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. An application in the RSRB ROSS system must also be completed prior to RSRB review of the WIRB application.

   • For Study New to WIRB: After logging onto WIRB Connexus, select “Submissions”, then “New Research”.

   • For Approved Study on File at WIRB: If WIRB has already approved the study, sponsor should have sent an Invite to access the submission and the protocol will be in the Workspace. If study is not in the Workspace, request an Invite from sponsor (or from WIRB Client Services).

If you experience any technical issues with the system or need assistance while working through the application, use the Live Support Online chat or contact Client Services.

Need Help?

2. 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”.

Smart Form Application Tips:

   • Section “Site” – Other IRB: “Does this site have an obligation to use another IRB?” Response of “No” is acceptable. If response of “Yes” is indicated, the WIRB IRB of Record letter is required (click here to access the letter).

   • Section “Recruitment, Consent and Subject Payment Information” – WIRB Consent: “Would you like to use the previously approved consent form?” Response of “No” should be indicated for all applications. If the study has previously been approved by WIRB, obtain a copy of the approved consent template from the Workspace (or email or call WIRB client services) so institutional language may be inserted as applicable. The RSRB reviewed consent(s) will be included with each initial application.

Additional Tips:

   • WIRB Connexus works best with Internet Explorer, Safari and Firefox.

   • 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).
     o If you need to return to an incomplete application, select “Submissions”, “My Unfinished SmartForm Submissions”.

3. 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 WIRB application and Investigator Confirmation sign-off form
- Sponsor’s Protocol
- Subject Consent Form(s)
- Investigator’s Drug Brochure (if applicable or current version not on file with WIRB)
- IDE documentation for device studies (if applicable)
- Study recruitment materials such as ads or brochures (if applicable)
- HURC Review (if applicable)
- IBC Review (if applicable)
- *Investigator’s current medical license and Investigator’s CV
  *WIRB only requires the medical license and CV of the Principal Investigator, unless he/she is not a medical doctor (MD), in which case the medical license and CV of the Investigator that is the MD for the study is required.
- Department Letterhead (unless consent forms already included on 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.

4. Once the submission form is completed and all required documents are uploaded in the WIRB Connexus application, add the RSRB WIRB Liaisons as managers:
   - Suzanne Coglitore, suzanne_coglitore@urmc.rochester.edu
   - Emily Flagg, emily_flagg@urmc.rochester.edu

   To add managers, at the “Workspaces” home page, identify the “TBD – Pending” status for the application and click the link to that study; select the “Site (or Study) Participants” button, 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.

5. 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.
     o If consent changes are made after the RSRB begins administrative review, the RSRB staff may upload revised consent(s) prior to completing the submission.
   - Upload the required RSRB cover letter to Connexus and complete the WIRB submission.
   - Send email confirmation to study team confirming the WIRB application was submitted.

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.