UCLAwebIRB

Creating a New Study Application

Training Course for Investigators and Study Staff

V: 08.16.2021

This training will cover…

- Navigating the OHRPP website
- Requesting a webIRB account
- Creating a New Study application
- Responding to IRB Requests
- Additional resources

This training will NOT cover…

- Detailed review of the IRB application
- Protocol development/questions within the application
- Post-approval applications (AM, CR & PAR)

Before getting started

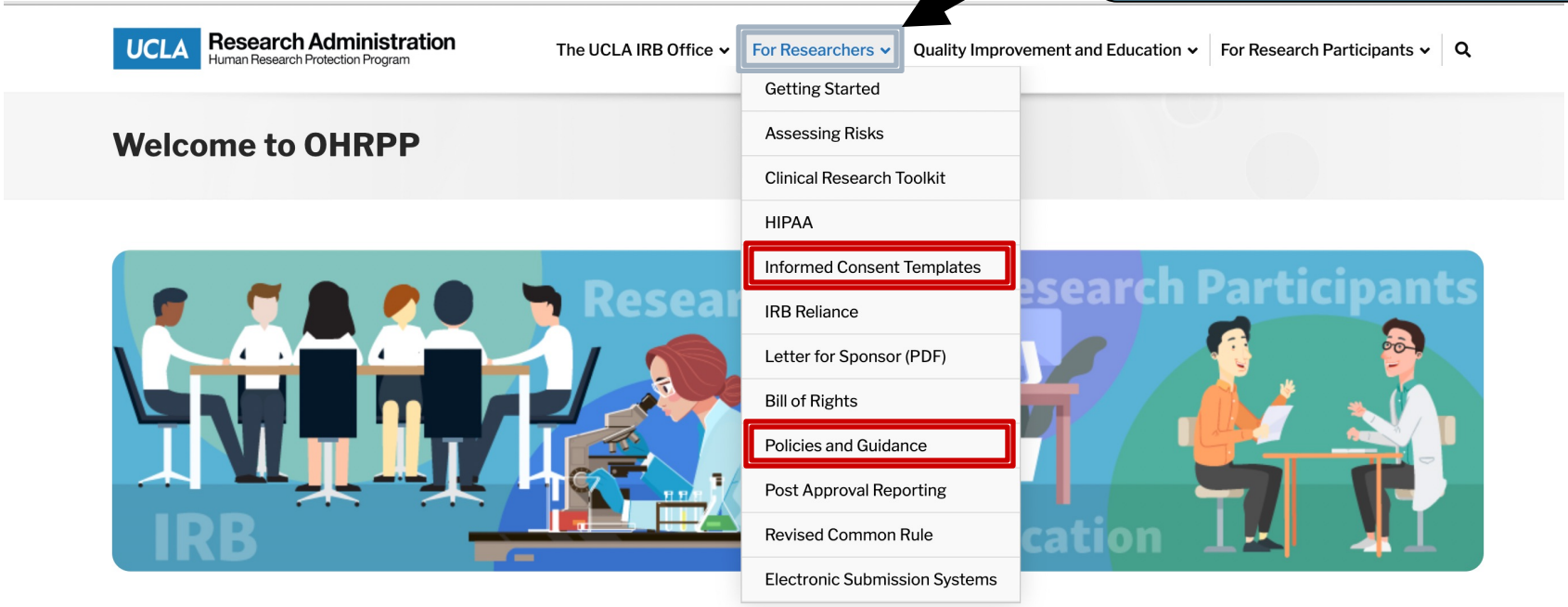
Visit the OHRPP website for the following resources:

- Guidance and policy
- Forms and templates
- Decision trees
- More information about the UCLA IRBs

OHRPP Website

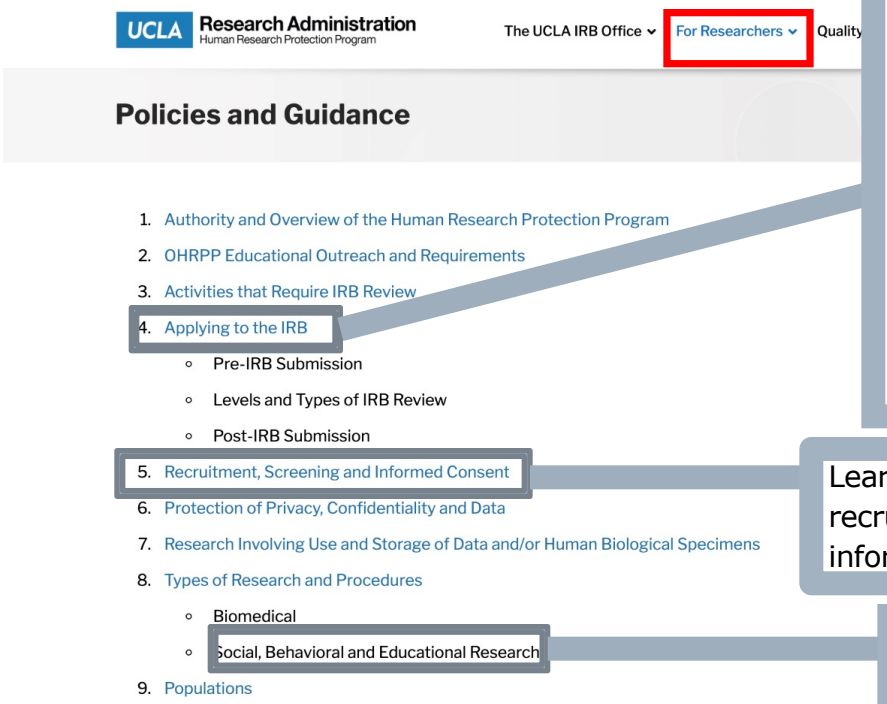
To access this information:

Click here to access guidance and templates



The Office of the Human Research Protection Program (OHRPP) is the administrative arm of the UCLA Human Research Protection Program (HRPP). The OHRPP in partnership with the research community is responsible for ensuring the safety and welfare of participants in Human Research Projects conducted under the aegis of UCLA. The OHRPP, which is a Division within the Office of Research Administration, provides the campus and the five UCLA Institutional Review Boards (IRBs) with professional guidance and administrative support.

Guidance Documents



4. Applying to the IRB

Pre-IRB Submission:

- Getting Started with an IRB Application-A Guide for Investigators and Research Staff
- Brief Overview of webIRB Submission Procedures
- Conducting Risk-Benefit Assessments and Determining Level of IRB Review
- Describing Research Design and Methods
- Scientific or Scholarly Review of Human Subjects Research Protocols
- Tip Sheet: Minimal Risk
- Funding Considerations for Federally-Funded and Industry Sponsored Human Research
- Funding Applications and UCLA IRB Review
- Tip Sheet: Delayed Onset Determinations
- Research Supported by the Department of Defense
- Additional Requirements for Federally Supported Research

Learn about the acceptable informed consent and recruitment methods, and how to incorporate required information into recruit material

Social, Behavioral and Educational Research

- Research Involving the Internet
- Tip Sheet: Online Survey Protection Considerations
- Deception or Incomplete Disclosure
- Research Involving Students and/or Conducted in Educational Settings

CITI Training

Visit the OHRPP CITI training help page to determine the appropriate training required: https://ohrpp.research.ucla.edu/citi-training/

Before you can submit your project, all persons listed in the study application (Section 1.1) who will engage in human subjects research must complete either the Human Subjects Research Training ***OR*** the Good Clinical Practice (GCP) training. Both trainings are valid for three years.

- NIH-funded clinical trials *require* GCP training
- If accessing medical records, UCLA research HIPAA training is required. Research HIPAA training is only required once, no expiration.

How to request a webIRB account

To request a webIRB account, email: weblirbhelp@research.ucla.edu

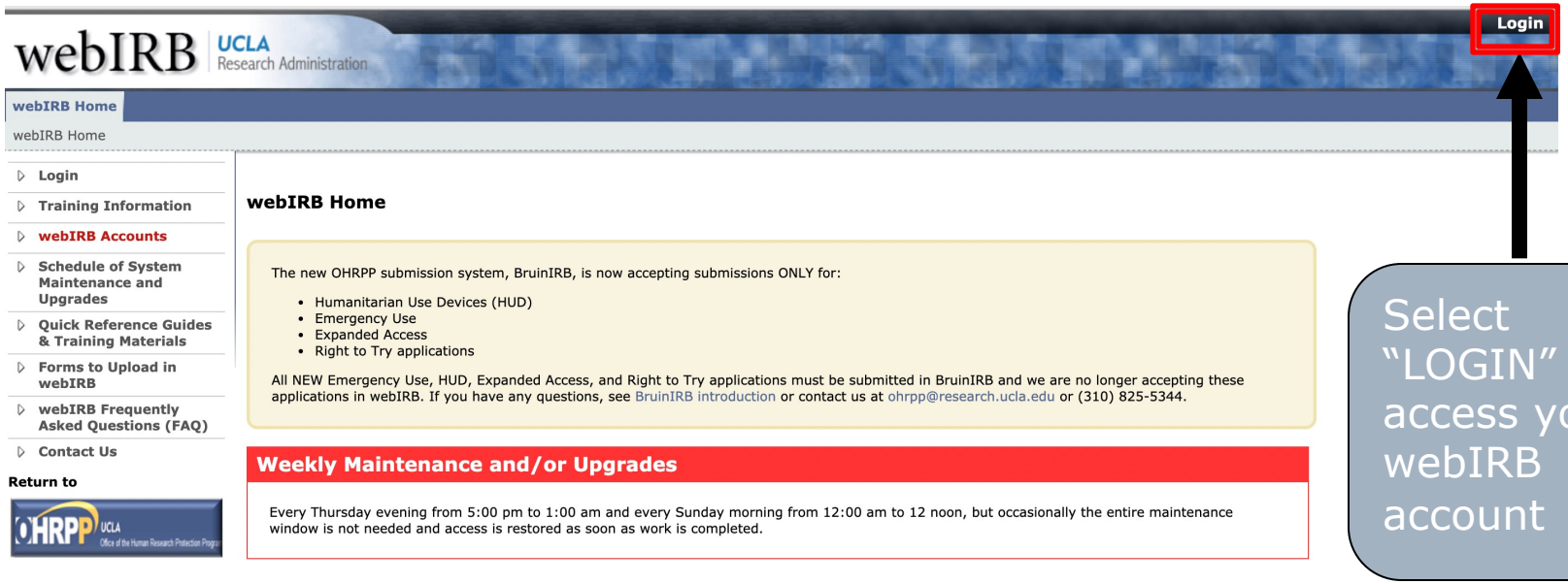
If you are not qualified to be a PI under UCLA Policy 900, you must secure a *faculty sponsor* and have them email the following information:

- Your full name
- Your email address
- Your UCLA Logon ID
- Your 9-digit UID
- Your department/division

webIRB Official Site

Once you are ready to set up your webIRB account and create a *New Study* application visit:

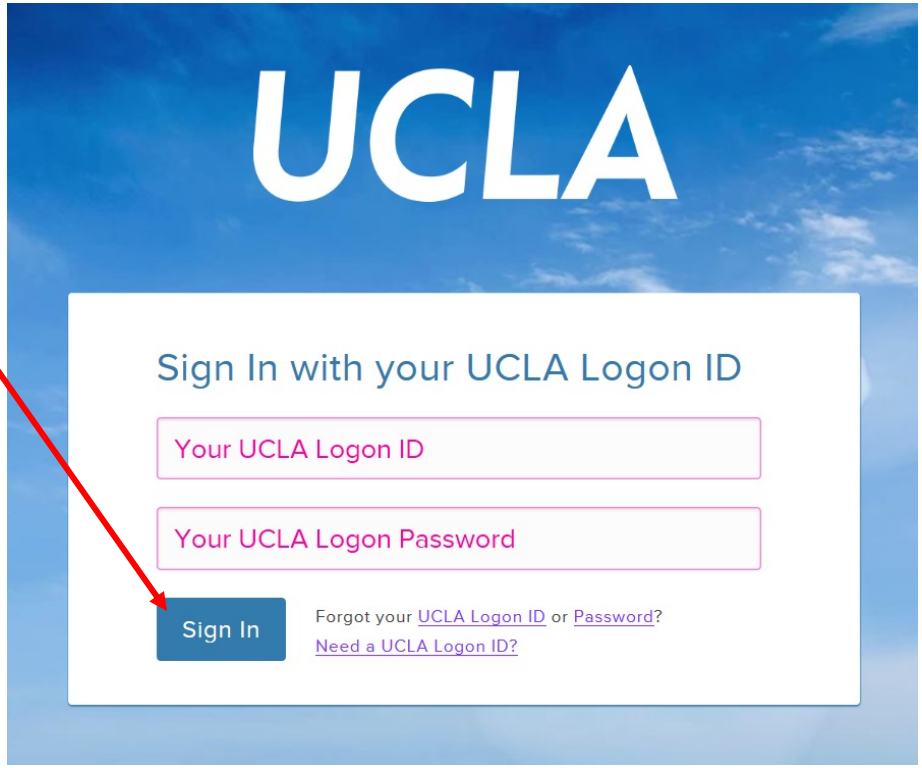
https://webirb.research.ucla.edu



Select "LOGIN" to access your webIRB account

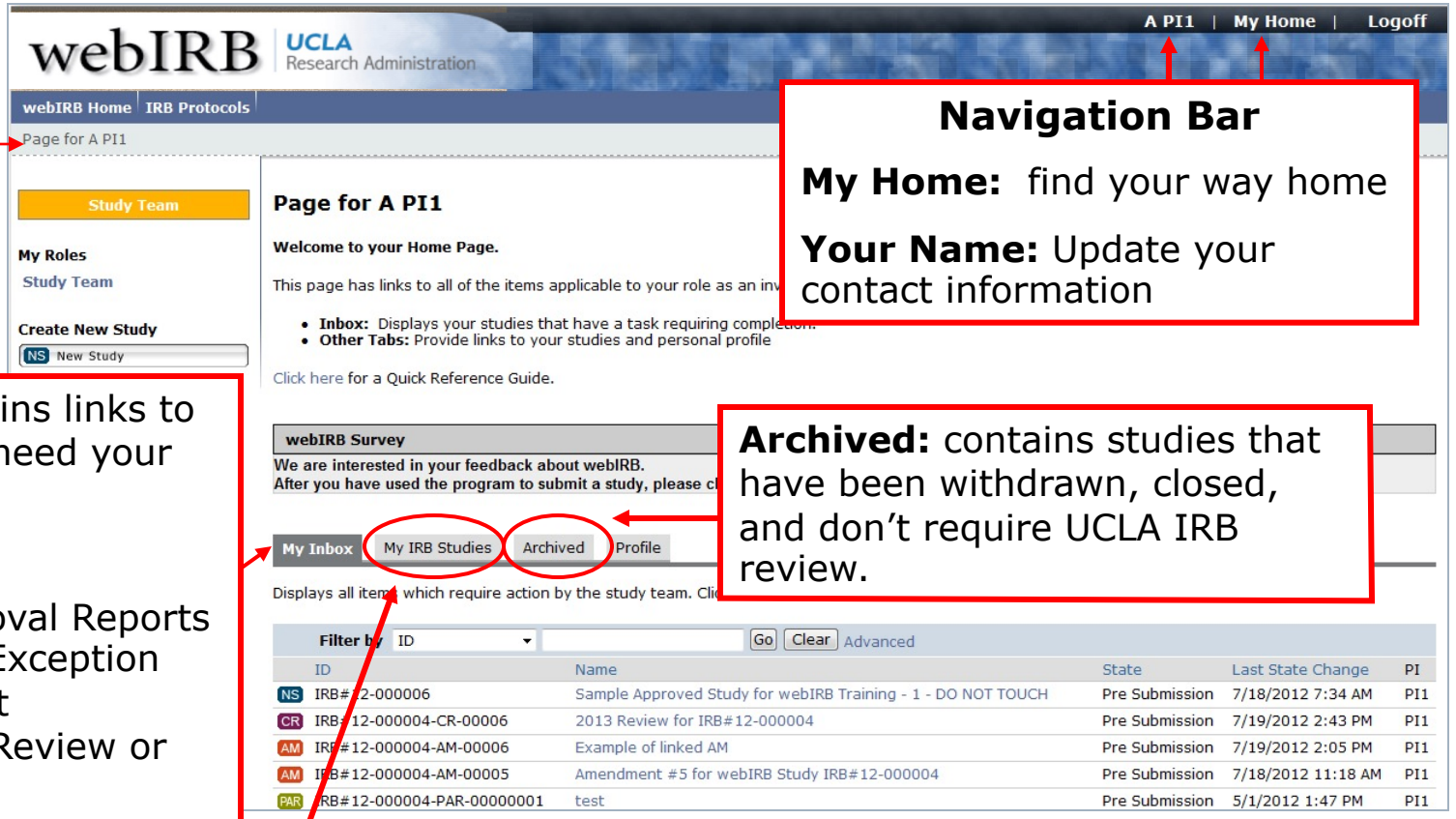
Login

1. Enter your UCLA Logon ID and password
2. Click **Sign In**



"My Home" Page

Breadcrumb: Find your way through the study workspaces



Navigation Bar

My Home: find your way home

Your Name: Update your contact information

My Inbox: contains links to submissions that need your attention:

