

Veterinary Neurology and Neurosurgery Service Virginia Tech, Blacksburg VA 24061 (540) 231-4621

Investigative Clinical Project Consent Form	

I, the undersigned, hereby certify that I am the owner (or duly authorized agent of the owner) of the aforementioned animal named _______. I further understand that I have been asked or requested to participate in a Virginia-Maryland College of Veterinary Medicine (VMCVM) investigative project. The study that my animal is participating is entitled:

Molecular Combinatorial Therapy for Canine Malignant Glioma

Principal Investigator: Dr. John Rossmeisl; 540-231-3595; jrossmei@vt.edu

I acknowledge that this study involves investigation of the efficacy of convection enhanced delivery (CED), a type of minimally invasive surgical therapy, of tumor- selective chemotherapeutic drugs locally into my dog's brain tumor. Extensive pre-clinical testing on the drugs being used in the study has demonstrated their safety for use in the brain, and CED is a well established method of delivery of therapeutic agents to brain tissue of animals and humans. Before giving my consent by signing this form, I acknowledge that I have been informed of the purpose and nature of this study and its associated procedures, as well as the most commonly experienced adverse effects associated with clinical management of my animal's brain tumor that may result from the course of treatment I have elected. I also acknowledge that my attending clinician has reviewed current standard of care treatments available for my dog's brain tumor beyond what is being offered in this clinical trial.

- 1. The owner/agent understands that general anesthesia carries a risk to the animal.
- 2. The owner/agent acknowledges that during the performance of the investigational therapy, unforeseen conditions may be revealed that in the attending veterinarian's professional judgement necessitates an extension or modification of the treatment course initially described. Therefore, he/she hereby gives consent to perform such extensions and/or modifications as necessary.
- 3. The owner/agent hereby agrees that possible complications of the procedure have been explained to him/her and that a successful outcome cannot be guaranteed (see Craniotomy Complications handout).
- 4. The owner/agent agrees to carry out instructions, if any, given to them and will return for follow-up examinations as requested by the attending clinician or principal investigator.
- 5. The owner/agent acknowledges that they have been informed of related costs (if any) they will incur during participation in this clinical trial.
- 6. The owner/agent retains the right to withdraw their dog from the study at any time following issuance of such a request to the principal investigator.

- 7. The owner/agent acknowledges that this type of therapy is investigational. There may be no benefit for your dog, and it is not known if there will be a reduction in the size of tumor or improvement in clinical signs following treatment. We have no information on the potential for this treatment slowing the progression of disease.
- 8. The owner/agent acknowledges and agrees that in the event of the death or euthanasia of their dog, they will consent to and submit their animal's remains to the Veterinary Teaching Hospital for performance of a post-mortem (autopsy) examination.

I understand that at any time I have questions about my decision to participate in the study to which I am consenting, I am encouraged to ask the attending clinician or principal investigator. With a thorough understanding of the information described above, I voluntarily consent to have my animal participate in this study.

This research has been reviewed, approved, and funded by the National Institutes of Health (NIH) and the National Cancer Institute (NCI). In addition, the research and procedures have been additionally reviewed and approved by Virginia Tech Institutional Animal Care and Use Committee and the Veterinary Teaching Hospital Review Board of the Virginia-Maryland Regional College of Veterinary Medicine. If questions arise regarding your rights as a participant or pet owner, the Hospital Board contact person is: Dr. Terry Swecker, Hospital Director, Veterinary Teaching Hospital, Virginia Tech, Blacksburg, VA 24061-0443; (540) 231-7823.

Owner or Agent Signature:	 Date:
Attending Clinician Signature:	 Date:
Prinicipal Investigator Signature:	 Date: