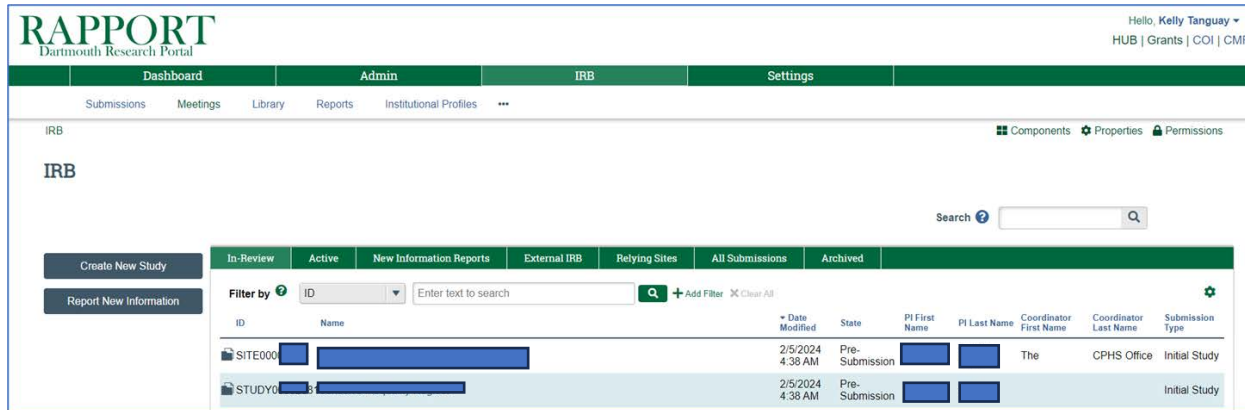


Rapport IRBv.10 -2024 release



IRB

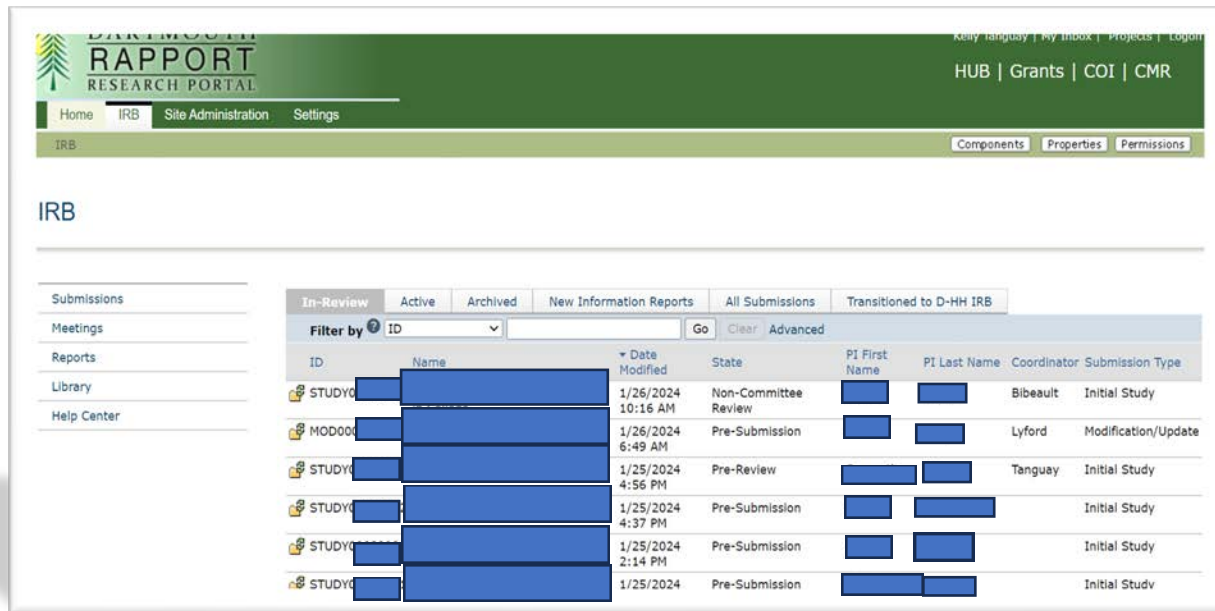
Search

Create New Study
Report New Information

In-Review Active New Information Reports External IRB Relying Sites All Submissions Archived

