

## Informed Owner Consent Form

### Blood-based cardiac biomarkers for the assessment of heart enlargement in Cavalier King Charles spaniels with pre-clinical myxomatous mitral valve disease

Sonya Wesselowski, DVM, MS, DACVIM (Cardiology), Assistant Professor  
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#### 1. Purpose of the project

The purpose of this study is to identify the results of a blood test (cardiac biomarker) that predict the severity of heart enlargement in Cavalier King Charles spaniels (CKCS) with asymptomatic myxomatous mitral valve disease (MMVD).

#### 2. Eligibility for participation

Clinically healthy CKCS that are not receiving any cardiac medications, have never had clinical signs of cardiac disease (lethargy, exercise intolerance, persistent cough, labored/heavy breathing, fainting episodes) and do not have an active or chronically managed non-cardiac illness that could impact the cardiovascular system are eligible. Dogs with heart murmurs not compatible with MMVD and dogs that are too stressed to complete the evaluation are not eligible.

#### 3. Expected duration of participation

A single evaluation of approximately 2-4 hours duration.

#### 4. Description of procedures

On the day of enrollment, a brief history will be taken and a brief physical examination will be performed. The procedures below will be performed without sedation.

- 1.) Blood pressure: Will be measured with a cuff around a leg. A small area of hair will be clipped on the underside of the paw where the cuff and coupling gel will be placed.
- 2.) Chest x-ray: Dogs will be gently restrained on their side and a digital chest x-ray taken.
- 3.) Echocardiogram (cardiac ultrasound): Dogs will be gently restrained on their right and left sides. Hair will be clipped on both sides of the chest and an ultrasound probe with gel will be placed against the skin to obtain images.
- 4.) Blood sampling: Approximately 10-15 mL of blood (2-3 teaspoons) will be collected from a superficial vein in the neck or leg.
- 5.) Recording of heart sounds: A recording of heart sounds will be obtained using a digital stethoscope with the dog standing.
- 6.) Recording of an electrocardiogram (ECG): While dogs are lying on their side, a small device (AliveCor) will be gently held against the side of the chest over the heart to record the heart rhythm for 1 minute.

Owners will receive a written report detailing the pertinent results of the echocardiogram, chest x-ray, and blood pressure measurement, including a recommendation for follow-up or medication that can be provided to the regular veterinarian.

Date \_\_\_\_\_

Owner/agent initials \_\_\_\_\_

*It is the responsibility of the Primary Investigator (PI) to retain the **signed** copies of all consent forms for a period of five (5) years, as is standard within the Texas A&M University System.*

## 5. Possible discomforts and risks

Blood collection: A small amount of swelling and/or bruising may occur at the site of blood collection. If this were to occur, it would most likely resolve within 24 hours.

Echocardiogram: Hair must be clipped to perform the echocardiogram. In very rare cases, the hair does not grow back or, if it does grow back, it has a different color. Dogs must lie quietly on a raised table for the procedure and are gently restrained. Most dogs tolerate this very well. Dogs who cannot cooperate for this procedure will be excluded from the study.

Blood pressure: Hair must be clipped on the underside of the paw. In very rare cases, the hair does not grow back or, if it does grow back, it has a different color.

## 6. Possible benefits of study

Your animal may receive no direct benefits from participation in this study.

## 7. Alternative diagnostics, procedures, or treatments

None.

## 8. Confidentiality

Owner and patient confidentiality will be maintained. No identification of individuals shall be made when reporting or publishing the data arising from this study.

## 9. Financial obligations

There are no financial obligations by the owner to Texas A&M University for participation in this study. However, the owner will be responsible for all other costs associated with the assessment, diagnosis, and/or treatment of the participating animal.

## 10. Compensation or therapy for accidental injury or complications

In the event of complications or accidental injuries associated with this study, the owner of any participating animal is financially responsible.

## 11. Primary contact person

To obtain further information regarding this study contact:

Dr. Sonya Wesselowski  
Department of Small Animal Clinical Sciences  
College of Veterinary Medicine & Biomedical Sciences  
Texas A&M University  
4474 TAMU  
College Station, TX 77843-4474  
979-845-2351  
swesselowski@cvm.tamu.edu

## 12. Participation and right to withdraw

Enrolling your animal for participation in this study is voluntary, and refusal to participate involves neither penalty nor loss of care to which your animal is otherwise entitled. You have the right to withdraw your animal from the study without penalty at any time and for any reason.

Date \_\_\_\_\_ Owner/agent initials \_\_\_\_\_

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**13. Termination of participation by principal investigators**

The investigators have the right to terminate the study for any or all participants at any time and for any reason.

**14. Unforeseen risks**

Unforeseen risks might arise at any time during the study. The investigators will promptly inform you of any new information that may affect your willingness to continue to have your animal participate in the study.

