

WIRB Submission Process Changes

All new WIRB Submissions from VCU must first be submitted to the VCU IRB for institutional review and not directly to WIRB. Beginning August 1, 2013 all WIRB protocols will be submitted through RAMS---IRB. At that time several procedural changes will occur. Please review the following submission steps carefully:

- 1. CRS Injury Language Review:** The CRS will review consent forms for industry funded clinical trials to ensure compliance with subject injury language in contracts.
 - a. The PI / Study team emails the informed consent documents to CRSAdmin@vcu.edu before submitting a WIRB study in RAMS---IRB.
 - i. Email subject line should include PI name, sponsor name, and study number or title.
 - ii. Email should include:
 1. Informed consent document(s), attached
 2. Clinical trial agreement (CTA), as appropriate, attached
 3. Sponsor contact information for negotiation purposes
 4. PT number associated with the study
 - b. The CRS will review and negotiate the appropriate revisions to the subject injury language directly with the sponsor or contract research organization (CRO), as appropriate.
 - c. Once CRS has completed negotiation of the language, they will send an approval memo with the VCU/Sponsor approved ICF template via email to the department for inclusion in the WIRB submission packet.
- 2. Submit WIRB Submission through RAMS---IRB:** Study teams will directly prepare and submit the WIRB submission through RAMS IRB, unless the CRS is contracted to perform the regulatory and IRB submissions. This replaces the prior method where WIRB documents were being sent via email or VCU filedrop to CRS for submission.
 - a. Documents that should be uploaded into the RAMS---IRB study workspace include:
 - i. Study protocol
 - ii. Informed consent form(s)
 - iii. Memo from CRS indicating injury clause language in consent has been approved
 - iv. Medicare Cost Analysis form
 - b. The CRS will prepare the RAMS---IRB submission and the WIRB submission when a study team contracts with the CRS to perform these services.
 - c. Information about training for WIRB submissions (and other IRB submissions) can be found at http://www.research.vcu.edu/irb/rams_irb.htm
- 3. The CRS will review via the submission in RAMS---IRB**
 - a. The CRS review will:
 - i. Verify documentation of how payment will be made for WIRB review. If the sponsor will not pay WIRB directly, it will be necessary to provide a VCU index code where IRB fees will be charged.
 - ii. Ensure that the documentation of Injury Clause review and approval has been done
 - iii. Ensure a Medicare Cost Analysis has been completed
 - b. The CRS will no longer be verifying that current forms are being utilized, that addresses match across documents, or that the correct number of items (e.g., investigator CV's) are included. This will be the responsibility of the individual preparing the WIRB submission packet.

- c. When the CRS review is complete, the RAMS---IRB submission will be forwarded to the Office of Research Subjects Protection (ORSP) for further institutional review.
- 4. The ORSP conducts an institutional review**
- a. The review will:
 - i. Request that a COI review be conducted
 - ii. Verify mandatory training completion
 - iii. Confirm appropriate HIPAA PHI pathway
 - b. Upon completion of the ORSP review, the PI will receive an email memo indicating the review is complete and the study may be submitted to WIRB.
- 5. The Study Team submits the study to WIRB**
- a. ORSP will no longer submit study/review documents to WIRB.
 - b. The PI / Study Team is responsible for submitting all required documents to WIRB. In addition to all study related documents, the following documents must be included with the WIRB submission in order for a review to occur:
 - i. ORSP memo indicating institutional review is complete
 - ii. Verification that injury clause language has been reviewed

Please contact CRSAdmin@vcu.edu if you have questions about ICF injury clause review. Please contact ORSP@vcu.edu for questions about WIRB submissions in RAMS---IRB.