The Rapport IRB 2024 release involved:

- **Cosmetics** changes - These include minor changes to the display.
- **SmartForm** changes – These do not change what information and materials CPHS needs to review. You will continue to answer the same questions and submit the same materials.
- **Dashboard** - New homepage
- **Compare** button - New feature
- **Study Update workflow** - The process for submitting a Study Update for an External IRB study has changed.
- **External IRB Study ID** - Studies that rely on an External IRB will have a new Study ID that begins with SITE0000XXX.
When you first log in to the system you will be on your Dashboard.

- **My Inbox** tab: Items awaiting your action.
- **My Reviews** tab: Items awaiting your review.
- **Create** dropdown: Menu with creator buttons.
- **Recently Viewed** component: Lists the last several items viewed, with the most recent at the top. Click an item to go to that item’s workspace.
The IRB Workspace is home to the Create New Study and Report New Information Buttons.

You can filter by the tabs to find any existing items.
IMPORTANT! This page always appears. This page is meant to capture External Sites. Complete this page if your study involves External Sites where the investigator will conduct or oversee the research.
Use Questions 5 & 6 to indicate whether the external site’s IRB will review or request to rely on CPHS.
There is now a single page, **Local Site Documents**, for all supporting materials (consent forms, recruitment materials, and other attachments).
Change - Documents tab display

This change to the way documents are displayed under the Documents tab does not impact the way materials are reviewed. The division of Study Related Documents and Site Related Documents is assigned by the Rapport system.

### 2024 version

<table>
<thead>
<tr>
<th>Study Related Documents</th>
<th>Category</th>
<th>Final</th>
<th>Last Finalized</th>
<th>Document History</th>
</tr>
</thead>
<tbody>
<tr>
<td>exemption-form</td>
<td>IRB Protocol</td>
<td></td>
<td></td>
<td>History</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Site Related Documents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Draft</td>
</tr>
<tr>
<td>screener-survey.pdf</td>
</tr>
<tr>
<td>interview-protocol.pdf</td>
</tr>
<tr>
<td>consent-form.pdf</td>
</tr>
</tbody>
</table>

### Previous version

<table>
<thead>
<tr>
<th>Draft</th>
<th>Category</th>
<th>Final</th>
<th>Last Finalized</th>
<th>Document History</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interview-protocol.pdf</td>
<td>Other</td>
<td></td>
<td></td>
<td>History</td>
</tr>
<tr>
<td>exemption-form</td>
<td>IRB Protocol</td>
<td></td>
<td></td>
<td>History</td>
</tr>
<tr>
<td>consent-form.pdf</td>
<td>Other</td>
<td></td>
<td></td>
<td>History</td>
</tr>
<tr>
<td>screener-survey.pdf</td>
<td>Surveys and Questionnaires</td>
<td></td>
<td></td>
<td>History</td>
</tr>
</tbody>
</table>
New – Compare feature

The **Compare** button allows you to:
- View your changes while editing your submission
- View any changes made by the CPHS office through a clarification request.
From the study workspace, click **Update Study Details**.
New-Study Update to External IRB study

1. *Summarize the updates:*
   test study update for external IRB study

Click **Save**. Click **Continue** to move to the next page.
New-Study Update to External IRB study

Make your changes to update the study.

Click **Save**. Click **Continue** to move to the next page.
New-Study Update to External IRB study

Use the Compare button to view your changes.
New-Study Update to External IRB study

When study updates are complete, click Add Comment from the Study Update workspace.
New-Study Update to External IRB study

Use the 1. Comment box to include a detailed description of the study update changes, and a note that the Study Update is ready for CPHS review.

Be sure to select IRB Coordinator for Question 3. This will notify the IRB Coordinator that the Study Update is complete and ready for review.
New-migrated External IRB studies have new Study ID (SITE000XXXX)
IRB RAPPORT Create and Submit a Study

1. From the Dashboard,
2. Click Create,
3. Select Create New Study,
Basic Information page

4. Complete the **Basic Information** page and click **save** to create a study record.

Click Save. Click Continue to move to the next page.
Study Funding Sources page

Editing: STUDY00032941

1. Identify any funding NOT processed by Dartmouth’s Office of Sponsored Projects:

   ![Add button]

<table>
<thead>
<tr>
<th>Funding Source</th>
<th>Sponsor’s Funding ID</th>
<th>Grants Office ID</th>
<th>Attachments</th>
</tr>
</thead>
<tbody>
<tr>
<td>There are no items to display</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. Identify funding processed by Dartmouth’s Office of Sponsored Projects:

   ![Add button]

<table>
<thead>
<tr>
<th>Funding Source</th>
<th>Sponsor’s Funding Id</th>
<th>Project Title</th>
<th>Project Status</th>
<th>PI First Name</th>
<th>PI Last Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>There are no items to display</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Click Save. Click Continue to move to the next page
Study Team Members

1. Identify each additional person involved in the design, conduct, or reporting of the research:

<table>
<thead>
<tr>
<th>Name</th>
<th>Roles</th>
<th>Financial Interest</th>
<th>Involved in Consent</th>
<th>E-mail</th>
<th>Phone</th>
</tr>
</thead>
</table>

There are no items to display.

