Study Team User's Manual

October 2009

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Welcome to *eIRB*

Our on-line *eIRB* system streamlines the process of submitting, approving, tracking, and managing IRB applications.

eIRB is available via Internet connection 24 hours a day, 7 days a week.

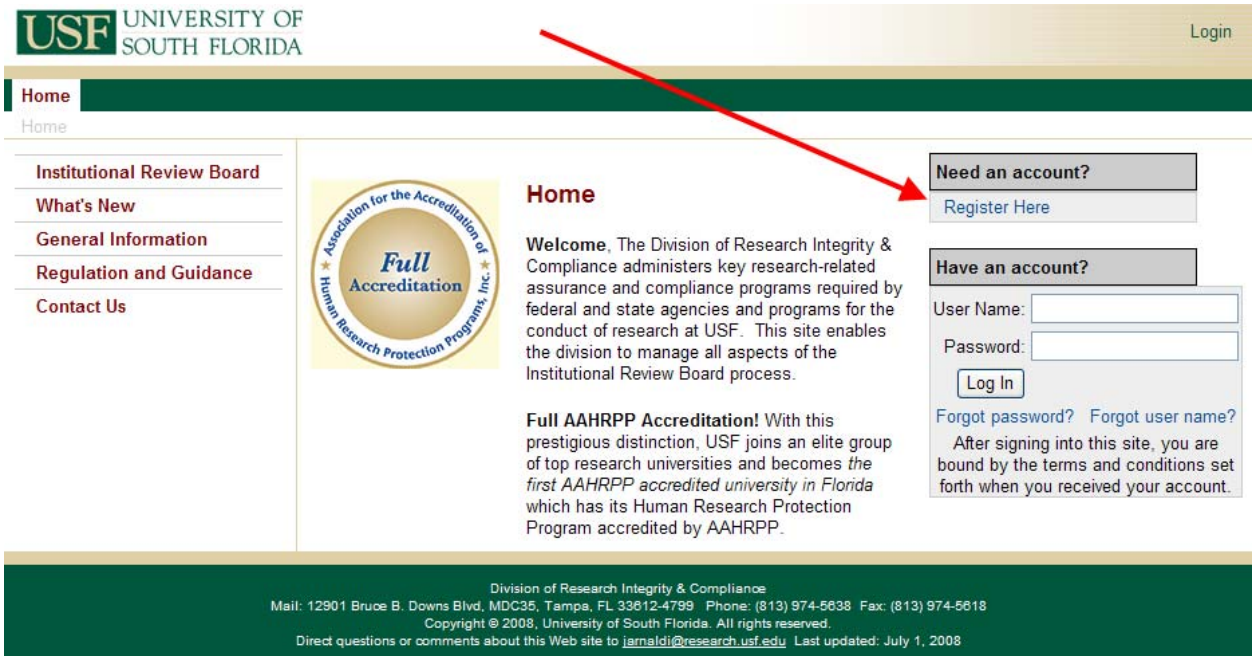
The *eIRB* HelpDesk is available during regular business hours at (813) 974-2880.

Accounts

New Account Registration

To open your new *eIRB* account:

1. Go to the *eIRB* Web Site: https://eirb.research.usf.edu/prod
2. Click **Register Here** on the right hand side of the page.



3. Complete the required fields (*) and provide your USF Net ID and Employee ID.
4. Select all relevant roles, such as Study Staff, PI, Department Approver.
5. Click **Register.**
6. Within two business days your new account will be activated and you will receive an e-mail containing your account information (i.e., User Name & Password).

Account Changes

It is important to keep your account information current. To make changes to your account, click your name in the upper right hand corner of your screen to open your account properties.

Then make the necessary changes and click **Apply**.

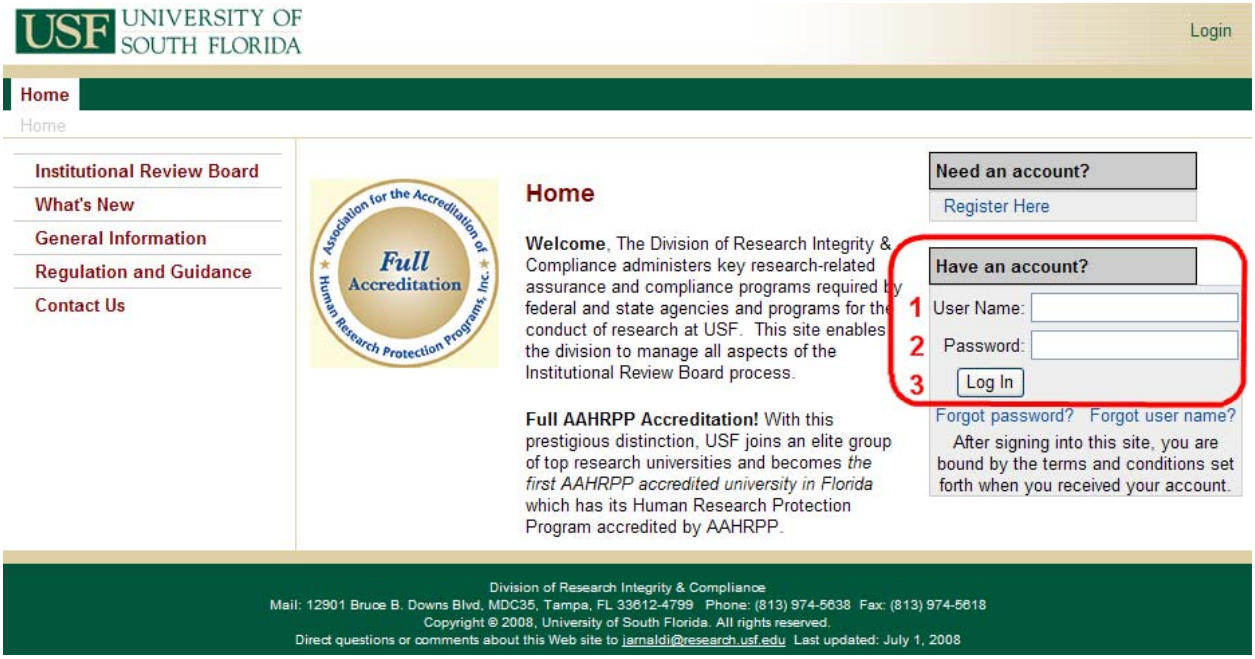
Passwords

To change your password, click on your name (as described above). On your Account page, click the **Account** tab. Then, in the respective boxes, type in your old password, your new password, and your new password again. Click **Apply**.

Navigation

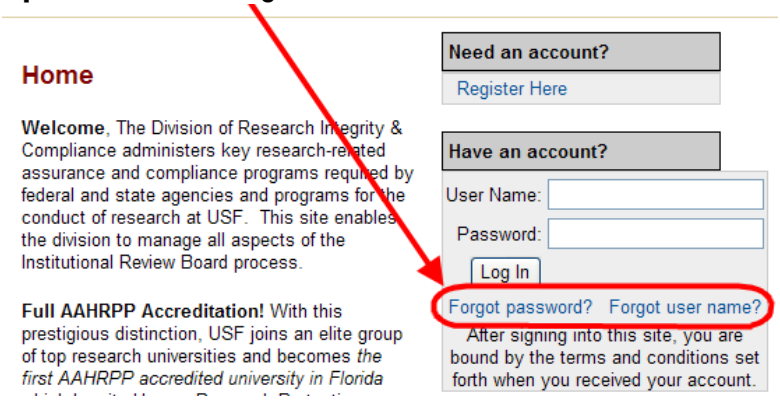
Log In

1. Type your **User Name** in the login section on the right side of the *eIRB* screen.
2. Type in your **Password.**
3. Click **Log In**.



Forgot Your User Name or Password?

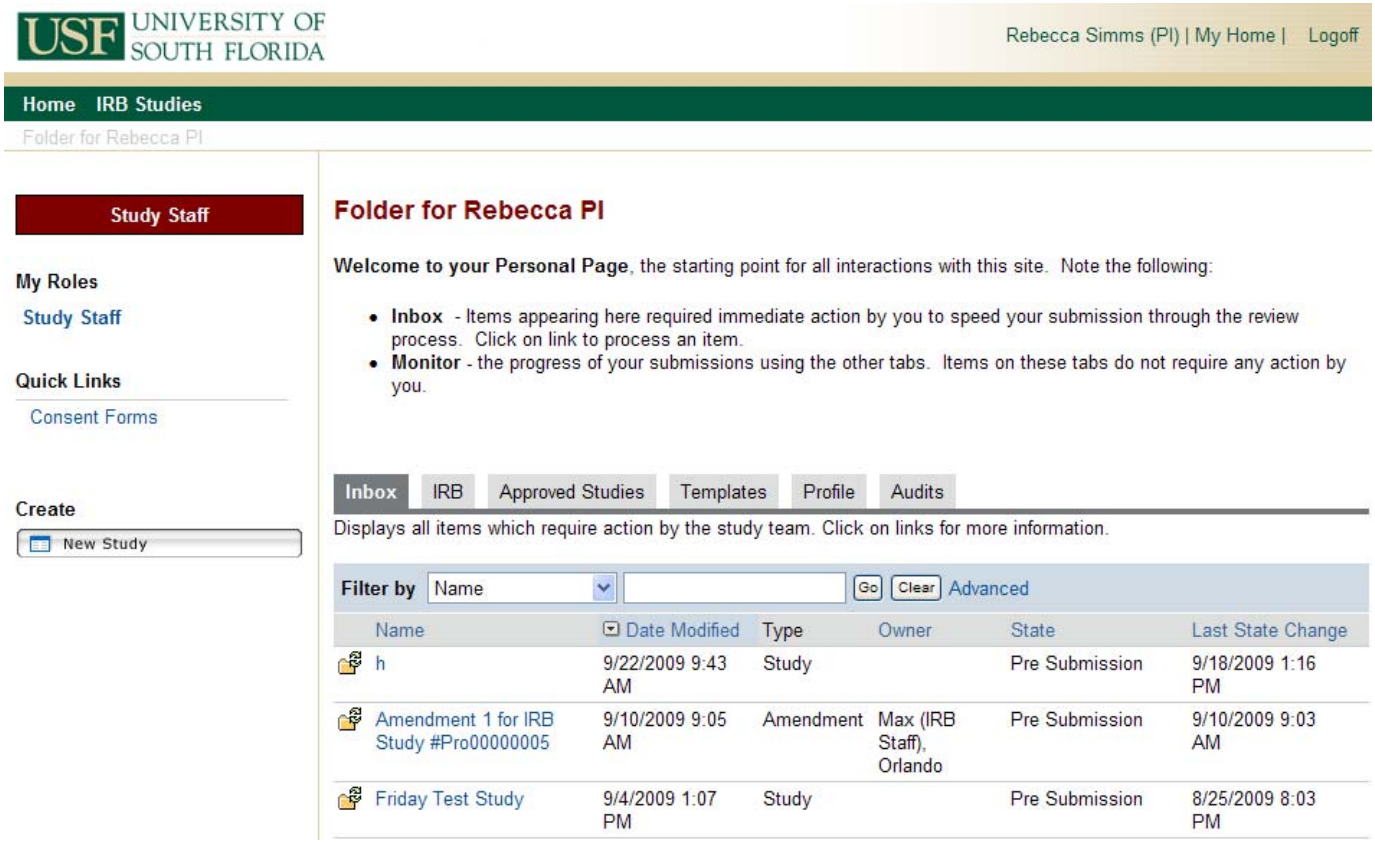
1. Click **Forgot password** or **Forgot user name**.



2. The respective information will be sent to your e-mail of record.

My Home Folder

After logging in, the screen displays your **Folder** which is like a personal home page. Here you will be able to view and manage those studies relevant to your **Role**.



