RAPPORT
CPHS Study Submission Guide

September 2016

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Logging in to RAPPORT

To log in to RAPPORT, enter your NetID and enter your Dartmouth password In the Password field. If you have forgotten your NetID or password, use the links below the login field in RAPPORT or contact the CPHS office for assistance.

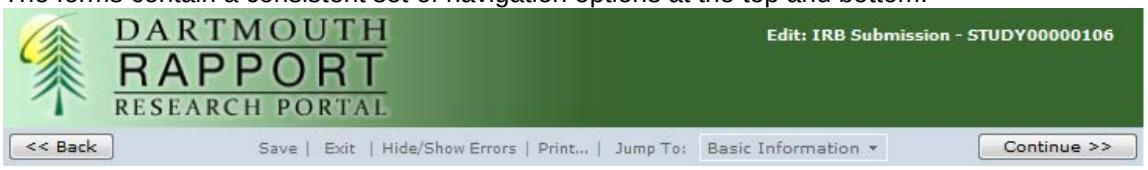
RAPPORT is secure, which means only authorized individuals have access to it. When you log in to the system, you get a personalized view of the information and possible actions pertinent to you.

Creating a New Study

You can prepare a new study for CPHS review by entering information into a series of online forms, or SmartForms. The number of forms included may change based on the answers you provide. The forms tell you where to attach files to provide supporting information.

Form Navigation & Saving Options

The forms contain a consistent set of navigation options at the top and bottom.



■**Back:** Displays the previous form without saving your changes. If you are on the first form, you will go back to the previous page where you opened the submission.

■**Save:** Saves your work and stays on the current page.

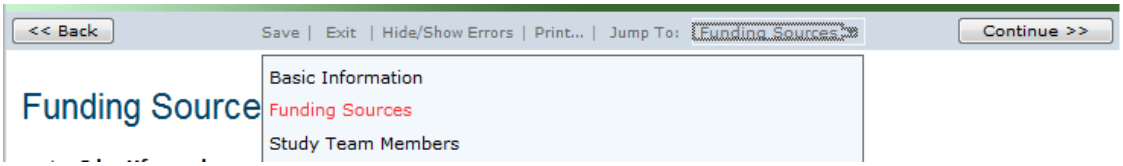
■**Exit:** Closes the current view and moves you back to the study's workspace. If you've made any changes on the current form, the system will prompt you to save them before closing.

■ **Hide/Show Errors:** Checks for problems, usually that a required question was not completed, with the information you've currently saved, and displays the Error/Warning Messages panel at the bottom of your

page. The link next to each problem gives you an easy way to navigate to the view containing the error so you can correct it. Click Refresh to view an up-to-date list of problems after making changes.

■**Print:** Creates a read-only version of the current view and all its values. You can use this option to create a printed copy of an individual view.

■ **Jump To:** Enables you to quickly navigate to each individual view in your project. Click the arrow to view a list of all available views. The red text indicates your current view.
Based on the answers you provided so far, this list is customized to display all views that are relevant to you at any given time. The system will save any values on the current view before jumping to the selected view.



■**Continue:** Checks for answers to all required questions, saves your changes, and moves to the next page. If there are required questions without answers, the view is not saved and the SmartForm does not advance.

Before you begin, gather files and information about your study such as:

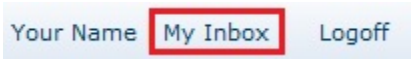
- Supporting information files (for a list, see Checklist of Information to Attach on page 18)
- Financial interest status for each of your study team members
- Contact information and IRB oversight information for external sites involved in the study

Tips: If you regularly create studies with a similar set of team members, you can save time by defining the default team members to be added to each study you create. For instructions, see the online help.

Similarly, you can save time by defining the default list of ancillary reviewers to be added to each study you create. For instructions, see the online help.

To create a new study for review:

1. From My Inbox, click **Create New Study**. 

   Note: If you do not see the Create New Study button, click the **My Inbox** link (upper right).
   

2. Fill in the applicable boxes and answer the questions.

Tip: A red asterisk (*) precedes each question that requires an answer. If you cannot answer a required question at this time, or if you need to stop and continue at a later time, see Form Navigation and Saving Options on page 4. If you do not answer a required question initially, you must return and answer it before you can submit the study for review.

3. Click **Continue** to move to the next form.

4. When you reach the final page, click **Finish** to exit the study.

Tip: When you create a study, you are assigned to be the primary contact who receives all communications from the CPHS. The principal investigator you specified also receives the communications. You can change the primary contact later as described in Changing the Primary Contact on page 7.

You can continue to edit the study until you submit it for review. See Editing a Study on page 6.

Important! The study has not been submitted for review yet. For instructions, see Submitting the Study for Review on page 12.

Editing a Study

You can continue to make changes to a study until you submit it for CPHS review. You can also make changes if the CPHS requests clarifications or modifications.

To edit a study:

1. From My Inbox, click the name of the study to open it.
   Note: If the study does not appear in your inbox, see Accessing a Study on page 14.

2. Click **Edit Study** on the left.

3. Make changes as appropriate.

4. Exit the study.

Tip: Choose one of these ways to exit:

- Click the **Exit** link. If prompted to save the study, click **Yes**.
- Click **Continue** on each form, and then click the **Finish** button on the final form.

Velos Registration

RAPPORT is used to register a study in Velos. If your study requires Velos registration, select Yes to the Velos registration question on the Research Setting page. You will then be directed in the SmartForm to complete an additional page. Once the fields on this page have been completed, you will be provided with the Velos number and the information you have entered can be transferred to Velos.

- Studies for which you have completed the required fields will be automatically transferred to Velos overnight.

- Alternatively, if a study needs to be transferred to Velos sooner, you can make this happen by clicking the **Update Velos** button in the study workspace.

To verify that your study information has been transferred to Velos, go to the Velos Registration page. The box shown below will display the following information if all necessary fields were completed: a Velos number, validation, and the data and time the study was last delivered to Velos.

Example: a study not yet completed or sent to Velos

Velos Number:	Validated:	Last Delivered to Velos:
F14-25958	Never	Never

Example: a study with all necessary fields completed and information sent to Velos

Velos Number:	Validated:	Last Delivered to Velos:
F14-25958	Validated	12/2/2013 9:41 AM EST

Changing the Primary Contact

The study's primary contact for receiving communications from the CPHS can be changed at any time. For example, it may help to provide a contact person in addition to the PI if the PI does not check e-mail frequently.

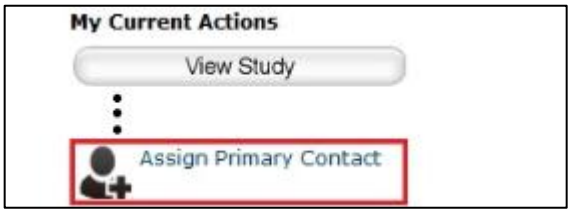
Notes:

- To change the primary contact, you must either be a member of the study team or the IRB coordinator assigned to the study.
- By default, the person who created the study in the system is the primary contact.
- The PI continues to receive notifications regardless of the primary contact assignment.

To change the primary contact:

1. Open the study by clicking the study's name. (For instructions about finding the study, see Accessing a Study on page 14.)

2. Click **Assign Primary Contact** from the My Current Actions list on the left.
   A new window opens.



3. Click **Clear** to remove the current contact.

4. Begin typing the name of the new contact.
   A list of matching names appears.

5. Select the correct name using the mouse or down arrow key.

6. Click **OK**.

Note: If the primary contact is also engaged in the research, make sure the list of team members within the study includes the person.

Note: The primary contact needs to log in to RAPPORT to be able to access this study. If they have a non-Dartmouth or DH organization next to their name, they might not have the rights to log in. If this is the case, contact the CPHS office to confirm their access rights.

Checking the Study for Errors

Checking the study for errors and omissions helps you include all the relevant information, which is critical for receiving a timely review of your study.

Using these types of error checking helps you supply all the information the IRB needs:

- **Automatic system error checking** identifies any omitted answers to required questions on the form when you click Continue. A red asterisk (*****) precedes each blank or question that requires an answer. Keep in mind that the system cannot catch every omission while you edit the study if you skip questions that cause more forms to be added to your study.
- **Visually inspecting the forms** to see what you may have missed, especially:
  - Questions that are relevant to your study but are not required for all studies
  - Documents that should be attached (see Checklist of Information to Attach on page 18)

  To perform a visual inspection, open the study, by clicking **Edit Study** on the left ,and look through the forms in order. **Using the Hide/Show Errors option** to find and correct all errors before submitting the study. The system automatically checks for errors when the PI attempts to submit the study. However, if you are filling out the forms on behalf of the PI, it is best to check the study for errors before the PI attempts to submit it, using the steps below.

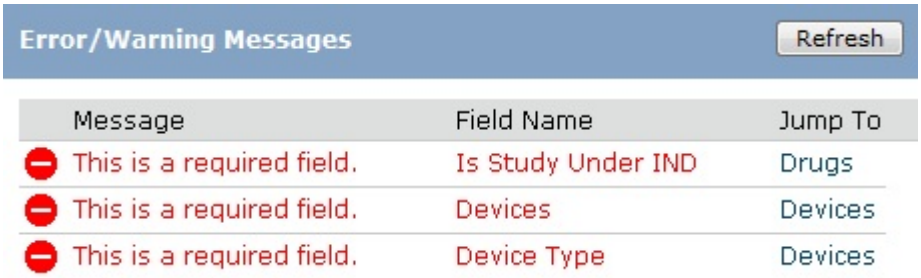
To use Hide/Show Errors to find and correct errors:

1. Open the study Click **Edit Study** on the left.

2. From the top navigation area, click **Hide/Show Errors**.

   The Error/Warning Messages pane appears at the bottom of the window, listing all the current errors and where to find them.



3. For one of the errors listed, click the link in the Jump To column to go to the form containing the error.

4. Click **Continue** to identify the specific questions on the form with errors.

5. Fill in the missing information.

6. Click **Refresh** in the Error/Warning Messages pane to update the list of errors.

7. Continue correcting errors until no errors are listed.

Send to PI for Submission

If you create a study a study on behalf of a PI, you may want to use RAPPORT to send the PI an email to let him/her know that this study is ready to either:

- Be submitted to the CPHS

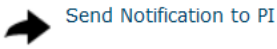
OR

- Have a PI proxy assigned who can submit it to the CPHS (see Assign PI Proxy on page)

To send this email notification to the PI:

1. Click the title of the study to open it.

2. Click **Send to PI** on the left.



3. Click **OK** to accept choice and close this window.

Assign PI Proxy

A PI may assign proxy rights to one or more members of the study team. A proxy can perform PI responsibilities on your behalf, such as submitting the study to the CPHS, modifying the study, and submitting continuing reviews.

To assign a PI proxy:

1. Click the name of the study to open it.

2. Click **Assign PI Proxy** on the left. 

3. The **"Assign PI Proxy"** window will open.

4. Select study team members to act as proxy.

   Note: if the person you wish to assign is not appearing here, that person will need to be added to the study team.
   To add them, click **Cancel** to close this window. Click **Edit Study** on the left.

5. Click **OK** to accept the names selected as proxy and close this window.

   Note: If the Initial Study application has already been approved, a Modification will need to be created to add the study team member to the study. Once the Modification has been approved, the study team member can then be assigned Proxy.

   Note: Proxies, PI's and Primary Contact are sent notifications. As a member of the study team, however, the proxy may always log in and access the study details.

Ancillary Review Overview

The review process for studies, modifications, and continuing reviews optionally includes ancillary reviews. Ancillary reviews allow individuals, departments, and other organizations to give feedback on the submission in parallel with the CPHS review. The system does not prevent a submission from being reviewed or approved by the CPHS with ancillary reviews outstanding. Decisions about how, when, and whether to interrupt the CPHS review process to wait for ancillary reviews are left to CPHS policies and staff.

Ancillary reviews can occur during the **Pre-Submission** state.

Initiating Ancillary Reviews

PI's, and Proxies can add ancillary reviewers to a study, modification, or continuing review as follows:

- PI's and Proxies can add ancillary reviewers to a submission before submitting it for CPHS review.
- PI's and Proxies can add individuals and organizations as reviewers.

Organizations must be set up in advance with specific ancillary reviewers or no one will receive the ancillary review notification for the organization. Any Person selected as an ancillary reviewer will receive ancillary review notification directly. A PI's research profile can be set up with a set of default ancillary

reviewers, such as her department chair, to be included in all new studies (but not modifications or CRs) she creates.

When a study is created, any ancillary reviewers identified in the PI's profile gain access to the study. When the PI, CPHS or Proxy adds more ancillary reviewers, they also gain access. When the study is submitted for CPHS review, the reviewers receive notifications.

Note: Ancillary reviewers identified in the PI's profile are not automatically included in modifications and CRs created by the PI. Any ancillary reviewers must be added manually for each modification and CR.

Notifications and Ancillary Review Feedback

Ancillary reviewers are identified as required or optional by the person adding them to a research profile or an individual submission. A required ancillary reviewer receives the submission in My Inbox, where it remains until the review accepts the submission. An optional reviewer does not see the submission in My Inbox. Both required and optional reviewers receive a notification and can use the Submit Ancillary Review activity to provide feedback.

Ancillary review feedback is visible on the Reviews tab to everyone who can access the submission.

Decisions Regarding Ancillary Review Feedback

Depending on CPHS policies and the individual situation, the CPHS staff may choose to use ancillary reviews in many different ways. For example:

- Letting the CPHS review and approval proceed without the response of a required ancillary reviewer.
- Letting the CPHS review proceed, but waiting for an required ancillary reviewer response before approving the submission.
- Pausing the CPHS review process at any point until the required ancillary reviewers respond. This may involve forcing completion of the ancillary review by requesting clarifications or modifications from the study team (to officially put the submission back in the study team members' inboxes).

Discarding a Submission

If you realize that a new submission, whether an initial study, modification or continuing review, has been created in error, you may use the Discard activity. This will archive this submission and no further actions can be performed on it. To discard a study, click the Discard button in the study workspace.

Note: you can only discard a study before it has been submitted to the CPHS, while still in the the Pre-Submission state. Once it has been submitted, you must Withdraw it to remove it from CPHS review and return it to the Pre-Submission state, and then Discard it. See Withdrawing a Study on page 16.

Submitting the Study for Review

After entering all required information into the forms and attaching files, the principal investigator or PI proxy must **Submit** the study to the CPHS for review.

Tips:

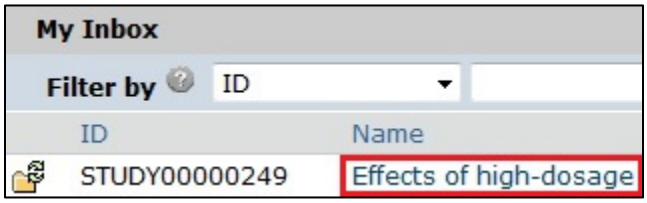
- Make sure you attach all applicable information to the study, as identified in Checklist of Information to Attach on page 18.
- Check for missing information before attempting to submit the study, as described in Checking the Study for Errors on page 8. Any errors or omissions not corrected are shown when attempting to submit the study and must be corrected before you can submit it for review.
- Identify any person or organization outside the CPHS who needs to review the study. Add them to the list of ancillary reviewers by clicking Manage Ancillary Reviews. For instructions, see the online help.

Important! Only the principal investigator or PI Proxy for this study can complete the following steps.

To submit the study for CPHS review:

1. Log in to the system.

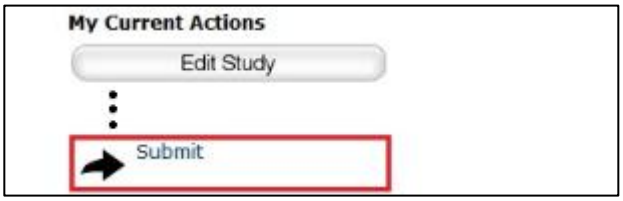
2. Make sure you are in My Inbox.
   Note: If you do not see My Inbox, click the **My Inbox** link (top right part of the page).



3. Click the name of the study to open it.

   Tip: If the study does not appear in the list, perhaps it was already submitted, or it does not include you as a study team member. To find the study, try clicking **IRB** in the top left navigation area. If you do not see it in that list, see Accessing a Study on page 14 for more ideas.

4. Click **Submit** from the My Current Actions list on the left.



   Tip: If any errors or warnings are shown, click the link in the Jump To column to go to the form containing the problem. For more information, see Checking the Study for Errors on page 8. When all errors are corrected, try submitting the study by clicking Submit again.

What to Expect After Submitting

Submitting information to the CPHS initiates a series of activities that may include:

- Review within your department
- Pre-review by a CPHS staff member
- Review by the CPHS committee or a designated reviewer
- Communication of the CPHS decision to the investigator

Any of these may lead to a request for the investigator to take further action, such as providing clarifications or modifying the study. **Whenever you need to act, you receive an e-mail notification, and the study appears in My Inbox when you log in to RAPPORT.**

Important! Make sure the appropriate person is listed as the primary contact to receive the e-mail and see the study in My Inbox (along with the PI, who always receives these). By default, the person who created the study is the primary contact. See Changing the Primary Contact on page 7.

Checking the Status of Your Study

You can see the state your study by finding it one of the following lists:

- My Inbox
- IRB In-Review Studies
- IRB Active Studies

You can also see a diagram showing the state of your study within the CPHS review process by opening the study. For example:

For instructions about opening your study from these lists, see Accessing a Study on page 14.

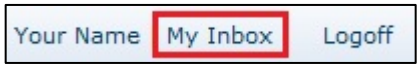
Accessing a Study

You may want to open a specific study to view or update its contents, submit it for review, review it, or take other actions on the study.

Note: Your access to a study is personalized based on your role in the system and the role you play in relation to the particular study. In addition, the actions you can take on a study are personalized.

To open a study, click its name when you find it in a list of studies.

To find a list that includes the study, try these suggestions:

Check this list...	For...	How to find this list
My Inbox	Studies assigned to you for action, such as a study you are: ▪ Preparing to submit ▪ Assigned to review	Click the **My Inbox** link in the top right navigation header. 
IRB In-Review tab	Studies the IRB has not reviewed or for which it has not communicated a	Click **IRB** in the top left navigation area and select the **In-Review** tab.

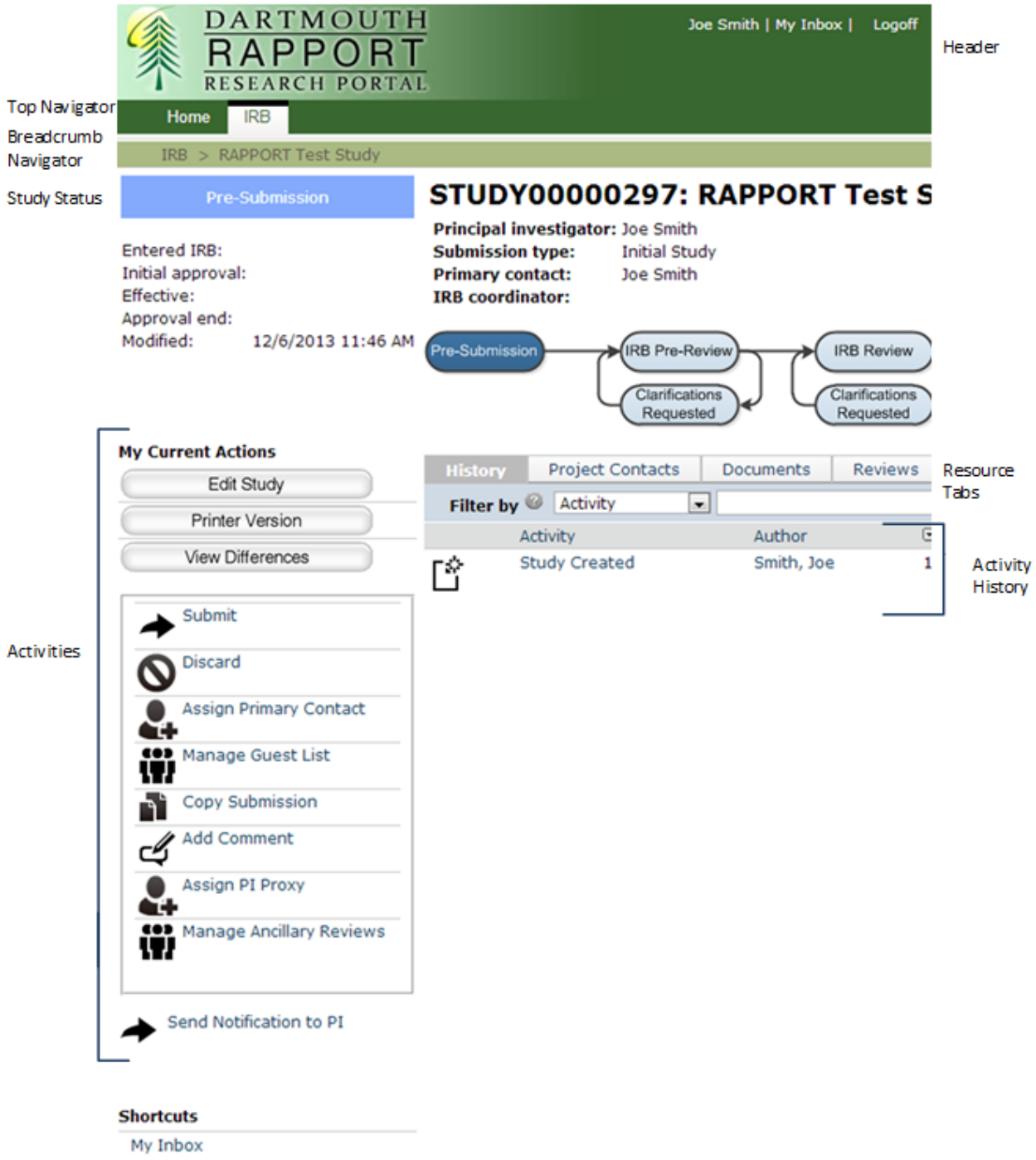
Check this list...	For...	How to find this list
	decision	
IRB Active tab	Studies approved by the IRB and currently in progress	Click **IRB** in the top left navigation area and select the **Active** tab.
IRB All Submissions tab	All studies, continuing reviews, modifications, and reportable new information (RNI) entered into the system that you have permissions to view	Click **IRB** in the top left navigation area and select the **All Submissions** tab. **Tip:** Try filtering this list by the study name or principal investigator. Next to Filter by, select **Name** or **Investigator**. Then type the beginning of the name and click **Go**.
IRB New Information Reports tab	Reportable new information (RNI) submissions, possibly related to one or more studies	Click **IRB** in the top left navigation area and select the **New Information Reports** tab.

Navigation Elements within a Study

Once you open a study, you see the study workspace. The workspace is your access point for:

- Viewing the study contents and details, including all actions performed on it
- Performing actions on the study

The figure below identifies the key workspace elements that help you find your way around RAPPORT and perform actions on the study.



The key elements shown (from top to bottom) are:

- **Header:** Provides links to your profile and to My Inbox, and lets you log off
- **Top navigator:** Provides links to the major sections of the system you are allowed to access
- **Breadcrumb navigator:** Tracks your movement through the hierarchy of pages and enables you to quickly move back to a previous location
- **Study Status:** This shows the current status of the study. Approval and expiration dates are found beneath the study status.
- **Activities:** Lets you take appropriate actions—such as viewing the study—based on the study's current status
- **Resource tabs:** Gives access to collected study information, such as the study team membership, documents attached to the study, and older versions of the study.
- **Activity history:** Displays the actions taken previously on this study
- **Shortcuts area:** Provides quick links to other frequently used areas of the system, and to documentation resources

Withdrawing a Study

After a study has been submitted to the CPHS, it can be withdrawn from review by accessing the study workspace. Click the Withdraw button in the study workspace and enter any relevant comments. The study will be returned to the Pre-Submission state where you can choose to change and resubmit it.

Responding to a Request for Clarifications or Modifications

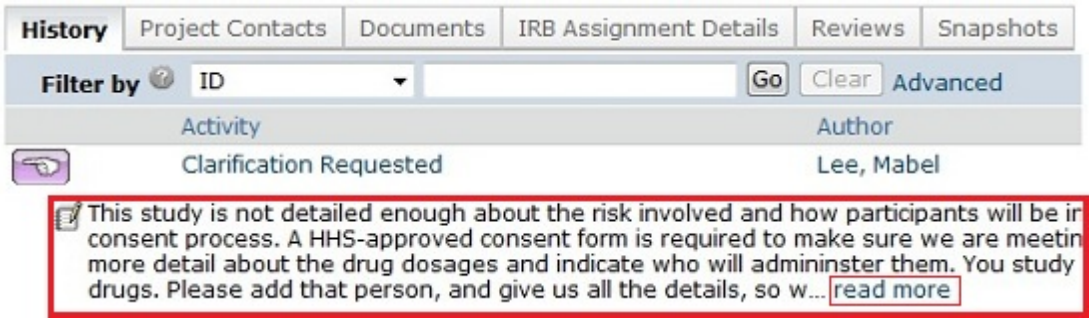
At any stage during the review process, the CPHS may request clarifications to the study content. Similarly, the official CPHS determination may be that the study requires changes before research can begin.

