myRESEARCH IRB TRAINING GUIDE

January 2020

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Questions and Issues

For policy related questions and issues including how to fill out the application, please contact the **Stony Brook University Institutional Review Board** (631) 632-9036 or email at ORC_OVPR@stonybrook.edu.

What is myRESEARCH?

MYRESEARCH is the new electronic system that will replace IRBNet. It will automate the development, review, and approval processes of your study while managing all major administrative aspects of the research and compliance lifecycle – from application submission, through amendments, continuing reviews and any type of compliance reporting (i.e., protocol deviations, unanticipated problems involving risks to subjects or others).

Getting a myRESEARCH Account

Faculty and staff users will log into the system using their **SBU NetID and password**. If your login attempt is unsuccessful, please contact ORC_OVPR@stonybrook.edu.

Overview

This training pertains to the following:

Research Study	**Details related to the specific information related to a study**
Research Study Site	**Details related to a specific institution's site (study team, consent forms, etc.)**
Modification	**Details related to changes made to a study**
Continuing Review	**Details related to the review of an already approved study**
Reportable New Information (RNI)	**Report of information related to the specific study**

myRESEARCH integrates the following aspects of research management into a single system:

- Conflict of Interest (COI) applications
- IRB applications
- IACUC applications
- Institutional Biosafety applications
- Grant applications
- Research Agreements

Roles in myResearch

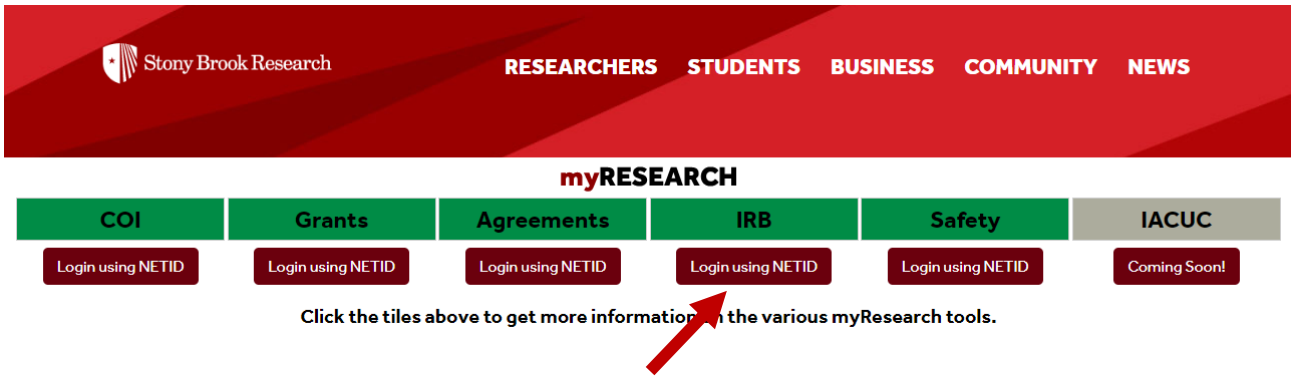
Registered User	Individuals authorized to input information in MYRESEARCH (must have an SBU NetID Single Sign On)
Principal Investigator	Individual in charge of the research. Only this person can submit the initial study, continuing review application, or modifications. This is also the only person that can submit a response.
Study Staff	Individuals involved in developing the study application and listed on the application as a study team member. A co-investigator or a study coordinator is a study team member.

Submission Process

- Pre-submission state: Principal Investigator (PI) or study team members are working on an application
- Pre-Review: IRB Coordinator reviews the application for completeness
- IRB Review: IRB member(s) review the application and make a determination about the study
- Post Review: The IRB Coordinator sends the determination information back to the PI and study team members

Logging into myResearch Portal

Navigate to myResearch.stonybrook.edu → Click the **Login using the NetID** button (under IRB)

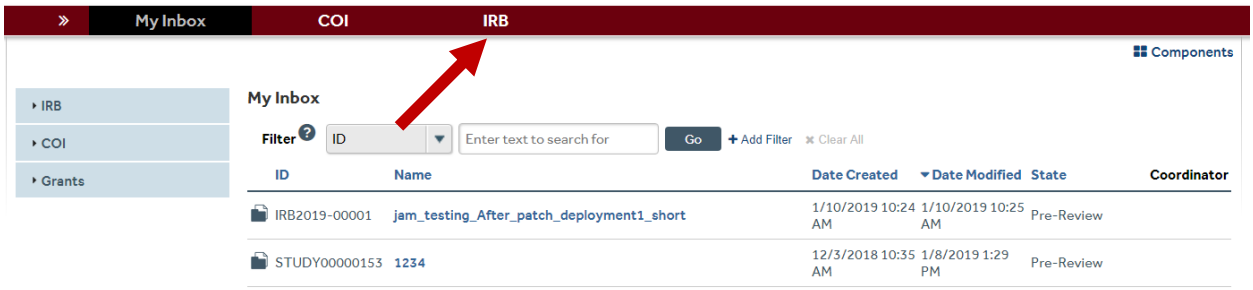


Accessing the myResearch Portal

All SBU-affiliated personnel can access the portal using their **SBU NetID and password**. If your login attempt is unsuccessful, please contact ORC_OVPR@stonybrook.edu.

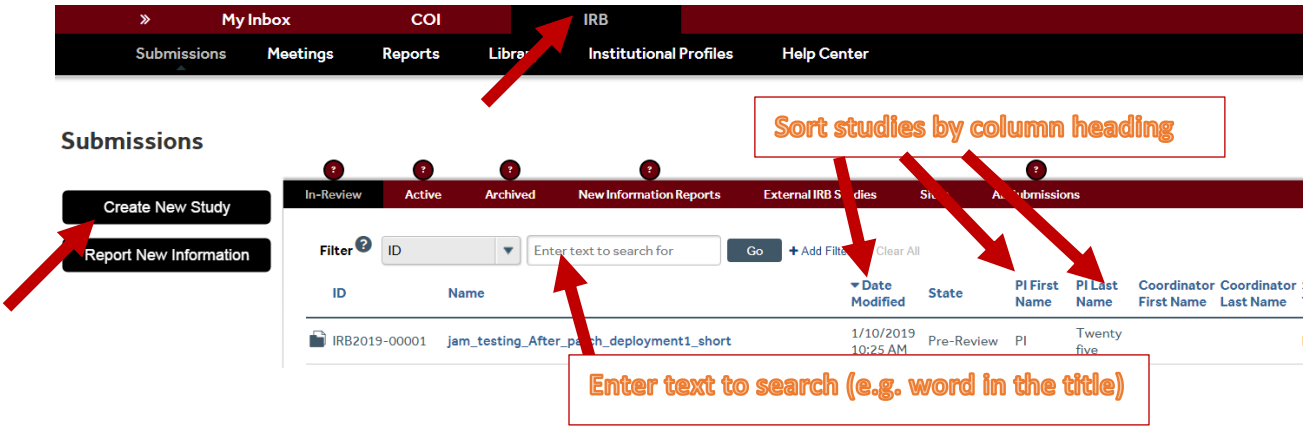
My Inbox → IRB Tab

When you first log into the system, you will see your inbox (**My Inbox**). From this page, click **IRB** from the top menu bar. The tabs available to you on the menu bar are based on the user roles that you have for your account.



