

VMC/Clinical Sciences Clinical Research Review Board Protocol
IACUC Approved March 10, 2009

Purpose:

1. To serve 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. The Clinical Research Review Board (CRRB) will not replace the IACUC, but will facilitate the review and approval process for clinically based research projects. Special attention is to be given to (or primarily for) projects that do not undergo peer review (non-competitive research).
3. To act as a resource for faculty in the Veterinary Medical Center (VMC) performing clinical studies on client-owned animals or utilizing novel techniques in patient management that one day may be described in the literature. At the request of a faculty member, review novel clinical procedures that the faculty member is conducting in the VMC to ensure oversight of procedures that are not currently part of a research project but that may someday be described as a series of case reports. If the information is to be collected prospectively, an IACUC A-100 should be filed.
4. Establish acceptable templates for written informed owner consent for all prospective research trials involving client, staff, or student-owned animals evaluated at the VMC.

Review Process:

1. The intent of the CRRB is to assist in the approval process and not to duplicate the work already being performed by IACUC. **It is critical to avoid any perception of IACUC responsibilities being delegated to the CRRB, as that is not allowed by federal regulation.**
2. All **prospective**, research protocols involving client, staff, or student-owned animals require IACUC approval. This process is identical to the approval process for any protocol utilizing alive or dead animals for teaching or research.
 - a. Many proposals will not need to be evaluated by the CRRB. However, if IACUC has any questions regarding the scientific or clinical merit of the proposal, the proposal can be tabled pending an evaluation by the CRRB. The Research Integrity and Compliance Review Office will contact the chair of the CRRB (Currently Dr. Lappin, Department of Clinical Sciences) when a PI is requested/required to obtain an opinion of the CRRB as a condition of approval of their A-100 and provide a copy of the A-100 and any other supporting documentation. In some cases, the IACUC may have specific questions to be addressed by the CRRB; while other times, the IACUC may request a more general review.

- b. To save time during the IACUC review, if the investigator believes an opinion from the CRRB would be beneficial, the IACUC will allow for a pre-review (See Appendix A). However, it is expected that the materials submitted to the CRRB be identical to those that will be submitted to the IACUC. To initiate a review, please send your A100 and informed owner consent form by email attachment to the chair of the CRRB (mlappin@mail.colostate.edu).
 - c. IACUC currently requires informed owner consent on all research projects involving client-, staff- or student-owned animals. The investigator must submit a copy of their client consent form to the Director of the VMC for review if client- staff-, or student-owned animals at the VMC are utilized (See page 2 of the A-100 form). The investigator must submit a signed copy of the approved client consent form or an approval email from the VMC Director to the IACUC. The Clinical Review Board will aid the VMC director in determining the content of the written informed owner consent form if asked by the VMC Director or IACUC.
3. A faculty member with questions regarding their use of novel techniques in the clinic may bring these questions forward to the CRRB. The CRRB Board may simply answer the faculty member's question after evaluating the technique in question or it may suggest the faculty member obtain IACUC approval if it appears that the use of the novel technique is developing into a prospective clinical trial.
4. The CRRB consists of the eight members of the Department of Clinical Sciences Research Committee plus the VMC Director (Currently Dr. Dean Hendrickson).
5. When requested, proposals that are in question will be reviewed electronically by the chair of the CRRB as well as one to two other members of the CRRB 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 CRRB will work with the investigator to help resolve issues concerning the protocol in question.
6. When possible, the opinion of the CRRB will be transmitted by email to the IACUC Coordinator and the investigator within five working days. The investigator should then respond to the comments of the CRRB which will review the comments and forward them to the IACUC for final review. The IACUC may then have a subcommittee review the responses or the responses may need to go to full committee for additional comments.
7. If the investigator completes a pre-review with the CRRB, the comments should be attached to the A100 when submitted to the IACUC (see Appendix A).

APPENDIX A

MEMORANDUM

To: Clinical Researchers
From: Laura Martin and Bill Moseley, IACUC Coordinators
Date: May 21, 2008
Re: Review of Clinical Research Protocols by the Clinical Research Review Board

In an effort to ensure adequate peer review of all research projects involving the use of animals, the CSU Institutional Animal Care and Use Committee (IACUC) has requested the assistance of the Clinical Research Review Board (CRRB). The CRRB will review protocols at the request of an individual investigator or at the request of the IACUC during its review and approval process, particularly for animal protocols for clinical research projects which have not received an external peer review (generally these have been internally or non-funded research projects).

In recent months, a number of protocol approvals have been slowed because it was necessary to solicit review by CRRB's panel of clinical experts prior to the IACUC issuing approval for the protocols. One way to speed the IACUC's review of clinical research protocols is for investigators to request the CRRB review *prior to* submitting an A-100 to the IACUC for review.

If you obtain a review of your protocol from the CRRB prior to submitting it to the IACUC, please simply provide the email or other documentation from the CRRB chair indicating the review and the CRRB's comments as attachments to your A-100. This will allow the IACUC to take the CRRB's review and any adjustments on your part into consideration during their review your protocol. We hope that this will allow for more efficient review and lead to more expeditious approvals of clinical research protocols.

For information on the CRRB and its review process please see the CVMBS website at: <http://www.cvmbs.colostate.edu/clinsci/clinicalreviewpro2007.pdf>.

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