

PARTICIPANTS NEEDED FOR RESEARCH ON CANINE CANCER

THE STUDY

The research project “*Heritable and Sporadic Genetic Lesions in Canine Lymphoma and Osteosarcoma*” is part of Dr. Jaime Modiano’s laboratory program “**Genetics of Canine Cancer**”. This program is part of a collaborative effort between Dr. Modiano at the AMC Cancer Research Center in Denver, CO and Dr. Matthew Breen at North Carolina State University in Raleigh, NC; it is supported by the American Kennel Club Canine Health Foundation (AKC CHF Grant 2254) along with several breed clubs and animal health organizations. The purpose of the project is to determine how genes impact the development of cancer in dogs. Specifically, the researchers will study abnormalities in genes and chromosomes in **canine lymphoma** (cancer of white blood cells in the lymph glands) **and osteosarcoma** (bone cancer), to determine if these abnormalities are inherited, and to assess their clinical significance (that is, if they are predictive regarding response to treatment and prognosis).

PARTICIPANT REQUIREMENTS

Golden Retrievers, Rottweilers, and Mastiffs with known pedigrees can participate in this study. Dogs from other breeds require prior approval from one of the investigators. The affected dog(s) can be male or female (intact or neutered), and 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), or appendicular stage I or II osteosarcoma (no evidence of metastatic disease) from a licensed veterinarian. There must be at least two unaffected first-degree relatives (parents, siblings, or offspring) of the affected dog that will consent to participate (through donation of >10 ml of EDTA-anticoagulated blood). Owners of affected dogs will sign informed consent forms authorizing pre-treatment excisional biopsies, and committing to treat the affected dog with an acceptable protocol (e.g., the “Wisconsin” protocol for multicentric lymphoma or limb amputation and systemic chemotherapy for appendicular osteosarcoma) at least until it can be determined if remission is achievable. Dogs who have been previously treated are not eligible for the study.

PROCEDURES

Enrollment will open on or about June of 2002 and continue until approximately December of 2004. 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 are requested and approved by the owner of the dog. The following steps must be followed precisely to facilitate enrolment and proper treatment of samples:

1. The owner and/or attending veterinarian must contact Dr. Jaime Modiano at the AMC Cancer Research Center in Denver at least 24 hours prior to surgery or biopsy procedures. No participants can be enrolled without prior approval from one of the investigators.
2. The owners of the affected dog must read and sign an informed consent form (available from Dr. Modiano), and must submit a copy of the dog's pedigree.
3. Contact information for at least two individuals who own first-degree relatives (parents, sibs, offspring) of the affected dog who will be willing to participate in the study must be provided.
4. Dr. Modiano's laboratory personnel will send special shipping media, materials, and pertinent instructions by overnight courier to the attending veterinarian.
5. A viable tumor sample must be obtained using aseptic technique (surgery or biopsy) by a licensed veterinarian. This sample must be placed into the sterile containers containing the shipping media and returned to Dr. Modiano's laboratory by overnight courier. Samples are generally not received on Saturdays or Sundays. Since samples will undergo degradation upon prolonged storage, we request that procedures performed on Fridays be avoided, whenever possible.
6. A blood sample (10 - 15 ml) must also be submitted in EDTA ("purple-top" tubes) in an appropriate shipping container.

For additional information contact Dr. Modiano at 303-239-3408 or at modianoj@amc.org. Information and updates will also be posted on the AMC Cancer Research Center web site (www.amc.org), possibly as early as October of 2001.

COMPENSATION FOR PARTICIPATION AND FOR THERAPY OR INJURIES

The study will not provide compensation or treatment for any accidental injury that may occur while a 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:

1. The study will provide \$250 for each affected participant to defray portions of the costs associated with the biopsy procedures. Formalin-fixed samples or samples submitted in any fashion other than that described above are unsuitable for the study and cannot be accepted.
2. The study will pay for shipping costs and for histopathology/immunohistology tests. Results will be sent by fax to the attending veterinarian.

INSTRUCTIONS TO VETERINARIANS

- Blood samples and tumor tissue will need to be submitted at the time of diagnosis. For all cases, it also will be necessary to obtain tissues at the time of death or necropsy.
- Histopathology support will be provided exclusively by IDEXX laboratories in Broomfield, CO. Special tests may be performed by IHC Services in Smithville, TX, or other commercial or academic laboratories at the discretion of the investigators. Any information that has diagnostic relevance will be communicated to the referring veterinarian in a timely manner.
- Owners of unaffected sibs or first degree relatives must be contacted to arrange for donation of blood for each participant recruited.
- Veterinarians must contact the Principal Investigator ahead of time to arrange FedEx or other billing associated with sample submission.
- We will require follow-up information on each patient, including specific treatment protocol, time to remission, disease-free interval, condition and time of relapse (if applicable), survival time, and cause of death. We will make every effort to contact you regularly to obtain information on this patient, or you can fax updates from the medical record to Dr. Modiano at 303-239-3560.

For more information, contact the Principal Investigator, Dr. Jaime Modiano at 303-239-3408 or 303-239-3587.

SPECIFIC INSTRUCTIONS FOR SAMPLE SUBMISSION:

Peripheral blood samples: two to three EDTA tubes (5 ml each) shipped at room temperature. Samples can be shipped by regular mail. If blood is shipped with additional samples in formalin, please isolate the blood tubes in a sealed, impermeable (e.g., Ziplock) bag.

Tumor samples: we require fresh, sterile, viable tissues for this study. It is imperative that tissues be obtained from viable areas, as necrosis will hinder our ability to use the samples. Sterile, viable tissue allow for the establishment of immortalized cell lines that can be used in the laboratory for years to come to study the processes that lead to cancer, as well as to develop novel therapies. A large enough sample of viable tissue allows the investigators to allocate a suitable sample for fixation and histopathology, so it is not necessary to submit fixed tissues.

Collection of viable tissue requires exceptional attention to detail and aseptic technique. The excised, sterile tumor must be placed in a sterile container with a sterile support medium (provided by the investigators as tissue culture media with antibiotics). If the tumor sample is too large to fit in the container (conical tube) provided, it can be cut into smaller sections using sterile instruments while the tumor is placed on a sterile surface (for example, a sterile sponge or the surgical drape). The tissue must never contact a non-sterile surface (for example, the operating table or the instrument table). Sterile saline (0.9% NaCl) is unacceptable as transport media because the lack of a pH buffer makes the solution acidify rapidly, diminishing the viability of the tissue.

The container (tube or tubes) with the sterile tumor sample should be placed on ice (a suitable ice pack for shipping) immediately and shipped overnight via Federal Express, observing all regulations for shipping of viable tissues. The Principal Investigator has a dedicated account at AMC Cancer Research Center to cover shipping costs. Please contact for instructions. Also, please contact the Principal Investigator in advance to arrange sample processing immediately on arrival.

PLEASE NOTE: ELIGIBILITY CRITERIA REQUIRE SUBMISSION OF VIABLE TISSUES FOR PARTICIPATION.

For more information, contact the Principal Investigator, Dr. Jaime Modiano at 303-239-3408 or 303-239-3587.