



Novel Biomarker and Therapeutic Target for CKD in Dogs Clinical Trial Information Handout

Background and Importance of Study:

Chronic Kidney Disease (CKD) is defined as the presence of functional abnormalities in one or both kidneys over a prolonged period of time. Serum creatinine is currently used as a marker of kidney function, but it cannot detect early changes in kidney function. Detecting CKD early has significant importance because early treatment could slow the rate of disease progression, improve the patient's quality of life and prolong survival times. In addition, early detection of kidney disease will give us the best chance to identify the underlying cause to target our treatment better. There is a critical need for us to identify biomarkers of kidney function that can be used to diagnose early kidney disease. This proposed research project aims to characterize a new biomarker for kidney disease that will hopefully allow us to predict outcomes and/or therapeutic responses.

Who can be enrolled in this study?

- 1. Dogs diagnosed with stable IRIS stage II -IV CKD (serum creatinine > 1.4 mg/dL or SDMA > 18 and lack of appropriate urine concentration, USG < 1.045)
- 2. Dogs must be willing to eat a renal diet.

What will exclude patients from enrollment:

- 1. Evidence of lower urinary tract infection based on urinalysis or urine culture
- 2. Dogs receiving alkaline therapy (sodium bicarbonate or potassium citrate), diuretics or steroids.
- 3. Dogs diagnosed with Cushing's disease

What is involved in study participation:

- Each dog will be seen for 4 study visits after enrollment into the study. These visits will occur every 3 months for one year
- At study enrollment each dog will have the following testing performed: a renal biochemistry panel, PCV/TP, urinalysis, urine protein-to-creatinine ratio, and blood pressure measurement
- At each study visit after enrollment each dog will have a renal biochemistry panel performed.

What costs does this study cover?

- **Study Enrollment Visit:** examination fee, blood and urine collection for renal biochemistry, PCV/TP, urinalysis, urine protein-to-creatinine ratio, and blood pressure measurement.
- Follow up Study Visits (4 total): examination fees, blood collection for renal biochemistry panel
- Study Renal Diet: Purina NF for 12 months (study duration)

How do I get my pet scheduled and enrolled in this study?

• For more information, please contact: Dr. Harris at anharr25@ncsu.edu