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**Veterinary Clinical Review Committee**

**Protocol Submission Form[[1]](#footnote-1)**

*NOTE: Please refer to the flowchart for VCRC determination before filling out this form. Submit completed form to SSVM\_VCRC@rowan.edu.*

**I. GENERAL INFORMATION**

* **Project Title:**
* **Date of initial submission:**
* Funding source (if applicable):
* **Principal Investigator (PI)** Name, e-mail, phone number:
	1. Department and Supervisor Name:
	2. CITI Training (Yes/No, List modules and dates completed):
	3. Experience and qualifications for performing the work described

**II. OTHER PERSONNEL involved in protocol AND handling animals**

**SSVM Personnel**

Provide details for *each* SSVM-affiliated individual (other than PI listed above) involved in this protocol:

**1. Name:**

* Email:
* Department and Supervisor:
* CITI Training (Yes/No, List modules and dates completed):
* Role in project:
* Experience and qualifications for performing the work described:

**2. (**Repeat the above as needed, starting with Name):

**Non-SSVM Personnel**

Provide details for *each* non-SSVM-affiliated individual involved in this protocol:

**1. Name:**

* Affiliation:
* Email:
* CITI Training (Yes/No, list modules and dates completed) if necessary *(PI may indicate “N/A” here)*
* Role in project:
* Experience and qualifications for performing the work described

**2. (**Repeat the above as needed, starting with Name):

**III. PROJECT INFORMATION**

1. **Species involved (Only ONE species per submission form)**:
2. **Source of animals** (e.g., client-owned, shelter-owned, stray, etc.):
3. **Type of project** (e.g., clinical research, observational research, clinical trial, teaching with live animals, etc.)
4. **Lay summary** (limit 250-350 words). It should be understandable to someone with a high school-level biology background. Include the overall goal, rationale / purpose, and relevant background. (NOTE: This “Lay summary” can also be used in your consent form)
5. **Animal population**: (limit 200 words) Describe the population being studied or used and the condition (if applicable), number of participants, and recruitment methods. Include:
	1. Justification of animal numbers. If this is a teaching protocol, what resources were used to determine numbers? If this is an agricultural animal used for teaching, please indicate which sections of the Ag Guide were consulted.
	2. Power calculation, if applicable. Methods and assumptions for this calculation.
	3. For pilot studies: how does this study guide or support future research.

1. **Inclusion and exclusion criteria**, as applicable:
2. **Time and duration**: Estimated time each enrolled participant will be involved (e.g., number of hours, days, weeks, etc.). Will there be follow-up? Please include total project duration expected (e.g., 1 month, 6 months, 1 year, 3 years, etc.), what is the endpoint, and if the endpoint might be reached sooner than anticipated. If this is a teaching protocol, include the length of time each individual animal will participate and how that duration is justified. If an agricultural animal is being used for teaching, please indicate which sections of the Ag Guide were consulted.
3. **Experimental plan.**
4. Detail all procedures involving animals (limit 500 words). (e.g., observations, diagnostics, treatments, sample collection, injections, surgeries, etc.). Be specific about amounts, volumes, sites, methods, etc.
5. Pain or stress considerations (limit to 250 words): Will any procedures or actions cause pain, or stress (acute or chronic), even temporarily? If so, describe how this will be mitigated or alleviated. Unless you are using a recognized, documented methodology, e.g., “Fear Free™,” you must explain and describe methods. E.g., stating “humane handling” is not sufficient, as that can have many interpretations; explanations or examples must be included.
6. Statistical design and analysis (limit to 250 words), if applicable. If not, indicate “n/a”. BRIEFLY describe how data will be collected and analyzed, including statistical tests.
7. Outcomes and monitoring (limit to 250 words). List expected outcomes (from the protocol, not the natural conditions of animal) and define response and success/failure criteria, if applicable. How will participants and outcomes be monitored, namely if there are treatment or intervention responses expected. Is an early or statistical endpoint possible? Are outcomes expected that might lead to a change in methodology?

**IV. RISKS AND BENEFITS ASSESSMENT.** (Please be specific and thorough)

1. Potential risks. List and describe all foreseeable risks to animals, owners/caretakers, or others, even if minimal. “Minimal risk” is defined as, *“the probability and magnitude of harm or discomfort anticipated in the (activity) are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.’*” If the risk is more than minimal, this must be documented in this protocol and consent form.
2. **Risk mitigation plans.** Describe plans to address and minimize the above risks. Please be specific, as described above in pain mitigation plans.
3. **Adverse events**. List potential adverse events, likelihood, sequelae, and how they will be managed and reported. *NOTE: An adverse event reporting form and reporting procedures are under development by the VCRC.*
4. **Potential benefits**. Describe expected benefits to animals, owners/caretakers, or others. Include any incentives (for owners and/or animals) provided for participation.
5. **Risk vs benefit evaluation**. Evaluate the balance between risk and benefit (risk versus benefit ratio) **for animal participants**. You may also include the risk versus benefits for the owner/caretaker, society, or others.
6. **(Optional) 3 R’s**. (limit 250 words). If applicable, describe how your protocol adheres to the biomedical/experimental research tenet of the 3Rs (Replacement, Reduction, **Refinement**). If the 3Rs are not applicable to your protocol (clinical research with an animal for the benefit of that animal), please briefly explain.
7. **Client consent form.** Attach a copy of your Client Consent Form to this submission. Protocols will not be reviewed without it.

**IV. OTHER INFORMATION**

1. **Previous peer review.** If this protocol has been previously reviewed by another organization, attach a copy of the application.
2. **Hazardous materials**. Will anyone on this project be handling or using hazardous materials (e.g., chemicals, feces, infectious agents, biological toxins, recombinant DNA, etc.)? If “yes,” contact the Rowan Institutional Biosafety Committee (IBC), the Environmental Health and Safety Department, and provide IBC or EHS approval documentation. Please note that completing and submitting this form is *not* contingent on IBC or EHS approval.

Principal Investigator Signature Date

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*FOR SSVM VCRC ADMINISTRATIVE USE ONLY:*

*Review type: Date of review: Initials:*

*VCRC Determinations: Date: Initials:*

*Assigned protocol # (after approval):*

1. The initial version of this document was developed using Colorado State University College of Veterinary Medicine and Biomedical Sciences’ Clinical Review Board protocol submission form [↑](#footnote-ref-1)