UNIVERSITY OF MICHIGAN PROCEDURES FOR CEDING TO QUORUM REVIEW IRB (QUORUM)

Getting Started With Quorum	
Who Is Quorum REVIEW IRB?	Quorum Review IRB (Quorum) is an independent (commercial) IRB located in Seattle Washington.
How do I contact Quorum?	**Account Manager**: Callie Rich Telephone 1-877-472-9883 (toll free) Email: crich@quorumreview.com Web: www.Quorumreview.com
What is Quorum's application system called?	Quorum's online submission system is called the OnQ Client Portal. This secure web portal allows investigators online access to electronic submissions, status reporting, Board correspondence, and approval documents.
How do I begin working with Quorum?	• Each applicable study team member is required to register a unique user name and email in OnQ. • Study teams access required Quorum forms by visiting the Quorum Forms page. Contact Quorum with questions related to forms. • Study teams are required to complete the Site information Questionnaire
How do I get started in OnQ??	Quorum offers an introductory webinar designed to familiarize study teams with Quorum services. Contact the Quorum account manager to arrange for this webinar.
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, per Quorum policy.** Team members should obtain copies of the following and upload in the Ceding Application: • Approved protocol • Investigator brochures (if applicable) • Quorum Approved Consent / Assent template(s) • Documentation of Quorum approval for the **overall study** which includes the current approval period (upload in section 44 of the eResearch application) Obtain the U-M/Quorum Coversheet from the Single IRB of Record webpage. Complete with protocol information and upload in section 44 of the eResearch application.
After IRBMED Agrees to Cede IRB Oversight to Quorum	
U-M IRBMED has issued an Acknowledgement Letter agreeing to cede IRB oversight to Quorum. Now what?	IRBMED will upload a copy of the signed coversheet into the eResearch workspace. Study Team will send the following to Quorum as a part of the application packet: • Signed U-M/Quorum Coversheet • Copy of IRBMED Acknowledgement letter allowing the study to proceed under Quorum IRB oversight • A copy of Section 25-1 from the acknowledged eResearch application After obtaining the Quorum approval for U-M as a performance site, attach the following in the eResearch activity called Upload Non-UM IRB Approval Documents: • Quorum approval notice for U-M as a site • All Quorum-approved consent document(s) for U-M These documents provide notification to the IRBMED and Ancillary Committees that the study team is approved by Quorum 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.,** o **Research Pharmacy (aka IDS): changes in dosing, addition of medication prescribers;** o **RDRC/SHUR: changes in radiation dosing;** o **CRAO: billing calendar updates, changes that would impact subject injury language in consent;** o **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 Quorum or Sponsor (eg: interim analysis or enrollment complete need not be reported) • Study Terminations from Quorum Once all activity is completed and the team receives permission from Quorum to terminate the study, the team must terminate the eResearch application via a continuing review/Termination submission.