Filter by ID Enter text to search + Add Filter X Clear All

| ID | Name | Date Modified | State | PI First Name | PI Last Name | Coordinator First Name | Coordinator Last Name | Submission Type |
|---------|------|------------------|----------------|---------------|--------------|------------------------|-----------------------|-----------------|
| SITE000 | | 2/5/2024 4:38 AM | Pre-Submission | | | The | CPHS Office | Initial Study |
| STUDY0 | | 2/5/2024 4:38 AM | Pre-Submission | | | | | Initial Study |



IRB

Submissions Meetings Reports Library Help Center

In-Review Active Archived New Information Reports All Submissions Transitioned to D-HH IRB

Filter by ID Go Clear Advanced

| ID | Name | Date Modified | State | PI First Name | PI Last Name | Coordinator | Submission Type |
|--------|------|--------------------|----------------------|---------------|--------------|-------------|---------------------|
| STUDY0 | | 1/26/2024 10:16 AM | Non-Committee Review | | | Bibeault | Initial Study |
| MOD000 | | 1/26/2024 6:49 AM | Pre-Submission | | | Lyford | Modification/Update |
| STUDY0 | | 1/25/2024 4:56 PM | Pre-Review | | | Tanguay | Initial Study |
| STUDY0 | | 1/25/2024 4:37 PM | Pre-Submission | | | | Initial Study |
| STUDY0 | | 1/25/2024 2:14 PM | Pre-Submission | | | | Initial Study |
| STUDY0 | | 1/25/2024 | Pre-Submission | | | | Initial Study |

The Rapport IRB 2024 release involved:

- **Cosmetics** changes- These include minor changes to the display.
- **SmartForm** changes –These does 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.

New: Dashboard

RAPPORT
Dartmouth Research Portal

rap_irb10

Hello, ERA testpiseven

Dashboard IRB

Page for ERA testpiseven

Create ▾

My Inbox My Reviews

My Inbox

Filter by ID ID Enter text to search

+ Add Filter X Clear All

| ID | Name | Date Created | Date Modified | State | Coordinator |
|-------------|--|-------------------|-------------------|----------------|---------------|
| MOD00012260 | Modification / Update #6 for Study kmt_test study initial study with external sites_ | 1/10/2024 2:45 PM | 1/17/2024 2:08 PM | Pre-Submission | Kelly Tanguay |

1 items

page 1 of 1

25 / page

Recently Viewed

Recent Pinned

- STUDY00032880: Study (Test)
- STUDY00032873: kmt test ini...udy 1.5.2024
- RNI00001454: test RNI to FC
- STUDY00032872: external IRB kmt 1.4.24

- 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.

Change-IRB Workspace display

RAPPORT
Dartmouth Research Portal

rap_irb10

Hello, ERA testpiseven ▾

Dashboard IRB

Submissions Meetings Library Reports Help Center

IRB

IRB

Create New Study

Report New Information

Search ?

In-Review Active New Information Reports External IRB Relying Sites All Submissions Archived

Filter by ? ID Enter text to search + Add Filter ✕ Clear All

| ID | Name | Date Modified | State | PI First Name | PI Last Name | Coordinator First Name | Coordinator Last Name | Submission Type |
|---------------|--|--------------------|----------------|---------------|-------------------|------------------------|-----------------------|-----------------------|
| MOD00012260 | Modification / Update #6 for Study kmt_test study initial study with external sites_ | 1/17/2024 2:08 PM | Pre-Submission | ERA | testpiseven Kelly | Tanguay | | Modification / Update |
| STUDY00032880 | Study (Test) | 1/15/2024 12:11 PM | Pre-Review | ERA | testpiseven | | | Initial Study |

2 items

◀ page 1 of 1 ▶

25 / page

- 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.

New-Research Locations SmartForm page

RAPPORT

Dartmouth Research Portal

Validate

Compare

<<

Basic Study Information

External IRB

Study Funding Sources

Study Team Members

Study Scope

Research Locations

Local Site Documents

You Are Here: External IRB Test study

Editing: STUDY00032881

Research Sites

1. Identify each site where the investigator will conduct or oversee the research:

+ Add

| Site | Contact | Email | External IRB Review | Rely on CPHS | Reliance Agreement |
|-------------------------------|---------|-------|---------------------|--------------|--------------------|
| There are no items to display | | | | | |

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 over see the research.

New-Research Locations SmartForm page

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

OK

OK and Add Another

Cancel

Use **Questions 5 & 6** to indicate whether the external site's IRB will review or request to rely on CPHS.

