myRESEARCH Radioactive Drug Research Committee (RDRC)

TRAINING GUIDE

November 2024

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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 Radioactive Drug Research Committee** (631) 632-9036; or Email ORC_OVPR@stonybrook.edu

What is myRESEARCH?

MYRESEARCH is the electronic system. 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, and any type of compliance reporting (i.e., protocol deviations, etc).

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**

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

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

Roles in myResearch

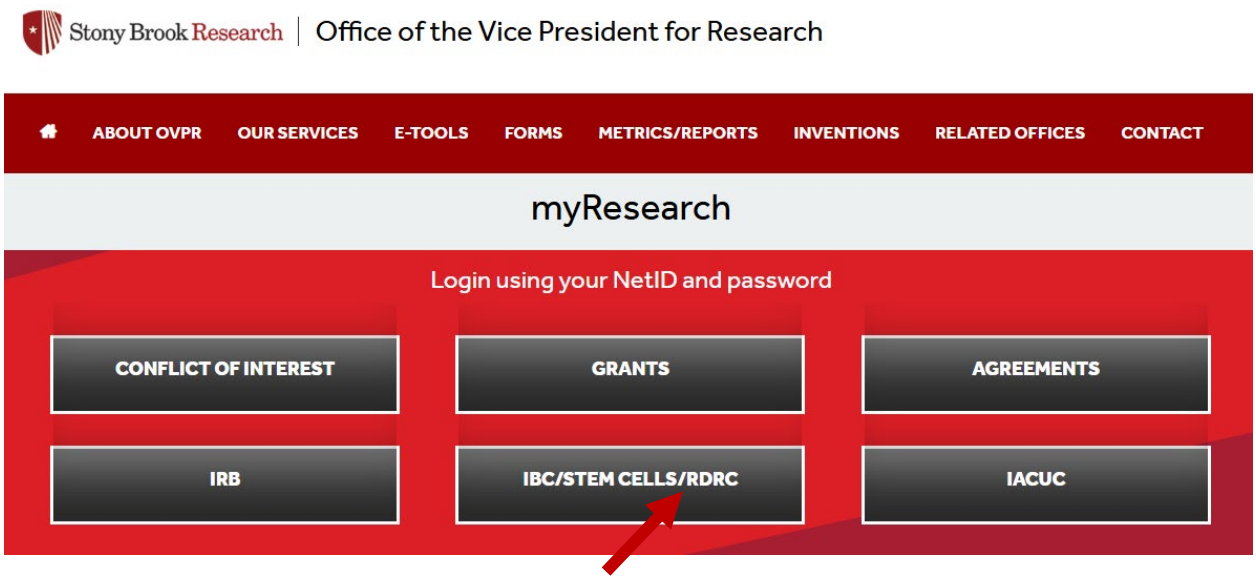
Registered User	Individuals authorized to input information in MYRESEARCH (must have an SBU NetID Single Sign On)
Principal Investigator	Individual in charge of the research. Only this person can submit the initial study, continuing review application, or amendments. This is also the only person that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

Submission Process

- Pre-submission state: Principal Investigator (PI) or study team members are working on an application
- Pre-Review: RDRC staff reviews the application for completeness
- IBC Review: RDRC members review the application and make a determination about the study
- Post Review: RDRC staff 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 IBC/STEM CELLS)

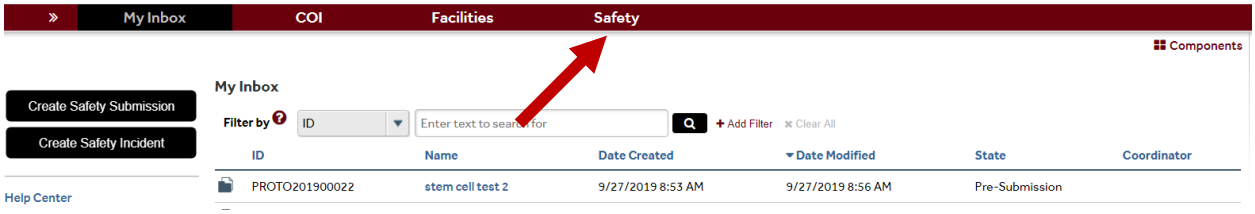


Accessing the myResearch Portal

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.

