

### Document Title: University of Michigan Procedures for Ceding to WCG IRB

Getting Started With WCG	
Who Is WCG ?	WCG Institutional Review Board is an independent (commercial) IRB located in Washington State.
How do I contact WCG?	Main Contact: Christopher Gennai Fax: (360) 252-2498 Web: <a href="http://www.wirb.com">www.wirb.com</a> Telephone: (360)252-2460 Email: <a href="mailto:cgennai@wirb.com">cgennai@wirb.com</a>
What is WCG’s application system called?	WCG’s online submission system is called <a href="#">Connexus</a> . This secure web portal allows investigators online access to electronic submissions, status reporting, Board correspondence, and approval documents.
How do I begin working with WCG?	Each applicable study team member will need to register a unique user name and email address in Connexus. This allows access to secure WCG 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: <a href="#">Connexus Training</a> or contact WCG Client Services.
Do I still need to work with U-M IRB?	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. For additional directions, see the Ceding guidance. For IRBMED study teams - locally required boilerplate language is available on the <a href="#">IRBMED sIRB website</a> .
Working With IRBMED	
What documents do I need for the U-M Ceding application?	Study teams must obtain the approved versions of project documents <b>from the WCG website, per WCG policy</b> . Team members should obtain copies of the following and upload in the Ceding Application: <ul style="list-style-type: none"> <li>• WCG Approved protocol</li> <li>• WCG approved Consent / Assent template(s)                             <ul style="list-style-type: none"> <li>○ <b>IRBMED Only:</b> Applicable locally required boilerplate language must be inserted as TRACKED changes. ➤ The boilerplate does not apply to assent forms, but for other consents (e.g., sub-study consents, pregnant partner consents, etc.), it will be assessed on a case-by-case basis but generally, if the topic is touched on in that consent form, the applicable boilerplate applies.</li> </ul> </li> <li>• Investigator Brochures/Package Insert (if applicable)</li> <li>• Documentation of WCG approval for the <b>overall study</b> which includes the current approval period (upload this documentation in section 44 of the eResearch application).</li> </ul>
After U-M IRB Agrees to Cede IRB Oversight to WCG	
U-M IRB has issued an Acknowledgement Letter agreeing to cede IRB oversight to WCG...now what?	Send the following to WCG as a part of the application packet: <ul style="list-style-type: none"> <li>•The tracked copy of the Informed Consent</li> <li>•Copy of IRBMED Acknowledgement letter allowing the study to proceed under WCG oversight</li> </ul> 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. <ul style="list-style-type: none"> <li>•WCG approval notice for U-M as a site</li> <li>•All finalized WCG approved consent documents for U-M</li> </ul> These documents provide notification to the U-M IRB and Ancillary Committees that the study team is approved by WCG to begin research activities.
What are my continuing obligations to the U-M?	Study teams have other types of continued reporting that must be submitted in eResearch after initial review. The continued reporting is outlined on page 3 of the ceded guidance.

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