New-Local Site Documents SmartForm page

2024

Validate Compare

You Are Here: External IRB Test study

Editing: STUDY00032881

Local Site Documents

- Consent forms:** (include an HHS-approved sample consent document, if applicable) [?](#)
[+ Add](#)

| Document | Category | Date Modified | Document History |
|-------------------------------|----------|---------------|------------------|
| There are no items to display | | | |
- Recruitment materials:** (add all material to be seen or heard by subjects, including ads) [?](#)
[+ Add](#)

| Document | Category | Date Modified | Document History |
|-------------------------------|----------|---------------|------------------|
| There are no items to display | | | |
- Other attachments:**
[+ Add](#)

| Document | Category | Date Modified | Document History |
|-------------------------------|----------|---------------|------------------|
| There are no items to display | | | |

Basic Study Information
External IRB
Study Funding Sources
Study Team Members
Study Scope
Research Locations
Local Site Documents
Research Setting

There is now a single page, **Local Site Documents**, for all supporting materials (consent forms, recruitment materials, and other attachments).

Previous Version

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: Consent Forms and Recruitment Materials ▾

Consent Forms and Recruitment Materials

- Consent forms:** (include an HHS-approved sample consent document, if applicable) [?](#)
[Add](#)

| Document | Category | Date Modified | Document History |
|-------------------------------|----------|---------------|------------------|
| There are no items to display | | | |

Refer to the following templates and instructional documents:

 - CPHS Full Committee Consent Template
 - CPHS Assent Template
 - CPHS Information Sheet Template
 - CPHS Waivers or Alterations Request Form
- Recruitment materials:** (add all material to be seen or heard by subjects, including ads) [?](#)
[Add](#)

| Document | Category | Date Modified | Document History |
|-------------------------------|----------|---------------|------------------|
| There are no items to display | | | |

<< Back Save | Exit | Hide/Show Errors | Print... | Jump To: Supporting Documents ▾

Supporting Documents

Attach supporting files, naming them as you want them to appear in the approval letter:

[Add](#)

| Document | Category | Date Modified | Document History |
|-------------------------------|----------|---------------|------------------|
| There are no items to display | | | |

Change- Documents tab display

2024 version

| History | Funding | Contacts | Documents | Follow-on Submissions | Reviews | ... | |
|-------------------------|---------|----------------------------|-----------|-----------------------|------------------|-----|--|
| Study Related Documents | | | | | | | |
| Draft | | Category | Final | Last Finalized | Document History | | |
| exemption-form | | IRB Protocol | | | History | | |
| Site Related Documents | | | | | | | |
| Draft | | Category | Final | Last Finalized | Document History | | |
| screener-survey.pdf | | Surveys and Questionnaires | | | History | | |
| interview-protocol.pdf | | Other | | | History | | |
| consent-form.pdf | | Other | | | History | | |

Previous version

| History | Funding | Project Contacts | Documents | Follow-on Submissions | Reviews | Snapshots |
|------------------------|----------------------------|------------------|-----------|-----------------------|------------------|-----------|
| Draft | Category | | Final | Last Finalized | Document History | |
| interview-protocol.pdf | Other | | | | History | |
| exemption-form | IRB Protocol | | | | History | |
| consent-form.pdf | Other | | | | History | |
| screenener-survey.pdf | Surveys and Questionnaires | | | | History | |

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.

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.

You Are Here: external IRB kmt 1.4.24
Editing: IRB00030156

Basic Study Information

1. * **Title of study:**
external IRB kmt 1.4.24

2. * **Short title:**
external IRB kmt 1.4.24

Local Site Documents

1. **Consent forms:** (include an HHS-approved sample consent document, if applicable)

| Document | Category | Date Modified | Document History |
|--|--------------|---------------|------------------|
| View updated consent(0.01) | Consent Form | 1/26/2024 | History |
| View testing Study Update, new consent (0.01) | Consent Form | 1/5/2024 | History |
| View test.docx(0.01) | Consent Form | 1/4/2024 | History |

Differences

ERA testpiseven • modified 9 minutes ago • version 2.0+ (Modification EXTUPDATE00000001 review complete: undefined)

Added: updated consent

2. **Recruitment materials:** (add all material to be seen or heard by subjects, including ads)

| Document | Category | Date Modified | Document History |
|-----------------------|-----------------------|---------------|------------------|
| View test.docx(0.01) | Recruitment Materials | 1/4/2024 | History |

3. **Other attachments:**

| Document | Category | Date Modified | Document History |
|-----------------------|----------------------------|---------------|------------------|
| View test.docx(0.01) | Surveys and Questionnaires | 1/4/2024 | History |

