



eIRB User Manual for Research Staff





Table of Contents

eIRB Access	3
Log-in to eIRB	4
Overview of the eIRB Submission and Review Process.....	7
Create a New Application and Specify Personnel	8
Navigation	9
Submit the Application	12
Application Validation and Submission	13
The Study Workspace	15
Responding to Requested Changes	18
Submit a Reportable Event for the Study.....	22
Submit a Modification to the Study	23
When the Modification is complete, the PI must submit the modification to the IRB by using the Submit to IRB Activity.....	25
Submit a Continuing Review for the Study.....	26
Frequently Asked Questions.....	Error! Bookmark not defined.
Roles and Abbreviations:.....	27
Contact Us	28



eIRB Access

The website is available via any Internet connection anytime with a supported browser.

<http://eirb.rutgers.edu>

Getting Help

If you have problems, need help, or have questions about the eIRB please contact your [local IRB office](#).

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 **Rutgers NetID** username and password.

Login

Login as

User Name:

Password:

After signing into this site, you are bound by the terms and conditions set forth when you received your account.

Personal Folder

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

The screenshot shows the eIRB Sandbox interface. At the top, there is a navigation bar with 'EIRB SANDBOX HOME', 'IRB STUDIES', and 'USER PROFILES'. Below this, a 'Current Role' section is set to 'RESEARCH STAFF'. A 'My Roles' section allows switching between 'Research Staff' and 'Create' (with a 'New Study' button). A 'Quick Links' section contains 'Consent Forms'. The main content area features a 'Welcome to your Personal Page' message and an 'Inbox' section with tabs for 'Inbox', 'IRB Studies', 'All Submissions', and 'My Profile'. A table of IRB studies is displayed below, with columns for ID, Name, Date Modified, Type, Owner, State, Last State Change, Campus, and Study.

ID	Name	Date Modified	Type	Owner	State	Last State Change	Campus	Study
Pro2013003193	Tissue Bank Test	8/27/2013 4:09 PM	Study		Pre Submission	8/27/2013 3:33 PM	New Brunswick/Piscataway	
Pro2013003192	I See All Biopower Tissue Bank	8/27/2013 3:43 PM	Study		Pre Submission	8/27/2013 2:48 PM	New Brunswick/Piscataway	
Pro2013003185	Test Tissue/Data Bank	8/27/2013 12:09 PM	Study		Pre Submission	8/22/2013 11:52 AM	New Brunswick/Piscataway	
Pro2013003188	Training	8/23/2013 11:16 AM	Study		Pre Submission	8/23/2013 10:16 AM	Newark	
Pro2013003187	_Protocol - Fri Aug 23 10:19:26 EDT 2013	8/23/2013 11:16 AM	Study		Pre Submission	8/23/2013 10:16 AM	Newark	
Pro2013003189	training	8/23/2013 10:37 AM	Study		Pre Submission	8/23/2013 10:16 AM	Newark	
Pro2013003184	Test 1234	8/14/2013 3:40 PM	Study		Pre Submission	8/14/2013 3:40 PM	Newark	
Pro2013003150	Test 1234	8/13/2013 4:16 PM	Study		Pre Submission	5/29/2013 10:54 AM	Newark	
Pro2013003182	RBS Tissue Bank	8/13/2013 3:00 PM	Study		Pre Submission	8/13/2013 2:15 PM	New Brunswick/Piscataway	
Pro2013003178	Trainer	8/9/2013 10:57 AM	Study		Pre Submission	8/9/2013 10:27 AM	Newark	

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 *My 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

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 Administrator Review

An IRB Administrator will be assigned to the study. The IRB Administrator will conduct an administrative 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 letters are recorded by the IRB Administrator 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 Specify Personnel

