UVMClick IRB
Study Submission Guide

September 2018

Table of Contents

How to Login

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.

- Navigate to https://irb.connect.uvm.edu/IRB
- You will need a UVM Net ID and password to login successfully.
- Click the green "Login" button.
- Enter your UVM Net ID and password.
- If you do not know your Net ID or your password, contact us for assistance.

How to Create 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.

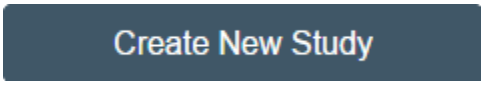
Note: A continuing review, modification, or RNI (reportable new information) submission can be handled similarly to a study. For differences, see Submit Continuing Review and New Information on page 16.

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 19)
- Training and Financial interest status for each of your study team members
- For External Studies: Contact information and IRB oversight info for external sites involved in the study

To create a new study for review

1. From "My Inbox" or the IRB>Submissions screen, Click **Create New Study**.



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 Change the Primary Contact on page 10.

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

   ****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, click the SAVE link at the top of the Smartform. If you do not answer a required question initially, you must return and answer it before you can submit the study to the RPO Office for review.

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

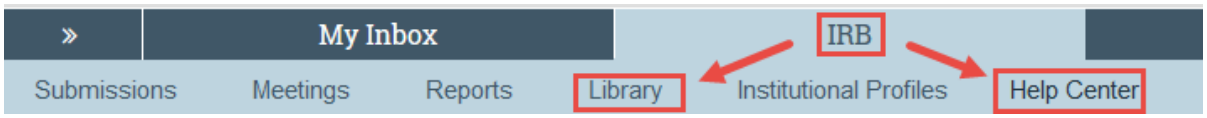
You can continue to edit the study until you submit it for review. See How to Edit a Study on page 6.

Important! The study has not been submitted for review yet. For instructions, see Submit the Study for Review on page 8.

Find More Information

There are Huron Informational Guides, Videos and instructional field level help text that can be found while logged into UVMClick.

Resource	Description	How to Access It
Help for a field or page	More information about a question or form.	Click ? next to the question. Not all questions will have help text.
Help system	The online help contains procedures and information for all users. This includes Guides and any available Videos.	1. Click the **My Inbox > Help Center** link on the left. 
IRB Researcher's Quick Reference 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.
Single IRB Review for Multi-Site Studies	An overview of the single IRB review process for multi-site studies.	1. Click the **Help Center** link on the left. 2. On the **Videos** tab, click the name of the Video to open it.
IRB Library	Document templates, checklists, and IRB procedures.	Click the **Library** link on the left.

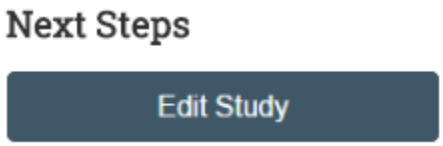


How to Edit a Study

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 Access a Study on page 11.
2. Click the **Edit Study** button on the left under "Next Steps".



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.

Check 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.

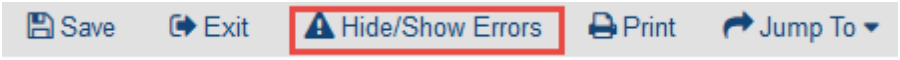
Using these types of error checking helps you supply all the information the IRB needs:

- **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 through advanced branching.
- **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 19)

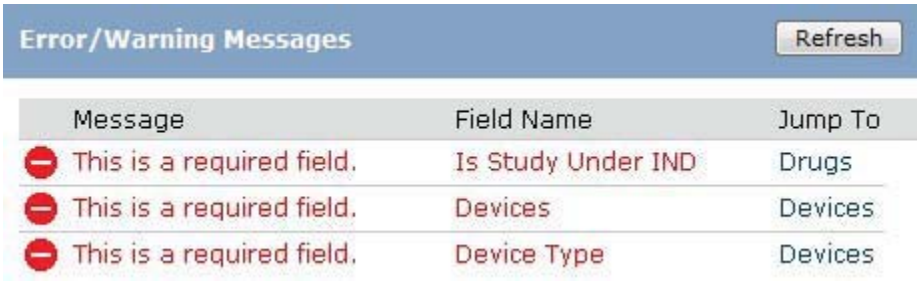
  To perform a visual inspection, open the study and look through the forms in order. To open the study, see How to Edit a Study on page 6.
- **Using the Hide/Show Errors option** to find and correct all errors before submitting the study. The system automatically checks for errors when the PI attempts 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 and click the Edit Study button, as explained in How to Edit a Study on page 6.
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.

