**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:**

**Investigator:**

# PURPOSE

The usual treatment of [*describe the animal’s condition]* is [*describe the usual treatment or treatments*].

The purpose of this study is to *[Give a general description of the study and the kind of information that it is hoped to be gained and how the information will help others or society. Indicate any sponsor of the study and whether the sponsor is the manufacturer of the drug/device being studied].*

# DESCRIPTION OF PROCEDURES

If you agree to have your animal participate in this study, the participation will last for *[list the expected duration of the enrolled animal’s participation (e.g., three visits to the hospital over two months; will consist of this appointment and will last for about a half an hour)]*.During the study, you may expect the following procedures to be used: *[Describe in lay language all procedures that will be performed on the enrolled animal for the purpose of the study. The description should identify who will conduct each procedure (e.g., licensed veterinarian, technician, student, owner). The description should also identify any biological samples that will be collected and indicate if standard treatment is being withheld]*.

# RISKS

The possible risks for your animal from participation are: *[Describe in lay language all foreseeable risks, discomforts, and side effects that may arise from the study and their likelihood and severity. If standard treatment is being withheld, indicate any risks associated with the withholding. If there is any morbidity and mortality associated with any of the proposed procedures, such risk must be clearly stated in this paragraph. If there are no known discomforts or risks, state that there are no foreseeable risks at this time from participating in this 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/will not]* have costs from your animal’s participation in this study.  *[If there will be costs, state specifically what they will be]*. 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/will not]* be compensated for your animal’s participation in this study. *[If a person is to receive money or another token of appreciation for their participation, explain when it will be given and any conditions of full or partial payment (e.g., If you decide to not continue your participation in the study, you will be compensated $5 for each visit that is completed.) If the payment is $75 or more, add the following: “You will need to provide your social security number and address in order for us to pay you and to fulfill government reporting requirements. Measures are in place to protect the confidentiality of this information. You may elect to forego receipt of payment(s) and continue in the research study if you decline to provide your social security number and address.” Information regarding documentation required for participant compensation may be obtained from the Controller’s Department; 294-2555 or http://www.controller.iastate.edu.]*

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 *[insert procedure (e.g., surgery 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 at your own expense if your animal is not enrolled in the study.

CONFIDENTIALITY

Government regulatory agencies and *[list all other applicable groups (e.g., any sponsor, University or department review board)]* 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. *[If one could identify the animal from the photographs or video images, this should be stated.]*

# QUESTIONS OR PROBLEMS

You are encouraged to ask questions at any time during this study. For further information about the study, contact *[investigator name and phone number].*

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# OWNER SIGNATURE

**Title of Study:**

**Investigator:**

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: