# INSTITUTIONAL REVIEW BOARDS — Companion Piece

**Document Title: University of Michigan Procedures For Ceding to Advarra**

| **Getting Started With Advarra** | | |
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| 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**: Betsy Casillo<br>Office Telephone: (513)619-1679<br>Email: Betsy.Casillo@advarra.com | **U-M Client Services Coordinator:** Annie Hoang<br>Office Telephone: (443)283-1524<br>Email: ann.hoang@advarra.com |
| What is Advarra's application system? | 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 U-M IRB? | 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. For additional directions, see the Ceding guidance. For IRBMED study teams - locally required boilerplate language is available on the IRBMED sIRB website. | |

| **Working With U-M IRB** | |
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| 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:<br>• Advarra Approved Protocol<br>• Advarra Approved Consent / Assent template(s)<br>● **IRBMED Only -** Applicable locally required boilerplate language must be inserted as TRACKED changes. ➢ The boilerplate does not apply to assent forms, but for other consents (e.g., sub-study consents, pregnant partner consents, etc.), it will be assessed on a case-by-case basis but generally, if the topic is touched on in that consent form, the applicable boilerplate applies.<br>• Investigator brochures (if applicable)<br>• Documentation of Advarra approval for the overall study which includes the current approval period (upload in section 44 of the eResearch application) |

| **After U-M IRB Agrees to Cede IRB Oversight to Advarra** | |
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| U-M IRB has issued an Acknowledgement Letter agreeing to cede IRB oversight to Advarra. Now what? | Send the following to Advarra as a part of the application packet:<br>• The tracked copy of the Informed Consent<br>• Copy of IRB Acknowledgement letter allowing the study to proceed under Advarra oversight<br>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:<br>• Advarra approval notice for U-M as a site<br>• All finalized Advarra-approved consent documents for U-M<br>These documents provide notification to the IRB and Ancillary Committees that the study team has been approved by Advarra. |
| What are my continuing obligations to U-M? | Study teams have other types of continued reporting that must be submitted in eResearch after initial review. The continued reporting is outlined on page 3 of the ceded guidance. |


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