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This protocol has been approved by the MJR-VHUP Privately Owned Animal Protocol Committee and the University of Pennsylvania Institutional Animal Care and Use Committee.

**POAP #.**

**MATTHEW J. RYAN VETERINARY HOSPITAL  
UNIVERSITY OF PENNSYLVANIA  
OWNER INFORMED CONSENT FORM**

**Protocol Title:** Evaluation of safety and efficacy of perioperative administration of desmopressin in dogs with mammary tumors

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**Why am I being asked to volunteer my pet?**

You are being invited to have your pet participate in a research study because he/she has mammary tumor(s) which may be malignant (carcinoma). Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of your pet being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study and they will give you this consent form to read. You may also decide to discuss it with your family or primary care veterinarian. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about this form. If you decide to participate, you will be asked to sign this form.

### **What is the purpose of this research study?**

The purpose of this study is to evaluate the effectiveness of a drug called desmopressin (DDAVP) when administered prior to and 24 hours post mastectomy.

Mammary tumors are the most common cancer in the female dog. Between 40-50% of mammary tumor are malignant and about 50% of the malignant tumors may metastasize (spread to other areas of the body.) While surgical removal of mammary tissue (mastectomy) is the preferred method of treatment, it does not always prevent metastasis (spread of the cancer cells).

DDAVP is a drug that is commonly used to treat bleeding disorders in dogs. Recently this drug has been found to also have anti-cancer properties. Our goal is to evaluate whether DDAVP can help delay recurrence of the cancer and prolong survival. DDAVP has been found to be safe and effective in treating bleeding disorders in dogs.

### **How long will my pet be in the study? How many other pets will be in the study?**

Your dog will be in this study until disease progression occurs. We are planning to enroll a total of 24 dogs at VHUP.

### **What am I being asked to do?**

Your dog is eligible to participate in this trial if:

1. She is suspected to have a mammary gland carcinoma, without prior history of mammary carcinoma
2. She is scheduled for a mastectomy with ovariohysterectomy (spaying- if applicable) at VHUP
3. You have consented to her to be randomized to receive DDAVP or placebo
4. A diagnosis of mammary carcinoma is confirmed on histopathology (microscopic examination of biopsy samples)

Once a diagnosis of mammary carcinoma is confirmed via histopathology, your dog will be monitored for cancer spread through examinations and chest x-rays, performed every four months for the first year and every 6 months thereafter. Any dogs found to have suspicious lesions on their x-rays will have them repeated one month after the suspicious lesion was noted. Tests will be performed to assess her overall health. These tests include a CBC (complete blood cell count), blood chemistries (to evaluate organ function), urinalysis, and lymph node aspirates/biopsies whenever possible.

### Treatment

- Dogs enrolled into this study will be randomized to either receive a dose of DDAVP or a placebo (saline) immediately prior to surgery and another dose of DDAVP or placebo 24 hours after the surgery. DDAVP and the placebo will both be given as a subcutaneous (SQ, under the skin) injection.
- Your dog's individual dose will be calculated according to her body weight.
- If your dog is found to not have cancer, or to have a type of cancer other than mammary carcinoma, she will be discharged from the study prior to any follow up appointments and you will be financially responsible for all costs related to the surgery, such as: pre-surgical staging tests, the surgery itself, post-operative care, and histopathology (biopsy).

### Follow-Up

- Your dog will have a re-evaluation visit every four months up to a year, then follow-up visits will occur every 6 months until metastatic disease presents itself.
- A post-mortem examination (necropsy) is required for all dogs that participate in this study. This is necessary to determine the extent of metastasis, side effects of the treatment, and the cause of death (if other than euthanasia). If your dog dies or is euthanized somewhere other than VHUP, you must notify the primary investigator of your dog's death and arrange for transportation of your dog's body to VHUP within 24 hours.

In the event that your dog should pass away during her time of participation in the study, a necropsy (post-mortem exam to determine the cause of death) will be required. Your dog's body will be treated with respect at all times. While there is no cost to you for the necropsy procedure, there will be a charge if you wish to have your dog's body privately cremated and her ashes returned to you.

### **What are the possible risks or discomforts to my pet?**

The risks associated with DDAVP when administered at the dose and schedule used in this study is well tolerated and side effects are uncommon. Possible side effects include increased blood clotting, fluid overload resulting in high blood pressure, and blood electrolyte abnormalities.

### **What if new information becomes available about the study?**

During the course of this study, we may find more information that could be important to you and your pet. This includes information that, once learned, might cause you to

change your mind about your pet being in the study. We will notify you as soon as possible if such information becomes available.

