Document Title: University of Michigan Procedures for Ceding to NCI CIRB (CIRB)

Getting Started With NCI CIRB	
Who Is CIRB FOR THE NATIONAL CANCER INSTITUTE?	CIRB is a central IRB that conducts all IRB reviews of selected National Cancer Institute (NCI)-sponsored trials.
How do I contact CIRB?	Telephone 888-657-3711 Fax: 301-560-6538 Email: ncicirbcontact@emmes.com Web: www.ncicirb.org
What is NCI CIRB's application system called?	NCI CIRB's application system is IRB Manager on the www.ncicirb.org website. This secure portal allows investigators to access necessary forms. Reference documents known as Quickguides for how to use this system.
How do I begin working with CIRB?	• Principal Investigators must be registered with NCI CIRB. • All Investigators and Staff must have a CTEP ID # • Protocols are available for download on the CTSU website.
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 IRBMED sIRB website.
Working With U-M IRB	
What documents do I need for the U-M Ceding application?	Study teams must obtain the approved versions of project documents **from study Sponsor, CTSU website.** Team members should obtain copies of the following for the Ceding Application: ● NCI CIRB Approved Protocol ● Investigator brochures (if applicable) ● NCI CIRB Approved template consent/assent document(s) ○ **IRBMED only:** Applicable locally required boilerplate language must be inserted ○ **IRBMED only:** U-M Site-Specific and Research HIPAA Authorization document must be included ● CIRB approval notice for the **overall study** which includes the current approval period (upload in section 44.1 of the eResearch application)
What are the requirements for the informed consent document(s)?	**IRBMED ONLY:** CIRB approved U-M specific boilerplate language must be inserted by the U-M Study team into the CIRB approved template document(s) and the U-M Site-Specific and Research HIPAA Authorization document should attached separately. The resulting documents become the draft U-M Consent and is submitted as a part of the ceding application to IRBMED. Only a tracked version of each consent/ assent document needs be uploaded. IRBMED will create the clean PDF versions at the time of Acknowledgement.
Review Process	U-M IRB will conduct review of the request to cede oversight. Once the UM Acknowledgment Letter has been sent to the study team, the checkbox in the Upload Non-UM IRB Approval Documents should be checked and the NCI CIRB approval letter for UM should be attached. In addition to the eResearch application, the study team will need to submit project specific information to NCI CIRB via IRBManager on the www.ncicirb.org website. As a part of this process the U-M PI is required to complete and submit the CIRB Study-Specific Worksheet. Overall instructions for Opening a Study with NCI CIRB are found here. **NOTE:** UM Study Team cannot begin study activities until they have received notification from the U-M IRB that they have ceded oversight AND Notification from NCI CIRB that they have assumed responsibility as IRB of record for a particular study.
After U-M IRB Agrees to Cede IRB Oversight to CIRB	
What are my continuing obligations to 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.

File Name: CSP_CP.201N.working WITH NCI CIRB_2023_June	Target Audience: Research Community
Author/Responsible Unit: Coordinated Services and Practices (CSP) unit	Date Released: 1.17.2024
Date Modified: N/A	