When you are in other sections of the *eIRB* system, you can easily get back to your Folder by clicking the link to **My Home**.

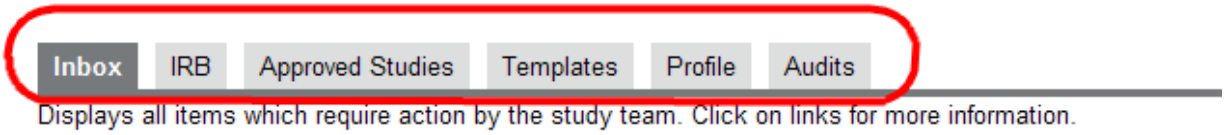
Roles

A person can have multiple **Roles** in *eIRB* (PI, Co-PI, Study Coordinator, Department Approver, IRB Committee member, etc.). Different Roles provide access to different applications, information, and activities.

Your current **Role** will be displayed in the red banner at the top of the column on the left side of your Folder and will be **Bold** in the listing of your available Roles. If you have more than one role, each time you log in be sure that the correct role is selected. Click on a role to make it your current role.

Navigation Tabs

The central area of your Folder (My Home) provides a row of navigation tabs.

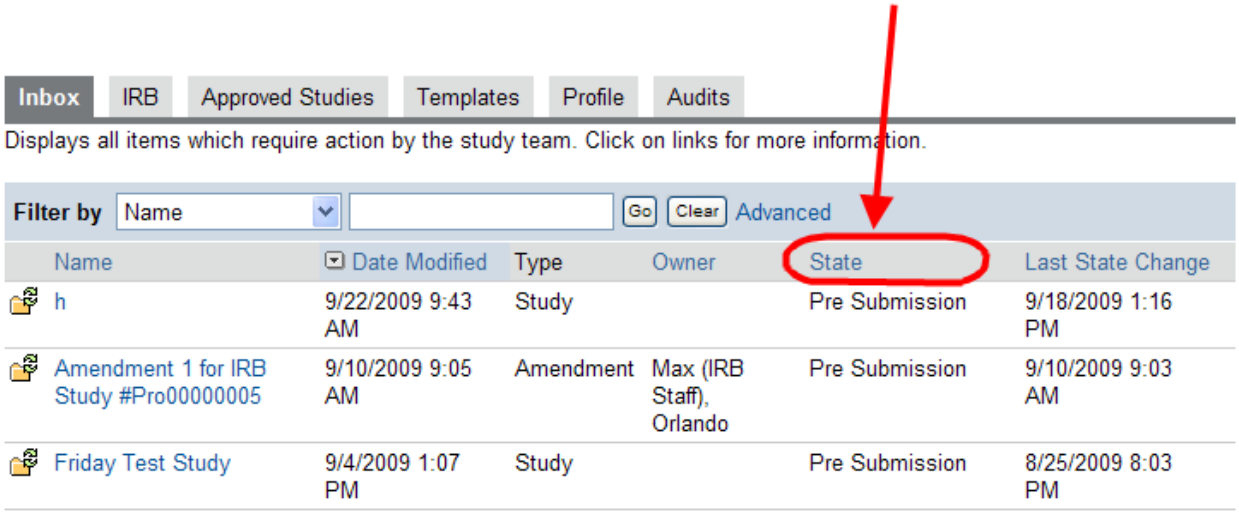


Inbox Tab

Inbox lists all applications (studies, amendments, continuing reviews, and reportable events) that require action by you or other staff on your study team in your current Role.

Whenever you log in or return to your Folder (My Home), your **Inbox** is displayed.

To find out where the application is in the IRB process, look in the **State** column.



You can access an application listed in your **Inbox** by clicking the application **Name**.

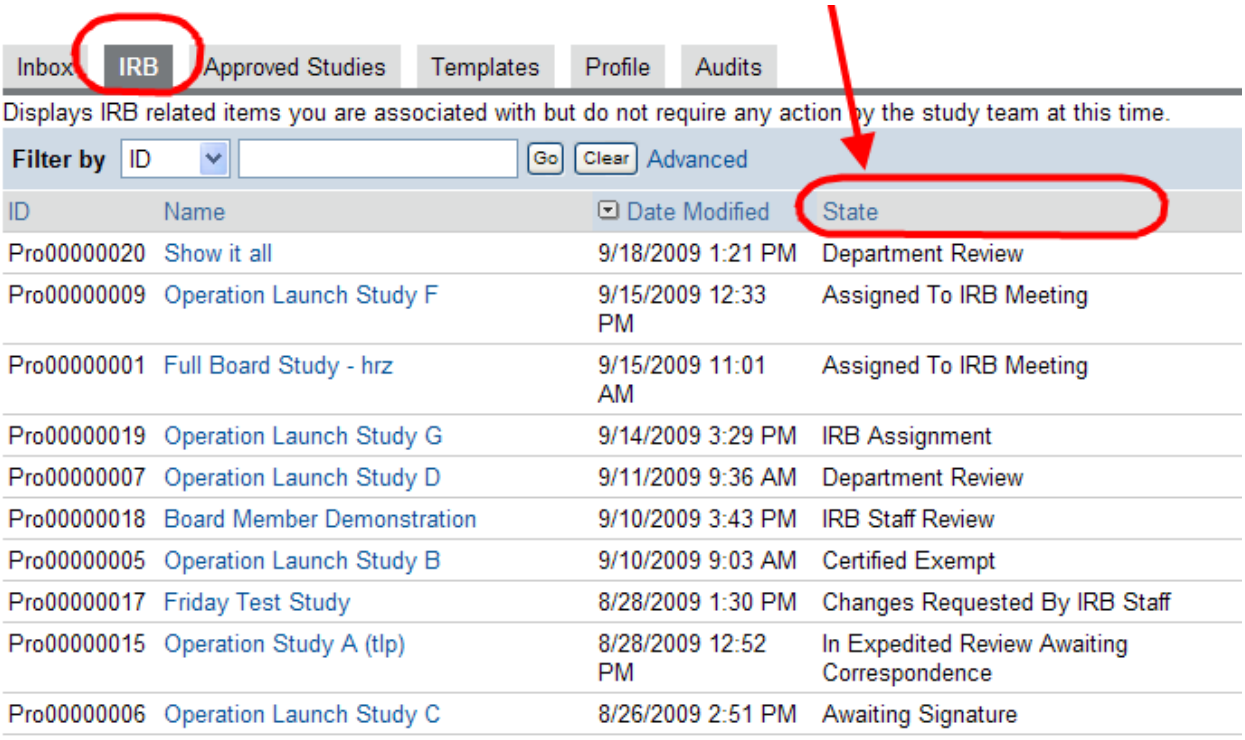
Once you have completed the required activities, the application is moved electronically from one respective Inbox to the next according to who needs to work on it next.

