

OWNER CONSENT FORM

“Genetic Basis of Tricuspid Valve Dysplasia in Labrador Retrievers”

Sections of Cardiology and Medical Genetics, University of Pennsylvania School of Veterinary Medicine
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Official Use Only - This protocol has been approved by the Ryan –VHUP Privately –Owned Animal Protocol Committee and the University of Pennsylvania Institutional Animal Care and Use Committee. POAP #231.

As the owner or duly authorized agent for the owner of _____ (pet name) you are being asked to have your pet participate in a study to collect DNA from dogs affected with Tricuspid Valve Dysplasia (TVD), and their unaffected relatives, in order to discover the genetic basis of this disease and to develop genetic markers that could help eliminate the disease. Before giving your consent to your pet's participation, please read the following, ask as many questions as needed to understand what your participation involves, and fill out, sign, and date the statement at the end of this document.

DISEASE DESCRIPTION

Tricuspid valve dysplasia is congenital heart disease resulting from malformation of tricuspid valve leaflets, chordae tendinae, or papillary muscles. These structural changes in the heart valves lead to varying degrees of tricuspid regurgitation and the clinical sign of a heart murmur. Clinical signs may or may not be evident at a young age depending on the severity of the disease. Ultimately, significant valve leakage may lead to congestive heart failure. Labrador Retrievers as a breed have a high rate of congenital malformation of the tricuspid valve and TVD is suspected to be inherited in this breed.

PURPOSE OF STUDY

I certify that I am over the age of 18 and hereby grant permission for my pet to participate in a study designed to collect DNA from dogs and their relatives affected with TVD, in order to determine the genetic basis for this disease.

DESCRIPTION OF PROCEDURES

I understand that in the course of this study, the investigators may obtain and use blood from my pet to further their understanding of the disease and facilitate genetic testing. I consent to the use of the blood and will provide a pedigree and requested medical information concerning my dog, provided that neither my animal nor I are identified in any publications, reports or presentations without my written authorization. I also give consent for the investigators to contact the individuals indicated below, who are the breeders of my dog or owners of dogs that are related to my dog.

I understand that the investigators are requesting the hearts from dogs that pass away. This request is voluntary, I may decline and my dog is still able to participate in the study. If I agree and my dog passes away, I will have my veterinarian remove my dog's heart after death, preserve it and send it to the investigators.

RISKS ASSOCIATED WITH PROCEDURE

This study requires that up to 10 ml of blood be obtained from my pet to obtain DNA. The risk involved in drawing blood is minimal. However, my dog may experience mild redness or bruising at the collection site. Additionally, the hair may be shaved/clipped in some cases to facilitate visualization of the vein. I have chosen the veterinarian who will be performing this procedure, and will not hold the University of Pennsylvania responsible for any complications associated with drawing the blood.

TREATMENT AND POTENTIAL BENEFITS

I understand that there is no guarantee that my pet will benefit from its participation in this study. However, such participation may provide veterinarians with additional information and a better understanding of TVD and, ultimately, this may influence the course of treatment or genetic testing to help other dogs in the future.

COSTS AND BENEFITS TO OWNER

I understand that the University of Pennsylvania is currently requesting funding to support this research and can not cover the costs of drawing blood from my animal or the shipping costs involved. I am volunteering to cover these costs to support research on this heart condition with hopes that in the future, the knowledge gained will allow this disease to be more effectively detected and eliminated from the canine population. In the event that DNA from my pet is used in the development of commercially available diagnostic markers or medical or surgical treatments, I understand and agree that any proceeds or benefits from such development are the sole and exclusive property of the University of Pennsylvania, and that my dog will have access to any publically available tests or procedures.

CONFIDENTIALITY

I understand that any information about my pet, obtained from this study, will be kept confidential. No information by which my pet can be identified will be released or published without my written authorization.

AUTHORIZATION- "Genetic Basis of Tricuspid Valve Dysplasia in Labrador Retrievers"

I have read and understand the foregoing statements and agree to allow my pet to participate in this study, including donation of a blood sample for DNA isolation. If I have additional questions regarding this study, I may phone or fax the principal investigators at the numbers listed above. To the best of my knowledge, the information I have supplied below is accurate. Upon signing below, I am free to make a copy of this consent form.