Date \_\_\_\_\_

Owner/agent initials \_\_\_\_\_

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## INFORMED OWNER CONSENT

### Blood-based cardiac biomarkers for the assessment of heart enlargement in Cavalier King Charles spaniels with pre-clinical myxomatous mitral valve disease

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Sonya Gordon, DVM, DVSc, DACVIM (Cardiology), Associate Professor

I, \_\_\_\_\_ (name), of

\_\_\_\_\_ (address)

\_\_\_\_\_ (City, Zip)

hereby consent to the participation of the following animal in the study cited above. I certify that I am the legal owner (or agent of the owner) of, and am responsible for this animal. I have read, received a copy of, and understand the Informed Owner Consent Form.

#### Animal Details

Name: \_\_\_\_\_

Breed: \_\_\_\_\_

Age: \_\_\_\_\_

Signature of Owner or Agent: \_\_\_\_\_ Date: \_\_\_\_\_

Signature of Investigator: \_\_\_\_\_ Date: \_\_\_\_\_

Witness: \_\_\_\_\_ Date: \_\_\_\_\_

#### **I have received a copy of the consent form**

\_\_\_\_\_

This consent form has been reviewed and approved by the Clinical Research Review Committee of the Texas A&M University College of Veterinary Medicine & Biomedical Sciences (CVM).

**For questions about this study**, please contact Dr. Sonya Wesselowski, Dept. of Small Animal Clinical Sciences; CVM; Texas A&M University; 4474 TAMU; College Station, TX 77843-4474; 979-845-2351; [swesselowski@cvm.tamu.edu](mailto:swesselowski@cvm.tamu.edu)

**For questions regarding your rights as the owner of a participating animal**, please contact Dr. Robert Burghardt, Associate Dean for Research and Graduate Studies; CVM; Texas A&M University; 4461 TAMU; College Station, TX 77843-4461; 979-845-5092; [crcc@cvm.tamu.edu](mailto:crcc@cvm.tamu.edu)

Date \_\_\_\_\_

Owner/agent initials \_\_\_\_\_

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## INTAKE FORM

Client Name:

Address:

Phone Number:

Email Address

Primary Care  
Veterinarian

Doctor:

Phone Number:

Clinic Name:

Address:

Dog's Name:

Date of birth:

Coat color (circle)

Blenheim

Tri-color

Black & Tan

Ruby

Sex (circle)

Intact Female

Spayed Female

Intact Male

Neutered Male

Does your dog take the following medications? Please circle YES or NO.

1. Furosemide/Salix/Lasix

YES

NO

2. Pimobendan/Vetmedin

YES

NO

3. Enalapril/Benazapril

YES

NO

Does your dog receive heartworm prevention?

YES

NO

If YES, please write in the type of heartworm prevention you give:

Please list all current medications/supplements your dog receives:

Has your dog been diagnosed with any chronic illness? If yes, please list here:

Does your dog:  
Please circle YES or NO.

1. Have a cough?

YES

NO

2. Have breathing difficulty?

YES

NO

3. Currently have an abnormal activity level at home?

YES

NO

4. Have a history of fainting spells?

YES

NO

5. Currently have an abnormal appetite?

YES

NO

**IF YOU ANSWERED YES TO ANY OF THE QUESTIONS ABOVE, PLEASE PROCEED TO THE ASSOCIATED QUESTIONS ON PAGE 2.**

<p><b>1. COUGH</b></p>	<p>Answer the following questions about your dog's cough:</p> <p>1. Is the cough provoked by (circle all that apply):</p> <p style="text-align: center;">Exercise      Excitement      Drinking water      Eating</p> <p>2. How would you describe the cough (circle most appropriate):</p> <p style="text-align: center;">Dry      Wet      Honking      Other (write in):</p> <p>3. On a daily basis, how frequent is the cough (circle most appropriate descriptor):</p> <p style="text-align: center;">Rare      Occasional      Frequent      Incessant</p> <p>4. Does the cough wake your dog up at night?</p> <p style="text-align: center;">YES      NO</p> <p>5. Does the cough impact your dog's quality of life?</p> <p style="text-align: center;">YES      NO</p>
<p><b>2. BREATHING DIFFICULTY</b></p>	<p>Please provide additional description regarding the breathing difficulty you have appreciated:</p>
<p><b>3. ACTIVITY LEVEL</b></p>	<p>In what way is your dog's activity level abnormal?</p>
<p><b>4. FAINTING SPELLS</b></p>	<p>Answer the following questions about your dog's fainting spells:</p> <p>1. How many fainting spells have you witnessed:</p> <p>2. How long does it take your dog to return to normal after an episode:</p> <p>3. Which of the following best describe your dog prior to the episode(s):</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Exercising/Excited</li> <li><input type="checkbox"/> Urinating/Defecating</li> <li><input type="checkbox"/> Coughing</li> <li><input type="checkbox"/> Sleeping/resting and just got up to move</li> <li><input type="checkbox"/> Other (write in):</li> </ul> <p>4. During the episode does your dog do any of the following (check all that apply)</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Lose consciousness</li> <li><input type="checkbox"/> Lose bladder control</li> <li><input type="checkbox"/> Lose bowel control</li> <li><input type="checkbox"/> Limbs become limp</li> <li><input type="checkbox"/> Limbs become rigid</li> <li><input type="checkbox"/> Limbs repetitively paddle</li> <li><input type="checkbox"/> Salivate excessively</li> <li><input type="checkbox"/> Clench the jaw</li> <li><input type="checkbox"/> Other (write in):</li> </ul>
<p><b>5. APPETITE</b></p>	<p>In what way is your dog's appetite abnormal?</p>



