

MANAGING RELIANCE DOCUMENTATION FOR MULTIPLE FWAs AND/OR PIs

ABOUT THE MULTI-SITE LIAISON ROLE IN IREX

In IREx, the "Multi-site Liaison (MS Liaison)" is someone who (1) manages reliance for multiple FWAs (e.g., if your institution has multiple FWAs or oversees the HRPP functions for an affiliate institution) or (2) needs to manage reliance for multiple investigators independently conducting the same study at your institution. As a MS Liaison, *for each site/investigator engaged on a study*, you will document a cede/reliance decision and local considerations. To help ensure you complete each step for each site or investigator, IREx has created tailored dashboards for the MS Liaison.

HOW DO I KNOW I HAVE MULTIPLE SITES OR INVESTIGATORS PARTICIPATING ON THE SAME STUDY?

Your Study is in IREx Email: If you have multiple sites or investigators on a study, you will receive multiple emails.

Your Participating Site Dashboard: You can view studies at your site on the Participating Site Dashboard by selecting the participant box on the left-hand side of the IREx homepage.

		Participating Site's Studies						
2 reviewer	Your site is the reviewer for 2 studies	Q Search:						
5 participant	Your site is a participant in 5 studies	Study Title	Your Site ↓†	PI ↓†	Reviewing IRB ↓î	Expiration Date ↓↑	To Do	Ļ≞
10 USETS	There are 10 users at your sites	20200302B SM Upload	GUMC	Mana Shahgoli	Mellon Univ. Med Ctr		Register	
	😤 Home	20200316 User Feedback Group Test Study	Goodall		Jefferson		Register	

REGISTERING FOR A STUDY AS A MULTI-SITE LIAISON

Once you have what's needed from your study team to document reliance and local considerations, register for the study:

Registration 2020030	for 02B SM Upload	
Step 1: S	elect one PI or Site	Step 2: Verify Participation
	You have multiple Pla Please pick one to ge You can complete information for the others f	s or Sites / FWAs on this study. et started. rom your multi-site dashboard.
	Goodall University Jessica Moore	
	Goodall University Med Mana Shahgoli	lical Center

Next, confirm whether the site (FWA) and investigator are correctly listed for your site. These questions give you the control to ensure your site and investigator are correct.

□ First, select the site or PI you want to register. You can register additional FWAs or investigators once you access the study page dashboard. Registering gives you access to the study; it is not the cede decision.

Email address					
mshahgoli@gumc.cdu					
First Name	Last Name				
Mana	Shahgoli				
of your FWA components is part of this study but is not listed below: 1) Cancel this registration 2) G Homepage and use the "Components" button to add it 3) Return to register using the component y					
Homepage and use the Componen					
Goodall University Medical Ce	enter - FWA#78899657				
Goodall University Medical Ce GUMC component - Goodall U	enter - FWA#78899657 University Medical Center Psychiatry Hospital - FWA#78899657				

No

If the r	e investigator or site are <u>not</u> listed correctly, registration page allows you to MAKE EDITS:	Confirm	n Your Engag	ged FWAs / Components
C	 Clarify your FWA For example, perhaps it is your component that is engaged on this study. 	The SIR of your f Homepa	B or Study M FWA compon age and use t	Ianager identified your site/FWA as shown below. Edit the information if it is incorrect. If one ients is part of this study but is not listed below: 1) Cancel this registration 2) Go to the the "Components" button to add it 3) Return to register using the component you added sity Medical Center - FWA#78899657
		I GI	JMC compor	nent - Goodall University Medical Center Psychiatry Hospital - FWA#78899657
(Add other engaged FWAs If your PI and site are correct, but your PI engages an	8	Does Man study, to y	a Shahgoli engage OTHER SITES / FWAs for this ● Yes ● N our knowledge?
	auditional FWA, answer fes to the question "Does [PI NAME] engage OTHER		Other Sites	: / FWAs Engaged By This PI
	SITES/ FWAs for this study, to your knowledge?". Then, list the additional		List any oth Liaison(s) to	er sites / FWAs that may be engaged by this study team for this study. IREx will notify the HRPP o confirm engagement.
	FWA. If you do not oversee the FWA, the		Search by	v name or FWA number • Add Site
	appropriate liaison will be notified to confirm engagement. You will also identify the Primary HRPP for the group of FWAs		Hartford	College of Medicine - FWA#00003216
	engaged ("Combo Site").			
			Designate	Combo Site Primary
			Please id	entify the Primary HRPP for this Combo Site
			Goodall	Jniversity Medical Center
0	Does Mana Shahgoli engage Goodall University Medical Center FWA #78899657 or its components for this study?) Yes	; • No	o Change your PL If your EWA is engaged but the
8	Does Mana Shahgoli engage OTHER SITES / FWAs for this study, to your knowledge?	O Yes	i 🖲 No	Pl is wrong, you can indicate that in the question that asks, "Does ANOTHER Pl engage [YOUR
8	Does ANOTHER PI engage Goodall University Medical Center FWA #78899657 or its components for this study?	r _{@ Yes}	s 🔘 No	study?". Enter the correct PI information and make sure your FWA is listed correctly.
	Confirm PI Details			After registering your engaged FM/A your local DI will
	Email address			automatically be given access to the study
	yanis.mann@gumc.cdu			
	First Name Last Name			
	Yanis Mann		8	Ooes Mana Shahgoli engage Goodall University Medical ⊚ Yes ● Center FWA #78899657 or its components for this study?
0	Indicate your site is not engaged If applicab	ole, by	8	Does Mana Shahgoli engage OTHER SITES / FWAs for this • Yes •

