## Getting Started With Quorum

**Who Is Quorum?**

Quorum Review IRB (Quorum) is an independent (commercial) IRB located in Seattle Washington.

**How do I contact Quorum?**

Account Manager: Sheryll Horiuchi available Monday - Friday, 10 AM – 7 PM ET

Telephone 206-436-3250 (direct line); or 1-888-776-9115 (toll free)

Email: shoriuchi@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 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 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)
- Approved template consent
- Quorum approval notice for the study which includes the current approval period (upload in section 44 of the eResearch application)

Obtain the U-M/Quorum Coversheet **from the IRBMED webpage.** Complete with protocol information and upload in section 44 of the eResearch application.

**What are the requirements for the informed consent document(s)?**

IRBMED required boilerplate language must be inserted by the U-M Study team into the approved sponsor template. The resulting document becomes the Draft U-M Consent and is submitted as a part of the packet to Quorum once IRBMED agrees to Cede IRB oversight.

## 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
- Draft U-M consent

After obtaining the Quorum approval for U-M as a performance site, **post correspondence** in eResearch and attach:

- 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.,
  - RDRC/SHUR: changes in dosing, addition of medication prescribers;
  - CRAO: billing calendar updates;
  - 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 from Quorum or Sponsor
- 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 CR submission.