HURON

Click® IRB

Study Submission Guide

October 2016

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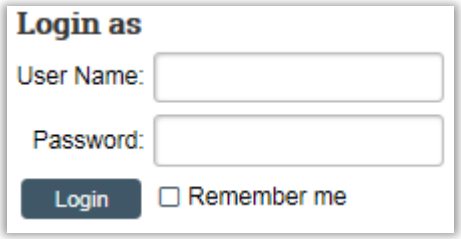
Logging In

The IRB system 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.

To log in:



1. If you do not see the form shown to the right, click the **Login** link located at the top right corner of your screen.
2. Type the user name and password you received into the boxes.

Tips: Press the Tab key after typing your user name to move to the Password box.

If you do not know your user name or password, contact the IRB for assistance. (See Contacting Support on page 18.)

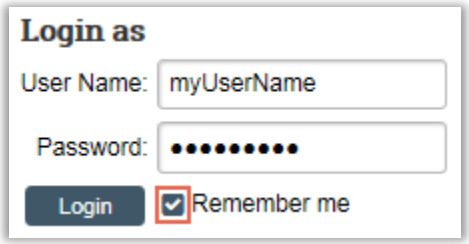
3. Click **Login** (or press Enter).

Automatically Logging In

You can set the IRB system to log you in automatically when you access the IRB web site.

Important! Do not enable autologin if you are using a shared or public computer. Autologin could cause a security breach by allowing others to take actions as though they were you.

To turn on autologin:



1. The next time you log in, check the **Remember me** box before clicking Login.

To turn off autologin:

1. Click the **Logoff** link in the upper right corner.
2. Click **Logoff**.
3. Click **Clear Autologin** (or **Clear All Autologin**).

Creating a New Study

You can prepare a new study for IRB review by entering information into a series of online forms. 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.

The simplest approach is to follow the forms in order, answering the questions and clicking Continue to save your information and move to the next form. When you reach the end of the series of forms, click the Finish button.

Note: A continuing review, modification, or RNI (reportable new information) submission can be handled similarly to a study. For differences, see Submitting Continuing Reviews and New Information on page 15.

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 17)
- 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.

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

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 **My Inbox** in the top navigator.

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

   Tip: When you create a study, you are assigned to be the primary contact who receives all communications from the IRB on behalf of the study team. (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 9.

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

   Tip: A red asterisk (*) precedes each question that requires an answer. If you do not answer a required question initially, you must return and answer it before you can submit the study for review.

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

You can continue to edit the study until you submit it for review. See Editing a Study on page 5.

Important! The study has not been submitted for review yet. For instructions, see Submitting the Study for Review on page 7.

Finding More Information

Resource	Description	How to Access It
Help for a field or page	More information about a question or form.	Click ? next to the question or at the top of the form.
IRB Study Submission Guide	Instructions for submitting a study for review.	1. Click the **Help Center** link on the left. 2. On the Guides tab, click the name of the guide to open it.
IRB Study Reviewer's Guide	Instructions for reviewing an IRB submission.	
IRB Staff Administration Guide	An overview of the IRB review and administration process.	
IRB Library	Document templates, checklists, and IRB procedures.	Click the **Library** link on the left.

Editing a Study

You can continue to make changes to a study until you submit it for IRB review. You can also make changes if the IRB requests clarifications (except during committee review) 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 10.
2. Click **Edit Study** on the left.
3. Make changes as appropriate. When updating a study document previously submitted to the IRB, revise it in tracked-changes format and replace the original document with the tracked-changes version. When the IRB approves the document, all tracked changes will be accepted and comments removed in the final version.
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.

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:

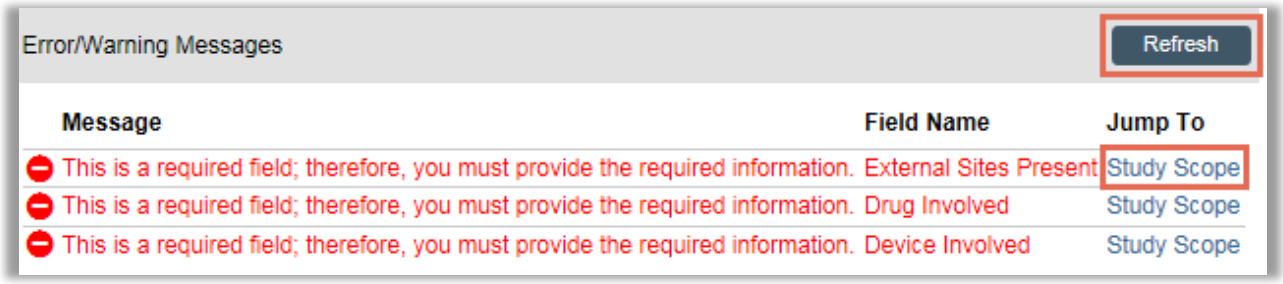
- **Automatic system error checking** identifies any omitted answers to required questions on the form when you click Continue. A red asterisk (*) precedes each blank or question that requires an answer. Keep in mind that the system cannot catch every omission while you edit the study if you skip questions 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 17)

  To perform a visual inspection, open the study and look through the forms in order. To open the study, see Editing a Study on page 5.
- **Using the Hide/Show Errors option** to find and correct all errors before submitting the study. The system displays a warning at the top of the page if you try to move to another page of the study or save the study without completing all required fields. However, it is possible to exit a study without completing all required information. Further, 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, as explained in Editing a Study on page 5.
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.

Submitting the Study for Review

After entering all required information into the forms and attaching files, the principal investigator must submit the study for IRB review.

Tips:

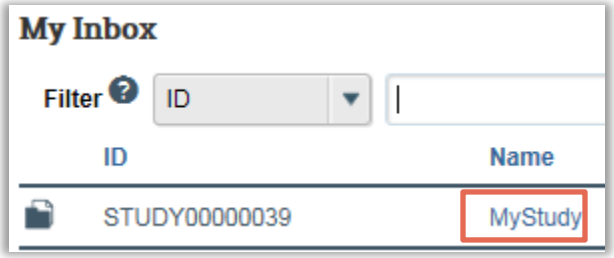
- Make sure you attach all applicable information to the study, as identified in Checklist of Information to Attach on page 17.
- Check for missing information before attempting to submit the study, as described in Checking the Study for Errors on page 6. Any errors or omissions not corrected are shown when attempting to submit the study and must be corrected before you can submit it for review.
- Identify any person or organization outside the IRB who needs to review the study. Add them to the list of ancillary reviewers by clicking Manage Ancillary Reviews.

To submit the study for IRB review:

Important! Only the principal investigator can complete the following steps.

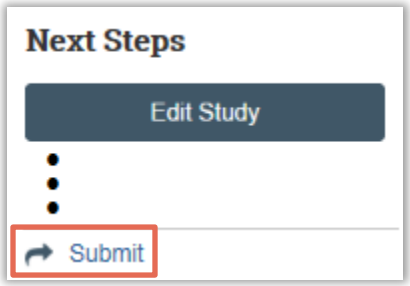
1. Log in to the system.
2. Make sure you are in My Inbox.

   Note: If you do not see My Inbox, click **My Inbox** in the top navigator.
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 navigator . If you do not see it in that list, see Accessing a Study on page 10 for more ideas.

4. Click **Submit** from the Next Steps 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 6. When all errors are corrected, try submitting the study by clicking Submit again.

5. Click **OK** to agree to the statement presented on the screen.
6. When prompted, log in again to verify your identity as the study's PI.
7. Click **Submit**.

What to Expect After Submitting

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

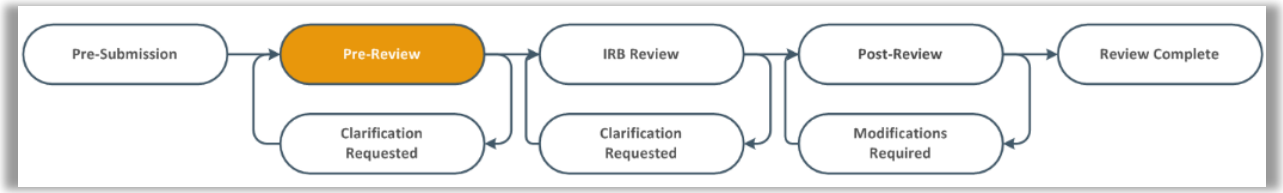
- Review within your department
- Pre-review by an IRB staff member
- Review by the IRB committee or a designated reviewer
- Communication of the IRB decision to the investigator

Any of these may lead to a request for the study team to take further action, such as providing clarifications or modifying the study. **Whenever the study team needs to act, the PI receives an e-mail notification, and the study appears in My Inbox for all study team members when they log in to the IRB system.**

Important! Make sure the appropriate person is listed as the primary contact to receive e-mail and see the study in My Inbox (along with the PI and any PI proxies, who also receive these). By default, the person who created the study is the primary contact. See Changing the Primary Contact on page 9.

Checking the Status of Your Study

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



You can easily open your study from one of the following lists (depending on its status):

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

For instructions about opening your study from these lists, see Accessing a Study on page 10.

Changing the Primary Contact

The study's primary contact for receiving communications from the IRB 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.

The primary contact can also edit the study just as a study team member can.

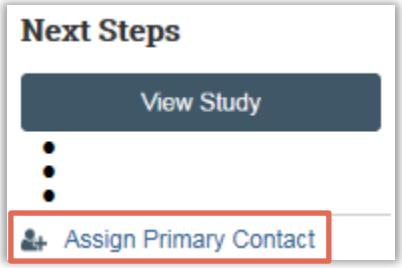
Notes:

- To change the primary contact, you must 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 and any PI proxy continue to receive notifications regardless of the primary contact assignment.
- Modifications or continuing reviews have the same primary contact as the initial study. To change the primary contact on these submissions, do so in the initial study.

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 10.)
2. Click **Assign Primary Contact** from the Next Steps list on the left.

   A new window opens.



3. Roll over the **Clear** button and click it 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.

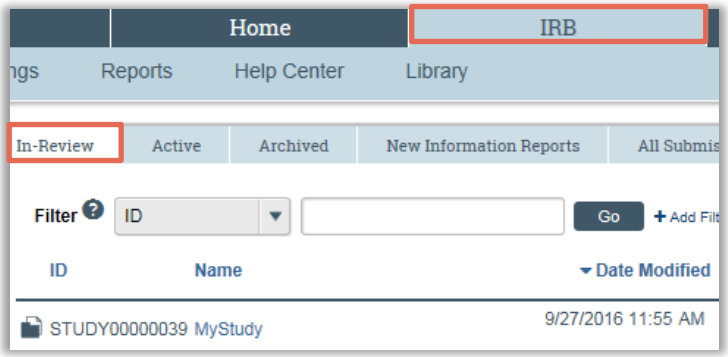
Accessing a Study

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 **My Inbox** in the top navigator . 
IRB In-Review tab	Studies the IRB has not reviewed or for which it has not communicated a decision	Click **IRB** in the top navigator and select the **In-Review** tab. 
IRB Active tab	Studies approved by the IRB and currently in progress	Click **IRB** in the top navigator 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 navigator and select the **All Submissions** tab. **Tip:** Try filtering this list by the study name or principal investigator. Next to Filter, select **Name** or **Investigator**. Then type the beginning of the name and click **Go**. For more information, see Filtering and Sorting Data on page 11.
IRB New Information Reports tab	Reportable new information (RNI) submissions, possibly related to one or more studies	Click **IRB** in the top navigator and select the **New Information Reports** tab.

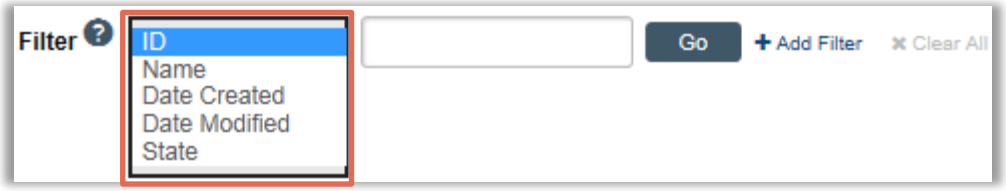
Filtering and Sorting Data

Many pages contain tables you can filter and sort to help you find the data you want.

- Filtering reduces the list to only the data that meets the criteria. You can also combine multiple filter criteria.
- Sorting displays the data in ascending or descending order by a particular column.

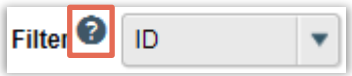
To filter data:

1. Select the column to filter by from the drop-down menu. The menu lists only the columns you can filter by. **Note:** To combine multiple filter criteria, such as, ID, name, **and** Date Created, use the add filters feature.



2. In the next box, type the beginning characters for the items you want to find. If you do not know the beginning characters, type a % symbol as a wildcard before the characters. Examples:
   - 71 shows all items beginning with 71
   - %71 shows all items containing 71 in any position

Tip: For examples and a list of operators you can use, click the Help icon.



3. Click **Go** to apply the filter.

   The table shows only those rows that are an exact match.

