**Shreiber School of Veterinary Medicine**

**Informed Consent Form**[[1]](#footnote-1)

*If there is a “patient ID sticker,*

*place here*

*Instructions for PI: This is a* ***template*** *for you to use and modify as applicable. Complete all items in blue, as needed, replace the blue text with black, and remove blue instructions prior to submission to VCRC for approval. Use plain language and short, clear sentences at 8th grade reading level. A copy of your consent form must be submitted along with your protocol submission form.*

**Project Title**:

**VCRC Protocol #:** (assigned after protocol approval):

**Principal Investigator:**

**Contact information:**

Sponsor (if applicable):

This form provides information about the study so you may make an informed decision about your animal’s participation. The SSVM Veterinary Clinical Review Committee (VCRC) has approved this study. Participation is voluntary.

**Please read and sign below.**

**1. What is the purpose of this study (or protocol)?** {*Briefly describe the purpose of the study in lay/plain language – 8th grade level; put into CoPilot to revise/check, if necessary)*

**2. What am I and/or my pet being asked to do? What procedures/treatments will my [species] experience if enrolled in this study (or protocol)?** {*Use lay language to describe what procedures, evaluations, or treatments the animal will be involved in. Include frequency of any tests, procedures, or observations, volumes or amounts of samples, and retention or discarding, if applicable. You may also state whether this is considered routine care or if there are varied or additional procedures performed. Include a statement if there are any new investigational procedures being performed and safety and efficacy, if known. . . If this is a “new” procedure, treatment, or intervention, etc., please include a statement regarding whether it is investigational, if safety and efficacy have or have not been established for the indicated use, and/or if the procedure or product has been approved for other uses. You may also include information regarding the number of animals participating (and any information regarding control vs test group, if appropriate). Include a statement clarifying that if the pet is or becomes sick/injured, the owner should inform any treating veterinarian that their pet is in a research study.*

**3. What are the potential benefits to my [*species*] for participating in this study (or protocol)?** *{List all possible benefits} Optional language: My (species) disease may get better, stay the same, or get worse while participating in this study.”* ***OR*** *“Your pet may not benefit from participation in this study. However, we may learn additional information about your pet’s disease which may affect how your pet is treated.”*

*{Optional language: “Results of this study will not be available immediately. The goal is to develop new treatments and techniques that may benefit future patients. Study results may not be provided to me.”*

**4. What are the possible risks to my [*species*]?** *{Include all potential risks and side effects associated with this study including those associated with both standard of care/ regular husbandry and experimental procedures, if applicable..} Include any of the following if appropriate/relevant to the protocol:*

*“It is possible my [species] may experience unexpected side-effects (Please list if appropriate).” Or*

*“It is possible my [species] condition may not improve or it may worsen.” {Optional: up to and including death}. or*

*“My [species] will be observed closely for side effects and appropriate medical care will be provided.”*

**5. Are there any monetary costs or benefits associated with enrolling my [species] in the study (or protocol)?** {*Include study incentives, a list of all specific procedures and costs covered by the study, and financial support for adverse events if available; be specific including how adverse events both related and unrelated to the study will be managed financially*}. *Include statement regarding,* ***“any tests, procedures, or treatments beyond those specifically covered as listed here, are the financial responsibility of the owner.”***

**6. What else, if anything, do I need to do to participate in this study (or protocol)?** *{describe other study requirements in detail, such as administration of drugs, completion of study notebooks, etc.}. Also include, if applicable, relevant information regarding consideration of pet’s reproductive status or risks in breeding animals.*

**7. When is the Study (or protocol) over? Can my pet leave the study (or protocol) before it ends?** *Define when the overall study is to end and timeline. Explain what events could lead to early study closure. Include a statement that the owner can elect to withdraw their pet from the study at any time. If early withdrawal could expose the pet to medical risks, describe how those risks will be minimized or prevented. The following are some suggested wording you may use:*

*“This study is over for your pet after you have completed all visits, and all information has been collected. This study may also be stopped at any time by your veterinarian or the study Sponsor without your consent because:*

* *The Primary Investigator feels it is necessary for your pet’s health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.*
* *You have not followed study instructions.*
* *The Sponsor or the Principal Investigator has decided to stop the study.*
* *If you decide to have your pet participate, you are free to withdraw your pet from the study at any time. Withdrawal will not interfere with your pet’s future care.”*

**8. Who can see or use my pet’s information? How will my personal information be protected?** *Optional language: “We will do our best to make sure that the personal information in your (species) medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, you and your (species) name and any other identifiable information will not be used. If this study is being overseen by groups outside of the institution, they may review your (species’) research records. You will always have access to important medical information about your (species), but you may not be able to access certain study specific information until the completion of the study.”*

**Consent statements (initial if you agree)** *(Remove or modify any of the following if not applicable to the specific study or protocol listed herein)*

\_\_\_\_ I have read the information above and understand the purpose and requirements of the *clinical study / teaching protocol* entitled "*enter protocol/study name here*”

\_\_\_\_If I choose not to participate in this study (or protocol), it will not affect the care for my [*species*].