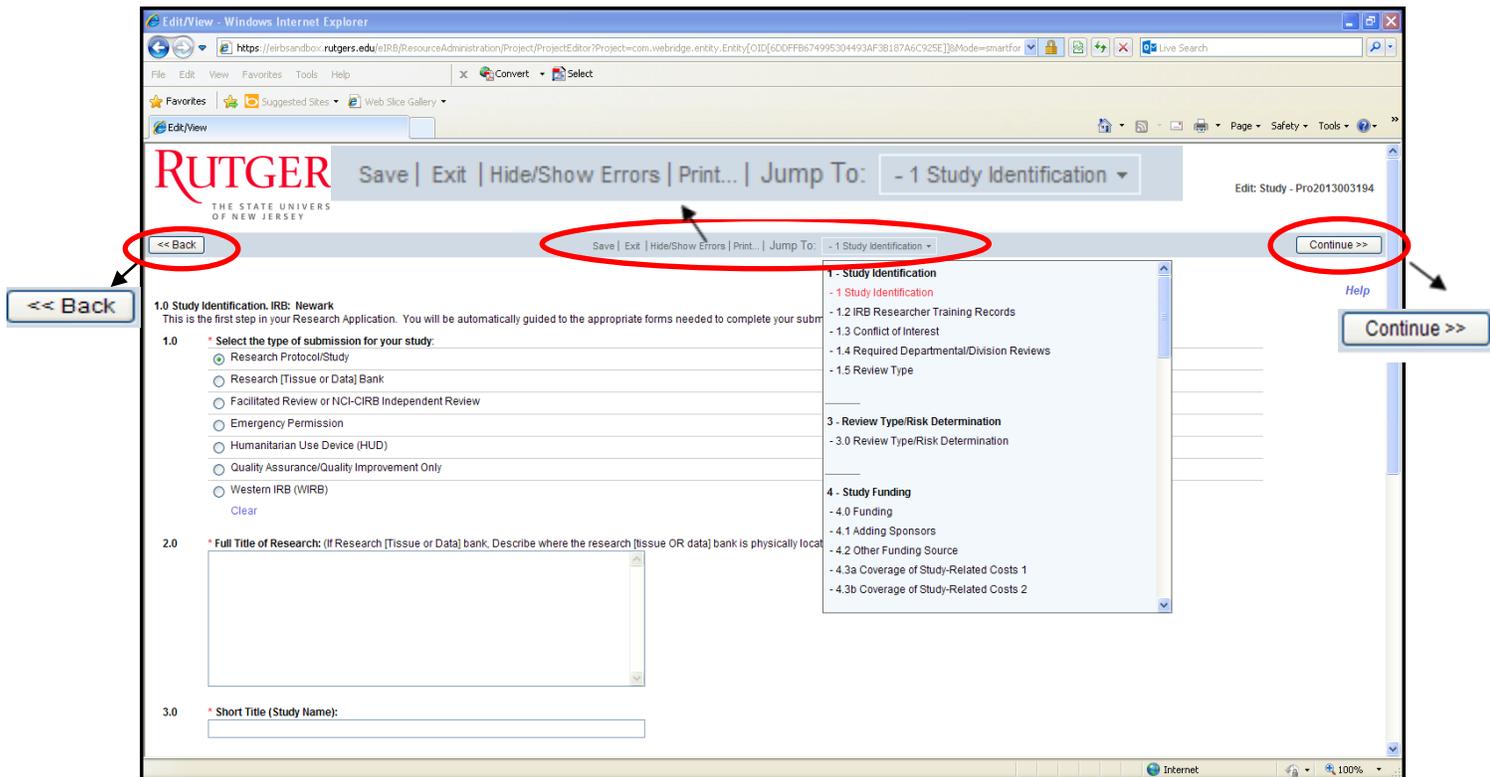
The screenshot shows the eIRB Sandbox interface for a Training Principal Investigator. The user's current role is 'RESEARCH STAFF'. A 'Create' button with a 'New Study' option is highlighted with a red box. A large yellow callout box contains the text: 'My Roles: When you are using eIRB, you must tell the system which ROLE you want to work in. Research Staff'. Below this is a table of study entries:

ID	Name	Last State Change	Campus	Study
Pro2013003193	Tissue Bank Test	3/27/2013 3:33 PM	New Brunswick/Piscataway	
Pro2013003192	I See All Biopower Tissue	3/27/2013 2:48 PM	New Brunswick/Piscataway	
Pro2013003185	Test Tissue/Data Bank	3/22/2013 11:52 AM	New Brunswick/Piscataway	
Pro2013003188	Training	3/23/2013 10:16 AM	Newark	
Pro2013003187	_Protocol - Fri Aug 23 10	3/23/2013 10:16 AM	Newark	
Pro2013003189	training	3/23/2013 10:16 AM	Newark	
Pro2013003184		8/14/2013 3:40 PM	Newark	Study Pre Submission
Pro2013003150	Test 1234	8/13/2013 4:16 PM	Newark	Study Pre Submission
Pro2013003182	RBS Tissue Bank	8/13/2013 3:00 PM	New Brunswick/Piscataway	Study Pre Submission
Pro2013003178	Trainer	8/9/2013 10:27 AM	Newark	Study Pre Submission

- 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 navigation 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.

Navigation



- 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 provide a value.	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.

Note: You may only add Rutgers researchers with a Rutgers NetID, Non-Rutgers researchers will be required to obtain a Rutgers Guest NetID.

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 sections 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.

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:

Current State

PRE SUBMISSION

Edit Study

Printer Version

View SmartForm Progress

My Activities

PI Submit Study

Notify Co-Investigators to Agree to Participate

SS Withdraw

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 the bolded word listed above the study description.

The screenshot displays the Rutgers eIRB Sandbox interface. At the top, the Rutgers logo and 'eIRB Sandbox' are visible. The navigation bar includes 'EIRB SANDBOX HOME', 'IRB STUDIES', and 'USER PROFILES'. The main content area shows the 'Current State' of a study, 'Study:Tissue Bank Test (Pro2013003193)', which is circled in red. Below this, a 'PRE SUBMISSION' section offers options like 'Edit Study', 'Printer Version', and 'View SmartForm Progress'. A 'My Activities' sidebar on the left has 'Submit Study' circled in red. A central workflow diagram illustrates the process: Pre-Submission leads to Department Review, which leads to IRB Review, then Post Review, and finally Review Complete. Arrows indicate a sequence, with feedback loops for 'Clarifications' and 'Clarifications Requested'. A table at the bottom lists activities with columns for Activity, Author, and Activity Date.

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 all co-investigators must have agreed to participate 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 bottom of the screen to submit the application for the study.

Submit Study

Investigator Assurances:

I certify that all information provided in this application represents an accurate description of the intended study.

I agree to follow and abide by all policies and procedures, as well as by all federal, state and local laws concerning the protection of human subjects in research, including, but not limited to:

- Implementing no changes in the approved protocol or consent form without prior approval of the Institutional Review Board (IRB).
- Conducting the research using only the qualified personnel listed on the approved protocol.
- Submitting a timely report of any adverse events.
- Notifying the IRE of any changes to the protocol during working days.
- Reporting all deaths.
- Immediately notifying the IRB of any protocol deviations.

I agree with the above statement: *

I understand that as Principal Investigator, I assume full responsibility for the conduct of the study, and for the protection of the rights and welfare of human subjects involved in this research.

Required Department Approvals:
GASTROENTEROLOGY
MEDICINE

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: *

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-mails

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 from 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 to open your 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 screenshot shows the 'Tissue Bank Test' workspace in the eIRB Sandbox. The interface includes a navigation sidebar on the left, a main study information panel, a review process flowchart, and a history table. Red numbers 1 through 9 are placed over the interface to indicate key features:

- 1: Current State section
- 2: Study: Tissue Bank Test (Pro2013003193 - New Brunswick/Piscataway)
- 3: Principal Investigator: Training Principal Investigator
- 4: Edit Study icon
- 5: Printer Version icon
- 6: My Activities section
- 7: Pre-Submission step in the flowchart
- 8: Department Review step in the flowchart
- 9: IRB Review step in the flowchart

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.
2. The panel displays summary information about the study. The amount of information will change depending on the study's progress through the review process.
3. The IRB number for the study.
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 date/time stamp and the name of the person 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.

