

**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 Form

***{instructions: please complete the items in blue using non-technical, lay language (recommended 8th grade reading level or lower) and convert to normal black text; please remove instructions in blue; please add in any information/details (such as pre-appointment instructions, housing, home-care, etc.) and remove any non-relevant sections to best fit your study needs. ChatGPT*** [***https://chat.openai.com/***](https://chat.openai.com/) ***can help to put things into lay language by asking it to “rewrite this at the 6th grade level “…”; however, avoid sharing sensitive/confidential information unless using a secure version. Additional readability resources are available on the CRB website:*** [***https://www.research.colostate.edu/orcc/crb/best-practices/***](https://www.research.colostate.edu/orcc/crb/best-practices/) ***}}***

**Study Title:**

{*Provide a few sentences regarding the rationale for this study and details in lay language:*

1. *purpose and objective of the study*
2. *statements that products are investigational and safety and efficacy have not been established for the indicated use or that the product has been approved for other uses*
3. *treatment groups and number of study animals, including likelihood of animal being assigned to a control group versus a treatment group*

I understand that the veterinarians at this hospital are doing research to improve animal health, animal care, and education. The details of the *Study Title* Clinical Trial have been explained to me by:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

***Please initial the following lines to note your understanding of the parts of this study:***

**\_\_\_\_\_\_\_** My *pet* must have a {confirmed diagnosis of {*condition*}/or be undergoing the following procedure {*procedure*} in order to be a part of this study.

**\_\_\_\_\_\_\_**  The reasons for this study are *{add purpose/goal here}*.

**\_\_\_\_\_\_\_**  Other (non-study) treatment options {*include brief description*} have been discussed with me, and I understand the benefits of those treatments compared to participation in the study.

**\_\_\_\_\_\_\_** As part of this study, my *pet* will have the following things done {*add lay description of the procedures to be followed, including a list of expected number and length of appointments. This can be provided as a separate study calendar}*.

**\_\_\_\_\_\_\_** I understand that it is possible my *pet* will not get better from being a part of this study {*OR*} I realize participation in the study will not have a clinical benefit to my pet.

\_\_\_\_\_\_\_ *{if applicable*} I understand that this study uses device(s), drug(s) and/or substances that are currently experimental and not approved by any United States regulatory board (i.e. the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), or the U.S. Environmental Protection Agency (EPA). Safety and efficacy cannot be guaranteed for experimental treatments.

\_\_\_\_\_\_\_ All treatments and procedures used in this study have been carefully tested to decrease the chance of negative side effects. However, I realizeit is possible my *pet* will have side-effects which could be mild, moderate, or severe (including death). *{Select the potential severity of side-effects in the previous statement and provide a lay description of those side effects here}.*

*\_\_\_\_\_\_\_* My *pet* will be watched closely for side effects and corrective action will be taken if needed {*provide details if appropriate including who will cover the cost of treatment*}.

**\_\_\_\_\_\_\_** I understand that while my *pet* is enrolled in the study, the study will pay the following costs: {*include study incentives here*}.

**\_\_\_\_\_\_\_** I understand that for my *pet* to participate in this study, I will be responsible for the following costs: {*include owner’s financial responsibility here in detail. Include a statement regarding financial responsibilities of the owner in the case of adverse events unrelated to the study*}.

**\_\_\_\_\_\_\_** {if applicable} I understand that I must return to CSU for the described recheck visits following entry into the study: *{include details, consider using bullet points or a study calendar for clarity*}.

\_\_\_\_\_\_\_ I understand that in addition to the recheck visits, I will be required to *{describe other study requirements in detail, such as administration of drugs, completion of study notebooks, etc.}.*

\_\_\_\_\_\_\_ I understand that my completion of the above study requirements {*choose: has/does not have*} risks to humans, other animals, or the environment. {*describe human user safety in detail using lay language*}. {if applicable} I am able to complete these requirements according to the instructions.

\_\_\_\_\_\_\_ If I have any questions about the study requirements or my *pet*, I can contact *{add specific requirements for reach out or emergency contact information}.*

**\_\_\_\_\_\_\_** I understand that study personnel will provide timely updates if study information changes, including new risk information (for example, adverse events occurring at greater frequency or severity than stated in this consent form or development of unexpected adverse events), changes to study protocol, or other information that could impact my requirements or risk or the requirements or risk to my *pet*.

\_\_\_\_\_\_\_ I may remove my *pet* from this study at any time without penalty. {*include any specific withdrawal information that limit timing of withdrawal, incentives, or may impact pet or owner safety*}

**\_\_\_\_\_\_\_**  I understand that the veterinarian in charge may remove my *pet* from this study at any time. Reasons for study removal might include my *pet* not meeting study enrollment requirements, the study not benefiting or harming my *pet,* I am unable to follow study requirements, or if the study is completed.

**\_\_\_\_\_\_\_\_** I realize that the costs for treatment once off study will not be covered. *{include if delayed adverse events will be covered}*

\_\_\_\_\_\_\_\_ I understand that the study will be completed when *{include details about study completion for the enrolled pet*}.

**\_\_\_\_\_\_\_**  I understand that information and samples collected during this study are the property of the investigator and may be stored for future use.

**\_\_\_\_\_\_\_** I give my permission to publish information 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 discuss this study with my own veterinarian and ask his/her advice. *{provide limitations here if masking is needed}*

**\_\_\_\_\_\_\_** *{OPTIONAL}* If my *pet* dies, a postmortem examination at this hospital will be necessary to explain the cause of death.

**\_\_\_\_\_\_\_**  I understand that someone may contact me after my *pet* has finished this study to collect follow-up information. This may occur several months to years following the end of the trial.

**\_\_\_\_\_\_\_** I have had time to ask questions about this study and feel comfortable enrolling my *pet* in this study based on the information provided.

**\_\_\_\_\_\_\_** I understand that the funding for this study is provided by {*enter funding source here. OR To maintain confidentiality during treatment development, the sponsor of this study has requested that their identity not be disclosed.}*

**\_\_\_\_\_\_\_** The investigators in this study declare no conflicts of interest. OR *One or more investigators on this study has a financial interest in the development of this treatment. For this potential conflict of interest, a management plan has been implemented by the institution.*

As a result of discussion with \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, and after reading the above, I confirm that I am the legal owner/guardian of \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ and 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 tests.

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

 Owner or authorized agent of the owner

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

For questions about this study, please contact: *CSU Study Specific contact information* (*example* PI or study coordinator phone and e-mail)

For questions about the ethical conduct of animal research at Colorado State University (CSU), please go to the CSU Reporting Animal Welfare Concerns website: <https://www.research.colostate.edu/orcc/iacuc/reporting-animal-welfare-concerns/> or email the CSU Institutional Animal Care and Use Committee (IACUC) Staff: CSU\_IACUC@colostate.edu