Tip: If you do not see the expected items in the list, click **Clear All** in the Filter area to remove the filter.

To use multiple filters:

1. In the Filter area, click **Add Filter**.

2. Enter filter criteria as explained in the previous section.
3. Click **Go** to apply the filters.

The table shows only those rows that match all the filter criteria.

To sort data:

Click the column header you want to sort by. Click it a second time to reverse the sort order. The arrow indicates the column by which the data is sorted and the sort order, either ascending (up arrow) or descending (down arrow). **Note:** If the column header is not a link, you cannot sort by that column.

Responding to a Request for Clarifications or Modifications

At any stage during the review process, the IRB may request clarifications to the study content. Similarly, the official IRB 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, any PI proxy, and the study's primary contact receive an e-mail. The study also appears in each study team member's Inbox.

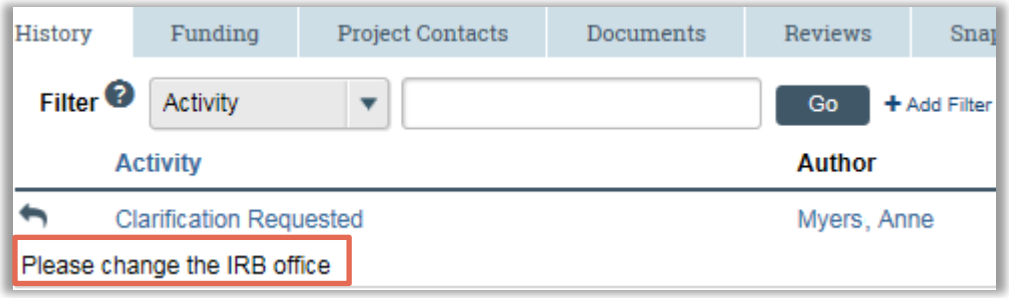
Important!

- Any study team member can update the study, but only the PI can submit the response to the IRB.
- Failure to respond promptly slows the review and approval process for your submission. In some cases, your submission may be rescheduled for review at a later IRB meeting because the committee requires your response before making a decision.

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

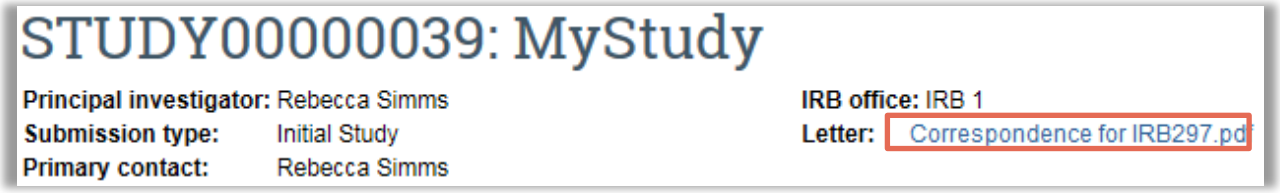
1. From My Inbox, click the name of the study to open it.
2. Locate the details of the request, as described here:

   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 5.

   Notes:

   - In most cases, you can update all aspects of the study, including adding, updating, or removing attached documents.
   - When updating a study document previously submitted to the IRB, revise it in tracked-changes format and replace the original document with the tracked-changes version. When the IRB approves the document, all tracked changes will be accepted and comments removed in the final version.
   - 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. (PI only) 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.
   - If clarifications were requested during committee review, you may be asked to make changes to the study after the review is complete.
   - For an RNI submission, click Submit RNI Response instead.

5. Click **OK**.

The study returns to the review process.

For information about completing an action plan for an RNI submission, see Responding to Action Required on page 15.

Changing Documents on Your Study

Note: The procedures in this section assume the documents on your study are Microsoft Word format.

You may need to modify a study's documents when:

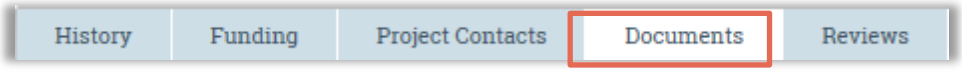
- The IRB requires changes prior to approval.
- Submitting a modification to an approved study.