## Functional Evaluation of Cardiac Health (FETCH) Questionnaire for Dogs

This form is designed to help us better understand how your dog's heart disease has impacted his or her comfort and limited the quality of interactions with you or other family members. The information will help us to develop better medications and methods to treat dogs with heart disease. Your answers will be confidential.

The items listed below describe ways in which some dogs are affected. If you believe an item does not apply to your dog or that it is not related to your dog's heart disease, then circle 0 (Not at All) and go on to the next item. If the question does apply to your dog, then circle the number corresponding to how much it impacted your dog's comfort or sociability. If there is any question that you are uncomfortable answering, just leave it blank (this will not affect your dog's care in any way). Remember to consider the THE LAST 7 DAYS ONLY.

**How much did your dog's heart disease impact your dog's comfort or sociability during the last 7 days by:**

	Not At All	Very Little	2	3	4	Very Much
	0	1	2	3	4	5
1. making breathing difficult?	0	1	2	3	4	5
2. making your dog cough?	0	1	2	3	4	5
3. making your dog wheeze when breathing?	0	1	2	3	4	5
4. making your dog generally tired, fatigued or low on energy?	0	1	2	3	4	5
Is your dog on forced exercise restriction?						
Yes	↓					
No	↓					
Skip Q. 5 and go to Q. 6	↓					
Answer Q. 5 and skip Q. 6	↓					
5. making recreational pastimes, (playing in the yard, playing fetch, etc) difficult?	0	1	2	3	4	5
6. limiting your dog's favorite activities due to exercise restriction.	0	1	2	3	4	5



	<b>Not At All</b>	<b>Very Little</b>				<b>Very Much</b>
	<u>0</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>
7. making your dog sit or lie down to rest during walks?	0	1	2	3	4	5
8. making walking around or climbing stairs difficult?	0	1	2	3	4	5
9. causing fainting or collapsing episodes?	0	1	2	3	4	5
10. making it difficult for your dog to get comfortable?	0	1	2	3	4	5
11. making it difficult for your dog to sleep through the night?	0	1	2	3	4	5
12. making your dog eat less than normal?	0	1	2	3	4	5
13. changing the types of foods your dog is willing to eat?	0	1	2	3	4	5
14. increasing the number of urination accidents in the house?	0	1	2	3	4	5
15. making your dog vomit?	0	1	2	3	4	5
16. limiting your dog's ability to spend time with the family (can't get up stairs to join with the family, can't get onto the bed or couch, etc.)	0	1	2	3	4	5
17. making your dog irritable or unwilling to be touched?	0	1	2	3	4	5
18. making your dog less bright and peppy?	0	1	2	3	4	5

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Investigators: Dr. Sonya Wesselowski & Dr. Sonya Gordon

Contact: [TAMUCardiology@cvm.tamu.edu](mailto:TAMUCardiology@cvm.tamu.edu)



## Other important information for owners

- The discharge summary you received contains the pertinent information your primary veterinarian will need to provide further care.
- Please make a copy of the discharge summary and bring it to your primary care veterinarian's office.
- If your discharge summary indicated that cardiac medications were recommended, these medications will need to be filled by your primary care veterinarian. Please note that in some cases labwork is needed before and shortly after starting cardiac medications. Routine labwork such as a CBC or chemistry panel was not performed as part of this study.
- We are unable to provide you or your primary care veterinarian with copies of x-rays or echocardiogram images.
- Blood samples that were obtained today will all be banked and batch analyzed at the end of the study. These results will be coded by study ID and not available to owners.
- This is the third and final weekend clinic for this study.
- The discharge summary will indicate the recommended timeframe for a recheck of your dog's heart disease. This recheck can be done with your regular veterinarian (who can consult with TAMU Cardiology if needed) or you can schedule an appointment with the cardiology service at Texas A&M's veterinary teaching hospital if you want to continue care with our team. Participation in this study does not establish your pet as an existing patient of Texas A&M to allow for on-going medical advice if you choose not to make an appointment at our teaching hospital in College Station.

*Thank you for your participation and helping us to learn more about heart disease in the Cavalier King Charles Spaniel.*

X \_\_\_\_\_

Date \_\_\_\_\_