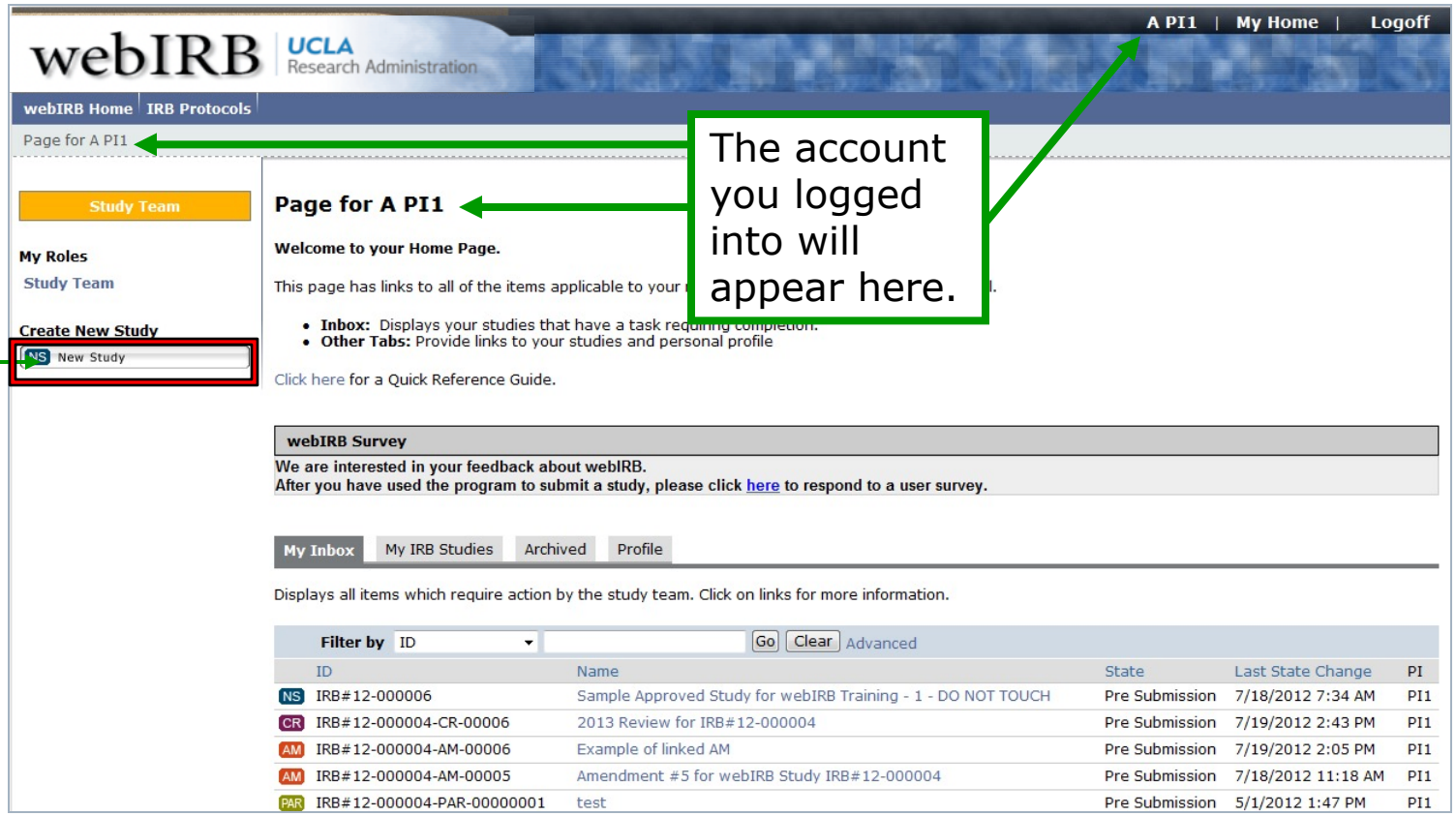
NS = New Study
PAR = Post-Approval Reports & Single Subject Exception
AM = Amendment
CR = Continuing Review or Closure

Archived: contains studies that have been withdrawn, closed, and don't require UCLA IRB review.

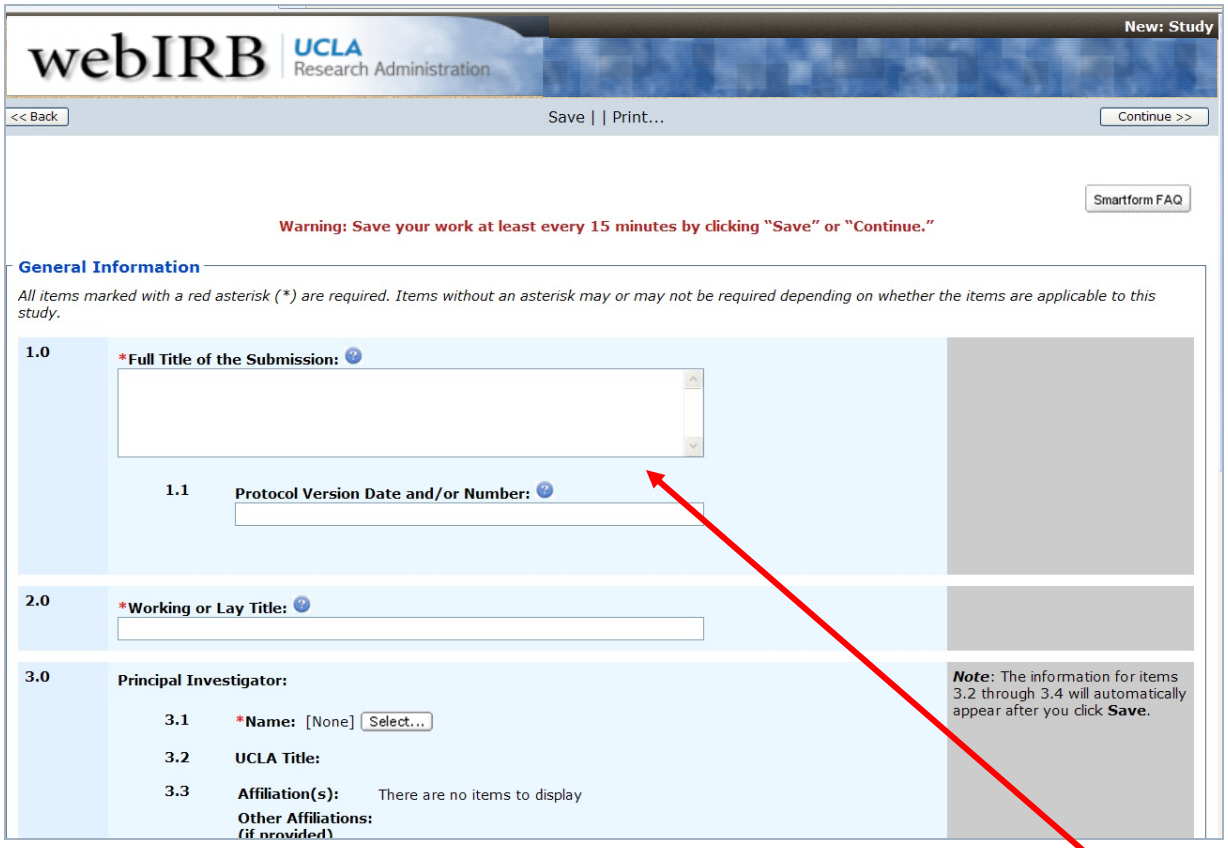
My IRB Studies: contains all open studies

Create a "New Study" application

Click to create a **New Study**



"General Information" Page



The **General Information** Section of the Study Smartform will appear.

Provide a response to each question.

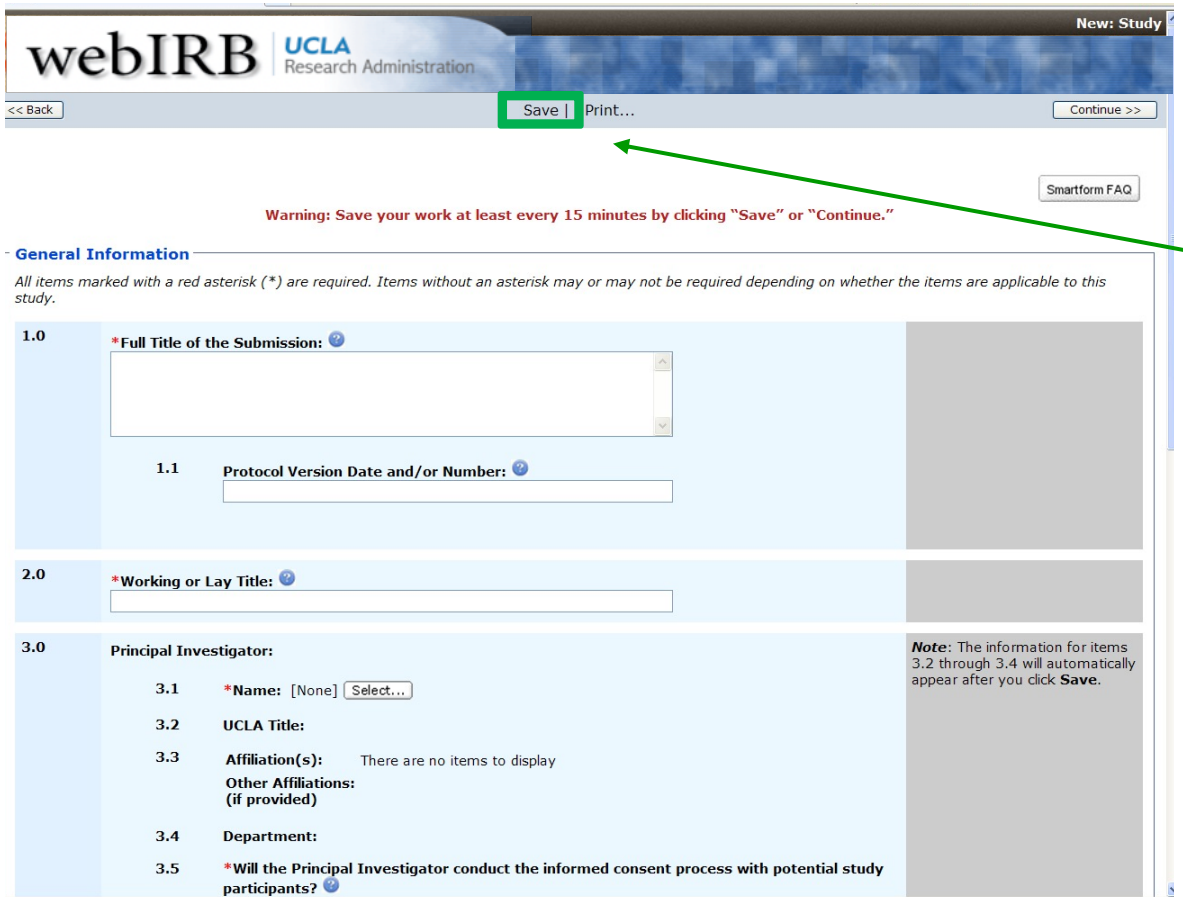
The questions with a red asterisk (*) are required.

For help with answering a question, click on

or refer to the guidance in the grey text box.

Insert the descriptive title. Avoid using generic titles like, "My Thesis" or "New Study".

Tip: Save your work!



After completing **all required** items on this page, click **Save** after completing the entire General Information section.

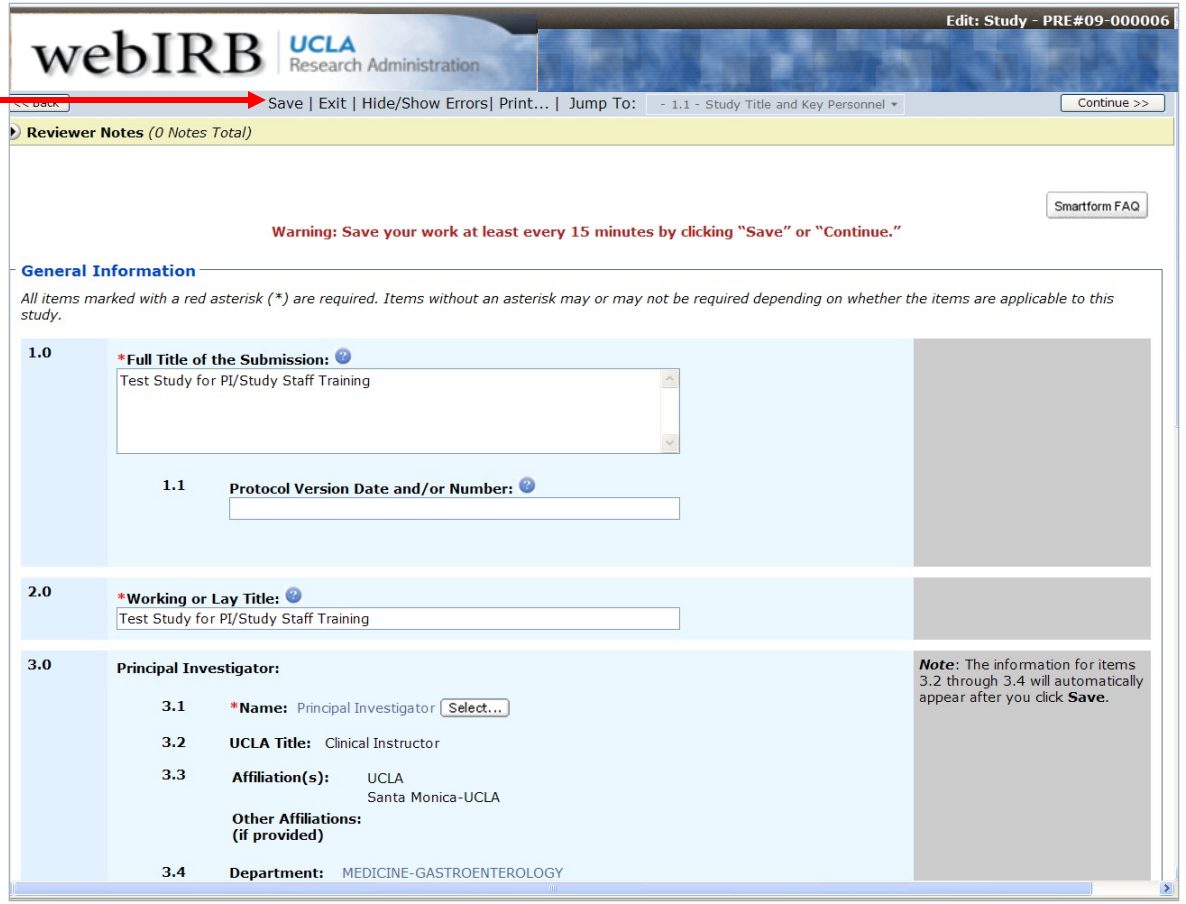
Before moving to the next page or logging off, select "**Save**". After clicking "Save" more activities will appear at the top of the page.

Tip: Save your work!

