
**Department of Veterinary Clinical Sciences
College of Veterinary Medicine
University of Minnesota**

Genetics of Cancer in Companion Animals

Principal Investigator: **Jaime F. Modiano, VMD, PhD**

Rev. January 2011

Project Description

You are being asked to allow your dog to take part in the development of a sample bank to support research studies of cancer genetics. The studies include various components that will examine (1) heritable risk for cancer in specific breeds, (2) abnormalities in genes that are important in the origin and progression of cancer, (3) and how these abnormalities influence the response to treatment and overall outcome of dogs with cancer. The findings from this study will enhance our understanding of why cancer happens, and thus help us to improve care for this disease in dogs and people.

Up to 1,500 dogs will be enrolled in this research study over a 3-year period (2011-2014). Material collected may be shared with investigators at other institutions to maximize each patient's contribution to the understanding of cancer.

Please read this form carefully and fill out as much information as possible, paying special attention to the demographics on page 2 and checking the appropriate boxes on pages 5 and 6. **If you do not have some of this information readily available, we would be grateful if you would provide contact information on page 2 that can be used for follow-up.** Please initial the bottom of each page on this form, and also provide your pet's name and sign and date the authorization on page 6.

A) Who is conducting this study?

The samples collected for the bank support projects being conducted by Dr. Jaime F. Modiano and his colleagues at the University of Minnesota. Current collaborations are in place with Dr. Matthew Breen at North Carolina State University (NCSU) in Raleigh, NC; Dr. Elaine Ostrander at the National Human Genome Research Institute (NHGRI) of the National Institutes of Health (NIH) in Bethesda, MD; Dr. Kerstin Lindblad-Toh at the Broad Institute of MIT and Harvard University in Cambridge, MA; and Dr. William Kisseberth at the Ohio State University in Columbus, OH.

B) Why is this study being done?

The purpose of this study is to determine the role of genetics in the development of cancer in dogs. Specifically, we plan to define mutations of cancer-related genes that may be passed on from parents to offspring and that may impact response to conventional treatments. Current projects in the Modiano laboratory involve the study of **lymphoma** and **leukemia** (cancers of white blood cells), **osteosarcoma** (bone cancer), **hemangiosarcoma** (cancer of cells that line the blood vessels) and **melanoma** (cancer of pigmented skin cells), although we are also interested in other cancers. Our colleagues are working on brain tumors, mammary tumors, cancers of the gut, lung cancer, and others. We also will be collecting samples from healthy dogs, and from dogs with illnesses other than cancer so that we can compare them with samples from cancer patients.

Owner Initials _____

Date _____

Demographic Information

My dog's gender is: Male Female

My dog is spayed or neutered: Yes (Date if known _____) No

My dog's date of birth was: _____ (mm/dd/yyyy)

AKC Registration # _____ **OR** My dog is not registered **OR** Unknown

I can provide a pedigree for my dog: Yes No

To the best of my knowledge, a dog related to my dog is enrolled in the study:

Yes No

•If yes, dog's and owner's names and/or AKC registration #: _____ **AND**

•My dog's relation to the dog named above is _____
Parent, sibling, offspring, etc.

My preferred contact information for follow-up: _____
Email **AND/OR** Phone

AND/OR Address

Procedures

If you agree to take part in this study, we will ask you to do the following things:

1. If your dog has cancer and has not yet started treatment (**including Prednisone or other corticosteroids**), your veterinarian may obtain samples for diagnosis (a biopsy) or as part of the routine and accepted treatment (surgery). You agree to allow your veterinarian or animal health professional to obtain blood and/or urine samples from your dog and to donate both the tumor samples and the blood/urine samples to the sample bank.
2. If your dog does not have cancer, your veterinarian may obtain samples for diagnosis of other diseases (a biopsy) or as part of the routine and accepted treatment (surgery). You agree to allow your veterinarian or animal health professional to obtain blood and/or urine samples from your dog and to donate both the tissue samples and the blood/urine samples to the sample bank.
3. If your dog is already being treated for his or her cancer or other disease, you agree to allow your veterinarian or an animal health professional to obtain blood samples for the study and to provide the investigators with **copies of pathology reports and other pertinent information from your pet's veterinary record**.
4. If your dog is healthy, and you wish to donate blood or urine samples to serve as control material from comparison with samples from sick animals, you agree to allow your veterinarian or animal health professional to obtain blood and/or urine samples from your dog and to donate them to the sample bank.
5. You will approve enrollment of your dog in the study by signing this form. You can either agree to allow your dog to participate in all applicable components at the discretion of the investigators and your pet's veterinarian, or you can choose specific components of the study listed at the end of this form.
6. You will agree to provide a copy of your dog's 3-generation pedigree or AKC registration (if applicable), your name, and contact information (address including at least city or town and state, and telephone number and/or electronic mail address) and to allow a member of the investigators' interview team to contact you for follow-up. Follow-up may consist of completing a survey (which you can choose to do electronically using email and the World Wide Web, by telephone, or by mail) within the first 10-days of enrollment, up to three more times during the first year, and up to once yearly thereafter for two more years. The survey will include questions about your dog's health, including treatment and outcome if he or she had cancer, and about your pet's general environment and lifestyle.