If an application isn't in your Inbox, it's someone else's turn to work on it. If an item is still in your Inbox, it still requires your attention.

IRB Tab

The **IRB** tab lists all applications with which you are associated regardless of the state they are in.

In the **IRB** tab, you can monitor the **State** of any application you're associated with. You can view applications under the IRB tab by clicking the application Name.



ID	Name	Date Modified	State
Pro00000020	Show it all	9/18/2009 1:21 PM	Department Review
Pro00000009	Operation Launch Study F	9/15/2009 12:33 PM	Assigned To IRB Meeting
Pro00000001	Full Board Study - hrz	9/15/2009 11:01 AM	Assigned To IRB Meeting
Pro00000019	Operation Launch Study G	9/14/2009 3:29 PM	IRB Assignment
Pro00000007	Operation Launch Study D	9/11/2009 9:36 AM	Department Review
Pro00000018	Board Member Demonstration	9/10/2009 3:43 PM	IRB Staff Review
Pro00000005	Operation Launch Study B	9/10/2009 9:03 AM	Certified Exempt
Pro00000017	Friday Test Study	8/28/2009 1:30 PM	Changes Requested By IRB Staff
Pro00000015	Operation Study A (tlp)	8/28/2009 12:52 PM	In Expedited Review Awaiting Correspondence
Pro00000006	Operation Launch Study C	8/26/2009 2:51 PM	Awaiting Signature

Application Workspace

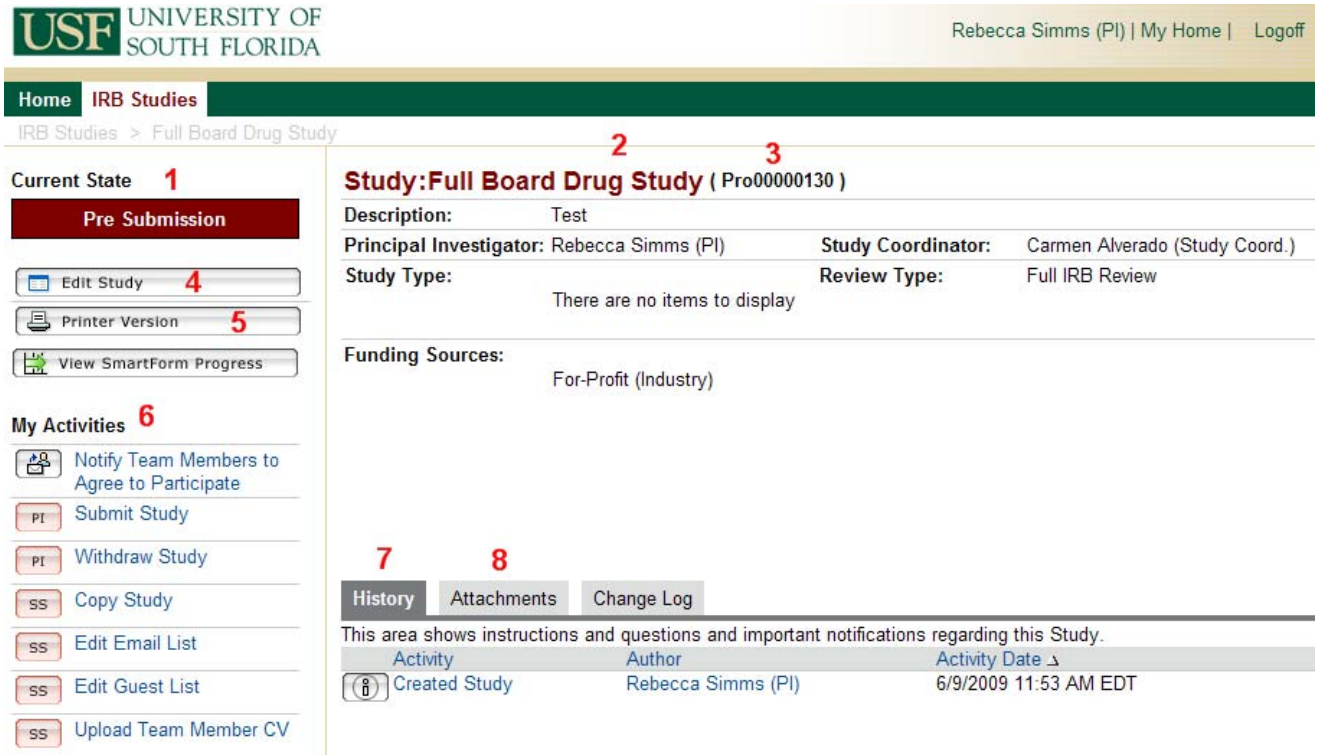
Work on an application begins in the application **Workspace** which is like a home page for the application. Open an application Workspace by clicking on its **Name** in your **Inbox**.

The application Workspace provides:

- information about the application
- links to specific sections and documents related to the application
- buttons to initiate **Activities** and move the application to the next step in the IRB process (these buttons are only available to you when the application is in your Inbox)
- history of all activities performed on the application

After a study has been approved, tabs for Adverse Events, Amendments, and Continuing Reviews are displayed next to the History tab in the study workspace.