To change documents prior to study approval:

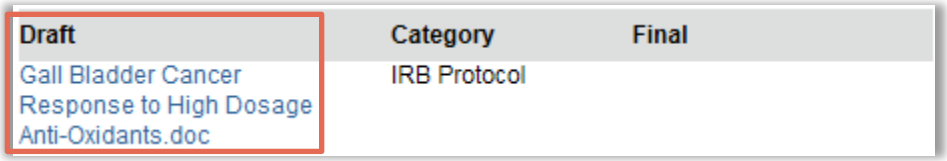
Note: These steps apply if the IRB decision was modifications required, disapproved, or deferred.

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

2. Click the **Documents** tab.



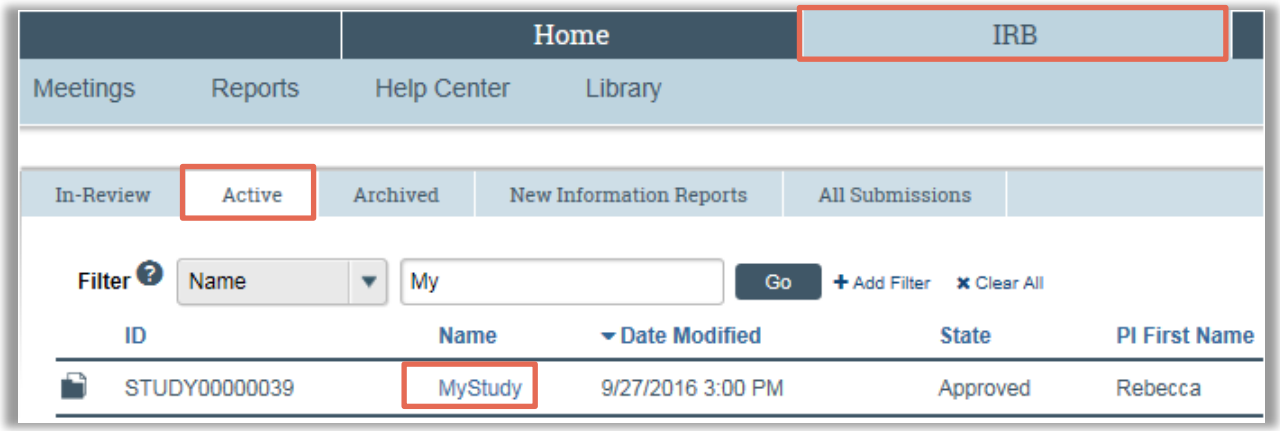
3. Click the document in the Draft column and save it to your computer.



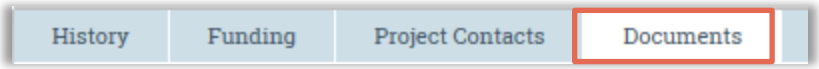
4. Open the document.
5. Enable the Track Changes feature and update the document.
6. When finished, replace the original study document with the tracked-changes version. When the IRB approves the document, all tracked changes will be accepted and comments removed in the final version.

To change documents on an approved study:

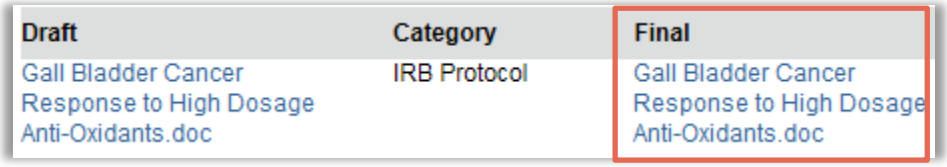
1. Click **IRB** in the top navigator and select the **Active** tab.



2. Click the name of the approved study.
3. Click the **Documents** tab.



4. Click the document in the Final column and save it to your computer.



Tip: In some cases, you may only be able to use the draft document because the final document is a PDF. In this case, the draft document may contain tracked changes and comments. To make its content match the final PDF, use the review features in Microsoft® Word to accept all the changes and remove any comments. Use this clean document as a starting point for your revisions.

5. Open the document and revise it in tracked-changes format.
6. When finished, replace the original document with the tracked-changes version in the modification. When the IRB approves the document, all tracked changes will be accepted and comments removed in the final version.

Submitting Continuing Reviews and 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 updates for an active study	From the Active tab, click the study name (see Accessing a Study on page 10)	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 to an active study			
Request to close study			
New information or an adverse event report	My Inbox 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 IRB review yet	Within the study (see Accessing a Study on page 10)	Edit Study	See Editing a Study on page 5.

Responding to Action Required

After reviewing a new information report (or adverse event), the IRB may require specific actions to be taken in response to the reported issue. A responsible party is assigned to complete the action.

