UNIVERSITY OF MICHIGAN PROCEDURES FOR CEDING TO A Non-UM Institutional IRB

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**.** Team members should obtain copies of the following and upload in the Ceding Application: • Non UM- IRB Approved protocol • Investigator brochures (if applicable) • Non UM IRB Approved template consent • Approval notice for the **overall study** which includes the current approval period. The type of letter may vary depending on when UM joins as a site, but it **MUST** contain the most recent approval interval for the proposed non-UM Institutional IRB. (upload in section 44 of the eResearch application) • Coversheet for the Non-UM IRB (if applicable)
After IRBMED Agrees to Cede IRB Oversight to Non-UM Institutional IRB	
U-M IRBMED has issued an Acknowledgement Letter agreeing to cede IRB oversight to a Non-UM IRB. Now what?	Study Team will send the following to the Non-UM Institutional IRB: • Copy of IRBMED Acknowledgement letter agreeing to cede IRB oversight • A copy of section 25-1 **only** from eResearch application. (**Note:** Required only if Non-UM IRB is responsible for development of UM Site Specific consent document(s)) After obtaining approval from the non-UM Institutional IRB for U-M as a performance site, attach the following in the eResearch activity called Upload Non-UM IRB Approval Documents: • Approval notice from non-UM Institutional IRB for U-M as a site • All approved consent and/or assent document(s) for U-M These documents provide notification to the IRBMED and Ancillary Committees that the study team is approved by non-UM IRB 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, 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 Non-UM Institutional IRB or Study Sponsor (eg: interim analysis or enrollment complete need not be reported)
	• Study Terminations from Non-UM Institutional IRB
	Once all activity is completed and the team receives permission from the Non- UM Institutional IRB to terminate the study, the team must terminate the eResearch application via a continuing review/Termination submission.