UNIVERSITY OF MICHIGAN PROCEDURES FOR CEDING TO WESTERN IRB (WIRB)

Getting Started With WIRB	
Who Is WIRB?	Western Institutional Review Board (WIRB) is an independent (commercial) IRB located in Washington State. WIRB also works with several Affiliate IRBS to provide access to studies. Affiliate IRBs include: Copernicus Group, Inc.; Aspire IRB; New England IRB; and Midlands IRB. Teams will need to contact WIRB to determine if the study they are interested in conducting is eligible to be reviewed by WIRB. Teams should use WIRB procedures to access existing Affiliate projects. Contact WIRB with any questions about this relationship.
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
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 register?	Go to the Connexus website for registration.
How do I get started in Connexus?	Registered team members are asked to attend a short online training session. Obtain more information at: Connexus Training or contact WIRB Client Services.
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 Single IRB of Record website 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 • WIRB approved Consent / Assent template(s) • Investigator Brochures/Package Insert (if applicable) • Documentation of WIRB approval for the **overall study** which includes the current approval period (upload this documentation in section 44 of the eResearch application). Contact Christopher Gennai if assistance is needed obtaining this documentation.
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 1) the IRBMED Acknowledgement Letter and 2) a copy of section 25-1 **only** from the eResearch application to WIRB. Teams must also 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, attach the following in the eResearch activity called Upload Non-UM IRB Approval Documents. • 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.,** o **Research Pharmacy (aka IDS): changes in dosing, addition of medication prescribers;** o **RDRC/SHUR: changes in radiation dosing;** o **CRAO: billing calendar updates, changes that would impact subject injury language in consent;** o **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 that are not built into the study design from WIRB or Sponsor (eg: interim analysis or enrollment complete need not be reported) • 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 continuing review/Termination submission.