### **Document Title: Relying Site Directions for PSite Application**

### A. Introduction

The purpose of this document is to help study teams that are relying upon an University of Michigan (U-M) IRB for the purpose of regulatory oversight on a multi-site research study. U-M IRBs use a PSite application to collect information from the external sites. This guidance document has been prepared jointly by the IRB-HSBS and IRBMED to summarize harmonized procedures established between the two departments.

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

### B. Process

1. After logging in the relying site PI will land on a page that looks like the picture below. On this screen the individual will see any participating site applications that they have been added to. So if they are collaborating on more than one project with the University of Michigan as the single IRB, there will have more than one listing.

articipating Sites	My Inbox	In Progress	Approved	Exempt and Not Regulated	Approaching Expiration	Archived	
Participating S	ites						
ID		▲ Name					
SITE00000002		Participating S	ite - Eastern Michiga	in University			
1 items				4 page 1 of 1 ⇒			10 / page

2. The relying site PI will then click on the participating site application that is to be revised. This will open up the participating site workspace where they will be able to select "Edit Project" on the left side of the screen or download the template documents from the "documents" tab.

	Current State Pre Submission	Participating Site - Eastern Michigan U	niversity (snteadooddoz/ Humadatazsz)
	Edit / View	Main Documents	
	Edit Project		
	Print Project		
	Activities		
	Error Check		Pre- IRB Review Approved Submission
-	Submit Post Correspondence		Study Team Action
	Withdraw		Required
		Local She PI: Nicole Duffy Institution: Eastern Michigan University Participating She Faam Members: Name Vers Nicole Duffy	Role F1
		Activities and Correspondence	
			No data to display.
ile Name: CSP_2023/.	June/28_PG209.Relying	Site Directions for PSite Application	Target Audience: Research Community
		s and Practices (CSP) unit	Date Released: 1.17.2024

	Site Specific IRB Documents:	
	Name	Version
	There are no items to display	
	Study Wide Documents	
Г	University of Michigan IRB Approved Consent Template Documents	
	Name	Version
	TEST decx	8.01
	University of Michigan IHB Approved Recruitment Templete Documents	
	Name	Version
Template		
	TEST.docx	0.01
Template documents	University of Michigan IRB Approved Protocol Documenta	
uocuments	Name	Version
	TEST.docx	8.01
	University of Michigan IRD Additional Documents	
	Name	Version
L	There are no items to deplay	

3. Once "edit project" is selected there will be two pages of questions to be filled out. On the top of the first page, they will have the opportunity to add more study team members. U-M asks that at least one Co-Investigator, one or two study coordinators and an IRB personnel member be added to the application. To do this, click "+Add"

	General Information		
	The following questions will collect information necessary for the University of Michigan IRB, as the	he Single IRB in a Multi-site study, to approv	re an individual performance site. For more information regarding this process, consult your start-up packet.
	Site Name: Eastern Michigan University		
	Your site Principal Investigator (PI) name: Nicole Duffy		
	* 2 Add site Co-Investigator(s), Lead Study Coordinator, and one additional Study Coordin * Add	ator, and one IRB Staff Member point of o	contact from your institution:
	Name	Role	Email
3.)	2 Update Nicele Duffy	PI	nidulfj@cmich edu

- a. Another popup will open where a search can be performed for each team member and the team member role can be assigned.
  - i. If the team member does not come up in the search have them create a "friend account".

The following questions will callect information necessary for the University	Add Site Team Member
Site Name: Eastern Michigan University	' Team Member
Your site Principal Investigator (PI) name: Nicole Duffy	
* 2 Add site Co-Investigator(s), Lead Study Coordinator, and one add	•
Name	Note: If the user is not in the system, you may close A New June Account .
Cif Update Nicole Duffy	Required     OK OK and Add Another Cancel
* 3 Select all vulnerable populations your site intends to enroll in this s Population Type	
Children	
Pregnant Women	
Human fetuses	
Neonates	-
Prisoners	
Lmancipated Minors, mature minors	
Wards of the State	
D. Analitati Incolati Atala	

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Date Modified: N/A	

## **Practice Guide**

4. Once study team members are added, click "save". At this time, all the study team members will be able to access the application and someone else could continue the application, if needed. Page 1 asks about local information specific to the study enrollment, this will need to be filled out before being able to click "continue".