Below is an example of a study Workspace screen:

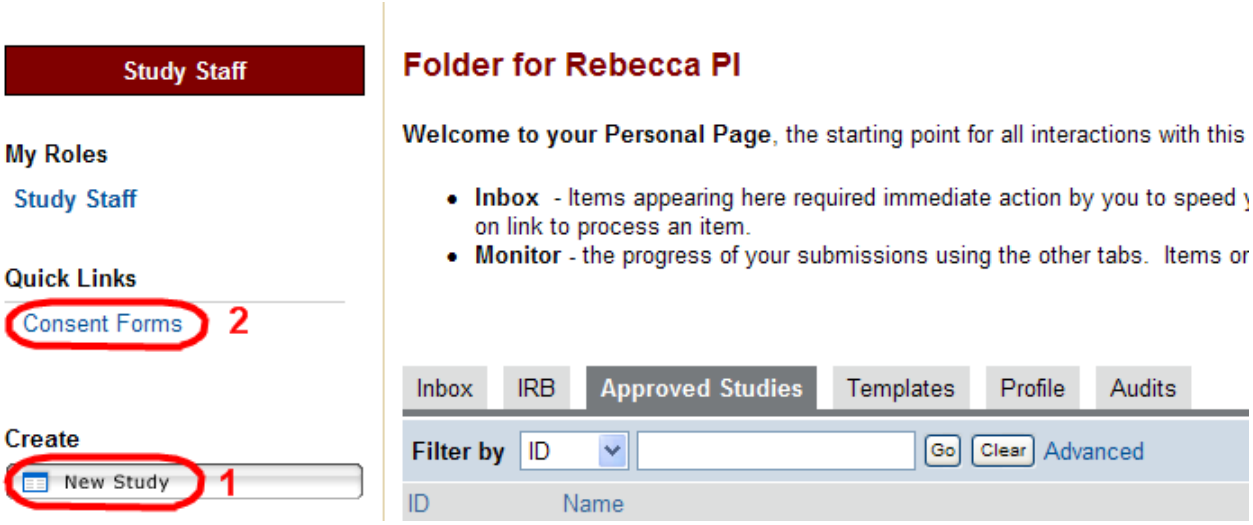


Key to the study **Workspace** screen:

1. **Current State** indicates the stage in the IRB review process for this study. This changes as Activities are completed.
2. The summary panel displays information about this study. The information changes when a study becomes active.
3. IRB Study Number.
4. **Edit Study** button opens the application SmartForm for editing (while the study is in your study team's Inbox only). When the application is not in your Inbox, the button is **View Study** and will provide read-only access.
5. **Printer Version** button opens all of the relevant SmartForm screens in one easy-to-print window.
6. The left column lists actions and **Activities** that can be performed on the study under its **Current State**. The list will vary depending on the Current State. The legend on each button indicates which Role (i.e., PI only or any study team member) can perform this activity. Click the button/link to open the Activity screen.
7. The **History** tab lists chronologically all actions that have been performed on the study. Click the Activity name in the listed History to view details.
8. The **Attachments** tab lists all documents that have been uploaded for this application. Successive versions are archived automatically so that you have access to the most currently approved versions, i.e., protocol, informed consent, advertisement, etc.

Create a New Study

In the role of PI or Study Staff, you can create a new study (Initial Application) by clicking the **New Study** button (**1**) in the column on the left side of your Folder (My Home).



If you want to create a new informed consent document, open an informed consent template by clicking the Quick Links for **Consent Forms** (**2**). Save the appropriate template to your computer and revise as needed. Attach the new or revised copy of the consent form to your application within the study SmartForm.

You can also create a new study by copying a study to use as a template. Open the Study Workspace for the original study and under My Activities click **Copy Study**. After you complete the Copy Study screen, the copy will appear under your **Templates** tab in your Home folder.

The IRB Study Number is assigned automatically the first time you save the study (or after you complete the first page of the application and click **Continue**).

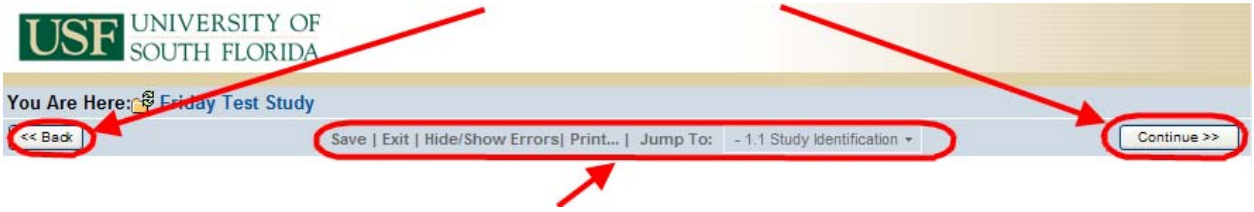
Working with Smart Forms

All applications in *eIRB* use SmartForms which present only those questions that are relevant to your study. It is important that you respond to each question displayed on the SmartForms.

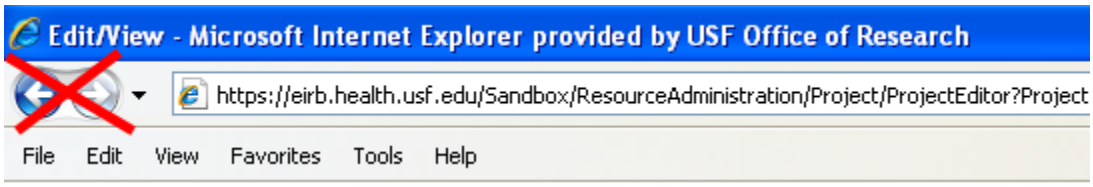
Required fields are marked with a red asterisk *****.

You can answer text questions by typing directly into the text box or by pasting in text from other documents. **Add** (attach) relevant documents where indicated.

Navigation controls are located in the navigation bar at the top and bottom of each page. Use the **Continue** and **Back** buttons to move to the next or last-viewed screen.



