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Consent to Assess Clinical Outcomes in the Course of New Veterinary Treatments

This Form to be used in conjunction with the ISU Veterinary Medical Center "Consent to Treatment and/or Operation"

Title of Study: The Effects of Canine ABCB1-1Δ mutation on common pre-anesthetic medication combinations.

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PURPOSE

There is a gene mutation (ABCB1-1Δ or MDR1) in dogs that results in an increase in sensitivity to certain drugs, including several drugs used for anesthesia/analgesia. The most common dog breeds that carry this gene mutation include: Collie, Longhaired Whippet, Shetland Sheepdog, Australian Shepherd (and miniature), Waller, White Swiss Shepherd, Old English Sheepdog, Border Collie. However, multiple studies have found a widespread breed distribution, including mixed breed dogs.

The purpose of this study is to compare sedation effects of common preanesthetic drug combinations in dogs with and without the ABCB1-1Δ gene mutation to better inform veterinarians regarding dosing recommendations and potential side effects in affected dogs.

DESCRIPTION OF PROCEDURES

If you agree to have your dog participate in this study, the participation will last for three hospital visits, the first visit will be short (< one hour), the subsequent two visits will last approximately 6 – 8 hours. All procedures on your dog will be performed by a licensed veterinarian with the assistance of either another licensed veterinarian, a veterinary technician, or a veterinary student. At the first visit, a cheek swab of the mouth will be taken to submit for genetic testing to see if your dog carries the gene mutation. The study will require 12 dogs in each genetic group (two normal copies of the gene (normal/normal), one normal copy of the gene and one mutation (normal/mutation) and two copies of the mutated gene (mutation/mutation). Once we have filled study subject spots for a group, additional dogs may not be used for the sedation part of the study. Genetic testing results will be provided to all owners of tested dogs, regardless of their further participation in the sedation part of the study.

If your dog qualifies for the study according to his/her genetic profile, at the second visit your dog will have a complete physical exam and blood will be drawn to check a packed red cell volume (PCV) and a blood chemistry to evaluate liver and kidney function to ensure your dog is healthy prior to sedation. Your dog will be administered 3 common preanesthetic drugs (maropitant, acepromazine and butorphanol). Your dog will be observed for up to 6 hours after sedation. We will be monitoring and documenting the level of sedation, heart rate, respiratory rate, blood pressure and body temperature. You will return at least 7 days later and your dog will receive the 3 drugs again but at a different dose and the same protocol will be followed. All drug doses are within recommended dose ranges for canine clinical patients.

RISKS

The possible risks for your animal from participation are:

Maropitant may cause some gastrointestinal upset in the form of signs of nausea (drooling). Acepromazine may be expected to cause sedation and can have some effects on the cardiovascular system including a decrease in blood pressure. However, at the dose to be used in this study and in healthy dogs, it is not expected that these effects would have a negative impact on your dog. Butorphanol may also be expected to cause sedation. The sedative effect of both of these drugs may last for a few hours after your dog returns home from the hospital.

Your dog may experience some amount of stress associated with the hospital environment and handling for sample collection and drug administration. As well, your dog may experience a small amount of discomfort with the needle stick for intravenous or subcutaneous drug administration. However, if it is determined that at any time your dog is experiencing an excessive level of stress, they will be removed from the study.

Additionally, there may be unforeseen risks of participation in this study. In the event of unforeseen risks, the investigator will use his or her judgment to guide the care of your animal and discuss options with you when possible under the circumstances. The investigator may terminate your animal's participation in the study if continuation is not in the best interest of your animal or as otherwise deemed prudent or necessary by the investigator. In the unexpected event of your animal's death during the study, a post-mortem examination may be required to determine the cause of death (i.e., the death may or may not be related to the research and may even be the result of a natural cause). The need for autopsy will be determined by the investigator and the ISU Attending Veterinarian and/or the Institutional Animal Care and Use Committee; the investigator will pay for any costs associated with the necropsy.

COSTS AND COMPENSATION

You will not have costs from your animal's participation in this study. You will be responsible for any costs associated with the normal course of treatment, the treatment of any complications that may arise, and unrelated medical conditions.

You will be compensated for your pet's full participation in this study in the form of the results of the genetic testing ($70 value) and baseline bloodwork (~ $156 value). You will still receive genetic testing results if your dog cannot be used for the drug testing part of the study.

VOLUNTARY PARTICIPATION AND RIGHT TO WITHDRAW

Participation in this study is completely voluntary. You may choose not to have your animal participate. If you decide to have your animal participate, please realize that once drug administration has been performed this cannot be reversed. However, you may change your mind and withdraw your animal from further participation in the study at any time. If you decide not to have your animal participate in the study or if you withdraw your animal from the study early, it will not affect your right to receive treatment for your animal at the Iowa State University College of Veterinary Medicine. We can discuss the usual treatment options noted above and any alternative diagnostics, procedures, or treatments that may be available if your animal is not enrolled in the study.

CONFIDENTIALITY

Government regulatory agencies may inspect and/or copy the records for your animal for quality assurance and data analysis. These records may contain private information. Additionally, the investigators may use data generated from this study, including photographs and video images, in scientific journal articles or presentations and for educational purposes. Neither you nor your animal will be identified individually in such articles, presentations, or educational programs. However, as video will be collected as part of this study, it is possible that your dog could be identified by his or her appearance from those video images.

QUESTIONS OR PROBLEMS

You are encouraged to ask questions at any time during this study. For further information about the study, contact Dr. Bonnie L. Hay Kraus (bhkraus@iastate.edu)

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OWNER SIGNATURE

Your signature indicates: (1) you voluntarily agree to your animal's participation in this study; (2) you are the legal owner of the animal or are an agent of the owner with authority to consent to the animal's participation in this study; and (3) you have read this Owner Consent Document and your questions have been satisfactorily answered. You will receive a copy of this Owner Consent Document prior to your animal's participation in the study.

Printed Name of Owner or Agent: _____

Owner or Agent's Signature: _____

Name of Animal: _____

Date: _____

INVESTIGATOR STATEMENT

It is my opinion that the owner or owner's agent understands the purpose, risks, benefits, and the procedures that will be followed in this study and has voluntarily agreed to participate.

Investigator Signature: _____

Date: _____