Both situations require the study staff to take similar actions. In either case, the PI and the study's primary contact receive an e-mail, and the study appears in My Inbox for each member of the study team.

To view the details of the request and respond with the changes:

1. From My Inbox, click the name of the study to open it.

2. Locate the details of the request, as described here:
   For clarification requested: In the Activity column under Clarification Requested, read the request details.



If applicable, click the **read more** link to display the remaining text.

For modifications required: Click the letter link near the top of the page on the right side. The letter contains the modification requirement details.

3. Edit the study to incorporate changes as needed. For instructions, see Editing a Study on page 6.
   Notes:
   - In most cases, you can update all aspects of the study, including adding or removing attached documents.
   - If clarifications were requested during committee review, you cannot edit the study, and you see the View Study button instead. In that case, respond to the reviewer by commenting in the Submit Response form, as described in the next step

4. Click **Submit Response** to return the study to the reviewers.
   Notes:
   - The Submit Response form gives you space to type a point-by-point response to the requests and to attach a file. However, any permanent study information should be incorporated into the study itself.

5. Click **OK**.

The study returns to its previous state in the review process.

Submitting Modifications, Continuing Reviews and Reporting New Information

The table below summarizes how to get started submitting each type of information to the IRB.

To submit this type of information...	...start here...	...and click this button	Notes
Continuing review (renewal) updates for an active study	From the Active tab, click the study name (see Accessing a Study on page 14)	Create Modification / CR	You can submit a continuing review and a modification at the same time. The first form prompts you to identify the type of information to submit. To request study closure, submit a CR. Based on the research milestones completed, the study may be closed.
Modifications (revisions) to an active study			
Request to close study			

To submit this type of information...	...start here...	...and click this button	Notes
New information or an adverse event report	For new information about a particular study, start from the Active tab and click the study name (see Accessing a Study on page 14) For information affecting multiple studies, start in My Inbox	Report New Information	Report new information as soon as you become aware of it. The form identifies the types of information you must report.
New study for review	My Inbox	Create New Study	See Creating a New Study on page 4.
Updates to a new study that hasn't been submitted for CPHS review yet	Within the study (see Accessing a Study on page 14)	Edit Study	See Editing a Study on page 6.

Checklist of Information to Attach

Be prepared to attach several files to your study. While editing the study, several forms provide places to attach related files. In some cases, a template file is provided, such as for the protocol.

When attaching each file, name it as you want it to appear on the CPHS approval letter.

Attach the information listed below (if relevant to your study) to the location identified.

Protocol: **(Basic Information** page) **Choose one option below**

- Sponsor Protocol and CPHS Protocol Plus
- CCRC Protocol and CPHS Protocol Plus
- Social, Behavioral, and Non-Clinical Research Plan
- Data, Specimens, and Registries Research Plan
- Exempt Application
- Not Human Subjects Research Application

Funding information: (Funding Sources page, with each source)

- Grant applications

Drug details: (Drugs page, with each drug, or on main Drugs page if not specific to one drug)

All Drug attachments must be attached on the Supporting Documents Page

Device details: (Devices page, with each device, or on main Devices page if not specific to one device)

All Device attachments must be attached on the Supporting Documents Page

Recruitment and consent details: (Recruitment Materials page)

- Consent documents:
  - Consent forms
  - Assent forms
  - Model Consent Forms
  - For non-written consent, a script of the information provided orally to the subjects
  - Requests for Waivers or Alterations of Consent
- All material to be seen or heard by subjects, such as:
  - Evaluation instruments and surveys
  - Advertisements, including printed, audio, and video
  - Recruitment materials and scripts
  - Foreign-language versions of materials for subjects

All other relevant documents: (Supporting Documents page)

- Certificates of Confidentiality
- Correspondence Templates
- Device Product labeling/instructions
- Drug and Device Investigator Brochures
- Drug Package Inserts
- DSMB Reports
- Investigator Protocol Attachments
- Participant Guides
- Progress Reports
- Retention Materials
- Surveys and Questionnaires
- Verification of each IDE or HDE number
- Verification of each IND number

Contacting Support

For additional answers to your questions, feel free to use the following resources:

Resource	How to access it
Documentation	See Finding More Information on page 4
Training materials on the web site	http://www.dartmouth.edu/~cphs/tosubmit/rapporteducation.html
CPHS support staff	E-mail: CPHS.Tasks@dartmouth.edu Phone: 603-646-6482