CSU Veterinary Teaching Hospital Clinical Review Board Protocol (VTH CRB)

Purpose:

1. The CSU VTH Clinical Review Board (CRB) serves as an expert resource for the IACUC for questions or concerns regarding clinical studies. This function will be especially important for internally funded studies that have not undergone the scrutiny of peer review.

2. CRB does not replace the IACUC, but will conduct the review and approval process for projects that involve client-owned animals with the intent to treat or diagnose existing medical conditions. Special attention will be given to projects that do not undergo peer review (non-competitive research).

3. CRB acts as a resource for faculty in the VTH performing clinical studies on client-owned animals or utilizing novel techniques in patient management that one day may be described in the literature.

4. CRB establishes acceptable templates for written informed owner consent for all prospective research trials involving client, staff, or student-owned animals evaluated at the VMC. Guidelines (http://csu-cvmbs.colostate.edu/documents/clinical-sciences-vme-client-consent-guidelines.pdf) and a template (http://csu-cvmbs.colostate.edu/Documents/clinical-sciences-owner-consent-form.docx) for the Client Consent Form can be found on the Clinical Sciences Faculty and Staff Resources Page and Research Resources.

VTH CRB Review Process:

1. **All prospective, research protocols involving client, staff, or student-owned animals** require IACUC approval either through a full IACUC approval process or by approval of the Clinical Research Review Board. The first step in this process is to submit your study to the Veterinary Clinical Studies Wizard https://vprnet.research.colostate.edu/RICRO/veterinary-clinical-studies-vcs-wizard/ on the IACUC website. The study will be evaluated to determine if it requires IACUC review or review by the Clinical Research Review Board.

   a. If the study is waived from IACUC review, it will be assigned a Veterinary Clinical Study number and an online protocol and client consent form can be submitted for review by the Clinical Research Review Board at https://clinicalsciencescsu.wufoo.com/forms/z3m3j8q102xrj6/

   b. If the study requires full IACUC review, the Clinical Research Review Board will support IACUC by reviewing and approving the client consent form. To initiate this review, please email the following information to Dr. Dawn Duval, Chair of the CRB.
      i. Client Consent Form
      ii. Copy of the submitted IACUC protocol.

   c. Because the CRB will be reviewing client consent forms, PIs are no longer required to send them to the VTH Director for review and approval.
2. A faculty member with questions regarding their use of novel techniques in the clinic may bring these questions forward to the CRB. The CRB may simply answer the faculty member’s question after evaluating the technique in question or it may suggest the faculty member submit an IACUC protocol if it appears that the use of the novel technique is developing into a prospective clinical trial.

3. The CRB currently consists of 12 members of the Department of Clinical Sciences Research Committee including a current member of IACUC, one outside member from another department in CVMBS, and the VTH Director.

4. When requested, protocols will be reviewed via email by the chair of the CRB as well as at least two other members of the CRB selected by the chair. Occasionally, an ad hoc reviewer might be selected due to specific expertise. Care will be taken to avoid use of reviewers with potential for conflict of interest, in particular, collaborators on the project to be reviewed. The CRB will work with the investigator to help resolve issues concerning the protocol in question.

5. When possible, the opinion of the CRB will be emailed to RICRO and the investigator within 14 calendar days. The investigator should then respond to the comments of the CRB which will review the comments and forward them to RICRO to update the protocol. During IACUC review of the protocol, the reviewers may have additional comments for the PI to address. IACUC review may occur via DR or FCR.

6. If the investigator completes a pre-review with the CRB, the comments should be attached to the protocol when submitted to the IACUC (see Appendix A).

7. Studies approved by the CRB will be requested to submit an annual update regarding the current status of the study.
APPENDIX A

MEMORANDUM

To: Clinical Researchers
From: Research Integrity and Compliance Review Office (RICRO)
Date: January 14, 2015
Re: Review of Projects using Client-Owned Animals at the VTH, by the VTH Clinical Review Board (CRB)

In an effort to ensure adequate peer review of all research projects involving the use of client-owned animals at the VTH, the CSU Institutional Animal Care and Use Committee (IACUC) has requested the assistance of the VTH CRB. The VTH CRB will review protocols at the request of a PI, or at the request of the IACUC during its review and approval process, particularly for projects which have not received an external peer review (generally these have been internally, privately, or non-funded research projects).

**In order to provide an efficient review of your project, please submit the relevant materials to VTH CRB prior to or at the same time as your IACUC protocol submission.**

If you obtain a review of your protocol from the CRB prior to submitting it to the IACUC, please simply provide the email or other documentation from the CRB chair indicating the review and the CRB’s comments in the Attachments section of your protocol. This will allow the IACUC to take the CRB’s review and any adjustments on your part into consideration during their review. We hope that this will allow for more efficient review and lead to more expeditious approvals of clinical research protocols.

Thank you, and good luck with your project.

Research Integrity and Compliance Review Office (RICRO)
http://ricro.colostate.edu/
(970) 491-1553