

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 oversight. 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
 - Pending are those created but not submitted, or returned for additional information
 - 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
 - Purpose of Study
 - MIT PI, Study Personnel, & Point of Contact
 - Funding Source
 - Subjects-consistent with the approved protocol, noting MIT specific subjects.
 - 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):

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 *
Please Select
Collaborator
Lead Site
Relying Site

Organization *
Search Organization

Point of contact
Point of contact

Approval Date
mm/dd/yyyy

Expiration Date
mm/dd/yyyy

Add Attachment

Add

Institution Type	Name	Point of contact	Notes	Approval Date	Expiration Date	Action
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Note: You can edit an existing Engaged Institution if it already appears in your protocol, but it 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 *
Lead Site
Please Select
Collaborator
Lead Site
Relying Site

Organization *
University of Chicago

Point of contact
Josh Dean

Approval Date
mm/dd/yyyy

Expiration Date
mm/dd/yyyy

Add Attachment

Institution Type	Name	Point of contact	Notes	Approval Date	Expiration Date	Action
Lead Site	University of Chicago	Josh Dean				[Edit] [Add] [Delete]

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

IRR # - [Redacted] Amendment
PI: [Redacted] IRB Admin: [Redacted]
Lead Unit: [Redacted] Risk Level: No greater than minimal risk... FDA Risk Level: [Redacted]
Approval Date: 03/24/2015 Last Approval Date: [Redacted] Expiration Date: 04/11/2025 Data Classification: [Redacted]
Anticipated Start Date: [Redacted] Anticipated End Date: 01/31/2026 Submission Status: [Redacted]

General Additional Forms Study Details Attachments Permissions Research Team History Summary Actions Certification Other Information **Reliance Protocol**

Create Reliance Request

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

Reliance Request - [Redacted]

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.

- 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.
- 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**

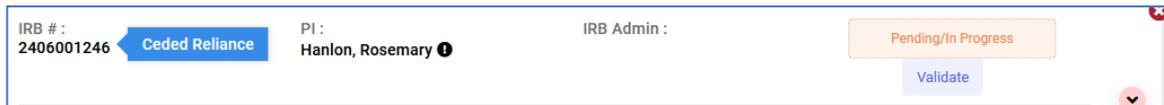
Creating a Relying IRB – Cede Request

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

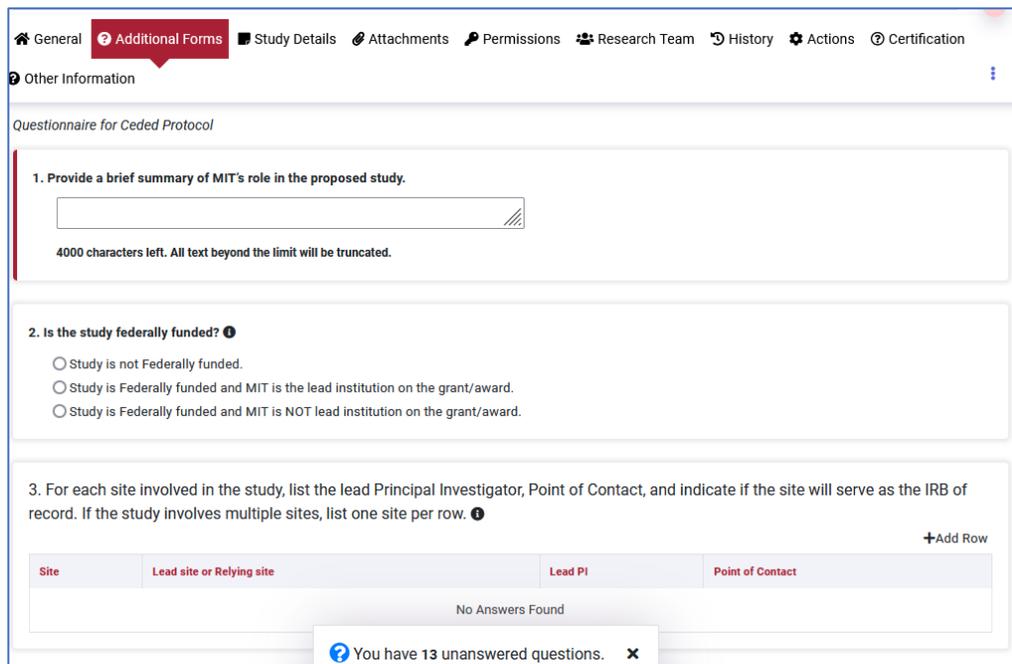
2. The new protocol will present for you to maintain your entries: Complete the General section and Save to proceed:

- a. **Title** must match the reviewing site IRB
- b. Select **Type = Cede**
- c. **Purpose of Study**

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



- 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



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:

<https://couhes.mit.edu/single-irb-review>

And FAQ on Single IRB:

<https://couhes.mit.edu/single-irb-review/single-irb-review-fags>

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.

