

COLLEGE OF VETERINARY MEDICINE

DEPARTMENT OF CLINICAL SCIENCES

CLIENT INFORMED CONSENT FORM

Title: microRNA profiling canine mammary tumor exosomes by deep-sequencing and qRT-PCR microarray analysis

1. **Why is the study being performed?** This study is a part of a project aiming to evaluate an early test for detection of canine mammary cancer. The hope is that this study will lead to a simple blood test that allows early detection of the tumor when it may be more easily treated.
2. **Which animals / patients can participate in the study?** Any female dog > 5 lbs with mammary cancer that has not yet undergone any form of treatment (surgery, chemotherapy, radiation, or others), as well female dogs >5 lbs that are >6 months of age with non-cancerous conditions of the mammary gland and similar-size and age healthy dogs (for comparison) are eligible to participate.
3. **Why might my animal NOT be able to participate in the study?** Patients that have already had treatment for their mammary cancer are not eligible to participate in this project. Dogs <5 lbs or <6 months of age will not be eligible.
4. **What will be happening to my animal if we participate in the study?** Dogs will be gently restrained, and 10 ml of blood (about 2 teaspoons) will be collected from a vein in the neck or leg, and direct pressure will be applied for a short period of time after blood collection. A small area of hair may be clipped for blood collection.

Dogs with mammary cancer will have one initial blood draw at their first visit to the Bailey Small Animal Teaching Hospital, and up to four more of these blood draws during the course of treatment at Auburn. Dogs with non-cancerous mammary disease and healthy controls will only have blood drawn once. Consent of dogs with mammary cancer to participate in this study authorizes collection of up to 50 ml (five separate blood draws of 10 ml each) during the course of treatment.

5. **Are there any benefits from the study for my animal?** This study will pay for the initial Oncology Service consultation fee for participating pets with mammary cancer. For healthy control dogs, you will receive free laboratory tests (one Complete Blood Count and serum biochemistry panel) as part of the initial health screening procedure for enrollment in this project. While there is likely no direct benefit for your pet at this time, this study may help us develop a test to detect this tumor earlier and/or learn more about the disease to help benefit future patients with this type of cancer.
6. **Are there any risks or discomforts for my animal?** Blood draws of this volume are usually very well-tolerated in most dogs except very small dogs (which is why dogs <5 lbs are excluded). The main complication is mild bruising at the site of blood collection that will rapidly resolve on its own (usually a few days).

COLLEGE OF VETERINARY MEDICINE

DEPARTMENT OF CLINICAL SCIENCES

CLIENT INFORMED CONSENT FORM

7. **Unforeseen adverse events.** Significant adverse events that affect your dog's health are very unlikely, and if they occur will be managed by your family veterinarian or veterinarians at the Bailey Small Animal Teaching Hospital.
8. **Are there other treatment options other than participating in the study?** This study is only evaluating a new type of blood test for mammary cancer; it does not at this time alter any treatment options.
9. **Owner responsibilities** You are required to bring your dog to the initial and if applicable, follow-up appointments as determined to be appropriate by the attending veterinarian (patients with mammary cancer only). Blood collection will be coordinated to occur with other treatment and recheck visits at the Bailey Small Animal Teaching Hospital, will only be required up to a maximum of five times, and no more frequently than one week between collections.
10. **Participant dismissal** Because the comfort of your dog is our top priority, your dog may be removed from the study if blood collection causes significant distress or we cannot successfully get blood after three tries during a visit.
11. **Financial obligations of all parties.** The cost of a consultation with the Oncology Service will be paid for through research funds. Dogs with mammary cancer will have no financial obligation related to blood collection for the study. You are responsible for the costs of any diagnostics or treatments you choose to pursue for mammary cancer. Healthy control dogs will receive fully discounted baseline labwork (one CBC and chemistry panel) at their initial visit. **Access to study information:** We would be happy to share the results of your dog's microRNA testing with you, although it is still in the early stages of investigation and may not be useful clinically. Data generated from this project will be included in Dr. Fish's doctoral dissertation (which will be publicly available) and any peer-reviewed research articles that are accepted.
12. **Confidentiality** All information about you and your dog will be kept confidential, and any research data generated from your dog will be anonymized for future presentations or publications.
13. **Contact persons regarding this study**
Participants may contact any of these individuals with questions about this study.

Eric J. Fish, DVM. Clinical Pathology resident and PhD student in the lab of R. Curtis Bird, PhD. Department of Pathobiology, College of Veterinary Medicine, Auburn University. EJF0007@auburn.edu. (716) 531-8551.

R. Curtis Bird, PhD. Professor of Molecular Biology and Cancer Genetics. Department of Pathobiology, College of Veterinary Medicine, Auburn University. birdric@auburn.edu (334) 844-2707.

Annette N. Smith, DVM, MS, DACVIM (Oncology, SAIM). Robert & Charlotte Lowder Distinguished Professor, Department of Clinical Sciences, College of Veterinary Medicine, Auburn University. smith30@auburn.edu (334) 844-4690.

14. **Hospital review contact person**
Participants with concerns about any research study at the AU College of Veterinary Medicine may also contact:

COLLEGE OF VETERINARY MEDICINE

DEPARTMENT OF CLINICAL SCIENCES

CLIENT INFORMED CONSENT FORM

Doug Allen, DVM, MS, DACVS. Director, Veterinary Teaching Hospital. College of Veterinary Medicine, Auburn University. (334) 844-4690.

Frank F. "Skip" Bartol, PhD. Associate Dean of Research and Graduate Studies. College of Veterinary Medicine; Auburn University. (334) 844-3700.

15. Owner acknowledgements:

As legal owner of (or agent for) this animal, I understand and acknowledge the following:

- a. I am agreeing to participate in a research study at the AU College of Veterinary Medicine.
- b. I am free to withdraw my consent and to discontinue participation in the study at any time.
- c. The decision for my animal to participate in this study is mine alone and participation is voluntary.
- d. The decision to withdraw from the study or to disregard the recommendations of the veterinarians involved in the study, relieves the investigators of current and future obligations (both medical and financial) to the pet and/or owner covered by this study.
- e. I am responsible for decisions and financial obligations related to treatment(s) sought or required for my animal at AU-VTH or at any other veterinary facility that are NOT specified in this document. This would include treatment for disease progression or for medical complications - related or unrelated to the study.
- f. Any decision to discontinue participation in this study, whether to pursue other therapies or to have my animal euthanized, does not entitle me to any financial reimbursement for costs incurred during participation.
- g. I have discussed the procedures / benefits and risks of study participation and had the chance to have my questions about the study answered.

Owner signature

Date

16. Investigator assurances

- a. I have explained the study details and answered questions to the best of my ability.
- b. If the animal is a patient in the Auburn University Veterinary Teaching Hospital, I have discussed enrolling the patient into this study with the senior faculty member responsible for this patient's care.

Primary Investigator

Date

Witness

Date



ATTN:1/10/2017

COLLEGE OF VETERINARY MEDICINE

DEPARTMENT OF CLINICAL SCIENCES

CLIENT INFORMED CONSENT FORM

This study has been reviewed and approved by the Clinical Research Review Committee of the College of Veterinary Medicine (CRRC) and the Auburn University Institutional Animal Care and Use Committee (IACUC).
(Effective date – Feb 2010)