Cornell University
College of Veterinary Medicine

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Owner Informed Consent Document for:

Patient Name Client Name Case #

1. **Title of clinical study: <u>Metabolic Investigation of Canine Hepatocutaneous Syndrome</u>**

2. **Investigator(s) Name and Contact Information: Dr. John Loftus, (607) 253-3060.**

3. **Why is this clinical study being done and why is my dog being invited to take part in this clinical study?**

   Hepatocutaneous syndrome (HCS) is an uncommon to rare, but painful and ultimately fatal disease. We are currently investigating metabolomic profiles and proglucagon-derived hormones (glucagon, GLP-1, and GLP-2) in dogs with this disease to further our understanding of the disease and identifying new ways of treating it. In order to determine if proglucagon-derived hormones are present at abnormal levels in dogs with HCS, we also need samples from healthy dogs and dogs with diabetes mellitus (DM) that do not have HCS for comparison. Your dog may be invited to participate if it has suspected or diagnosed HCS, DM or as a healthy dog for comparison.

4. **If I choose to enroll my dog in this clinical study, what will happen to my dog, what will my time commitment be, and what are my responsibilities?** If you agree to let your dog participate in this study, the study's procedures, time requirements, and responsibilities are as follows: Two samples of whole blood before (8 ml) and after (4 ml) a meal will be collected. Urine will be obtained (collected by free catch unless another collection method is pursued for medical reasons related to your dog's visit). There are no other time requirements or responsibilities.

5. **What happens if I do not want to enroll my dog in this clinical study or I enroll my dog, but I change my mind later?** Participation in any clinical study is voluntary. If you decide not to participate in the study, your choice will not affect your dog's future medical care at Cornell University. We fully understand and support your decision.

   You can remove your dog from the study at any time. It will not affect your access to future medical care for your dog at Cornell University outside of this clinical study. It is important to let us know early on if you decide to remove your dog from the study. Data that have already been collected may be included in the study.

6. **What are the benefits for my dog or other dogs?** Possible benefits include further information about a disease your dog may have (HCS), or if your dog is a healthy control, you are benefitting this study on behalf of other dogs. Healthy dogs will have lab work performed at no cost to you as a client. Studies like this represent the future of medicine and are needed to improve the diagnosis and treatment of disease.

7. **Are there any risks in participating in this clinical study?** The risks anticipated during the study are minimal and may include a small hematoma from blood collection. Risks of urine collection are only present if a sample is being obtained from a method other than free catch, which will ONLY be done if deemed necessary for other reasons as part of their veterinary care. Every effort will be taken to minimize these risks.

   If you believe your dog becomes injured, ill, or appears uncomfortable while participating in the study, the investigator at the telephone number listed on the first page of this form should be notified. Seek emergency medical advice for your dog if needed. At the Cornell University for Hospital for Animals,

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medical services will be offered following the hospital's standard procedures and fees, unless discussed otherwise in this document.

8. **Can my dog be removed from the study without my OK?** Yes. If it is in the best interest of your dog or the study, investigators may prevent your dog from continuing to participate. Study investigators will explain why your dog was removed from the study.

9. **What happens to the information collected for the clinical study?** All identifying client and animal details will be considered confidential. Data resulting from the study will become the property of Cornell University. Specimens collected may be used in future research and may be shared with other organizations or commercial entities. The specimens could lead to new discoveries and treatments.

10. **What about cost?** There are no costs to you for your dog to participate in the study. The following costs are not covered by the study: any medical care during your visit. Any tests or procedures unrelated to the study are the responsibility of the owner.

11. **Is there anything else I should know?** Institutional Animal Care and Use Committee (IACUC) approval has been obtained: Approval Date: 9/21/2017 Approval #:2017-0094.

12. **Who can I talk to if I have questions?** If you have questions or concerns, please contact the investigator noted above. You may talk to the Hospital Director at 607-253-3030 if you cannot reach the investigator. If your dog needs medical assistance, please contact the investigator or treating clinician. Seek emergency medical advice as needed.

CONSENT:

By signing below, I have been given the opportunity to ask all questions I currently have regarding this study and they have been answered to my satisfaction. I agree to permit my dog to participate in this clinical study and undergo the procedures described to me above. I understand the statements in this informed consent document and that a signed and dated copy of the consent form will be given to me.

Signature of Owner Printed Name of Owner Date

Contact Investigator Use Only:

1st Witness Signature Printed Name Date

Hospital Use Only: CEM21 Submission Date: 2/13/2019 CUHA Director Approval Date: 2/13/2019 Approval Number: 19-03