



Research Collaboration with U-M Health Statewide Network of Care Site

A. Introduction

This Practice Guide provides information for U-M study teams wishing to conduct research at one of the [U-M Health Statewide network of care locations](#) (“research collaboration site”). Procedural requirements for working with U-M and external IRBs are outlined below.

B. Adding a Research Collaboration Site

U-M IRB has oversight						
	Intake Form	MSR/SITE Application model	Add site in eR sec 3	Add site lead as “other”	Add recruitment details in eR sec 8	Add non-engaged determination in eR sec 44
SITE IS ENGAGED IN RESEARCH:						
As a Performance site to a clinical trial	✓	✓				
As a performance site to a secondary use project	✓		✓	✓		
As a referral/recruitment site	✓		✓	✓	✓	
SITE IS NOT ENGAGED IN RESEARCH:						
As a site to recruit from	✓		✓		✓	✓
As a site to collect data only or research space only	✓		✓			✓

External IRB has oversight					
Site is:	Intake Form	Add site details in eR sec 1.8 (or sec 3 for HSBS)	Add recruitment details in eR sec 8	Email the external IRB and copy the Clinical Affiliate Research Group	Site must submit to external IRB
Engaged in research	✓	✓		✓	✓
Not engaged in research	✓		✓	✓	

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U-M IRB has oversight

The research collaboration site is engaged:

1) as a performance site to a Human Subjects Research project:

- i) New Study (not yet IRB-approved):
 - (1) Fill out the [intake form](#)
 - (2) Application type: Multi-site Research application – Fill this out as outlined in the [eResearch instructions](#).
 - (3) After the application is approved, add a [Participating Site application](#) for the research site and open a U-M Performance site application using the Ceded application type.

- ii) Amendment (study already IRB-approved):

- (1) Fill out the [intake form](#)

- If the study is already on a multi-site application type:

- (2) Open an amendment to add details about the research site.
 - (3) After the amendment is approved, add a [Participating Site application](#) for the research site.

- If the study is not already on a multi-site application type:

- (2) Open a new study and select the multi-site application type. This application will serve as the coordinating center application, while the existing application will serve as the U-M performance site application.
 - (a) Fill this new application out as outlined in the [eResearch instructions](#).
 - (3) Once this multi-site application is approved, add a [Participating Site application](#) for the research site.

NOTE: Collaborators will need a [friend account](#) to be on the participating site applications.

2) as a performance site to a secondary use project:

- i) New Study (not yet approved) and/or Amendment (study already in progress):
 - (1) Fill out the [intake form](#)

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- (2) Add the lead collaborator and primary contact from the site as “other” on the study team. To complete this step the collaborator will need a [friend account](#).
- (3) Add the site to section 3 of the application as a performance site.
 - (a) Ensure that the answer is “yes” for the site being engaged in research.
- (4) Provide the site IRB with U-M IRB’s exempt determination.

3) as a referral/recruitment site:

- i) Fill out the [intake form](#)
- ii) If the site is performing any of the research activities that make them ‘engaged’ in human subjects research, then add them as a performance site in section 3. When adding the site to section 3 – answer the engaged in research as “yes”. For additional information, refer to the [OHRP guidance](#), a few examples of engaged activities are listed below.
 - Interacting with potential subjects to screen
 - Accessing, using, and obtaining identifiable data for the purposes of research.
 - (1) Add the lead collaborator and primary contact from the site as “other” on the study team. To complete this step the collaborator will need a [friend account](#).
- iii) Add recruitment activity details to eResearch section 8-1.3

The Research Collaboration site is not engaged:

4) Only used as a site to recruit from, a site to collect data from, or a research space site:

- i) Fill out the [intake form](#)
- ii) Add the site as a performance site in section 3.
 - (1) Answer “no” to the engagement question
- iii) If recruitment takes place at the site, add recruitment activity details to eResearch section 8-1.3
- iv) Provide the “not engaged” letter from the performance site in section 44.1.

External IRB has oversight

The research collaboration site is engaged:

- (1) Fill out the [intake form](#)

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- (2) If the site's activities do engage the site in human subjects research, as described in the [OHRP guidance](#), add the details associated with the site's participation in research to section 1.8 of the ceded application (section 3-1 for HSBS ceded application).
- (3) Email the external IRB and copy Clinical-Affiliate-Research@umich.edu to indicate that a collaboration site is being added as a performance site.
 - (a) The site will also have to fill out an application/local context form, depending on the external IRB, and sign a reliance agreement with that external IRB to become a performance site on the study.

The research collaboration site is not engaged:

- (1) Fill out the [intake form](#)
- (2) If the site's recruitment activities do not engage the site in human subjects research, as described in the [OHRP guidance](#), add the site to the details of the recruitment section in eResearch, section 8-2-2 of the ceded application.
- (3) Email the external IRB and copy Clinical-Affiliate-Research@umich.edu to indicate that a collaboration site is being added as a recruitment site. This will allow the IRB of record to guide the study team on the proper way to document this research partnership in their system.

C. Resources:

- [U-M Health Statewide Network of Care](#)
- [Research Collaboration Intake Form](#)
- [MSR – Single IRB application eResearch instructions](#)
- [Participating Site application instructions](#)
- [OHRP – Engagement of Institutions in Human Subjects Research](#)

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