Adipose-derived feline stem cell therapy in cats with inflammatory bowel disease

Colorado State University

Appointment Desk: (970) 297-5000
http://csu-cvmbs.colostate.edu/vth/

Place Patient Identification Sticker Here

Clinical Trials: Owner Informed Consent
Allogeneic Adipose-derived Mesenchymal Stem Cell Therapy for Cats with Inflammatory Bowel Disease.

I understand that the veterinarians at this institution are engaged in research for the improvement of animal health, patient care, education, clinical investigation, and scientific innovation. The detailed procedures of the "Stem Cell" Clinical Trial have been explained to me by:

Dr. _____ on _____.

Please check the following boxes to confirm your understanding of the components of this particular study:

☐ My cat must have a histopathologic diagnosis of Inflammatory Bowel Disease (IBD) in order to be eligible to participate in this study. Any additional significant or relevant disease will disqualify my cat from participation. My cat must also have been on a hypoallergenic or hydrolyzed diet for a minimum of 2 weeks, but continue to have diarrhea, to be eligible.

☐ The purpose of this study is to determine if stem cell treatment is as effective as steroid (prednisolone) treatment for cats with IBD.

☐ My pet will be treated by CSU Clinicians, with the same standard of care as any other clinical patient. My pet will undergo standard diagnostic procedures including blood draws and endoscopic or laparoscopic- assisted intestinal biopsies under anesthesia. I will be asked to sign an anesthesia consent form, and the risks associated with both the procedure and anesthesia will be explained to me.

☐ If my cat meets the eligibility requirements, he/she will be assigned to one of two groups. Stem Cell Group: treated with 2 intravenous injections of stem cells two weeks apart and placebo oral medication for 6 months, or Steroid Group: treated with 2 placebo intravenous injections of saline buffer and prednisolone oral medication for 6 months. I realize that I will not be told which group my cat is assigned to, and it is possible my pet will not benefit from either of these treatments. If that appears to be the case, after 2-months (or anytime thereafter) my clinician and I may decide to try different or additional treatments for the remainder of the study period. Regardless of group assignment, I agree to keep my cat on its current hydrolyzed/hypoallergenic diet throughout the course of the study.

☐ I understand that the study requires me to bring my cat back to CSU for a recheck appointment 2 & 6 months after the start of the study. I will bring a recent fecal sample to each of those appointments, and I am willing to fill out a questionnaire at the initial appointment and each of the recheck appointments. Any additional appointments during, or after the study period are not a part of the study, even if they are recommended by your clinician.

☐ I understand that this stem cell therapy has been used in a pilot study of cats with chronic diarrhea, and none of the cats that received the stem cells had any adverse reaction, either during injection or for the 2-3 months following injection while they were still being monitored for the study. Similar stem cells have been given to cats with kidney disease, asthma, and gingival stomatitis with minimal if any adverse side effects. Stem cells are routinely used in horses, dogs, and people to good effect, with minimal or no side effects. However, I realize it is possible my pet will experience side-effects; these could range from non-specific changes in appetite or activity, to an allergic-like reaction, even death. My pet will be observed

closely for side effects and I will notify the clinician if these appear or I have questions or concerns. Cats are generally more tolerant of prednisolone than dogs or humans, but may still experience increased thirst & urination, hunger, thin skin or muscle wasting, even diabetes mellitus. The potential side effects of stem cell therapy and prednisolone have been explained to me and I understand the risks and potential benefits.

☐ Alternate (non-study) treatment protocols have been discussed and I understand the relative benefits of those treatments. I understand that I will keep my cat on the treatment regimen (two injections 2 weeks apart followed by daily oral treatment) for the first 2 months of the study unless specifically directed to do otherwise by my attending clinician and reported to the study investigators. I also understand that I will not make a change to my cats diet, or add any supplements, during the first 2 months of the study unless specifically directed to do otherwise by my attending clinician, and reported to the study investigators.

☐ I understand that the cost of the initial appointment, the injections, and the 2-month and 6-month recheck appointments are paid for by the study. The study will also cover the cost of the diagnostic tests during those appointments that are specified by the study protocol. Any diagnostics performed that are not specified in the study protocol (e.g. abdominal ultrasound, chest radiographs, etc.) will be my financial responsibility. Those diagnostics not covered by the study would be discussed with you before they are performed, and only performed with your consent.

☐ I understand that I must administer the oral medication according to the schedule provided by the attending clinician. There are several options for oral medication (pills, liquid), should one prove difficult, I would be willing to try the other form. If for any reason I cannot administer the oral treatment I must notify the attending clinician as soon as possible. The cost of the stem cell injections and the oral treatment are paid for by the study.

☐ I give my permission to publish data and photos obtained from this study for the benefit of the scientific community. I understand that my pet will not be identified individually.

☐ I may withdraw my pet from this study at any time without penalty.

☐ The attending clinician in charge may withdraw my pet from this study if he/she determines that my pet is adversely affected, or needs additional treatments during the first 2-months of the study.

☐ I may discuss this procedure with my own veterinarian and ask his/her advice.

☐ I understand that someone may contact me after my pet has finished this clinical trial to collect follow-up treatment and outcome information. This may occur several months to years following completion of the trial.

☐ I have been given the opportunity to have ample time to make the decision to enroll my pet in this particular study and feel comfortable moving forward with enrollment in this study based on the information provided.

☐ I understand that the funding for this study is provided by the Winn Feline Foundation.

As a result of discussion with Dr. _____, and after reading the above, I voluntarily consent to participate in this project and will follow the instructions of the veterinarians-in-charge.

Signed _____ Date _____
Owner or authorized agent of the owner

Witnessed By: _____ Date _____