Client Consent Form
Colorado State University Veterinary Teaching Hospital
300 West Drake Road, Fort Collins, CO 80523

Client ID

Client Information – What is the study about?

Chronic kidney disease is a common disease in older cats. This is typically a progressive disease for which there is no definitive treatment. Currently, other than kidney transplantation, only supportive care home treatments are available to try and slow the progression of the disease. Recent studies have shown that stem cell therapy has the potential to improve kidney function in rodents with kidney failure. Proposed benefits of stem cell therapy include improvement of renal values, promotion of cellular regeneration and healing, prevention of fibrosis and improvement of proteinuria.

We have previously performed a pilot study in cats where stem cells were injected intravenously. In this study no cat suffered any ill effect from the treatment and a few cats had mildly improved creatinine and Glomerular Filtration Rate (a measure of kidney function). The purpose of this study is to further explore intravenous stem cell therapy for chronic renal failure in cats with Stage IV disease.

Is your cat eligible to participate?

Cats that have been diagnosed with chronic stable kidney disease (creatinine > 5.0 mg/dL), without evidence of hereditary kidney disease, based on bloodwork and ultrasound evaluation, are eligible for entry into the study. Eligible cats must have a current labwork panel (CBC, chemistry, urinalysis, urine culture, thyroid level, and blood pressure) and evaluation of the kidneys by ultrasound. If a heart murmur is present, cardiac ultrasound (echocardiogram) is
required to rule out significant heart disease. Concurrent diseases such as diabetes, hyperthyroidism, cancer or heart disease would also be reasons for exclusion from the study.

Other concurrent therapies such as kidney diets, famotidine, potassium supplementation, ACE inhibitors and anti-hypertensives are allowed, but no changes in therapy can be made during the study time period. Subcutaneous fluid administration is required during the period of the study. This is necessary to offset the stress of hospital visits and procedures necessary during the study. If your cat is not currently on SQ fluids, a minimum of twice weekly therapy is required. This should be initiated at least two weeks before beginning stem cell therapy to allow an accurate baseline labwork to be obtained.

**What does the study involve?**

Stem cells that have been grown from the adipose (fat) of young healthy specific-pathogen free cats (the cats are not harmed during the collection process) will be slowly injected intravenously via a intravenous catheter every two weeks for three treatments.

Blood and urine tests (CBC, biochemistry, urinalysis and urine protein-creatinine ratio) will be performed immediately before the first injection, at each visit, and again 2 weeks and one month after the final injection.

**What are the risks?**

This procedure has previously been performed in several cats, who have had no major complications, however, there is still a slight risk that the injection may trigger a reaction if the cells were to lodge in a blood vessel somewhere in the body (particularly in the lungs). This is why the cells are diluted in a solution and the injection is given slowly. One side effect of therapy may be vomiting or nausea, similar to that seen with a vaccine reaction. If your cat should experience this, premedications can be given prior to additional treatments, or alternatively you can decide to discontinue the treatments entirely.

As these stem cells are from another cat, one might expect that there is an immune reaction to the cells. However, allogeneic (transfer between individuals) stem cell therapy is current being performed in many species, including humans, with no obvious sign of the body rejecting the stem cells. It is important to know that if your cat experiences decompensation of its kidney disease and requires hospitalization (which can commonly happen in Stage IV cats), we are unfortunately unable to cover the cost of this event.

**Is there compensation for your participation?**

The cost of preparing the stem cells as well as all costs of visits, labwork and injections are graciously covered by a grant from Frankie's Fund for Feline Stem Cell Research, provided your cat is able to travel to CSU for the study. If your cat develops other illnesses unrelated to the treatment, the study will also not be able cover those costs, nor can the study cannot cover the costs of ancillary treatments for kidney failure that your cat may already be receiving or may need to receive in the future.
Owner Consent

I have read the explanations of the study provided above and I understand the above stated conditions and I agree to allow my cat to undergo the procedures described above. If I have any concerns or questions related to this study I should contact Dr. Jessica Quimby at (970) 297-5000 or jquimby@colostate.edu.

Signed: ____________________________________________

Date:______________________________________

Witness:____________________________________________