

# **PARTICIPANTS NEEDED FOR A NEW STUDY ON EARLY DETECTION AND RISK ASSESSMENT OF CANINE OSTEOSARCOMA**

The COED (Canine Osteosarcoma Early Detection) study will open for enrollment at the University of Minnesota on August 22, 2022.

## **Purpose**

Osteosarcoma is a common disease of dogs, with tens of thousands of new cases diagnosed each year in the United States. This disease is treatable, but not curable. Even with the best available standard of care, about 65% of dogs with osteosarcoma will die or be euthanized due to their disease within one year of diagnosis, more than 80% within two years, and more than 90% within three years.

The COED study (Canine Osteosarcoma Early Detection), supported by the Irish Wolfhound, Rottweiler, Great Dane, Golden Retriever, Irish Setter, and Leonberger breed foundations/clubs and by the AKC Canine Health Foundation (AKC CHF grant 03032-MOU), is designed to develop a reliable, minimally invasive blood-based test for early detection and risk assessment of canine osteosarcoma. Such a test could then be combined with strategic and rationally designed treatments to kill the tumors before they form. Since all large and giant dogs have an elevated risk of bone cancer, this work has the potential to benefit a multitude of breeds, as well as mixed-breed dogs. This study will recruit up to 400 large-breed dogs from a variety of backgrounds.

## **Eligibility**

Dogs eligible for this study must:

- Be of one of these six breeds: Irish Wolfhounds, Rottweilers, Great Danes, Golden Retrievers, Irish Setters, and Leonbergers, **OR:**
- Be from other large and giant breeds, or large and giant dogs of mixed breeding, ***weighing more than 30 kg (66 lbs.) with a body condition score less than or equal to 6 out of 9 (as attested by a veterinary health professional)***
- Be at least 4.5 years old
- Be currently healthy: no cancer, no undiagnosed “lumps or bumps” (***including inside the oral cavity***), no serious chronic health conditions – and still have their spleen
- Never have been diagnosed with any cancer
- Live in one of the contiguous 48 states of the United States of America (samples from Alaska and Hawaii and international samples, including from Canada and Mexico, cannot be accepted due to shipping constraints)

## Owners' responsibilities prior to enrollment

Owners who are interested in having their dogs participate in this study should:

1. Communicate with their veterinary clinics about the COED study. When a dog is enrolled, staff from the Modiano Lab (University of Minnesota) will send the vet clinic a sample collection kit with supplies and instructions for collecting whole blood, serum, and plasma. The samples *must* be overnighted back to the Modiano Lab as indicated in the instructions and in the packaging provided, via FedEx. This means that the dog's vet clinic *must* be able to process plasma and serum in house and *must* be able to arrange to have FedEx pick up the samples the same day *for overnight shipment*. If the clinic cannot schedule a pickup for overnighting, owners *must* be able to deliver the samples to a FedEx office for overnighting on the same day the samples are collected.
2. Understand what costs sample submission may incur. There is no cost to participate in the study, and the study pays the costs for shipping the sample collection kits both ways. However, owners may incur costs from their veterinary clinic for collecting and processing the samples. In addition, there may be costs incurred for weighing the dog, determining a body condition score, measuring the dog's accurate height, filling out the paperwork, and examining the dog to attest that it is generally healthy and free from undiagnosed "lumps or bumps." For "attested to by a veterinary professional", a vet tech appointment is acceptable if that is all that is required for these services at the veterinary clinic where the dog will be examined and the samples will be obtained. For questions, the clinic staff can contact the Modiano Lab (+1-612-626-8452) or Dr. Modiano directly ([modiano@umn.edu](mailto:modiano@umn.edu)).

## Enrollment

Once interested owners have determined that they are able to submit the samples as described above, they can visit the link below to fill out a short eligibility questionnaire for their dog:

<https://z.umn.edu/COED>

The eligibility questionnaire must be filled out in its entirety for each dog enrolled. The questionnaire will show an alert if the dog does not meet the eligibility requirements or if questions have been left unanswered. When the dog's owner or responsible individual completes a questionnaire for an eligible dog, they will receive an automated email to confirm that answers have been recorded and an email or phone call will follow for scheduling.

**NOTE:** If you believe you have completed the questionnaire but didn't receive an automated email, be sure to check your spam or junk folders.

Enrollment will be randomized, so every owner who completes a request during the open enrollment phase will have the same probability of being selected. At this time, enrollment requests are expected to be accepted starting on (or about) August 22, 2022, and at least through the end of December of 2022.

## Scheduling

The study is expected to enroll new cases for at least 18 months after it opens. The health of enrolled dogs will be monitored with periodic emailed surveys for at least 1-1/2 years thereafter, and, ideally, for the duration of the participating dog's lifetime. To maximize the likelihood of success of this project, it will be imperative for owners to return the surveys promptly. ***Due to shipping constraints and the number of samples per week that the study can process***, it is important for owners to be patient as they wait for contact to schedule their enrolled dogs.

When contacted, owners will be asked to make their appointment at their vet clinic early in the day on one of the dates offered by the Modiano Lab staff, which will be on a Monday, Tuesday, or Wednesday. In order that the limited weekly slots for samples can be filled, owners should please make appointments ASAP and ***confirm that they have made their appointment in an email reply which should include the vet clinic's shipping information: contact name at the clinic, clinic name and address, and clinic phone number***, which the Modiano Lab staff will need to send sample collection materials. If any owner is unable to schedule an appointment for any of the dates offered, the Modiano Lab staff will make every effort to continue working with them find one than does.

A consent form will be attached to the contact email. Owners will need to fill it out completely, ***initialing the bottom of each page***, and signing the last page. They must then take it with them to the sample collection appointment, give it to the vet or tech collecting the samples to sign and date the last page, and ask them to include the entire form with the samples.

**NOTE:** The COED Study **is not intended as a diagnostic for disease**. It is an experiment to determine whether the blood/plasma/serum test can be used as a tool for early detection and risk assessment of osteosarcoma. Neither owners nor veterinarians will receive a diagnostic report.