The screenshot displays the Rutgers eIRB Sandbox interface. At the top, it shows the Rutgers logo and 'eIRB Sandbox'. The main content area is titled 'Studytraining (Pro201300140 - Newark)'. Below this, there is a 'Current State' section with 'IN REVIEW' and various action buttons like 'View Study', 'Printer Version', and 'View Differences'. A 'My Activities' sidebar is on the left. A workflow diagram shows stages: Pre-Submission, Department Review, IRB Review, Post Review, and Review Complete. The 'History' tab is selected, showing a table of activities. A red circle highlights the 'History' tab in the sidebar.

Activity	Author	Activity Date
IRB Administrator Ownership Re-assigned	Punsal, Jennifer M	8/7/2013 3:02 PM EDT
Assigned to Jennifer Punsal:		
Study Approved By Department	Reviewer, Departmental	6/14/2013 1:29 PM EDT
vhtj		
2nd Reminder to Dept Chair	Administrator, System	5/22/2013 5:03 PM EDT
Study Submitted for Review	Principal Investigator, Training	5/17/2013 11:40 AM EDT

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, detailing the change made or your reason for disputing it. When finished, click the *OK* button.

The screenshot displays the Rutgers IRB system interface. At the top, the Rutgers logo and navigation tabs (IRB Home, IRB Studies, User Profiles) are visible. The main content area shows a study titled "Localized Aggressive Periodontitis-Microbial & Host Markers for Susceptibility". A sidebar on the left lists activities: "Submit Changes", "Request Extension", and "Change IRB of Record". A detailed view of an "IRB Staff Change Request" is shown, with a "Response Required! Click here to respond..." link circled in red. Other red circles highlight the "Submit Changes" and "Request Extension" buttons in the sidebar.

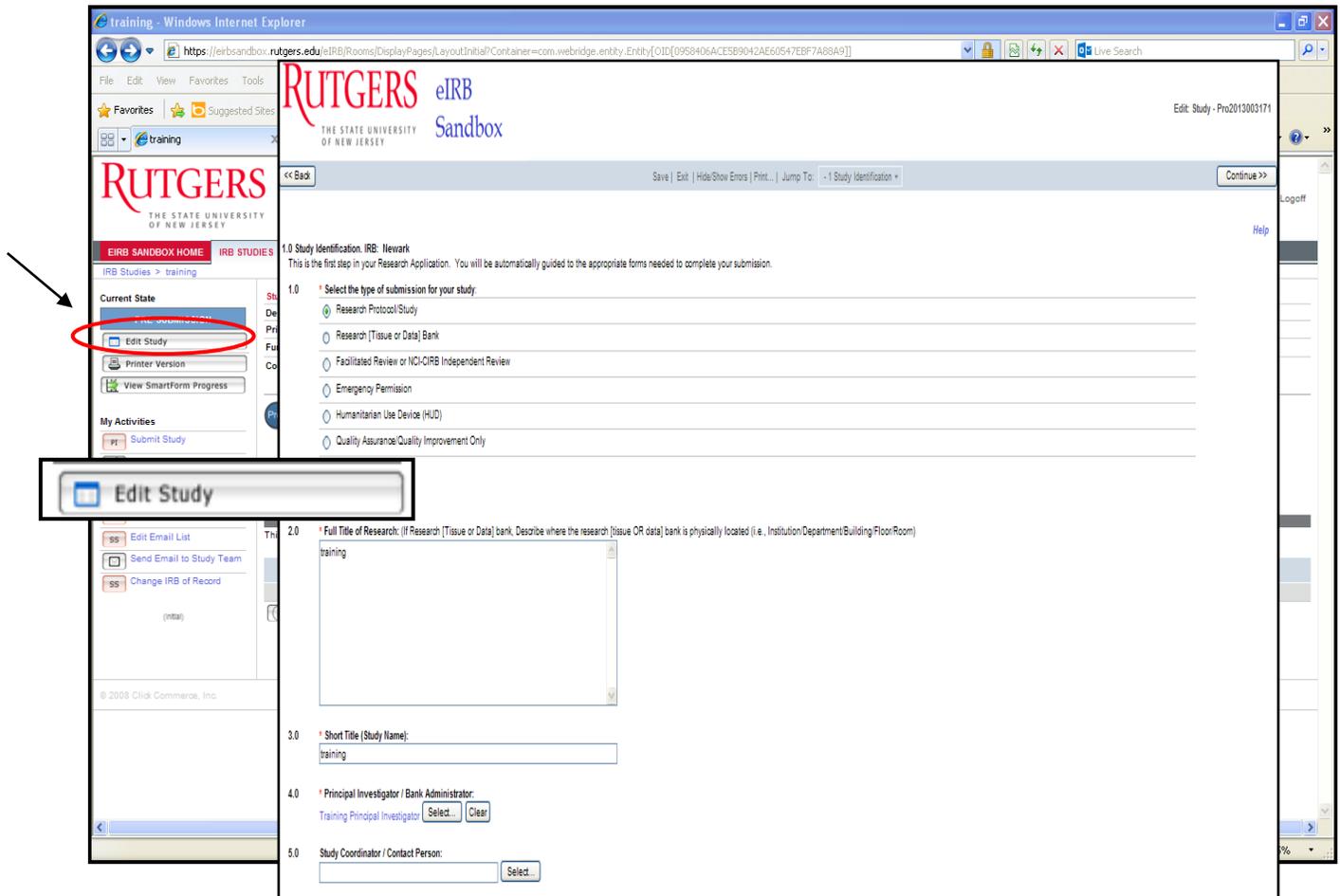
- **!** You have 90 days to respond to the requested changes or your study will be automatically withdrawn from the system.
- If you know that you will need more than 90 days, you may request an extension from the IRB by selecting the *Request Extension* activity to call for another 90 days to respond.
- 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 anytime.

