### Getting Started With Chesapeake

<table>
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<tr>
<th>Who is Chesapeake IRB?</th>
<th>Chesapeake IRB (Chesapeake) is an independent (commercial) IRB located in Columbia Maryland.</th>
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| How do I contact Chesapeake? | Web: http://chesapeakeirb.com/  
Telephone: (410) 884-2900  
Fax: (410) 884-9190  
Email: info@chesapeakeirb.com |
| What is Chesapeake’s application system called? | Chesapeake’s online submission system is called the Center for IRB Intelligence or CIRBI. |
| How do I begin working with Chesapeake? | Each applicable study team member will need to register a unique user name and email address in CIRBI. This secure web portal allows investigators online access to electronic submissions, status reporting, Board correspondence, and approval documents. |
| How do I register? | Go to CIRBI Registration. |
| How do I get started in CIRBI? | Chesapeake offers training webinars and one-on-one telephone support services to its investigative teams. Obtain more information by contacting Chesapeake Client Services at info@chesapeakeirb.com. |
| 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/Package inserts (if applicable)  
Chesapeake will provide  
- Documentation of Chesapeake approval for the study which includes the current approval period (upload in section 44 of the eResearch application). Contact Chesapeake Client Services via email at info@chesapeakeirb.com if assistance is needed. |

| After IRBMED Agrees to Cede IRB Oversight to Chesapeake | Send a copy of 1) the IRBMED Acknowledgement Letter, 2) a copy of section 25-1only from the eResearch application, and 3) a copy of the revised consent template (in the event any changes to the sponsor consent were made) You must then complete any remaining Chesapeake requirements to receive approval as a performance site. After obtaining Chesapeake approval for U-M as a performance site, post correspondence in eResearch and attach:  
- Chesapeake approval notice for U-M as a site  
- All Chesapeake-approved consent documents for U-M  
These documents provide notification to the IRBMED and Ancillary Committees that the study team is approved by Chesapeake 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.,  
  o Research Pharmacy (aka IDS): changes in dosing, addition of medication prescribers;  
  o RDRC/SHUR: changes in radiation dosing;  
  o CRAO: billing calendar updates;  
  o 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 Chesapeake or Sponsor  
- Study Terminations from Chesapeake  
Once all activity is completed and the team receives permission from Chesapeake to terminate the study, the team must terminate the eResearch application via a CR submission. |