

Client Name: _____ Client Phone: _____

Patient Name _____ Clinic: _____



**INFORMED CONSENT FOR
Azodyl Renal failure Trial (ART)**



Clinical Investigators: Mark Rishniw, Paul Pion, Veterinary Information Network

Background information:

Chronic renal failure (CRF) is a common and debilitating condition that usually affects older cats. As kidneys fail, waste products build up in the blood, causing ill-health, and can lead to death or euthanasia. Reducing these waste products may improve the quality of life in cats with CRF. In humans, this is done by dialysis or kidney transplantation, which are not commonly performed in cats.

Recently, a novel product, Azodyl, consisting of beneficial, “waste-metabolizing” bacteria, has been introduced into the veterinary market. The manufacturer claims that these bacteria, if fed consistently to a patient with CRF, will decrease the levels of waste products in the blood and improve quality of life. The bacteria are harmless and reside within the intestines, where they extract and neutralize the waste products from the blood. If these claims are true, many cats may benefit from this type of therapy.

Purpose of Study: The *safety* of Azodyl has been demonstrated. Cats do not develop any side effects from the medication. However, the *effectiveness* of Azodyl is still under investigation. This study hopes to examine the effects of Azodyl, by comparing it to a placebo (which is also harmless), in cats with stable CRF.

Eligibility: To be eligible for participation in this study, your cat must have previously documented stable uncomplicated chronic renal failure/insufficiency.

Procedures: (1) Venipuncture (drawing of blood) on 4 separate occasions (once a month over four months), to be performed by the primary care clinician (your vet).

(2) Feeding the contents of a capsule (Azodyl or placebo) once or twice daily for 2 months. The contents will be sprinkled on the food.

Associated Risks: There is only 1 minor short-term associated risk with this procedure. I understand the following risk(s) associated with the study’s procedures:

(1) Venipuncture may result in minor bleeding/bruising at the site of needle insertion and momentary pain

My cat may be upset about going to the veterinary clinic and having blood collected.

Compensation: All blood analysis and medications associated with the trial (Azodyl or placebo) will be provided or paid for by the investigators. Veterinarians will be compensated for their time.

Questions about this project may be directed to Mark Rishniw BVSc, MS, DACVIM at 916-275-1650 or mrishniw@vin.com.

To minimize bias by owners and veterinarians, results of the blood test, and knowing the contents of the capsules will only be available during the study if medically necessary (by veterinary request), and at the end of the study period for your pet.

I understand that my cat's(s) participation in this study is entirely voluntary. Refusal to participate carries no medical penalty, and I am free to withdraw my animal from this study at any time without medical penalty or prejudice.

I acknowledge that I have read and understand this consent form and all my questions have been answered to my satisfaction.

I have been given a copy of this consent form.

Printed Name: **Owner** (or authorized agent)

Signature Owner (or authorized agent)

Date

Printed Name: **Witness**

Witness Signature

Date

Please return the signed consent form to:

Mark Rishniw
T4-002A Veterinary Research Tower
Tower Rd,
Cornell University
Ithaca NY 14853