	g questions will collect information necessary for the University of Michigan IF	RB, as the Single IRB in a Multi-site stud	to approve an individual performance site. For more information regarding this process, consult your start-up packet.	
Site Name: E	Eastern Michigan University			
	incipal Investigator (PI) name: Nicole Duffy			
	Co-Investigator(s), Lead Study Coordinator, and one additional Study C	Coordinator, and one IRB Staff Membe	point of contact from your institution:	
+ Add			· ·	
	Name	Role	Email	
C Updat	te Nicole Duffy	PI	niduffy@umich.edu	
	vulnerable populations your site intends to enroll in this study: ation Type			
Children				
Pregnar	int Women			
Human	fetuses			
Neonation	tes			
Prisone	ors			
Emanci	ipated Minors, mature minors			
U Wards o	of the State			
Cognitiv	ively Impaired Adults			
Other				
None     A Informed	I Consent: Unload any completed University of Michiaan IRB informed	consent template documents with your	site specific language (excluding site-specific informed consent short forms, to be uploaded in question 51:	
* 4 Informed Note: To retrie	l Consent: Upload any completed University of Michigan IRB informed e eve University of Michigan IRB informed consent templete documents go to	consent template documents with you the Documents tab on the Participating	site specific language (excluding site specific informed consent short forms, to be uploaded in question 5); ite workspace and look for Study Wide Documents	
* 4 Informed Note: To retriv	I Consent: Upload any completed University of Michigan IRB informed ( eve University of Michigan IRB informed consent template documents go to	the Documents lab on the Participating	ite workspace and look for Study Wide Documents	
4 Informed Note: To retriv + Add Name	I Consent: Upload any completed University of Michigan IRB informed eve University of Michigan IRB informed consent template documents go to no items to display	consent template documents with you the Documents tab on the Participating Ven	ite workspace and look for Study Wide Documents	
* 4 Informed Note: To refix	eve University of Michigan IRB informed consent template documents go to no items to display y that non-English speaking subjects will be enrolled? D No <u>Clear</u> e estimated number of subjects to be enrolled at your local alte:	the Documents lab on the Participating	ite workspace and look for Study Wide Documents	
* 4 Informed Note: To refin * Add Name There are r O Yes O 6 Enter the * Adult * Children	eve University of Michigan IRB informed consent template documents go to no items to display y that non-English speaking subjects will be enrolled? D No <u>Clear</u> e estimated number of subjects to be enrolled at your local alte:	the Documents lab on the Participating	ite workspace and look for Study Wide Documents	
* 4 Informed Note: To refin * Add Name There are r O Yes O 6 Enter the * Adult * Children	eve University of Michigan IRB informed consent template documents go to no items to display y that non-English speaking subjects will be enrolled? D No <u>Clear</u> e estimated number of subjects to be enrolled at your local alte:	the Documents lab on the Participating	ite workspace and look for Study Wide Documents	
* 4 Informed Note: To retri- ( + Add Name There are r 5 is it likely O Yes O 6 Enter the * Adult * Children * Individua	eve University of Michigan IRB informed consent template documents go to no items to display y that non-English speaking subjects will be enrolled? D No <u>Clear</u> e estimated number of subjects to be enrolled at your local alte:	the Documents tab on the Participating	ite workspace and look for Study Wide Documents	
* 4 Informed Note: To refor ★ Add Name There are r 5 Is it likely ○ Yes ○ 6 Enter the * Adult * Children * Individua * 7 Do arey ○ Yes ○	In terms to display of Michigan IRB informed consent template documents go to no items to display that non-English speaking subjects will be enrolled? No Clear evaluated number of subjects to be enrolled at your local site:	the Documents tab on the Participating Ver	ite workspace and look for Study Wide Documents	
* 4 Informed Note: To refor ★ Add Name There are r 5 Is it likely ○ Yes ○ 6 Enter the * Adult * Children * Individua * 7 Do arey ○ Yes ○	In terms to display of Michigan IRB informed consent template documents go to no items to display that non-English speaking subjects will be enrolled? No Clear evaluated number of subjects to be enrolled at your local site:	the Documents tab on the Participating Ver	ile workspace and took for Study Wide Documents	

5. After clicking "continue", the second page will open up. This page is specific to local IRB information. It is preferred that an IRB staff member fills this out or at least confirms the information. Once this section is filled out, click "Continue".

File Name: CSP 2023/June/28 PG209.Relving Site Directions for PSite Application	Target Audience: Research Community	
Auth IRB Section		
Date This section should be filled out or confirmed by your designated local IRB point of contact.		
* 1 Is your site's Human Research Protection Program (HRPP) AAHRPP accredited?		
* 2 Are the participant selection and recruitment procedures associated with this study protocol compliant with your local Ves O No Clear	ite's laws, policies, and are they acceptable within the context of your site's local area?	
*3 Are the Informed consent/assent procedures and documents associated with this study protocol compliant with your lo	cal laws and your site's policies?	

