

## **HRRC Process When Submitting to WIRB**

To avoid re-review charges imposed by WIRB, HRRC review will occur prior to submission to WIRB. A conditional approval form from the HRRC will be required before COMIRB will forward the study to WIRB.

To obtain HRRC conditional approval, submit the standard package of documents to HRRC.

Required documents include (# of copies):

- HRRC Approval Form with appropriate signatures (2)
- HRRC budget, if appropriate (1)
- COMIRB / WIRB application form (2)
- Full Protocol (1)
- Consent Form (s) (2)
- HIPAA Authorizations Form(s) (1)
- Clinical Trial Agreement with all attachments (1)
- If an IDE is involved: FDA letter, relevant publications and any reimbursement information provided by the sponsor (1)

All studies going to WIRB should be indicated by checking the box indicated on the first page of the HRRC Approval Form. The revised form is available from the HRRC Home Page.

HRRC review will occur within 5 business days if a complete package is received.

Results of the review will be communicated via e-mail to the PI and Study Coordinator.

If any revisions to documents are required, these will be reviewed by the HRRC within 4 business days from the time the documents are re-submitted.

Once all HRRC issues are resolved, a pink form titled HRRC Conditional Approval For WIRB Studies form will be sent via campus mail to the PI. This form needs to be included in the package submitted to COMIRB. See attached example.

COMIRB will provide the WIRB-approved version of the Consent Form and the final Authorization Form to the HRRC.

When WIRB approval is received and the budget and Clinical Trial Agreement are finalized, the HRRC Approval Letter will be sent to the PI via campus mail and to the Study Coordinator via e-mail, along with the Business Plan and Research Charge Form.

Contact Mary Schumer at 303-724-5446, if you have any questions.