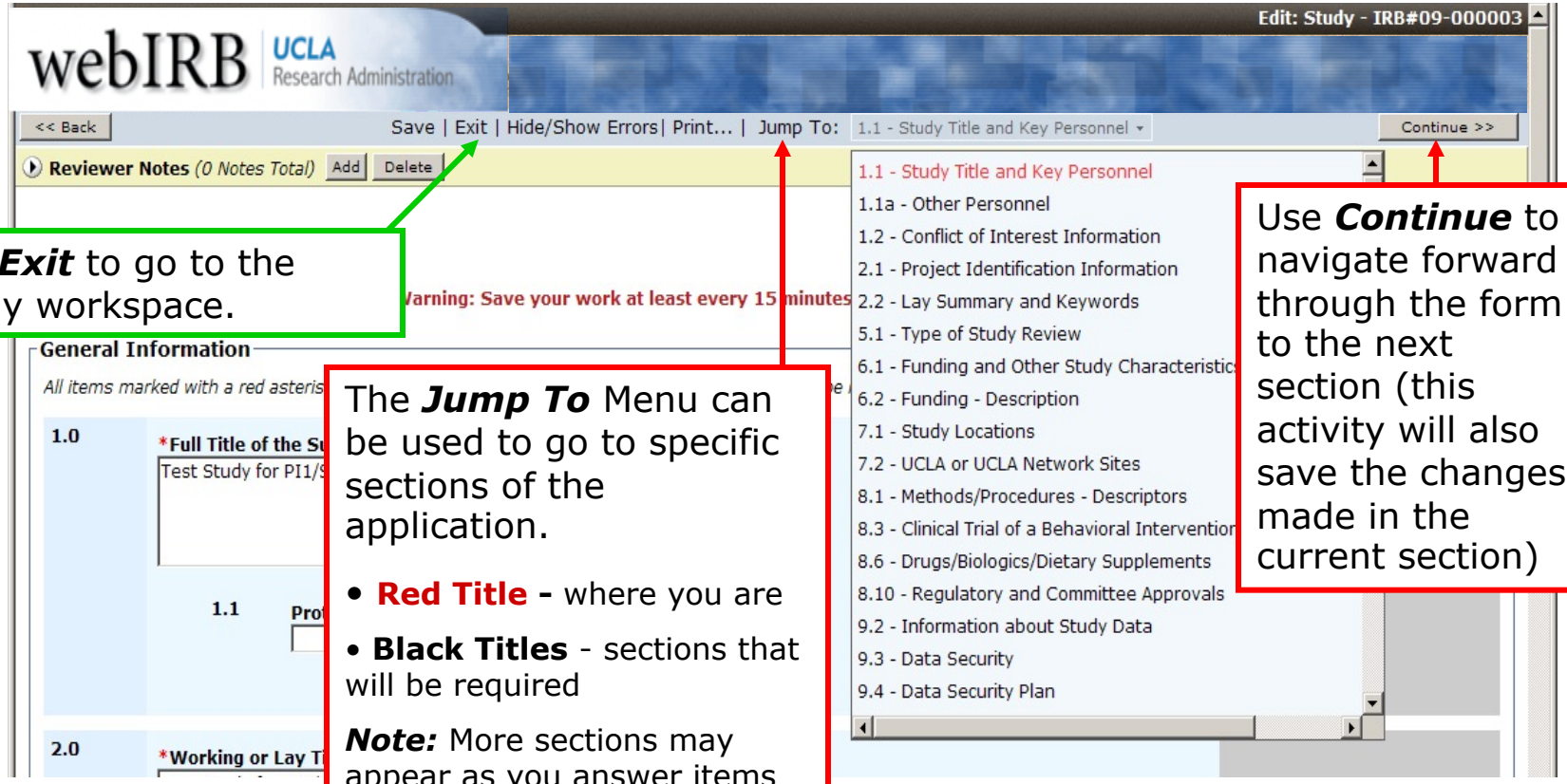
Note the additional actions that will appear in the menu bar after clicking **Save.**

Important Note:

- webIRB does not have an auto-save feature.
- Click **Save** periodically (every 15 minutes) to ensure that your work is saved.



Navigation Tools



Use ***Exit*** to go to the Study workspace.

The ***Jump To*** Menu can be used to go to specific sections of the application.

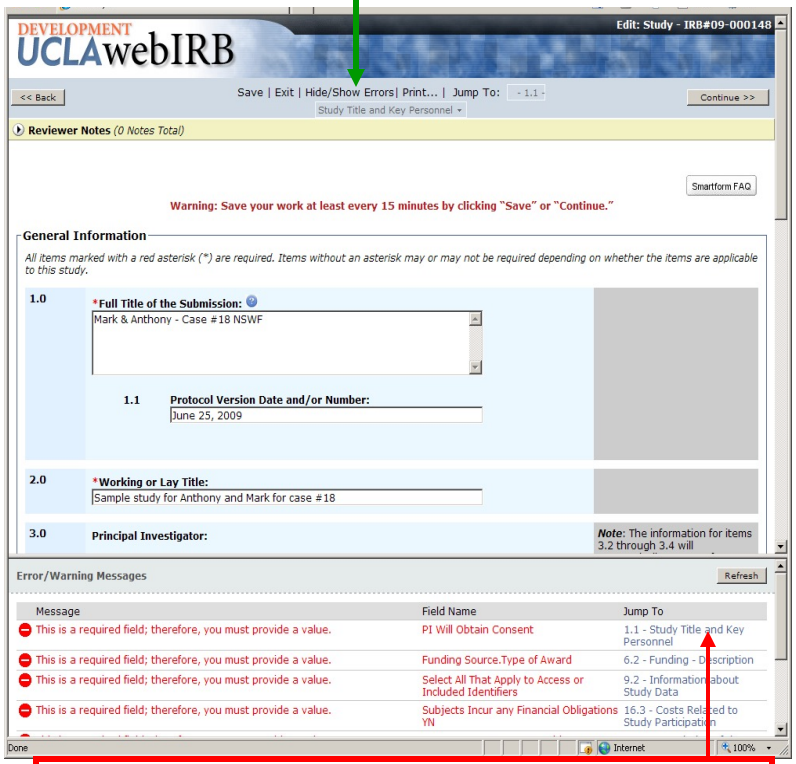
- **Red Title -** where you are
- **Black Titles** - sections that will be required

Note: More sections may appear as you answer items in the form

Use ***Continue*** to navigate forward through the form to the next section (this activity will also save the changes made in the current section)

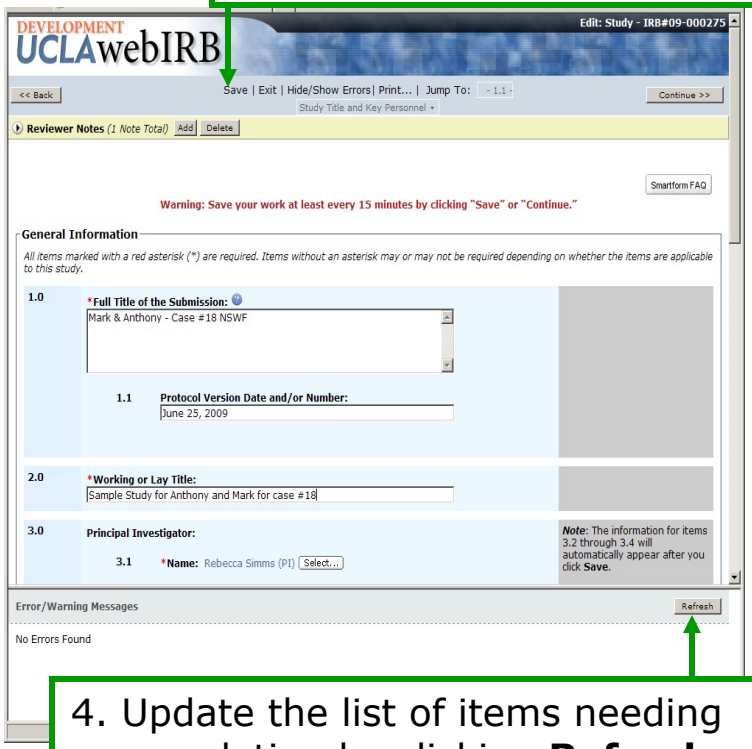
Checking Your Progress

1. Click **Hide/Show Errors**



2. A screen will appear with links to pages needing completion. Click the links to go to the pages.

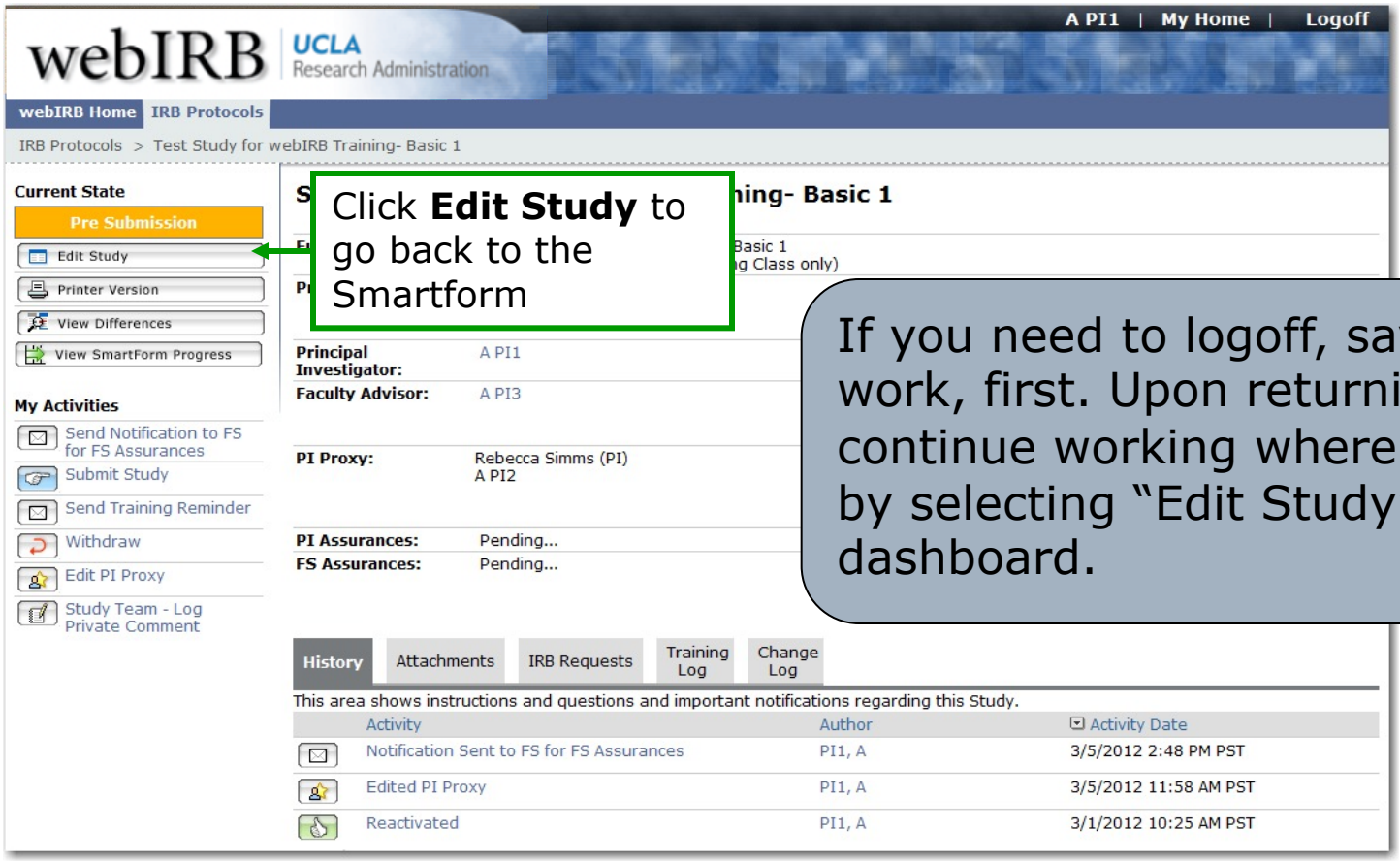
3. Remember to click **Save** after providing your response(s).



4. Update the list of items needing completing by clicking **Refresh.** The error screen will update.

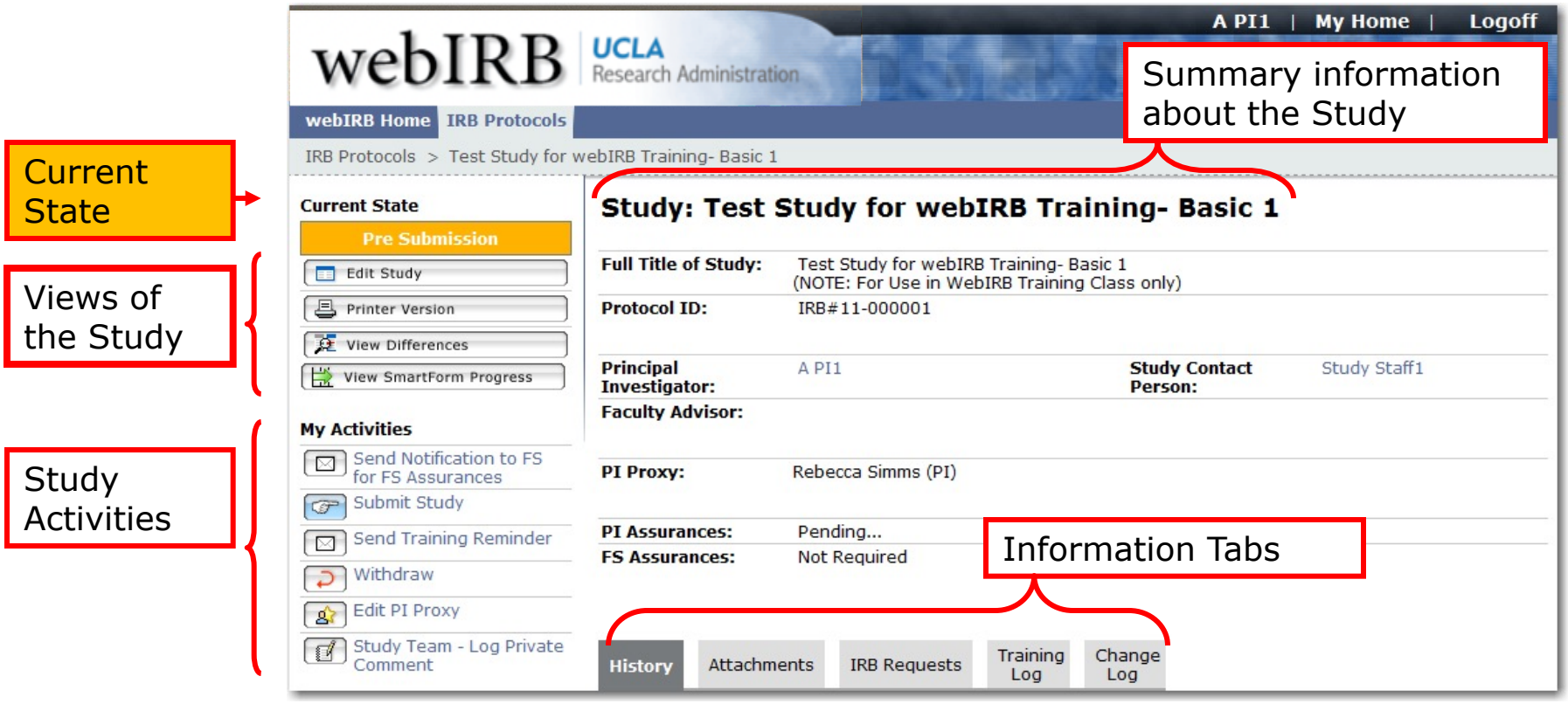
   Click **Hide/Show Errors** again to hide the screen

Navigation Tools

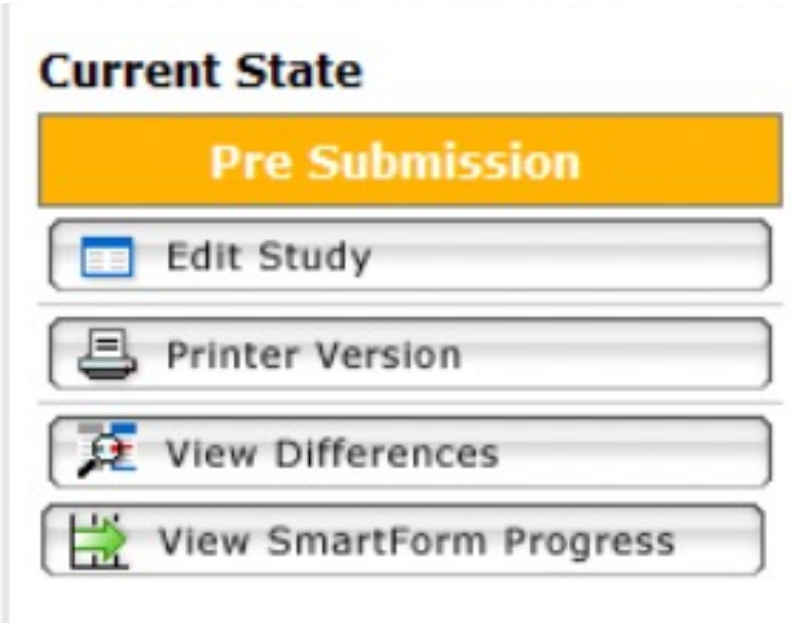


If you need to logoff, save your work, first. Upon returning, you can continue working where you left off by selecting "Edit Study" on your dashboard.

