Rowan eIRB User Manual for Investigators and Research Staff

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Rowan eIRB Access

The website is available via any Internet connection anytime with a supported browser.
http://eirb.rowan.edu

Getting Help

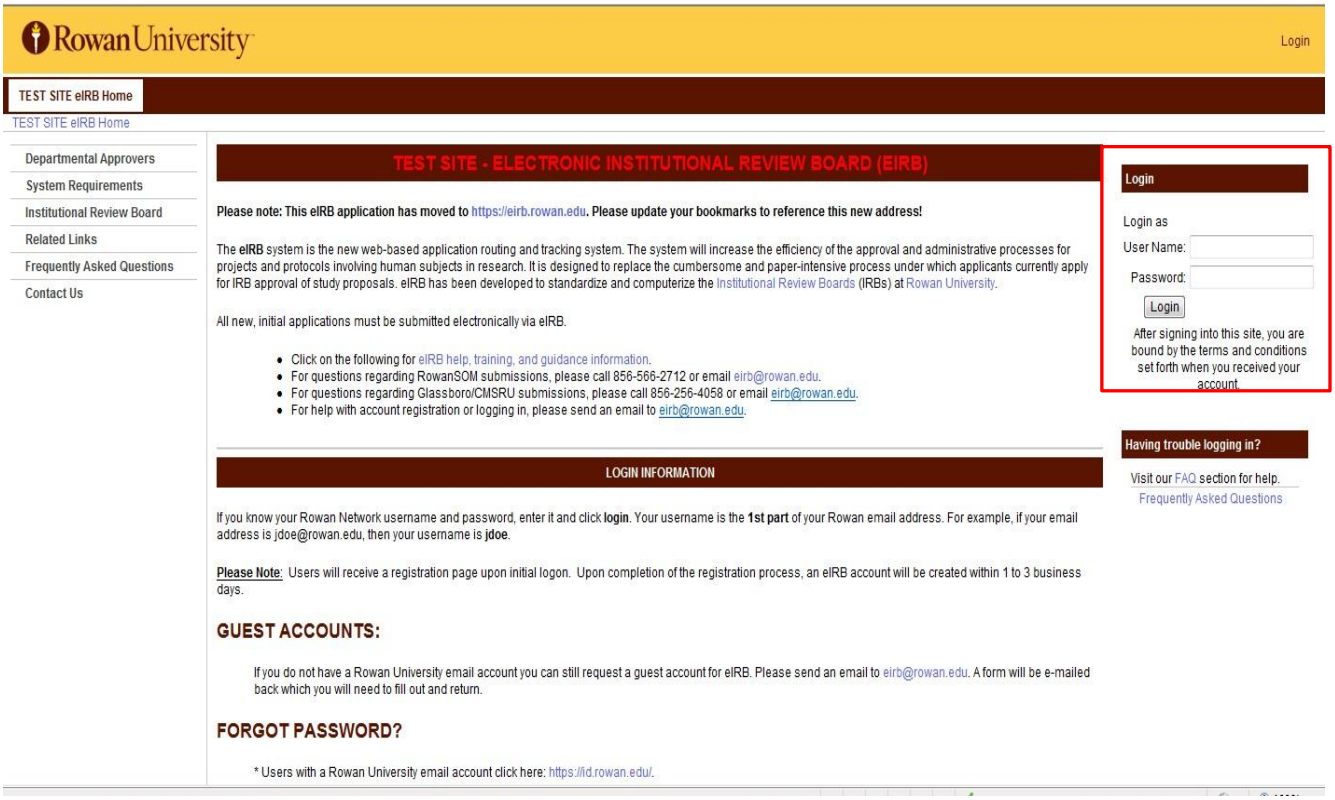
If you have problems, need help, or have questions about the Rowan eIRB please contact the RowanSOM IRB office at (856) 566-2712 or the Glassboro/CMSRU IRB Office at (856) 566-4058.

Using the new eIRB website, you can:

- Create and edit an electronic application for IRB studies
- Add other investigators and study personnel to assist in editing the study application.
- Prepare the study application via ***"SmartForms"*** that present only those sections that are applicable and relevant to your study.
- Attach scanned or electronic documents to the study.
- Print out the application in a ***'printer-friendly version'***.
- Validate the application before submission to catch common mistakes and reduce the number of changes required after submission.
- Submit a single application electronically to the IRB.
- Track the progress of the application as it is automatically routed for review and signoff to the appropriate organizations (department heads) before being received by the IRB.
- Receive email notifications anytime a reviewer sends the application back for requested changes.
- Receive the approval letter via email once the study is approved. A copy of the approval letter and approved consent forms will be posted online with the study and available for download at anytime.
- View a time stamped log of all changes made to the application and any correspondence sent between the study team and the IRB.

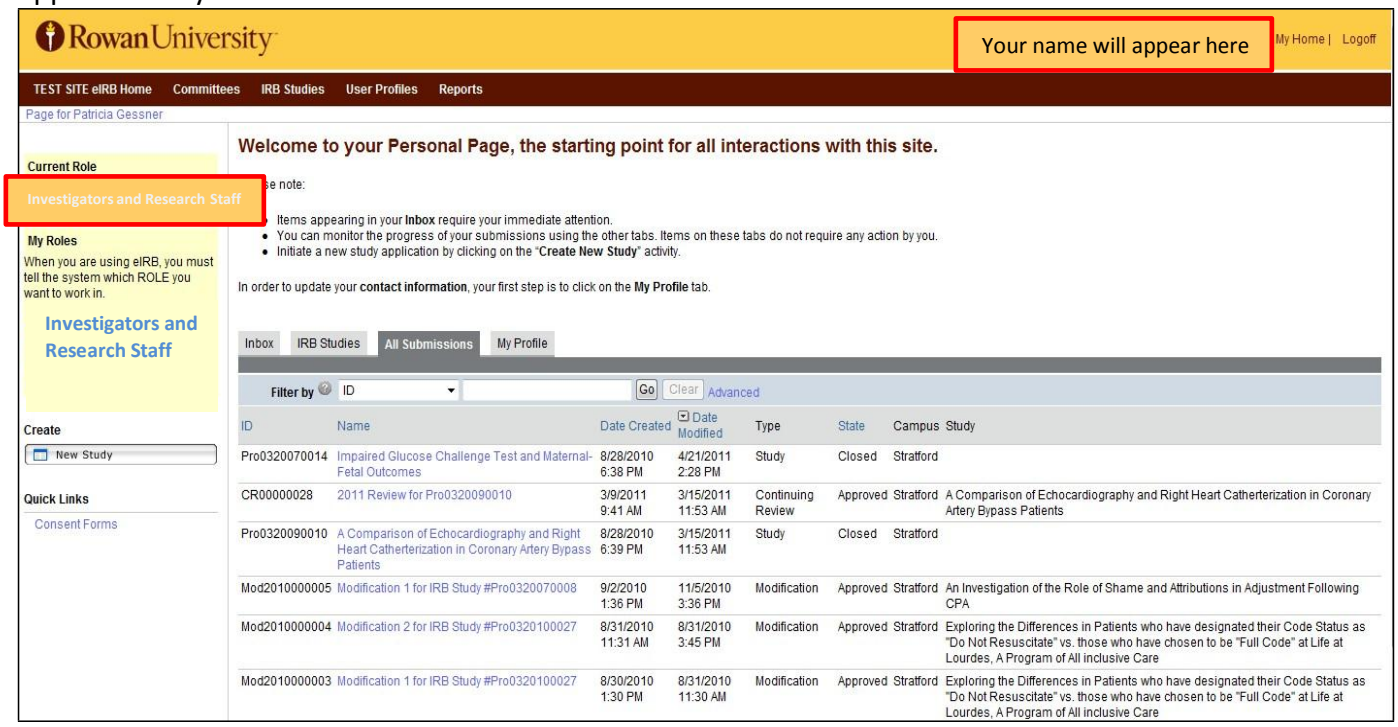
Log-in to eIRB

You can log into the eIRB website using your core username and password.



Personal Folder

Your eIRB experience is personalized allowing you access to all of the studies you are working on or reviewing. When you log into eIRB you are taken to your person folder, which displays links to the items applicable to you.



Left Navigation Bar

1. ***'My Roles'*** allows you to select between user roles if you have more than one. Select the correct role as each role has its own inbox. Your role determines your access level or what you are able to view/edit.

2. *The* ***'(Create)' New Study*** button allows you to start a new IRB application from scratch.

Top Navigation Bar

3. Your ***'Name'*** allows you to change personal information.
4. ***'My Home'*** is the default user page which always returns you to this page view.
5. ***'Logoff'*** ends your session and logs you out of the system.

Tabbed Area

6. The ***'Inbox'*** tab displays all studies you are a part of that require some task to be completed by the study team.
7. The ***'IRB Studies'*** tab allows you to search through all respective IRB studies that you are a part of, regardless of where the study is in the submission and review process.
8. The ***'All Submissions'*** tab lists new studies, continuing reviews, modifications, and reportable events you are listed on, but do not require your attention
9. The ***'Profile'*** tab allows you to edit and view your personal training profile and research certifications.

Overview of the eIRB Submission and Review Process

The following steps illustrate the basic application review process:

Step 1: PI and Study Staff

Prepare and submit application.

Step 2: Dept/Div Review

If applicable, the application is routed for approval and sign-off:

- Department Review – This is a blocking review where the IRB will not see the project until it has departmental approval.

Step 3: IRB Staff Review

An IRB Staff Member will be assigned to the study. The IRB Staff Member will conduct an administrative staff review and manage the scheduling of the study.

Step 4: IRB Review

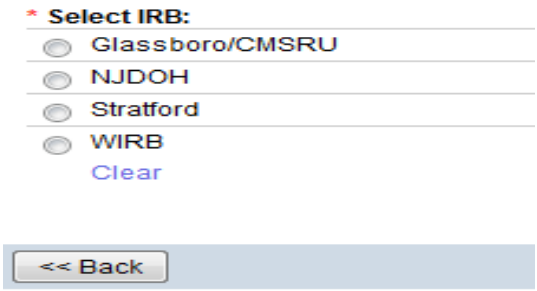
The IRB committee will review the application and provide an approval. Committee decisions and approval letter are recorded by the IRB Staff Member in eIRB and sent to the PI.

