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**Place Patient Identification Sticker Here**

Veterinary Medical Center

601 Vernon L. Tharp Street

Columbus, OH 43210-1089

(614) 292-3551 Phone

(614) 292-1454 Fax

[**https://vet.osu.edu/vmc/**](https://vet.osu.edu/vmc/)

**Owner Informed Consent**

Study Title: Assessment of the Effects of Gabapentin on Blood Pressure in Cats with and without Chronic Kidney Disease

Principal Investigator: Jessica Quimby, DVM, PhD, DACVIM (Quimby.19@osu.edu; 614-292-3551)

This form is designed to provide you with information about this study, so you may make an informed decision about your animal’s participation in the project. This study has been reviewed and approved by The OSU Institutional Animal Care and Use Committee.

**Please read the following items.**

**1. What is the purpose of this study?** Stress associated with transportation, examination and diagnostic procedures is a major barrier to the feline patient’s capacity to receive regular veterinary care. Recently gabapentin has become popular as a medication prescribed to reduce stress and improve compliance during veterinary visits. In cats, anecdotal experience indicates that appropriate doses of gabapentin calm the CKD patient but may result in a lower blood pressure than without the medication. Taken together, it is necessary to explore the pharmacodynamics of the anti-anxiety dose of gabapentin in feline CKD so that these patients can safely benefit from its use. Therefore the purpose of this study is to demonstrate the effects of an anti-anxiety dose of gabapentin on blood pressure in CKD cats. A normal cat group will also be enrolled as a comparator to determine if this effect is exacerbated in CKD as a recent study reported no effect on BP in normal cats. A better understanding of this phenomenon will inform the use of this medication to palliate the stress of CKD cats during veterinary visit and determine to what effect blood pressure measurements are affected.

**2. Is my cat eligible to participate?** Two groups of cats will be enrolled: healthy cats with no known concurrent illness and normal laboratory test results, and cats with IRIS stage 2 and 3 CKD (serum creatinine ≥ 1.6-5.0 mg/dL). Exclusion criteria include other uncontrolled systemic illnesses, complications of CKD such as kidney infection or ureteral obstruction, decompensation of CKD requiring hospitalization and intravenous fluid therapy or current gabapentin therapy. Other concurrent therapies such as dietary management, potassium supplementation, anti-hypertensive medications and subcutaneous fluids are acceptable if they are given consistently throughout the study period.

**3. What procedures/treatments will my cat experience if enrolled in this study?** Both normal and CKD cats will receive a physical examination, a blood pressure measurement, and a one-time blood and urine collection for a complete blood count, biochemical profile, thyroid level, and urinalysis. After confirmation of enrollment, your cat will return for two subsequent visits approximately one week apart. At each visit a single oral dose of either gabapentin or placebo pill will be administered followed by a syringe of water to ensure swallowing. Your cat’s behavior will be observed in response to simple tests (i.e bladder palpation while lying on their side and lying in a padded trough) two times during the day. Three hours after pill administration your cat will have a blood pressure measured and a small blood sample drawn.

**4. What are the potential benefits to my cat for participating in this study?** Your cat will receive complimentary lab work. Results of this study will not be available immediately. The goal of the study is to acquire information that could be beneficial managing patients with CKD in the future. It is possible that your cat may not benefit directly from this study.

**5. What are the possible risks to my cat?** Your cat may experience transient stress of being in the hospital and mild discomfort of having blood drawn. If you cat is excessively stressed at any time, we will not continue with drawing the study procedures. A blood draw can result in bruising at the site of the blood draw. In rare cases, using a needle to collect urine directly from the bladder may result in hematuria, nausea or very infrequently bladder rupture. Your cat will be observed closely for side effects and appropriate medical care will be provided.

**6.  What are the financial costs and/or benefits associated with enrolling my cat in this study?** There is no cost to you for enrolling your cat in this study. You will receive complimentary physical examination for your cat and diagnostic testing including a complete blood count, biochemical profile, thyroid level, urinalysis and blood pressure. In the unlikely event that an adverse event would occur that requires treatment, the cost will be covered by the study.

**Please initial each statement**

\_\_\_\_I realize that any tests, procedures, or treatments beyond those specifically listed above are my financial responsibility.

\_\_\_\_ I have read the information above and understand the purpose and requirements of the clinical trial entitled "Assessment of the Effects of Gabapentin on Blood Pressure in Cats with and without Chronic Kidney Disease”

\_\_\_\_I understand that my cat must have a diagnosis of CKD or be a normal cat with no other concurrent conditions in order to participate in the study.

\_\_\_\_ After confirmation of enrollment, I understand my cat will need to return for two total visits over the course of the 7-10 day study period.

\_\_\_\_ Data and fluid samples collected from my cat will become the property of the institution.

\_\_\_\_I give my permission to publish data and images obtained from this study. I understand that all personal identifying information will be removed from scientific publications.

\_\_\_\_If I choose not to participate in this study it will not affect the care of my cat.

\_\_\_\_I may withdraw my cat from this study without penalty. Withdrawal of my cat will not interfere with future care. I understand that investigators may continue to collect information from my cat’s medical record following withdrawal.

\_\_\_\_The study team reserves the right to remove my cat from this study for failure to meet study requirements or if it is in the best interests of my cat.

\_\_\_\_I may discuss this study with others and ask advice from my own veterinarian.

\_\_\_\_ Someone may contact me after my cat has finished this study to collect follow-up treatment and outcome information. This may occur several months to years following completion of the study.

\_\_\_\_I have had time to ask questions regarding this study and feel comfortable moving forward with enrollment in this study based on the information provided.

\_\_\_\_I hereby grant to the College of Veterinary Medicine at The Ohio State University, Columbus, OH the right to publish, broadcast, webcast, or disseminate in any other form or medium any or all of the following:

* Stories, photographs, video, audio, and other images or likenesses of my animal for use in news stories, publications, promotional materials, including advertisements, web features and/or any other official purposes.
* I understand that I will not receive financial compensation for this use.
* All photographs, video, audio, images, likenesses, stories, and other materials will remain the property of Ohio State.

For additional questions or concerns about the study, please contact *Dr. Jessica Quimby* at Quimby.19@osu.edu. Or if you would like to discuss any concerns with an individual not directly related with the study, please contact Ms. Lora Montgomery, Assistant Director, Customer Service at 614-292-5772 (Montgomery.1012@osu.edu)

As a result of discussion with \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, and after reading the above, I voluntarily consent for my [species] to participate in this study and will follow the instructions of the study team, as it pertains to therapy and follow-up procedures. I certify that I am the legal owner/guardian of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

Signed \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Owner or authorized agent of the owner

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