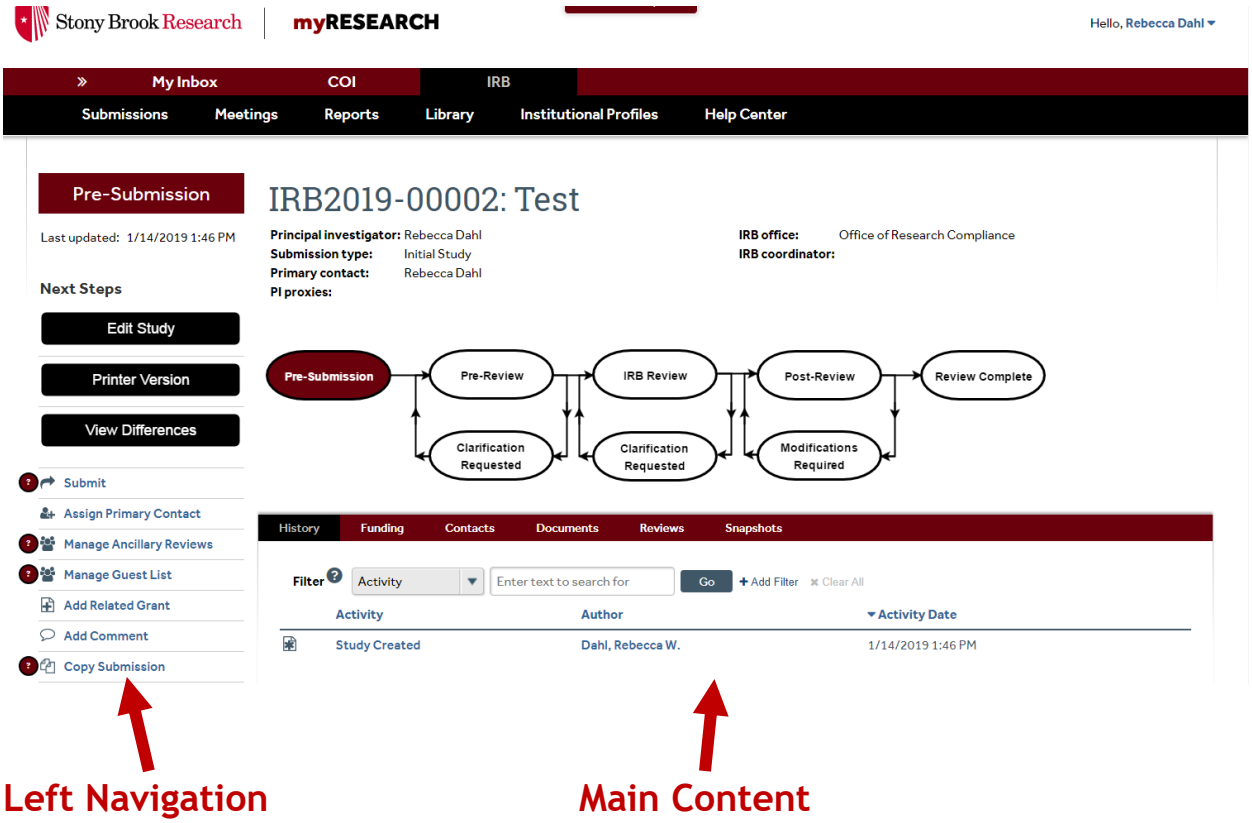
IRB Main Screen Navigation

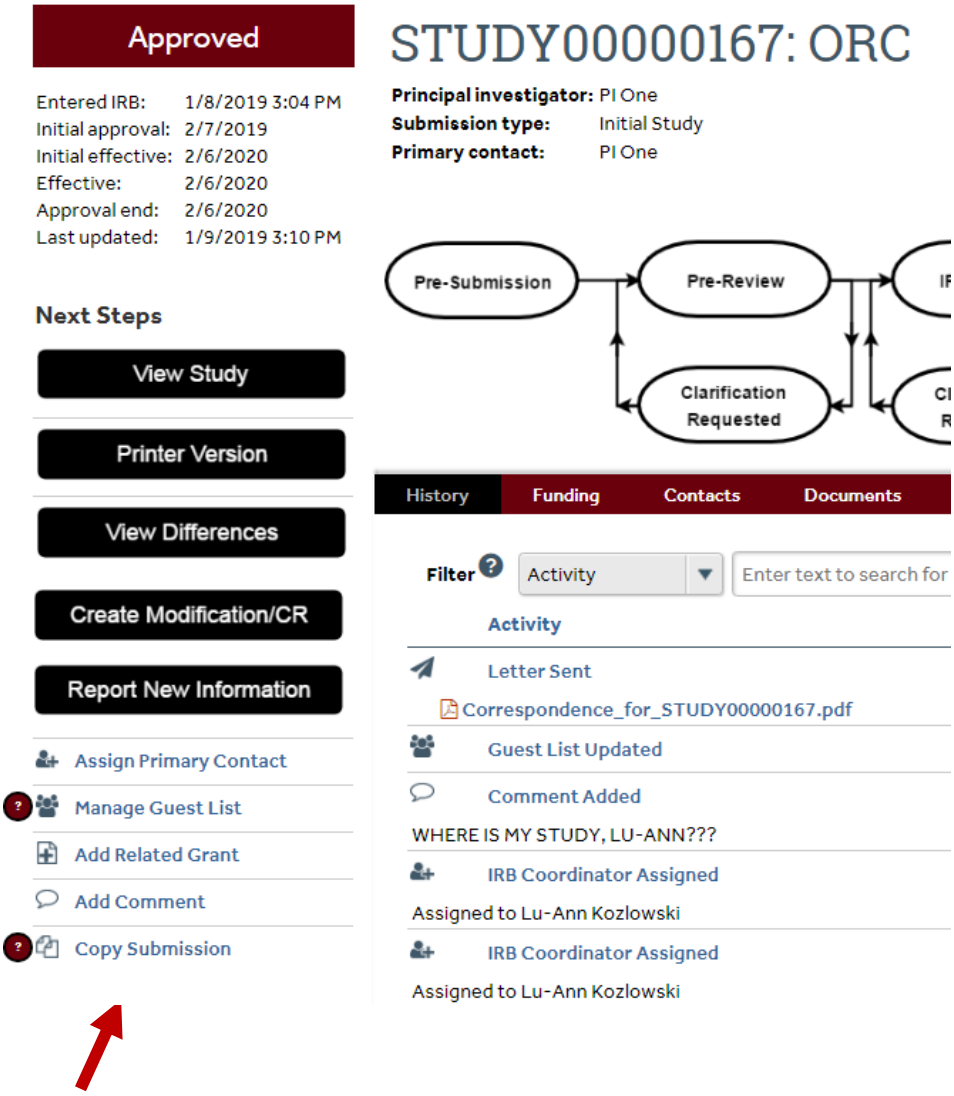
On the IRB page, you can do a variety of functions including “Create New Study”. You can also search for specific study applications (through the use of the filter bar) and sort the data based on column name (by clicking on the respective column heading). To view details of a particular study application, click on either the ID or the name.



