## Getting Started With Quorum

<table>
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<th>Who is Quorum?</th>
<th>Quorum Review IRB (Quorum) is an independent (commercial) IRB located in Seattle Washington.</th>
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</table>
| How do I contact Quorum? | **Account Manager:** David Kim  
Telephone 206-436-3297-(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://www.OnQClientPortal.com). 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 the Quorum forms by visiting the Quorum [Forms page](http://www.quorumreview.com/forms). Contact Quorum with questions related to forms.  
• Study teams are required to complete the [Site information Questionnaire](http://www.quorumreview.com/forms). |
| 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://www.onqclientportal.com) 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](http://www.onqclientportal.com). 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](http://www.onqclientportal.com)  
• 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. |