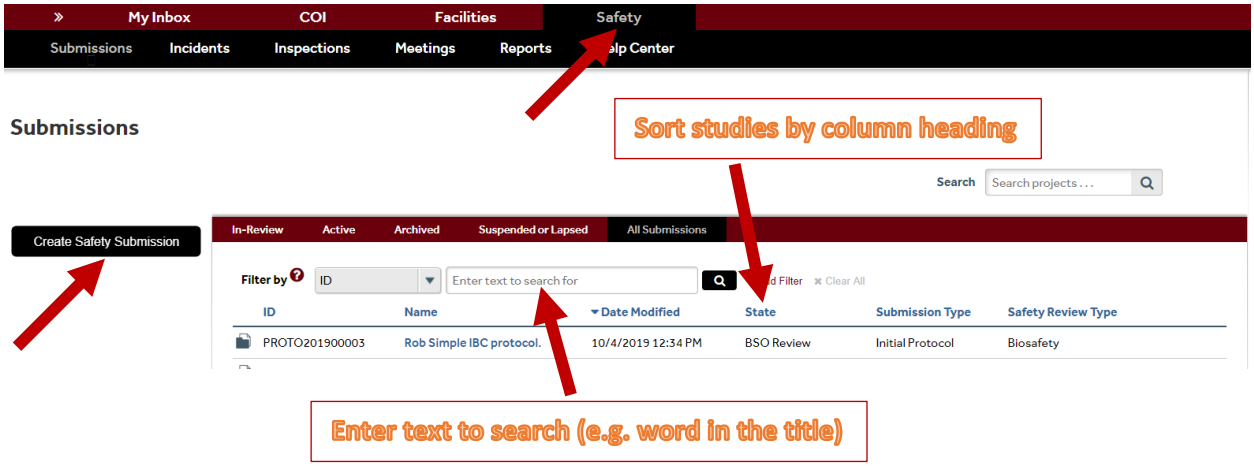
My Inbox → Safety Tab

When you first log into the system, you will see your inbox (**My Inbox**). From this page, click **Safety** 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.



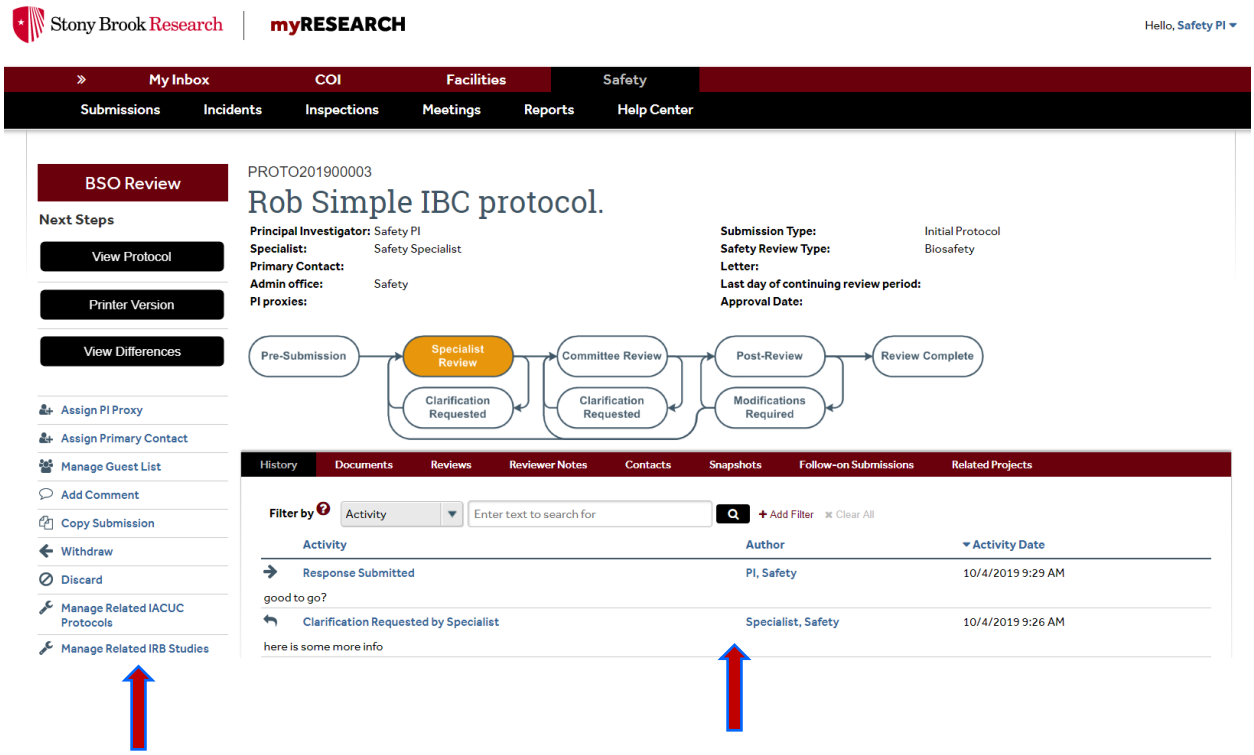
Safety Main Screen Navigation

On the Safety page, you can do a variety of functions including “Create Safety Submission”. 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 study name.