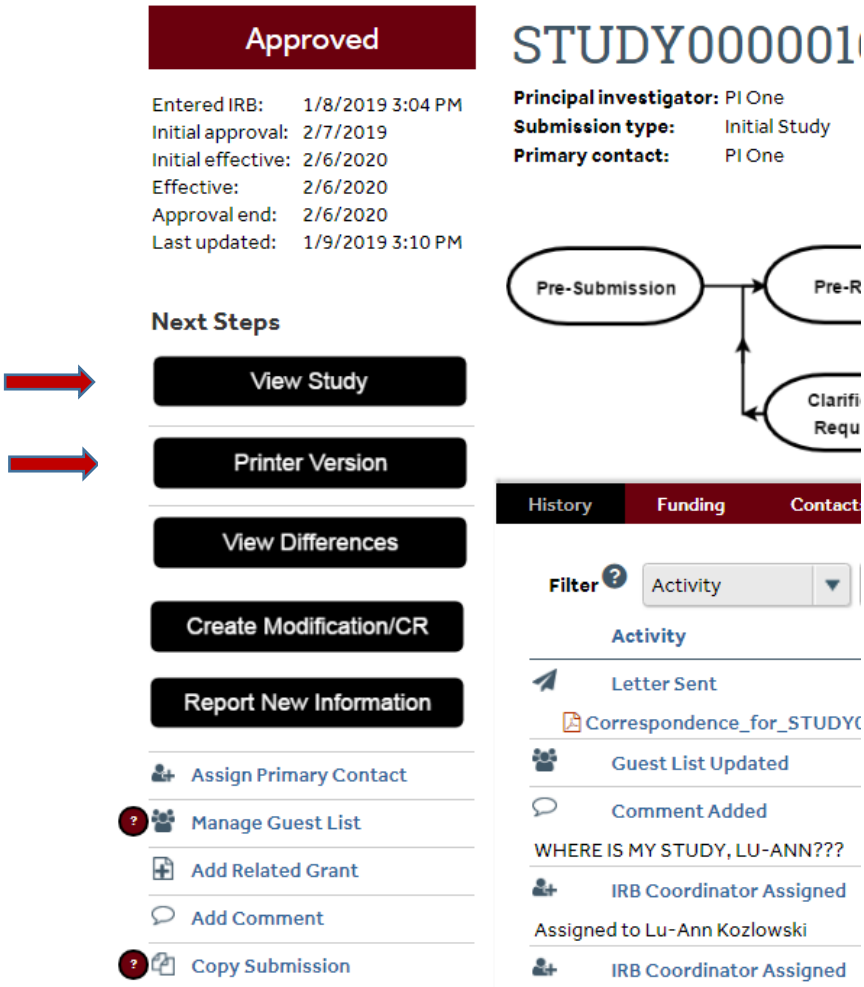
Main Workspace

The Main Workspace page can be subdivided into the left navigation area and the main content area on the right.





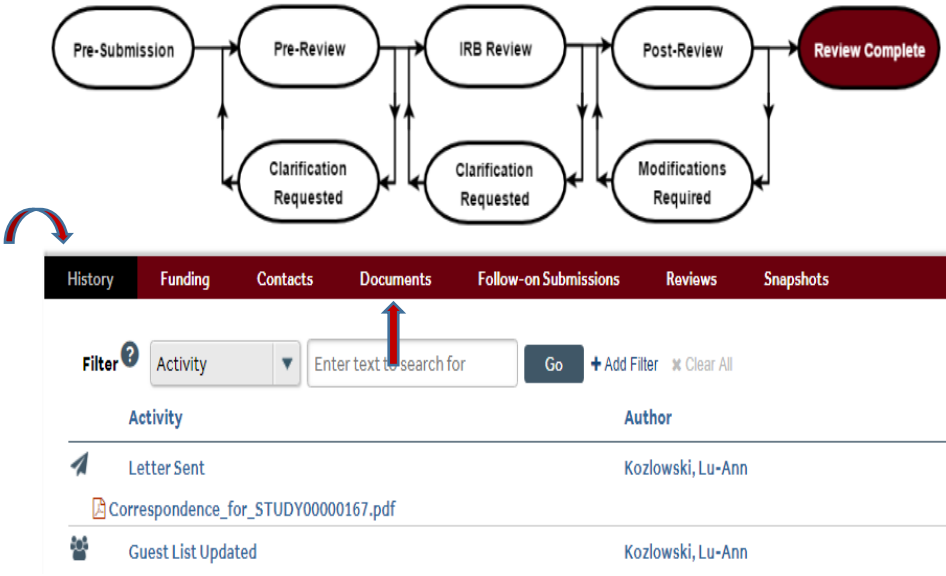
Within the main workspace, you can view the **Current State** of the application on the left navigation area and the main content area. The left navigation area contains all the buttons and activities that are available to you based on the state of the application. One of the buttons on the left navigation side of the **Main Workspace** is called “Copy Submission”. This allows you to make an exact copy of an existing application.



If the application is still in a state where you can edit the application, you can edit the application by clicking on the **Edit Study** button in the left navigation area. In addition, there will be a **View Study** button to enable you to view the application in a read-only format on page at a time. **Printer Friendly Version** will allow you to scroll through the entire application on one page.

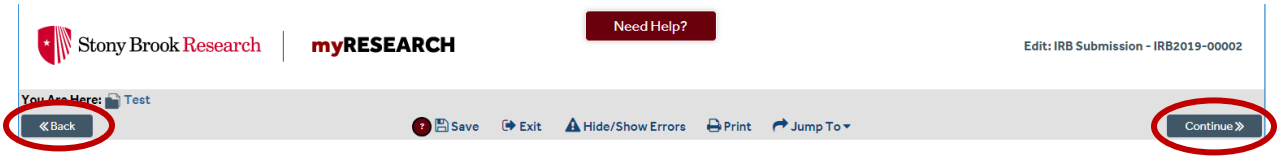
The right side contains the **Main Content**. The application title and ID appear at the top of the **Main Content** area. A summary box is displayed right below. Depending on the application, there is different information that is displayed in the summary box. The Main Content area includes the flow chart indicating the current status of the submission.

The **History** and **Documents** tabs always appear for all applications. The **History** tab contains a chronological log of all of the activities that have happened in the application. It includes the person responsible and the date/time the activity occurred.



Creating a New Application

To create a new application, click on the **Create New Study** button on the left navigation area. After you click to create the new application, you will automatically be redirected to the first page of the "SmartForm" or area where the questions are located. From there, you can navigate the page using the controls found at the top and bottom of the page.



While completing your application, several areas will ask you to attach a related file. Examples are listed below.

