GUIDELINE FOR SUBMITTING TO A CENTRAL IRB

OHSP Policy 401 Functions of the RSRB Office indicates that study assignments are based on the Investigator’s submitting department, type of sponsorship, and IRB Authorization Agreements (if applicable). To determine whether a study should be submitted to a central IRB, see the flow chart below.

Specifically, for submissions to Western IRB (WIRB), see instructions on the following page. Documentation to address sponsor requests inquiring about WIRB’s role in reviewing research for the University may be found on the RSRB website under the “Applying to WIRB” section.

NOTE: WIRB will not review any UR study prior to RSRB administrative review.
When submitting new WIRB applications for INITIAL review:

1. WIRB submissions should be initiated, but **not submitted** by the study team, online via [WIRB Connexus](https://www.wirb.com/). An application in the RSRB ROSS system must also be completed prior to RSRB review of the WIRB application.

2. After logging onto WIRB Connexus, select “Submissions”, then “New Research”. If you experience any technical issues with the new system or need assistance while working through the application, use the Live Support Online chat or contact client services.

3. Under “Submission Types”/”IRB Submissions”, select “Smart Form” in the drop down box and then click “Initial Review” to begin the application. Enter a submission name (such as the short title of the study for your future reference) and click “SAVE”.

4. At the end of the WIRB application there will be a separate page entitled “Investigator Confirmation of Board Requirements”. The PI should sign and date this page and upload it as a document in WIRB Connexus.

**Required WIRB submission documents:**

IMPORTANT: When uploading documents within WIRB Connexus click “Next” in order for the system to validate any documents uploaded. If uploading is not complete, click “Save and Submit Later”.

- Completed and signed (by PI) WIRB application form
- Sponsor’s Protocol
- Subject Consent Form(s)
- Investigator’s Drug Brochure (if applicable and current version is not on file with WIRB)
- IDE Documentation (for device studies, if applicable)
- Study recruitment materials (ads, brochures, etc.)
- HURC Review (if applicable)
- IBC Review (if applicable)
- *Investigator’s current medical license
- *Investigator’s current CV
  *WIRB only requires the CV and medical license of the Principal Investigator, unless he/she is not a medical doctor (MD), in which case the CV and medical license of the Investigator that is the MD for the study is required.
- Department Letterhead
- Any additional documents that require IRB review

Complete the WIRB online submission form, but **DON’T click the submit button**. The “Forms & Guides” link includes the Connexus User Guide to reference for additional instruction as needed.
5. Once the submission form is completed and all required documents have been uploaded on WIRB Connexus, add the RSRB WIRB Liaisons: Nicole Mason, nicole_mason@urmc.rochester.edu, and Emily Flagg, emily_flagg@urmc.rochester.edu, as managers. At the study home page/site workspace, select “Site (or Study) Participants”, under ‘Access Level’ select role of “Manager”, under ‘Invitee Represents’ select “Institution”. The system will send an automatic email notification alerting them that the study is now ready for RSRB review and to complete the submission.

- For RSRB staff: To search for the pending submission enter “TBD” in the ‘IRB Tracking’ column.

6. Once the RSRB administrative review is complete, the RSRB WIRB liaison will conduct the following activities:

- Review the online documents in WIRB Connexus and the ROSS online application.
  - If consent changes are requested by the RSRB after the study team has notified RSRB of the new submission, the RSRB staff will upload revised consent(s) prior to completing the submission.
- Upload the required UR RSRB cover letter to WIRB Connexus.
- Complete the WIRB Connexus submission.
- Send email confirmation to the study team indicating that the WIRB application has been sent to WIRB.

Once WIRB approval is granted, WIRB will maintain oversight of the study. Therefore, subsequent submissions (e.g., amendments, continuing reviews, reportable events) go directly to WIRB for review.

**ADDITIONAL TIPS:**

- WIRB Connexus works best with Internet Explorer, Safari and Firefox.
- When logging into the system, there may be a delay as the system is always refreshing the full database.
- If duplicate submissions for the same study are created in error, the duplicate copies may be deleted.
- The application may be saved at any point after the submission name is entered and saved (i.e., a record is created).
  - If you need to return to an incomplete application, select “Submissions”, “My Unfinished SmartForm Submissions”. 

Guideline for Submitting to Central IRB  
v. 8/15/2013