<table>
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<th>Getting Started With Quorum</th>
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<tr>
<td><strong>Who is Quorum?</strong></td>
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| **How do I contact Quorum?** | **Account Manager:** Callie Rich  
Phone 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. |

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<th>Working With IRBMED</th>
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| **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. |

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<th>After IRBMED Agrees to Cede IRB Oversight to Quorum</th>
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| **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. |

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<th>What are my continuing obligations to IRBMED and U-M?</th>
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| 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 (e.g: 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. |