Shreiber School of Veterinary Medicine of Rowan University
Veterinary Clinical Review Committee (VCRC)
INSTRUCTIONS FOR PRINCIPAL INVESTIGATOR (PI)

OUTSIDE of providing clinical care to a patient(s), are you planning to use or observe live animals, use residual samples, or use veterinary data **for the purposes of: research, publication,** or for teaching students handling animals? If so, you MUST read the following and follow the "***Flowchart VCRC determination.pdf***."

The **Veterinary Clinical Review Committee (VCRC)** of the Shreiber School of Veterinary Medicine (SSVM) was established to provide ethical and animal welfare oversight of veterinary clinical research and teaching protocols involving privately owned or unowned animals and led by SSVM faculty, staff, and investigators. The VCRC protects the safety and welfare of the participating animals and ensures appropriate informed consent is obtained. The VCRC will evaluate the balance of risks and benefits in each protocol, prioritizing the patient's perspective. Risks should be minimized and clearly outweighed by the anticipated benefit. The broader goal of the VCRC is to protect animals, their owners, investigators, faculty, staff, and Rowan University SSVM by ensuring the ethical and humane treatment of all participants in clinical research and veterinary teaching protocols.

The SSVM VCRC reviews and approves all prospective veterinary clinical research and teaching with animals protocols before implementation. No research and/or teaching activity involving live animals may proceed until the VCRC has reviewed and approved of the protocol, including the consent form.

DETAILS & CLARIFICATION:
*If your activity with live animals, residual samples, or veterinary data is for **any purpose other than providing clinical care to the patient (**e.g., other purposes may include research, teaching, publication), **follow the "Flowchart VCRC determination"** attached. Approval must be sought and obtained from the VCRC PRIOR TO engaging in research or teaching with animals activities. The following are some examples of activities for which you must receive approval **PRIOR TO** engagement in said activity:*

- *Any research project or study including all clinical trials and research.*
- *Taking leftover blood, tissue, or other samples from a patient to use for research or teaching.*
- *Demonstrating invasive procedures (e.g., blood draws, multiple radiographs) on animals when procedures are performed outside of the standard recommended clinical workup of the animal.*
- *Initiating treatment plans with the purpose of collecting data **for** publication as research.*

***NOTE:** The below does NOT apply to teaching students while you are in the clinic, in the field, or elsewhere providing requisite care to patients. The following is for activities that are considered unnecessary for the animal.*

If the Flowchart indicates that you should submit a protocol form to the VCRC, you will find that form and all documents in the Teams – Committee on Research folder: VCRC Documents for PIs. ***NOTE***: If you are applying for a grant, please submit the forms only AFTER the funding agency has accepted and funded your proposal. For projects not requiring funding, forms should only be submitted AFTER your study is fully developed and clearly designed, with all methods and procedures finalized. Please note

that the VCRC's role is to provide ethical and welfare oversight, not to serve as a resource for study design or methodology development. *Submissions should therefore be complete and polished*. (There are a few resources provided in the Teams folder: Study design and methods)

1. Determine who will be the Principal Investigator (see Definitions below). The PI will submit their protocol for review.
2. Download the **SSVM VCRC Protocol Submission form** from Teams (VCRC Documents for PIs) (Please note that forms needed for research utilizing residual extra samples is currently TBD. Faculty will be updated accordingly.)
3. Enter your protocol's information into it. Please refer to the "Definitions" section at the end of this document for clarification on terminology.
    - If you exceed word limits, your form will be sent back to you without review
    - Complete only ONE form PER SPECIES
4. Download the **Informed Consent Form Template** from Teams (VCRC Documents for PIs)
5. Edit and modify the Informed consent template as necessary for your study.
    - The VCRC will review the consent form you plan to use. The study investigators will be responsible for obtaining signatures and consent from the owners
6. Submit the following to SSVM_VCRC@rowan.edu:
    - Completed Protocol Submission form
    - Completed Client consent form
    - Additional info as needed
7. Within 3 working days of submitting the above, you will hear back from the VCRC regarding whether your submission is complete and can be sent for review by the VCRC. You will also be notified as to what date your protocol will be discussed by the VCRC.
    - ***NOTE regarding DATES for submissions***: In the near future, the VCRC will require that protocols are submitted for review, at minimum, 15 working days prior to a scheduled monthly VCRC meeting. VCRC meeting dates will be posted on a TBD webpage or other site. Protocols will be reviewed in the order they are received. To help ensure timely review, we encourage early submission. During periods of high submission volume, your protocol may be scheduled for review at the following month's meeting. At this time (August 19, 2025), protocols will be reviewed and meetings will be convened on an as-needed basis.
8. After the VCRC reviews your protocol, you will be notified as to the outcome and any requests for further information. The outcome options are:
    - Approve
    - Conditional approval
    - Defer (modifications required and re-review will be necessary)
    - Reject (no feasible modifications could make the protocol acceptable, for example, if it breaches fundamental ethical principles, compromises animal welfare to an unacceptable level, or poses harms that clearly outweigh the anticipated benefits)

