

**Place Patient Identification Sticker Here**

**Appointment Desk: (970) 297-5000**

<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:**

This consent form will give you information about the study. This study was approved by aveterinary institutional review board to make sure the research was important and done in a way that is fair to animals.

***Please read the following items and initial at the end:***

**Why are we doing this study?**

*{add study purpose, objectives, and goals here, this can be several sentences. Include**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}*

**What will happen to my (species) in this study?** *{please summarize the essential study elements and consider using bullets for clarity; this may include a description of treatments and procedures that are considered standard of care and/or part of the study protocol. Please include treatment groups and number of study animals, including likelihood of animal being assigned to a control group versus a treatment group . You may provide additional clarification by including a separate 1 page study calendar with a list of expected number and length of appointments and what procedures will occur at each appointment}*

**What benefits could my (species) get from being in this study** *{List benefits including all incentives}* I understand that my pet might not benefit from this study {OR} I realize participation in the study will not have a clinical benefit to my pet. *{optional language following}.* We won't know the results of this study right away. The goal of this study is to develop new treatments and techniques that might help other animals in the future. You might not get the results of the study.

**What bad effects could this study have on my (species)?** *{Include the potential risks and side effects associated with this study including those associated with both standard of care and experimental procedures.}*  There is a chance my pet might have unexpected reactions *{optional including getting really sick or even dying}*. My (species) will be watched carefully for any side effects and if needed, they’ll get the right medical help. *{include who will pay for the medical help and what it might entail}*

**What other treatments or procedures could my (species) have instead of this study?***{Please provide a brief list or statement of alternative treatment options}*

**What will I have to pay for if my (species) is in this study?** *{include study incentives and financial support for adverse events if available; be specific including how adverse events both related and unrelated to the study will be managed}*. I understand that I have to pay for any tests or treatments that aren't part of this study, even if they're for different health problems. I realize that the costs for treatment once off study will not be covered.

**What do I have to do for my pet to be in this study?** *{include information on recheck visits, home treatments and care, study journal completion, and human, other animal, and environmental risks}*

\_\_\_\_I have read the information above information and understand my choices and what the study called “enter study name here” is about.

**Please initial each statement:**

\_\_\_\_\_\_\_ My (species) has met the conditions to take part in this study *{optional}* I understand that my (species) must have a {confirmed diagnosis of {*condition*} /or be having the {procedure} to participate.

\_\_\_\_\_\_ I have looked at what happens in this study, and I am able and agree to do what is asked.

\_\_\_\_\_\_\_ If I have any questions about what I have to do or what is happening to my *(species)*, 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 information about bad effects that can happen to my (species) or changes to what I or my (species) have to do for my (species) to be in the study.

\_\_\_\_Data, tissue, and fluid samples *{include as appropriate}* collected from my (species) will belong to the researchers. They might also gather details from my (species) medical records after the study is finished.

\_\_\_\_ I agree to let data and pictures from this study be shared or published. I know that all personal information about me will be kept private.

\_\_\_\_If I decide not to join this study it will not affect the care of my (species).

\_\_\_\_I can take my (species) out of this study anytime without any trouble. Taking my pet out will not change how they are treated in the future. The researcher may continue to collect information from my (species’s) medical record even after we leave the study. {*include any specific withdrawal information that limit timing of withdrawal, incentives, or may impact pet or owner safety*}

\_\_\_\_The study team can take my (species) out of this study if they don’t meet the rules, if I cannot do what the study requires, if it is best for my (species), or if the study ends.

\_\_\_\_I can ask my veterinarian for advice about this study. *{provide limitations here if masking is needed}*

\_\_\_\_*{if applicable*} I know that this study is testing new drugs, substances, or devices that haven’t been approved by American regulatory boards like the FDA (U.S. Food and Drug Administration), USDA (U.S. Department of Agriculture), or EPA (U.S. Environmental Protection Agency). This means that the safety and efficacy of the treatment is not proven.

\_\_\_\_*{optional}* I agree to let my (species) have an exam (autopsy) *{at this institution}* if they pass away while in the study *{optional* or after it is done*}*.

\_\_\_\_*{optional}* Someone might get in touch with me later to ask about how my pet is doing after the study ends. This may happen several months to years later.

\_\_\_\_*{optional}* The person leading the study helped make the treatment. Because of that, there is a plan in place to manage any problems.

\_\_\_\_\_\_\_ I know that the money for this study comes from {enter funding source here. OR To keep things confidential while they work on treatments, the people paying for this study have asked us to keep it private.}

\_\_\_\_I have had time to ask questions about this study, and I feel okay with letting my (species) be in it.

\_\_\_ *{Add any required institutional specific language here.}*

After talking with \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, and reading this study consent form, I agree to let my (species) take part in this study. I will follow what the study team says about treatment and follow-up care. I confirm that I am the legal owner/guardian of\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

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/*](https://www.research.colostate.edu/orcc/iacuc/reporting-animal-welfare-concerns/)

or email the CSU Institutional Animal Care and Use Committee (IACUC) Staff in the Office for Research Collaboration & Compliance: *CSU\_IACUC@mail.colostate.edu*