JAMES L. VOSS
VETERINARY TEACHING HOSPITAL
COLORADO STATE UNIVERSITY

Place Patient Identification Sticker Here

Appointment Desk: (970) 297-5000
http://csu-cvmbs.colostate.edu/vth/

Clinical Trials: Owner Informed Consent

Efficacy of cannabidiol (CBD) in the treatment of canine epilepsy

I understand that the veterinarians at this institution are engaged in research for the improvement of animal health, patient care, education, clinical investigation, and scientific innovation. The detailed procedures of the *Efficacy of cannabidiol (CBD) in the treatment of canine epilepsy* Clinical Trial have been explained to me by:

Dr. _____ on _____.

Please check the following boxes to confirm your understanding of the components of this particular study:

☐ My pet must undergo an MRI of the brain and a spinal tap in order to confirm epilepsy to be eligible to participate in this study.

☐ The purpose of this study is to evaluate the efficacy of CBD in the treatment of canine epilepsy. My pet will be given a placebo for half the study (12 weeks) and CBD for half the study (12 weeks) with a 4 week washout in between treatments. I understand that I will not know when my pet is being given each medication.

☐ My pet will be treated by a group of veterinarians specializing in clinical research. My pet will be treated with an oral CBD product and its effect on the seizure activity of my dog will be monitored.

☐ This product is primarily comprised of cannabidiol (CBD), a prominent non-psychotropic cannabinoid extracted from C. *sativa*, that has been shown to have anti-convulsant properties. CBD products offer a safe alternative to the psychoactive constituent, Δ^9–tetrahydrocannabinol (THC), in the treatment of canine epilepsy. I understand that this product is intended for animal use only. I realize that it is possible my pet will not benefit from this treatment.

☐ All drugs and methods used have been carefully tested individually to minimize potential toxicity. However, I realize it is possible my pet will experience unexpected side-effects which could be mild, moderate or severe (including death). Potential side effects include vomiting, diarrhea, wobbliness (ataxia), elevated liver enzymes, and worsening of my pet's seizure activity. My pet will be observed closely for side effects and appropriate action will be taken.

☐ The potential side effects of CBD treatment have been explained to me and I understand the risks and potential benefits.

☐ Alternate (non-study) treatment protocols have been discussed and I understand the relative benefits of those treatments.

☐ I understand that all costs associated with this study will be fully covered, including the MRI, spinal tap, blood work and CBD product.

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☐ I understand that one or more of the investigators in this study may have a conflict of interest. For this particular study, the principal investigator is serving as a consultant to the pharmaceutical company, Applied Basic Science Corporation.

☐ I understand that I am responsible for any additional costs, including costs associated with any adverse effects of the CBD treatment.

☐ I understand that I must return to CSU or my local veterinarian for the prescribed recheck examinations (every 4 weeks) following entry into the study. I realize that the costs for treatment once the study is completed will not be covered.

☐ Blood specimens and biopsy samples are an integral part of the treatment program and will be done at intervals at the recommendation of the veterinarian in charge. Tissue and fluid samples collected from my pet will become the property of Colorado State University.

☐ I give my permission to publish data and photos obtained from this study for the benefit of the scientific community. I understand that my pet will not be identified individually.

☐ I may withdraw my pet from this study at any time without penalty.

☐ The veterinarian in charge may withdraw my pet from this study if he/she determines that my pet is adversely affected.

☐ I may discuss this procedure with my own veterinarian and ask his/her advice.

☐ If my pet dies, a postmortem examination at CSU will be necessary to explain the cause of death.

☐ I understand that someone may contact me after my pet has finished this clinical trial to collect follow-up treatment and outcome information. This may occur several months to years following completion of the trial.

☐ I have been given the opportunity to have ample time to make the decision to enroll my pet in this particular study and feel comfortable moving forward with enrollment in this study based on the information provided.

As a result of discussion with Dr. _____, and after reading the above, I voluntarily consent to participate in this project and will follow the instructions of the veterinarians-in-charge, as it pertains to therapy and follow-up procedures.

Signed _____ Date _____
Owner or authorized agent of the owner

Witnessed By: _____ Date _____