

**Patient Name:** \_\_\_\_\_

**Case Number:** \_\_\_\_\_

**OWNER CONSENT AGREEMENT**  
**Use of Accelerometry to Detect Seizure Activity in Dogs with Idiopathic Epilepsy**

As the owner or authorized agent for the owner of \_\_\_\_\_ you are being asked to have your dog participate in a clinical study being performed at NC State Veterinary Hospital. Please read the following and ask as many questions as needed to understand what your participation involves, before giving your consent to your dog's participation by signing and dating the statement at the end of this document.

**PURPOSE OF STUDY**

The purpose of this trial is to assess the potential use of an accelerometer, or activity monitor, as a means to detect seizure activity in dogs with epilepsy.

**EXPECTED DURATION OF PARTICIPATION**

The total duration of participation will be 6 months. During this time, your dog will wear a collar mounted activity monitor. You will be required to visit the veterinary hospital on 3 occasions during the study.

**PROCEDURES**

If you choose to enroll your pet in the study, the following procedures will be performed:

**Initial Study Visit:** An activity monitor will be mounted on a collar worn by your dog and you will be instructed on its proper use. You will also be asked to complete a Quality of Life survey. You will be provided a video surveillance system and instructions on how to set this up in a room in your home. This is to monitor seizure activity when your dog is left unattended. Your dog must be kept confined to the room with the video monitoring when left unattended. You will also be supplied with study forms that must be completed with the date, time and duration of any seizures that you observe in your dog.

**Interim 3-month Study Visit:** The function of the device will be checked and your records reviewed.

**6-month End of Study Visit:** You will be asked to complete a second Quality of Life survey and your records will be reviewed. You will be required to relinquish both the activity monitor and the video monitoring system at this visit.

Your dog will be humanely treated at all times and all investigative procedures will be performed using the customary methods applied to all other client-owned patients at NC State University Veterinary Hospital.

**POSSIBLE DISCOMFORTS AND RISKS**

There are no known risks and side effects associated with use of a collar mounted activity monitor.

**TREATMENT AND POTENTIAL BENEFITS**

There may be no direct benefit to your dog from its participation in this study. However, such participation may provide additional information about the extent of your dog's disease and, therefore, influence the course of treatment to help your dog or other animals in the future. Other than the potential benefits outlined herein, you will not receive any compensation for your dog's participation in this study.

**FINANCIAL OBLIGATIONS**

The study will cover the cost of the scheduled study visits. Complications may arise during the course of therapy due to the underlying disease and/or treatments rendered. You are expected to assume financial responsibility for all diagnostic efforts and medical treatments that might be required as a result of such complications.

**EXTENT OF CONFIDENTIALITY OF RECORDS**

The results of all study tests will be discussed both with you and your referring veterinarian (unless you wish otherwise). Except for this disclosure, all information obtained in this study will be considered confidential and

used only for research purposes. The identity of any individual animal in the study will be kept confidential when results of the study are presented, unless you are contacted and provide written authorization to do otherwise.

#### VOLUNTARY PARTICIPATION AND RIGHT TO WITHDRAW

Participation in this study is entirely voluntary. You may withdraw your dog at any time without prejudicing its present or future care. Refusing to participate will involve no penalty or loss of benefits. Your dog may be withdrawn from the study if your veterinarian finds it necessary and/or in your dog's best interest. If your dog is withdrawn from the study for any reason, its progress may continue to be followed and clinical data may continue to be collected from your dog's medical records without additional authorization.

#### TERMINATION OF PARTICIPATION BY THE INVESTIGATOR(S)

In return for considerable time, effort and expense on the part of the study, you are responsible for cooperating to the best of your ability with the specific requirements set forth as follows:

1. Make scheduled appointments.
2. Collect data at home on date, time and duration of seizure activity.
3. Set up the video monitoring system in a room of your home, and keep you dog confined to this room when left unattended.
4. Keep activity monitor secured to your dog.
5. Return activity monitor and video monitoring system at completion of study.

In the event that any of these requirements are not met, the principal investigator may elect to terminate your dog's participation in the study, and all costs originally covered by participation in the study will be billed to you.

#### UNFORSEEN RISKS

In any clinical trial, some currently unknown risks may be identified. The investigator(s) will inform you of any new risks or changes in the way the study will be conducted as soon as any such information becomes available.

#### UNIVERSITY COMMITTEE ON ANIMAL RESEARCH

This study has been approved by the Institutional Animal Care and Use Committee (IACUC) at North Carolina State University. Questions regarding this review can be directed to the IACUC office at (919) 515-7507.

#### CONTACT PERSON(S) FOR THE STUDY

The principal investigator of this study is Dr. Karen Muñana. If any questions should arise, she can be contacted by phone at 919-513-6231 or email at [Karen\\_Munana@ncsu.edu](mailto:Karen_Munana@ncsu.edu). Alternatively you can contact Julie Nettifee, the study technician at 919-513-6812 or [janettif@ncsu.edu](mailto:janettif@ncsu.edu) with any study related questions.

#### CONSENT

By signing below, I authorize my dog to participate in the proposed study described above. I have been fully informed about the proposed study. I understand that any procedure, even routine blood sampling, has the potential for complications. I understand that only properly trained personnel will be allowed to participate in the proposed study. I will not hold the College of Veterinary Medicine or North Carolina State University responsible for complications resulting from participation in the study. I will receive a copy of this signed consent form.

Owner/Agent's Name (please print): \_\_\_\_\_

Owner/Agent's Signature: \_\_\_\_\_ Date \_\_\_\_\_

Witnessed: \_\_\_\_\_ Date \_\_\_\_\_

