

Genetics of Canine Cancer

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INFORMED CONSENT OF PARTICIPANTS

1) Who is conducting this study?

This study involves research being conducted by Dr. Jaime F. Modiano and Dr. Matthew Breen at the AMC Cancer Research Center and North Carolina State University, respectively.

This research project has been reviewed by the AMC Institutional Review Board.

2) Why is this study being done?

The purpose of these studies 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. The tumors that will be analyzed in the study are lymphoma (cancer of white blood cells in the lymph glands) and osteosarcoma (bone cancer). Breeds included in the study are Golden retrievers, Rottweilers, Mastiffs, and others with prior approval of the principal investigator.

3) How will this study involve me and my dog?

We are asking that you allow your dog (who may have a diagnosis of lymphoma or osteosarcoma, or may be related to a dog with such diagnosis) to participate in this study. Participation will involve obtaining a blood sample, and if your dog is affected, a tumor sample. These samples can generally be obtained at the time of an annual health examination or during procedures routinely used to diagnose the disease.

In order to be eligible for inclusion in this study, affected dog(s) can be male or female (intact or neutered), they must be between 4 months and 12 years old, in otherwise good enough health to tolerate diagnostic procedures (radiographs, blood draw, and biopsy), and treatment. Dogs must have a diagnosis of multicentric lymphoma (stage II – IV, no bone marrow involvement), or appendicular (in the limbs) stage I or II osteosarcoma (no evidence of metastatic disease) from a licensed veterinarian. Alternatively dogs must have a first-degree relative (parent, sib, offspring) that is enrolled in the study. Participation will specifically involve the donation of a portion of the tumor tissues removed surgically from your dog as part of the diagnosis and/or treatment for this tumor. No additional tissue beyond that required for diagnostic or therapeutic purposes will be removed from your dog for this study. Participation also will involve the donation of a small volume (10 to 20 ml) of blood from your dog that will be obtained at the same time that blood is drawn for other routine diagnostic procedures (complete blood count and serum chemistry profiles required for surgery). For healthy dogs that are first-degree relatives of dogs with cancer, only a blood sample will be taken.

4) How long will my and my dog's participation in the study last?

Participation in this study will include the regular admission and discharge procedures to a Veterinary Referral Hospital. Materials for this study (blood and tumor samples) will be obtained during the normal procedures for diagnosis and treatment of cancer that you have requested and approved for your dog. Donation of tumor tissue and blood will not lengthen your dog's hospital stay.

5) What are the benefits, if any, from joining this study?

The study will provide \$250 for each affected participant to defray portions of the costs associated with the biopsy procedures and the study also will pay for shipping costs and histopathology/immunohistology tests. Dogs will derive no direct benefit from participating in this study. Their care and treatment will be similar to that provided to cancer patients that are not included in this study. The results from this study may improve the outcome and quality of life of dogs with cancer in the future. Moreover, an improved understanding of the genetic basis of canine cancer may also lead to recommendations for judicious breeding practices and prevention strategies.

6) What is the possible discomfort or risk of allowing my dog to join the study?

Participation in this study will pose no additional discomfort or risk to your dog beyond that associated with the elective surgical procedure 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.

7) Are there other ways to treat my dog's disease or are there other ways to answer the research question?

There are many treatment options for cancer in dogs. Your veterinarian will explain the available options to you. The treatment protocols required to participate in this study are the "standard-of-care," that is, they represent the best options we know to induce remission and extend survival with acceptable (good) quality of life.

There is no other way to answer the research question. You can choose for your dog to receive an alternative treatment and to not participate in this study. This decision will not affect your dog's prognosis or the treatment that he or she receives from your veterinarian.

8) What will happen to the information the study keeps on my dog?

Donation of your dog's blood and tumor tissues will remain strictly confidential. Any publication or communication of results of any and all experiments performed with these materials will protect the anonymity of the donor. The AMC IRB and the AKC Canine Health Foundation may inspect the records for accuracy and scientific integrity.

9) What if my dog needs treatment due to problems in this study?

This study does not provide compensation or treatment for any accidental injury that may occur while your dog is a participant. Participation in this research project will help defray charges incurred for the diagnostic procedures through which samples for the study will be obtained (see item 5 above). Charges for approved services (sample acquisition, biopsy, shipping) will be billed to the grant from the AKC Canine Health Foundation that funds this project. AMC Cancer Research Center will not be responsible for compensation or care related to research projects.

10) What will happen if I say “No” to this study?