Step 5: PI and Study Team

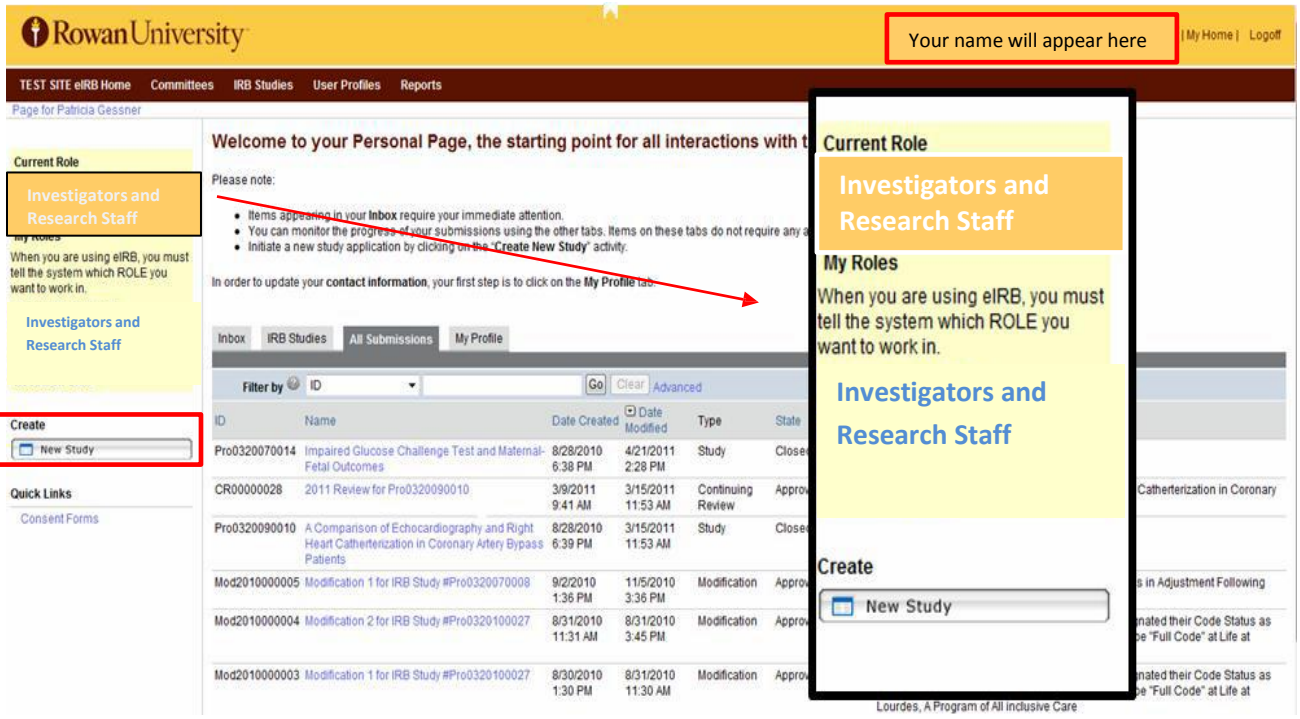
- Conduct research.
- Report adverse events.
- Submit requests for continuing reviews.
- Submit modifications to initial submissions.

Create a New Application and Select IRB

Select appropriate IRB based on the Principal Investigator's Home Department/Organization
Note: For NJDOH staff and non-NJDOH staff select "NJDOH" as the IRB
Note: For clinical trials only at RowanSOM, select WIRB



Create a New Application and Specify Personnel

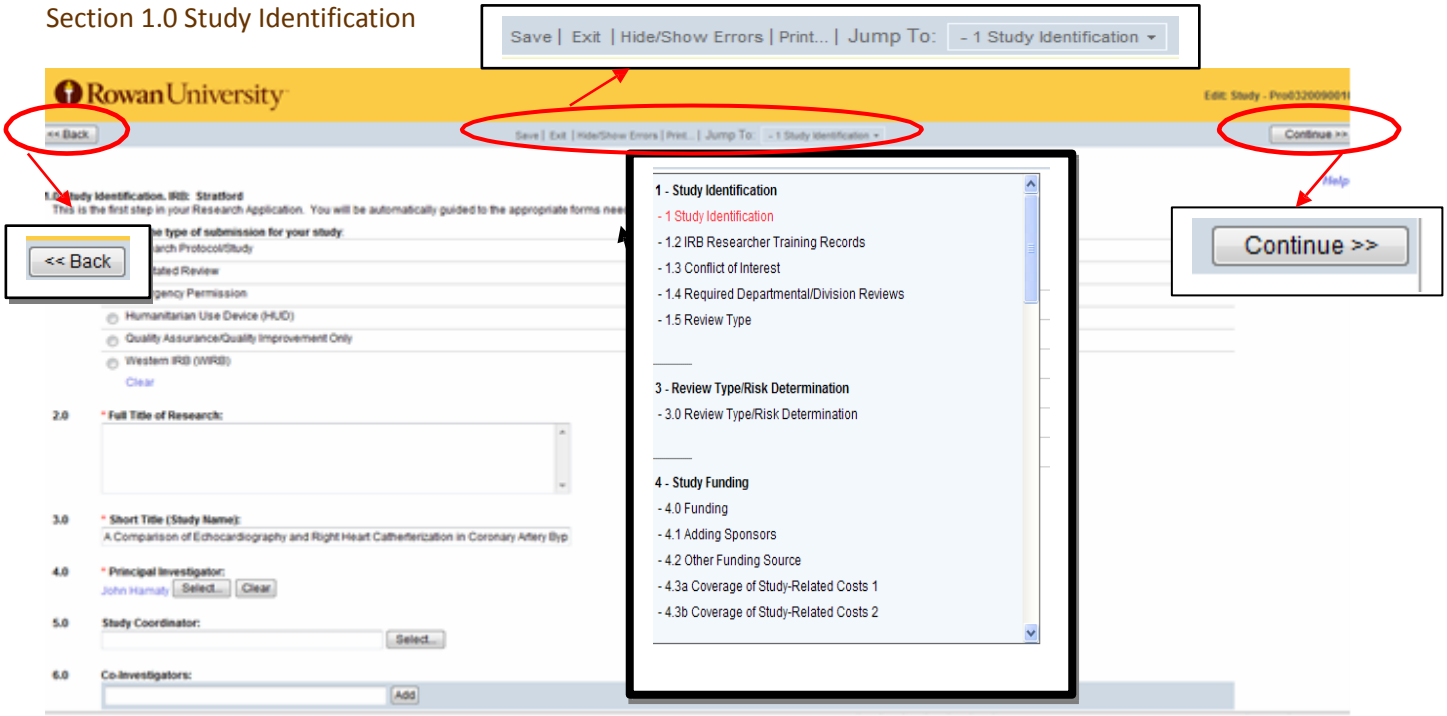


- ☐ Create a new study by using the ***'New Study'*** button in your personal folder. This will open a new application so you can fill in the identifying information for this study.
- ☐ Once the smart-form opens, enter at least the required fields, those marked with a red asterisk * are mandatory.
- ☐ You can answer the text questions by typing directly within the form or by pasting in information from another application, such as Word.
- ☐ Select the ***'Continue'*** button in the navigator bar to save and move to the next screen.

! If you need to finish an application at a later time, you can use the '*Save*' button at the top of the screen. Simply exiting will not save changes.

Study Identification

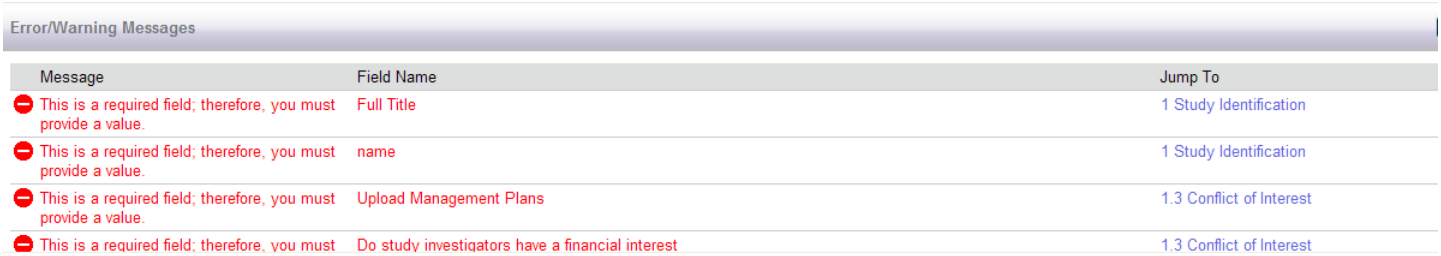
Section 1.0 Study Identification



- Use the ***'Back'*** and ***'Continue'*** buttons to move back and forward on the screen.
- The ***'Save'*** button will allow you to save any changes made to the application.
- **! *Exit* will close the application screen without saving changes. Always save the application before exiting.**
- ***'Print'*** will produce a printer friendly view that can be printed.
- ***'Jump To'*** allows you to select a screen within the application process and go there directly by selecting a link from the drop down box.

• ***'Hide/Show Errors'*** will show any errors and mandatory fields not yet completed.

• Below is an example of the results of ***'Hide/Show Errors'***. This can be used to gauge your progress and determine any additional fields that will need to be completed in the application.



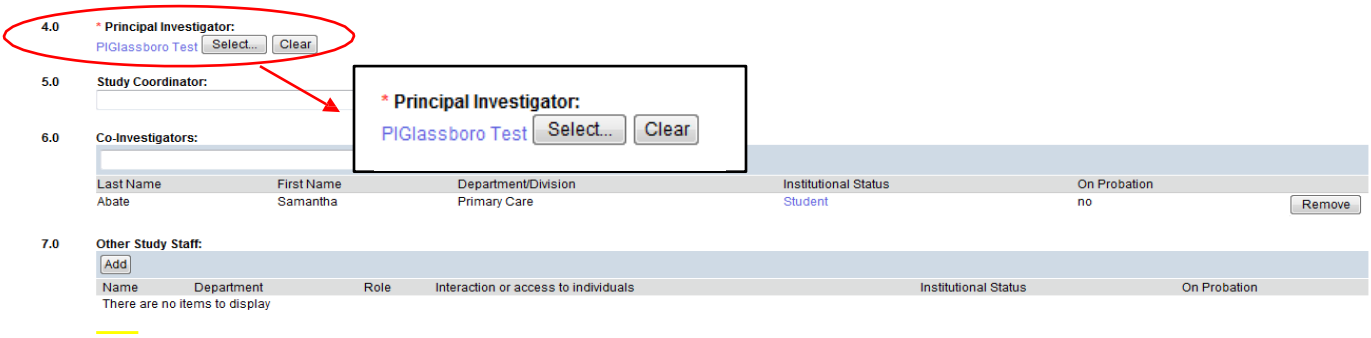
Error/Warning Messages

Message	Field Name	Jump To
This is a required field; therefore, you must provide a value.	Full Title	1 Study Identification
This is a required field; therefore, you must provide a value.	name	1 Study Identification
This is a required field; therefore, you must provide a value.	Upload Management Plans	1.3 Conflict of Interest
This is a required field; therefore, you must	Do study investigators have a financial interest	1.3 Conflict of Interest

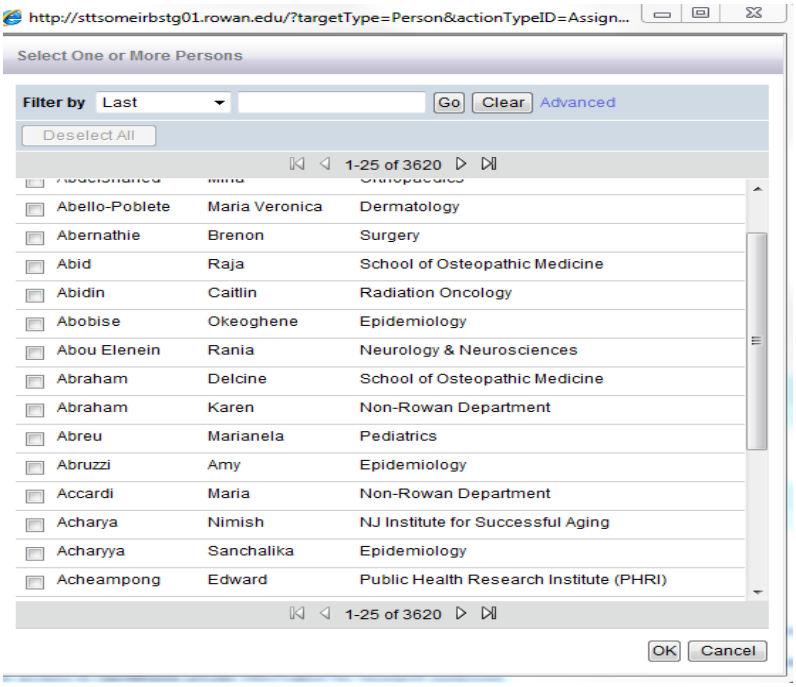
Assign Study Personnel

As the creator of a new study application, you will specify who has permission to edit and view the study. On ***the 'Study Identification'*** screen, you can select the Principal Investigator for the study submission. If you are signed in as the PI, this will default to your name.

Only the users specified (as the PI, study coordinator, co-investigators, or other study staff) will be able to edit and save the study application. If you would like to give a new person permission to edit the study later on, you will have to add them to one of these questions at that time.



By clicking the ***'Select button'***, a search page will open that will allow you to search for a person by last name, first name, organization, project ID, or user ID. An example search is shown below.



How To Upload Documents to your Application

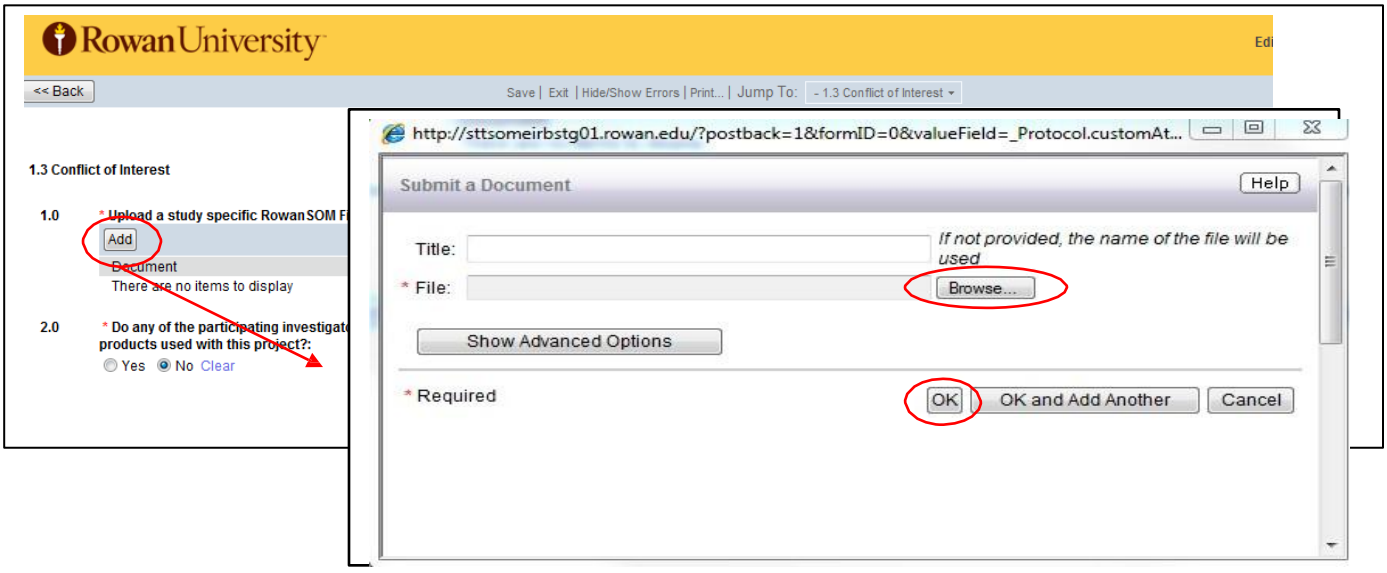
Required documents that will need to be uploaded are the Financial Disclosure Form, the Study Protocol, surveys, questionnaires, data collection form (if applicable) informed consent/assent (with version dates and pagination). Non-Rowan study site (studies taking place at Kennedy requires the PCP form). In addition, if your study involves biohazards and/or radiation, please upload the Institutional Biosafety Committee approval, and/or Radiation Safety Committee approval.

1. Click the ***'Add'*** button and a new window will appear
2. Enter a ***'Title'*** and ***'version date'*** for the document you are uploading
3. Click ***'Brouse'***…and select the file you want to attach
4. Click ***'Open'***
5. Click ***'Ok'*.**

1.3 Conflict of Interest

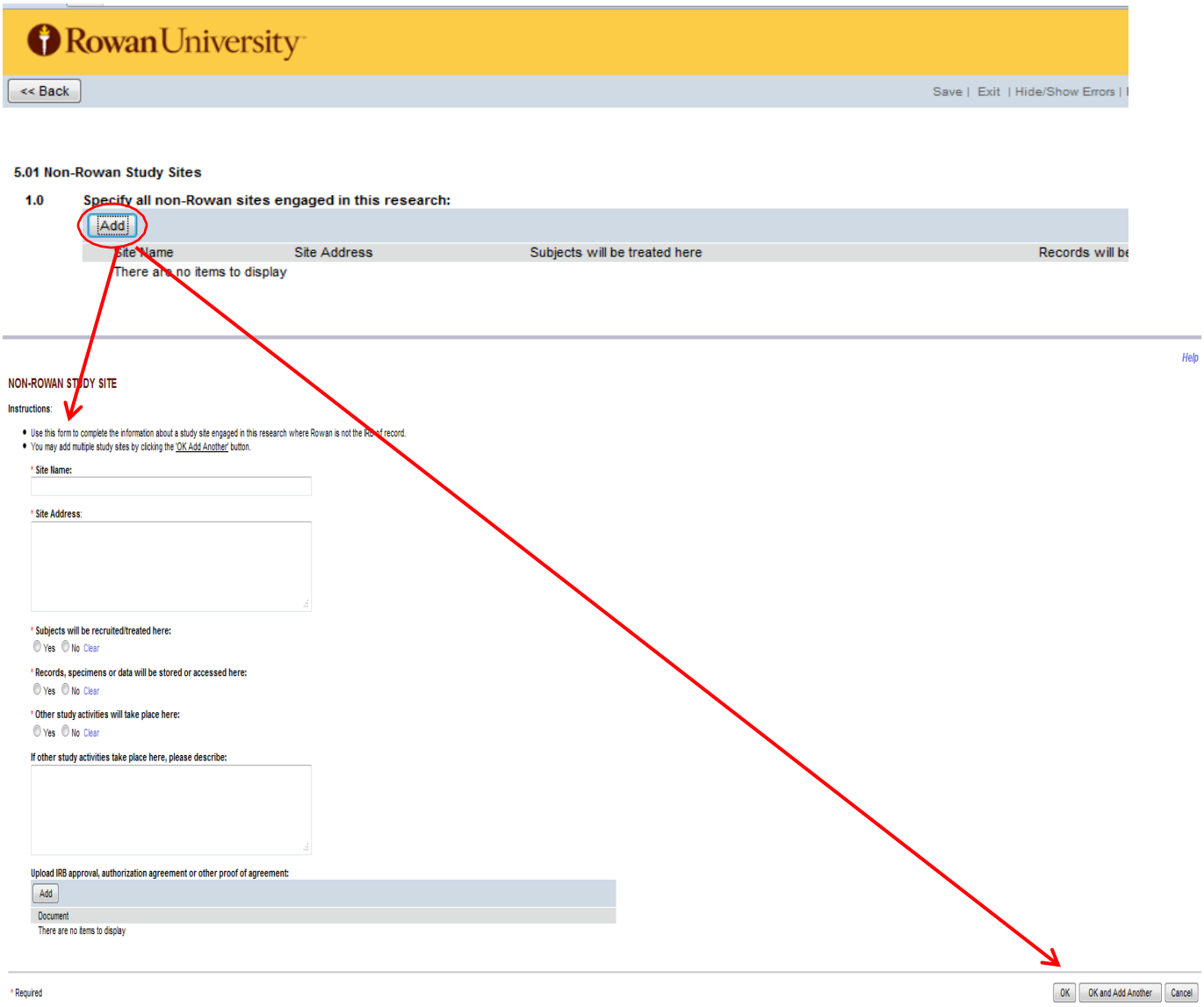
The investigator must complete the Financial Disclosure Form and list all co-investigators, study coordinator and other http://www.rowan.edu/som/hsp/forms/universityforms.html. After the form has been signed by all listed, please upload into section 1.3 of the application.

'Select Browse', locate your document on your computer, then upload. ***'Title the document'*** you upload (e.g. – 2014 Financial Disclosure Form), then select ***'OK'.***



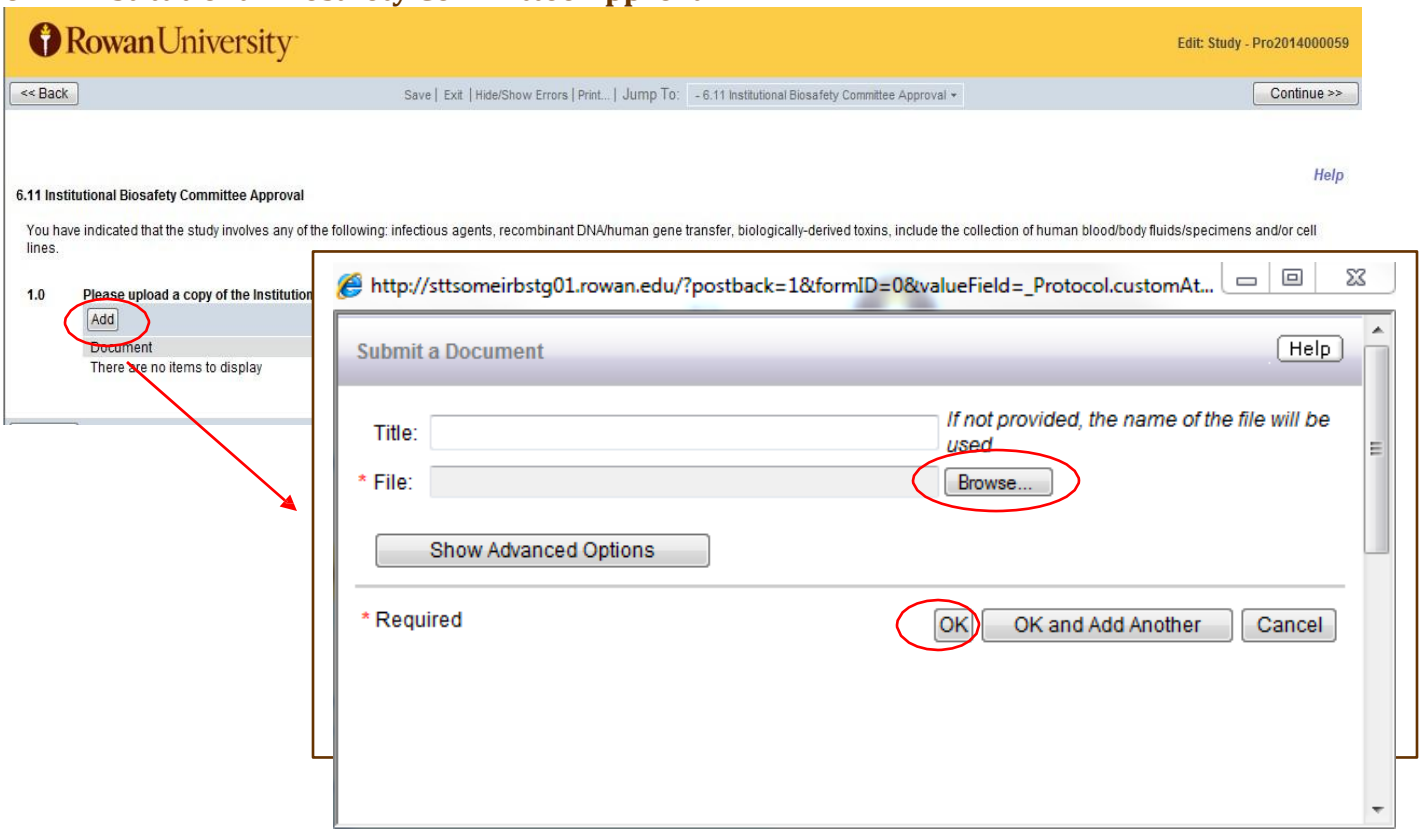
5.01 Non-Rowan Study Sites

The Investigator must identify non-Rowan Study Sites in this section. An approval letter from the site, on company/institutional letterhead must be signed by the authorized personnel at the non-Rowan study site. Once signed and completed, the investigator would 'add' the non-Rowan Study Site, complete the information in the pop-up box/non-Rowan Study Site and upload the signed letter. After upload the investigator will click 'OK' if not adding another site, or 'OK and Add Another' if another non-Rowan Study Site.

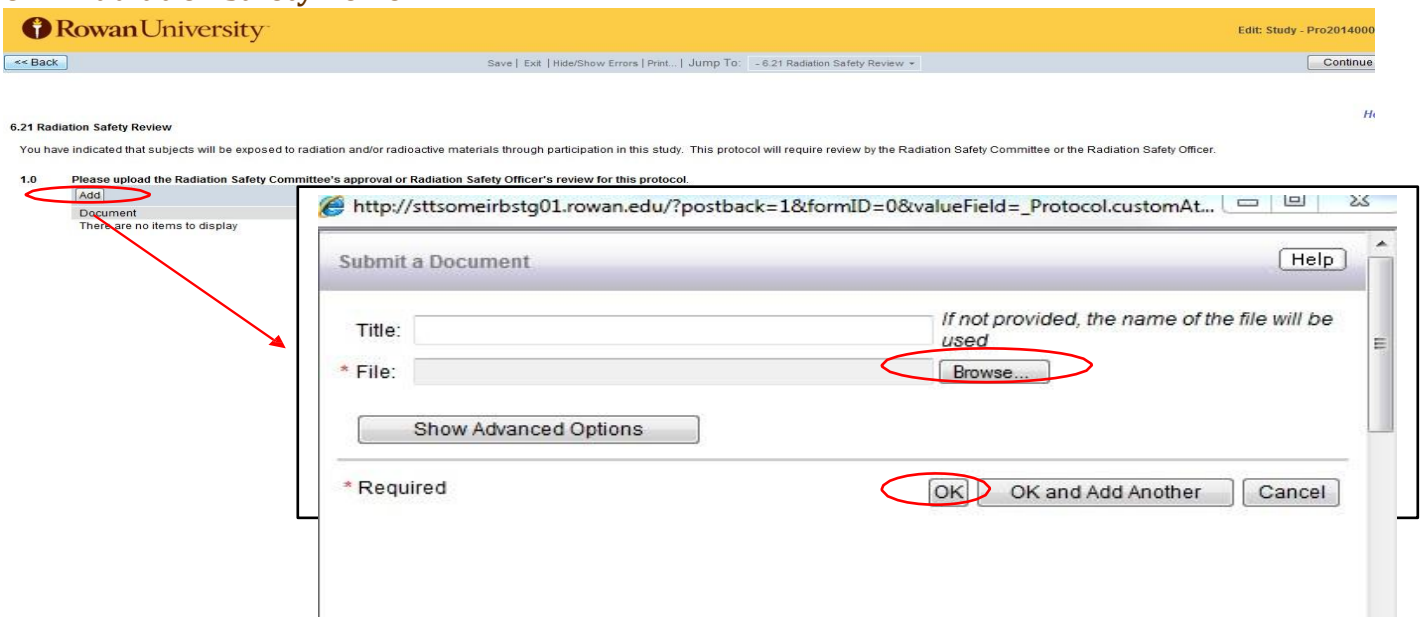


6.01 Rowan required Pre-Approvals

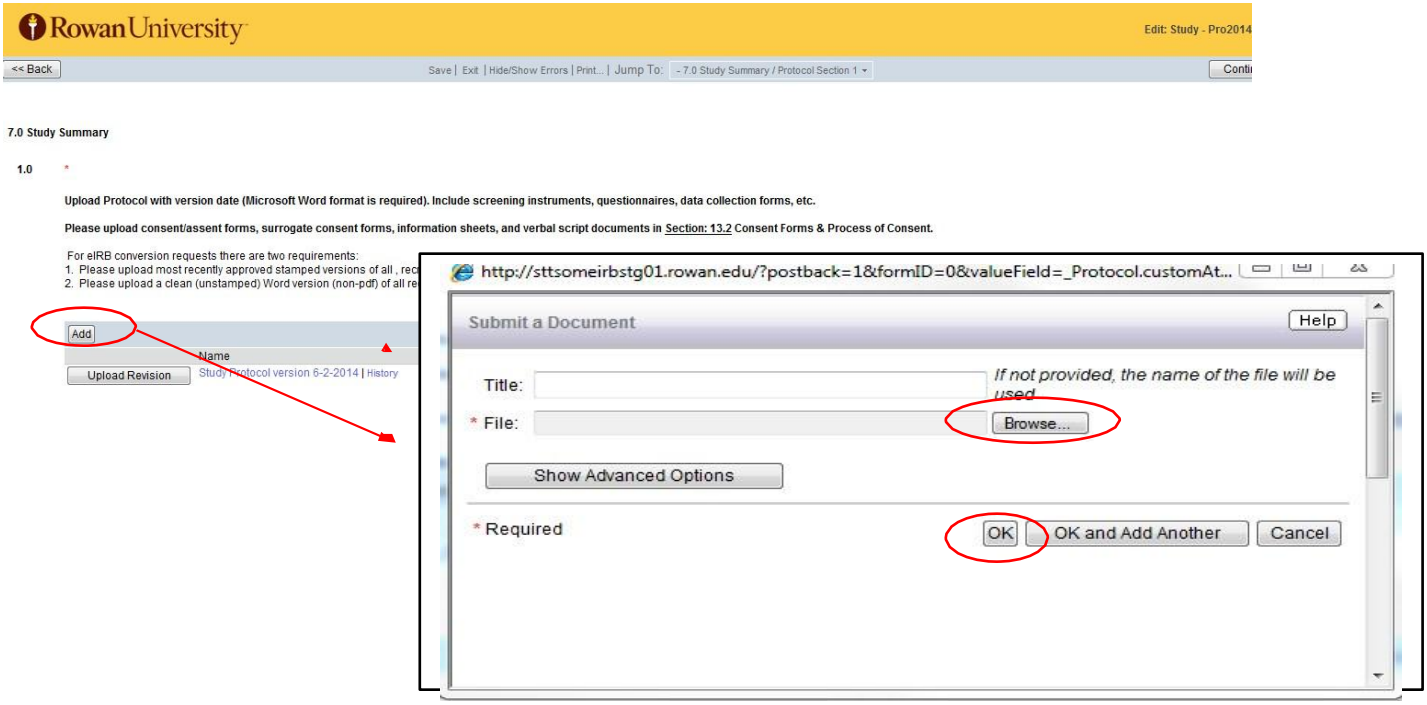
6.11 Institutional Biosafety Committee Approval



