

CLIENT INFORMED CONSENT FORM

Title: MMX™ peptide therapy in spontaneous canine melanoma

1. **Why is the study being performed?** This study is designed to test a new drug that may be useful in treating melanoma, or skin cancer, which most commonly occurs in the mouth, in dogs. This drug, called MMX™, is a peptide, which is a chain of amino acids, the basic building blocks of all proteins. In this study, we will be determining the lowest dose at which the drug works to shrink melanoma.
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 stage II or III malignant melanoma. This means that there is no obvious evidence of spread of the cancer to lymph nodes, but microscopic spread is still possible.
3. **Why might my animal NOT be able to participate in the study?** It is very important that your dog has not had any chemotherapy within 30 days. In addition, dogs with signs of kidney or liver failure, dogs with any other cancers or tumors and dogs that are immune suppressed, either because they are being given immunosuppressive drugs or have low white blood cell counts, cannot participate.
4. **What will be happening to my animal if we participate in the study?** Your dog will need daily injections of the drug for 29 days. It will also need to come to the Small Animal Hospital at the College of Veterinary Medicine at Auburn once each week for evaluation and for you to receive the injections for the next week. We will train you to give daily injections to your dog, which is very similar to what owners with diabetic dogs, and diabetics themselves have to do. You will be expected to give 6 of the 7 injections a week, for a total of 24 injections. Before the drug is started and each week for 5 weeks, your dog will be sedated, examined, about 10 mls of blood (or about 2 teaspoons) and a sample of urine will be taken for testing. At the start and end of this trial, your dog will also have radiographs (“x-ray photos”) taken, a CT scan (“cat scan”) performed and a needle inserted into lymph nodes near the tumor to take a small sample. These need to be performed under anesthesia. At the end of 5 weeks, any remaining tumor will be surgically removed, if possible,.
5. **Are there any benefits from the study for my animal?** This drug may shrink your dog’s tumor, either making it go away completely, or making it smaller and easier to remove during surgery. Additional benefits include free intensive monitoring of your dog and your dog’s tumor, At the end of the study, any remaining tumor will be surgically removed, if possible, at no cost to you.
6. **Are there any risks or discomforts for my animal?** Your dog may be uncomfortable with the daily shots that must be given, but that is only due to the needle stick. No side effects have been observed in any dogs injected with this drug. The drug may also fail to shrink your dog’s tumor, allowing it to grow and metastasize, making it necessary to use chemotherapy and/or surgery sooner. Delaying standard treatment for 5 weeks while in the trial is unlikely make the tumor more difficult to treat once the trial is complete. If, after 5 weeks, the tumor in your dog has not gotten smaller, you will be offered the chance for another 4 weeks of treatment with the drug, at no cost to you, or you may choose to pursue the standard treatment at that time. Regardless of your choice, the tumor will be removed at no cost to you, if surgery is possible.
7. **Unforeseen adverse events** It is impossible to predict all of the side effects that might occur, but previous use of this drug has been shown to be very safe. Should an unforeseen side effect occur, it will be treated to the best of our ability. Any side effects that you notice should be written down in the daily logbook and reported to the principal investigator (Dr. Bruce Smith) or to your dog’s Oncology Service veterinarian. As part of this study, your dog will need to be anesthetized and will undergo surgery. These procedures do have risks, including the risk of death due to anesthesia, as well as the possibility of bleeding, infection, pain and incomplete removal of the tumor.

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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 some combination of chemotherapy, radiation therapy, surgery and/or vaccination. These treatments will be at your expense.
9. **Owner responsibilities** Owners must return their dog to the Small Animal Hospital of the College of Veterinary Medicine once a week for four visits and are then expected to return for follow-up care as directed. Owners must also administer a daily shot and record daily observations in a logbook that will be returned to Auburn University at the end of the 4-week trial.
10. **Participant dismissal** Failure to administer MMX™, failure to bring your dog back at the required time or starting any other therapy while enrolled in the trial will result in dismissal from the trial.
11. **Financial obligations of all parties** MMX™ will be provided for you free of charge and you will not be charged for any of the testing done during the 5 weeks of the trial or for the surgery to remove your dog's tumor at the end of the trial. 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. Any other treatment your dog receives, such as chemotherapy or the melanoma vaccine will be your financial responsibility. 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, including surgical removal of the tumor.
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.
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.

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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 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. 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.
- g. 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.
- h. 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

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)