



This guidance is intended to help study teams recognize when they have engaged external collaborators, how they should be managed in their IRB application, and making a formal request for U-M to be the IRB of Record for their external collaborator(s).

<p>External collaborators who are engaged in U-M's research must have IRB oversight, either via an agreement or via IRB approval from their own institution</p> <p>A researcher is engaged when performing any of the following:</p> <ul style="list-style-type: none"> • Obtaining informed consent, • Interacting with subjects, or • Access, use, obtain identifiable data (including coded data with access to link) 	<p>Single IRB review is now required for federally-funded research</p> <ul style="list-style-type: none"> • If U-M receives a sub-contract, discuss who should be the IRB-of-Record with the other institution • External Collaborators on non-fed funded research may be covered by their own IRB or via an agreement. You can discuss this with the IRB staff contact.
<p>External collaborators should only be listed on our IRB application if they are engaged in the research and relying on our IRB</p>	
<p>External engaged collaborators must always be listed as “other” on the study team</p>	
<p><i>If research is exempt:</i></p> <ul style="list-style-type: none"> • Collaborators must obtain an exemption from their own institution (if they have an IRB) and should <u>not</u> be listed on U-M study team • <i>Collaborators without an IRB (e.g., community partners) – discuss with the IRB staff contact</i> 	<ul style="list-style-type: none"> • AVP for Research will determine whether U-M will be the IRB of Record for a collaborator, after the necessary relationship information is provided (see MiCores Information below).

Application Requirements:

The following about the external collaborator should be clearly described in the application:

1. Listed on the study team as **“other”**
2. Their institution (if applicable) listed in 3-1 (Performance Sites)
3. **Role described in 5.1.3/5-1.4 (Study Team Expertise)** (how are they engaged - see definition above)
4. Current CV must be provided
5. Documented human subjects training – if not using PEERRS, documentation of their equivalent training must be sent to peerrs@umich.edu.
6. External collaborator or institution's role in the research and/or access to data should be described in the consent form, including their retention and future use of data, if any
7. If the external collaborator will access or obtain identifiable information as part of this research, the procedures for this must be included in Section 11 or in the Data Management Plan and they should be advised that an UFA/DUA is required for this data access or sharing unless it is covered a subcontract with the external institution. If data will be accessed or shared, the process for this should be described in 11-4 (Future Research)
8. If the external collaborator will **recruit and/or consent subjects at their own site**, and they will use **site-specific materials, these must be uploaded** in the appropriate sections of the application. The IRB may request that you use the Multi-site application type.
9. **Engaged collaborators may not begin research activities until the agreement is complete**

Submit Request in MiCores:

1. When instructed to by the IRB, submit a request in [MiCores](#)
 - a. You will be given additional information on this process
2. If the PI is a student, the request should be made in the FA's name
3. These requests will run parallel to your IRB application review
4. Please see our [Collaborative Research](#) page for more information