### Getting Started With Quorum

<table>
<thead>
<tr>
<th><strong>Who is Quorum Review IRB (Quorum)?</strong></th>
<th>Quorum Review IRB (Quorum) is an independent (commercial) IRB located in Seattle Washington.</th>
</tr>
</thead>
</table>
| **How do I contact Quorum?** | **Account Manager:** David Kim  
  Telephone 206-4363297 (direct line); or 1-877-472-9883 x 297 (toll free)  
  Email: dkim@quorumreview.com  
  Web: [www.QuorumReview.com](http://www.QuorumReview.com) |
| **What is Quorum’s application system called?** | Quorum’s online submission system is called the [OnQ Client Portal](http://OnQClientPortal). 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](http://forms). Contact Quorum with questions related to forms.  
  - Study teams are required to complete the [Site Information Questionnaire](http://siteinformation). |
| **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-U-M IRB (Ceding Application)” in section 1-1.1. Refer to the [Central IRB at University of Michigan Workflow](http://centralirb) 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 IRBMED 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, 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.,  
    - 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 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. |