Suggested attachments:

- Completed checklist of meeting Department of Energy requirements, if applicable
- Other site-related documents not attached on previous forms

Change-Study Update to External IRB study workflow

IRB > external IRB kmt 1.4.24

External IRB

Entered IRB: 1/4/2024 2:10 PM
Initial approval: 1/1/2024
Initial effective: 1/4/2024
Effective: 1/4/2024
Last updated: 1/5/2024 12:01 PM

STUDY00032872: external IRB kmt 1.4.24

Principal investigator: ERA testpiseven
Submission type: Initial Study
Primary contact: ERA testpiseven
PI proxies: Wendy Aarnio

IRB office:
IRB analyst:
Local IRB acknowledgement letter:

External IRB:
External IRB approval letter:

Next Steps

View Study

Printer Version

Update Study Details

Report New Information

History

Funding

Contacts

Documents

Follow-on Submissions

Reviews

Snapshot

Filter by ?

Activity

Enter text to search



+ Add Filter X Clear All

Activity



Update EXTUPDATE00000001 complete

Study Update: EXTUPDATE00000001



Study Update EXTUPDATE00000001 Opened

From the study workspace, click **Update Study Details**.

New-Study Update to External IRB study

Study Update Information

You Are Here: external IRB kmt 1.4.24 > _IRBSubmission

Creating New: IRB Submission

Study Update Information

1. * Summarize the updates:

test study update for external IRB study.

Use the text box to summarize the updates:

Click **Save**. Click **Continue** to move to the next page.

Exit Save Continue

New-Study Update to External IRB study

Validate

Compare

<<

Basic Study Information

External IRB

Study Funding Sources

Study Team Members

Study Scope

Research Locations

Local Site Documents

Research Setting

You Are Here: external IRB kmt 1.4.24

Editing: IRB00030156

Basic Study Information

1. * Title of study:

external IRB kmt 1.4.24

2. * Short title:

external IRB kmt 1.4.24

3. * Brief description:

external IRB kmt 1.4.24

4. * Will an external IRB act as the IRB of record for this study?

Make your changes to update the study.

Click **Save**. Click **Continue** to move to the next page.

✕ Exit

💾 Save

Continue ➔

New-Study Update to External IRB study

Use the **Compare** button to view your changes.

Compare

Compare current state of version:

0.2 [No description]

with

0.2 [No description]

1/26/2024 5:26:13 PM

Changes found on 1 step:

Study Update Information

Study Update Details

▼ IRB00030156

Basic Study Information

External IRB

Study Funding Sources

Study Team Members

Study Scope

Research Locations

Local Site Documents

Local Site Documents ?

1. Consent forms: (include an HHS-approved sample consent document, if applicable) ?

| Document | Category | Date Modified | Document History |
|---|--------------|---------------|-------------------------|
| View updated consent(0.01) | Consent Form | 1/26/2024 | History |
| View testing Study Update, new consent (0.01) | Consent Form | 1/5/2024 | History |
| View test.docx(0.01) | Consent Form | 1/4/2024 | History |

Differences

ERA testpiseven • modified a few seconds ago • version 2.0+ (Modification EXTUPDATE00000001 review complete: undefined)

► **Added:** updated consent

2. Recruitment materials: (add all material to be seen or heard by subjects, including ads) ?

| Document | Category | Date Modified | Document History |
|--------------------------------------|-----------------------|---------------|-------------------------|
| View test.docx(0.01) | Recruitment Materials | 1/4/2024 | History |

3. Other attachments:

| Document | Category | Date Modified | Document History |
|--------------------------------------|----------------------------|---------------|-------------------------|
| View test.docx(0.01) | Surveys and Questionnaires | 1/4/2024 | History |

Suggested attachments:

- Completed checklist of meeting Department of Energy requirements, if applicable
- Other site-related documents not attached on previous forms

New-Study Update to External IRB study

IRB > external IRB kmt 1.4.24 > Update #2 for external IRB kmt 1.4.24

Updating Study

Last updated: 1/26/2024 5:26 PM

Next Steps

Edit Study Details

Printer Version

Manage Ancillary Reviews

Add Comment

Discard

Summary

EXTUPDATE00000004: Update #2 for external IRB kmt 1.4.24

Principal investigator: ERA testpiseven

Submission type: Study Update

Primary contact: ERA testpiseven

IRB office: CPHS

IRB analyst: Kelly Tanguay

Financial Interest: No

History

Documents

Reviews

Snapshots

Filter by ?