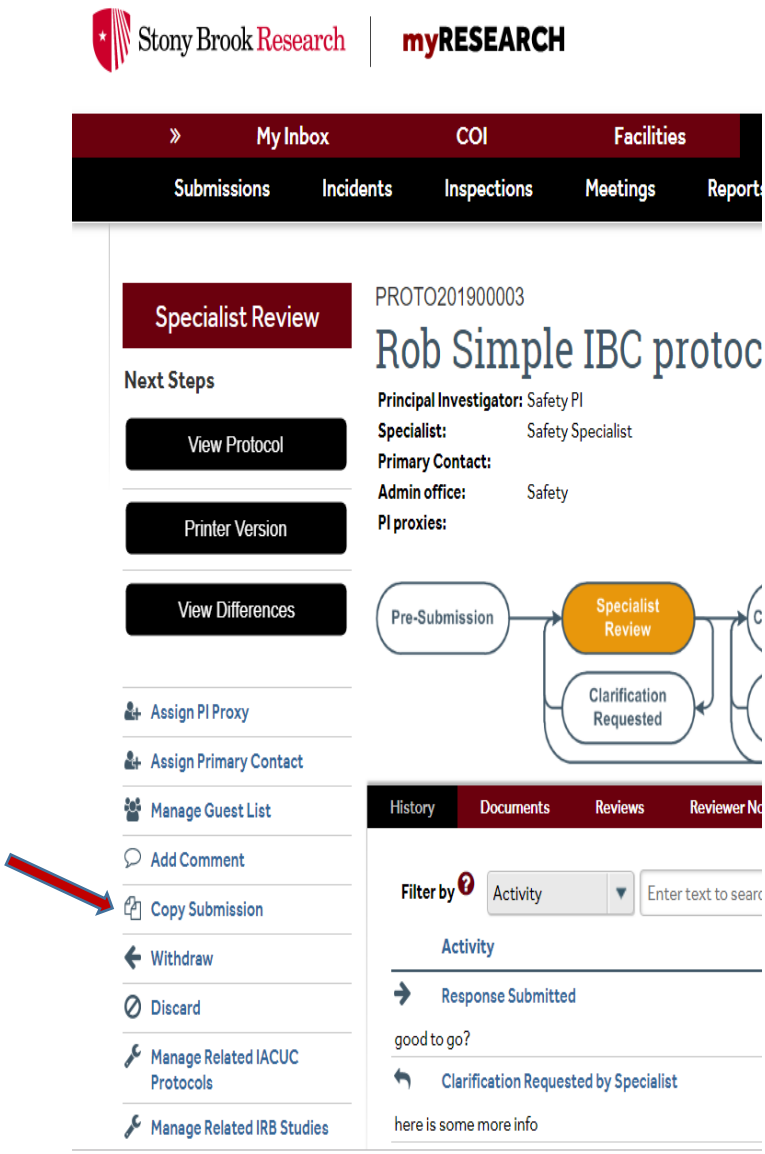


Main Workspace

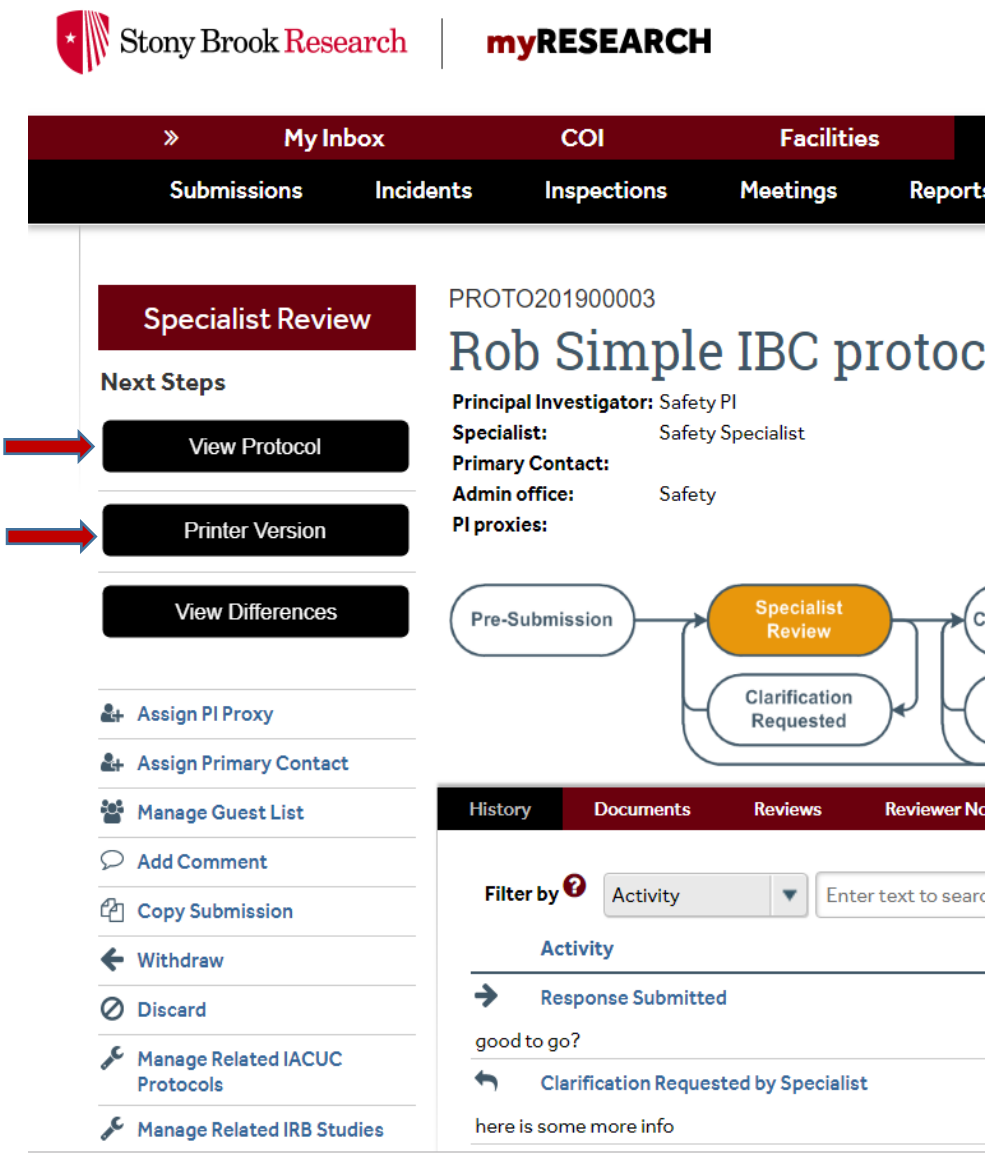
The Main Workspace page can be subdivided into the left navigation area and the main content area on the right.



Left Navigation **Main Content**

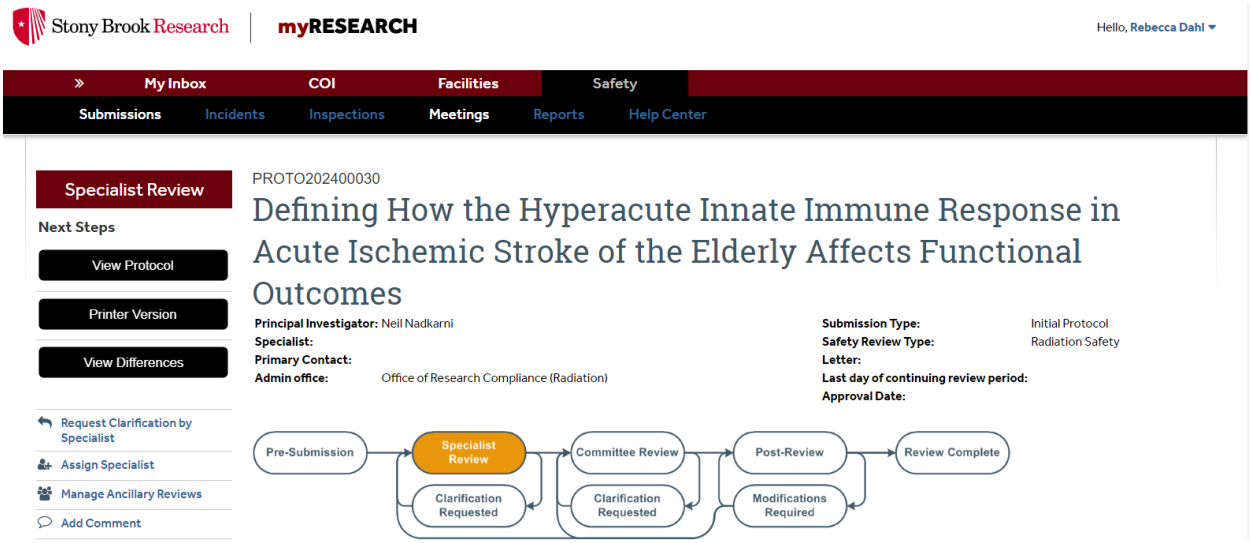


Within the main workspace, you can view the **Current State** of the application on the left navigation area and the main content area. The left navigation area contains all the buttons and activities that are available to you based on the state of the application. One of the buttons on the left navigation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