Study Workspace



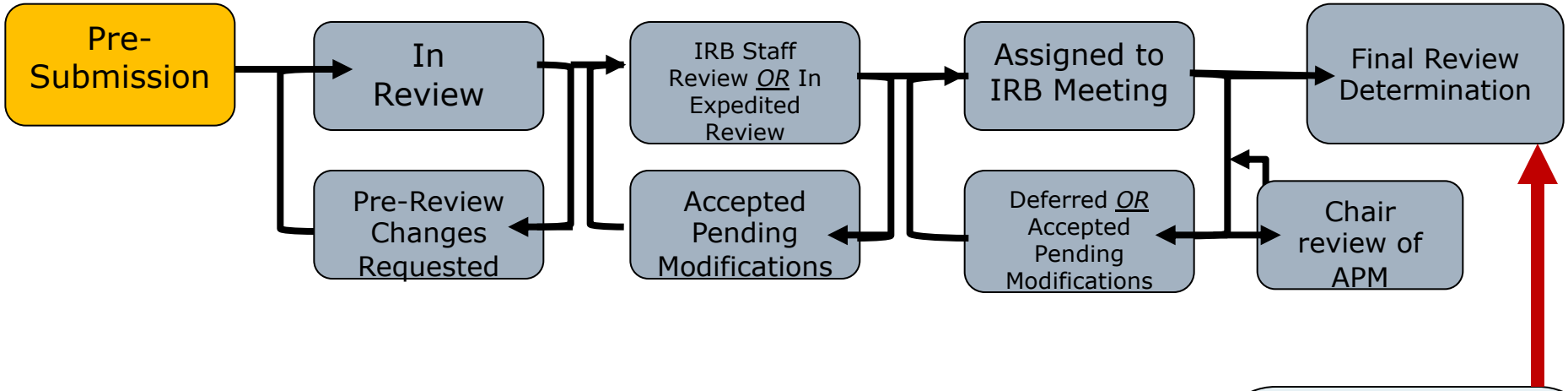
Current State of the Application



As your application is triaged through the IRB review process, the **Current State** of your application will change.

Note: Your study application may remain in the same current state for several days or weeks depending on various factors including your response time, the volume of submissions or the type of review (exempt, expedited or full board).

Current State of the Application



As your study application undergoes the IRB review process, the IRB might ask for additional clarification or information prior to moving your application along to the next phase of the review process. To avoid delays, please respond to any requests for clarification or additional information within a timely manner.

IRB final review determinations can be:

- Approved
- Approved-No CR
- Certified Exempt
- External Review Accepted
- Disapproved

Note: IRB#

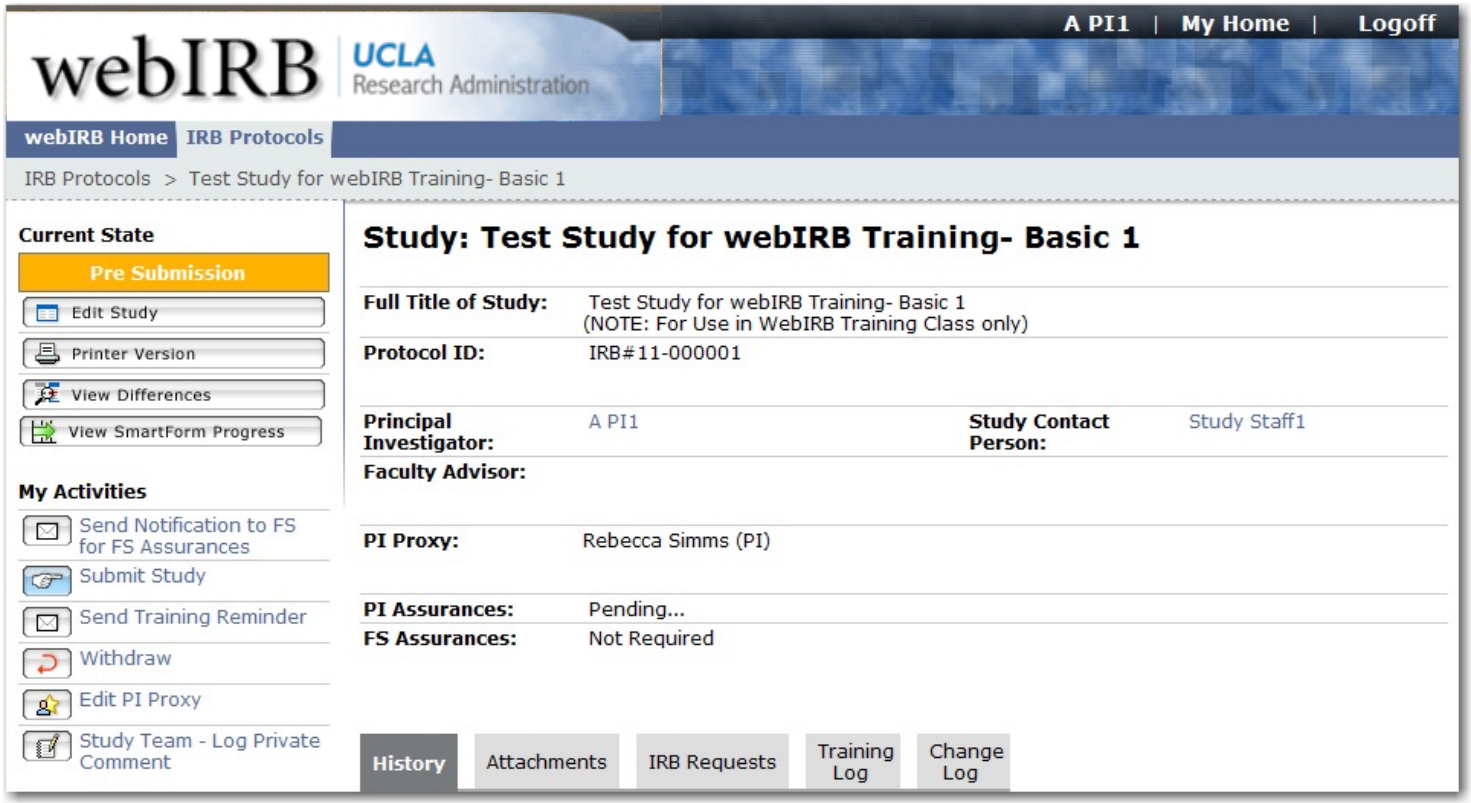
- Before submission, studies get a PRE#.
  For example, PRE#21-000010
- After submission, studies get an IRB#.
  For example, IRB#21-000325

Note: The PRE# and the IRB# will *not* match

It is important to note your assigned IRB# for the study. When corresponding with the IRB, the staff may ask for your IRB# to easily identify your study.

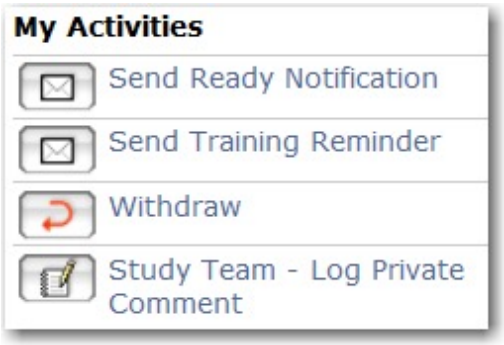
Study Workspace

Study Activities

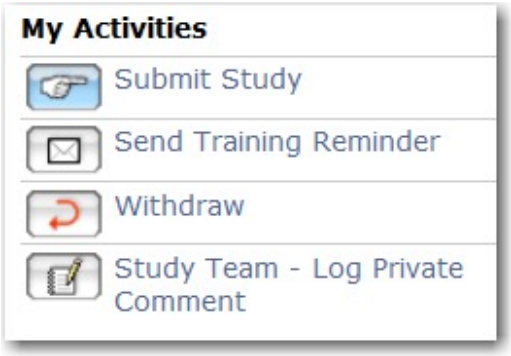


My Activities

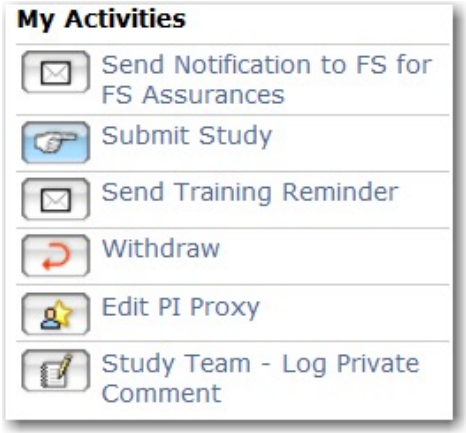
Study Staff



PI Proxy



PI

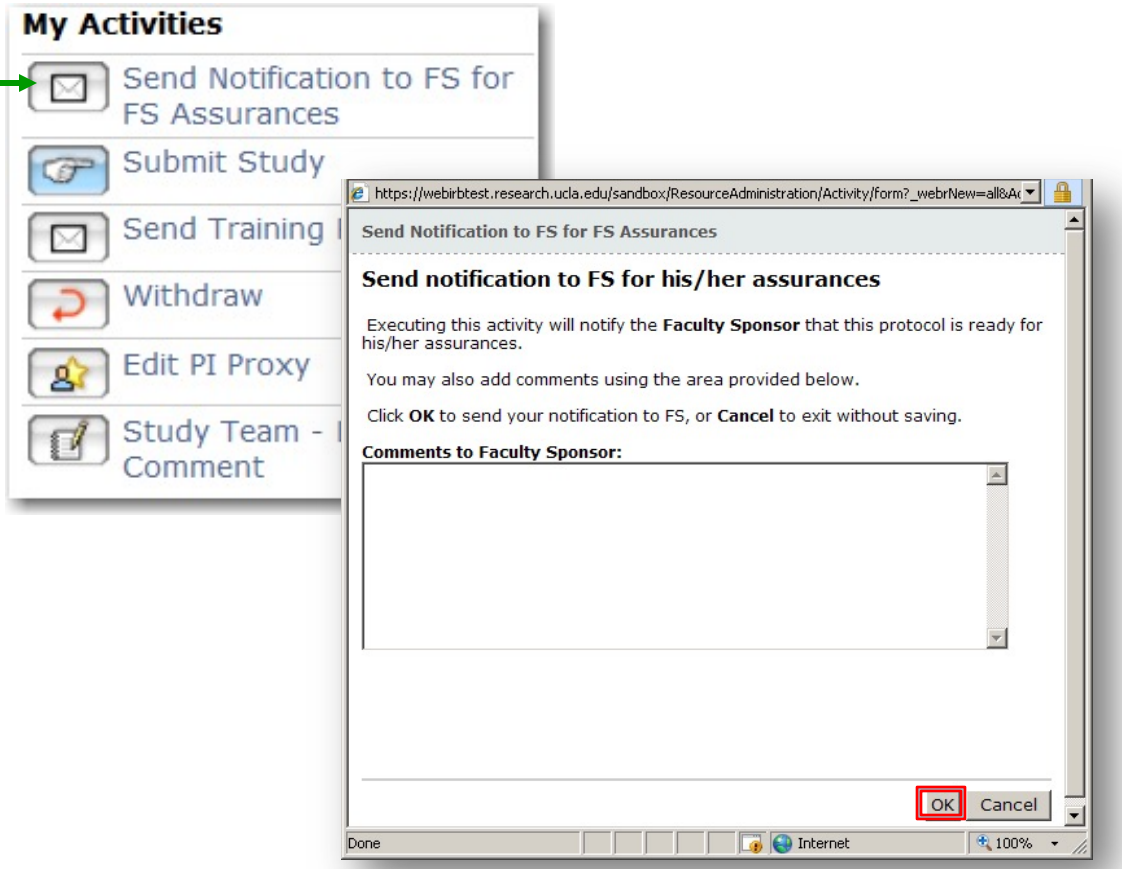


Available activities differ by the current state of the protocol and role of the person.

Faculty Sponsor

My Activities: Send Notification to FS

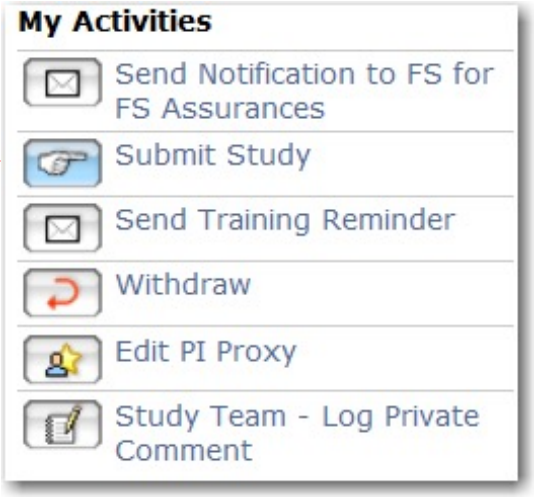
- If you have a Faculty Sponsor (FS) for the study, his/her assurances are required ***before*** the study can be submitted.
- Click on the activity **Send Notification to FS for FS Assurances** to send an email notification to your FS.
- The email will provide a link to the study workspace.
- This activity is only available to the PI.



My Activities: Submit Study & Send Ready Notification

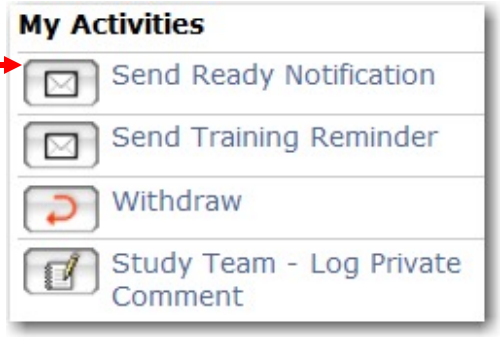
Click on the activity **Submit Study** when the application is complete.

This activity is only available to the PI, PI Proxies, and FS.

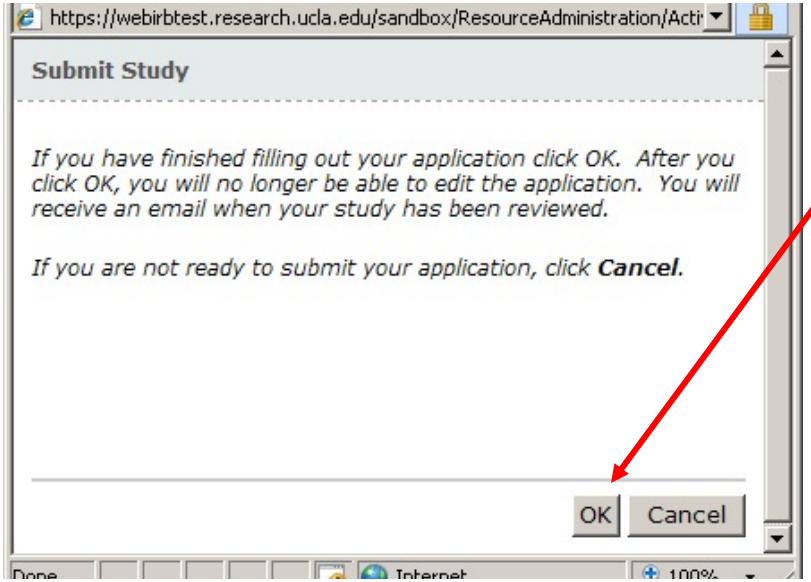


Send Ready Notification is available to all personnel listed in section 1.1.

An email will be sent to the PI, PI Proxies, and FS that contains a link to the study workspace.