Activity

Enter text to search

+

Add Filter

×

Clear All

| Activity | Author | Activity Date |
|-----------------------------|------------------|-------------------|
| + Minor Version Incremented | testpiseven, ERA | 1/26/2024 5:26 PM |

When study updates are complete, click **Add Comment** from the Study Update workspace.

New-Study Update to External IRB study

Add Comment



Your comment is visible to anyone with access to this submission.

1. Comment:

This Study Update involves a new consent form.
The Study Update is ready for review.

2. Supporting documents:

+ Add

Name

Description

There are no items to display

3. Who should receive an e-mail notification?

☐ PI/PI Proxy/Primary Contact

☐ Study Team

☒ IRB Coordinator

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)

External IRB

Entered IRB: 11/3/2021 2:37 PM
Initial approval: 3/9/2017
Effective: 11/8/2021
Approval end: 2/10/2023
Last updated: 11/9/2023 10:15 PM

SITE00000

| | |
|-------------------------|---------------|
| Principal investigator: | |
| Submission type: | Initial Study |
| Primary contact: | |
| PI proxies: | |

| | |
|-------------------------------|---|
| IRB office: | CPHS |
| IRB analyst: | Kelly Tanguay |
| External IRB: | Massachusetts Institute of Technology COUHES (MIT IRB |
| External IRB approval letter: | |

Next Steps

[View Study](#)

[Printer Version](#)

Update Study Details

Report New Information

[View/Edit CPHS Notes](#)

History

Funding

Contacts

Documents

Follow-on Submissions

Reviews

⋮

Filter by ?

Activity▼

Enter text to search

🔍 + Add Filter ✕ Clear All

| Activity | Author | ▼ Activity Date |
|---|-----------------------|--------------------|
| <div> ⓘ Data Migrated </div> | Administrator, System | 11/9/2023 10:15 PM |
| <div> ⓘ Data Moved from Obsolete External Study Submission </div> | Administrator, System | 11/9/2023 9:55 AM |
| Obsolete External Study Submission: STUDY000 <div></div> | | |

IRB RAPPORT Create and Submit a Study

1. From the **Dashboard**,
2. Click **Create**,
3. Select **Create New Study**,

The screenshot displays the RAPPORT Dartmouth Research Portal interface. The top navigation bar includes the 'RAPPORT' logo, the user identifier 'rap_irb10', and a greeting 'Hello, ERA testpiseven'. Below this, a green navigation bar contains 'Dashboard' (highlighted with a green arrow) and 'IRB'. The main content area shows a 'Page for ERA testpiseven' with a 'Create' button (highlighted with a green arrow) and a 'My Inbox' section. A dropdown menu is open from the 'Create' button, showing options: 'IRB', 'Create New Study' (highlighted with a green arrow), and 'Report New Information'. The 'My Inbox' section includes a search bar, a table with columns 'Name', 'Date Created', 'Date Modified', 'State', and 'Coordinator', and a message 'No data to display'. The footer shows pagination: 'page 1 of no results' and '0 / page'.

