Committee on the Use of
Humans as Experimental Subjects

**Office of the
Vice President
for Research**

COUHES CONNECT Reliance Protocols
MIT as Reviewing IRB
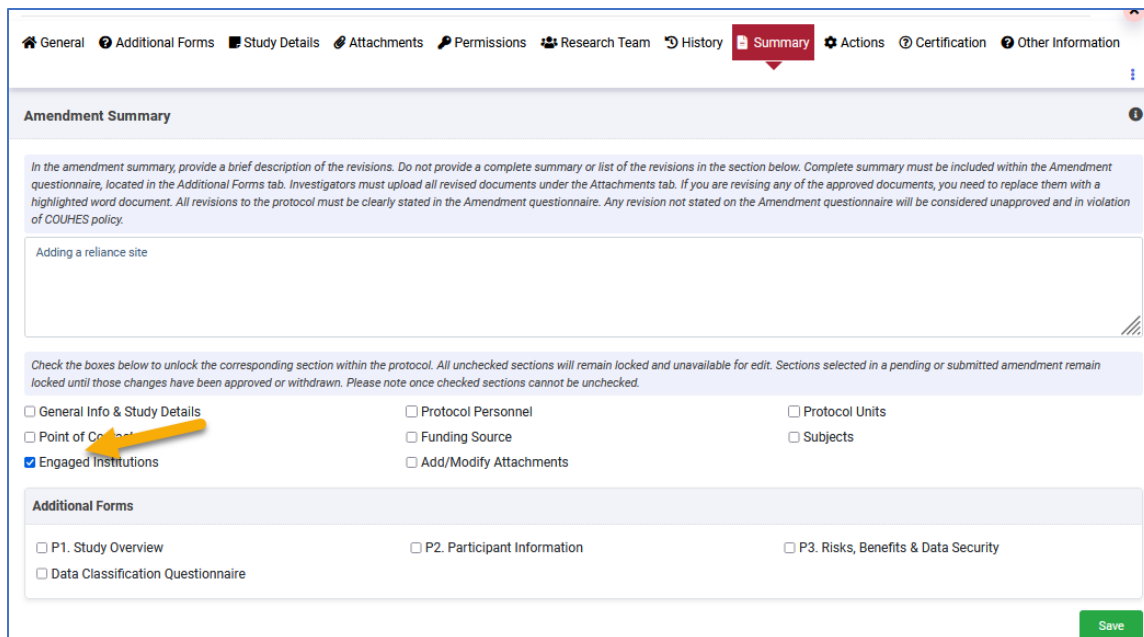**to support Single-IRB requests**

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

1. 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: http://web.mit.edu/ist-train/COUHESConnect/Create/#/

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.

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.

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.

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:

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

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
  - o **A. Description** (entered in the window, but editable in this screen)
  - o **B**. selected **Site**
  - o **C**. required **Reviewing Reliance Questionnaire**

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

  - o 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**

- o **Pending** lists your in-progress requests: created but not submitted.

- o **Submitted** lists requests under review at COUHES

- o **Executed** lists your approved requests where MIT agrees to serve as the Reviewing IRB.

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-faqs

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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.