UNIVERSITY OF MICHIGAN PROCEDURES FOR CEDING TO SCHULMAN ASSOCIATES IRB (SCHULMAN)

Getting Started With Schulman		
Who Is SCHULMAN ASSOCIATES IRB?	Schulman Review (Schulman) is an independent (commercial) IRB with locations in Cincinnati, Ohio and Ft. Lauderdale, Fl.	
How do I contact Schulman?	**U-M Account Manager**: Maria Stivers Office Telephone (513)794-5743 Mobile Telephone: (859) 760-6772 Fax: 513.761.1460	Email: mstivers@sairb.com Web: http://www.sairb.com/ General Contact Information
What is Schulman's application system called?	Schulman's online submission system is called eTools. This secure web portal allows investigators online access to electronic submissions, status reporting, Board correspondence, and approval documents.	
How do I begin working with Schulman?	• Study team members register unique user names and emails in eTools • The Schulman Forms page outlines the forms, templates and guidance documents teams may find helpful. Contact Schulman with questions related to forms.	
How do I get started in eTools?	Schulman offers eTools demonstrations online to individual study teams or groups who are interested in finding out more information about the system. Contact Schulman account manager to arrange for webinars.	
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: • Approved protocol • Schulman Approved Consent / Assent template(s) • Investigator brochures (if applicable) • Documentation of Schulman approval for the overall study which includes the current approval period (upload in section 44 of the eResearch application) Obtain the U-M/Schulman Coversheet **from IRBMED webpage.** Complete with protocol information, and upload in section 44 and upload into section 44 of the eResearch application.	
After IRBMED Agrees to Cede IRB Oversight to Schulman		
U-M IRBMED has issued an Acknowledgement Letter agreeing to cede IRB oversight to Schulman. Now what?	IRBMED will upload a copy of the signed coversheet into the eResearch workspace. Send the following to Schulman as a part of the application packet: • Signed U-M/Schulman Coversheet • A copy of section 25-1 of eResarch application • Copy of IRBMED Acknowledgement letter allowing the study to proceed under Schulman IRB oversight After obtaining the Schulman approval for U-M as a performance site *post correspondence* in eResearch and attach • Schulman approval notice for U-M as a site • All finalized Schulman-approved consent documents for U-M These documents provide notification to the IRBMED and Ancillary Committees that the study team is approved by Schulman 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 Schulman or Sponsor (eg: interim analysis or enrollment complete need not be reported)
	• Study Terminations from Schulman
	Once all activity is completed and the team receives permission from Schulman to terminate the study, the team must terminate the eResearch application via a continuing review/Termination submission.	