Use the SmartForm navigation controls instead of the controls in the browser bar (e.g., Internet Explorer, Safari, AOL, Opera).



Save your application by clicking **Save** or **Continue**.

> **WARNING:** The **Back** button does not save changes. After you enter or edit data on a screen click **Save** before going **Back**!

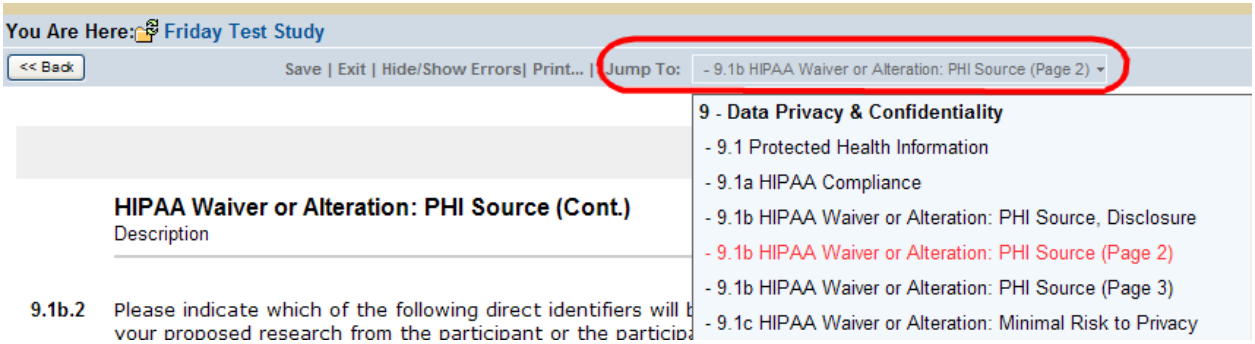
Use **Exit** to close the application and return to that application's Workspace.

> **WARNING:** Always **Save** before exiting!

Each section and question is numbered for easy navigation and reference. Numbering is consistent through all SmartForm applications; however, remember that only the relevant questions for each specific study are displayed.

Once new or revised data on a page has been saved, you can navigate directly to other sections and questions by using the **Jump To** drop-down menu. The title of the displayed page will be red. Items not relevant to this study will appear gray in the Jump To menu.

> **WARNING:** After you enter or edit data on a screen, click **Save** before using **Jump To**! The Jump To menu does not save.

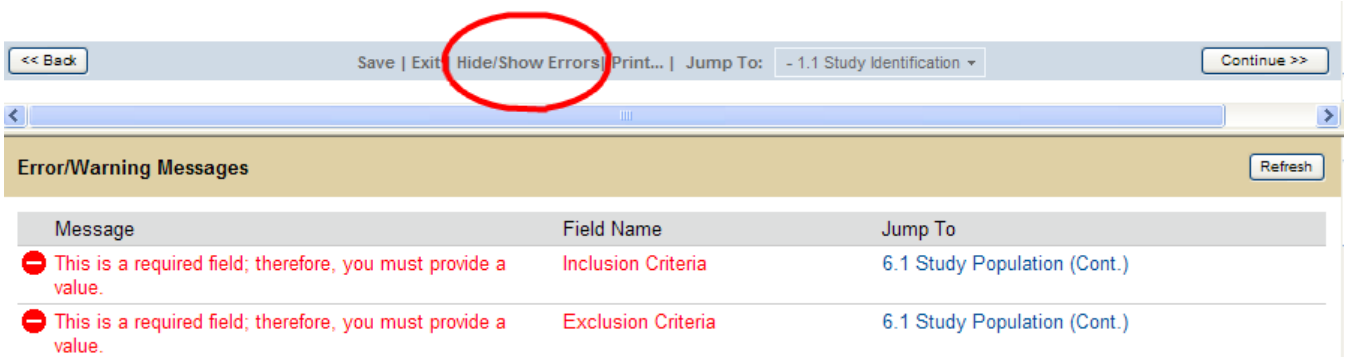


Attaching Documents

Attach documents, such as the protocol and consent forms, by using the **Add** button associated with the relevant question in the SmartForm. Before attaching a document, be sure you have named it using an accurate description. For example, Informed Consent-Spanish-Study000000342.

Hide/Show Errors

Within a SmartForm, use this tool to gauge your progress with the application. In the menu bar, click **Hide/Show Errors** to list the required fields that need to be completed.



Click the link again to toggle off (hide) Error/Warning Messages.

Completion and Submission: A Two-Part Process

1. **Complete the application**: The PI and Study Staff create and complete the application. The application remains in your Inbox.
2. **Submit the application**: The PI submits the completed application. Submission moves the application out of your Inbox to the next State.

Part 1 – Complete the Application

When an application is created, it starts out in the Pre-Submission State. In this State, all Study Team members can work on it, attach documents, and save changes.

To prepare a completed application for submission to the IRB:

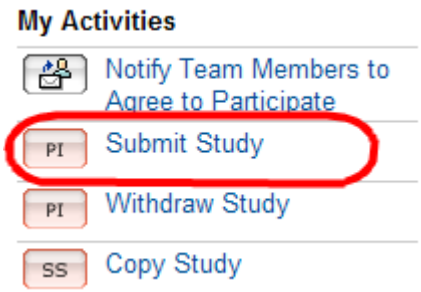
1. In the study Workspace under My Activities, click **Notify Team Members to Agree to Participate (1)**. Click **OK** to send notice to team members.

2. When they receive the notice, all Study Staff must agree to participate and must respond to the Conflict of Interest questions.

Part 2 – Submit the Application

Only the Principal Investigator for the study can submit an application.

1. To submit the study to the IRB, the PI will open the application Workspace and click **Submit Study** under My Activities.



