

Document Title: University of Michigan Procedures for Ceding to an External Institutional IRB

<p>Do I still need to work with U-M IRB?</p>	<p>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.</p> <p>For IRBMED study teams - locally required boilerplate language is available on the IRBMED sIRB website.</p>
<p>Working With U-M IRB</p>	
<p>What documents do I need for the U-M Ceding application?</p>	<p>Study teams must obtain the approved versions of project documents from study Sponsor. Team members should obtain copies of the following and upload in the Ceding Application:</p> <ul style="list-style-type: none"> • Non UM- IRB Approved protocol • Investigator brochures (if applicable) • Non UM IRB Approved template consent <ul style="list-style-type: none"> • IRBMED only: Applicable locally required boilerplate language must be inserted <ul style="list-style-type: none"> ○ 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. • Approval notice for the overall study which includes the current approval period. The type of letter may vary depending on when UM joins as a site, but it MUST contain the most recent approval interval for the proposed non-UM Institutional IRB. (upload in section 44 of the eResearch application) • Local context forms or reliance documentation from the Non-UM IRB
<p>After U-M IRB Agrees to Cede IRB Oversight to Non-UM Institutional IRB</p>	
<p>U-M IRB has issued an Acknowledgement Letter agreeing to cede IRB oversight to a Non-UM IRB. Now what?</p>	<p>Study Team will send the following to the Non-UM Institutional IRB:</p> <ul style="list-style-type: none"> • Copy of IRB Acknowledgement letter agreeing to cede IRB oversight • The U-M Specific informed consent documents • Filled out local context forms and reliance documentation <p>After obtaining approval from the non-UM Institutional IRB for U-M as a performance site, attach the following in the eResearch activity called Upload Non-UM IRB Approval Documents:</p> <ul style="list-style-type: none"> · Approval notice from non-UM Institutional IRB for U-M as a site · All approved consent and/or assent document(s) for U-M <p>These documents provide notification to the IRB and Ancillary Committees that the study team is approved by non-UM IRB to begin research activities.</p> <p>NOTE: UM Study Team cannot begin study activities until they have received notification from the U-M IRB that they have ceded oversight AND Notification from single IRB that they have assumed responsibility as IRB of record for a particular study.</p>
<p>What are my continuing obligations to local IRB and U-M?</p>	<p>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.</p>

<p>File Name: CSP_CP.201E.working WITH external IRB_2023_June</p>	<p>Target Audience: Research Community</p>
<p>Author/Responsible Unit: Coordinated Services and Practices (CSP) unit</p>	<p>Date Released: 1.17.2024</p>
<p>Date Modified: N/A</p>	