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. 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 documents will be converted into a PDF file.
- 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.

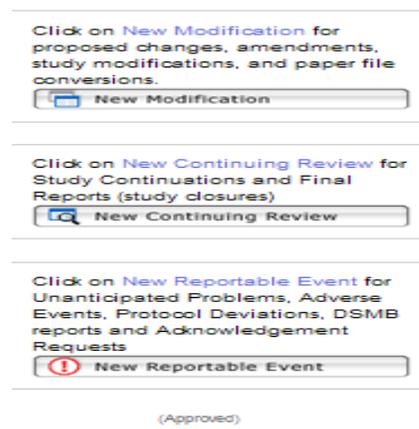
Submit a Reportable Event for the Study

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.

The screenshot displays the Rutgers eIRB Sandbox interface. At the top, the Rutgers logo and 'eIRB Sandbox' are visible. The user is logged in as 'Training Principal Investigator'. The main content area shows details for 'Modification 2 for IRB Study #Pro2013003136'. A red circle highlights the 'PRE-SUBMISSION' section on the left, which includes buttons for 'Edit Modification', 'Print-Friendly Modification', 'Edit Modified Study', 'Print-Friendly Study', and 'View Changes'. A modal window is open over the 'View Changes' button, listing options: 'Edit Modification', 'Print-Friendly Modification', 'Edit Modified Study', 'Print-Friendly Study', and 'View Changes'. The modal also shows an 'Activity Date' of 7/12/2013 11:38 AM EDT.

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.

! When the Modification is complete, the PI must submit the modification to the IRB by using the **Submit to IRB Activity**.



Submit a Continuing Review for the Study

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

A second 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 expires.

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.
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.



Roles and Abbreviations:

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.

Study Staff (SS): All individuals involved in research processes under a proposed or approved research study for which a RUTGERS 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.

Department Approvers (DEPT/DIV): Department/ Division Approvers are the individuals within each department/division who have signatory authority for a department/division.



Contact Us

<https://orra.rutgers.edu/contactus>