## Getting Started With Schulman

<table>
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<tr>
<th>Who Is Schulman?</th>
<th>Schulman Review (Schulman) is an independent (commercial) IRB with locations in Cincinnati, Ohio and Ft. Lauderdale, Fl.</th>
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</thead>
</table>
| How do I contact Schulman? | **U-M Account Manager:** Justin Osborne  
**Telephone:** (513)764-5760  
**Fax:** 513.761.1460  
**Email:** Josborne@sairb.com  
**Web:** [http://www.sairb.com/](http://www.sairb.com/)  
**General Contact Information** |
| What is Schulman’s application system called? | Schulman’s online submission system is called eTools. This secure web portal allows investigators online access to electronic submissions, status reporting, Board correspondence, and approval documents. |
| How do I begin working with Schulman? |  
- Study team members register unique user names and emails in eTools  
- The Schulman Forms page outlines the forms, templates and guidance documents teams may find helpful. Contact Schulman with questions related to forms. |
| How do I get started in eTools? | Schulman offers eTools demonstrations online to individual study teams or groups who are interested in finding out more information about the system. Contact Schulman account manager to arrange for webinars. |
| 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 Sponsor will provide the following documents which Study Team will attach to the appropriate sections of the Ceding Application:  
- Approved protocol  
- Sponsor template consent  
- Investigator brochures (if applicable)  
- Schulman approval notice for the study which includes the current approval period (upload in section 44 of the eResearch application)  
Obtain the U-M/Schulman Coversheet from IRBMED webpage. Complete with protocol information, and upload in section 44 and upload into section 44 of the eResearch application. |

## After IRBMED Agrees to Cede IRB Oversight to Schulman

| U-M IRBMED has issued an Acknowledgement Letter agreeing to cede IRB oversight to Schulman. Now what? | IRBMED will upload a copy of the signed coversheet into the eResearch workspace. Send the following to Schulman as a part of the application packet:  
- Signed U-M/Schulman Coversheet  
- A copy of section 25-1 of eResearch application  
- Copy of IRBMED Acknowledgement letter allowing the study to proceed under Schulman IRB oversight  
After obtaining the Schulman approval for U-M as a performance site post correspondence in eResearch and attach  
- Schulman approval notice for U-M as a site  
- All finalized Schulman-approved consent documents for U-M  
These documents provide notification to the IRBMED and Ancillary Committees that the study team is approved by Schulman 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;  
  - 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 Schulman or Sponsor  
- Study Terminations from Schulman  
Once all activity is completed and the team receives permission from Schulman to terminate the study, the team must terminate the eResearch application via a CR submission. |

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**Contact Information**

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**Central IRB at University of Michigan Workflow**