RAPPORT
Dartmouth Research Portal

rap_irb10

Hello, ERA testpiseven

Dashboard IRB

Page for ERA testpiseven

Create

My Inbox My Reviews

My Inbox

Filter by ID Enter text to search + Add Filter X Clear All

Name Date Created Date Modified State Coordinator

No data to display

page 1 of no results 0 / page

IRB

Create New Study

Report New Information

Modification...thdrawn 12/8

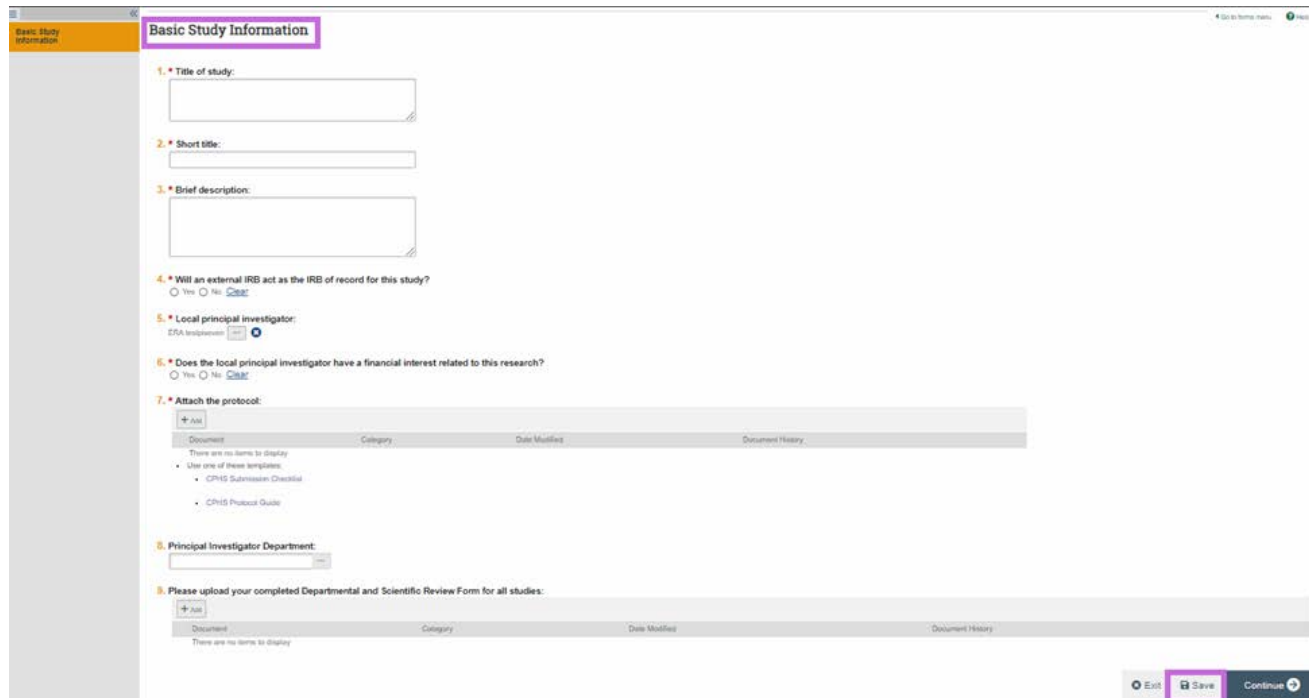
STUDY00032870: kmt_test stu...ernal sites

EXTUPDATE00000001: Update #1 fo...B kmt 1.4.24

MOD00012251

Basic Information page

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



The screenshot shows a web form titled "Basic Study Information" with a sidebar on the left. The form contains the following fields and sections:

- 1. * Title of study: [Text input field]
- 2. * Short title: [Text input field]
- 3. * Brief description: [Text area]
- 4. * Will an external IRB act as the IRB of record for this study?
 ☐ Yes ☐ No [Learn More](#)
- 5. * Local principal investigator:
 [Add](#) [Edit](#)
- 6. * Does the local principal investigator have a financial interest related to this research?
 ☐ Yes ☐ No [Learn More](#)
- 7. * Attach the protocol:
 [+ Add](#)

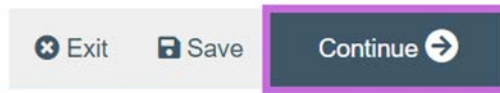
| Document | Category | Date Modified | Document History |
|--------------------------------|----------|---------------|------------------|
| There are no items to display. | | | |

 - Use one of these templates:
 - CPHS Submission Checklist
 - CPHS Protocol Guide
- 8. Principal Investigator Department:
- 9. Please upload your completed Departmental and Scientific Review Form for all studies:
 [+ Add](#)

| Document | Category | Date Modified | Document History |
|--------------------------------|----------|---------------|------------------|
| There are no items to display. | | | |

At the bottom right, there are three buttons: "Exit", "Save" (highlighted with a purple border), and "Continue".

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



Study Funding Sources page

Basic Study Information

Study Funding Sources

Study Team Members

Study Scope

Research Locations

Local Site Documents

Research Setting

Editing: STUDY00032941

[Go to forms menu](#)

Study Funding Sources ?

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

+ Add

| Funding Source | Sponsor's Funding ID | Grants Office ID | Attachments |
|-------------------------------|----------------------|------------------|-------------|
| There are no items to display | | | |

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

...

| Funding Source | Sponsor's Funding Id | Project Title | Project Status | PI First Name | PI Last Name |
|-------------------------------|----------------------|---------------|----------------|---------------|--------------|
| There are no items to display | | | | | |

Click Save. Click Continue to move to the next page

✕ Exit

💾 Save

Continue ➞

Study Team Members

You Are Here: 📁 Study (Test)

Editing: STUDY00032880

◀ Go to forms menu 🖨️ Print ▾ ? Help

Study Team Members

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

+ Add

| Name | Roles | Financial Interest | Involved in Consent | E-mail | Phone |
|------|-------|--------------------|---------------------|--------|-------|
|------|-------|--------------------|---------------------|--------|-------|

There are no items to display

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](#)

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

✕ Exit

💾 Save

Continue ➔

Local Study Team Members

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

+ Add

| Name | Roles | Financial Interest | Involved in Consent | E-mail | Phone |
|-------------------------------|-------|--------------------|---------------------|--------|-------|
| 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
- ☐ CRU 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 [Clear](#)

4. * Does the team member have a financial interest related to this research? ?