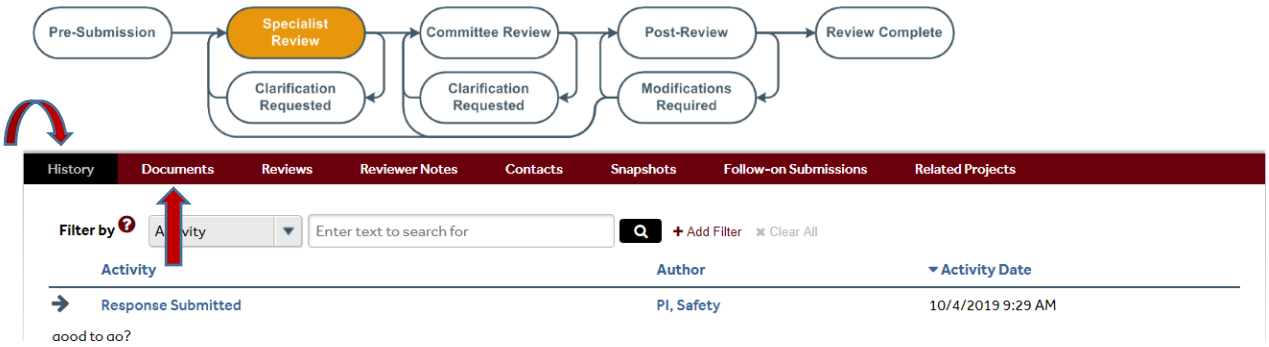


If the application is still in a state where you can edit the application, you can edit the application by clicking on the **Edit Protocol** button in the left navigation area. In addition, there will be a **View Protocol** button to enable you to view the application in a read-only format. **Printer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

The right side contains the **Main Content**. The application title appears towards the left of the **Main Content** area and the application ID is contained above the application title. A summary box is displayed below the application title. Depending on the application, there is different information that is displayed in the summary box.

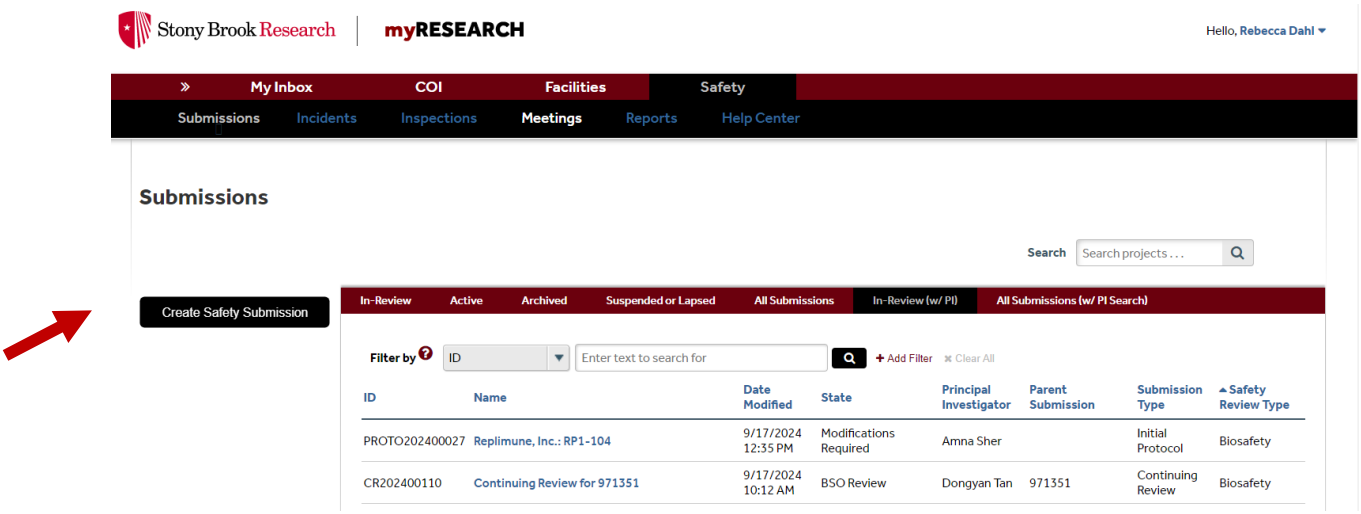


The **History** and **Documents** tabs always appear for all applications. The **History** tab contains a chronological log of all of the activities that have happened in the application. It includes the person responsible and the date/time the activity occurred. The **Documents** tab contains all documents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



Creating a New Application

To create a new application, click on the **Create Safety Submission** 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 "Formset" or area where the questions are located.



From there, you can navigate the page using the controls found at the top of the page.

