

Overview:

COUHES Connect supports electronic submission of single-IRB requests, replacing the PDF forms previously used. New and existing protocols are affected by this change in COUHES process. COUHES Connect single-IRB submissions do not replace SMARTIRB, reliance agreements or other required documentation to ensure proper oversite. For more information on the submission process and requirements, visit the COUHES website on Single-IRB Review.

For new single-IRB requests with MIT serving as the reviewing IRB, investigators will submit reliance requests through their existing protocol in COUHES Connect to be managed through that COUHES protocol. Relying sites related to this study must still complete Local Context form.

Procedure: MIT as Reviewing IRB

Creating a Reliance Request for New and Existing Protocols

- If you are starting a **new Initial protocol**, the following instructions address invoking the reliance request. Please refer to the online documentation for detailed instructions regarding the full submission instructions: <u>http://web.mit.edu/ist-train/COUHESConnect/Create/#/</u>
- 2. If you have an approved protocol, an Amendment is required to add or edit an Engaged External Institution as the Relying Site. It is recommended you restrict the amendment to *just* this item to support a timely approval of both the Amendment and the Reliance Request. If you include the relying site with a complex amendment, the reliance cannot be approved until the full amendment is reviewed and approved.

		—
mendment Summary		
n the amendment summary, provide a brief description questionnaire, located in the Additional Forms tab. Inve highlighted word document. All revisions to the protoco of COUHES policy.	n of the revisions. Do not provide a complete summary or list of the revision estigators must upload all revised documents under the Attachments tab. It of must be clearly stated in the Amendment questionnaire. Any revision not	is in the section below. Complete summary must be included within the Amendment you are revising any of the approved documents, you need to replace them with a stated on the Amendment questionnaire will be considered unapproved and in violat
Adding a reliance site		
Check the boxes below to unlock the corresponding se ocked until those changes have been approved or with	ection within the protocol. All unchecked sections will remain locked and un hdrawn. Please note once checked sections cannot be unchecked.	available for edit. Sections selected in a pending or submitted amendment remain
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- 3. Add the Relying Site as an Engaged Outside Institution:
 - Select Relying Site from the Institution Type drop down list.
 - Start typing the name in the Organization field to begin the elastic search. If you do not find
 your desired organization, you need to submit a request to add them as a new 'subaward
 organization' using this web form: https://kc.mit.edu/forms-requests/request-new-subaward-organization
 The organizations are shared with and used in MIT's KC proposal and subaward systems. You can note in the
 webform that this organization is needed for a Connect protocol.

Institution Type * Organization * Please Select Please Select Collaborator	tion	Point of contact Point of contact	Approval Date mm/dd/yyyy	Expiration Date mm/dd/yyyy
Lead Site Relying Site Justitution Tune Name	red.	et Notes		Add Attachment ~

Note: You can **edit** an existing Engaged Institution if it already appears in your protocol, but this amendment still needs to be routed and approved.

Engaged Outside Institutions (List any institution that will be engaged in the research. Institutions that will cede (rely) on COUHES for IRB review must be included here with an Institution Type of Relying Site. If MIT will cede review, list the reviewing IRB as the Lead Site.)										
Institution Type *	Organiza	tion *		Po	pint of contact	Арр	proval Date		Expiration Date	
Lead Site	~ Universi	ty of Chicago			Josh Dean	m	m/dd/yyyy	=	mm/dd/yyyy	
Please Select	Ĩ									
Collaborator Lead Site								1.	Add Attachmen	it ¥
Relying Site	d the limit will b	e truncated.						///,		
										×
In	stitution Type	Name	Point of contact	Notes		Approval	Date Expir	ration Date	Action	
— Le	ead Site	University of Chicago	Josh Dean					_	/ 0 1	

4. Once the relying site is added and saved, the **Reliance Protocol** tab appears in your protocol. Navigate to that tab to find the Create Reliance Request button:

IRR # · Amendment	PI:	IRB Admin :	Amendment in Progress Validate	E
Lead Unit :	Risk Level : No greater than minimal risk	FDA Risk Level :	Data Classification :	
Approval Date : 03/24/2015	Last Approval Date:	Expiration Date : 04/11/2025		
Anticipated Start Date :	Anticipated End Date : 01/31/2026	Submission Status :		•
🛠 General 🛛 Additional Forms 🗬 Study Details	& Attachments P Permissions 🔹 Research Team	🏵 History 🖺 Summary 🌣 Actions 🕜 Certifica	ation Other Information C Reliance Protocol	I
			Create Reliance R	Request
			- Ching	



5. Reliance Request window presents; Select a Site and provide the description.

Reliance Request -	:
Select the reliance site for which you need to create the reliance request.	
Reliance Site *	
Please Select	v
Description *	
Provide a brief description for the purpose of the request	
	1.
	Cancel Create

- 6. Reliance Requests uses the Parent protocol ID, appended with "RR###" and a Reviewing Reliance flag.
- The **Header** includes a link to the Parent Protocol and the title, as well as approval and expiration dates.
- The Reliance Protocol tab displays
 - A. Description (entered in the window, but editable in this screen)
 - o B. selected Site
 - C. required Reviewing Reliance Questionnaire

Reliance # : 9RR001 Reviewing Reliance	PI :	Parent Approval Date : 03/24/2015	Pending/In Progress	
Lead Unit : Economics	Anticipated Start Date :	Parent Last Approval Date : 04/12/2024		
Parent Protocol : 15030	Anticipated End Date : 01/31/2026	Parent Expiration Date : 04/11/2025		
Protocol title :				•
C Reliance Protocol & Attachment 3	History			Save Submit :
Description :				
Purpose of this reliance request for the se	elected site.If there are multiple reliance sites, c	reate a request for each one.		
Execution Date :	Expiration Date			
Reliance Site B				
Organization :		Institution Type :		
University of Chicago		Relying Site		
Persons :		Attachments :		
Notes :				
Additional Forms				

- The Attachment Tab displays:
 - A. Reliance Attachments Click Add Attachment to upload site-specific information.
 - B. Organization Attachments- view only of attachments maintained in the Protocol.

C Reliance Protocol Attachment D History	Submit
Reliance Attachments	Add Attachment
AB	
There is no attachments for this request.	

• The **History** tab: Displays the reliance request history (created by and dates)



7. Click *Submit* to route.

If you cannot complete your request in this session, click **Save** to retain your entries. You can return to this request in the new list in your Connect dashboard – **Reliance Requests**

- Pending lists your in-progress requests: created but not submitted.
- o Submitted lists requests under review at COUHES
- **Executed** lists your approved requests where MIT agrees to serve as the Reviewing IRB.

4 Pending Actions Protocols/Exempt Studies	Lili Amer	Progress idments/Renewals		12 IRB	Awaiting Response			 Start Exempt Create Protoc Create Cede I 	Evaluation col Request
Active Protocols In Progress P	Protocols All Prot	ocols En-Route Protoc	cols E	xempt Evaluation	s Restart F	Research Reque	Reliance	e Requests	Export
Sort by : Reliance Request Numbe	r Parent Protocol	Reliance Protocol Status	Title S	Submission Type	Reliance Site	Reliance PI	Execution Date	Expiration Date	
IRB Admin Update Timestamp	+								
Pending Submitted	Executed								
	RR001 request for each on	- Purpose of this reliance e.	e request f	for the selected s	ite. If there are	e multiple relia	nce sites, create	а	Last Update: 06/11/2024
Pending/In Progress	Expiration Date:	E	execution D	Date:		Submission T	ype:		View
	PI .	R	Reliance Sit	te: University of C	hicago				
	IRB Admin: Lombar	dozzi, Felicia P	Parent Prot	ocol:					
								1 - 1 of 1 Record	«« « 1 » »»

Related Documentation:

Please see the COUHES website for additional information regarding Single IRB Review: <u>https://couhes.mit.edu/single-irb-review</u> And FAQ on Single IRB: <u>https://couhes.mit.edu/single-irb-review/single-irb-review-faqs</u>

Getting Help

For protocol process or study related questions, please contact COUHES: couhes@mit.edu For questions regarding issues with Connect software, email the Support Team at ra-help@mit.edu.