Training

All personnel listed on the protocol must complete the following trainings ***prior to protocol implementation.***

1. CITI training course, "Researchers – Basic," Stage 1-Basic Course
    - To access CITI Courses, go to: CITI https://about.citiprogram.org/

- If you already have a CITI account through another institution, your previous trainings can be linked to Rowan (Contact Sharon Sanders sanderss@rowan.edu if issues arise). If you do not yet have a CITI account, please follow these steps:
  - Step 1 - Go to **http://www.citiprogram.org**
  - Step 2 - Click on "register" in the Create new account box on the CITI webpage
  - Step 3 - In the box titled "Select Your Organization Affiliation" type in Rowan. Rowan University will appear in a box under the type. Click on Rowan University.
  - Step 4 - Type in your First and Last Name. A prompt will ask for the Rowan NetID, but you will be able to continue without entering.
  - Once the account is setup, add the course "Researchers – Basic" and "Responsible Conduct of Research – Biomedical."
- For further information and details, please see: https://research.rowan.edu/officeofresearch/compliance/cititraining/

2. CITI training course, "Responsible Conduct of Research – Biomedical" (in "Animal Care and Use."), Stage 1 – RCR

3. (15 minutes) Client Consent: Best Practices for Veterinary Clinical Trials, by CTSA One Health Alliance (COHA) https://ilearn.tuftsctsi.org/product?catalog=OH2021_01_Online

4. Training required by other departments (Environmental Health, Institutional Biosafety Committee, etc.)

5. Species-specific training per protocol as instructed by VCRC

Additional training for PI:

6. Training Video *(coming soon. This will reside here: VCRC Documents for PIs)*

Definitions

- **Clinical veterinary research** (veterinary clinical research). An umbrella term for studies that involve animals and have the primary aim of deepening knowledge, advancing understanding, and improving animal health and welfare. It covers both observational and interventional designs that examine naturally occurring behaviors, experiences, diseases, injuries, or other conditions, and studies may take place in settings such as homes, clinics, shelters, outdoors, or other environments. The animals are usually client- or owner-owned (or stray) rather than institution-owned, and the research goal is to benefit the animals themselves rather than to create disease models.

- **Clinical veterinary *trial*** (veterinary clinical trial). A focused subtype of clinical veterinary research in which a specific intervention, such as a drug, device, procedure, environmental change, or management protocol, is prospectively tested in animals that have a defined condition. These trials are designed to measure the intervention's safety, efficacy, or optimal use, thereby identifying the best practice for treating that condition in that animal.

- **Conflict of Interest**: A financial or non-financial interest, or an opportunity for personal benefit, either for an individual or their immediate family member, that *may* improperly influence professional judgment or responsibility, including the review of research.

- **(Veterinary) Good clinical practice (vGCP).** "An international scientific quality standard for designing, conducting, monitoring, recording, auditing, analysing, and reporting clinical studies evaluating veterinary products. Compliance with this standard provides public assurance about the integrity of the clinical study data, and that due regard has been given to animal welfare and protection of the personnel involved in the study, the environment and the human and animal food chains."

- **Incentive.** A form of compensation or motivation, financial or otherwise, offered to encourage participation in a study or activity. Incentives are commonly used to improve recruitment and retention in both human and veterinary medicine.

- **Ownership of animals.**
    - **Privately owned animals**. Animals under the care of individuals, families, shelters, sanctuaries, zoos, or similar entities that are not owned or managed by a research institution or government agency.

    - **Unowned animals.** Stray or abandoned animals not under private ownership. This definition applies to *non*-wildlife species subject to relevant state and federal regulations and permits.

- **Principal Investigator (PI):** Individual responsible for oversight of the research or teaching protocol. The PI is also responsible for writing an accurate protocol to use or observe animal subjects or their tissues, and for designing practices, methods, and implementing the approved use(s) of said subjects. Ultimately, the PI assumes responsibility for the ethical conduct of the project and for the welfare of those animals involved. The PI is responsible for ensuring the activities on the protocol are conducted safely and meet institutional compliance and regulation standards. The PI is also responsible for ensuring all personnel are aware of procedures to follow, the value of the research and data and ethical integrity. SSVM employees who are employed as faculty or qualified administrative professionals (e.g., Research Associates or Research Scientists) may serve as PI. Students, post-docs, clinical fellows and residents cannot be PI's; however, they can be co-investigators. Co-investigators can develop and complete the VCRC protocol form; however, the form must be signed and submitted by the PI.

- **Research.** A systematic activity designed to test hypotheses, draw conclusions, and contribute to knowledge. Research is typically guided by a protocol outlining objectives, methodology, and procedures.

- **Risk**. The potential for harm, discomfort, or adverse outcomes to animals, humans, or the integrity of the research/teaching activity. Risk may arise from procedures, interventions, handling, housing, data collection, or other aspects of the protocol, and includes both the likelihood of harm and the severity of its possible consequences.

- **Minimal risk**. 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.

from COHA and Tufts CTSI: https://ilearn.tuftsctsi.org/product?catalog=RC2TU_2023_04

For any questions, please contact:
SSVM_VCRC@rowan.edu