Protocol: (**Basic Information** page)

Drug/Device: (**Drug/Device** page)

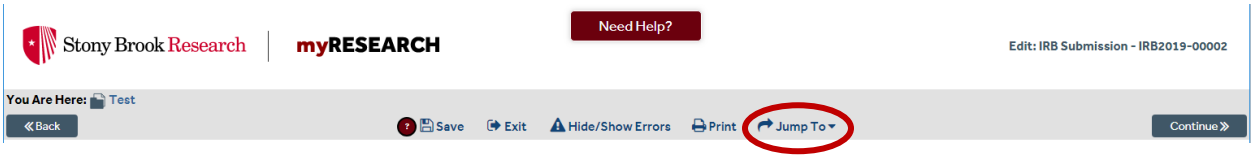
- Investigator Brochure
- Package Insert
- Product labeling/device instructions

Consent/Recruitment: (**Local Site Documents** page)

- Consent Forms
- Advertisements
- Recruitment Materials and Scripts

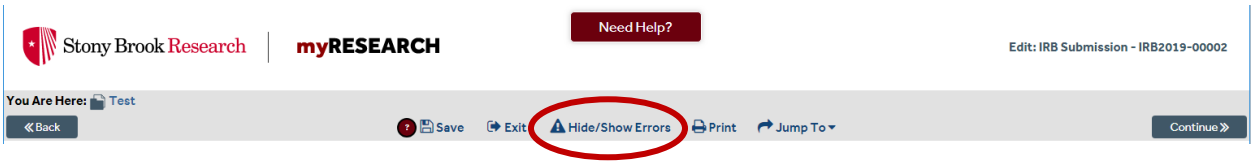
*** Review the New Study Submission Requirements Checklist (available on the ORC website) for guidance regarding required documents.**

A "Jump To" menu item will appear after you save the initial page of the application that will enable you to jump to specific sections of the application.



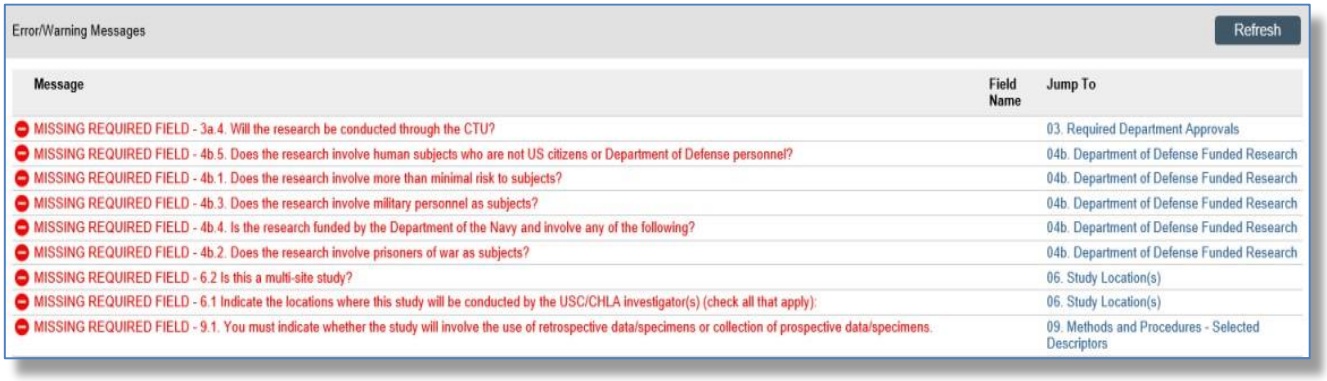
IMPORTANT NOTE: It is advised that you complete the application questions **in order** because the application shows questions/sections based on answers to earlier questions.

The "Hide/show Errors" menu item enables you to see if you have any unanswered questions on the application.



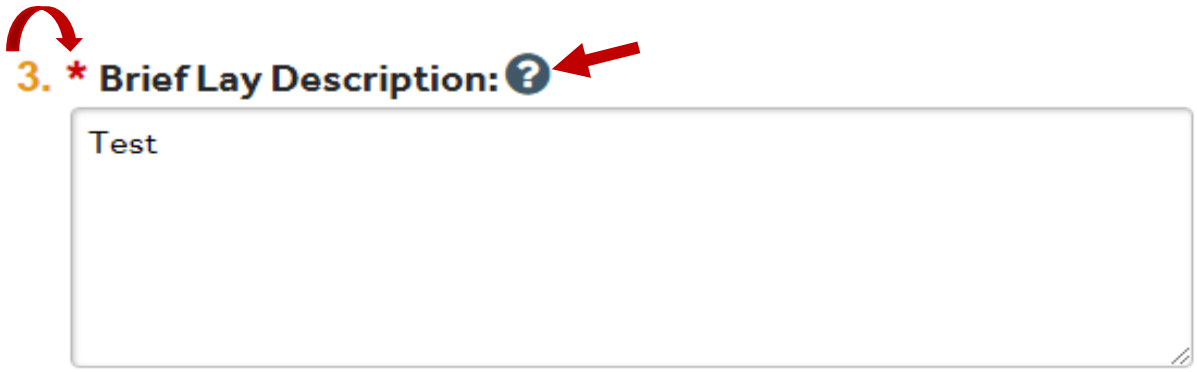
When the “Hide/Show Errors” is clicked or when you attempt to submit your studyall of the questions that are unanswered will appear in an “Error/Warning Messages” section.

For each error message, there is a “Jump To” link that will take you directly to the question which applies to the error message. The application can only be submitted when all issues are fixed.

