

GENETIC INVESTIGATION OF CANINE CANCERS

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INFORMED CONSENT FOR PARTICIPANTS

Lymphoma, Osteosarcoma, Hemangiosarcoma, Melanoma, Mast Cell Tumor, Bladder cancer.

Please initial the bottom of pages 1-4 to acknowledge that you have read and understand items 1-15 and complete pages 5 and 6 in clear writing. All six pages should be submitted along with the samples being submitted.

1) Who is conducting the study?

This study involves research being conducted by Dr. Matthew Breen at the College of Veterinary Medicine, North Carolina State University. The study is funded by grants from the AKC Canine Health Foundation, Morris Animal Foundation and by the NIH.

2) Why is this study being done?

This project is looking at two complimentary areas of cancer research

- 1) Identification of changes to genes that occur when a dog is affected by cancers.
- 2) Identification of specific regions of the canine genome that indicate predisposition of dogs to develop cancers.

The six cancers of interest in this study are lymphoma, osteosarcoma, melanoma, mast cell tumors and bladder cancer

It has been established that non-random chromosome aberrations are characteristic of specific types of many different cancers. The knowledge of such aberrations has identified areas of the human genome to be targeted for further research. In the dog the extent and identity of chromosome aberrations associated with specific cancers are still largely unknown. In ongoing studies of canine cancers we have defined regions of the canine genome that are associated with specific chromosomal aberrations and need to investigate additional cases to better define these regions and the genes they contain. In addition, studies that look at DNA polymorphisms across the entire genome, comparing dogs without and with cancer, have begun to define regions of the canine genome that identify dogs at high risk of developing cancers.

This project is using major recent advances in canine molecular cytogenetics and genome analysis to identify genes associated with canine cancers.

3) How will this study involve my dog?

If your dog is diagnosed with one of the six cancers listed above (diagnosis must be made by a licensed veterinarian) or is a first-degree relative (parent, sibling, offspring) of a dog diagnosed with one of these cancers, we are asking for you to allow your dog to participate in this study.

If your dog is a cancer free senior of the breed we also ask for blood samples.

Your dog may be eligible for one of three reasons:

A. For dogs diagnosed with lymphoma, osteosarcoma, melanoma, mast cell tumors and bladder cancer - participation will involve obtaining a small blood sample (5ml) and two samples of the tumor, prior to any chemotherapy treatment. One tumor sample needs to be placed in formalin and one in either transport medium (supplied) or a sterile container (if transport medium is not available). All three samples will be used for research purposes. In general your veterinarian will take a sample of the tumor as part of the routine diagnostic procedure. We ask that some of this tumor also be sent to us for use in this study. We also require a copy of the official pedigree of your dog and a copy of any pathology report relating to the tumor.

B. For dogs with a first-degree relative that has been diagnosed with lymphoma, osteosarcoma, melanoma, mast cell tumors and bladder cancer - participation will require the submission of a small EDTA blood sample (5ml), which may be taken by your veterinarian during your dog's annual health examination, a copy of the official pedigree and a copy of the pathology report relating to the diagnosis of the tumor in the first degree relative (you should be able to obtain this from your veterinarian).

C. For 'senior' dogs that are cancer free participation will involve obtaining only a small blood sample (5ml) and submitting this along with a copy of your dog's official pedigree.

It is important that if your healthy dog does develop cancer subsequent to being submitted as a 'cancer free' dog that you contact us and let us know. We will need details of the cancer type.

4) 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.

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

Individual dogs will derive no direct benefit from participating in this study. Their care and treatment will be no different to that provided to cancer patients that are not included in this study. The results from this study may help us to 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) How long will the study continue?

The study is part of an ongoing study that has been funded since 2004. We anticipate recruitment of new cases will be ongoing. Cessation of recruitment will be posted on the lab web site.

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

Donation of blood and tumor tissues from your dog 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. Funding agencies may inspect our records for accuracy and scientific integrity.

8) What will happen if I change my mind?

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 later to withdraw your dog from the study we ask that you notify the Principal Investigator in writing and state the reasons for withdrawal.

9) *Are there reasons why my dog may be excluded from the research?*

If the investigators cannot confirm the diagnosis of the cancer as submitted 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's samples may be excluded from the study. In addition, the principal investigators may terminate this study at any time for any reason.

10) *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. The study has no funding to pay for any portion of your dog's treatment or additional tests. Owners who choose to donate blood and the surgically removed tumors from their animals will have no financial obligations for use of these materials for the research investigations described herein. Since we would rather use limited research funds to perform the study, we ask that you be responsible for ensuring that the blood and tumor samples are sent to Dr. Breen by overnight courier and the cost associated with this. If this cost is beyond your means, please contact info@breenlab.org to enquire about availability of funds to help with this cost. The lab does not have funds but we may be able to connect you within your breed that does.