Submit 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.

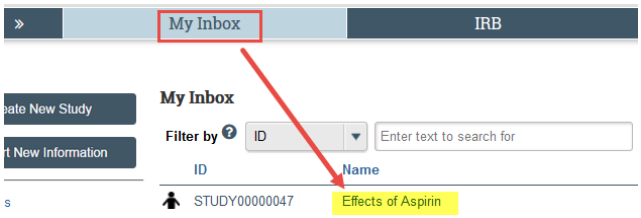
****TIPS****

- Make sure you attach all applicable information to the study, as identified in Checklist of Information to Attach on page 19.
- Check for missing information before attempting to submit the study, as described in Check the Study for Errors on page 7. 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. For instructions, see the IRB Quick Guide called "How to Request an Ancillary Review" in the UVMClick website. Ancillary Reviewers will have View access to the STUDY.

To submit the study for IRB review

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

1. Log in to the system.
2. Make sure you are in **My Inbox**.
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 at the** top navigation area. If you do not see it in that list, see Access a Study on page 11 for more ideas.

4. Click the **Submit** activity on the left.

****TIP**** If any errors or warnings are shown, edit the study to go to the form/view containing the problem. For more information, see Check the Study for Errors on page 7. 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 Study for Review

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

- Review within your department or another 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, Proxy and Primary Contact all receive 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-mails 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 Change the Primary Contact on page 10.

Check 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 Access a Study on page 11.

Change the Primary Contact

Every STUDY **must** have a primary contact. At the time of the initial application the primary contact is defaulted to the person creating the STUDY. This designation can be changed.

How is the Primary Contact different from a Proxy or a study team member?

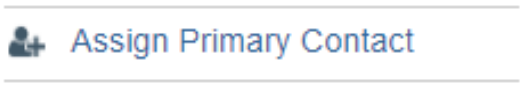
- The primary contact can also edit the study just as a study team member can, however, the primary contact will receive notifications and study team members will not.
- The contact and Proxy have the same security setting except the Proxy can submit requests to the RPO Office and the contact cannot

Notes:

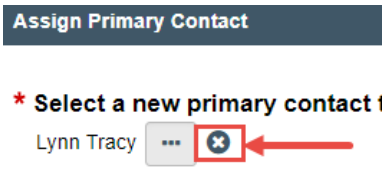
- To change the primary contact, you must be a member of the study team.
- By default, the person who created the study in the system is the primary contact.
- The PI and any PI proxy continue to receive notifications regardless of the primary contact assignment.
- Modifications or continuing reviews 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

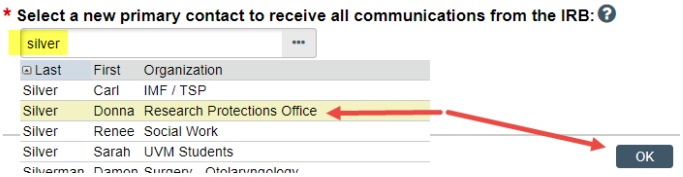
1. Open the study by clicking the study's name. (For instructions about finding the study, see Access a Study on page 11.)
2. Click Assign Primary Contact from Activity list on the left.



   A new window opens.
3. Click the X to remove the current contact.



4. Begin typing the name of the new contact.
   A list of matching names appear.
5. Select the correct name using the mouse or down arrow key.
6. Click **OK**.



Note: Make sure the selected contact is a study team member within the study.

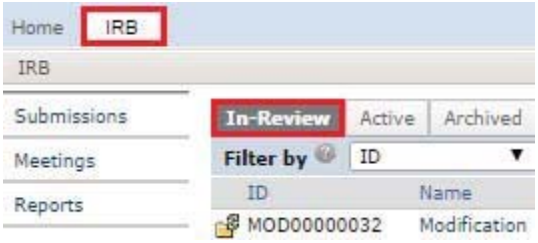
Access a Study

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, review the IRB Quick Guide called Searching for a Protocol found on the UVMClick website or 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 navigation header. 
IRB In-Review tab	Studies the IRB has not reviewed or for which it has not communicated a decision	Click **IRB>Submissions** in the top navigation area and select the **In-Review** tab. 
IRB Active tab	Studies approved by the IRB and currently in progress	Click **IRB>Submissions** in the top 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>Submissions** in the top 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>Submissions** in the top navigation area and select the **New Information Reports** tab.

How to Respond to Clarification Request

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 My Inbox for each member of the study team.

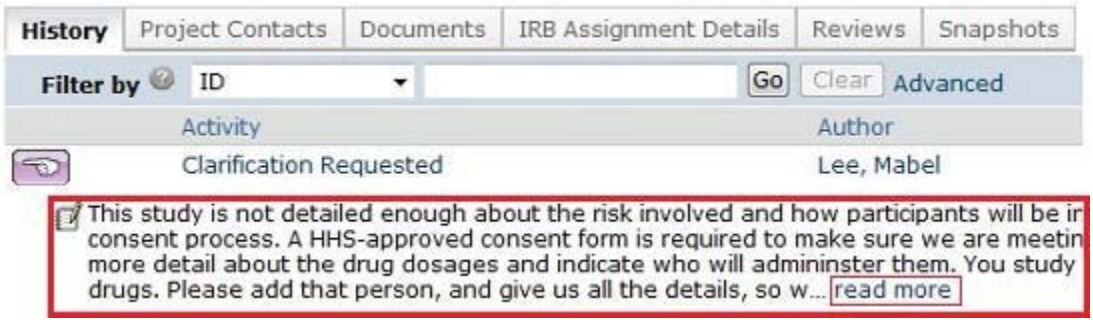
Very Important!

- Any study team member can update the study, but only the PI or Proxy 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

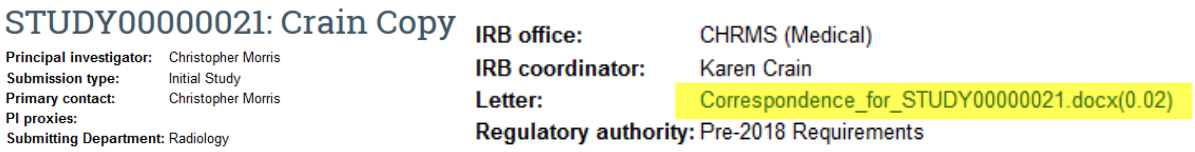
1. From My Inbox, click the name of the study to open it.
2. Locate the details of the request, as described here:

   For clarification requested: In the History tab under Clarification Requested, read the request details.



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

   For modifications required: Click the Correspondence 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 How to Edit a Study on page 6.

   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 or Proxy 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 applicable review process.

For information about completing an action plan for an RNI submission, see Submit Continuing Review and New Information on page 16.

How to Change Documents on your Study

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.

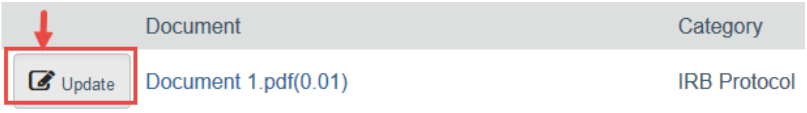
1. From My Inbox, click the name of the study to open it.
2. Click the **Documents** tab.

3. Click the document name 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. Here are the steps:

    a) Click Edit Study button.

    b) If replacing the Protocol document, scroll to the bottom of the Basic Information View and click the Update button next to the current Protocol document.