*7 Describe how your site gathers and evaluates financial conflicts of intere	art for the study team members (D) and other research team):	
8 Please upload any additional supporting documents related to your study	that have not already been uploaded.	
+ Add		
Name	Version	
There are no items to display		
The information provided in this application represents an accurate deeperature	scription of local context for the intended performance site.	
	🖺 Save 🗇 Exit 🛕 Hide/Show Errors 🔒 Print 🎢 Jump To 🗸	Contin

6. After the application is filled out:

5.)

- a. Perform an error check
- b. If there are no errors, then click "Save & Exit"

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	← → C ▲ https://erm-sandbox.documich.edu/ER8M_Sandbox/sd, ResourceAdministration/Project/Project/Enter/Project-com.webridge.entity.Entry/ODD/SE11F25CEA8983460A1270EA76C23266[3d] Ⅲ Ages @ elseum M RMAD B are Q Outhors 2 Wile D Single 18 Poly ID SAME NB @ REA ID Notwine Access MICENTATION AND C RESEARCH   REGULATORY MANAGEMENT :: **********************************	
	🖹 Save 🕐 Ext 🛕 Hide/Show Errors 🔒 Print 🏞 Jump To -	Edit: Site Application - SITE0000003 Save & Exit
a	Available Activities The Suburk Activities Crime Check Submit	
	🖺 Save 🔅 Exit 🛕 Hide/Show Errors 🔒 Print 🏞 Jump To -	Save & Exit

7. At this time, the relying site PI can "submit" the application.

Pre Submission Main Documents History Edit / View Edit Project	
Edit Project	
Print Project	
Activities	
Error Check Pre- IRB Review App	roved
Submit Staff Review Study Team	
Submit Action	
7.) Post Correspondence Required	
Withdraw	
Manage Documents Local Site PI: Nicole Duffy	
For IRB Office Staff Only Institution: Northwestern U	

8. After clicking "submit" a new window will open. This window is the Investigator Assurances; the investigator is expected to read and agree with these assurances.

- a. Once they have read the assurances they can agree via checking the box to indicate they agree.
- b. Once the box is checked, they click "OK" to submit the application.

🕑 Execute "Submit" on SITE00000003 - Google Chrome - 🗆 🗙
https://errm-sandbox.dsc.umich.edu/ERRM_Sandbox/sd/ResourceAdministration/Activity/form?ActivityType=com.webri
Submit
Participating Site - Northwestern U ( SITE00000003)
Investigator Assurances: Learning between the information provided in this application represents an accurate description of the interneted study activities of the participating site. Lagree to comply with University of Michigan Mulfi-site Research policies and procedures, sponser and grant contracts, agreements between participating insultations, as well as federal. State, and local lears and requisitions concerning the protection of human subjects in research, the use and management of funds and, where applicable, the appropriate billing of healthcare environments. The requirements include, but are not limited to:
 <ul> <li>Conducting the measurch as described in the University of Minisjan IRG-approved application.</li> <li>Implementing no charappe in the approved study, including the informed consent document, without prior approval of the University of Michigan IRB.</li> <li>Submitting Scheduled Continuing Review Data, including participating site termination, in a timely manner.</li> <li>Notifying the University of Michigan IRB of any unanticipated problems, adverse events, or other reportable events in a finely manner in accordance with the terms of the IRB's approval and published IRB guidelines.</li> <li>Your certification in eResearch Indicates that you have personally reviewed the most current steals of the tody porticed and final documents within eResearch Indicates that you have personally reviewed the most current steals of the your place of final documents within eResearch. The Consentation must be ready available in the event of an audit by the participating site, the University of Michigan IRB and compliance offices, health plans or government programs such as Medicate or Studied, and oversity entities including but not limited to OHRP and FDA.</li> </ul>
I understand that as Primary Investigator, I assume full responsibility for the conduct of the study, and for the protection of the rights and welfare of human subjects inversed in this research at this participating site.

9. This submission will then go to the IRB for review and approval. Once the submission is approved the workspace will indicate so and the relying site study team will also be able to access their IRB approved site specific documents on the documents tab.

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	Participating Ste - Eastern × 📑					× StConvert -
	Current State	Participating Site - Easte	m Michigan University (sm Amendments Continuing R		History	
	Edit / View					
File Name: CSP 2023/June/2	View Project					
	Printer-Friendly Version					
Author/Responsible Unit: Cc	Wew Differences		— —		— 📕	
	Create New		Pre- Submission	IRB Review	Approved	
Date Modified: N/A	Amendment					
	Continuing Report					
		Site PI: Nicole Duffy				
	Activities	Site Study Team Members:				

	Participating Site - Eastern Michigan University (stressource / HUMMONTERS2)								
	Site Specific Documents Finalized Documents		Modified				Version	_	
Y	EMU - Consent - v.1 Site Specific IRB Documents:		826291912				8.01		
	Name EMJ - Reculment					Version 0.01			

#### **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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