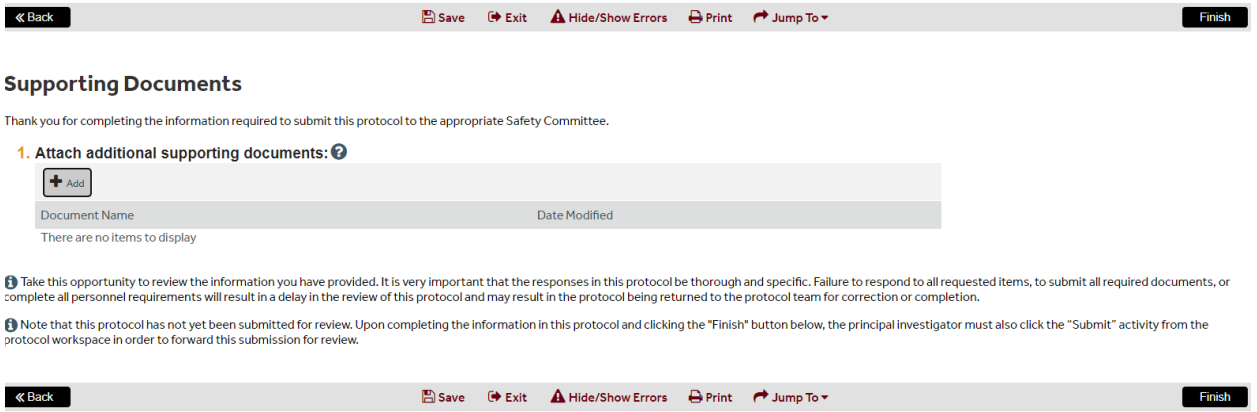
A “Jump To” menu item will appear after you save the initial page of the application. This will enable you to jump to specific sections of the application.

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

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

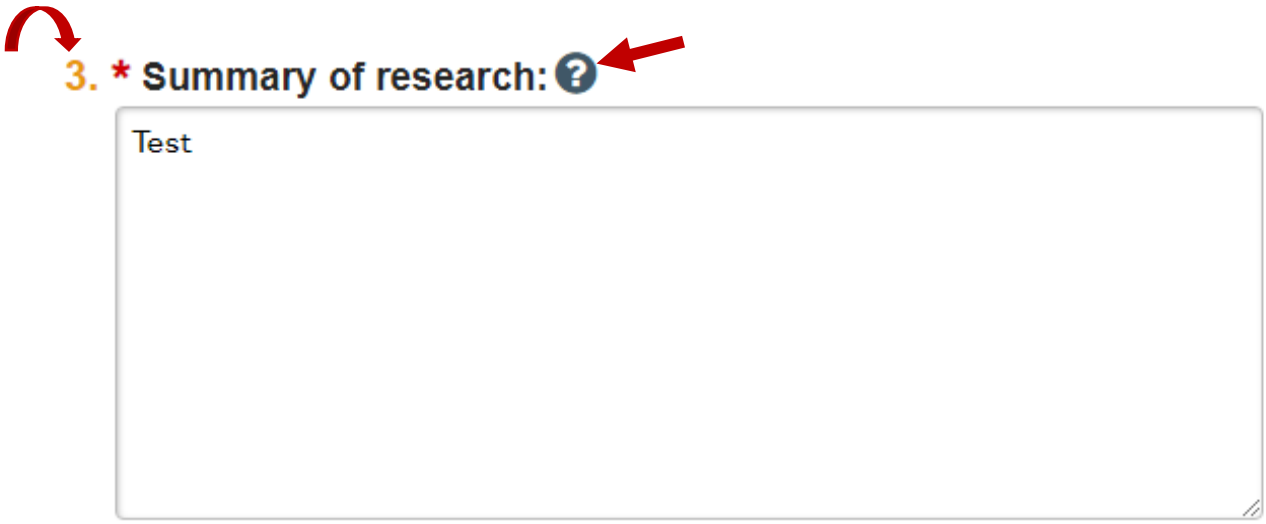
When the “Hide/Show Errors” is clicked or when the click on “Submit Application” all of the questions that are unanswered will appear in an “Error/Warning Messages” section.

At the end of the application, you will be able to upload/attach a file (if applicable).



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.