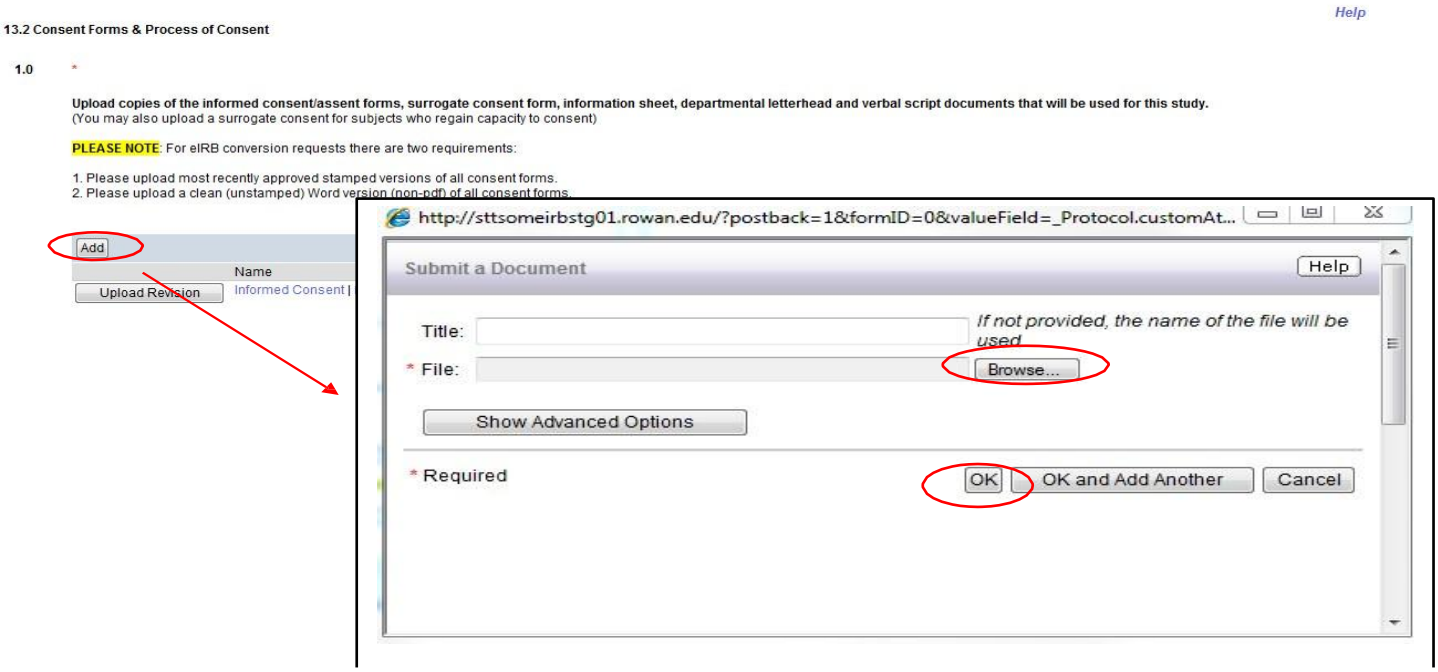
6.21 Radiation Safety Review



7.0 Research Protocol

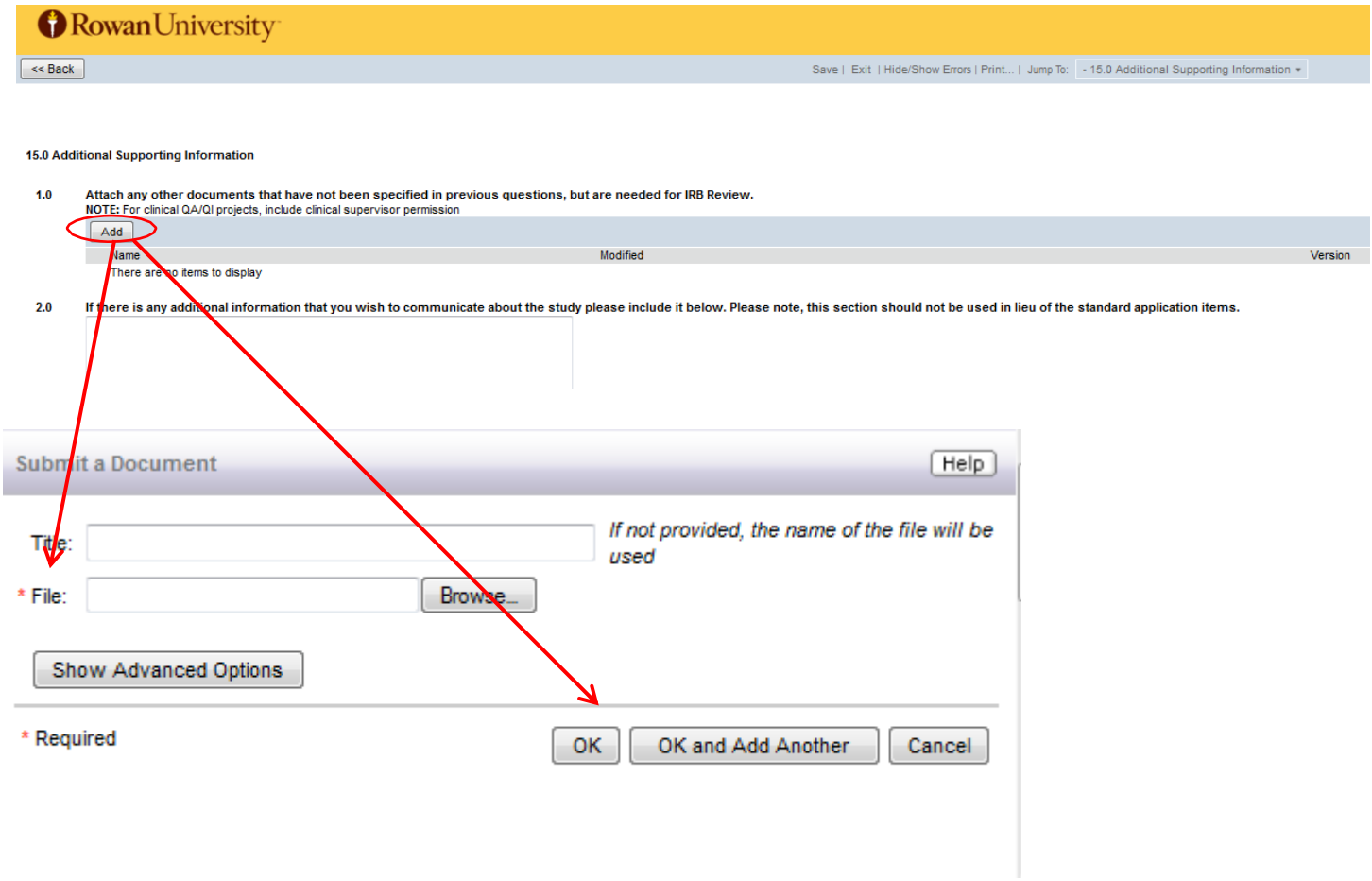


Section 13.0 Informed Consent and Waivers



Section 15.0 Additional Supporting Information

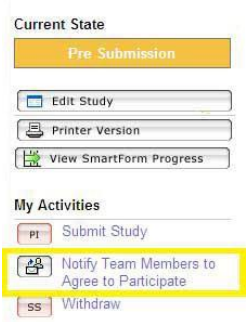
All additional supporting information that is applicable to the study that is not uploaded in any other section of the eIRB application must be uploaded in this section.



Submit the Application

! Please note, you are required to include the Department(s)/Division(s) for each study team member involved in this application. This is completed in section 1.4 "Required Departmental/Division Reviews"

Please note that all Co-investigators listed in your study must agree to participate in the study prior to submission. An email with a direct link to your study can be sent directly to your co-investigators by clicking on the ***"Notify Team Members to Agree to Participate"*** button as seen below:

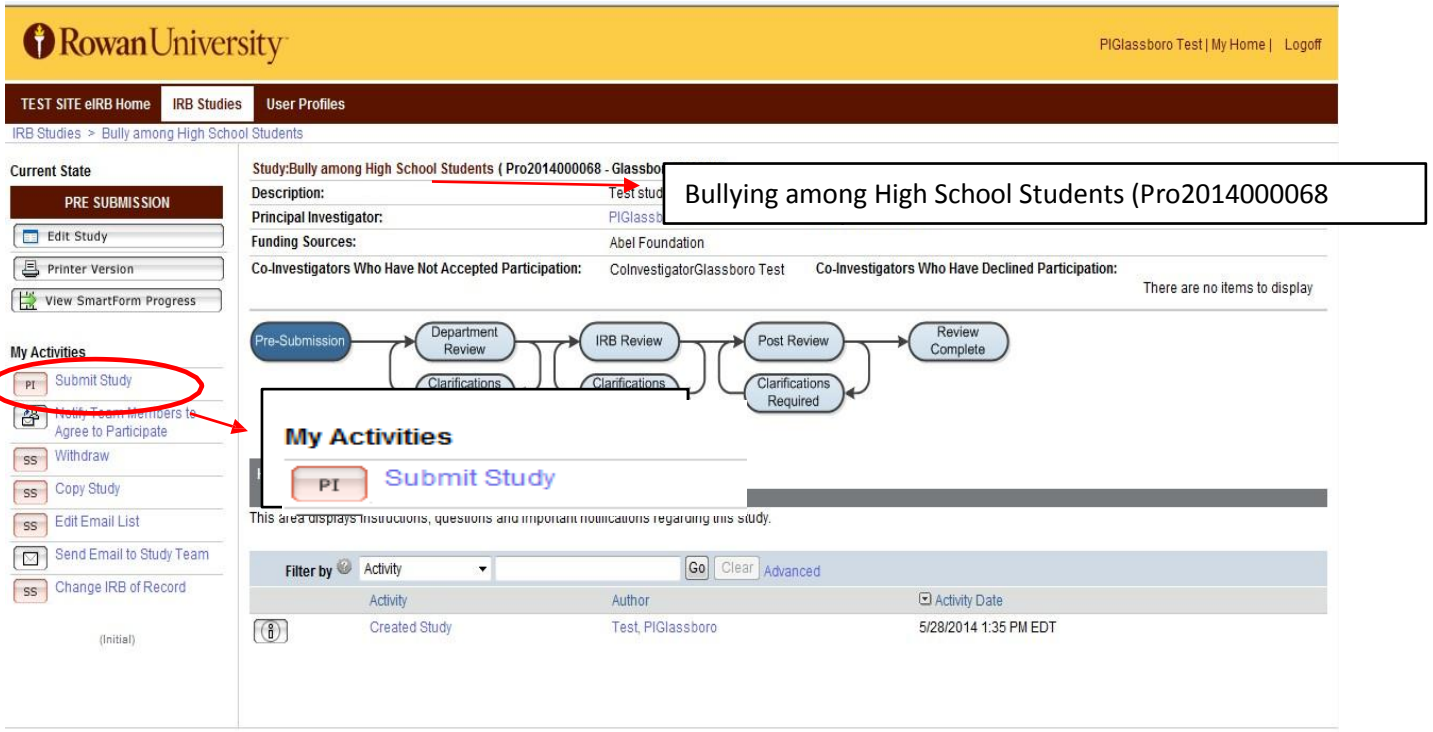


Once logged into your study, they will be required to use the ***'Accept Participation'*** activity in order to complete an affirmation of involvement.

Before the application is submitted, it will be validated to check for common errors. The application is also validated when the Principal Investigator submits the application to the IRB.

'Exit' the Smart Form version of the study by selecting ***'Exit'***. This will bring you to the '***Study Workspace'***.

You can identify the workspace you are in by bolded word listed above the study description.

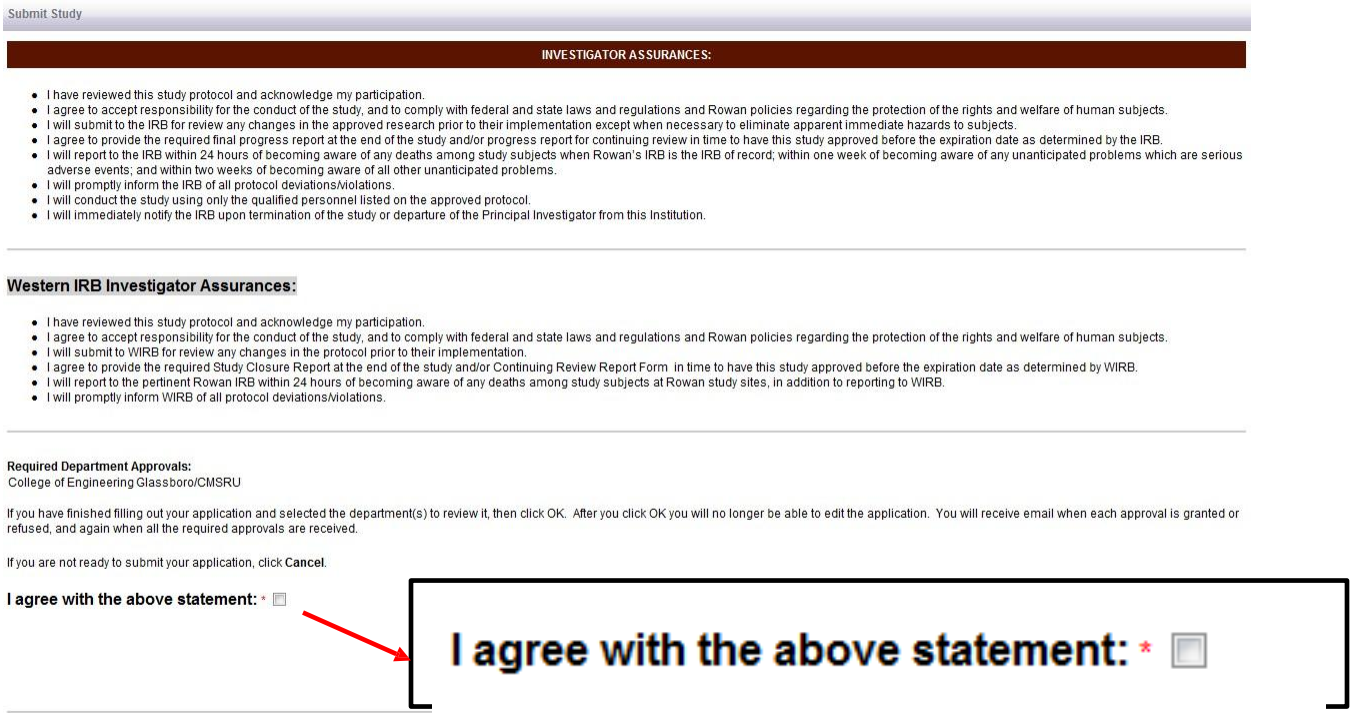


Application Validation and Submission

In the ***'Study Workspace'***, select ***'Submit Study'*** located in the left navigation bar. Only the Principal Investigator on the study can submit the application.

The system will run a final validation check on the entire application before submission. If there are any errors, they will be displayed on the submission screen that opens up and your application will not be submitted. The application must be error-free and have all co-investigators agreed to participation before it can be submitted.

On the new screen that opens up, read the Principal Investigator's assurances and check next to ***'I agree with the above statement'***. Select the ***'OK'*** button at the button of the screen to submit the application for the study.


Submit Study

INVESTIGATOR ASSURANCES:

- I have reviewed this study protocol and acknowledge my participation.
- I agree to accept responsibility for the conduct of the study, and to comply with federal and state laws and regulations and Rowan policies regarding the protection of the rights and welfare of human subjects.
- I will submit to the IRB for review any changes in the approved research prior to their implementation except when necessary to eliminate apparent immediate hazards to subjects.
- I agree to provide the required final progress report at the end of the study and/or progress report for continuing review in time to have this study approved before the expiration date as determined by the IRB.
- I will report to the IRB within 24 hours of becoming aware of any deaths among study subjects when Rowan's IRB is the IRB of record; within one week of becoming aware of any unanticipated problems which are serious adverse events; and within two weeks of becoming aware of all other unanticipated problems.
- I will promptly inform the IRB of all protocol deviations/violations.
- I will conduct the study using only the qualified personnel listed on the approved protocol.
- I will immediately notify the IRB upon termination of the study or departure of the Principal Investigator from this Institution.

Western IRB Investigator Assurances:

- I have reviewed this study protocol and acknowledge my participation.
- I agree to accept responsibility for the conduct of the study, and to comply with federal and state laws and regulations and Rowan policies regarding the protection of the rights and welfare of human subjects.
- I will submit to WIRB for review any changes in the protocol prior to their implementation.
- I agree to provide the required Study Closure Report at the end of the study and/or Continuing Review Report Form in time to have this study approved before the expiration date as determined by WIRB.
- I will report to the pertinent Rowan IRB within 24 hours of becoming aware of any deaths among study subjects at Rowan study sites, in addition to reporting to WIRB.
- I will promptly inform WIRB of all protocol deviations/violations.

