

Document Title: Participating Site Application Type - What, When, and How

A. INTRODUCTION

This document provides an overview of the Participating Site Application, for the research community, as well as when it should be used on studies where an University of Michigan IRB is acting as the single IRB. This guidance document has been prepared jointly by the IRB-HSBS and IRBMED to summarize harmonized procedures established between the two departments.

B. WHAT

The participating site application is a sub-application type that is housed within the Multisite research application. A participating site application cannot be initiated without having already initiated a Multisite research application. This application type will allow participating sites to report local context information, local personnel, site specific amendments, site specific reportable events and provide site specific continuing review data.

C. WHEN

This application type is used to register participating sites within the eResearch system on projects where U-M is the single IRB. These application types should not be initiated without having already gotten approval from the U-M IRB to be the single IRB for the project. If approval for single IRB support is still needed, reference the [sIRB request website](#) for directions on how to request single IRB support.

A participating site application type can be initiated before or after full IRB approval on the multi-site research application has been received. If it is unclear whether or not the specific multi-site project should be using this feature, contact the IRB.

See below in how to initiate the participating site application.

Note: Any and all study numbers seen in screenshots below are made up applications for the purpose of this document.

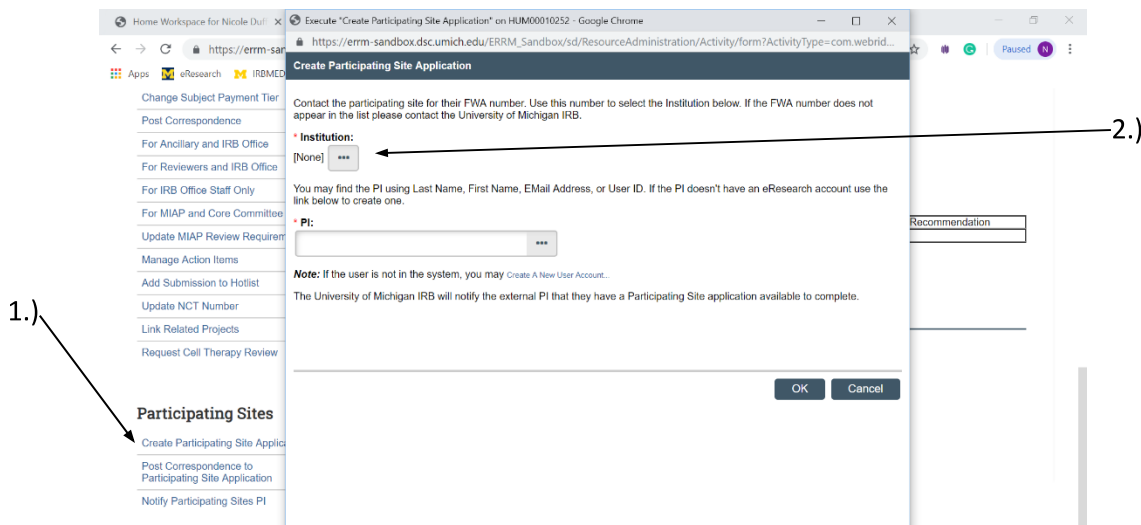
I. HOW TO INITIATE/USE

To initiate the Participating Site Application activity, please follow these steps.

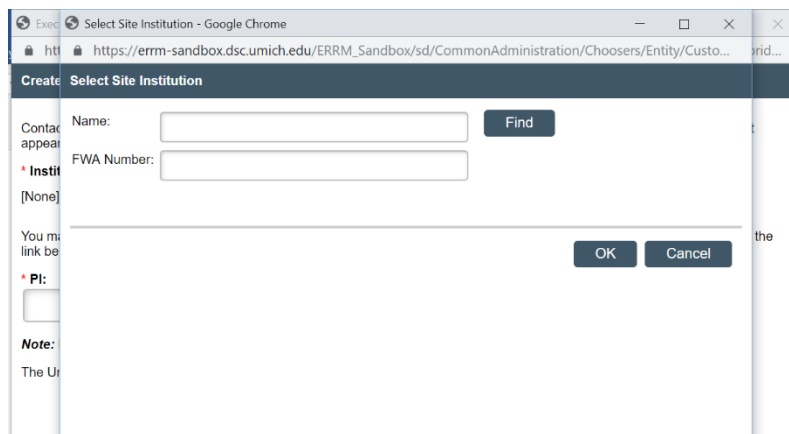
- 1.) Scroll down and click “Create Participating Site Application” on the left hand side of the screen.

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2.) After clicking on “Create Participating Site Application”, a popup screen open that asks for the External Institution and Principle Investigator(PI). Start by clicking on the “...” under Institution.



3.) After clicking on that another popup window will open that allows for the search for the Institution. This search can be done by name or FWA number, to get the best result it is recommended to search by FWA number. If the FWA number is unknown, try to search by Institution name. Once the participating site has been selected, click OK.



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- 4.) Now it's time to add a PI. To add the PI, the external collaborator will need to have a [friend account](#) and have already logged into [eResearch](#), with that friend account, at least once initiate their user profile.
- Try to search for them by their name to see if they already have a friends account. If they come up in the list, select the individual. If they do not, please move to the next step.
 - If the individual doesn't come up in the search that means they don't already have a friend account yet. To create one use this [link](#). Make sure the friend account is created using the email address associated with their Institution. It is also important to make sure the spelling is correct since as all participating site application information will be communicated through this friend account.

Create Participating Site Application

Contact the participating site for their FWA number. Use this number to select the Institution below. If the FWA number does not appear in the list please contact the University of Michigan IRB.

* **Institution:**
[None]

You may find the PI using Last Name, First Name, EMail Address, or User ID. If the PI doesn't have an eResearch account use the link below to create one.