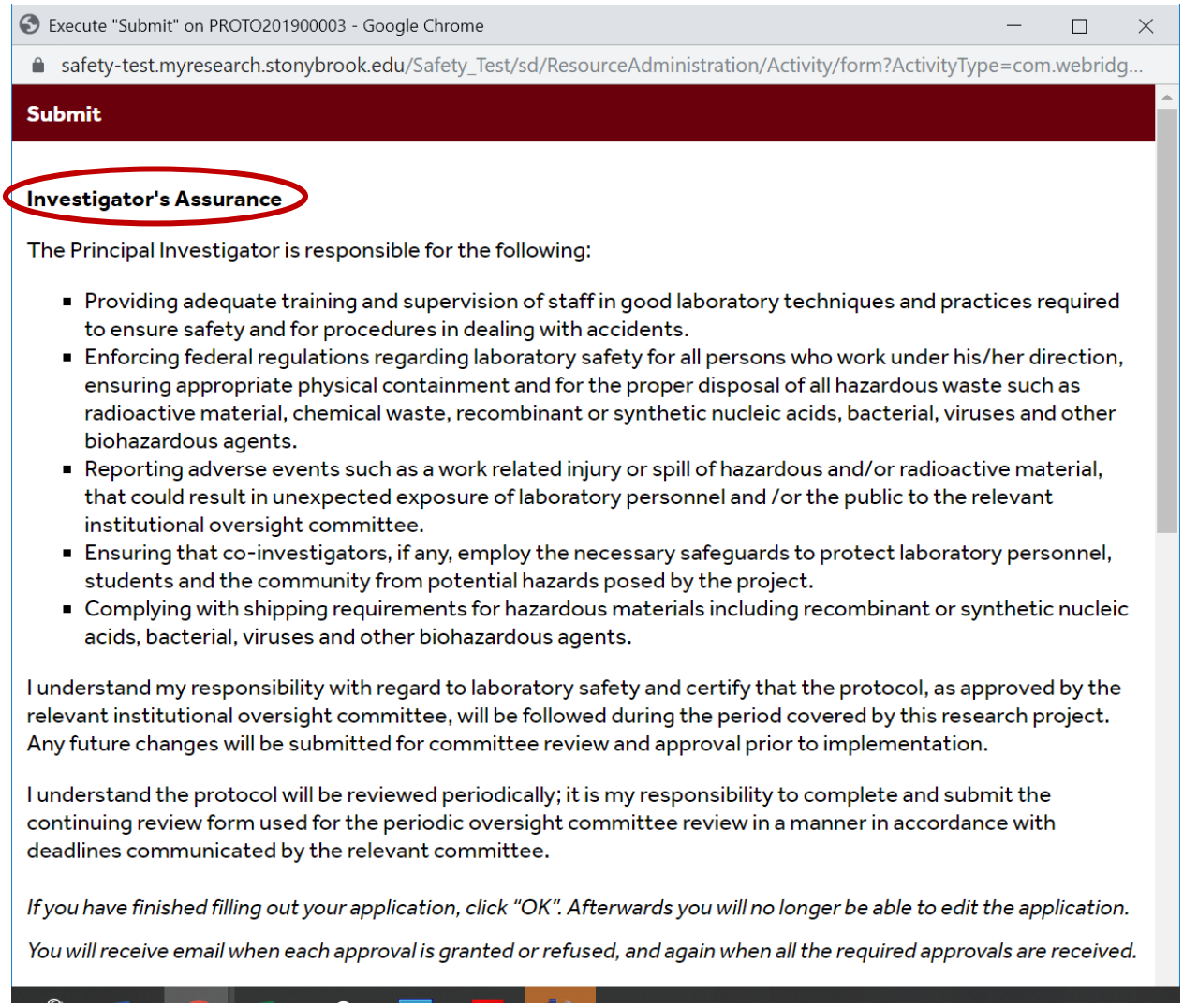
Manage Ancillary Reviews

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

- The PI's Department Chair can be selected as an ancillary reviewer.
- **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.**

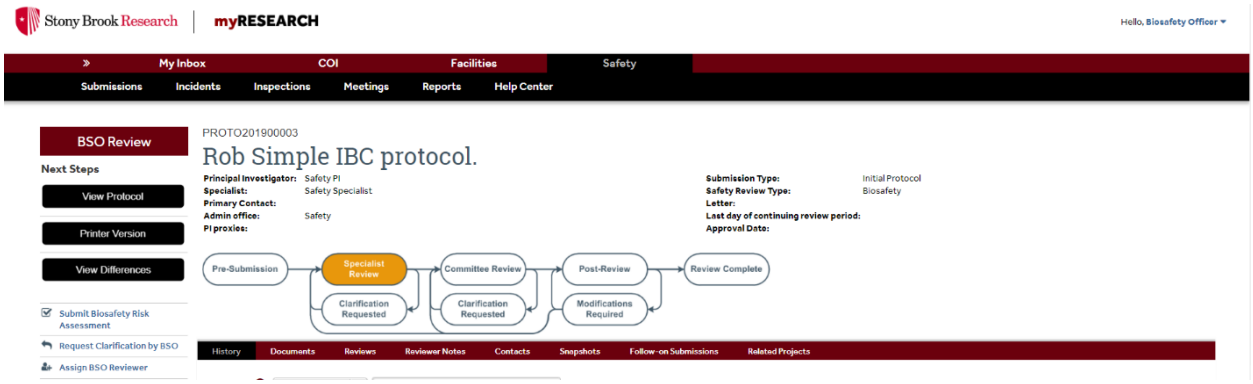
Submitting the Study

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 **Investigator's Assurance** page will pop up. The PI must carefully read the assurance page and click the **OK** button on the bottom-right hand side of the page.



