


UNIVERSITY OF MICHIGAN PROCEDURES FOR CEDING TO NCI CIRB (CIRB)

Getting Started With NCI CIRB

Who is  ?	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?	<ul style="list-style-type: none"> 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 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 webpage 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 study Sponsor, CTSU website . Team members should obtain copies of the following for the Ceding Application: <ul style="list-style-type: none"> NCI CIRB Approved protocol Investigator brochures (if applicable) NCI CIRB Approved template consent/assent document(s) 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)?	CIRB approved U-M specific boilerplate language must be inserted by the U-M Study team into the CIRB approved template document(s). The resulting document(s) 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 version at the time of Acknowledgement.
Review Process	<p>IRBMED 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.</p> <p>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.</p> <p>NOTE: UM Study Team cannot begin study activities until they have received notification from IRBMED that they have ceded oversight AND Notification from NCI CIRB that they have assumed responsibility as IRB of record for a particular study.</p>

After IRBMED Agrees to Cede IRB Oversight to CIRB

What are my continuing obligations to IRBMED and U-M?	<p>Study teams must submit the following events and information occurring at U-M via the Ceding Application in eResearch using standard submission formats:</p> <ul style="list-style-type: none"> Amendments to the study that impact U-M ancillary committees (i.e., <ul style="list-style-type: none"> Research Pharmacy (aka IDS): changes in dosing, addition of medication prescribers; RDRC/SHUR: changes in radiation dosing; CRAO: billing calendar updates, changes that would impact subject injury language in consent 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 CIRB or Sponsor (eg: interim analysis or enrollment complete need not be reported) Study Terminations from CIRB <p>Once all activity is completed and the team receives permission from CIRB to terminate the study, the team must terminate the eResearch application via a continuing review/Termination submission.</p>
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