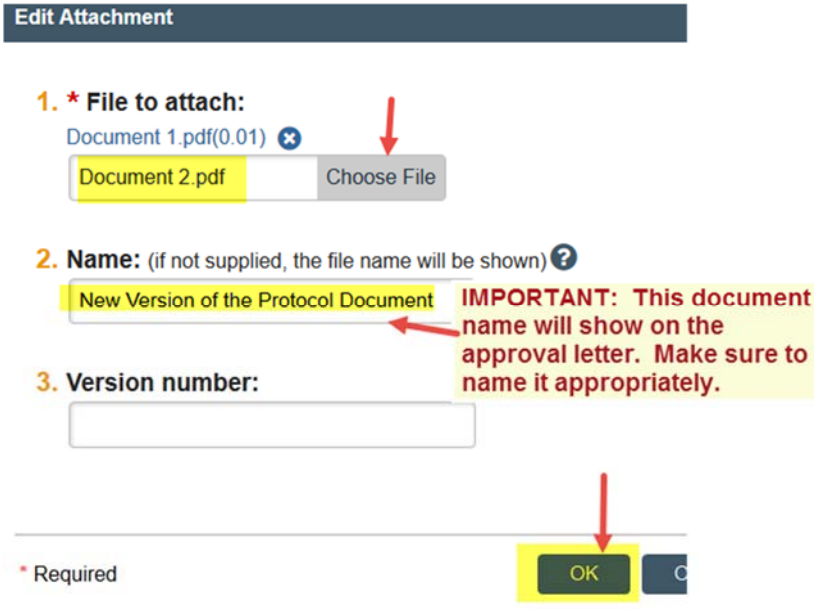


    c) Choose the new track changes document

    d) Optional but highly recommended: Type in a name. If nothing is entered in the name field, the system will default to the uploaded document title as the name. This is important as the NAME will display on the approval letter.

    e) Version Number is optional.

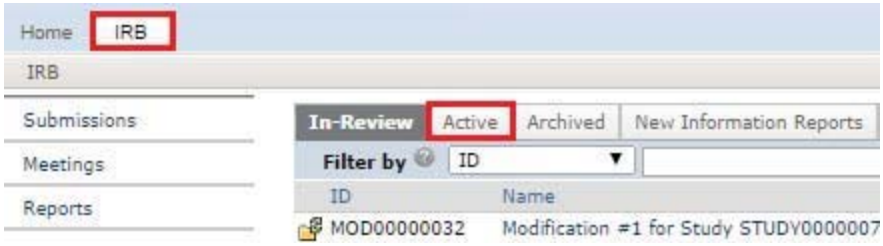
    f) Click OK



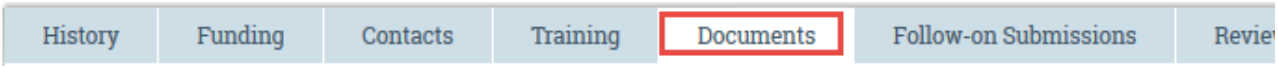
NOTE: When the IRB approves the document, all tracked changes will be accepted and comments removed in the final version.

To change documents on an approved study

1. Click **IRB** in the top left navigation area 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 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

   (See previous page for details).

NOTE: When the IRB approves the document, all tracked changes will be accepted and comments removed in the final version.

Submit Continuing Review 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 or to close a study Modifications to Study Team Membership Modifications to Other parts of the Study	From the Active tab, click the study name (see Access a Study on page 11)	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.
New information or an adverse event report	Start from the Active tab and click the study name (see Access a Study on page 11)	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 How to Create a New Study on page 4.
Updates to a new study that hasn't been submitted for IRB review yet	Within the study (see Access a Study on page 11)	Edit Study	See How to Edit a Study on page 6.

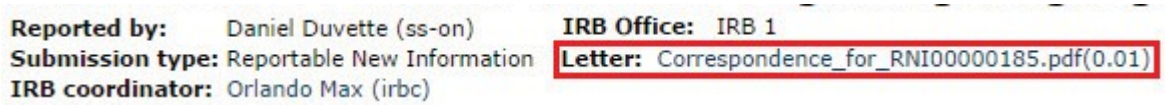
How to Respond to Action Required

After reviewing a new submission (or adverse event), the IRB may require specific actions to be taken in response to the reported issue. The IRB Coordinator will complete the action to send the submission back for clarifications.

