

## **Owner Information Sheet for a study to confirm the efficacy and safety of this new veterinary diet in dogs with idiopathic epilepsy.**

Dear Pet Owner.

Your pet has clinical signs consistent with idiopathic epilepsy. We need your help in conducting a study at the Royal Veterinary College (RVC). A reputable small animal health and wellness company has been advancing the science of pet nutrition using cutting-edge technology and research so that people can help their dogs or cats to be healthy and happy. Epilepsy, which is defined as the propensity to have seizures, is the most common chronic neurological disorder in humans and dogs. Epileptic patients are usually treated with seizure suppressing drugs (“antiepileptic drugs”(AED)), which are administered on a chronic, often life-long basis. In human medicine there has been considerable progress in the treatment of epilepsies over recent decades. However, in veterinary medicine there is still a lack of data about new treatment options for epileptic patients.

Since many years the influence of diet on epilepsy severity has been known in humans. Multiple diets have been developed and have been shown to improve seizure control. However, there is a lack of data about this possibility in veterinary medicine. A test diet has been developed and we think that this diet could improve the management of epileptic dogs, not only by reducing the seizure frequency, but also by decreasing the level of side-effects seen with standard antiepileptic drugs.

The purpose of the present trial is to confirm the efficacy and safety of this new nutritional strategy in the management of dogs with idiopathic epilepsy treated with phenobarbitone and/or potassium bromide. We will use a cross-over design, which means that your dog will first receive either a standard or the new diet, which will then be switched over to the other diet after a 3 month time period.

Before enrolment on to the study, tests will be carried out to confirm your pet is suitable for the study. This is at the expense of study sponsor.

- Multiple questionnaires will be used to assess your dog’s current seizure control, level of side-effects due to treatment, behaviour, and overall quality of life.
- A physical and neurological exam will be carried out by the veterinary surgeon – this is non-invasive. The veterinary surgeon and nurse at this point can answer any questions you may have about the study.
- Blood and urine samples will be taken to further assess your pet.
- Former diagnostics such as blood work, MRI and Spinal fluid analysis will be reviewed.

If your dog meets all criteria for inclusion, it will be enrolled in the trial. Otherwise, an appropriate treatment plan for your pet will be discussed with you and your referring veterinary surgeon.

- You will receive a dog food to take home and you will administer the food yourself (twice daily for 3 months), according to the instructions of the Investigator.
- Your dog needs to be continued with the current medication and this should only be changed after discussion with the investigator. The initial food (standard or new food) will be randomly assigned. Treatment will be blinded, which means that neither you nor the veterinary surgeon will know which diet is given to your dog.
- After 3 months of feeding the initial food you will be asked to return to the RVC with your pet for a follow-up visit during which your animal will be fully examined including collection of urine, faeces and blood samples.
- You will then receive the other food to be fed to your pet for a 3 month time period.
- At the end of the study, you will be asked to return to the RVC during which your animal will be fully examined including collection of urine, faeces and blood samples.

No charge will be made for the consultations, food or procedures in relation to this study. The antiepileptic drug treatment will not be included in the study, but the monitoring of these drugs will be. Personal data about you and your pet will be collected, processed and used for the administration of this study and for regulatory requirements in connection with this study. You will not be referred to by name or identified in any report or publication. If you have any concerns, you will be free to withdraw your pet at any time and this will not bias the future veterinary care of your pet. Your dog is not eligible to participate in this study if you intend to breed from him (or her) in the near future (in less than 2 weeks from completion of the study), or she is currently pregnant or lactating. We need to know he or she is otherwise in good health and not taking any interfering medication.

By signing the owner's consent form for the screening process, you will be authorizing us to proceed with tests required to evaluate if your dog can be included in the study. We thank you very much for your collaboration in this investigation. Your participation to this study provides an important contribution to canine epilepsy research and the treatment of pets with idiopathic epilepsy.

Many Thanks