### Getting Started With WIRB

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<th>Who Is</th>
<th>Western Institutional Review Board (WIRB) is an independent (commercial) IRB located in Washington State. WIRB has a reliance agreement in place with Copernicus IRB. Teams should use WIRB procedures to access existing Copernicus projects. Contact WIRB with any questions about this relationship.</th>
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| How do I contact WIRB? | Main Contact: Christopher Gennai  
Telephone: (360)252-2460  
Fax: (360) 252-2498  
Email: cgennai@wirb.com  
Web: www.wirb.com  
Back-up Contact: JayLynn Goddard  
Telephone: (800) 562-4789  
Fax: (360) 252-2498  
Email: jgoddard@wirb.com  
Web: www.wirb.com |
| What is WIRB’s application system called? | WIRB’s online submission system is called Connexus. This secure web portal allows investigators online access to electronic submissions, status reporting, Board correspondence, and approval documents. |
| How do I begin working with WIRB? | Each applicable study team member will need to register a unique user name and email address in Connexus. This allows access to secure WIRB areas for uploading and downloading of documents, approval notices, etc. |
| How do I get started in Connexus? | Registered team members are asked to attend a short online training session. Obtain more information at: Western Institutional Review Board WebEx Enterprise Site or contact WIRB Client Services for available times. |
| Do I still need to work with IRBMED? | Yes, study team members must complete an eResearch application to fulfill additional U-M research obligations (e.g., ancillary committee reviews). Select application type “Requesting Review by a Non-UM IRB (Ceding Application)” in section 1-1.1. Refer to the Central IRB at University of Michigan Workflow for more information on completing Ceding Applications. |

### Working With IRBMED

| What documents do I need for the U-M Ceding application? | Study teams must obtain the approved versions of project documents from the WIRB website, per WIRB policy. Team members should obtain copies of the following and upload in the Ceding Application:  
- Approved protocol  
- Sponsor template consent  
- Investigator Brochures/Package Insert (if applicable)  
- Documentation of WIRB approval for the study which includes the current approval period (upload this documentation in section 44 of the eResearch application). Contact Christopher Gennai cgennai@wirb.com or JayLynn Goddard via email: jgoddard@wirb.com if assistance is needed |

### After IRBMED Agrees to Cede IRB Oversight to WIRB

| U-M IRBMED has issued an Acknowledgement Letter agreeing to cede IRB oversight to WIRB...now what? | Send a copy of the 1) the IRBMED Acknowledgement Letter, 2) a copy of section 25-1only from the eResearch application, and 3) a copy of the revised consent template(in the event any changes to the sponsor consent were made) to WIRB. You must then complete any remaining WIRB requirements to receive approval of U-M as a performance site. After obtaining WIRB approval for U-M as a performance site, post correspondence in eResearch and attach  
- WIRB approval notice for U-M as a site.  
- All WIRB approved consent documents for U-M.  
These documents provide notification to the IRBMED and Ancillary Committees that the study team is approved by WIRB to begin research activities. |
| What are my continuing obligations to IRBMED and U-M? | Study teams must submit the following events and information occurring at U-M via the Ceding Application in eResearch using standard submission formats:  
- Amendments to the study that impact U-M ancillary committees (i.e.,  
  - Research Pharmacy (aka IDS): changes in dosing, addition of medication prescribers;  
  - RDRC/SHUR: changes in radiation dosing;  
  - CRAO: billing calendar updates;  
  - COI: addition/removal of study team members)  
- Scheduled Continuing Reviews  
- Serious Adverse Events that are related to the research per IRBMED guidance  
- Unanticipated Problems  
- Protocol deviations that may represent a systematic problem requiring local evaluation by IRBMED to determine that sufficient local resources are available for safe conduct of the study  
- Reports of Continuing and/or Serious Non-Compliance  
- Study holds or suspensions from WIRB or Sponsor  
- Study Terminations from WIRB  
Once all activity is completed and the team receives permission from WIRB to terminate, the team must terminate the eResearch application via a CR submission. |