☐ Yes ☐ No [Clear](#)

* Required

OK

OK and Add Another

Cancel

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

[? Help](#)

Title:

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

* File:

Choose File

Show Advanced Options

* Required

OK

OK and Add Another

Cancel

Study Scope

ValidateCompare<<

Basic Study Information

External IRB

Study Funding Sources

Study Team Members

Study Scope

Research Locations

Local Site Documents

Research Setting

You Are Here: External IRB Test study

Editing: STUDY00032881

Go to forms menuPrintHelp

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.

Exit

Save

Continue

Research Locations –Research Sites

RAPPORT
Dartmouth Research Portal

ValidateCompare<<

Basic Study Information

External IRB

Study Funding Sources

Study Team Members

Study Scope

Research Locations

Local Site Documents

You Are Here: External IRB Test study

Editing: STUDY00032881

Research Sites

1. Identify each site where the investigator will conduct or oversee the research:

+ Add

| Site | Contact | Email | External IRB Review | Rely on CPHS | Reliance Agreement |
|-------------------------------|---------|-------|---------------------|--------------|--------------------|
| There are no items to display | | | | | |

IMPORTANT! This **Research Sites/Locations** page always appears. **Complete this page if you answered YES to Question 3** on the previous **Study Scope** page.

Study with external sites-study scope



Answer **YES** to **Question 3** on the **Study Scope** page if there are external sites where the investigator will conduct or oversee the research.

Validate

Compare

<<

Basic Study Information

External IRB

Study Funding Sources

Study Team Members

Study Scope

Research Locations

Local Site Documents

Research Setting

You Are Here: External IRB Test study

Editing: STUDY00032881

[Go to forms menu](#) [Print](#)

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](#)



Study with external sites- Research Sites/Locations page



Validate

Compare

<<

Basic Study Information

External IRB

Study Funding Sources

Study Team Members

Study Scope

Research Locations

Local Site Documents

You Are Here: External IRB Test study

Editing: STUDY00032881

Research Sites

1. Identify each site where the investigator will conduct or oversee the research:

+ Add

Site

Contact

Email

External IRB Review

Rely on CPHS

Reliance Agreement

There are no items to display

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

OK

OK and Add Another

Cancel

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

Validate

Compare

<<

Basic Study Information

External IRB

Study Funding Sources

Study Team Members

Study Scope

Research Locations

Local Site Documents

You Are Here: External IRB Test study

Editing: STUDY00032881

Research Sites

1. Identify each site where the investigator will conduct or oversee the research:

+ Add

| Site | Contact | Email | External IRB Review | Rely on CPHS | Reliance Agreement |
|---------------|------------|---------------------|---------------------|--------------|--------------------|
| Research Site | Jane Smith | js@researchsite.edu | yes | no | |

Click **Save**. Click **Continue** to move to the next page.

✕ Exit

💾 Save

Continue ➔

Local Site Documents page

Validate Compare

Basic Study Information

External IRB

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Study Scope

Research Locations

Local Site Documents

Research Setting

You Are Here: External IRB Test study

Editing: STUDY00032881

Local Site Documents

1. Consent forms: (include an HHS-approved sample consent document, if applicable)

+ Add

| Document | Category | Date Modified | Document History |
|-------------------------------|----------|---------------|------------------|
| There are no items to display | | | |

2. Recruitment materials: (add all material to be seen or heard by subjects, including ads)

+ Add

| Document | Category | Date Modified | Document History |
|-------------------------------|----------|---------------|------------------|
| There are no items to display | | | |

3. Other attachments:

+ Add

| Document | Category | Date Modified | Document History |
|-------------------------------|----------|---------------|------------------|
| There are no items to display | | | |

- 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

You Are Here: 📁 Study (Test)

Editing: STUDY00032880

◀ Go to forms menu 🖨️ Print ▾ ? Help

Research Setting

1. * Does this study involve any sites outside of the United States where research is being done under your purview?

☐ Yes ☐ No [Clear](#)

2. * Is this a clinical trial?

