



## Recruiting Patients for a Clinical Trial at MSU Veterinary Medical Center: Chronic Kidney Disease in Cats

*Ethics approval (IACUC): 202500086*

### What is the purpose of this research study?

This study collects information about the physical status, blood pressure and selected laboratory parameters of cats that belong to one of two groups: a) they are healthy; b) they have been confirmed to have chronic kidney disease (CKD). The purpose of the study is to assess whether administration of a probiotic changes the natural gut microbial flora (microbiome) of these cats, and influences markers of renal (kidney) health and phosphate homeostasis through this microflora change.

### What am I being asked to do?

If you decide to have your cat participate in this study, you agree to the following:

- Have your cat participate in a study of approximately 6 months in length, with monthly assessments during that time. ***Please note: You can withdraw your cat from the study at any point.***
- As advised, give a supplement, which will either be a placebo or probiotic (sprinkled over a meal) to your cat daily for 2 periods of 8 weeks. Please note that some cats in the study will not receive the probiotic (control group), but you will not know which group your cat is in until after the study has finished.
- Every 4 weeks, answer questions regarding the current health status, diet and medications using a provided electronic diary template.
- Every 4 weeks, collect 2-3 sequential fresh stool samples of your cat, store them in cool (4°C or 39°F) provided containers (with ethanol) and send in provided postage bags, or bring them to MSU within 24 hours.
- 4 times over study period, present your cat for scheduled revisits for a physical examination, blood pressure measurement, and blood and urine sample. We anticipate these appointments to each take 30-60 minutes.

Week	What is done
0	Vet check + samples, submit baseline questionnaire, stool sample, start supplement 1
4	Submit home diary, stool sample
8	Vet check + samples, submit home diary, stool sample, stop supplement 1
12	Submit home diary, stool sample
16	Vet check + samples, submit home diary, stool sample, start supplement 2
20	Submit home diary, stool sample
24	Vet check + samples, submit home diary, stool sample, stop supplement 2, study ends

Your animal's participation in this study will be complete after 4 veterinary assessments or no more than 6 months after its first evaluation.

*Please note: The time intervals and samples taken are similar to those of our usual standard of care for cats with CKD. In other words, even if your cat does not participate in the study, above-mentioned checks (physical examination, blood pressure measurements, blood and urine samples) are often recommended at 3 monthly intervals. All procedures will be performed by a qualified veterinarian or under direct supervision of a qualified veterinarian.*

## **What are the possible risks or discomforts to my cat?**

Blood pressure measurements and physical examinations are non-invasive. In most cases, they will be performed with you present, to ensure your cat is as calm as possible.

The blood sample will be obtained from the neck vein. The hair over the vein may be shaved to help see the vein better. A small needle will be inserted into the vein, and approximately 6-8 ml (the equivalent of approximately 1-2 teaspoons) will be removed.

We will also obtain a urine sample (approximately 5 ml) directly from the urinary bladder, using a small needle and syringe. It is best that your cat is not allowed to urinate in the 2 hours immediately before the visit to ensure there is urine in the bladder.

We practice low-stress handling techniques and encourage you to discuss with your regular veterinarian if your cat may benefit from pre-visit medication to reduce anxiety (such as gabapentin). Sometimes, we apply a local anesthetic cream to the site where we will obtain a blood sample; this has no adverse effect but can extend the visit by 10-15 minutes. If we feel your cat becomes too stressed by the visits, we may discuss with you removing your cat from the trial.

## **What are the possible benefits of the study for my cat?**

- You will be able to discuss physical examination findings and blood pressure measurements with the attending clinician.
- You will have access to **most** of the blood and urine results 2-3 days after each visit.
- Your cat may benefit from the probiotic administration, though this long-term effect **remains to be confirmed**.

## **Will I be paid for my cat being in this study?**

You will not be directly paid for study participation. However, you gain access to:

1. Free consultations and examinations, including blood pressure measurements, if they fall into the study schedule.
2. Free blood and urine tests, as far as they relate to this research project.
3. Probiotics will be provided free of charge to you.

At your request, the research veterinarian will give you a printed estimate of the individual benefit and this will be recorded in your cat's record.

Any health examinations or diagnostics that do not relate to this research (e.g. if you request a different test or treatment at the time of the visit) will not be covered by the research project's budget and remain your obligation. Medication (besides the probiotic) and diet will not be covered by the project.

## **Can my cat leave the study before it ends?**

If you decide to have your cat participate, you are free to withdraw your cat from the study at any time. Withdrawal will not interfere with your cat's future care, but you will forego any benefits listed above.