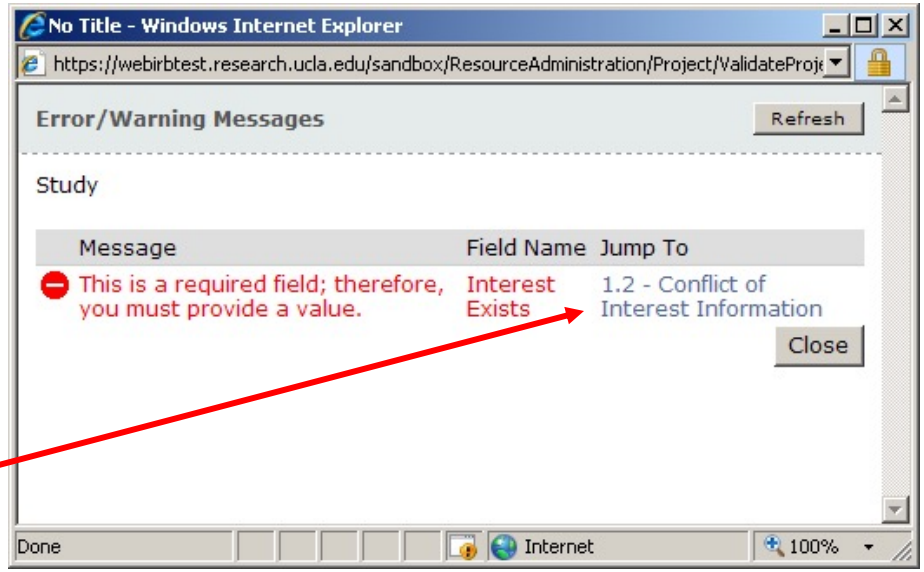


My Activities: Submit Study or Send Ready Notification



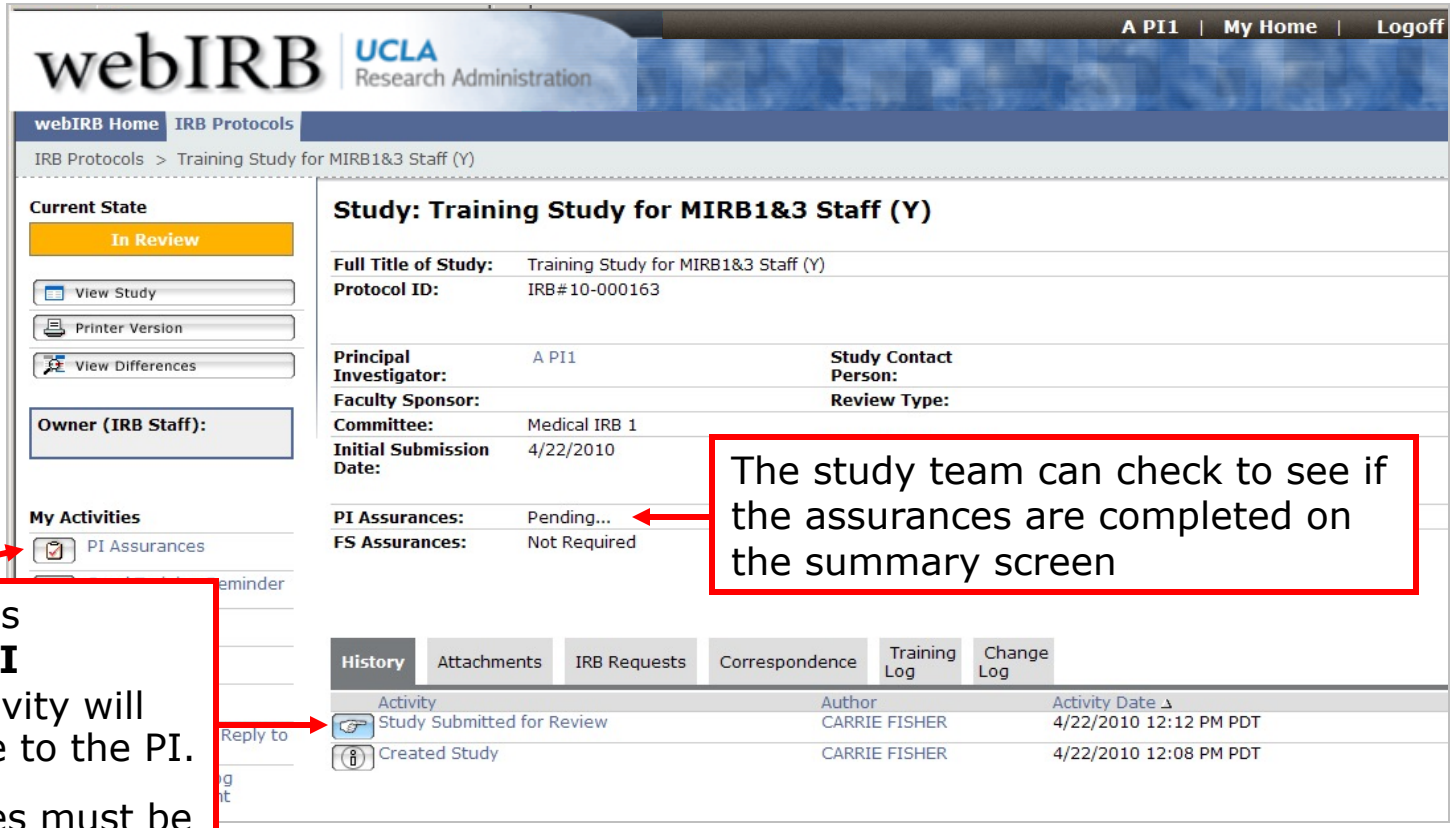
If the application is complete, you will get a **Submit Study** screen.

Click **OK** to submit.



- If there are still items to complete, you will get an **Error/Warning Message**.
- Use the blue link to jump to the Section with the incomplete item(s).

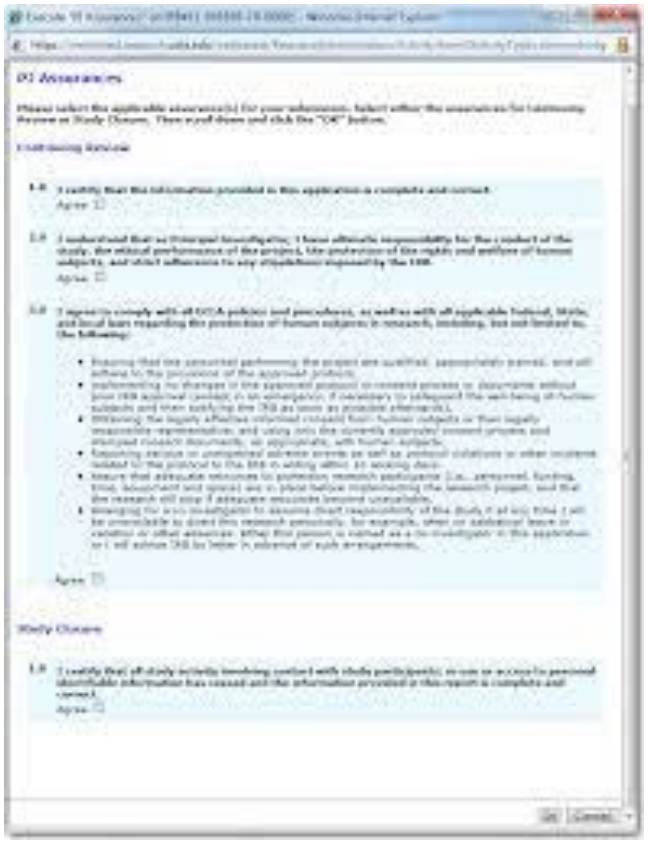
My Activities: PI Assurances



The study team can check to see if the assurances are completed on the summary screen

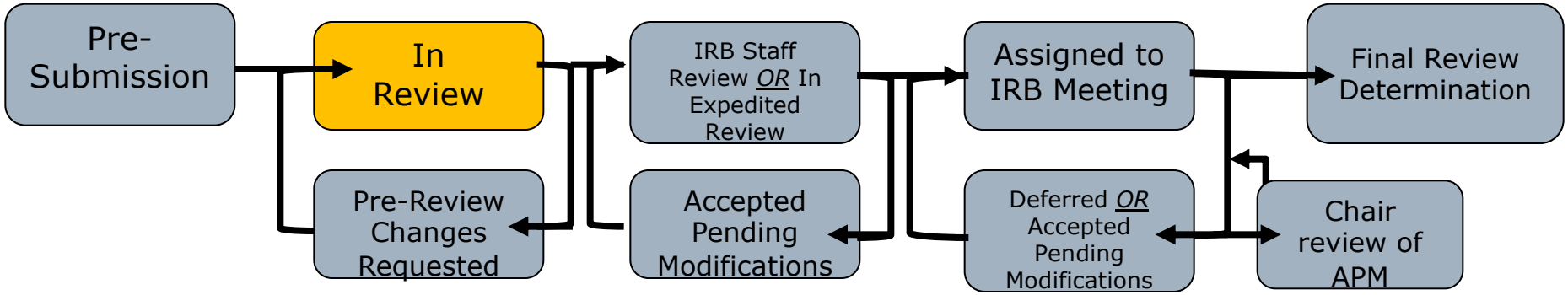
- ***After*** the study is submitted, the **PI Assurances** activity will become available to the PI.
- The PI Assurances must be completed by the PI (and only the PI) before the study can be approved.

My Activities: PI Assurances



Carefully read all assurances before selecting “OK”.

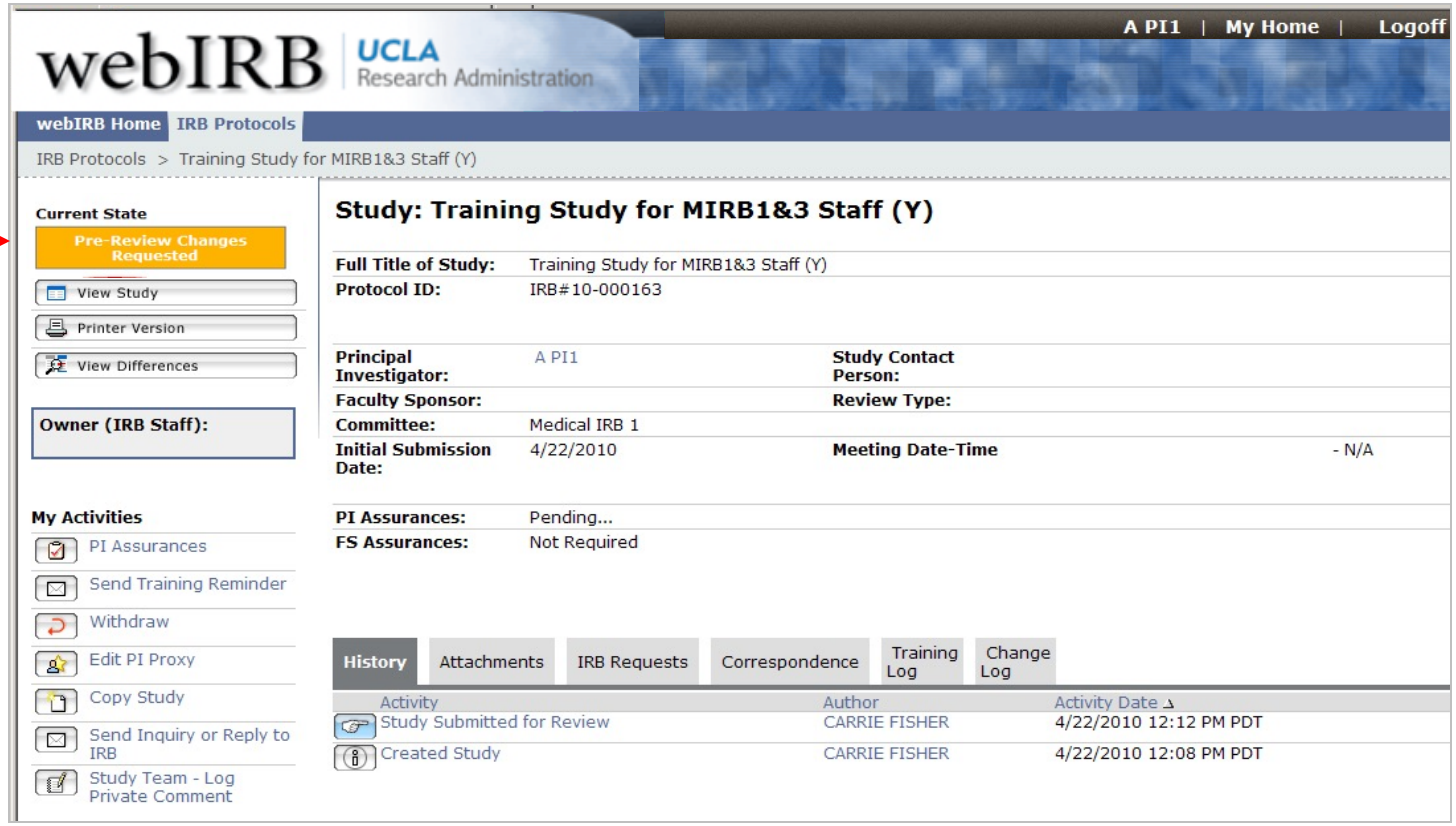
Current State of the Application



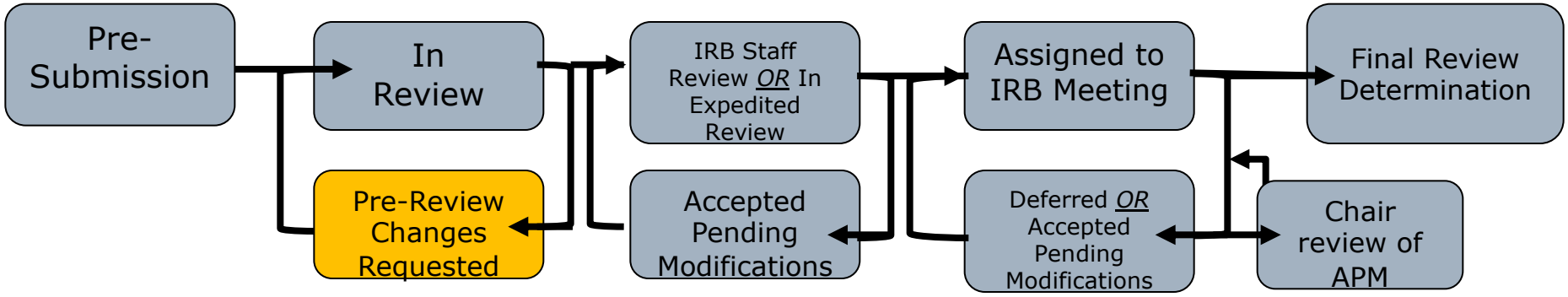
Once your application has been submitted, the current state of the application will change to "**Pre-Review**". At this time, if the IRB analyst assigned to your project determines that you are missing documents or information or requests clarification, then the status will change to "**Pre-Review Changes Requested**".

My Activities

If OHRPP staff request modifications or additional information, the current state of the study will change.



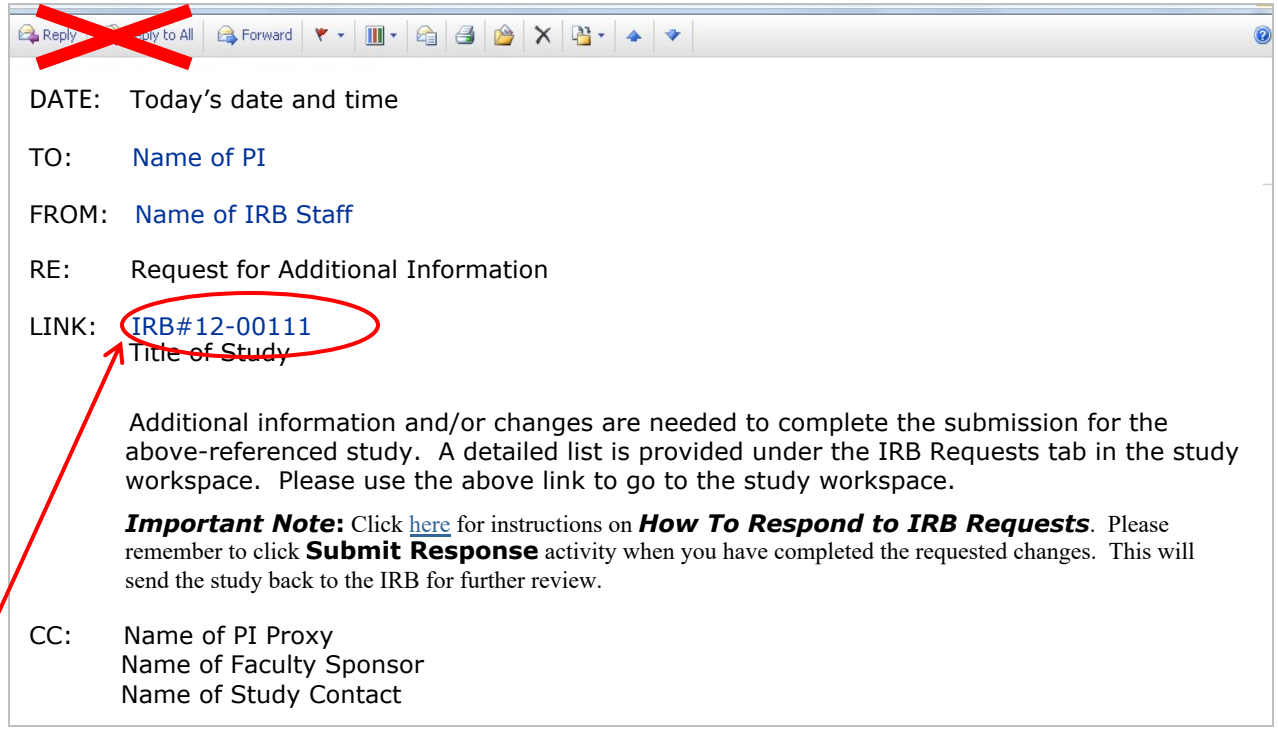
Current State of the Application



During the review process, the current state of your application will change. If your application is in any of the states at the top, it means the IRB has your application. If your application is any of the bottom states, it means action is required on your part to move your application along.

IRB Correspondence

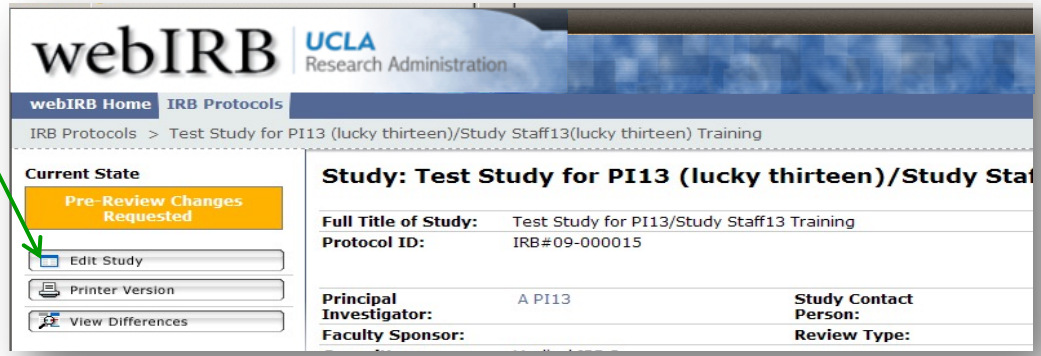
- The PI, PI Proxies, FS, and Contact Person will receive an email notification when the IRB:
  - ❖ requests pre-review changes
  - ❖ issues a letter (i.e., IRB Determination)
- Use the link in the email to go to the project workspace and respond to the IRB requests.
- **Do Not Reply to the email.**



Example of webIRB email notification the PI will receive when the IRB requests Pre-Review Changes to his/her study application.