☐ Yes ☐ No [Clear](#)

Click **Save**. Click **Continue** to move to the next page.

✕ Exit 📁 Save **Continue ➡**

Final Page

≡ Validate Compare <<

Basic Study Information

External IRB

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Study Scope

Research Locations

Local Site Documents

Research Setting

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**.

Add Comment

ⓘ

Your comment is visible to anyone with access to this submission.

1. Comment:

2. Supporting documents:

+ Add

| Name | Description |
|--------------------------------|-------------|
| There are no items to display. | |

3. Who should receive an e-mail notification? ⓘ

☐ PI/PI Proxy/Primary Contact

☐ Study Team

☒ IRB Coordinator

✕ Exit

💾 Save

Finish

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

Pre-Submission

Last updated: 1/15/2024 9:59 AM

Next Steps

Edit Study

Printer Version

Submit

Assign Primary Contact

Assign PI Proxy

Manage Ancillary Reviews

Manage Guest List

Add Related Grant

Add Comment

Discard

Send Notification to PI

STUDY00032880: Study (Test)

Principal investigator: ERA testpiseven

Submission type: Initial Study

Primary contact: ERA testpiseven

PI proxies:

IRB office: CPHS

IRB analyst:

Financial Interest: No

To submit to CPHS office:

- Click the "SUBMIT" arrow (left side of screen)
- On the next screen, finalize by clicking "OK"

To Submit to CPHS office:

1. Click the **SUBMIT** arrow (left side of screen)
2. On the next screen, finalize by clicking **OK**.

Filter by ?

Activity ▾

Enter text to search



+ Add Filter

✕ Clear All



| Activity | Author | Activity Date |
|---------------|------------------|-------------------|
| Study Created | testpiseven, ERA | 1/11/2024 9:37 AM |

Submit activity

The screenshot displays the RAPPORT Dartmouth Research Portal interface. The top navigation bar includes 'Dashboard', 'IRB', 'Submissions', 'Meetings', 'Library', 'Reports', and 'Help Center'. The main content area is titled 'IRB > Study (Test)' and features a 'Pre-Submission' section with a 'Last updated: 1/15/2024 9:59 AM' timestamp. A 'Next Steps' sidebar on the left lists actions such as 'Edit Study', 'Printer Version', 'Submit', 'Assign Primary Contact', 'Assign PI Proxy', 'Manage Ancillary Reviews', 'Manage Guest List', 'Add Related Grant', 'Add Comment', 'Discard', and 'Send Notification to PI'. The main content area also shows 'Principal investigator', 'Submission type', 'Primary contact', and 'PI proxies'. A 'Financial Interest' section is partially visible. A modal window titled 'Execute "Submit" on STUDY00032880 - Google Chrome' is open, displaying a 'Submit' button and a confirmation message: 'By signing below you are verifying that:'. The confirmation message lists three items: 'You have obtained the financial interest status ("yes" or "no") of each research staff.', 'You have obtained the agreement of each research staff to their role in the research.', and 'You will conduct this Human Research in accordance with requirements in the CPHS SOP.'. At the bottom of the modal, there are 'OK' and 'Cancel' buttons. A large green arrow points from the 'Submit' button in the sidebar to the 'OK' button in the modal.

RAPPORT Dartmouth Research Portal rap_irb10

Dashboard **IRB**

Submissions Meetings Library Reports Help Center

IRB > Study (Test)

Pre-Submission

Last updated: 1/15/2024 9:59 AM

Next Steps

- Edit Study
- Printer Version
- Submit
- Assign Primary Contact
- Assign PI Proxy
- Manage Ancillary Reviews
- Manage Guest List
- Add Related Grant
- Add Comment
- Discard
- Send Notification to PI

STUDY

Principal investigator
Submission type
Primary contact
PI proxies:

Financial Interest

To submit

- Click the "SUBMIT" button
- On the next screen

History

Filter by ?

Activ...

Stud...

Execute "Submit" on STUDY00032880 - Google Chrome

irb10-rapport.dartmouth.edu/rap_irb10/sd/ResourceAdministration/Activity/form?ActivityType=com.webridge.entity.Entity[OID[ACB93E39F3CE464F9A1563DA1ABE2DE4...]

Submit

By signing below you are verifying that:

- You have obtained the financial interest status ("yes" or "no") of each research staff.
- You have obtained the agreement of each research staff to their role in the research.
- You will conduct this Human Research in accordance with requirements in the CPHS SOP.

OK **Cancel**