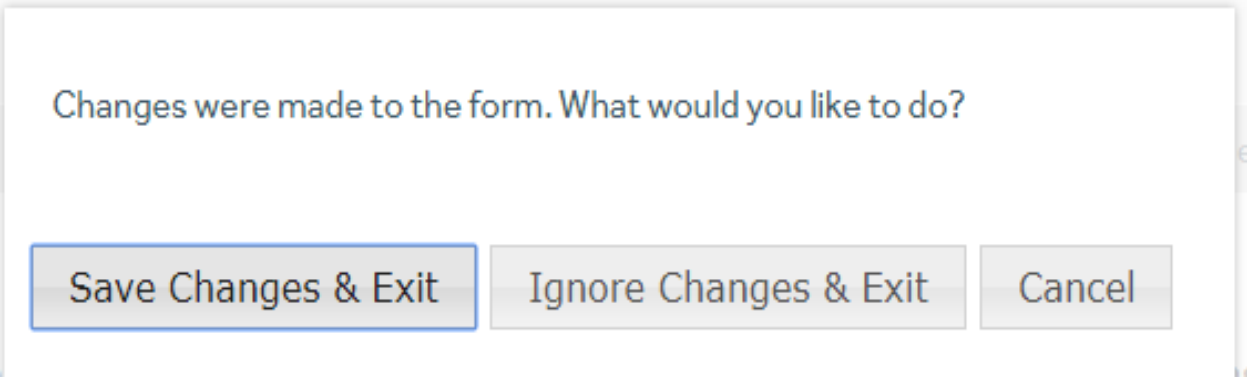


Overview of the Application SmartForm

- Each question on the SmartForm is numbered and those questions that have a red asterisk (*) must be answered.
- A question mark appears beside many of the SmartForm questions. If you click on the question mark, information will appear that will assist you in answering the question.



If you need to leave the application for any reason, you can save the document and return to the application at a later time. If you attempt to move to a different page within the SmartForm without saving your responses, you will receive the following prompt.



Manage Ancillary Reviews

Once you have completed the application SmartForm you will reach a **Final Page**. Read the next steps on this Final Page carefully to ensure that all required ancillary reviews are requested.

- For example, if your research involves an investigational drug, you will be required to click on "Manage Ancillary Reviews" in the **left navigation area** and add the hospital pharmacy. You must receive approval from the pharmacy before you begin your study.

IMPORTANT NOTE: New studies still require Department Chair approval prior to submission.

- The PI's Department Chair can be selected as an ancillary reviewer by carefully following the instructions on the Final Page.
- **Submission of new studies prior to Department Chair approval is not permitted in myResearch. The PI must wait for an email notification of Department Chair approval before submitting the study.**

Submitting the Study

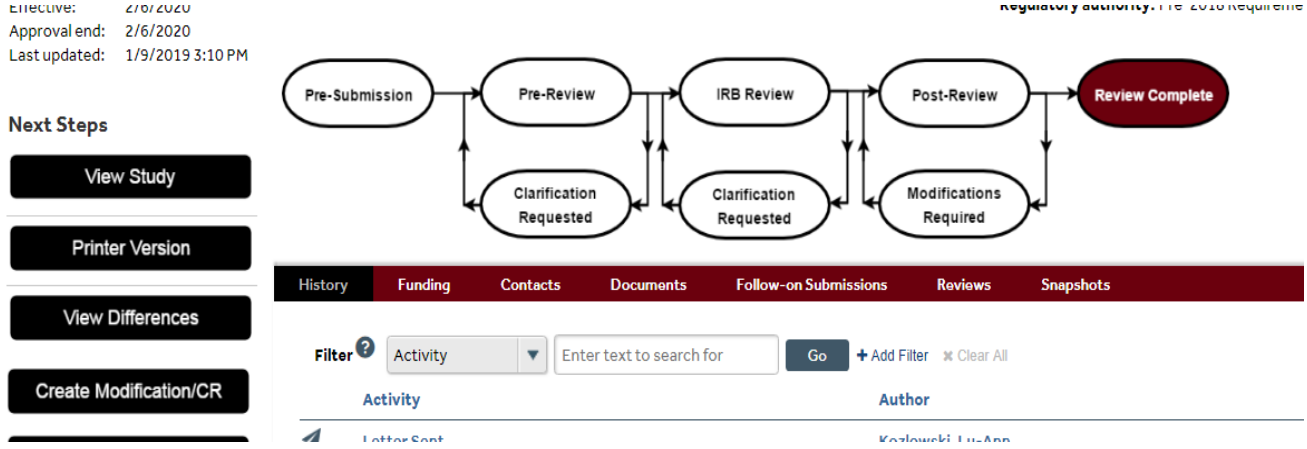
Once an email notification of Department Chair approval is received, the study can be submitted for review. **The PI** must click on the **Submit** button in the study's left navigation area.

An attestation page will pop up. The PI must carefully read the attestation page and click the **OK** button on the bottom-right hand side of the page.

When the PI submits the study, it is then routed to the Office of Research Compliance – Human Research Protection Program.

