Clinical Research Project
Client Consent Form

Study Title: Retrobulbar neurolytic ethanol injections for the treatment of end-stage canine glaucoma
Principal Investigator: Ian Herring, DVM, MS, DACVO
540-231-4621; iherring@vt.edu

One of the missions of the Virginia-Maryland College of Veterinary Medicine is to create, disseminate and apply medical knowledge through discovery, learning, and engagement. You are invited to participate in this mission by enrolling your animal in a clinical research study. Your participation is entirely voluntary, and you may withdraw your animal from the study at any time by notifying the Principal Investigator. There is no penalty if you choose not to participate.

Study Purpose:
In health, fluid is constantly being produced and exiting the eye, which creates a normal pressure system. When the fluid has trouble leaving the eye, it accumulates and pressure in the eye increases above a normal range; this is termed glaucoma and is a painful process. Medical and surgical options for the treatment of glaucoma exist, but ultimately the disease will progress and fail long-term therapy. At that time the eye has lost vision forever and serves only as a source of pain. To relieve this pain owners can choose different surgical options that require anesthesia and involve removal of parts of the eye or the entire eye. Although it is sad for owners to elect to have a pet’s eye removed, invariably patients display marked improvements in comfort after the procedure. Alternative therapies include an injection of medication into the eye to lower pressure, however this in itself can be painful, is not always successful, and may be associated with tumor (cancer) formation. We are investigating the use of retrobulbar (behind the eye) alcohol injections in dogs with end-stage glaucoma as a treatment option to provide pain relief. This therapy has been used in human, rabbit, and rodent patients, but has not been performed in dogs. We hope to compare the pain relief provided by this treatment with that achieved from removal of the eye. We hope it will serve as a future therapeutic option to provide pain relief in place of eye removal for dogs with end-stage glaucoma.

Study Design/Procedures:
After a veterinarian from the ophthalmology service has performed a physical and ophthalmic examination on your pet to ensure they are eligible to enroll in the study, your informed consent for enrollment will be obtained. The complete ophthalmic examination and physical examination will include routine non-invasive procedures performed on all patients presenting to the service. You will then fill out a pain score survey for your pet. This includes 7 questions in which you select one answer that best describes your pet.

Your pet will then be assigned an experimental ID number (1-20). Twenty dogs will be enrolled in the study, 10 will be enrolled into the treatment group to receive retrobulbar (behind the eye) alcohol injection and 10 will be enrolled into the control group to receive saline (physiologic) solution. Neither you nor the attending clinician will be aware of the group assignment; a computer will randomize the experimental ID number into one of the two groups. The administration of the injection is very quick. Your pet will be able to go home today after spending a few hours (roughly 3) at the VTH. Your pet will need to be sedated for the procedure, which means they will not be fully anesthetized, but given a combination of medications to make sure they do not move during the procedure and do not experience any pain during the injection. Sedation is performed on dozens of animals each week at the VTH without complication. Risks include adverse drug reaction and the potential to vomit while asleep; we will minimize these risks by making sure your pet has not eaten a large meal within 3 hours of sedation and by using drugs that can be reversed where applicable. Once sedated, your pet will receive an injection of a numbing agent behind the eye to make the procedure pain-free. Five minutes later your pet will receive the medication for their assigned treatment group and then sedation will be reversed. One and one-half hours after your pet is awake another ophthalmic examination will be performed to look for any side effects of the treatment. Two hours after your pet is awake, they will be discharged from the hospital. Your pet will go home on continued topical anti-glaucoma medications and with a week of systemic pain medications to ensure standard treatment is continued. You will be discharged with 4 pain score surveys that are identical the one you completed at the initial examination. These will need to be filled out 48 hours, 1 week, 2 weeks, and 3 weeks after discharge. Additionally, there will be 6 yes or no
questions related to any potential side effects of the injection; for example, does the eye appear more red, yes or no?

Surveys can be completed by mail, email, or over the telephone with Dr. Enders.