Allowing your dog to participate in this study is voluntary. However, by this consent, you agree to relinquish the rights to the cells, tissues, and any experimental results derived from their use for this study. If you decide not to allow your dog to participate now, or if you discontinue participation at a later time, you will not be penalized in any way. If you decide later to withdraw your dog from the study (terminate therapy), we ask that you notify the Principal Investigator in writing and state the reasons for withdrawal.

11) Are there reasons why my dog may be excluded from the research or for which my dog’s participation may be ended without my approval?

If the investigators cannot confirm the diagnosis of lymphoma or osteosarcoma using routine diagnostic procedures (analysis of the biopsy or additional special tests on the tumor), or if samples are acquired or shipped in a manner inconsistent with that described in the Procedures for Enrollment (attached), your dog may be excluded from the study. In the event that this were to happen, you will be notified and provided with any information pertinent to the diagnosis or treatment of your dog. You will not have to reimburse the study for any costs incurred. In addition, the principal investigator, Dr. Jaime F. Modiano, has the right to terminate this study at any time for any reason.

12) Are there costs that I will be expected to pay?

You will be responsible for all the customary charges from your veterinarian, including those incurred for diagnosis and treatment of your dog, but excluding those paid by the study that are described in item 5 above. The study will not pay for any portion of your dog’s treatment or additional tests, even when recommended by your veterinarian. Owners who choose to donate blood and the surgically-removed tumors from their animals will have no financial obligations to AMC Cancer Research Center related to the use of these materials for the research investigations described herein.

13) Will I be kept informed of research developments that might affect my or my dog’s participation in this study?

Significant new findings developed during the course of the research which may relate to your willingness to allow your dog to continue participation, or which may impact the prognosis or health of your dog, will be provided.

14) How many dogs will be included in this study?

We anticipate recruiting 150 eligible, affected dogs during the three years of the study.

15) What will my dog's blood and tumor sample be used for?

Samples will be used to verify the diagnosis and stage the tumor, and to obtain DNA, RNA, and proteins for further analysis. The DNA, RNA, and proteins will be used to analyze genes that may contribute to heritable cancer risk in the focus breeds and to identify genes that impact the prognosis to conventional treatments. This will generate information that may lead to strategies for prevention, as well as to development of new, more effective treatments.

16) For how long will my dog's samples be used?

In addition to using your sample(s) for this study, we would like to use your sample(s) for future studies. 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 who seek to improve the health of dogs and humans. Please indicate below (with your initials) your decision regarding the use of your samples.

_____ I approve the use of my sample(s) for this study only.

_____ I approve the use of my sample(s) for this study, as well as for future studies.

17) How will the identity of my dog's samples be protected?

The identity of dogs that participate in this study will not be shared with any registry. The Investigators will comply with all the customary practices of the sponsoring Parent Breed Clubs to protect the identity of every dog that participates in the study. However, you can choose to waive this and allow the Investigators to include your dog's name (without identifying last name or kennel name) and/or picture to be included in newsletters or other informational materials.

_____ I approve the use of my dog's name and/or picture for newsletters, web-based information, or other informational materials.

_____ I do not approve the use of my dog's name and/or picture for newsletters, web-based information, or other informational materials.

_____ I reserve the right to approve the use of my dog's name and/or picture for newsletters, web-based information, or other informational materials. If the need arises, I agree that the Investigators may contact me to explain the nature of the materials and I may choose to allow disclosure of my dog's name and/or picture at that time.

18) Who do I speak with if I have questions about the study?

To obtain more information about this study, you may call the Coordinator for the Institutional Review Board at AMC Cancer Research Center at (303) 239-3377 from 8 AM to 5 PM MDT. In addition, if you have questions regarding your participation in this study, you may call Dr. Jaime F. Modiano, the Principal Investigator of the study, at (303) 239-3408, or in writing at Center for Cancer Causation and Prevention, AMC Cancer Research Center, 1600 Pierce Street, Denver, CO 80214.

19) Who is responsible for protection of the dogs that participate in this study?

The Institutional Animal Care Committee at AMC Cancer Research Center has reviewed this study.

I, _____, have read this Consent Form. The content of this form and the nature of the research have been made clear to me. I have been given a copy of this form. I have had an opportunity to ask questions about the project and understand that I can ask questions at any time. I agree to allow my dog, _____, to participate in this study. Furthermore, I agree to donate to Dr. Jaime F. Modiano of the AMC Cancer Research Center blood and tumor 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 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. If I have any questions or problems which I feel are related to the study, I can contact the Principal Investigators whose names are on this form.

Signature of Owner or Agent _____

Date _____

Signature of Investigator _____

Date _____

Person Obtaining Consent _____

Date _____

(Attending veterinarian or representative)