2. *eIRB* will run a final validation check on the entire application before submission. If there are any required fields that have been left blank or staff who have not agreed to participate, they will be indicated and your application will not be submitted. The application must be error-free before it can be submitted.
3. After the application has been submitted, it moves out of the Pre-Submission State to the next State. Once submitted, it cannot be edited (unless changes are requested by a reviewer and it is returned to the Study Team Inbox).
4. After submission, required Department or Affiliate reviews are conducted *before* the study is routed to the IRB.

Progress Notifications

eIRB automatically sends e-mail notifications to the Study Staff when significant events occur in the review process. Be sure to keep your e-mail address current in the *eIRB* system! To change your e-mail address, see Account Changes on page 3.

The Study Staff will receive e-mail notifications at the following times:

- Requests for information and changes to the application.
- Official actions from the IRB (i.e., when the application is scheduled for a board meeting, once an application is approved/disapproved, etc.)
- When studies are due for Continuing Review

You can also check the progress of your application at any time by checking the **History** log.

History Log

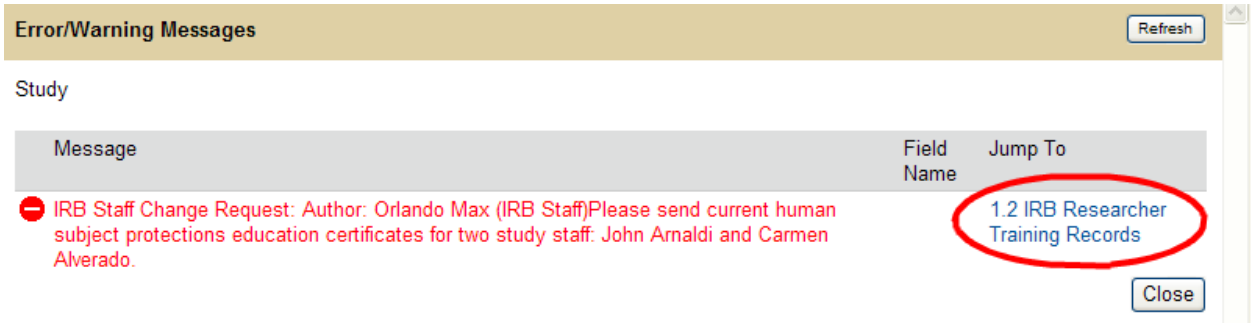
The **History** tab in the study Workspace displays the permanent history log of all actions that have been performed on the study. It lists chronologically those actions which you have permission to view.

Click an Activity name in the History log to view its details.

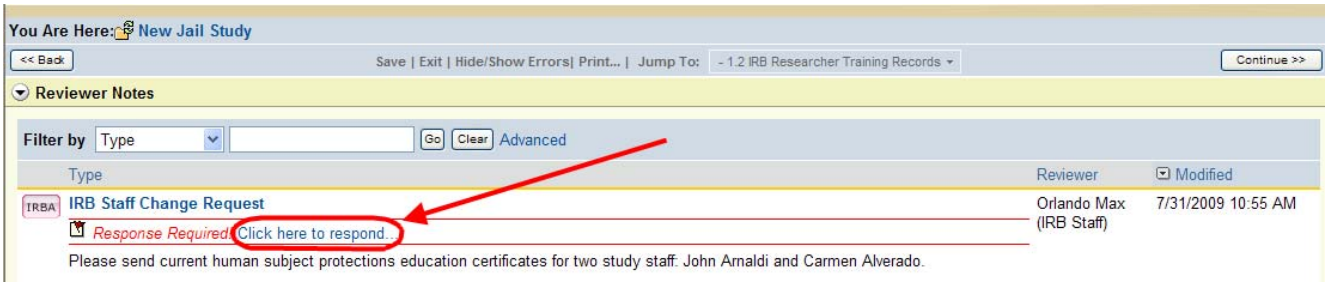
When an application is submitted to the IRB and then when it is approved, *eIRB* creates a **Project Snapshot** that is a permanent archive of the project and all its documents. Snapshots are stored in the history log and can be accessed there.

Respond to Requests for Revisions or Information

1. In your Folder **Inbox**, click the study Name to open the application workspace.
2. Under the **Reviewer Notes** tab, you will find all notes that have been added to the study. Each note provides a **Jump To** link that will take you to the page where the requested change needs to be made.

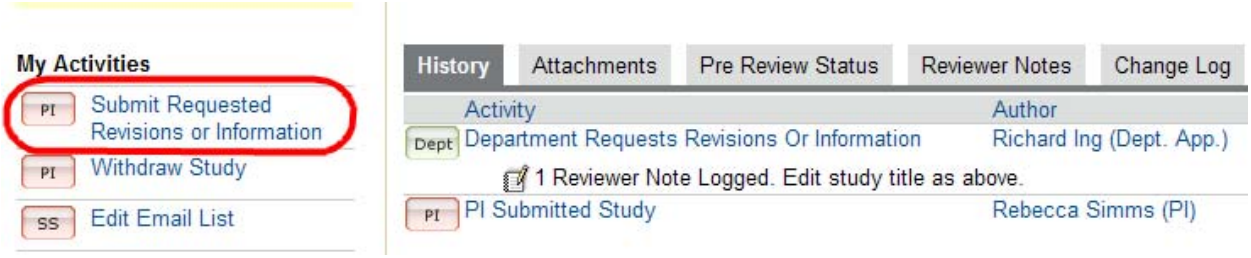


3. Respond to each change requested.



4. Be sure to **Save** before you **Exit** the SmartForm.

5. When the Study Staff have completed all of the requests, in the application workspace, click the **Submit Requested Revisions or Information** and complete the submission, attaching any documents requested.