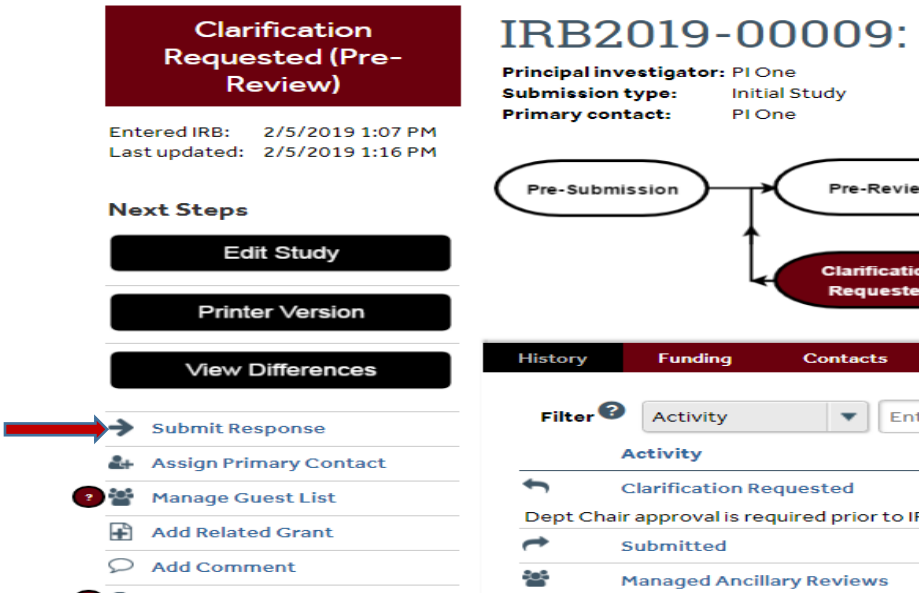
Clarifications Requested

If clarifications are required, you will receive an email notification with the submission ID link. Click the submission ID link in the email to be routed to the study page with details. Click the "History" tab and review the "Clarification Requested" activity. NOTE: If the reviewer attached a document, a link to open it appears on the "History" tab.



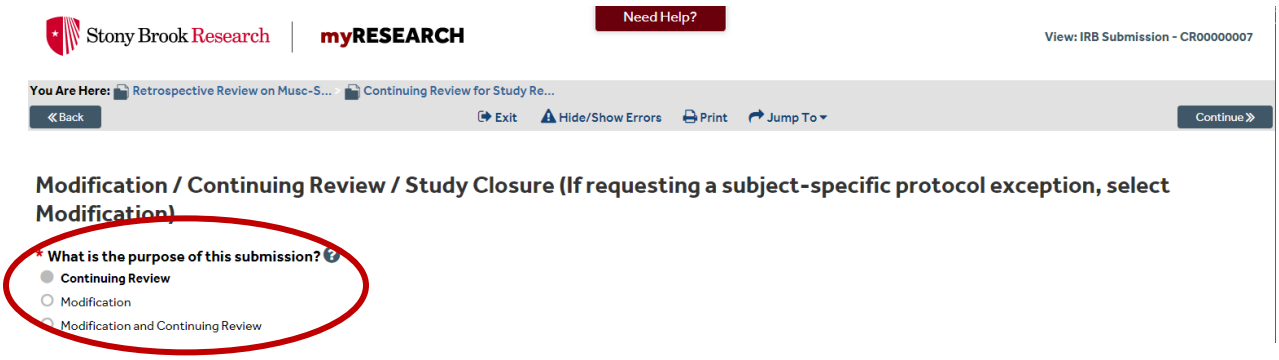
Respond to Clarification Requests

On the submission workspace, click "Submit Response". In the Notes box, explain your response to the review. Click "OK". The study has now moved back to the reviewer's inbox to continue the review.



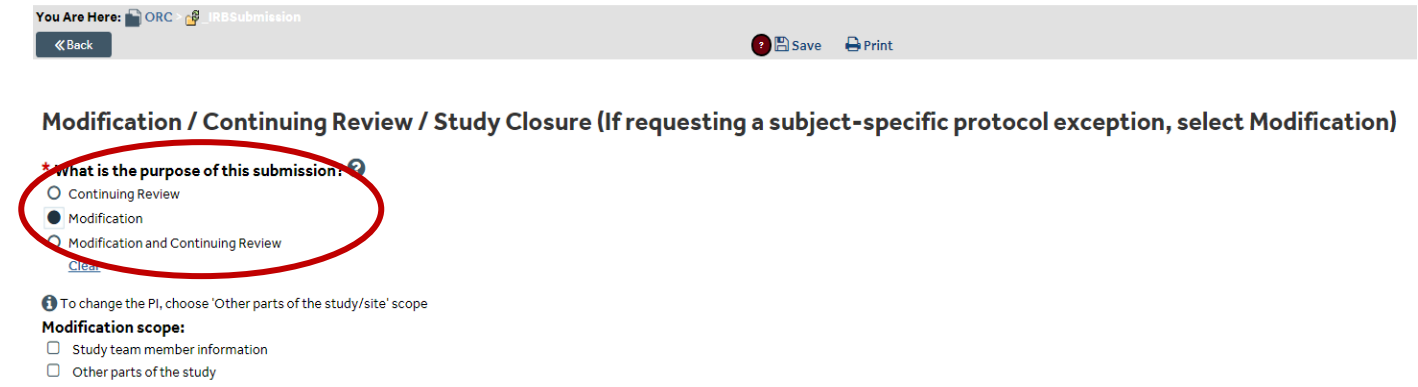
Continuing Review

You can submit a continuing review/annual review by clicking on the study in your inbox. Then click on **Create Modification/CR** in the left navigation area. This will take you to the questions asking about a modification or continuing review of your research. **If you are submitting the first continuing review in myResearch for a given study, you must choose Modification and Continuing Review and both modification scopes (Study Team Member Information and Other Parts of the Study).** This will allow you to add all required information, confirm accuracy of the imported study team list and upload documents associated with this study. Future continuing reviews will require only selection of Continuing Review if no information/documents need revision.