Required Department Approvals:
College of Engineering Glassboro/CMSRU

If you have finished filling out your application and selected the department(s) to review it, then click OK. After you click OK you will no longer be able to edit the application. You will receive email when each approval is granted or refused, and again when all the required approvals are received.

If you are not ready to submit your application, click **Cancel**.

I agree with the above statement: *

I agree with the above statement: *

Check the Status of the Application and Respond to Requested Changes

Once the application has been submitted to the IRB, the application is automatically routed to the required personnel in the review process. As part of the study team, you will receive notifications from the system indicating the completion of certain elements of the review process or requesting changes to be made to the application. You can also check the progress of your application by opening the ***'Study Workspace'*** in eIRB.

Receiving Progress Notifications and Update E-mail

The eIRB system automatically generates email notifications and sends them to the study team when significant events have occurred in the review process. The study team will always receive a notification when a reviewer requests changes be made to the application. In addition, the study team will receive notifications at the following times:

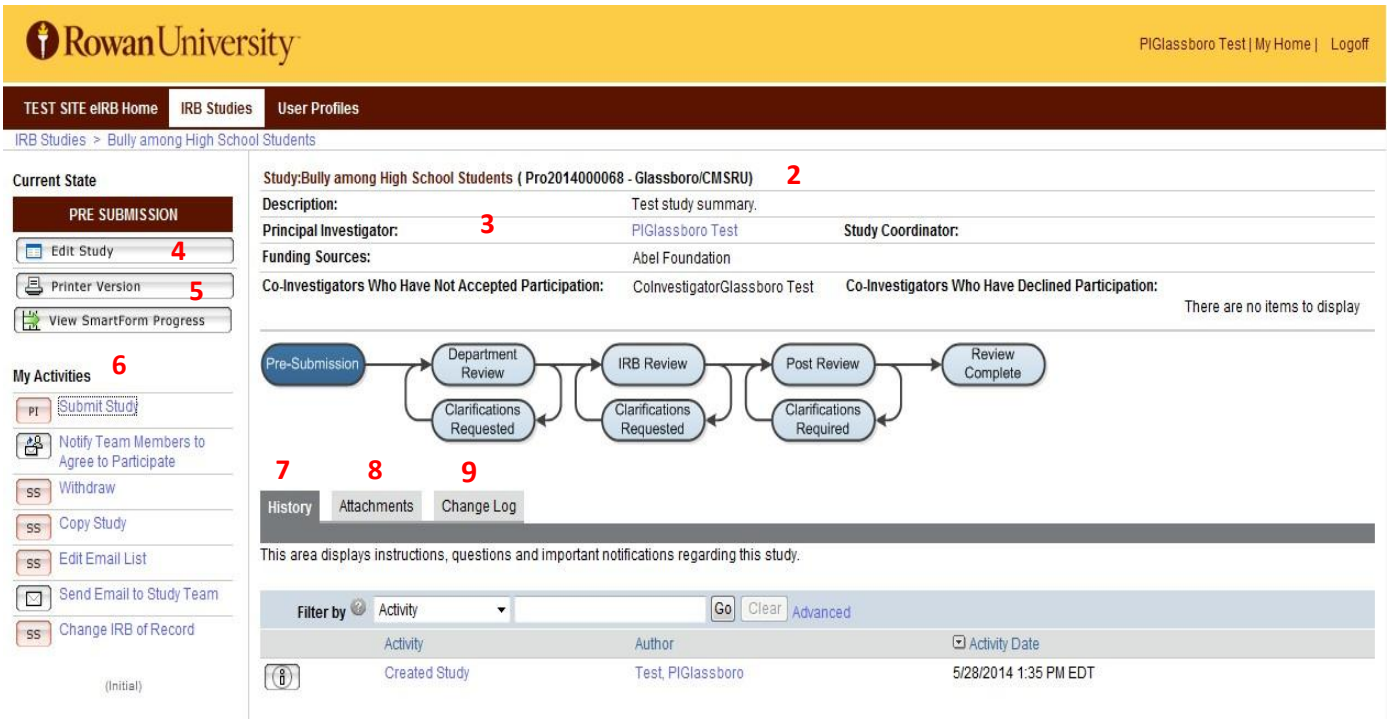
- Confirmation that the application has been submitted.
- Receipt at the IRB office.
- Official action letter form the IRB.

! Since the system uses this email address to send notifications about review progress, it is important that your email address recorded in the eIRB system is current,

- You can update your information by returning to ***'My Home'*** and selecting the ***'My Profile'*** tab.
- Select your ***'name'*** open you profile.
- Choose '***Edit Profile'*** located in the left navigation bar.
- Change any outdated contact information.
- Select **'Save/Exit'** to return to ***'My Home'***.

The Study Workspace

Every study created in the eIRB system is assigned a folder or workspace. When you click on a study to view it from your ***'My Inbox'***, the study's workspace is opened.



The workspace displays important information about the study and contains links to help navigate to any information contained in the study.

1. The ***'current state'*** displays the progress of this study in the review process. The ***'current state'*** will change depending on the study's progress through the review process.

2. The panel displays the '***Title of the Study'*** and the ***'IRB number'*** the study was assigned.

3. The ***'Description'*** provides summary information about the study, as well as the name of the Investigator.

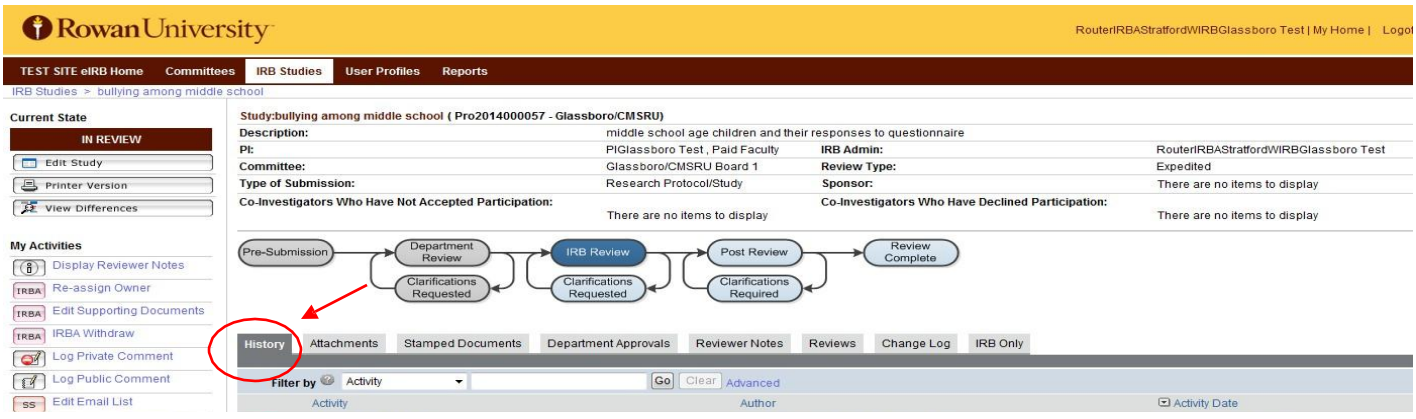
4. The ***'Edit Study'*** icon will open the application smart forms.
5. The ***'Printer Version'*** icon will open all of the relevant smart form screens in one easy to print window.
6. ***'My Activities'*** lists all of the available actions you can perform on the study. Click on them and complete the opened screen to perform the action.
7. The ***'History'*** tab records all actions performed on the study. Each action is recorded with the date, time, and person performing the action. You may click on the name of the activity to see the system details.
8. The ***'Attachments'*** tab contains all documents for a study.
9. The ***'Change Log'*** tab lists all changes made to a submission.

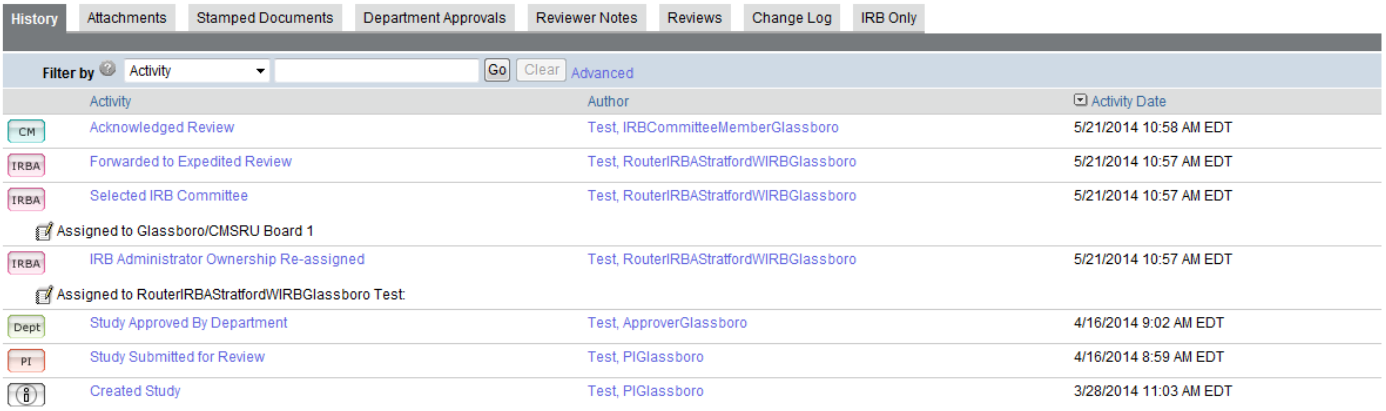
The Study History Log

Every study has a detailed ***'history log'***. For auditing purposes, every action performed on the study is recorded in the history log.

This information is viewable under the ***'History'*** tab. This is sorted in chronological order and displays only the actions you have permission to see. Each, activity, when performed, is recorded in the history log with a data/time stamp and the name of the performing the activity. You can click on the name of the activity to view the system details.

The history is updated after a new activity is completed by anyone working on the study.