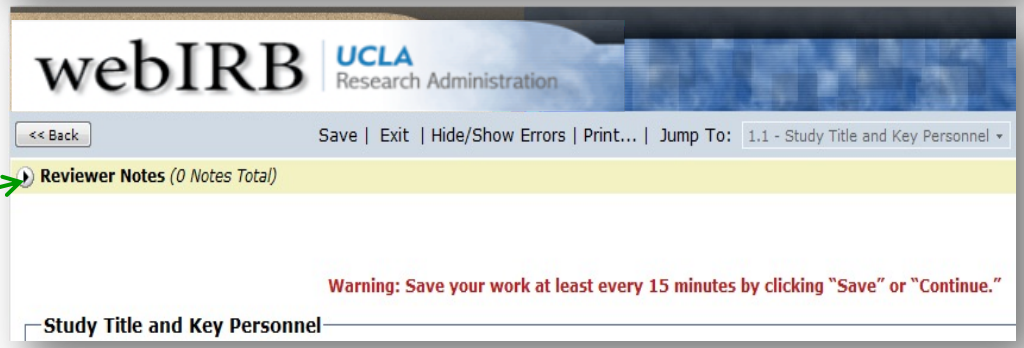
Responding to IRB Requests

- When responding to an IRB request for a Study click **"Edit Study"**
- Section 1.1 of the Study Smartform will appear.

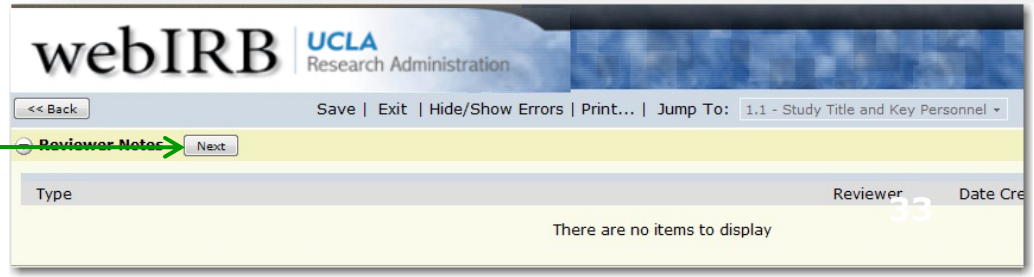


- To view the IRB requests in Section 1.1, click the arrow so that it points down .
- If there are no IRB requests for Section 1.1 you will see the message:

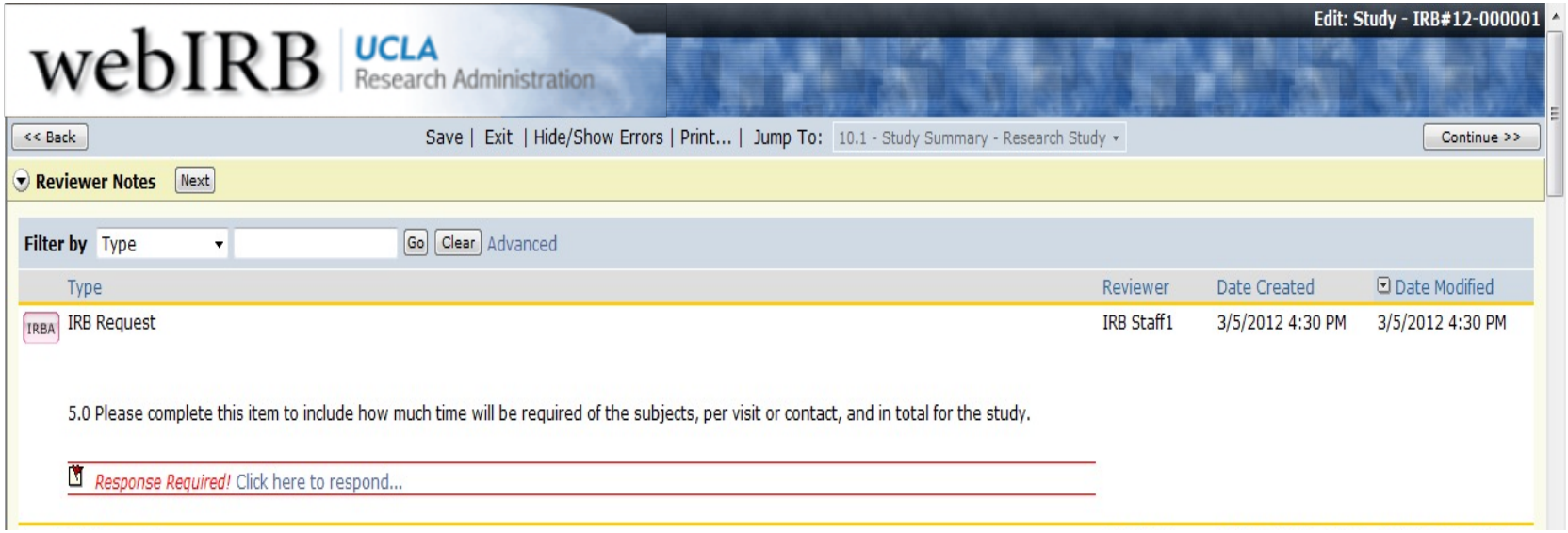
"There are no items to display".



Click on **"Next"** to view the next section with an IRB request.



Responding to IRB Requests (cont'd)



DO NOT select "Click here to respond…" yet, instead:

1. Make all the requested changes in the Smartform.
2. Click **Save** after making changes to the Smartform.
3. When the changes are complete (make sure to SAVE your changes), click - ***Click here to respond…*** A dialogue box will open.

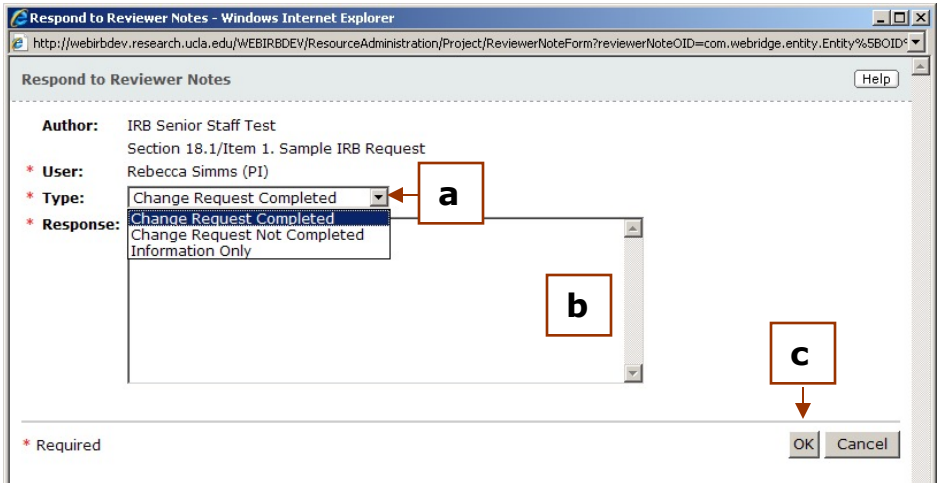
Responding to IRB Requests (cont'd)

When the dialogue box opens:

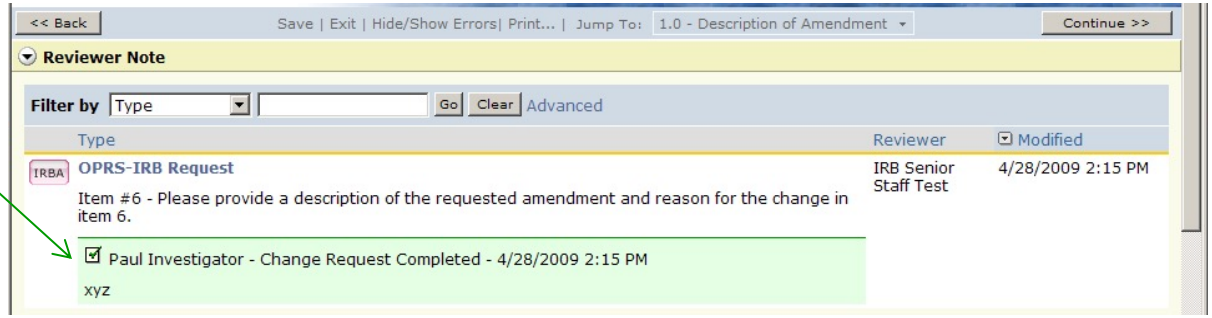
a. Use the drop-down menu to indicate how you are responding.

b. Write a response to the IRB in the text box (e.g., Done, Complete). You do not need to repeat the response provided in the Smartform.

c. Click ***OK***

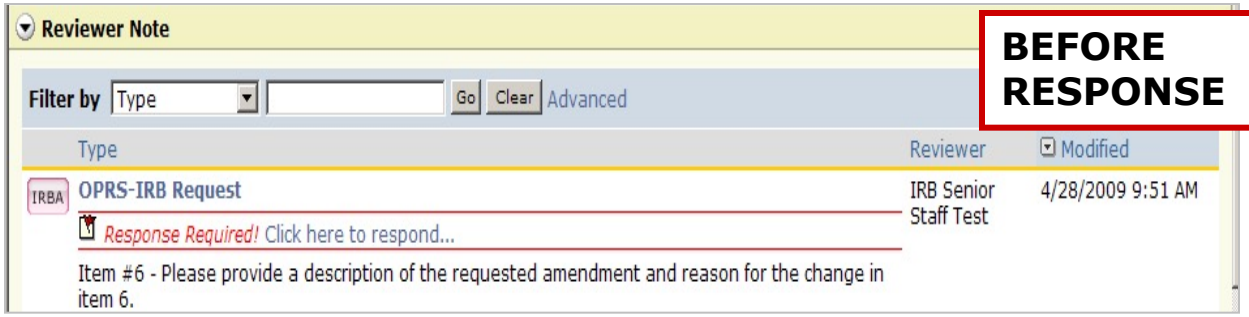


Your response will appear in a green text box.

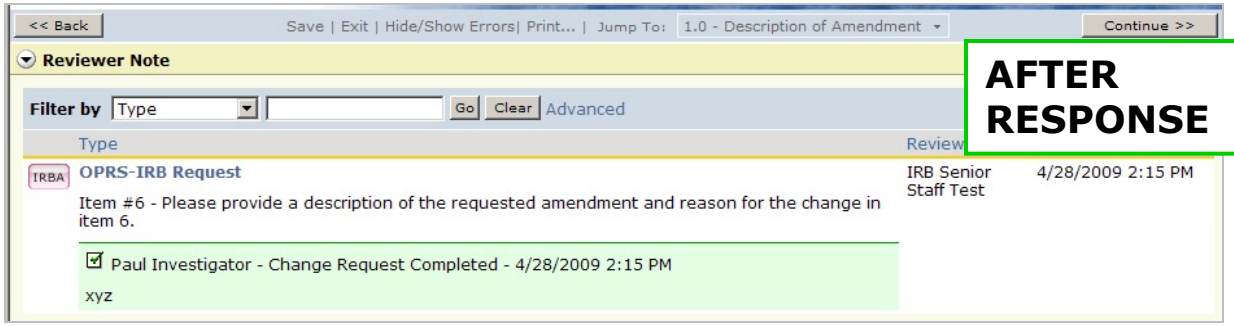


Responding to IRB Requests (cont'd)

When the response has been completed, the color of the notes will change from **red** to **green**.

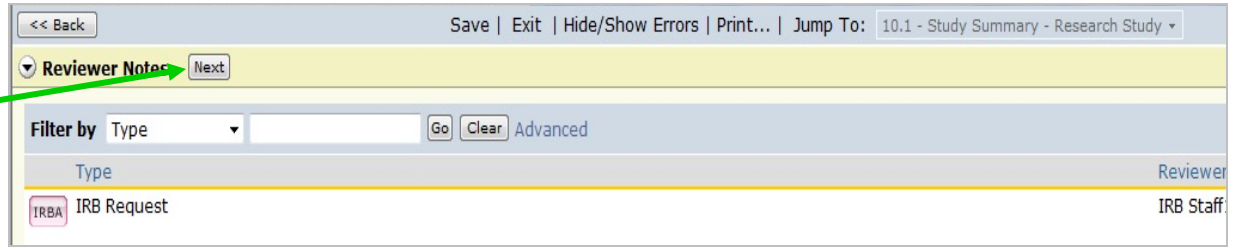


BEFORE RESPONSE



AFTER RESPONSE

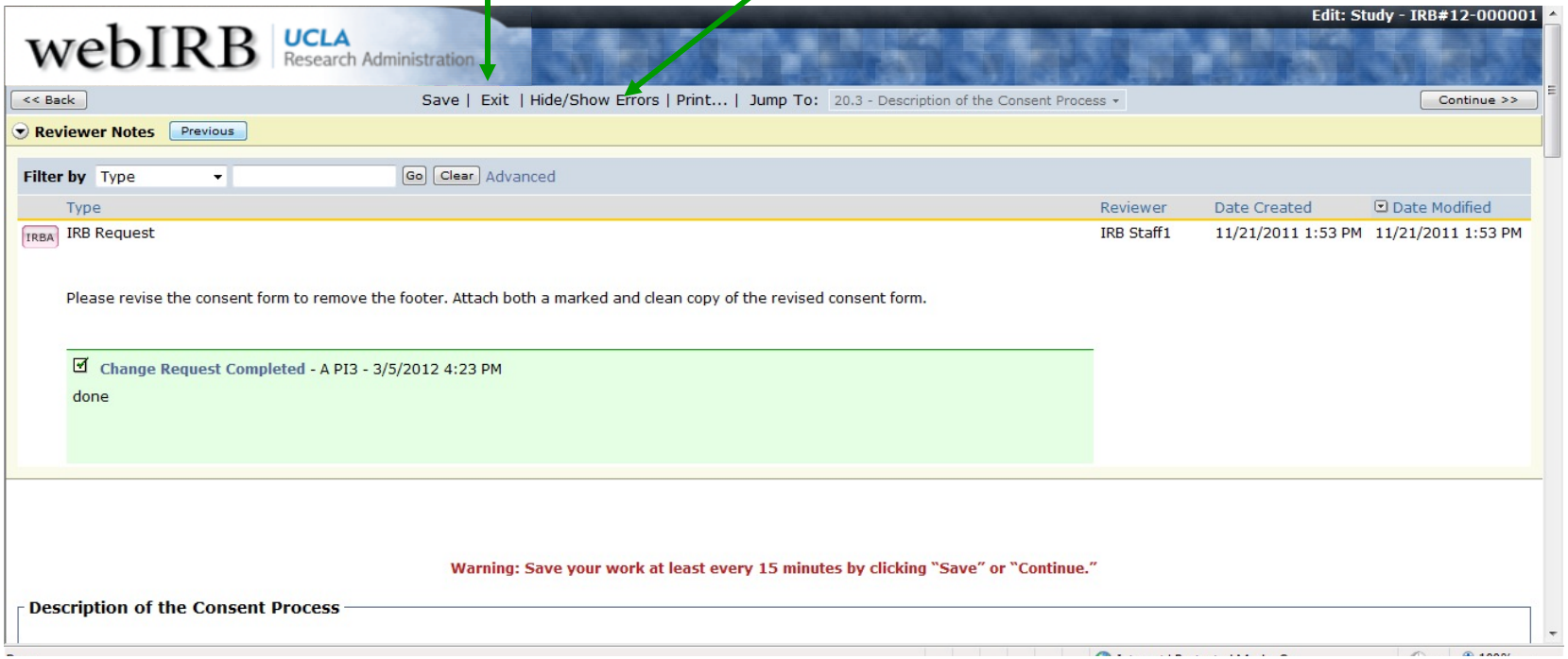
When there is more than one request, click **Next** to complete the additional requests.



