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 <u>sIRB request website</u> 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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Author/Responsible Unit: Coordinated Services and Practices (CSP) unit	Date Released: 1.17.2024
Date Modified: N/A	·

Practice Guide

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.

🚱 Exec	Select Site Institution - Google Chrome $ \Box$ $ imes$	×
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Create	Select Site Institution	
Contac appear * Instit	Name: Find FWA Number:	t
[None] You ma link be * PI: Note: The Ur	OK Cancel	the

File Name: CSP_PG207.Participating Site Application Overview - UM Staff_2023_June	Target Audience: Research Community
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Practice Guide

- 4.) Now it's time to add a PI. To add the PI, the external collaborator will need to have a <u>friend account</u> and have already logged into <u>eResearch</u>, with that friend account, at least once initiate their user profile.
 - a. 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.
 - b. 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 <u>link</u>. 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.	
OK Cancel	

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.)

Derticipating Cites

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Practice Guide

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.

2 m 1				
6	Execute "Notify Participating	Sites PI" on HUM00010252 - Google Chro	me	- 0
	https://errm-sandbox.d	lsc.umich.edu/ERRM_Sandbox/sd/Re	sourceAdministration/Activity	/form?ActivityType=com.web
No	tify Participating Sites i	PI		
Se	lect which Participating S	ites PI's to notify that they may comm	ence work on their University of	Michigan Site Application
	ane Projects	Site Application Name		Site Application Pr
- 2	SITE00000002	Participating Site - Eastern Michig	an University	Nicole Duffy
Pa	rticipating Sites that have	already been notified		
ID	Site Name	Site PI	PI Notification Date	
ID Th	Site Name ere are no items to displa	Site PI	PI Notification Date	
ID Th	Site Name ere are no items to displa	Site Pl	PI Notification Date	
ID Th	Site Name ere are no items to displa	Site Pl	PI Notification Date	
ID Th	Site Name ere are no items to displa	Site Pl y	PI Notification Date	
10 Th	Site Name ere are no items to displa	Site Pl	PI Notification Date	
ID Th	Site Name ere are no items to displa	Site Pl	PI Notification Date	

- 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.

articipating Sites	My Inbox	In Progress	Approved	Exempt and Not Regulated	Approaching Expiration	Archived	
Participating Si	tes						
ID		▲ Name					
SITE00000002		Participating Si	ite - Eastern Michiga	in University			
1 items				∉ page 1 of1 ▶			10 / page

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.

File Name: CSP_PG207.Participating Site Application Overview - UM Staff_2023_June	Target Audience: Research Community
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Π. **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.

Main Mataa	Main Notes						
Main Notes	Main IPB Documents	Amendments	Continuing Reviews	AE/080	History		More
The University of Michiga	Site Specific Documents						
Related Participating S	Kame		Modified			Version	
ID	EMU - Consent - v.1		828291912	48 PM		8.01	n Date
SITE00000002	Site Specific IRB Documents:						
SITE00000003	Name					Version	
SITE00000005	EM7 - Recyalment					0.01	

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.

	Comments:		
	Revised documents that were originally uploaded in the application should NOT be uploaded here, the application. Post Correspondence is a communication tool only, and will not update or submit your app	se documents should t lication.	
	For more information on working with documents, see Help.		
	Attach Documents Here:		
	+ Add		
	Name Version		
	There are no items to display		
	To send a notification of this posted correspondence, you MUST check a recipient below.		
```	Study Team Member		
$\backslash$			
$\backslash$			
$\backslash$	Assigned IKB		
\ r	Site Projects		
	SITE00000002 - Participating Site - Eastern Michigan University		
· •	SITE00000003 - Participating Site - Northwestern U		
	SITE00000005 - Participating Site - Johns Hopkins University		
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File Name: CSP_PG207.Participa	ating Site Application Overview - UM Staff_2023_June	Target	Audience: Research Community
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Date Modified: N/A			

## **Practice Guide**

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.

Main       IRB       Documents       Amendments       Continuing Reviews       Incident Reports       History         View Project       Pristee Friendy Version       Incident Report       Incident Report       Incident Report         Amendment       Continuing Report       Fre- Submission       ISB Review       Approved         Incident Report       Ste Pt: Nicole Duffy       Ets Study Team Members:       Incident Report		Approved									
Edit / View Verv Poljed Pristes Transfy Version Verv Differences Create New Amendment Continuing Report Incident Report Termination Report Ste Pt: Nicole Duffy Site Study Team Members:			Main	IRB	Documents	Amendments	Continuing Reviews	Incident Reports	History		
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View Differences Create New Anondraset Continuing Report Incident Report Termination Report Site Pit: Noole Duffy Site Study Team Members:		Printer-Friendly Version									
Create New Annotance Annotance Continuing Report Incident Report Termination Report Site Pit: Nicole Duffy Site Study Team Members:	<hr/>	View Differences									
Armondmeet         Pre- Submission         IRB Review         Approved           Continuing Report         Incident Report         Incident Report         Incident Report           Termination Report         Site Pt: Nicole Duffy         Incident Report           Site Study Team Membern:         Description         Description	$\backslash$	Create New						$\bigcirc$ $-$		— 🛑	
Continuing Report Incident Report Termination Report Site PI: Nicole Duffy Site Study Team Members:	X	Amendment						Pre- Submission	IRB Review	Approved	
Incident Report Termination Report Site Pt: Nicole Duffy Site Study Team Members:		Continuing Report									
Termination Report Site Pit: Nicole Duffy Site Study Team Members:		Incident Report									
Site Study Team Members:		Termination Report	Site Pt 1	Nicole Duffy							
A situation from the second			Site Stu	dy Team Mem	bers:						
Activities Name Role Email		Activities	Name				Role		Email		

#### QUESTIONS

- Email questions to
  - o IRB-HSBS: mardonne@umich.edu
  - o 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: <a href="https://its.umich.edu/academics-research/research/research/regulatory-management/reference-materials/participating-site-application">https://its.umich.edu/academics-research/research/research/regulatory-management/reference-materials/participating-site-application</a>
- For more information on multi-site research and supporting documents, reference: <u>https://umich.box.com/v/MultisiteResearchDocuments</u>

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