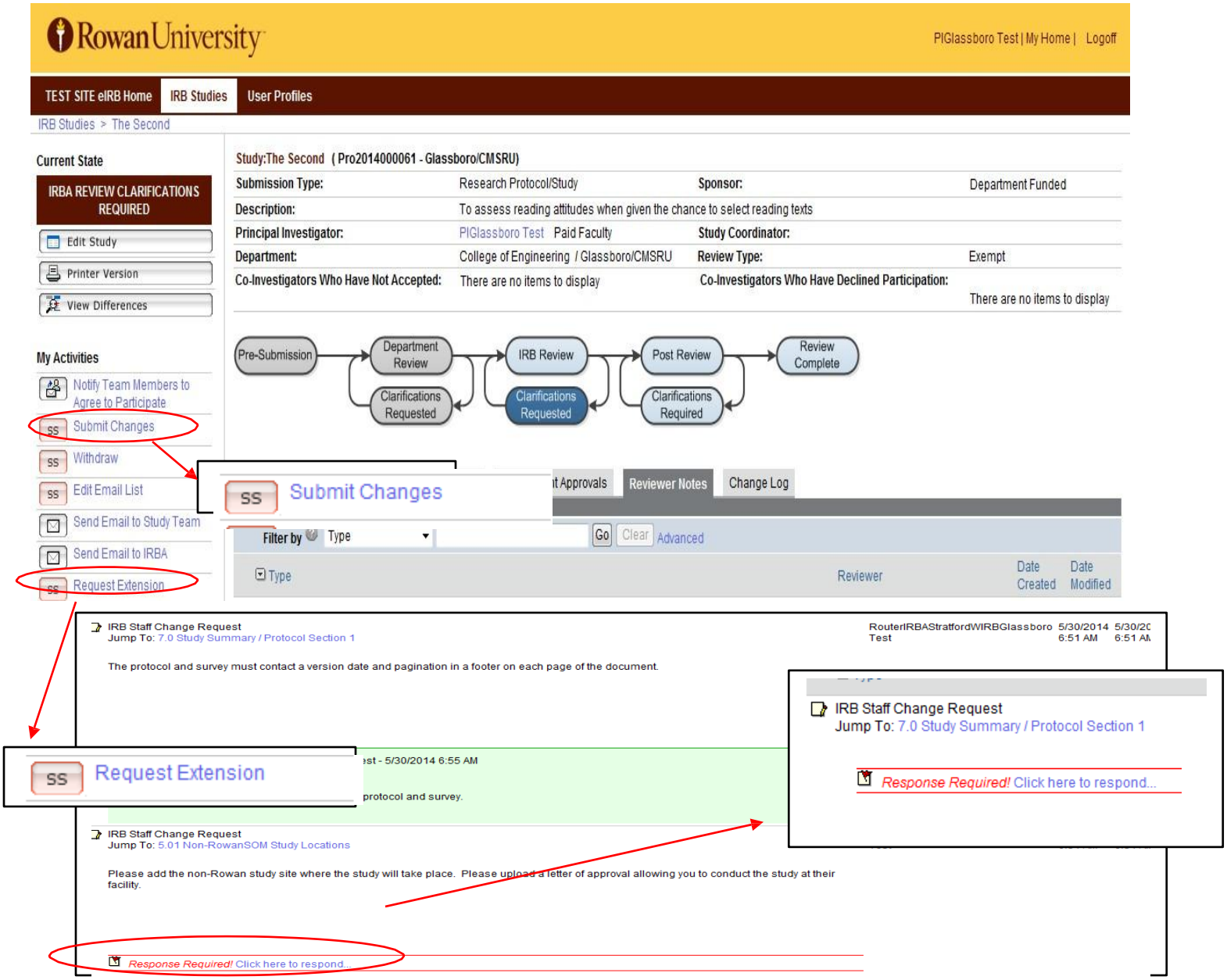


Responding to Requested Changes

The study team will receive an automated email notification when the study is sent back to them for requested changes.

Within the study workspace, you must click on the '***Reviewer Notes'*** tab to see requested changes.

1. Select the "***Click here to respond"*** link to respond to these requests.
2. ***'Navigate to the smart form application'*** and make any needed changes. Remember to save the changes before exiting the application.
3. When you are ready to submit your response navigate back to the study workspace and click the ***'Submit Changes'*** activity.
4. Paste the requested changes you copied into the text box. Write your response after each requested change, after each request change, detailing the change made or your reason for disputing it. When finished, click the ***'OK'*** button.



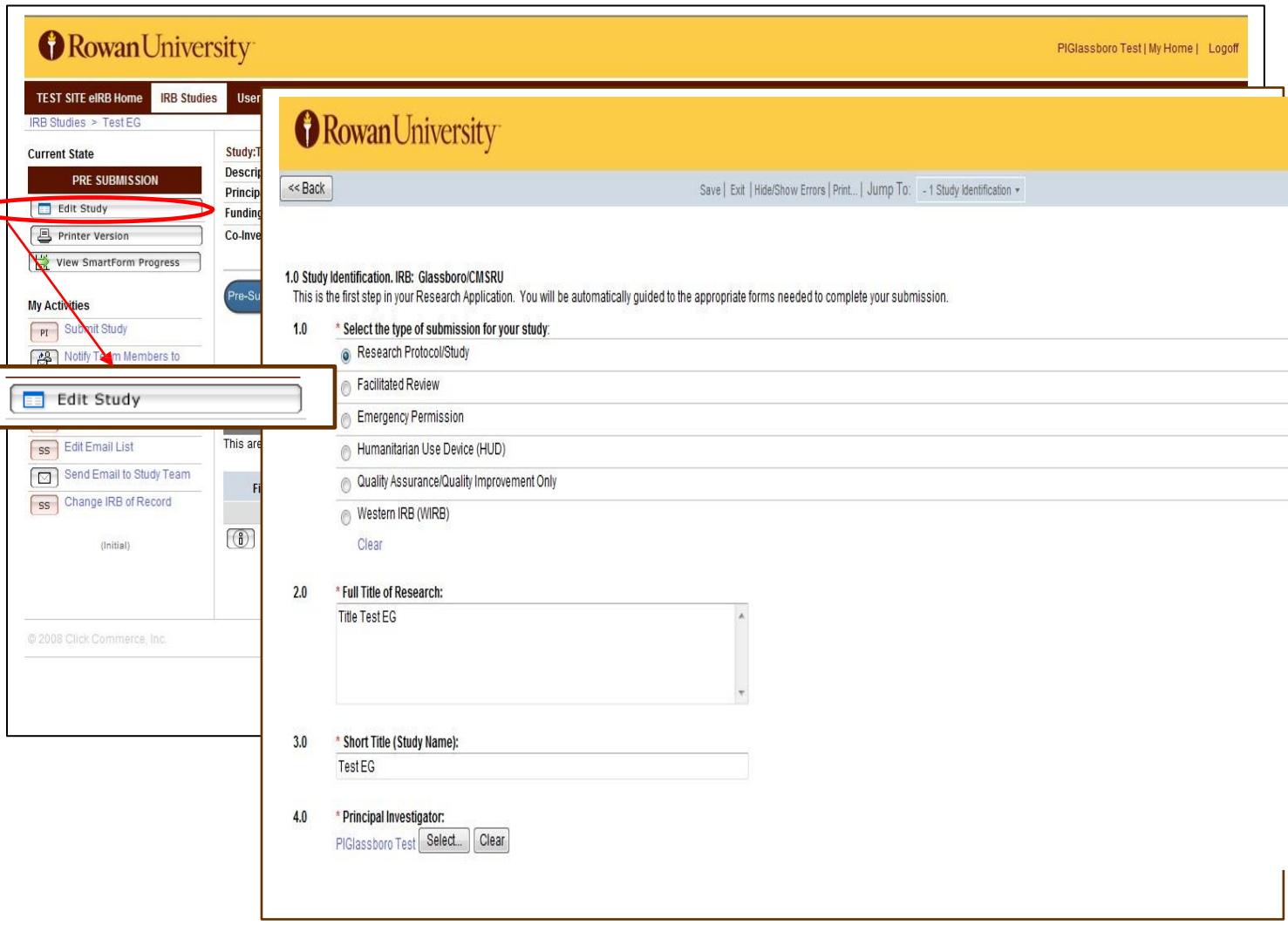
- ! **You have 90 days to respond to the requested changes or your study with be automatically withdrawn from the system.**
- If know that you will need more than 90 days, you may request an extension from the IRB by selecting the ***'Request Extension'*** activity to call for another 90 days to respond.
- The IRB will receive your request and either approve or deny you another 90 days. You may apply for up to 3 extensions or an additional 270 days to respond.

Edit an Application

A study application may be edited before it is submitted (during Pre Submission) or any time if changes are requested by reviewers or the IRB. The study will appear under the 'My Inbox' tab in all these occasions.

To open a study to make changes

1. From your Personal folder ('My Home'), click on the title of the study you wish to select listed in 'My Inbox'.
2. In the study workspace, click the *Edit Study* button. The first study application screen appears in edit mode.
3. Make any necessary changes and save the study by clicking the *Save* or *Continue* button.



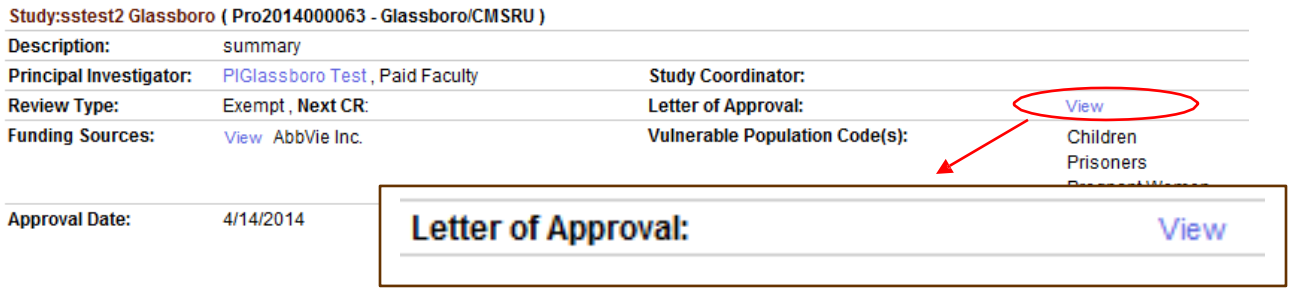
View the Approval Letter and Approved Consent Forms

When your study has been approved by the IRB, you will receive an email notification containing the approval letter. The approval letter will also be posted in the study workspace, and will be available for download at any time.

View the Approval Letter

1. From your Personal ***('My Home')*** folder, select the IRB Studies tab and click on the title of the approved study.

2. In the study workspace, the summary panel will now have an item for Letter of Approval. Click on the ***'View'*** link to the right.



3 The approval letter will open in a new window. You can then print the letter by selecting, '***File, Print'***… from the menu bar.

4. The approval letter will also be saved for recordkeeping in the history log under the activity as ***'Study: Approved'***. You can view the letter by clicking on this link then ***'View Approval Letter'*** in next window.

View the Approved Consent Form

1. Access approved consent forms. Once your study has been approved, the consent forms will be accessible from the study workspace under the ***'Stamped Documents'*** tab. All documents from the approved application will be available under this tab.

2. The ***'Approved Consent Forms section'*** will list all of the consent forms approved for use in the consent process. These Word documents will be locked in read-only mode.

- The Clean and Strikethrough Copies of Consent Forms found in the ***'Attachments'*** tab will contain unstamped versions of the approved consent form. These documents will be editable in MS Word and should be used if there is a future need to amend the consent forms.
- The remainder of the ***'Stamped Documents'*** tab displays any question in the application that allows you to upload a document or file. Use the tab to quickly locate any document in the application.

Submit a Reportable Event for the Study

Reportable events are used to report any of the following to the IRB:

- Acknowledgement Request
- Unanticipated Event
- Data Safety Monitoring Report
- Protocol Deviation

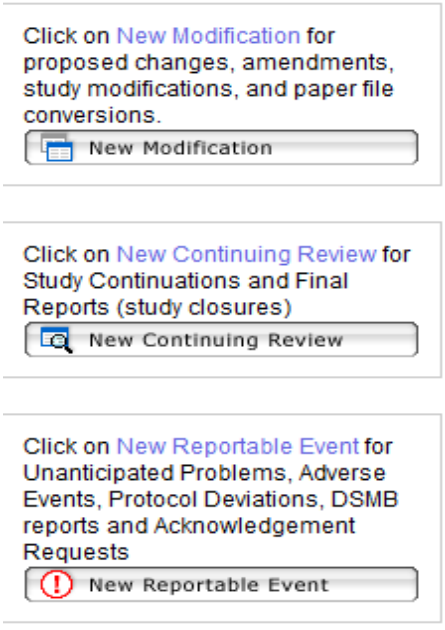
Create a New Reportable Event

1. In the approved ***'Study's Workspace'***, click the ***'New Reportable Event',*** button to start the application for a new reportable event.

2. Complete the first page of the application and select the '***type of reportable event'***.

3. Click the ***'Continue'*** button and complete the rest of the application. TIP: If this reportable event requires you to also submit an amendment to the study, click the ***'Create Related Modification'*** activity in the reportable event workspace.

