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

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 ____________

*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.*
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.

*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.*
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

Sonya Wesselowski, DVM, MS, DACVIM (Cardiology), Assistant Professor
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

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; crrc@cvm.tamu.edu

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.
## INTAKE FORM

<table>
<thead>
<tr>
<th>Field</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Client Name</td>
<td></td>
</tr>
<tr>
<td>Address</td>
<td></td>
</tr>
<tr>
<td>Phone Number:</td>
<td>Email Address</td>
</tr>
<tr>
<td>Primary Care Veterinarian</td>
<td>Doctor: Phone Number:</td>
</tr>
<tr>
<td>Clinic Name:</td>
<td>Address:</td>
</tr>
<tr>
<td>Dog's Name</td>
<td>Date of birth:</td>
</tr>
<tr>
<td>Coat color (circle)</td>
<td>Blenheim</td>
</tr>
<tr>
<td>Sex (circle)</td>
<td>Intact Female</td>
</tr>
</tbody>
</table>
| 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: | |
| Please circle YES or NO. Does your dog: | 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.**
1. **COUGH**

   Answer the following questions about your dog's cough:

   1. Is the cough provoked by (circle all that apply):
      - Exercise
      - Excitement
      - Drinking water
      - Eating

   2. How would you describe the cough (circle most appropriate):
      - Dry
      - Wet
      - Honking
      - Other (write in):

   3. On a daily basis, how frequent is the cough (circle most appropriate descriptor):
      - Rare
      - Occasional
      - Frequent
      - Incessant

   4. Does the cough wake your dog up at night?
      - YES
      - NO

   5. Does the cough impact your dog's quality of life?
      - YES
      - NO

2. **BREATHING DIFFICULTY**

   Please provide additional description regarding the breathing difficulty you have appreciated:

3. **ACTIVITY LEVEL**

   In what way is your dog’s activity level abnormal?

4. **FAINTING SPELLS**

   Answer the following questions about your dog's fainting spells:

   1. How many fainting spells have you witnessed:

   2. How long does it take your dog to return to normal after an episode:

   3. Which of the following best describe your dog prior to the episode(s):
      - Exercising/Excited
      - Urinating/Defecating
      - Coughing
      - Sleeping/resting and just got up to move
      - Other (write in):

   4. During the episode does your dog do any of the following (check all that apply)
      - Lose consciousness
      - Lose bladder control
      - Lose bowel control
      - Limbs become limp
      - Limbs become rigid
      - Limbs repetitively paddle
      - Salivate excessively
      - Clench the jaw
      - Other (write in):

5. **APPETITE**

   In what way is your dog’s appetite abnormal?
DIET HISTORY

1. Describe your pet's appetite over the last few weeks (check all that apply):
   □ Eats about the same amount as usual
   □ Eats less than usual
   □ Seems to prefer different foods than usual
   □ Eats more than usual

2. Over the last few weeks, has your pet (check one)
   □ Lost weight
   □ Gained weight
   □ Stayed about the same weight
   □ Don't know

3. Does your dog eat a diet that is labeled as grain free? (circle Y or N)
   YES    NO

4. Please list below the brands and product names (if applicable) and the amount of ALL foods, treats, snacks, dental chews, rawhides, and any other food your pet currently eats.

<table>
<thead>
<tr>
<th>Food</th>
<th>Form</th>
<th>Amount</th>
<th>How often</th>
<th>Fed since</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purina Dog Chow</td>
<td>dry</td>
<td>1 ½ cups</td>
<td>2x/day</td>
<td>Jan. 2011</td>
</tr>
<tr>
<td>Gourmet Beef Entrée</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>90% lean hamburger</td>
<td>microwaved</td>
<td>3 oz</td>
<td>1x/week</td>
<td>Jan. 2011</td>
</tr>
<tr>
<td>Milk Bone medium</td>
<td>dry</td>
<td>1</td>
<td>2x/day</td>
<td>Aug. 2010</td>
</tr>
<tr>
<td>Rawhide</td>
<td>dry</td>
<td>2x5&quot; strip</td>
<td>3x/week</td>
<td>Dec. 2011</td>
</tr>
</tbody>
</table>

5. Do you give any dietary supplements to your pet (for example: vitamins, glucosamine, fatty acids, or any other supplements)?
   □ Yes    □ No
   If yes, please list which ones and give brands and amounts:

<table>
<thead>
<tr>
<th>Supplement</th>
<th>Yes/No</th>
<th>Brand</th>
<th>Tablet/capsule #, size, &amp; frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Taurine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carnitine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antioxidants</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multivitamin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fish oil or cod liver oil</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coenzyme Q10</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (please list)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

6. How do you administer pills to your pet?
   □ do not give any medications
   □ give them without any food
   □ put them in my pet’s dog/cat food
   □ put them in a Pill Pocket or similar product
   □ put them in foods (list foods):

_____________________________________________________________________________________________________________________________
____________________________________________________________________________________________________________________
_____________________________________________________________________________________________________________________________
________________________________________________________________________________________________________________________
_____________________________________________________________________________________________________________________________
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:

<table>
<thead>
<tr>
<th>Not At All</th>
<th>Very Little</th>
<th>VeryMuch</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

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
↓
Answer Q. 5 and skip Q. 6

No
↓
Skip Q. 5 and go to 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
<table>
<thead>
<tr>
<th>Question</th>
<th>Not At All</th>
<th>Very Little</th>
<th>Very Much</th>
</tr>
</thead>
<tbody>
<tr>
<td>7. making your dog sit or lie down to rest during walks?</td>
<td>0 1 2 3 4 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. making walking around or climbing stairs difficult?</td>
<td>0 1 2 3 4 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. causing fainting or collapsing episodes?</td>
<td>0 1 2 3 4 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. making it difficult for your dog to get comfortable?</td>
<td>0 1 2 3 4 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. making it difficult for your dog to sleep through the night?</td>
<td>0 1 2 3 4 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. making your dog eat less then normal?</td>
<td>0 1 2 3 4 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. changing the types of foods your dog is willing to eat?</td>
<td>0 1 2 3 4 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. increasing the number of urination accidents in the house?</td>
<td>0 1 2 3 4 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. making your dog vomit?</td>
<td>0 1 2 3 4 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>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.)</td>
<td>0 1 2 3 4 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>17. making your dog irritable or unwilling to be touched?</td>
<td>0 1 2 3 4 5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18. making your dog less bright and peppy?</td>
<td>0 1 2 3 4 5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Blood-based cardiac biomarkers for the assessment of heart enlargement in Cavalier King Charles spaniels with pre-clinical myxomatous mitral valve disease (IACUC 2018-0320 CA)

Investigators: Dr. Sonya Wesselowski & Dr. Sonya Gordon

Contact: 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 ______________