**UNIVERSITY OF MICHIGAN PROCEDURES FOR CEDING TO ADVARRA**

## Getting Started With Advarra

### Who Is Advarra?
Advarra is a commercial IRB created by the merger of Schulman IRB and Chesapeake IRB in 2017. Advarra’s headquarters are in Columbia, MD with additional locations in Cincinnati, OH, Malvern, PA, Research Park, NC, Toronto, ON and Montreal, QC.

### How do I contact Advarra?
- **U-M Account Manager:** Kathleen Rankin  
  Office Telephone: (513)878-2409  
  Mobile Telephone: (513)375-8399  
  Email: kathleen.rankin@advarra.com
- **U-M Client Services Coordinator:** Sarah Weir  
  Office Telephone: (513)283-1534  
  Email: sarah.weir@advarra.com

### What is Advarra’s application system called?
Advarra’s online submission system is called CIRBI. This secure web portal allows investigators online access to electronic submissions, status reporting, Board correspondence, and approval documents.

### How do I begin working with Advarra?
Study team members will need to register a unique name and email address in CIRBI. This allows access to secure CIRBI areas for uploading and downloading documents, approval letters, etc.

### How do I get started in CIRBI?
CIRBI Reference Materials can be accessed for guidance documents, IRB rosters, and QuickSteps about the submission process. Contact the Client Services Coordinator for additional information.

### 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 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:

- Advarra Approved Protocol
- Advarra Approved Consent / Assent template(s)
- Investigator brochures (if applicable)
- Documentation of Advarra approval for the overall study which includes the current approval period (upload in section 44 of the eResearch application)

## After IRBMED Agrees to Cede IRB Oversight to Advarra

### U-M IRBMED has issued an Acknowledgement Letter agreeing to cede IRB oversight to Advarra. 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:

- A copy of section 25-1 of eResearch application
- Copy of IRBMED Acknowledgement letter allowing the study to proceed under Advarra oversight

After obtaining Advarra approval for U-M as a performance site, attach the following in the eResearch activity called Upload Non-UM IRB Approval Documents:

- Advarra approval notice for U-M as a site
- All finalized Advarra-approved consent documents for U-M

These documents provide notification to the IRBMED and Ancillary Committees that the study team has been approved by Advarra.

### 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 Advarra or Sponsor (eg: interim analysis or enrollment complete need not be reported)
- Study Terminations from Advarra

Once all activity is completed and the team receives permission from Advarra to terminate the study, the team must terminate the eResearch application via a continuing review/Termination submission.