UNIVERSITY OF MICHIGAN PROCEDURES FOR CEDING TO CHESAPEAKE IRB (Chesapeake)

Getting Started With Chesapeake		
Who Is CHESAPEAKE IRB?	Chesapeake IRB (Chesapeake) is an independent (commercial) IRB located in Columbia Maryland.	
How do I contact Chesapeake?	Dana Marvel Telephone: 443-283-1524 Email: dmarvel@chesapeakeirb.com	Web: http://chesapeakeirb.com/ Telephone: (410) 884-2900 (Main Reception) Fax: (410) 884-9190 (Main Fax) Email: info@chesapeakeirb.com
What is Chesapeake's application system called?	Chesapeake's online submission system is called the Center for IRB Intelligence or CIRBI	
How do I begin working with Chesapeake?	Each applicable study team member will need to register a unique user name and email address in CIRBI. This secure web portal allows investigators online access to electronic submissions, status reporting, Board correspondence, and approval documents.	
How do I register?	Go to CIRBI Registration .	
How do I get started in CIRBI?	Chesapeake offers training webinars and one-on-one telephone support services to its investigative teams. Obtain more information by contacting Chesapeake Client Services at info@chesapeakeirb.com.	
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 Central IRB at University of Michigan Workflow for more information on completing Ceding Applications.	
Working With IRBMED		
What documents do I need for the U-M Ceding application?	Study Sponsor will provide the following documents which Study Team will attach to the appropriate sections of the Ceding Application: • Chesapeake Approved Protocol • Chesapeake approved Consent / Assent template(s). • Investigator Brochures/Package inserts (if applicable) Chesapeake will provide • Documentation of Chesapeake approval for the **overall study** which includes the current approval period (upload in section 44 of the eResearch application). Contact Chesapeake Client Services via email at info@chesapeakeirb.com if assistance is needed obtaining documentation.	
After IRBMED Agrees to Cede IRB Oversight to Chesapeake		
U-M IRBMED has issued an Acknowledgement Letter agreeing to cede IRB oversight to Chesapeake. Now what?	Send a copy of 1) the IRBMED Acknowledgement Letter and 2) a copy of section 25-1only from the eResearch application to Chesapeake. Study team must then complete any remaining Chesapeake requirements to receive approval as a performance site. After obtaining Chesapeake approval for U-M as a performance site, *post correspondence* in eResearch and attach: • Chesapeake approval notice for U-M as a site • All Chesapeake-approved consent documents for U-M These documents provide notification to the IRBMED and Ancillary Committees that the study team is approved by Chesapeake 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 Chesapeake or Sponsor (eg: interim analysis or enrollment complete need not be reported)
	• Study Terminations from Chesapeake
	Once all activity is completed and the team receives permission from Chesapeake to terminate the study, the team must terminate the eResearch application via a continuing review/Termination submission.	