\_\_\_\_I may withdraw my [*species*] from this study (or protocol) at any time without penalty. Withdrawal of my [*species*] will not interfere with future care. *Include any specific withdrawal information that limit timing of withdrawal, incentives, or may impact pet or owner safety}. {Optional: “I understand that investigators may continue to collect information from my [species] medical record after withdrawal.”}*

\_\_\_\_ I understand that the Researcher may remove my *pet* from this study (or protocol) at any time, for reasons listed above.

\_\_\_\_I may consult about this study (or protocol) with my own veterinarian and ask for advice about participation. *{provide limitations here if masking and/or confidentiality are needed. Reiterate and include a statement clarifying that if the pet is sick/injured or seen by another veterinarian, the owner should inform any treating veterinarian that their pet is in a research study.}*

\_\_\_\_Any samples *{include as appropriate}* collected from my [*species*] will become the property of SSVM of Rowan University.

\_\_\_\_I give my permission to publish data and images obtained from this study. I understand that all personal identifying information will be removed from scientific publications.

\_\_\_\_I hereby grant to SSVM of Rowan University, the right to publish, broadcast, web cast, or distribute, in any other form or medium, any or all of the following:

* Stories, photographs, video, audio, and other images or likenesses of my animal for use in news stories, publications, promotional materials, including advertisements, web features and/or any other official purposes.
* I understand that I will not receive financial compensation for this use.
* All photographs, video, audio, images, likenesses, stories, and other materials will remain the property of the SSVM of Rowan University.

\_\_\_\_If I have additional questions or concerns about the study, its requirements, or my *species* within the study (or protocol), I can contact *{include contact information again and emergency contact info, if necessary}.*

I certify that I am over 18 years of age and the legal owner/guardian of (Animal(s) name(s)

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

**A copy of this consent form will be provided to you.**

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Owner or authorized agent of the owner

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

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**OPTIONAL STATEMENTS. IF YOU DON’T NEED THESE, DELETE THE TEXT BELOW:**

**- What happens if my pet is hurt during the study?** *Provide contact information for research-related problems. If applicable, describe what treatment will be provided for research related injuries. Explain how treatment for research related injuries would be paid and what the owner’s responsibilities would be. Describe procedure for emergency care, if applicable.*

*Optional wording sample for emergencies: If your pet has a medical emergency during the study, you should go to the nearest emergency room. You may contact the Principal Investigator or Emergency contact listed on page one of this form. You may also contact your own veterinarian, or seek treatment outside of {the institution}. Be sure to tell the veterinarian or staff that your pet is in a research study being conducted at {institution}. Ask them to call the telephone numbers on the first page of this consent form for further instructions or information about your pet’s care. If your pet is hurt or injured as a result of participation in this research study, please contact the investigator listed on page one of this form.*

**- What if new information becomes available about the study?** *Include a statement similar to the following, if applicable, “During the course of this study, we may find more information that could be important to you and your pet. We will notify you as soon as possible if we learn anything new during the study that might cause you to change your mind about your pet being in the study.”*

\_\_\_\_To the best of my knowledge, my [*species*] has met the requirements to participate in this study. *{Optional: “I understand that my [species] must have [confirmed diagnosis of XXX condition / undergo XXXX procedures] in order to participate}.”*

*\_\_\_\_ I reviewed the study schedule and commit to the requirements and follow-ups as needed.” Provide details, as needed.*

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

\_\_\_\_I have had time to ask questions regarding this study and feel comfortable enrolling my *species* in this study, based on the information provided

I understand that this study is being done to improve animal health, welfare, care, and education. After discussions with \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, and after reading the information above, I voluntarily consent for my [*species*] to participate in this study and will follow the instructions of the study team, including how it pertains to therapy and follow-up procedures.

1. This template was developed using COHA’s Informed Consent Template, dated 3/20/19; Colorado State University’s Clinical Review Board Consent Form Template, dated 3/8/24; Matthew J. Ryan Veterinary Hospital University of Pennsylvania Owner Informed Consent Form, version 9/09. [↑](#footnote-ref-1)