Discomfort and Risks

If your dog has cancer or another disease, there are no additional discomforts or risks beyond those associated with routine procedures that your veterinarian will perform as part of the accepted practice for diagnosis and treatment (surgical procedures for tumor biopsy or removal). There are no foreseeable risks to the health, comfort, or lifespan of your dog that may arise from the use of the donated cells and tissues in the laboratory.

If you agree only to allow your dog to provide blood samples, the only risk is associated with the blood-drawing procedure. Approximately the equivalent of 1-3 tablespoons (5 - 15 ml) of blood will be removed by putting a needle into your dog's vein. This is the standard method used to obtain blood for tests. Your dog may experience some discomfort when the needle goes into the vein. A bruise may form at the site. Only a single blood sample will be obtained for the study.

Because we are asking you to provide personal information (name and address), there is a potential risk for loss of privacy. Every effort will be made to keep your research records confidential, but this cannot

Owner Initials _____

Date _____

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be absolutely guaranteed. A complete explanation of the protocols we will follow to protect your personal information is provided in the Confidentiality section below.

Benefits

This study is designed for the researchers to learn more about cancer genetics. This study is not designed to treat any illness or to improve your dog's health. Also there are risks as mentioned in the Discomforts and Risk Section.

Cost to Subject

There are no costs to you for allowing your dog to participate in this study. However, all costs for your dog's medical care are your responsibility.

Subject Payment

You will not be paid for allowing your dog to participate in this study, but if a test or procedure is required for the research study and is not considered to be part of your dog's clinical care, then the research study and/or grant will pay for the cost of the test. Any relevant test results will be reported to the attending veterinarian.

Study Sponsor

This research is funded by the National Institutes of Health, the American Kennel Club Canine Health Foundation, Morris Animal Foundation, the Golden Retriever Foundation, and The National Canine Cancer Foundation.

Voluntary Participation and Study Withdrawal

Allowing your dog to participate and taking part in this study are strictly voluntary. You have the right to choose not to allow your dog to participate, and the right not to participate yourself if you do not wish to provide personal information or complete the follow-up questionnaires. If you do not take part in the study, your veterinarian will still take care of your dog. Your dog will not lose access to the veterinary care that you are seeking.

If you choose to allow your dog to participate and to take part in the study by providing personal information and follow-up, you have the right to stop at any time. To withdraw from the study, you can notify the investigators in writing at: **Modiano Lab/Comparative Oncology Sample Bank Program, Masonic Cancer Center University of Minnesota, 530 MCRB/MMC806, 420 Delaware St. SE, Minneapolis, MN 55455**. If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.

The investigators may decide to stop your participation without your permission for any reason. Also the sponsors may stop the study at any time.

Invitation for Questions

The researcher carrying out this study is Dr. Jaime F. Modiano. You may ask any questions you have now. If you have questions later, you may call Dr. Modiano at 612-625-7436. You will be given a copy of this form to keep.

If you have questions regarding your rights as a research subject, please call the University of Minnesota Institutional Animal Care and Use Committee at 612-626-5654.

Confidentiality

A. How will the identity of your sample and the information you provide be protected?

Your personal information will not be sold or disseminated to any person(s) not directly involved with this study. We will try to keep your research records confidential, but it cannot be guaranteed. Records

that identify you (including your dog's pedigree or AKC registration number) and the consent form signed by you, may be looked at by the following people:

- Federal agencies that oversee human subject research
- University of Minnesota Institutional Animal Care and Use Committee
- The investigator and research team for this study
- The sponsor or an agent for the sponsor
- Regulatory officials from the institution where the research is being conducted, to ensure compliance with policies or monitor the safety of the study

The results of this research may be presented at meetings or in published articles. However, your name will be kept private, and your dog will not be identified by name, family or kennel name, or AKC registration number. Results will not be reported individually to dog owners or breeders. Results from any test that is important for the care of your dog will be reported to your veterinarian.