4. A member of the study staff must submit the reportable event to the IRB using the ***'Submit'*** to IRB activity.



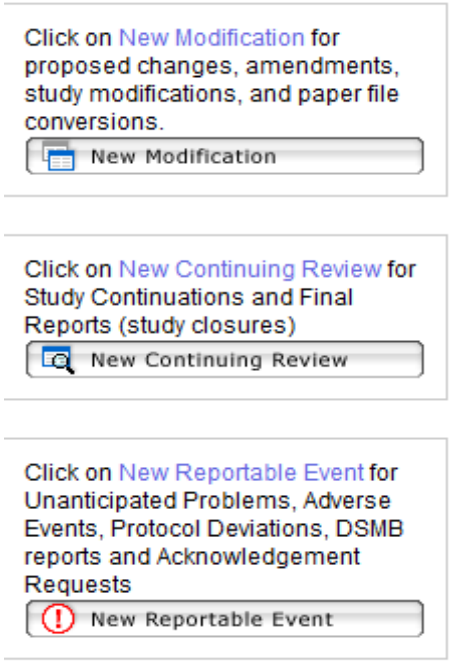
Submit a Modification to the Study

When you need to make a change to an approved study, you must submit a modification to the IRB for approval. When making changes, the approved study application is the working document and all required changes must be made in the Modified Study, which is a copy of the approved study.

When the IRB approves the modification, the Modified Study becomes the approved version of the study. All previously approved versions of the study are stored in the system for record keeping and audit purposes in the ***'History'*** folder.

Create a New Modification

1. In the approved study's workspace, click the ***'New Modification'*** button on the left navigation pane to start the application for a new modification. Complete the first page and click the ***'Continue'*** button.



! NOTE: The eIRB system only allows one modification to be in process at a time. All Modifications must be approved, rejected, or withdrawn before a new one is created.

2. Provide justification for any changes that need to be made in the study application.
3. When finished explaining the changes, '***save***' and '***exit***' to the ***'Modification Workspace'.***
4. All changes to the study **MUST** be made in the ***'modified study'***.

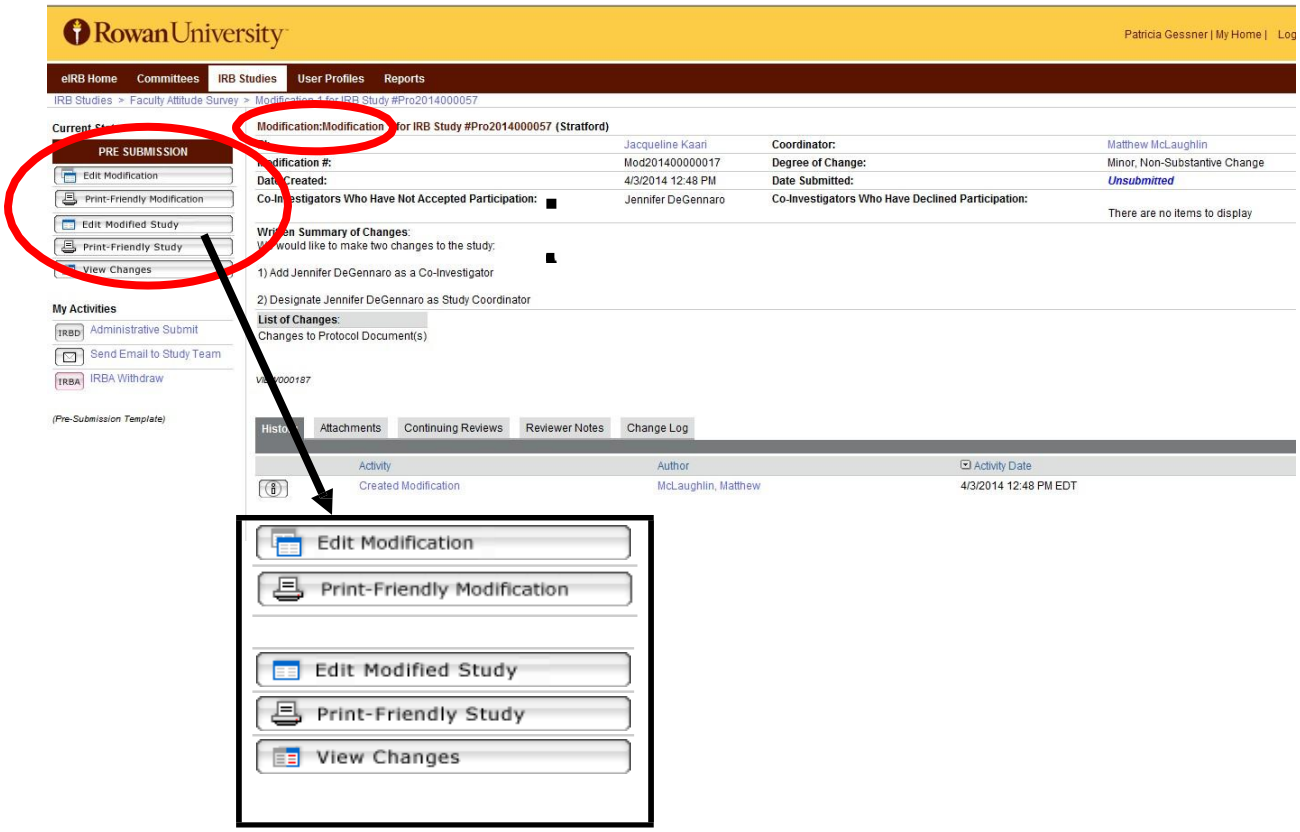
Edit the Modified Study

1. In the ***'Modification Workspace'***, click the ***'Edit Modified Study'*** button to open the study smart forms.

   Note this is a copy of the approved study that can be used to make your changes.

2. Make all the changes you detailed in the modification application.

3. To return to the modification workspace, click the '***Exit'*** button.



You can also '***Edit the Modification'*** in this workspace. ***'Printer Friendly'*** views of both the Modification and the Modified Study allow you to print and view in their entirety. The '***View Changes',*** button opens a window showing changes made to the original submission.

Submit a Continuing Review for the Study

! An email notification will be sent to the Principal Investigator and Study Coordinator 90 and 60 days prior to the Continuing Review due-date to the IRB.

A third reminder email notification will be sent 30 days prior to the Continuing Review due-date to the IRB if the Continuing Review has not yet been completed.

You should begin preparing an application for continuing review before your IRB approval ends. If the study is currently approved in the paper system, you must complete an Amendment before submitting a continuing review in the eIRB system.

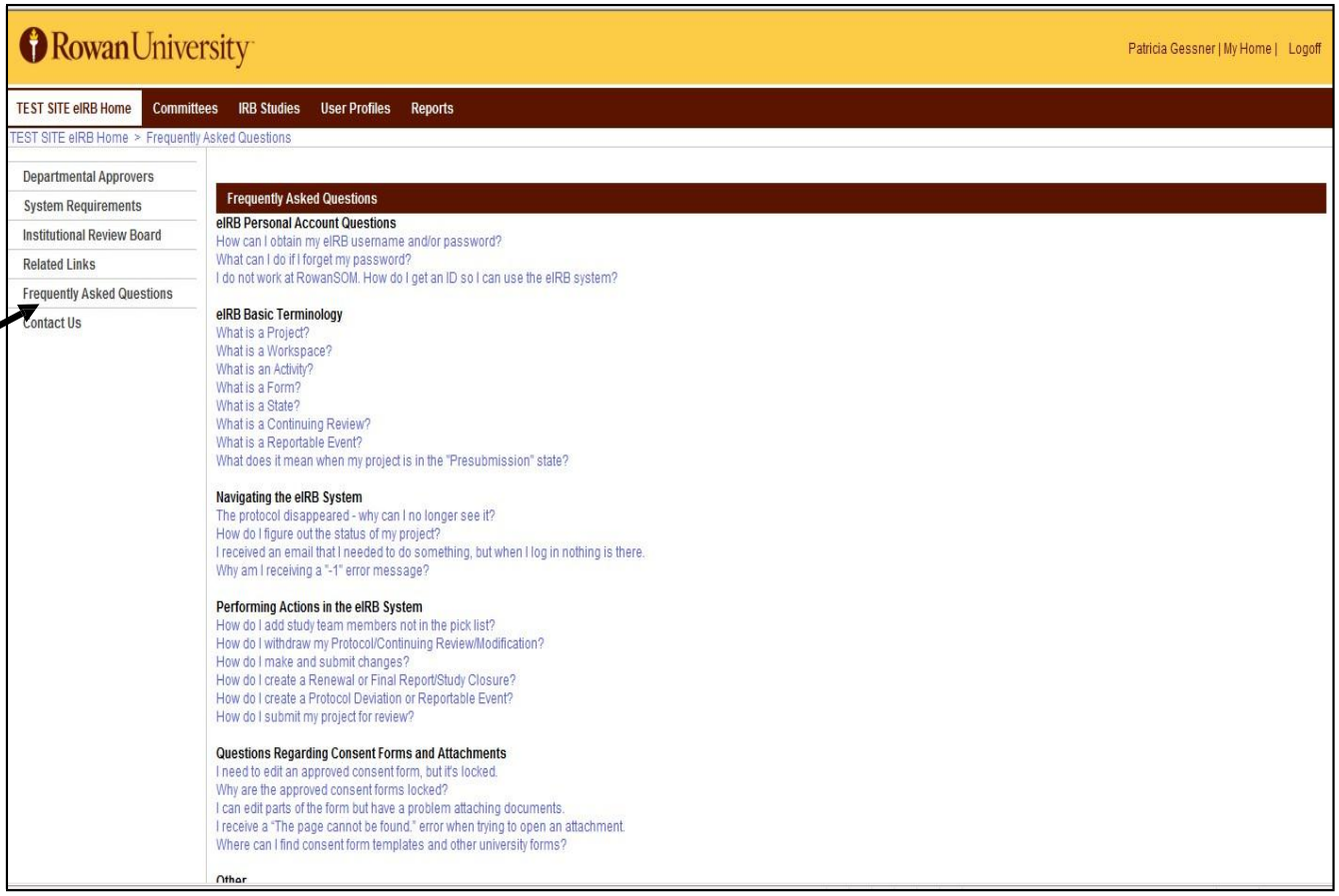
Create a New Continuing Review

In the approved study's workspace, click the ***'New Continuing Review'*** button to start the application for a continuing review.

1. Complete the first page of the application and select the status of the study ***(Continuing Review or Final Report)***.
2. Click the ***'Continue'*** button and complete the rest of the application.
3. When the continuing review is complete, any member of the study team may submit the continuing review to the IRB using the ***'Submit to'*** IRB activity.

Frequently Asked Questions

Visit the eIRB Home Page for answers to frequently asked questions.



Roles and Abbreviations:

Study Staff (SS): All individuals involved in research processes under a proposed or approved research study for which a Rowan University IRB is the IRB of record are considered "study staff." These personnel may include individuals who will have responsibility for the consent process, interactions or interventions with subjects, data collection, data analysis etc., or those who will have access to identifiable private information for research purposes.

Principal Investigator (PI): A principal investigator is the individual who assumes full responsibility for a research project, including the supervision of any co-investigators, research assistants, house staff and students. The Institutional Review Board only recognizes one principal investigator per human subjects research study.

Co-Investigator (SS): Co-Investigators are individuals involved with the PI in the scientific development or execution of a project. A co-investigator typically devotes a specified percentage of time to the project and is considered "key personnel."

Study Coordinator (SS): An individual who organizes and coordinates the study and study documentation under the supervision and direction of a PI.

Dept Approvers (Dept): Department/ Division Approvers are the primary and secondary individuals within each department who have signatory authority for a department/division.

The primary person is generally a Department Chair. The secondary person may be someone who has been designated by the Department Chair or Division Chief. The corresponding school Research Dean may also act as the signatory authority.

Contact Us

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