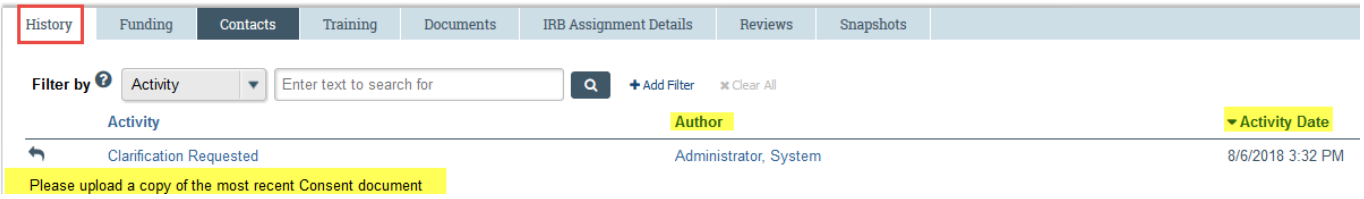
The system sends e-mail to notify the PIs, PI proxies, and primary contacts of all related studies as well as the submitter of the RNI (reportable new information) if applicable. The submission appears in My Inbox for the responsible parties.

To view the requested changes and respond to the IRB

1. From My Inbox, click the name of the submission to open it.
2. View the details of the submission and the requested changes, 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 requested changes and a summary of the IRB's decisions.



   Review the requested changes: Click the History tab and read the requested changes listed there. Also listed will be the author of the clarification request and the date/time the clarification was requested.



3. Take action inside or outside the system to resolve the requested changes.

   ****TIP**** If the requested changes require a change to a study, create a modification and submit it for review as mentioned in Submit Continuing Review and New Information on page 16.

4. Click **Submit Response** to indicate that the changes have been made.

   The Submit Response form gives you space to type notes. Summarize the actions taken to resolve the reported issues and change requests.

   NOTE: The response pop-up provides an opportunity to provide an attachment. Response documents can

be uploaded here. Do Not attach protocol documents (protocol, consent, recruitment materials etc) to the Response pop-up. Any protocol attachment additions should be made inside the smartform and not in the Response pop-up.

5. Click **OK**.

The submission is returned to the IRB staff to verify completion of the requested changes.

Checklist of Information to Attach

Be prepared to attach several files to your study. While editing the study, several views provide places to attach related files. Applicable template files can be found on our IRB website https://www.uvm.edu/rpo/human-subjects-research

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** view / 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** view / 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):
  - Sponsor protocol with the IND number
  - Communication from the FDA or sponsor with the IND number

Device details: (**Devices** view / 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):
  - Sponsor protocol with the IDE / HDE number
  - Communication from the FDA or sponsor with the IDE / HDE number

Recruitment and Consent details: (**Local Site Documents** view / page)

- Consent documents:
  - Consent forms
  - HHS-approved consent document
  - 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:
  - 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: (**Local Site Documents** view / page)

- Conflict of Interest Committee's determination for each financial interest related to the research
- Completed checklist of meeting Department of Energy requirements

NOTE: Many of the IRB Forms have transitioned into our UVMClick online smartform. Forms that have been deprecated and are now online entry within UVMClick include:

- Common Protocol Cover Form
- Amendment Form
- Key Personnel Form
- Continuing Review Form

As these forms are no longer uploaded documents, they have been removed from the IRB Forms website and therefore manual signatures are no longer required.

Contacting Support

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

Resource	How to access it
Documentation	See Find More Information on page 5
Training materials on the UVMClick web site	https://www.uvm.edu/ovpr/uvmclick-toolkits
UVMClick support staff	E-mail: uvmclick@uvm.edu
IRB support staff	E-mail: irb@uvm.edu or 802-656-5040