Responding to IRB Requests (cont'd)

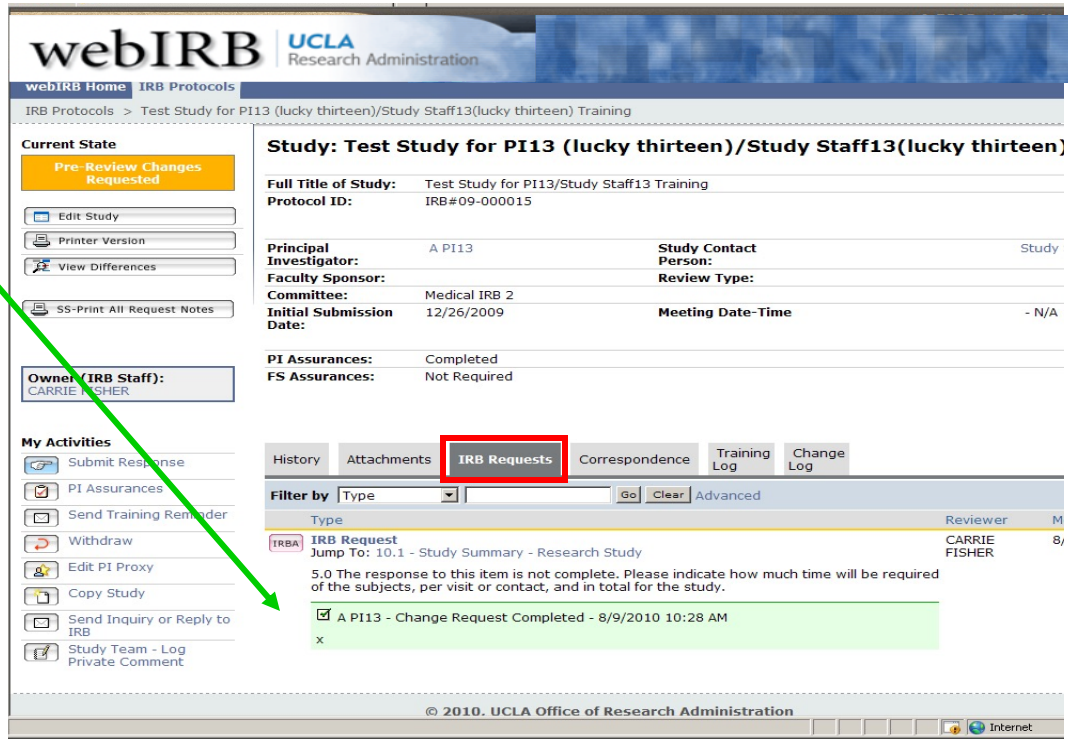
Click **Exit** to go back to the Study Workspace

Click **Hide/Show Errors** to view any incomplete Sections



Responding to IRB Requests (cont'd)

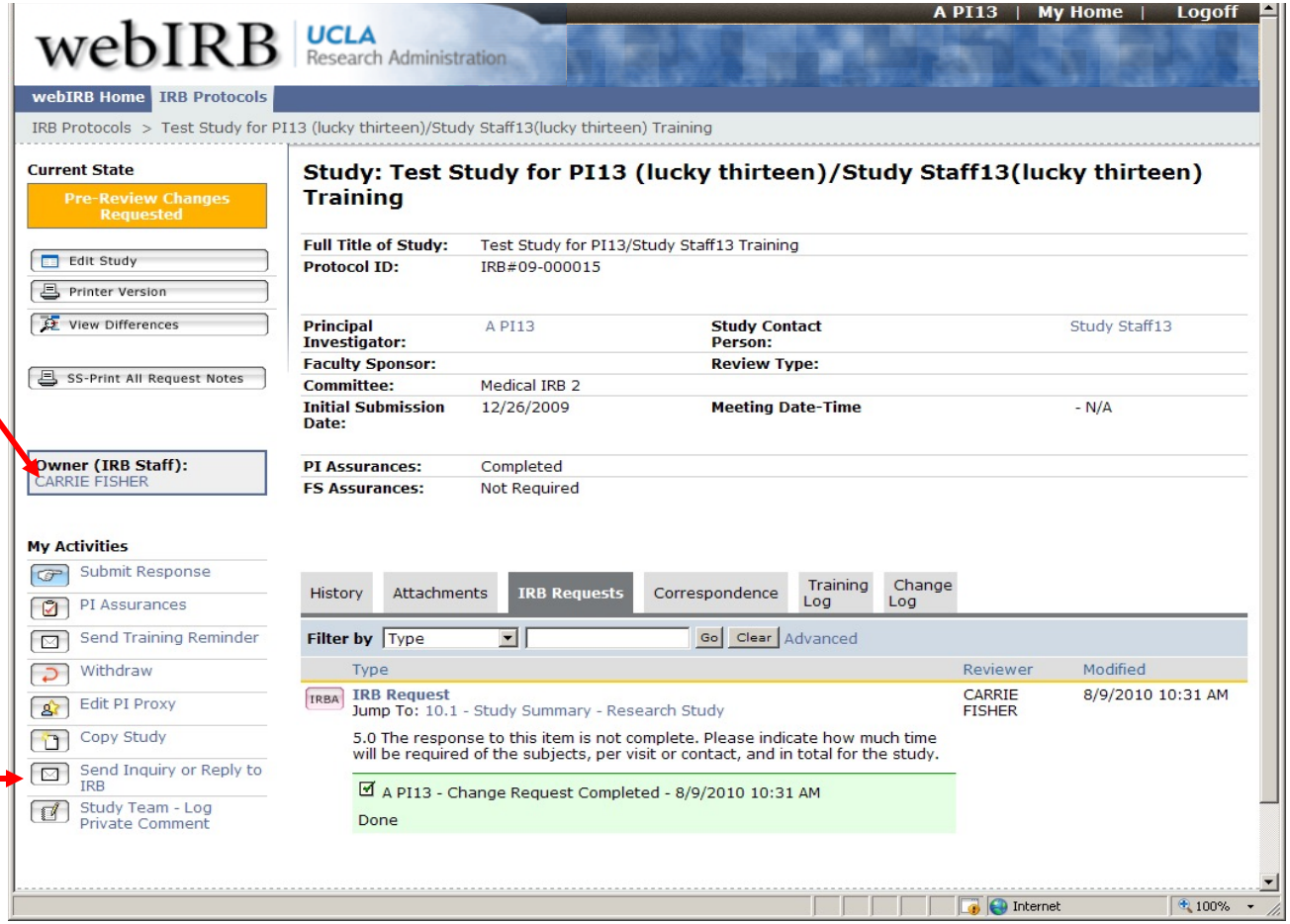
- When all of the requests have been completed, your response will appear in a green text box in the **IRB Requests** tab.
- All IRB requests must be completed/addressed before the response can be submitted.



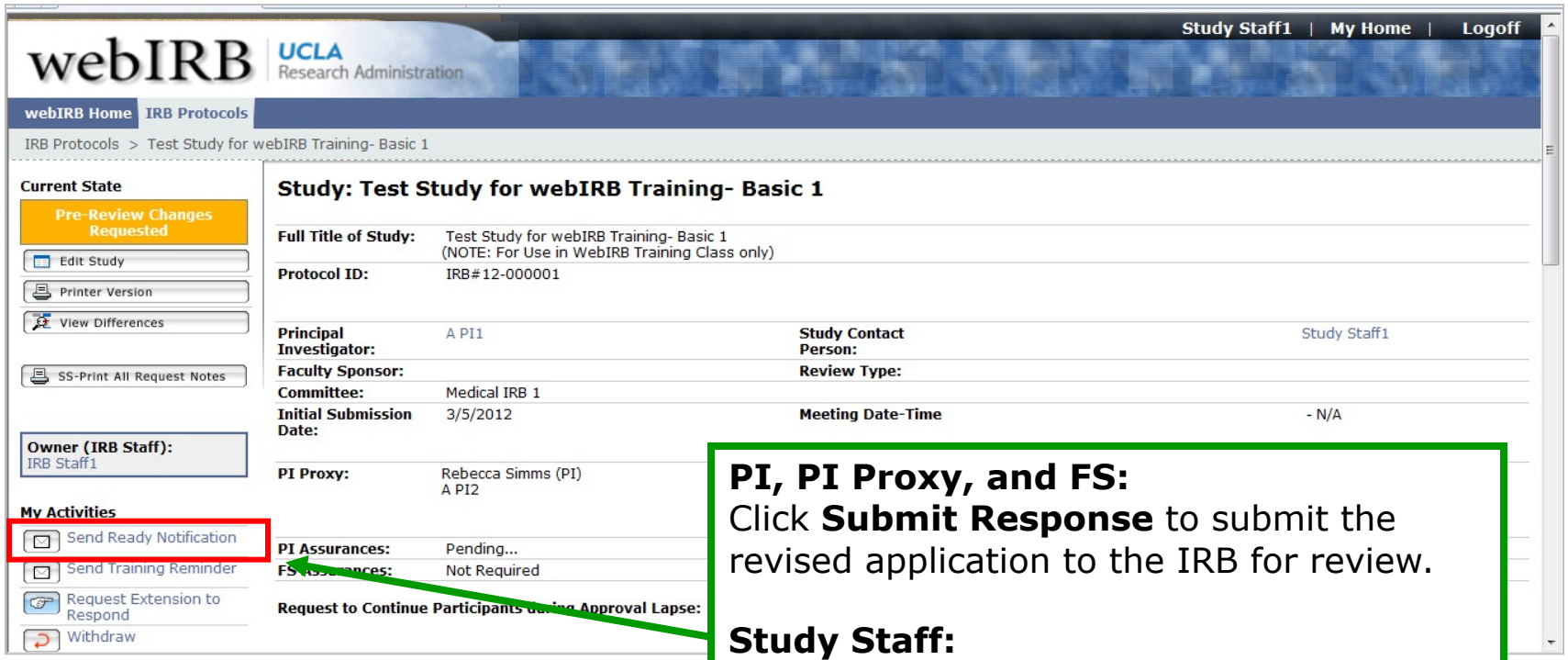
IRB Requests – Tips (cont'd)

The OHRPP Staff working on your study is listed here. Click their name for contact information.

- Use the **Send Inquiry or Reply to IRB** activity to communicate with IRB staff.
- An email notification will be sent to the Owner (IRB Staff).



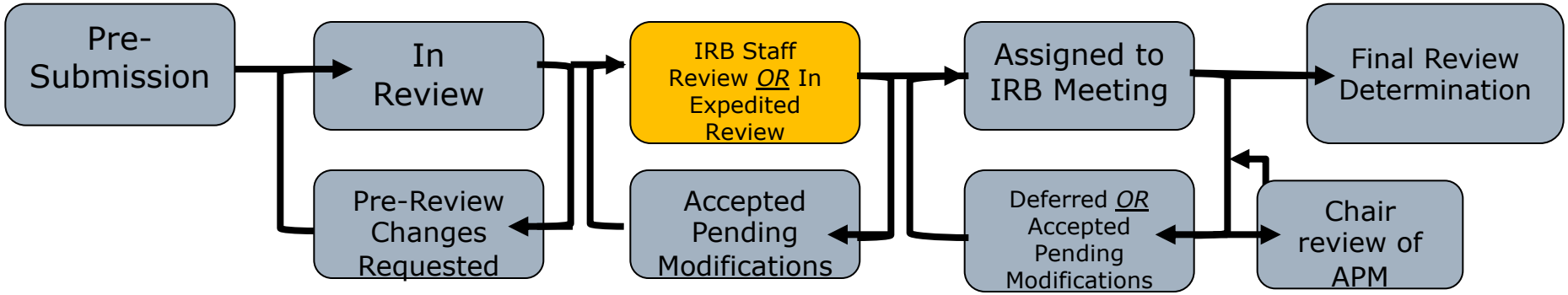
Responding to IRB Requests



PI, PI Proxy, and FS:
Click **Submit Response** to submit the revised application to the IRB for review.

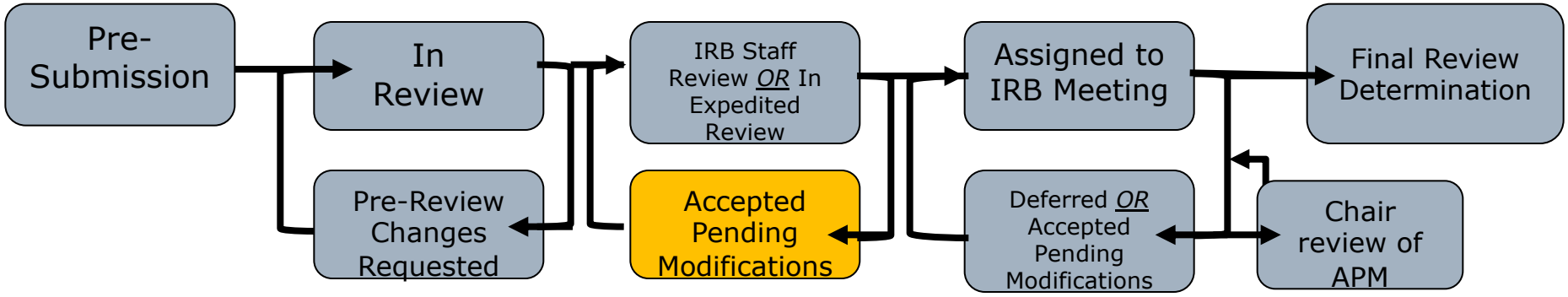
Study Staff:
Use the **Send Ready Notification** to let the PI know that the response is ready to be submitted.

Current State of the Application



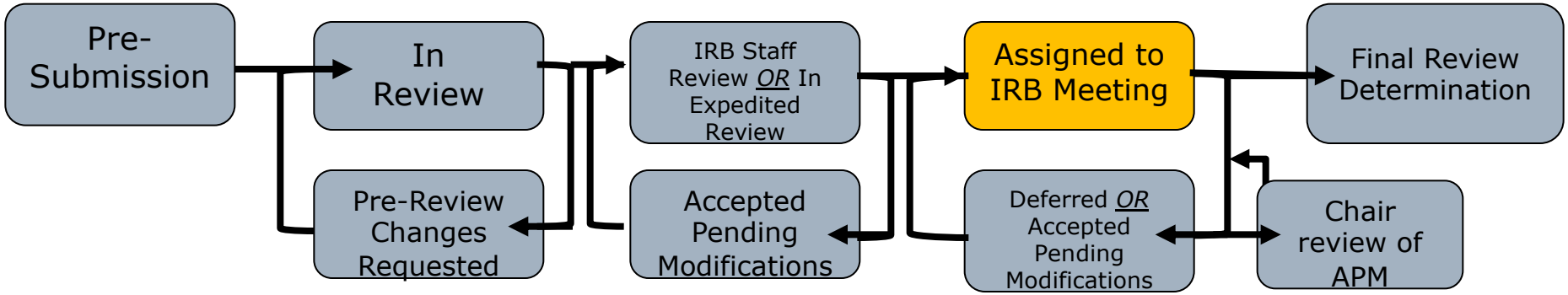
Once all requested changes are made, the current state of your application may return to, "**In Review**" on your end. However, during this current state, your study has been assigned to a designated reviewer. If the designated reviewer or the IRB have any changes they would like you to make, the current status will change to "**Accepted Pending Modifications**".

Current State of the Application



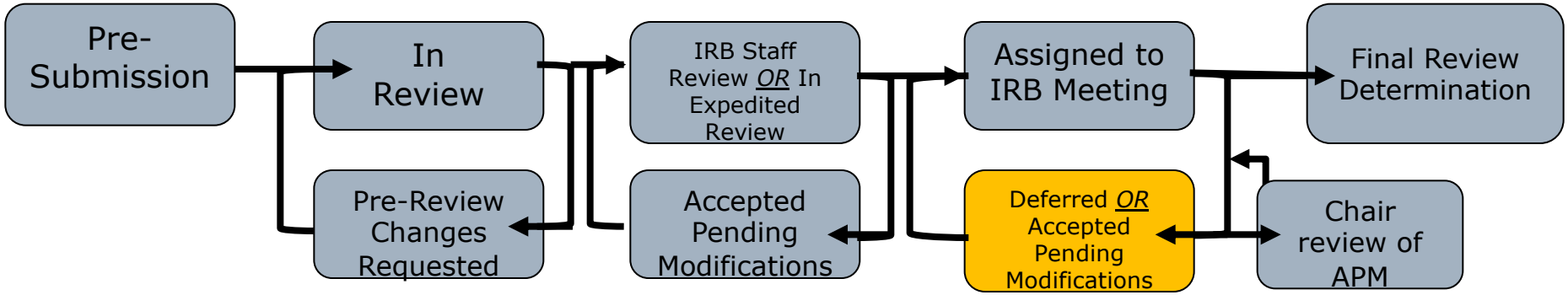
If the current state changes to "**Accepted Pending Modifications**", it means the designated reviewer requests changes to your application.