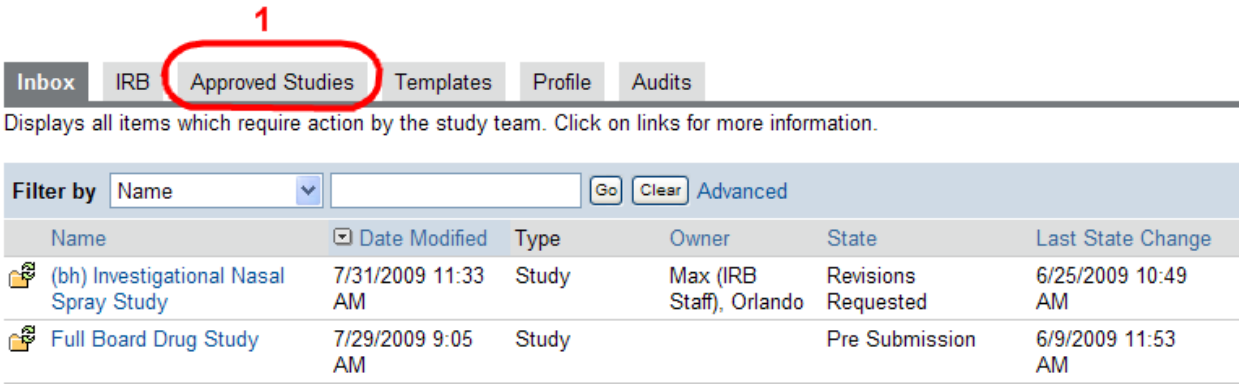
After you have submitted your response, the application will not be displayed in your Inbox because it has moved to the IRB. However, it will be listed under the **IRB** tab in your Folder (My Home), where you can view a read-only copy.

Approval Letter

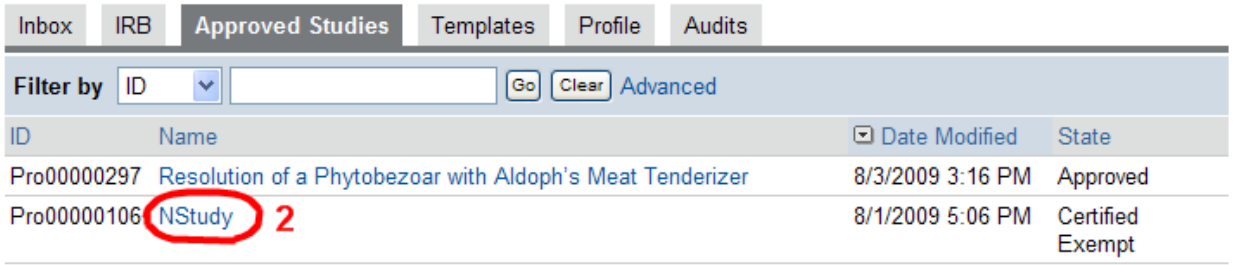
When the IRB has approved your study, you will receive an e-mail notification of approval. The approval letter will also be available in the study Workspace.

To view the approval letter in *eIRB*:

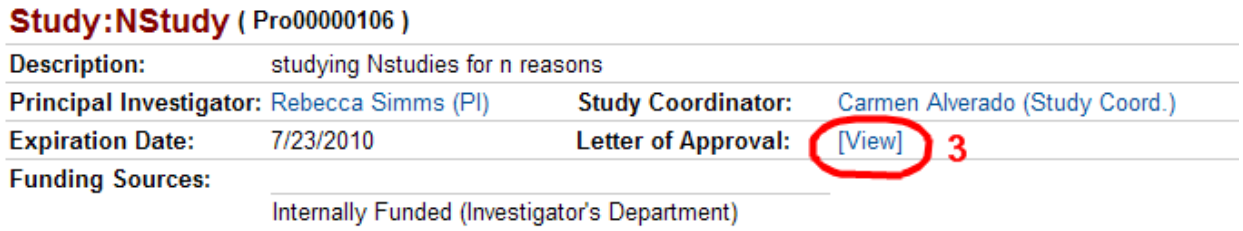
1. In your Folder (My Home), click the **Approved Studies** tab.



2. In the Approved Studies folder click the study name.



3. In the study workspace, the summary panel will now display a link to view the Letter of Approval. Click on **[View]** (**3**).



Attachments and Informed Consent Documents

All attachments to the study application, including the approved consent forms, can be viewed in the study Workspace under the **Attachments** tab.

After IRB approval, all attachment to the approved study can be viewed by following these steps:

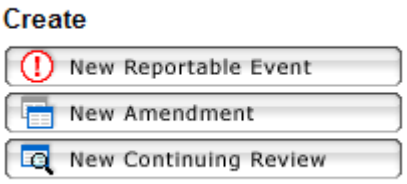
1. In your Folder (My Home), click the **Approved Studies** tab (see illustration **1** above).
2. In the Approved Studies folder click the study name (see **2** above).
3. In the study workspace, click the **Attachments** tab (see **3** below). A list of all attachments will be displayed.

- The Approved Consent Forms section will list all of the consent forms approved for use in the consent process. These documents will be read-only pdf files.
- The Clean and Strikethrough Copies of Consent Forms section 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. For major changes, you can attach a new revised document.
- The remainder of this screen displays each question in the SmartForm that allows you to upload a document or file. Scroll down to quickly locate any attachment to the application.

Creating Reportable Events, Amendments, & Continuing Reviews

After a study has IRB approval, you can create a study sub-project: a new reportable event, amendment, or continuing review application.

In the study Workspace, click the relevant activity button and then complete the SmartForm application that is displayed.



Workspaces for study sub-projects are similar to the study Workspace.

After a reportable event, amendment, or continuing review has been created and saved, it can be accessed in your Inbox until you submit it.

After it has been submitted, it will be routed to the IRB, and can be viewed in the study Workspace under the respective tab (Amendments, Continuing Reviews, Reportable Events).

If a previous amendment for this study is pending IRB approval, the New Amendment button will not be displayed (until after the previous amendment is approved).

If you have submitted a Continuing Review (CR) that is now pending review and you need to amend the study, you will need to either:

- wait until the CR is processed, or
- withdraw the CR and submit the Amendment (and then re-submit the CR after the Amendment is approved).

New Terms

- Modification Request = **Amendment**
- Progress Report = **Continuing Review**
- Determination = **Not Human Subjects Research**
- Information Reports and Adverse Events = **Reportable Events**