.

Your veterinarian may take images or biopsies of your pet’s tumor and continue to collect blood samples as part of the treatment plan independent of the study. However, these images, biopsies and the blood testing will all be used to determine how the vaccine functions. Your personal veterinarian will remain the primary care provider for your pet.

What are the possible risks or discomforts to my pet?
The study involves only 2 injections and 3 blood collections. It is not anticipated that your pet will endure any study-related discomforts. There have been no observed side effects to other tissues or organs in canine patients. In a small fractions of patients, about one in ten patients, there may be inflammation at the site of the vaccination. This swelling may even leak fluids. This reaction is known as a ‘sterile abscess’ and is not painful to the dog, and does not require treatment (no antibiotics). The site heals fairly quickly, usually within 10 days. Warm compresses can be applied twice daily to help reduce the swelling. Again, in 90% of dogs will have little or no reaction at the site of injection.
What are the possible benefits of the study for my pet?
The purpose of the study is to determine if the vaccine elicits immune responses that reduce the tumor. It is not known or predicted whether your pet will get any medical benefit, improved lifespan or reduction in tumor growth. The study is designed to determine if immunity to tumor proteins slows tumor growth, stops tumor growth, or eliminates tumors. These are all goals of the study.

Will I be paid for my pet being in this study and will I have to pay for my pet to participate?
You will not be charged for any of the treatments or blood collections associated with the study (if performed at the Veterinary Care Center, Norwalk, CT). If administered by your personal veterinarian, you will be responsible for fees associated with the administration of the vaccine by your personal veterinarian, postal fees to mail blood samples to Yale University, and a $1,000 donation (tax deductible) for the program (check made out to Yale University). The donation entirely supports the canine vaccine clinical trial. No personal or identifiable information about pets or pet owners will be revealed to the public from this study without your consent.

What happens if my pet does not appear to be doing well during the study?
If your pet has any clinical signs that are of concern to you, you should contact your personal veterinarian for immediate care. The progression of cancer is dependent on many factors including the age, gender, and stage of tumor in individual patients. Yale University veterinarians are not authorized to care for your pet.

Can I withdraw my pet from the study at any time?
Yes, you may withdraw your pet from the study at any time. To do so, please notify Dr. Mamula and your personal veterinarian of your decision. Withdrawing from the study will not interfere with your pet’s future cancer treatments or care. This study may also be discontinued at any time by your veterinarian or the study Principal Investigator if deemed not in the best interest of your dog.

By signing this form, you are agreeing to have your pet take part in this research study and confirm that you have read this consent form. Your signature also confirms that you are over 18 years of age and that you are the legal owner or authorized agent of this dog. You also permit Yale University to use your pet’s health information for research purposes. Finally, you acknowledge that a copy of this consent form will be given to you. Please contact Dr. Mamula if you have any further questions regarding the vaccination.

Pet’s Name: _______________

Owner/Agent (Please Print)  Signature of owner/agent  Date

Veterinarian/Vet staff  Veterinarian/ Vet Staff Signature  Date