### **What are the possible benefits of the study for my pet?**

Your pet may not get any benefit from being in this research study beyond what is expected for dogs receiving mastectomies. DDAVP may result in a longer survival if it has anti-cancer effects in mammary cancer. DDAVP may also help your dog's red blood cell count return to normal more quickly by decreasing bleeding that is associated with mastectomies.

### **What other choices do I have for my pet if I do not participate?**

If you chose not to participate in this study you may elect to pursue standard chemotherapy, supportive care, or no further treatment. You can discuss these options with the medical oncologists at VHUP, other medical oncologists, and your primary care veterinarian.

### **Will I be paid for my pet being in this study?**

You will not receive any payment for participation in this study. The cost of the surgery, pre-surgical staging tests, post-operative care, and histopathology (biopsy) will be paid for by the study ONLY if the biopsy results indicate mammary carcinoma. Desmopressin (DDAVP), and follow-up evaluations (including examination fees) are also paid for by the study.

### **Will I have to pay for anything?**

For un-owned dogs participating in the charitable shelter animal mammary tumor program, all study-related items will be covered by the study, including study drug, surgical-related costs, physical examinations, blood work, urinalyses, lymph node aspirates/biopsies, and radiographs.

Complications may occur during the study because of your dog's illness, as a result of treatment, or for unrelated causes. You will be responsible for all costs of tests and treatments except those specifically mentioned as being included in this study.

### **What happens if my pet is injured or hurt during the study?**

If your pet has a medical emergency during the study you should go to the nearest emergency room. You may contact the Principal Investigator or Emergency contact

listed on page one of this form. You may also contact your own veterinarian, or seek treatment outside of the University of Pennsylvania. Be sure to tell the veterinarian or his/her staff that your pet is in a research study being conducted at the University of Pennsylvania. Ask them to call the telephone numbers on the first page of this consent form for further instructions or information about your pet's care.

If you believe that your pet is hurt or injured as a result of participation in this research study, please contact the investigator listed on page one of this form.

**When is the study over? Can my pet leave the study before it ends?**

This study is over for your pet after he/she has been diagnosed with progression of metastatic disease, and all information has been collected. This study may also be stopped at any time by your veterinarian or the study Sponsor without your consent because:

- The Primary Investigator feels it is necessary for your pet's health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The Sponsor or the Principal Investigator has decided to stop the study.

If you decide to have your pet participate, you are free to withdraw her from the study at any time. Withdrawal will not interfere with your pet's future care. However, we ask that you provide us with information regarding your dog's status so that important study data can be collected.

**Who can see or use my pet's information? How will my personal information be protected?**

We will do our best to make sure that the personal information in your pet's medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, you and your pet's name and any other identifiable information will not be used. If this study is being overseen by groups outside of the Matthew J. Ryan Veterinary Hospital of the University of Pennsylvania, they may review your pet's research records. You will always have access to important medical information about your pet, but you may not be able to access certain study specific information until the completion of the study.

## Who can I call with questions, complaints or if I'm concerned about this research?

If you have questions, concerns or complaints regarding your pet's participation in this research study, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Chair of the Privately Owned Animal Protocol (POAP) committee at the Matthew J. Ryan Veterinary Hospital of the University of Pennsylvania by calling 215-898-5448 and leaving a message for Dr. Lili Duda.

When you sign this form, you are agreeing to have your pet take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer your pet. Your signature also means that you are permitting the Matthew J. Ryan Veterinary Hospital of the University of Pennsylvania (MJR-VHUP) to use your pet's health information collected for research purposes within our institution. You are also allowing MJR-VHUP to disclose that information to outside organizations or people involved with the operations of this study. Your signature also confirms that you are over 18 years of age and the legal owner or authorized agent of this pet. A copy of this consent form will be given to you.

**VHUP case #:** \_\_\_\_\_

**Pet's Name:** \_\_\_\_\_

_____	_____	_____
<b>Owner/Agent (Please Print)</b>	<b>Signature</b>	<b>Date</b>

I want / do not want (circle one) to be notified of the post mortem results \_\_\_\_\_  
*Initials*

_____	_____	_____
<b>Name of Person Obtaining Consent (Please Print)</b>	<b>Signature</b>	<b>Date</b>

_____	_____	_____
<b>Name of Study coordinator Confirming consent</b>	<b>Signature</b>	<b>Date</b>

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**Name of Investigator**

**Signature**

**Date**