Dog Information

Pet's Registered Name: _____

Call Name: _____ AKC#: _____

Chip #: _____ Date of Birth: _____ Sex (circle): M / F Intact / Neutered

Breed: _____ Coat Color: _____

Sire's Name: _____ AKC #: _____

Dam's Name: _____ AKC #: _____

Is your dog related to any dog that has been diagnosed with TVD or is a sire or dam of a TVD puppy?

Yes No (check) If yes, please state the relationship of your dog to a TVD-affected dog (please be specific and provide a pedigree)

Owner Information

Owner's Name: _____

Address: _____

Phone (day): _____ (evening/cell) _____

Fax: _____ E-mail: _____

Breeder Information

Owner's Name: _____

Address: _____

Phone (day): _____ (evening/cell) _____

Fax: _____ E-mail: _____

Signatures - REQUIRED

Yes No (check) - Upon my dog's death, I will have my veterinarian send the dog's heart (preserved in formalin) to Dr. Sleeper at the University of Pennsylvania.

Today's Date: _____

Client/Owner/Agent's Signature: _____

Client/Owner/Agent's Printed Name: _____

SAMPLE SUBMISSION-Instructions for Veterinarians and Owners/Shipping Instructions

Genetic Basis of Tricuspid Valve Dysplasia (TVD) in Labrador Retrievers

Thank-you for participating in this study, which requires a DNA sample (in the form of blood) from your dog/patient. In order to investigate the genetic basis of the disease, it is necessary to obtain DNA from affected as well as unaffected relatives of affected dogs (siblings/littermates, offspring, parents, and grandparents).

The blood supplied by you will be used to understand the cause of TVD in dogs, and to develop genetic approaches to detect the carrier animals. This will allow breeders to make breeding choices that can eliminate this disease from their breed.

Please follow these instructions to obtain a DNA sample and remember to provide all the necessary information when you send your animal's sample. If you have further questions, please feel free to contact us via email at cmichel@vet.upenn.edu or call at 215-898-3331 or 215-898-8894.

BLOOD SAMPLE COLLECTION:

1. Label EDTA purple top tubes, enough to hold 10mL of whole blood (one 10mL tube, 5 tubes of 2mL each, or 4 tubes of 3 mL each, depending on availability), with owner's last name and animal's call name (or AKC#).
2. If the dog weighs more than 10 pounds, draw a 10mL blood sample and fill the pre-labeled EDTA tubes. Tubes should be rocked gently to distribute anticoagulant, but should NOT be centrifuged. (Draw 1 ml/kg for puppies weighing less than 10 pounds.)
3. The blood sample must be kept cold but not frozen, just refrigerate until shipped.
4. Ideally, the sample should be sent as soon as possible following the blood draw, by overnight delivery keeping it as cool as possible using a cold pack (freezer pack), however the blood does *not* need to be frozen.

If for some reason the sample must be held for greater than 4 days, please freeze the sample after placing the blood tubes in sealable plastic bags (in case the glass tubes break during freezing).

5. Ship tubes by overnight delivery. Place samples in a small, insulated container, and include one or more frozen cold packs. Please provide adequate packaging to protect the tubes. Your veterinarian may have special styrofoam containers or cardboard mailers and you can use a Ziplock™ bag in bubble wrap for protection.

INCLUDE APPROPRIATE FORMS:

Please make sure that each sample is labeled with the dog's call name and the owner's last name. Include the completed and signed **Owner Informed Consent Form**, the dogs' **Pedigree**, and documentation from your veterinarian showing a **confirmed diagnosis of your pet's heart condition**.

SHIPPING:

Ship using overnight delivery. Please do NOT send samples on a Friday as they cannot be delivered on Saturday.

Please ship to:

Paula Henthorn/TVD
Section of Medical Genetics, Room 4030 Ryan Vet. Hosp.
University of Pennsylvania School of Veterinary Medicine
3900 Delancey St.
Philadelphia, PA 19104-6010
Phone no. (required by FedEx): 215-898-8894