**Optimization of Fluconazole Dosing Based on Body Weight in Dogs**

**Dog Owner Consent Form**

**Background**

Valley Fever is caused by a fungus that lives in the soil of the southwestern United States. The disease in dogs may range from asymptomatic to widespread illness in multiple organs. Orally administered fluconazole is currently the most widely used treatment for dogs with coccidioidomycosis (Valley Fever) in Arizona. Early work on the pharmacokinetics of fluconazole in dogs was done on beagles, which does not account for the size range of pet dogs. Fluconazole is largely excreted from the body through the kidneys, and large breed dogs may clear the drug more slowly than small dogs. This could result in large breed dogs receiving fluconazole doses that are higher than necessary to treat the fungus, which in turn may lead to more adverse events and higher drug costs.

This Study is for dogs taking generic fluconazole from a commercial source, such as Costco, Safeway, Walgreens, etc. The objective of this study is to determine if body weight has an important effect on the serum concentration of fluconazole in dogs. For analysis, dogs will be divided into small, medium and large groups to determine whether there are differences that should be used to optimize prescribing of fluconazole for dogs by weight category. Dogs who enroll in this study are already being treated with fluconazole twice daily for Valley Fever for at least 30 days.

The Study veterinarians will collect a single blood sample 12 hours (+/- 1 hour) from the previous dose the night before the test. We will weigh your dog, collect information about your fluconazole tablets from your prescription label, record the time of the dose the evening before, and draw a blood sample. The sample will be divided and a small portion will be used to determine the serum creatinine (an enzyme to determine normal kidney function) and the remainder will be frozen for testing fluconazole concentrations. The fluconazole tests will be run in batches.

**Volunteer and Procedures:** I volunteer my dog,\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, to give a

blood sample (5-6 mls, about a teaspoon) to test fluconazole concentrations to optimize dose recommendations for dogs in different weight categories.

I have read and understand the following procedures to prepare my dog to participate in the Study.\_\_\_\_\_\_ (initial)

**Before the test:**

**1)** Your dog’s PM dose of fluconazole will have the time of administration adjusted to be approximately 12 hours from his/her appointment to collect the blood for the study. When the Study veterinarian schedules the blood collection appointment, she will tell you what time to give the fluconazole. Please record it. You will need it in the morning. If you are bringing this consent form to the visit, you can record it here:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Time/date given.

**2)** Take a cell phone photograph of the entire label of your dog’s prescription bottle or bring the bottle with you to the blood draw appointment so the information about the dose, pharmacy, and brand of the fluconazole can be collected from the label.

**Day of test:**

**1) DO NOT** give fluconazole the morning of the test. Your dog can have breakfast and any other regular medication he/she takes. Bring your dog to the Study site, Tucson Veterinary Specialists, 1601 W. Ina Road, Tucson, 85704. If you accidentally gave the fluconazole in the morning, call the study veterinarian and we will reschedule your dog’s blood test.

I understand there is no health risk associated with drawing blood from my dog. My dog will

experience momentary pain as the needle penetrates the skin, and he/she may experience mild bruising at

the site of needle puncture.

I understand the samples will be stored and tested in batches, and I will not know the results of this testing. My veterinarian may be informed of the results of the testing if they are considered relevant to improving my dog’s treatment.

**Potential Medical Benefits:** My dog will derive no direct medical benefit from participating in this

study. The collective data from this study will be analyzed and used to improve treatment recommendations in dogs treated for Valley Fever in the future. If the results of the test from my dog suggest that his/her treatment could be improved by the results of the test, my veterinarian will be contacted.

**Potential Risks:** My dog may develop mild bruising at the site of the blood draw. Bruising will heal in a

few days.

**Costs to Owner:** There are no costs to participate in this study.

**Compensation:** There is no financial compensation for participating in this study.

**Confidentiality:** In publications and presentations resulting from this research study, information about

my dog or me will be kept in the strictest confidence and will not be released in any form identifiable to

me personally.

I am the Owner or duly authorized agent for the dog named above in this study. I have read and

understand the potential risks and benefits for participation of my dog in this study.

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Name of Owner (Print)

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Signature of Owner Date

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Name of Witness (Print)

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Signature of Witness Date

We will be running a second arm of this study to evaluate the 24 hour exposure of the dog’s blood and tissues to fluconazole, which generally has a relationship with the efficacy of a drug if it is in the “therapeutic range.” Dogs participating in this arm will have three blood samples taken over 6 to 8 hours, requiring the dogs to remain in the clinic for most of a day. If you are interested in having your dog participate in this arm of the Study as well, please provide your contact information below.

Dog’s Name\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Owner name/Email\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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