**Place Patient Identification Sticker Here**

**Appointment Desk: (970) 297-5000**

[http://csu-cvmbs.colostate.edu/vth/](http://csu-cvmbs.colostate.edu/vth)

Clinical Trials: Owner Informed Consent

*Limited sampling strategy for determining*

*mirtazapine pharmacokinetics in cats with liver 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 *Limited sampling strategy for determining mirtazapine pharmacokinetics in cats with liver disease* 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 pet must have a confirmed diagnosis of liver disease or be a healthy geriatric cat in order to be eligible to participate in this study.

*Group 1:* Healthy geriatric cats with a normal CBC, chemistry, urinalysis and thyroid level. Exclusion criteria for healthy geriatric cats include other systemic illness (diabetes, inflammatory bowel disease, hyperthyroidism, cancer, liver disease, heart disease, etc.).

*Group 2:* Cats that have been diagnosed with liver disease based on elevation of serum liver enzymes (specifically ALT or total bilirubin levels).

[ ]  The purpose of this study is to use a limited sampling strategy to determine if metabolism of mirtazapine is altered in cats suffering from liver disease. Mirtazapine is commonly used as an effective appetite stimulant and anti-nausea medication. The drug has become a mainstay of supportive care for cats with chronic and terminal diseases. In humans liver disease results in 30% decrease in clearance of the drug. However, the effect of liver disease on the metabolism of the drug in cats is unknown.

[ ]  My pet will be treated by a group of veterinarians specializing in clinical research. My pet will be treated with the following procedures: Giving a single oral dose of the appetite stimulant/anti-nausea medication mirtazapine and collecting two small blood samples during the day of administration at 1 hour and 4 hours after the pill is given. Your cat will need to stay in the clinic during this period. The samples will be analyzed by the Pharmacology Core Laboratory at CSU.

[ ]  I realize that it is possible my pet will not benefit from this treatment.

[ ]  All drugs and methods used have been carefully tested individually to minimize potential toxicity. However, I realize it is possible my pet will experience unexpected side-effects which could be mild, moderate or severe (including death). My pet will be observed closely for side effects and appropriate action will be taken.

[ ]  The potential side effects of mirtazapine have been explained to me and I understand the risks and potential benefits.

The side effects of mirtazapine in cats include increased activity, vocalization, and occasionally dysphoria or excitability that occur in a dose-dependent manner. Higher doses in cats have been associated with sedation, muscle tremors, elevated heart rates and low blood pressure. In general this medication is well tolerated and we do not expect these side effects at the dose administered.

[ ]  Alternate (non-study) treatment protocols have been discussed and I understand the relative benefits of those treatments.

[ ]  I understand that participation in this study will help us learn more about how to better treat cats suffering from liver disease.

[ ]  I understand that bloodwork (CBC, chemistry, UA, T4) for healthy geriatric cats will be paid for by the study. A chemistry panel will be paid for by the study for cats with liver disease. If your cat develops other illnesses unrelated to the treatment, the study will not cover those costs.

[ ]  I realize that the costs for treatment once off study will not be covered.

[ ]  Blood specimens are an integral part of the treatment program and will be done at intervals at the recommendation of the veterinarian in charge. Fluid samples collected from my pet will become the property of Colorado State University.

[ ]  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 veterinarian in charge may withdraw my pet from this study if he/she determines that my pet is adversely affected.

[ ]  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 Angelo Fund for Feline Therapeutics.

[ ]  I understand that one or more of the investigators in this study may have a conflict of interest. For this particular study, no conflicts of interest exist.

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, as it pertains to therapy and follow-up procedures.

Signed \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Owner or authorized agent of the owner

Witnessed By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_