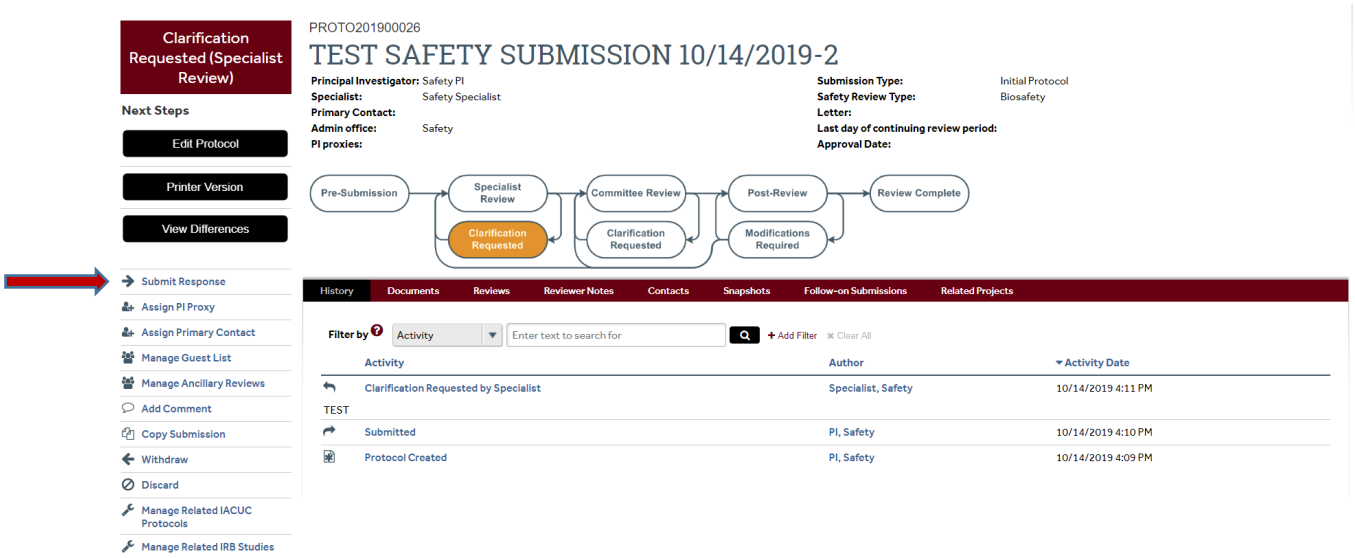
Clarification Requested

Click the submission ID link in the email to open the document. 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.



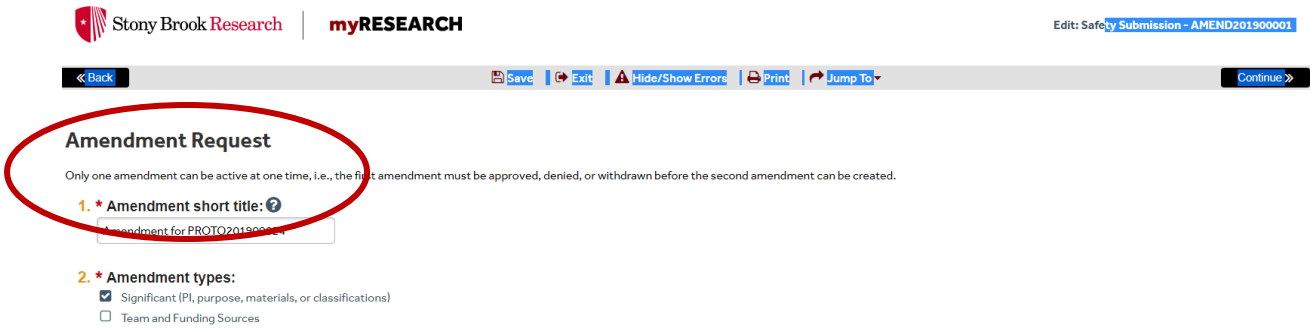
Respond to Clarification Requests

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.



Amendment Request

Click on **Create Amendment** in the left navigation area if you are submitting an amendment request. Enter data in all required fields. Submit the amendment



Safety Incident Report

Click on **Create Safety Incident** in the left navigation area if you are submitting an incident report.

This area of the Safety Incident will ask you to describe the incident, the nature of the incident, any associated principal investigators, any related safety research protocols, where it was discovered and if there are any additional supporting documents.