AUBURN UNIVERSITY

ATTN:3/6/2015

# COLLEGE OF VETERINARY MEDICINE

## CLIENT INFORMED CONSENT FORM

Title: **Evaluation of a conditionally replicative adenoviral vector for the treatment of canine osteosarcoma**

1. Why is the study being performed? This study is designed to test a new approach to treating canine bone cancer (osteosarcoma). This treatment consists of injecting a virus called canine adenovirus type 2 or CAV2 that has been modified. The modified virus is called a conditionally replicative adenovirus, or CRAd. When the modified virus infects a bone cancer cell, it can make more virus. The virus eventually kills the bone cancer cell, releasing hundreds of new viruses that can go on to infect and kill other bone cancer cells. The modified virus can only make more virus in bone cancer cells. In this way, the virus can seek out and destroy cancer cells all over the body. After a few days, the body's immune system will start to attack the virus and kill it, removing the virus from the body and stopping the treatment.

2. Which animals / patients can participate in the study? Your dog has been selected as eligible to participate in this clinical trial because it has been diagnosed with bone cancer in a leg and you have decided to proceed with treatment consisting of amputation followed by chemotherapy. Your dog must also have been vaccinated within 3 years for canine hepatitis.

3. Why might my animal NOT be able to participate in the study? Dogs whose tumors have been removed, who have had any previous treatment for bone cancer or who cannot demonstrate that they have had a canine hepatitis vaccine within 3 years are not eligible.

4. What will be happening to my animal if we participate in the study? Forty-eight hours after your dog's tumor is removed (either by amputation or limb-sparing surgery) your dog will receive an injection of the CRAd in a vein (usually in the neck). Because we need to obtain blood samples twice a day as well, we will put a catheter in the vein. This means that your dog will need to stay in the hospital for 6 days after it receives the injection. Because a virus is being used to deliver the gene, contact with other dogs will be limited, but you will be able to visit your dog. Your dog will need to return to the hospital for blood tests and evaluation 4 weeks after the injection.

5. Are there any benefits from the study for my animal? This treatment may kill or help kill tiny tumors (metastases) that are lodged in other areas of the body such as the lungs.

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6. Are there any risks or discomforts for my animal? There are three areas of risk with this procedure. Because a large dose of virus is being given, there is the initial risk of an allergic reaction or shock. This could be life-threatening, but can be treated with appropriate drugs. Secondly, there is the risk of "tumor lysis syndrome", which also resembles shock and occurs when many tumor cells die at once. This can also be life-threatening and can be treated with appropriate drugs. The final risk is that the virus may affect normal bone cells, causing either too much or too little bone to form. Both normal dogs and dogs with bone cancer have been injected with this virus previously and none of these reactions has been seen.

   In addition, your dog will experience some discomfort from the surgery you have chosen. While not part of this protocol, your dog will continue to receive appropriate pain medications and care of its surgery site while on this protocol.

7. Unforeseen adverse events It is impossible to predict all of the side effects that might occur, but previous use of this virus in dogs has been shown to be safe. In the event that your dog dies while enrolled in this trial, a post-mortem examination (necropsy or autopsy) will be performed to determine the cause of death.

8. Are there other treatment options other than participating in the study? If you do not choose to enroll your dog in this clinical trial, your dog may be treated with surgery and chemotherapy alone. These treatments will be at your expense regardless of whether you participate in this study.

9. Owner responsibilities Owners must return for chemotherapy injections and follow-up care as directed.

10. Participant dismissal. Failure to bring your dog to the hospital on the agreed upon day to begin the study, removal of the dog from the hospital during the study or failure to bring your dog in for follow up appointments may result in dismissal from the study.

11. Financial obligations of all parties You will be responsible for the costs of the treatment you have already selected (amputation or limb-sparing surgery and chemotherapy) including post-operative hospitalization up to the time when your dog is transferred to this study. You will not be charged for administration of the virus, the hospitalization required for this study, blood samples that are taken or laboratory tests performed as part of this study. Reasonable treatment of any side effects will also be provided free to your dog, but only if that treatment is provided by the Auburn University College of Veterinary Medicine. If your dog is dismissed from the trial, you will be financially responsible for any further costs associated with your dog's care and treatment

12. Access to study information If you desire, the general conclusions based on this study will be made available to you. Please make this request in writing to the principal investigator, Dr. Bruce Smith. In addition, we expect the study results will be published in the scientific literature.

13. Confidentiality The identity of dogs and their owners that participate in this study will remain confidential. If publications result from this study, the dogs involved will be identified in a way that will not allow their true identity to be known.

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14. Contact persons regarding this study
Participants may contact any of these individuals with questions about this study.
Bruce F. Smith, V.M.D., Ph.D., Principal investigator, Scott-Ritchey Research Center, College of Veterinary Medicine, Auburn University. (334) 844-5587, after hours (334) 750-1179, smithbf@auburn.edu
Dr. Annette Smith, Department of Clinical Sciences, College of Veterinary Medicine, Auburn University. (334) 844-4690.
Dr. Stephanie Schleis, Department of Clinical Sciences, College of Veterinary Medicine, Auburn University. (334) 844-4690.

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

16. 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 agree that a complete post-mortem examination (necropsy) may be performed, should my dog die while hospitalized on this study.
f. 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.
g. If I withdraw my animal from the study, I may be responsible for medical, diagnostic and treatment costs incurred even if these were originally covered by the study.
h. 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.
i. 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

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17. 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

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)