2. External team member information:

<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
</table>

There are no items to display.

* Please use this form for External Study Team members. External Study Team Members Form

Click Save. Click Continue to move to the next page.
Local Study Team Members

1. Identify each additional person involved in the design, conduct, or reporting of the research:

<table>
<thead>
<tr>
<th>Name</th>
<th>Roles</th>
<th>Financial interest</th>
<th>Involved in Consent</th>
<th>E-mail</th>
<th>Phone</th>
</tr>
</thead>
</table>

There are no items to display.

Add Study Team Member

1. * Study team member: [ ]

2. Role in research: (check all that apply)
   - Study Coordinator
   - Project Manager
   - Co-Investigator
   - Co-Principal Investigator
   - Sub-Investigator
   - Institutional Principal Investigator
   - Regulatory Specialist
   - Research Assistant
   - Graduate/Student Research Assistant
   - CRF Nurse
   - Research Nurse
   - Compliance Officer
   - Student Investigator
   - Other Research Team Member
   - Faculty Advisor

3. * Is the team member involved in the consent process?  
   - Yes  
   - No  

4. * Does the team member have a financial interest related to this research?  
   - Yes  
   - No  

* Required
External Study Team Members

2. External team member information:

Add

Name  Description
There are no items to display

* Please use this form for External Study Team members: External Study Team Members Form

Submit a Document

Title: 
If not provided, the name of the file will be used

File:  Choose File

Show Advanced Options

* Required
Study Scope

1. * Does the study specify the use of an approved drug or biologic, use an unapproved drug or biologic, or use a food or dietary supplement to diagnose, cure, treat, or mitigate a disease or condition?  
   - Yes  
   - No  
   - Clear

2. * Does the study evaluate the safety or effectiveness of a device or use a humanitarian use device (HUD)?  
   - Yes  
   - No  
   - Clear

3. * Are there external sites where the investigator will conduct or oversee the research?  
   - Yes  
   - No  
   - Clear

Click Save. Click Continue to move to the next page.
Research Locations – Research Sites

IMPORTANT! This Research Sites/Locations page always appears. Complete this page if you answered YES to Question 3 on the previous Study Scope page.
Answer **YES** to **Question 3** on the **Study Scope** page if there are external sites where the investigator will conduct or oversee the research.
IMPORTANT! This Research Sites/Locations page always appears. **Complete this page if you answered YES to Question 3 on the previous Study Scope page.**

1. Click **Add** to list each external site.
2. Complete the **Add Research Location** activity.
Study with external sites- Add Research Location activity

Add Research Location

1. * Site name: 

2. * Contact name: 

3. * Contact phone: 

4. * Contact e-mail: 

5. Will the external site’s IRB review the research? ○ Yes ○ No Clear

6. Will the external site rely on CPHS? ○ Yes ○ No Clear

7. Reliance Agreement:
   [None]  Upload

* Required

Use Questions 5 & 6 to indicate whether the external site’s IRB will review or request to rely on CPHS.
Study with external sites- complete page

Click Save. Click Continue to move to the next page.
Local Site Documents page

1. Consent form(s): Attach individual Word copies of each consent, assent, parental permission forms, information sheet. See the CPHS website: FORMS for templates.

2. Recruitment materials: Attach Word copies of the recruitment materials. Recruitment materials include Flyers, Social Media Posts, Recruitment Emails, Phone Scripts.

3. Other attachments: Attach individual Word documents of all other study materials. This includes study measures such as surveys and interview guides, Waiver and Authorization Request Forms, letters of support, International Research Form, Reaching involving Children Form.

Click Save. Click Continue to move to the next page.
Research Setting page

Editing: STUDY00032880

Research Setting

1. * Does this study involve any sites outside of the United States where research is being done under your purview?
   - Yes
   - No

2. * Is this a clinical trial?
   - Yes
   - No

Click Save. Click Continue to move to the next page.
Final Page

You Are Here: External IRB Test study
Editing: STUDY00032881

Final Page

You have reached the end of the IRB submission form. Read the next steps carefully:
1. Click Finish to exit the form.
2. Important! To send the submission for review, click Submit on the next page.

For a Study Update to an External IRB study, follow these steps:
1. Click Add Comment.
2. In the Comment box, let the CPHS office know that the Study Update is ready for review.
3. Select the IRB Coordinator checkbox to send a notification to them.
4. Click OK.

IMPORTANT: Click Finish DOES NOT send the submission to CPHS. When the study is ready for CPHS review, the PI or PI Proxy must submit from the study record workspace.

*NEW*
For a Study Update to an External IRB study, follow these steps:
1. Click Add Comment.
2. In the Comment box, let the CPHS office know that the Study Update is ready for review.
3. Select IRB Coordinator checkbox to send a notification to them.
4. Click OK.
Submit –Study Workspace

To Submit to CPHS office:
1. Click the SUBMIT arrow (left side of screen)
2. On the next screen, finalize by clicking OK.
Submit activity