11) *How many dogs will be included in this study?*

We anticipate recruiting at least 200 eligible tumor samples, and paired blood samples, together with their relatives, during this study. In addition we anticipate recruiting up a minimum of 30 unaffected 'seniors' for each of 10 breeds.

12) *What will my dog's blood and tumor samples be used for?*

The tumor sample submitted in formalin will be used to verify the diagnosis and stage of the tumor. The tumor sample submitted in a sterile tube (+/- sterile transport medium) will be used obtain tumor DNA, RNA and tumor cells, which will allow us to identify genetic changes associated with the tumor. The DNA obtained from the blood sample will act as a normal reference sample for that animal and will also be used to identify inherited risk factors. This will help us identify genes that impact the prognosis with conventional treatments and will generate information that may lead to strategies for prevention, as well as to development of new, more effective treatments.

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

In addition to using your sample(s) for this study, we may use samples submitted for this project also for future studies by ourselves and possibly by other bona-fide health researchers who seek also to improve the health of dogs and humans. These studies may include assessment of new genes that may be unknown at this time and development of treatments based on characteristics peculiar to these tumors. Sharing of samples will maximize the potential benefit derived from your dog's samples.

If you are submitting a blood sample from a cancer free dog we ask that you contact us if your dog subsequently develops a cancer. It is vital for this work that samples from cancer dogs are re-categorized as cancer patients if this happened.

If you are submitting samples from a cancer patient, we also need to know if your dog develops additional cancers.

In both cases, we may contact you periodically to ask about the health status of your dog.

14) 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 [please initial one option below]

_____ 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.

15) With whom do I speak if I have questions about the study?

To obtain more information about this study, you may contact

- Dr. Matthew Breen, the Principal Investigator of the study, preferably via e-mail at info@BreenLab.org

or by telephoning the Canine Genomics Lab at 919-513-1466

(NOTE: please leave a detailed message and call back number and we will return your call within 24 hrs)

or by regular mail at

Breen-Lab
Room 330, CVM Research Building
College of Veterinary Medicine,
North Carolina State University,
1060 William Moore Drive,
Raleigh,
NC 27607.

I, _____ (enter your name) have read this Consent Form and the nature of the research has 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, _____ (enter dog's name), to participate in this study. Furthermore, I agree to donate to Dr. Matthew Breen, of the College of Veterinary Medicine at North Carolina State University, tumor tissues and/or blood removed from my dog during the normal course of diagnosis and treatment for his/her 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. I agree 1) to notify the Principal Investigator if the health status of my dog changes, and 2) to be contacted by the Principal Investigator, or his agent, periodically to inquire about the health status of my dog. If I have any questions or problems that I feel are related to the study, I can contact the Principal Investigator whose name is on this form.

Signature of Owner or Agent _____

Date ____ / ____ / ____ Breed of dog _____

Call Name of dog _____

AKC Registration number _____

Sex of dog _____ Date of birth ____ / ____ / ____ Age at submission _____

Name and address of owner (please print clearly)

Contact telephone number:

Fax:

E-mail:

- OWNER PLEASE COMPLETE EITHER SECTION A, B or C
- VETERINARIAN, PLEASE COMPLETE SECTION D

A. My dog is being submitted as a cancer patient with a diagnosis of

(please check appropriate box)

- Lymphoma Osteosarcoma Hemangiosarcoma
 Melanoma Mast Cell Tumor Bladder cancer

Anatomical site(s) of tumor sample(s) submitted _____
(please label anatomical site on each collection tube)

Or **B. My dog is being submitted as a _____ of**
(please enter relationship to dog in study already)

(please enter name of the dog already in this study)

Or **C. My dog is being submitted as a cancer free senior of the breed**

Date of birth = Age at submission = Breed =

Veterinarian's details

D.

Person Obtaining Consent _____
(name of attending veterinarian or his/her representative)

Date ____ / ____ / ____

Name and address of Veterinary Practice/Hospital (please print clearly or use business stamp)

Telephone : ()

Fax : ()

E-mail:

PLEASE RETURN
THIS FORM TO:

**BREENLAB
Cancer Genomics Project
NCSU College of Veterinary Medicine
CVM Research Building (Room 330)
1060 William Moore Drive,
Raleigh,
NC 27607
Tel. 919-513-1466
Fax: 919-513-7301**