

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.

Procedure: Reviewing IRB vs. Relying IRB (ceded)

- For new single-IRB requests with MIT serving as the reviewing IRB, investigator will submit reliance requests through their existing protocol in COUHES Connect to be managed through the existing COUHES protocol. Relying sites related to this study must still complete Local Context form.
- For new single-IRB requests with MIT serving as a relying site, investigator must Create New Cede Request in COUHES Connect and enter the required information. The request must be submitted in conjunction with the requirements for the relying site.

Requirements for MIT to serve as the REVIEWING IRB

- Utilizes an Approved Connect Protocol (existing or newly created)
- Relying Sites listed as Engaged Institution
 - For approved protocols,
 - relying site must be added/updated via Amendment
 - the amendment approved before the reliance request can be executed
 - For new protocols
 - Add the relying site in your initial protocol
 - You can submit the reliance request with the initial, but it will not be executed until the protocol is approved.
- Reliance Request created, completed, and submitted
 - Identifies site(s) relying on MIT review
 - Describes the purpose of the request
 - Provide attachment(s) with site-specific information.
 - Complete the Reliance Questionnaire
- Track the review status on the Reliance Requests tab in your protocol
 - o Pending are those created but not submitted, or returned for additional information
 - o Submitted are under review
 - Executed are those with completed reviews where MIT agrees to serve as the reviewing IRB.

Requirements for MIT to serve as the RELYING IRB

- Utilizes Cede Request- a specific, content reduced, Connect Protocol consisting of:
 - Title must match the reviewing site's IRB
 - o Purpose of Study
 - o MIT PI, Study Personnel, & Point of Contact
 - Funding Source
 - Subjects-consistent with the approved protocol, noting MIT specific subjects.
 - o Study Details
 - Attachments the approved prime protocol & letter, consent form(s), site specific content
 - Additional Forms Ceded Reliance questionnaire
 - Departmental Approval (via routing)



Creating a Reliance Request for New and Existing Protocols

1. Add the Relying Site as an Engaged Institution (via amendment in existing protocols):

nstitution Type *	Organization *		Point of contact	Approval Date	Expiration Date
Please Select 🗸 🗸	Search Organization		Point of contact	mm/dd/yyyy	mm/dd/yyyy
Please Select					
Collaborator					
ead Site					Add Attachment 🗸
Relving Site					11.
) the limit will be truncated.				_
~					Add
Institu	ntion Type Name	Point of contact	Notes	Approval Date Expiration I	Date Action

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

stitution Type *	Organiz	ation *		Point of contact	Approval Date	E	Expiration Date	
Lead Site	✓ Univer:	sity of Chicago		Josh Dean	mm/dd/yyyy	-	mm/dd/yyyy	
Please Select								
Collaborator								
_ead Site						11.	Add Attachm	ent
Relying Site	d the limit will	be truncated.				///,		
	~							a
	In address Trans	Name	Point of contact	Notes	Approval Date	Expiration Date	Action	
	institution Type	Hume						

2. Once added and saved, the Reliance Protocol tab appears with a Create button:

IRR # · Amendment	PI:	IRB Admin :	Amendment in Progress	Validate	8
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 D	etails 🕜 Attachments 🎾 Permissions	🛎 Research Team 🔞 History 🚦 Summary 🏚 A	Actions ⑦ Certification ⑦ Other Information	€ Reliance Protocol	I.
				Create Reliance R	lequest

3. 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	~
Description *	
Provide a brief description for the purpose of the request	
	Cancel Create



4. Reliance Requests link to the Parent protocol, appended with "RR###" and a Reviewing Reliance flag.

Reliance # : RR001 Review	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 :	Anticipated End Date : 01/31/2026	Parent Expiration Date : 04/11/2025	
Protocol title :			•
C Reliance Protocol & At	tachment 🔊 History		Save Submit #

- The **Reliance Protocol tab** displays
 - Description (editable)
 - selected Site
 - required Reviewing Reliance Questionnaire
- The **Attachment Tab**: Upload any site-specific information, i.e. local context form.
- o The History tab: Displays the reliance request history
- 5. 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*

4 Pending Actions Protocols/Exempt Studies	1 In Progress Amendments/Ren	newals	12 Awaiting IRB Response	Start Exen + Create Pro + Create Cen	npt Evaluation otocol de Request
Active Protocols In Progress I Sort by : Reliance Request Numb	Protocols All Protocols En-	Route Protocols Exempt E	valuations Restart Research I	Requests Reliance Requests	Export
Pending Submitted	E Executed	this setting a second for the	sladad sita 1f thans an multipla	reliance cites areato e	
· · · · · · · · · · · · · · · · · · ·	request for each one.	this reliance request for the se	elected site. If there are multiple	reliance sites, create a	Last Update: 06/11/2024
Pending/In Progress	Expiration Date:	Execution Date: Reliance Site: Unive	Submiss	sion Type:	W View
	IRB Admin: Lombardozzi, Felicia	Parent Protocol:	any or onloago		
				1 - 1 of 1 Recc	ord «« « 1 » »»

Creating a Relying IRB – Cede Request

1. From your Connect Dashboard, select Create Cede Request from the Actions tile:

4 Pending Actions Protocols/Exempt Studies	ш	1 In Progress Amendments/Renewals	Ē	12 Awaiting IRB Response	 Start E + Create + Create 	Exempt Protoc Cede F	Evaluati ol Request	on	

- 2. The new protocol will present for you to maintain your entries: Complete the General section and Save to proceed:
 - a. Title must match the reviewing site IRB
 - **b.** Select **Type = Cede**
 - c. Purpose of Study

Гуре *	
Cede	Ň
Please Select	12
Cede	
Comprehensive Review	
Emergency Use	
Humanitarian Use Device (HUD)	
Single Patient Use	



Save: The header will update with a protocol ID# with a Ceded Reliance flag.

IRB # : 2406001246	Ceded Reliance	PI : Hanlon, Rosemary 🕕	IRB Admin :	Pending/In Progress	
				Validate	

- d. MIT PI, Study Personnel, & Point of Contact
- e. Funding Source
- f. Subjects-consistent with the approved protocol, noting MIT specific subjects.
- g. Engaged Outside Institution-not required; detail in the Additional Forms Questionnaire
- h. Study Details
- i. Attachments the approved prime protocol & letter, consent form(s), site specific content
- j. Additional Forms Ceded Reliance questionnaire

😭 General 🔞 Ac	lditional Forms 🛛 🕞 Study	Details 🛛 Ø Attachments	Permissions	s 🔹 Research Team	History Actions	⑦ Certification
Other Information	n					÷
Questionnaire for C	eded Protocol					
1. Provide a brie	f summary of MIT's role in t ers left. All text beyond the limi	he proposed study. will be truncated.	li.			
2. Is the study fe	derally funded? 🚯					
O Study is n	ot Federally funded.					
O Study is F	ederally funded and MIT is th	e lead institution on the g	ant/award.			
O Study is Fe	ederally funded and MIT is N	OT lead institution on the	grant/award.			
3. For each sit record. If the s	e involved in the study, I tudy involves multiple s	ist the lead Principal Ir ites, list one site per ro	ovestigator, Poir ow. 🚯	nt of Contact, and inc	dicate if the site will se	rve as the IRB of +Add Row
Site	Lead site or Relying site		L	ead Pl	Point of Contact	
			No Answers Foun	d		
		You have 13 u	nanswered que	stions. X		

k. PI Certification

3. **Submit** the cede protocol for departmental and subsequent COUHES review.

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.

