### Getting Started With Chesapeake

**Who is Chesapeake IRB (Chesapeake)?**
Chesapeake IRB (Chesapeake) is an independent (commercial) IRB located in Columbia Maryland.

**How do I contact Chesapeake?**
- Web: [http://chesapeakeirb.com/](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](http://chesapeakeirb.com/).

**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. 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
- Chesapeake approved Consent / Assent template(s).
- 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

**U-M IRBMED has issued an Acknowledgement Letter agreeing to cede IRB oversight to Chesapeake. Now what?**
Send a copy of 1) the IRBMED Acknowledgement Letter, 2) a copy of section 25-1 only 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.,**
  - 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 Chesapeake or Sponsor (eg: interim analysis or enrollment complete need not be reported)
- 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 continuing review/Termination submission.