B. Where will the information be stored?

Samples will be coded. Computer records of your dog's samples will only include the necessary information to allow us to contact you for follow-up. Consent forms and coding information will be kept in a secure location in the office of the Principal Investigator or the project coordinator. Even though every safety measure will be taken, there is a slight chance that someone who is not supposed to see information about you will accidentally see it.

If you have questions about injury related to the research, you may call Dr. Modiano and/or your veterinarian. Dr. Modiano should be informed about any injury your dog may experience while he or she is enrolled in this study.

Use of samples

The samples you provide are valuable and may be used in multiple study components. Because different aspects are conducted at different institutions, it is important to confirm your approval to share samples among investigators. You may choose to decline this permission. Please select study components in which you allow your dog's samples to be included and confirm approvals to share samples below:

<p><input type="checkbox"/> - I agree to allow the investigators to use my dog's samples for all applicable components of the projects, OR</p> <p>I approve the use of my dog's samples for the following aspects:</p> <p><input type="checkbox"/> - Mapping heritable factors that contribute to cancer susceptibility</p> <p><input type="checkbox"/> - Studies to determine the influence of genes in the origin and progression of cancer (this option may require a biopsy sample)</p> <p><input type="checkbox"/> - Studies to determine the association of genetic factors with response to treatment (this option requires that you allow your veterinarian to treat your dog with the accepted standard of care for the disease)</p> <p><input type="checkbox"/> - Studies to determine the association of genetic factors with overall outcomes (this option requires that you provide follow-up information regarding your dog's health and quality of life)</p>
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<p><input type="checkbox"/> - I agree to allow the investigators to share my dog's samples. My dog's pedigree or AKC registration number and contact information (if applicable for follow-up) will be made available to the Principal Investigator or Program Coordinator from participating labs that require this information with the sample; OR</p> <p><input type="checkbox"/> - I only allow these samples to be used in Dr. Modiano's lab. Neither samples nor pedigree information will be shared with other participating labs.</p>
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The samples you provide also may be valuable for future studies conducted by the investigator or by other scientists. These studies may include assessment of new genes that may be unknown at this time, development of treatments based on characteristics peculiar to these tumors, and sharing with other

investigators funded by the AKC Canine Health Foundation or other health-related organizations. The AKC Canine Health Foundation and the National Institutes of Health encourage sharing samples to maximize their value in studies that seek to improve the health and well-being of dogs and people. You may choose to allow use of samples for this study only, or you may choose to allow use of the samples in future studies at the discretion of the investigators. Please mark one of the following options:

I approve the use of my dog's sample(s) for this study only,

OR

I agree that the samples collected during this study may be kept for use in future research to learn about, prevent, treat, or cure cancer. Yes No

Injury and Compensation

You should inform your veterinarian if you decide to allow your dog to participate in this research study. The study does not provide compensation or treatment for any accidental injury that may occur while your dog is a participant. Care for your dog must be sought from a licensed veterinarian. The University of Minnesota will not be responsible for compensation or care related to this research project.

Authorization

I have read this paper about the study or it was read to me, and my questions about its content have been answered. I have had an opportunity to ask questions about the project and understand that I can ask questions at any time. I understand the possible risks and benefits of this study. I know that participation in this study is voluntary. **I choose to allow my dog(s), named _____, to participate in this study, and I will provide follow-up information as requested by the investigators.** Furthermore, I agree to donate to Dr. Jaime F. Modiano of the University of Minnesota tumor and other tissues removed from my dog during the normal course of diagnosis and treatment for its disease. I understand that these tissues will be used in studies of canine or feline cancer, and would otherwise be discarded. I also understand that by signing this Consent Form, I give up all future claims to these tissues and any experimental results that may be derived from their investigational use. I know I can stop being in this study and my dog will still get the usual veterinary care. I will get a copy of this consent form (initial all the previous pages of the consent form). If I have any questions or problems which I feel are related to the study, I can contact the Principal Investigator whose name is on this form. By signing below I agree to participate in this research study.

Signature: _____ **Print Name** _____ **Date** _____
Owner or Agent

Consent form explained by: _____ **Print Name** _____ **Date** _____
Veterinarian or Representative or Study Investigator
__ In person __ By telephone __ By electronic mail

Investigator _____ **Date** _____

Owner Initials _____

Date _____