The system sends e-mail to notify the responsible party, the submitter of the RNI (reportable new information), as well as the PIs, PI proxies, and primary contacts of all related studies. The RNI also appears in My Inbox for the responsible party.

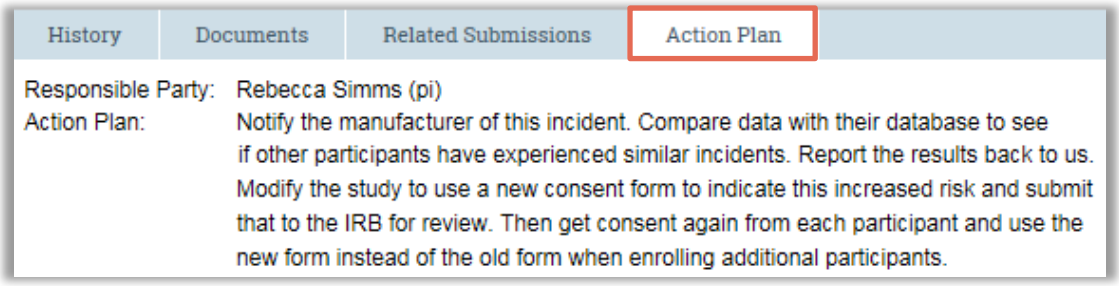
To view the action plan and respond to the IRB:

1. From My Inbox, click the name of the RNI submission to open it.
2. View the details of the RNI submission and the action plan, as described here:

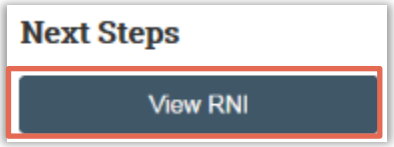
   Read the letter: Click the letter link near the top of the page on the right side. The letter typically contains the action plan and a summary of the IRB's decisions.

   Review the action plan: Click the **Action Plan** tab and read the action plan listed there, plus any history of the action plan that might be helpful.

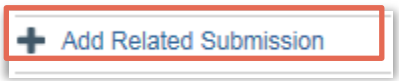
   

   Review the RNI submission details: If you aren't already familiar with the details of the information report, read it by clicking **View RNI** on the left side.

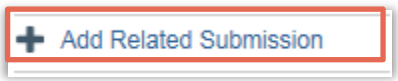
3. Take action inside or outside the system to complete the action plan.

   Tip: You can add related studies to the RNI submission to indicate that the information report applies to the studies. From the RNI submission, click **Add Related Submission** on the left.

   If the action plan requires a change to a study, create a modification and submit it for review as mentioned in Submitting Continuing Reviews and New Information on page 15. Then return to the RNI and add the modification using Add Related Submission. The study being modified must be added as a related submission before the modification can be added.

4. Click **Submit Action Response** to indicate that the action plan is complete.

   The Submit Action Response form gives you space to type notes and attach a file. Summarize the actions taken to resolve the reported issue and complete the action plan.

5. Click **OK**.

The RNI submission is returned to the IRB to verify completion of the action plan.

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 IRB approval letter.

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

Protocol: (Basic Information page)	
▪ Investigator protocol ▪ Complete sponsor protocol ▪ Site supplement to sponsor protocol	▪ HHS (Department of Health and Human Services) protocol
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)	
▪ Package insert ▪ Investigator brochure	▪ Verification of each IND number (one of these): o Sponsor protocol with the IND number o Communication from the FDA or sponsor with the IND number
Device details: (Devices page, with each device, or on main Devices page if not specific to one device)	
▪ Product labeling/device instructions ▪ Investigator brochure	▪ Verification of each IDE or HDE number (one of these): o Sponsor protocol with the IDE / HDE number o Communication from the FDA or sponsor with the IDE / HDE number
Recruitment and consent details: (**Recruitment Materials** page)	
▪ Consent documents: o Consent forms o HHS-approved consent document o For non-written consent, a script of the information provided orally to the subjects	▪ All material to be seen or heard by subjects, such as: o Evaluation instruments and surveys o Advertisements, including printed, audio, and video o Recruitment materials and scripts o Foreign-language versions of materials for subjects
All other relevant documents: (Supporting Documents page)	
▪ Conflict of Interest Committee's determination for each financial interest related to the research	▪ Completed checklist of meeting Department of Energy requirements

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 5
Training materials on the web site	ra-project.vprgs.msu.edu
IRB support staff	E-mail: irb@ora.msu.edu Phone: 517-355-2180

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