Three weeks after discharge you and your pet will return to the VTH for recheck examination. Your pet will be admitted to the hospital for evaluation by the anesthesiology service one day prior to enucleation (removal of the eye). While hospitalized your pet will continue to receive all their regular medications and diet. The following day your pet will have the affected eye removed and submitted for biopsy evaluation. After anesthesia your pet will recover in the ICU and receive standard postoperative care (pain medications). Your pet will be discharged the following day with a week of systemic pain medications. You will be discharged with 4 surveys that are identical to the one you completed at the initial examination. These will need to be filled out 48 hours, 1 week, 2 weeks, and 3 weeks after discharge. Surveys can be completed by mail, email, or over the telephone with Dr. Enders. The final survey will also include 5 questions regarding your satisfaction with the procedures performed during the study.

Exclusion criteria will consist of patient-specific historical, systemic, or surgical complications preventing adherence to the study protocol. Patients chronically administered systemic pain medications or diagnosed with glaucoma secondary to systemic, ocular, or orbital disease will be excluded from enrollment.

Risks and Benefits:
Your pet will continue to receive standard of care throughout the study protocol. Pets assigned to the control (saline) solution group will receive a numbing agent behind the eye prior to saline injection, will continue on topical anti-glaucoma medications, and be discharged with systemic pain medications.

Benefits of enrollment in the study:
• Continued standard of care means your pet will not intentionally become more uncomfortable during the study period.
• Typical cost of eye removal at the VTH is approximately 1100-1300 dollars. The surgical procedure would be subsidized by this study as well as the cost of the biopsy. This means you would ultimately save over 700 dollars to have your dog’s pain relieved by eye removal.
• Cost of the injection, preanesthetic bloodwork, urinalysis, and biopsy analysis would also be covered by the study for an approximate 1000 dollar savings in total.
• Surveys can be completed by mail, email, or over the phone, meaning you only have to make 3 trips to the VTH for the duration of the 6-week study. These visits include: the initial examination, drop off for surgery, pick-up after surgery.

Risks of enrollment in the study:
• Risks of retrobulbar (behind the eye) injections are minimal, but include bleeding, adverse drug reaction, and swelling. Canine, and equine patients routinely receive this type of injection at the VTH without complication.
• Risk of enrollment in the control group means your pet will not receive a treatment that could potentially relieve pain. It is still unknown if this treatment relieves pain in dogs. Your pet will continue on standard of care to ensure your pet will not intentionally become more uncomfortable during the study period.
• Risks of sedation and general anesthesia. These risks are minimized by the presence of board certified anesthesiologists presiding over the procedures involved in this study at the VTH.

Study Costs and Compensation:
Costs not covered by the study include the initial examination (100 dollars for first time patients, 60 dollars for established patients). Costs of anesthesia, hospitalization, and surgery are subsidized, but not completely covered and involve an approximately 400 dollar investment. A 50% deposit of this estimate would be required at the date of drop off for surgery and the remaining balance due at the time of discharge. Payment plans are conditionally available and specifics can be discussed with the business office. The cost of medications to go home is not covered by the study, but included in the 400 dollar estimate.

Confidentiality:
The data collected in the course of this study is confidential. In any publication or presentation of the study data, we will not include information that would make it possible to identify a research participant. Research records will be kept in a secure location; only researchers will have access to the records.

Statement of Consent:
In 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 any possible side effects.

I have read and understood the above information. I have been given the opportunity to ask questions and receive answers, and I consent to participate in the study. I further certify that I am the owner (or duly authorized agent of the
owner) of _____________________ .

(Animal’s name)

Owner or Agent Signature: ________________________________________ Date: ________

Attending Clinician Signature: ________________________________________ Date: ________

Please don’t hesitate to contact us if you have any questions or concerns about this study.

The research and procedures have been reviewed and approved by the Virginia Tech Institutional Animal Care and Use Committee and the Virginia-Maryland College of Veterinary Medicine Veterinary Teaching Hospital Board.

If you have any questions or concerns regarding the study and would like to talk to someone other than the researchers, please contact:

Hospital Director,
Veterinary Teaching Hospital
Virginia-Maryland College of Veterinary Medicine
Address: 245 Duck Pond Dr., Blacksburg, Virginia 24061-0443
Phone:  540-231-4621

You will be given a copy of this form to keep for your records.