answering No to each question and providing a reason why your FWA is not engaged in the box provided. You will no longer receive email notifications about the study.

8	Does Mana Shahgoli engage Goodall University Medical Orest Revealed In the study?
0	Does Mana Shahgoli engage OTHER SITES / FWAs for this study, to your knowledge?
8	Does ANOTHER PI engage Goodall University Medical Center FWA #78899657 or its components for this study?
	Goodall University Medical Center FWA#78899657 is not engaged in research for this study.
	Please briefly describe why your FWA is not engaged for this study. You will no longer receive study notifications.
	A Required
	For guidance determining whether your site is engaged in research, go here.

Reliance Resources

Status Summary

Local Considerations

HOW DO MULTI-SITE LIAISONS DOCUMENT RELIANCE AND LOCAL CONSIDERATIONS IN IREX?

After registering for the study, **Your Sites** Dashboard will be visible. All sites thought to be engaged will be listed.

- □ **Register other FWAs,** when ready.
- Document Local Considerations Complete the Three Parts Using the Dropdown:
 - Confirm the Institutional Profile (IP) -- The IP captures general information about your organization, over-arching state laws or institutional policies affecting research, and how your site operationalizes reliance. If you have already

Goodall University V

Your Sites

Institution

Manage Your Sites

Goodall University Medical Center 🗸

Study-wide IRB Approvals

Study Status

- completed the IP, you can edit or confirm the information provided.
- Complete the HRP Survey (if indicated) -- The HRP Survey asks about requirements of any applicable state or local laws, regulations, institutional policies, standards, or other local factors, including local site ancillary reviews, relevant to the specific study or trial that would affect the conduct or approval of the research at your institution.



Site-specific IRB Approvals

Review PI Survey (optional) -- Once your local PI has completed the PI survey, click the PI Survey in the dropdown to review and edit the survey, if needed. The PI will be notified of any changes and must re-attest. If the study has consent forms, the study team should submit them to the HRPP for local review before they upload the consents to the PI Survey.

Complete Agreements and Indicate Reliance:

 "Complete Agreements" will appear under the Reliance column if your site has not completed the required agreements to rely on the sIRB. You will not be able to indicate reliance until you complete the required agreements.

Manage Your Sites							
Institution	Study Status	Local Considerations	Reliance	Resources			
Goodall University 🗸	REGISTER	-	- 🧹				
Goodall University Medical Center 🗸		3 / 3 Surveys Complete -	Indicate Reliance	Site-Specific Info 🗸			

• Indicate Reliance -- To indicate that your institution will rely on the sIRB, your institution and the sIRB must agree on how to implement the flexible elements of the reliance agreement (e.g., handling HIPAA, auditing, and external reporting). Indicate reliance by accepting the sIRB's plan in the Study-specific Reliance Plan (SSRP).

USE THE SITE-SPECIFIC INFO MENU TO ACCESS INFORMATION

Access and edit your local study team contacts or download the Letter of Reliance and SSRP for the study from the **Site-specific Info** button.



HRP Survey Completed: 7/25/2022

PI Survey Completed: 7/12/2022

PI Attested: 7/12/2022