* **PI:**

Note: If the user is not in the system, you may [Create A New User Account...](#)

The University of Michigan IRB will notify the external PI that they have a Participating Site application available to complete.

- 5.) After the external PI has been added, click OK. The participating site now has their own application number. If the Multi-site project is still in review, the participating site PI will not be notified until after IRB approval has taken place. If the Multi-site project has already been approved, contact the IRB representative to send out the notification to the external site. The notification activity seen below is an IRB only function and study teams will rely on the IRB to send this notification out.

Participating Sites

[Create Participating Site Application](#)

[Post Correspondence to Participating Site Application](#)

[Notify Participating Sites PI](#)

5.)

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- 6.) After this activity is selected a popup screen will open. At that time, the IRB will be able to select any participating sites that the study team wants to be notified with the checkboxes. Once the IRB has selected all the sites to notify, they would click OK.

- 7.) The external PIs will then be notified that they have been added to a participating site application via an email notification, which includes a link to get into the system. They will have to log into the system with their Friend account information.
- 8.) After logging in the external PI will land on a page that looks like below. They will see any participating site applications they have been added to. So if they are collaborating on more than one project, it is possible they will have more than one listing.

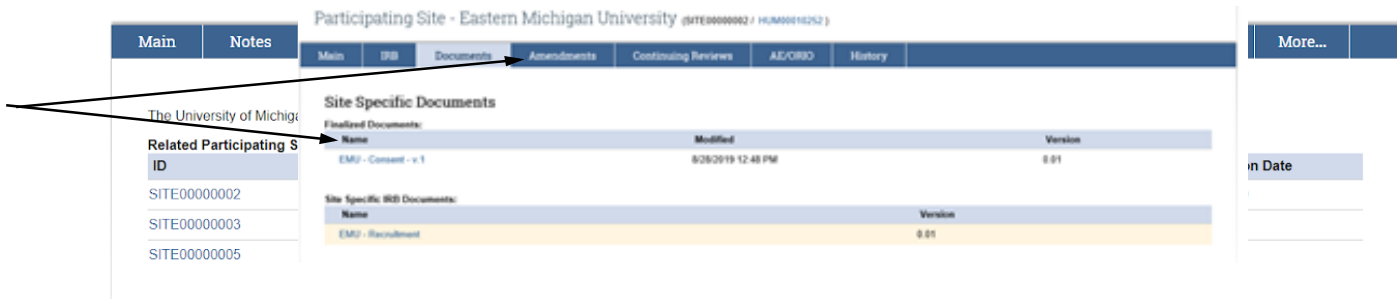
Participating Sites	My Inbox	In Progress	Approved	Exempt and Not Regulated	Approaching Expiration	Archived				
<p>Participating Sites</p> <table border="1"> <thead> <tr> <th>ID</th> <th>Name</th> </tr> </thead> <tbody> <tr> <td>SITE00000002</td> <td>Participating Site - Eastern Michigan University</td> </tr> </tbody> </table> <p>1 items < page 1 of 1 > 10 / page</p>							ID	Name	SITE00000002	Participating Site - Eastern Michigan University
ID	Name									
SITE00000002	Participating Site - Eastern Michigan University									

- 9.) See and refer external study teams to the document titled *“Relying Site Directions for PSite Application”* for further help filling out the participating site application.

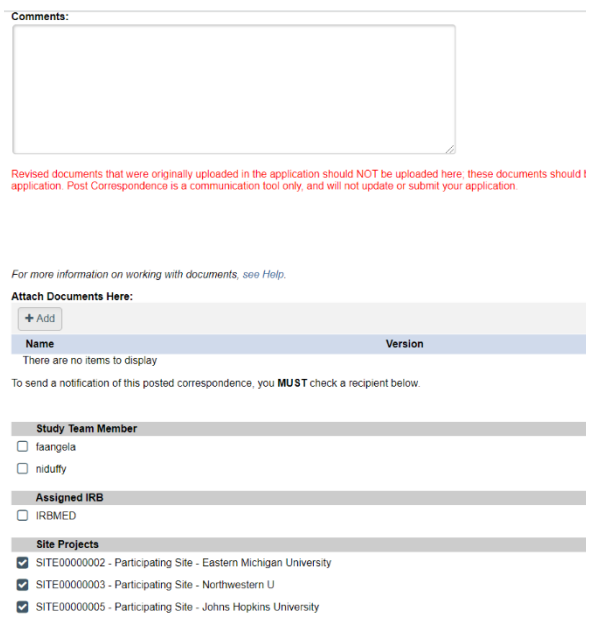
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II. HELPFUL TOOLS AND TIPS

- 1.) The related projects tab on the Multi-Site Research application will show any and all Participating Site applications that have been initiated under the MSR application. It also shows the current status of all the sites.



- 2.) The activity “Post Correspondence to Participating Site Application” will allow the U-M study team to correspond with any or all of the Participating Site Application(s). This activity will automatically select all when opened up, however if the correspondence only applies to select sites, the applicable sites can be the only ones selected by removing those who don’t apply.



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- 3.) External study teams will now have the ability to submit their own site-specific information in the form of an amendment, incident report or continuing review data. This information should be information that only applies to the individual site and not information that applies the entire study as a whole.



QUESTIONS

- Email questions to
 - IRB-HSBS: mardonne@umich.edu
 - IRBMED: niduffy@med.umich.edu

ADDITIONAL RESOURCES:

- For more eResearch information and how-to help, including how-to initiate amendments, reportable events and continuing reviews, reference: <https://its.umich.edu/academics-research/research/eresearch/regulatory-management/reference-materials/participating-site-application>
- For more information on multi-site research and supporting documents, reference: <https://umich.box.com/v/MultisiteResearchDocuments>

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