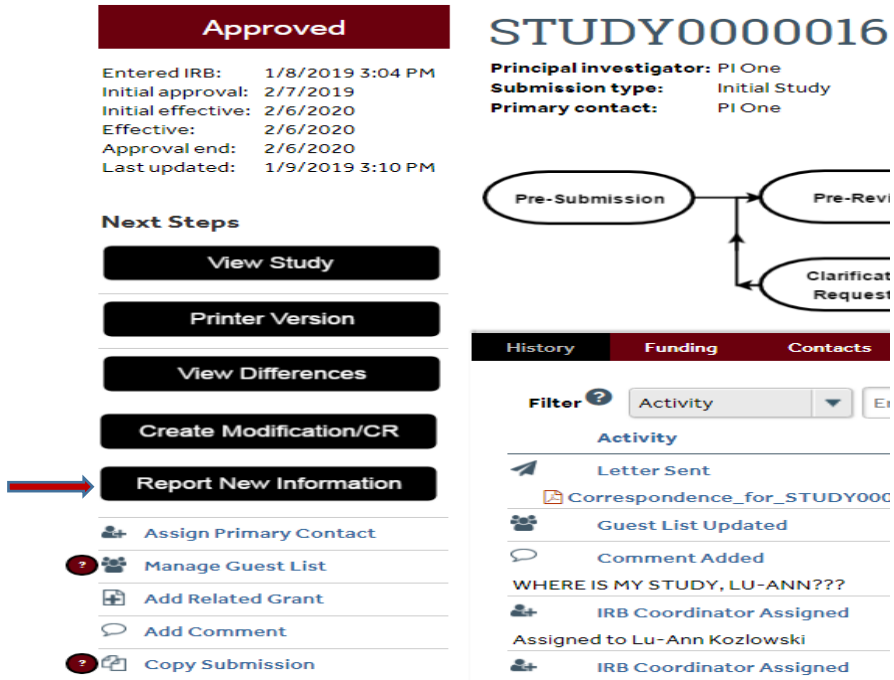
Modification or Protocol Exception Request

Click on **Create Modification/CR** in the left navigation area. Click on **Modification** if you are submitting a modification request and/or a protocol exception request.

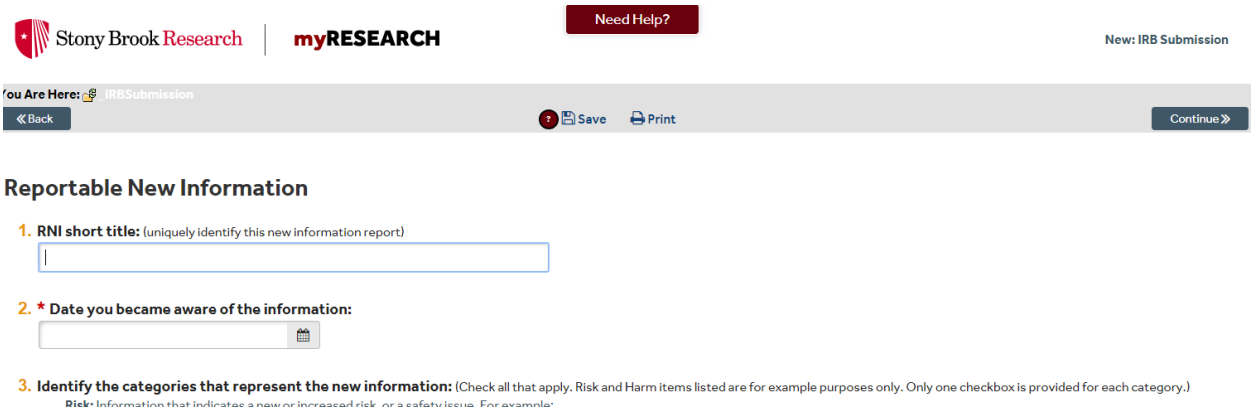


Reportable New Information (RNI)

You can submit new information (e.g. unanticipated problems, serious adverse events, protocol violation/deviation, etc) about your study by opening your study and clicking on **Report New Information** in the left navigation area.



Reportable New Information



Reportable New Information

You will be asked to choose a category that represents the new information. You will also be asked to provide details regarding the information you are reporting and whether the information indicates a new or increased risk, or a safety issue. Upload applicable documentation where prompted (e.g. Reporting Form for Unanticipated Problems (including SAEs)). If the RNI is associated with modifications to the study, submit the modification promptly to allow for timely review of the RNI and associated study changes. Refer to the RNI in the modification submission. NOTE: The RNI can be submitted by the individual that created the RNI only. If an individual other than the PI creates the RNI, the PI must use the “Add Comment” option in the left navigation area to confirm review and accuracy of RNI details/documentation **before** the RNI is submitted.

4. * Provide full detail regarding the information you are reporting.

Test

5. In the submitter's opinion:

a. * Does this information indicate a new or increased risk, or a safety issue?

○ Yes ● No Clear

From the Reportable New Information workspace, click “Submit RNI”. Click “ok”.