Current State of the Application



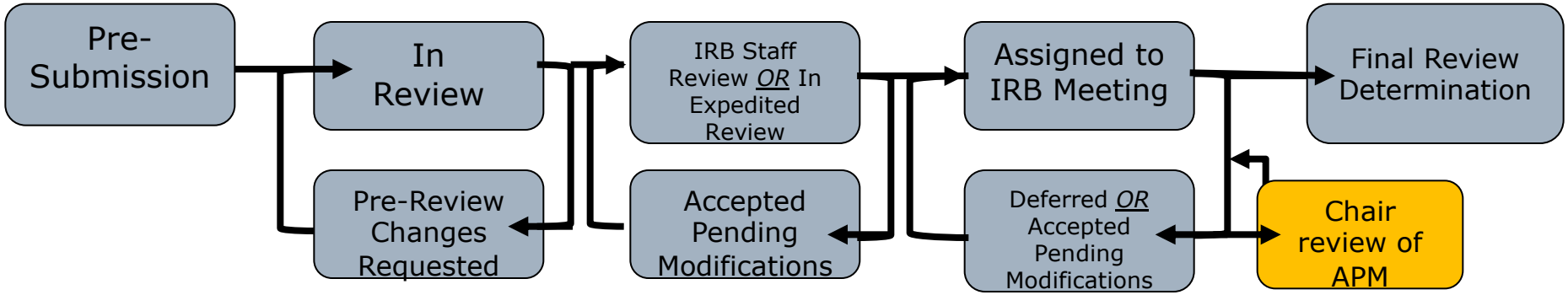
If your study requires review by the full board, the current state will change to "**Assigned to IRB Meeting**". After the IRB reviews your project, they will issue a review determination.

Current State of the Application



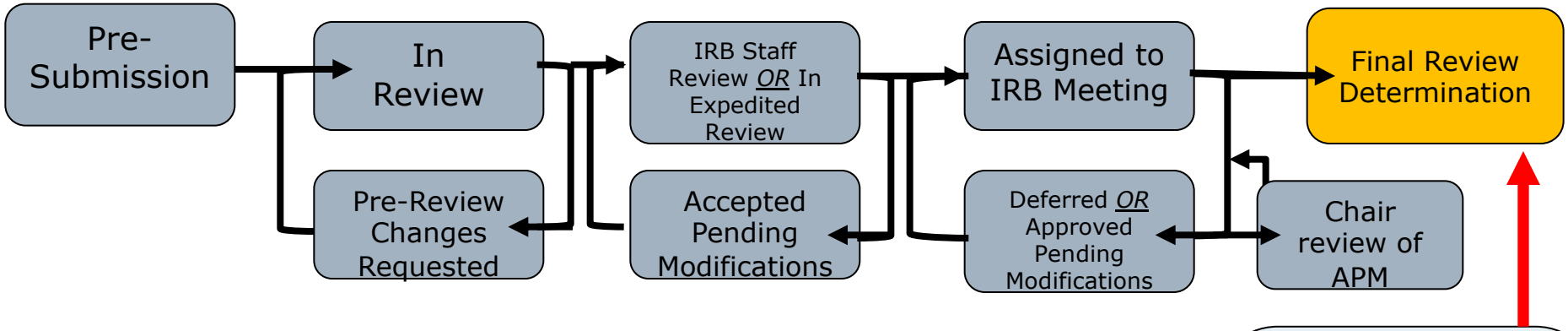
If the IRB does not approve your project after their initial review, it means they need more information for which the current state of your study will reflect either "**Deferred**" or "**Accepted Pending Modifications (APM)**". If the IRB defers your study, it means that the IRB lacked sufficient information to make a review determination. Therefore, the IRB will have to obtain additional information from you then the IRB will re-review your study at the next IRB meeting. You will receive an email if any additional action is requested.

Current State of the Application



If the IRB determines your study is "**Accepted Pending Modifications (APM)**", then you will be required to submit the changes requested in order to receive approval of your study. Upon submitting the changes, the IRB Chair will review and confirm these changes.

Current State of the Application



Once the designated reviewer or IRB Chair confirms that all the requested changes have been made, a final review determination will be issued.

IRB review determinations can be:

- Approved
- Approved-No CR
- Certified Exempt
- External Review Accepted
- Disapproved

Note: IRB Determinations

The "Current State" will reflect one of the following depending on your study type once the designated reviewer or the IRB determines your study may proceed:

- **Certified Exempt:** ***Exempt*** studies that are minimal risk and do not require review by the IRB. No Continuing Review (CR) required but annual assurance is required.

- **Approved-No CR:** Most ***Expedited*** studies that are minimal risk that meet certain criteria will receive approval that does not expire, no Continuing Review. Annual assurance is required.

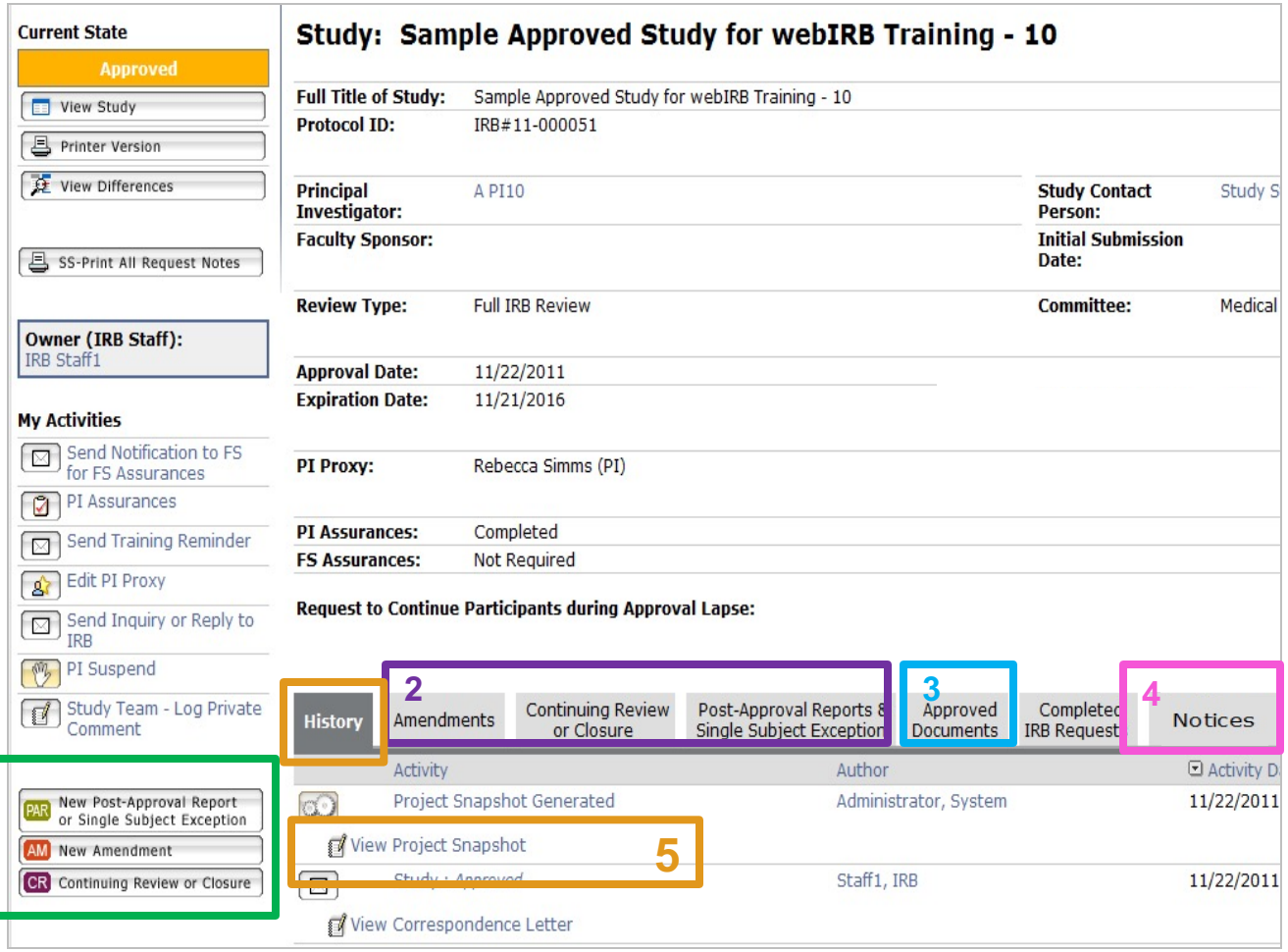
- **Approved:** Some ***Expedited*** studies and studies requiring ***Full Board*** review which are greater than minimal risk and will have an expiration date of no greater than one year. About 2 months before expiration of IRB approval, you will need to submit a CR application.

Note: IRB Determinations

If UCLA is relying on another institution for the IRB review of your collaborative (multi-site) research study and the UCLA IRB determines it is appropriate to cede review to another institution, the IRB determination will state, "**External Review Accepted**". The UCLA IRB may require additional documentation of the external review. When UCLA relies on another institution, continuing review is not required at UCLA however, annual assurances must be completed. For more information about collaborative research, please review OHRPP guidance on reliance.

Please review OHRPP guidance on the results of IRB review for more information about IRB determinations.

Approved Study Workspace

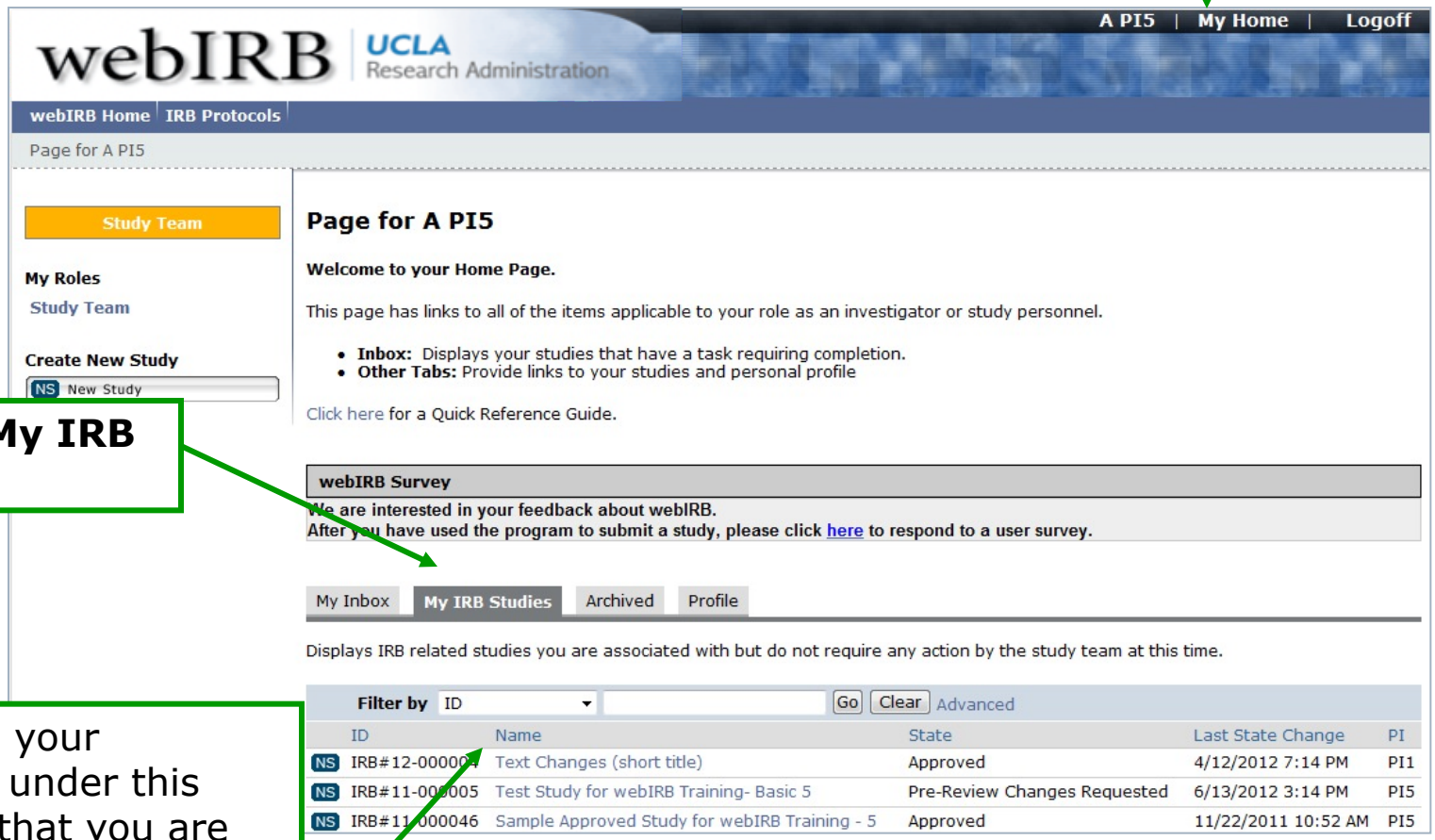


Unique features:

1. Create, **but not submit,** post-approval applications (i.e., AM, CR, and PAR).
2. All other workspaces are accessible.
3. Contains all currently approved documents
4. Contains all approval letters.
5. Contains a copy of the application.

View Active Studies

Click on **My Home**



Click on the **My IRB Studies** tab.

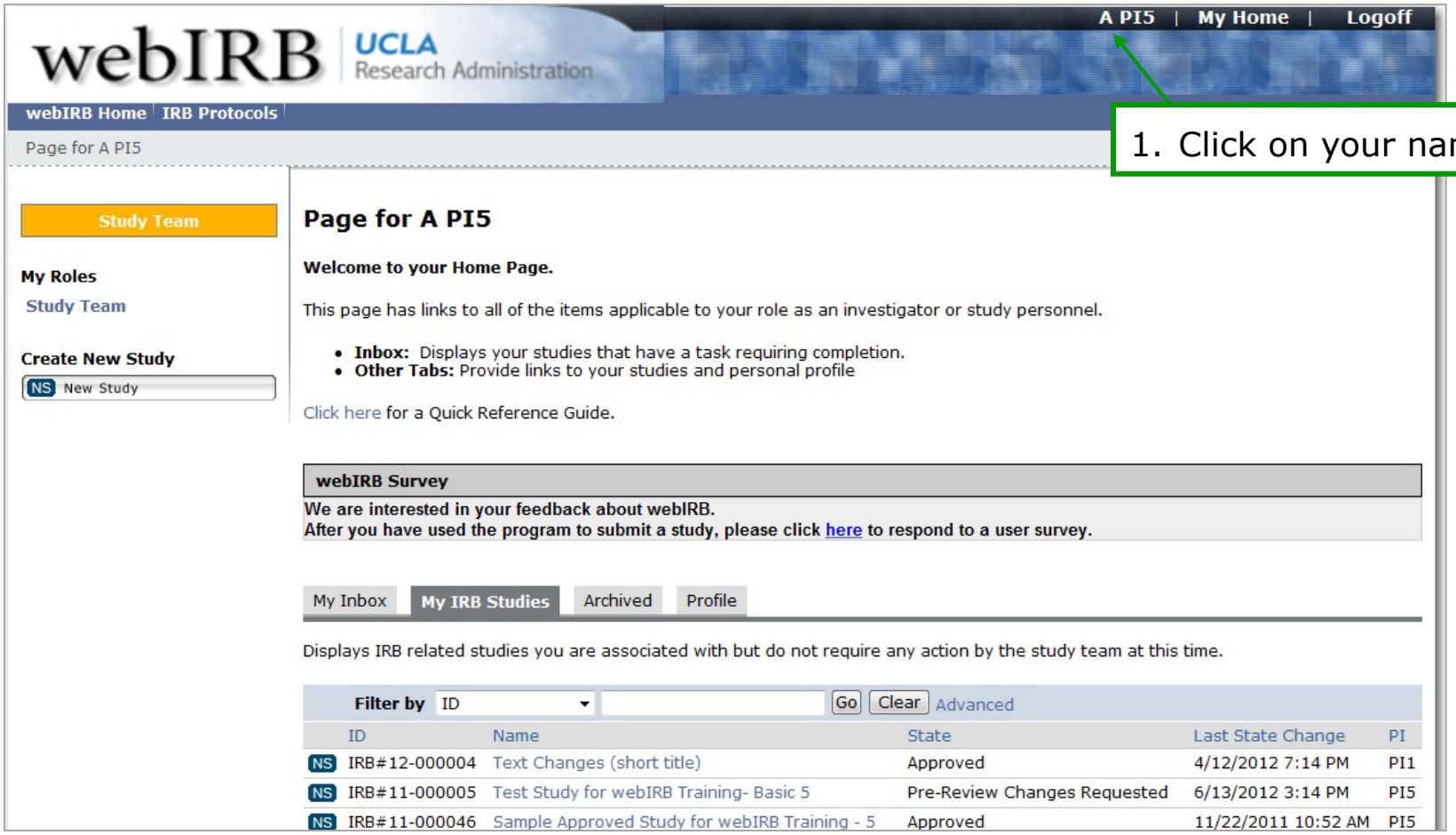
You may access your approved study under this tab. All studies that you are listed on will appear here. Select the study title to view the study.

Other Considerations

During this process, you may need to make additional changes such as:

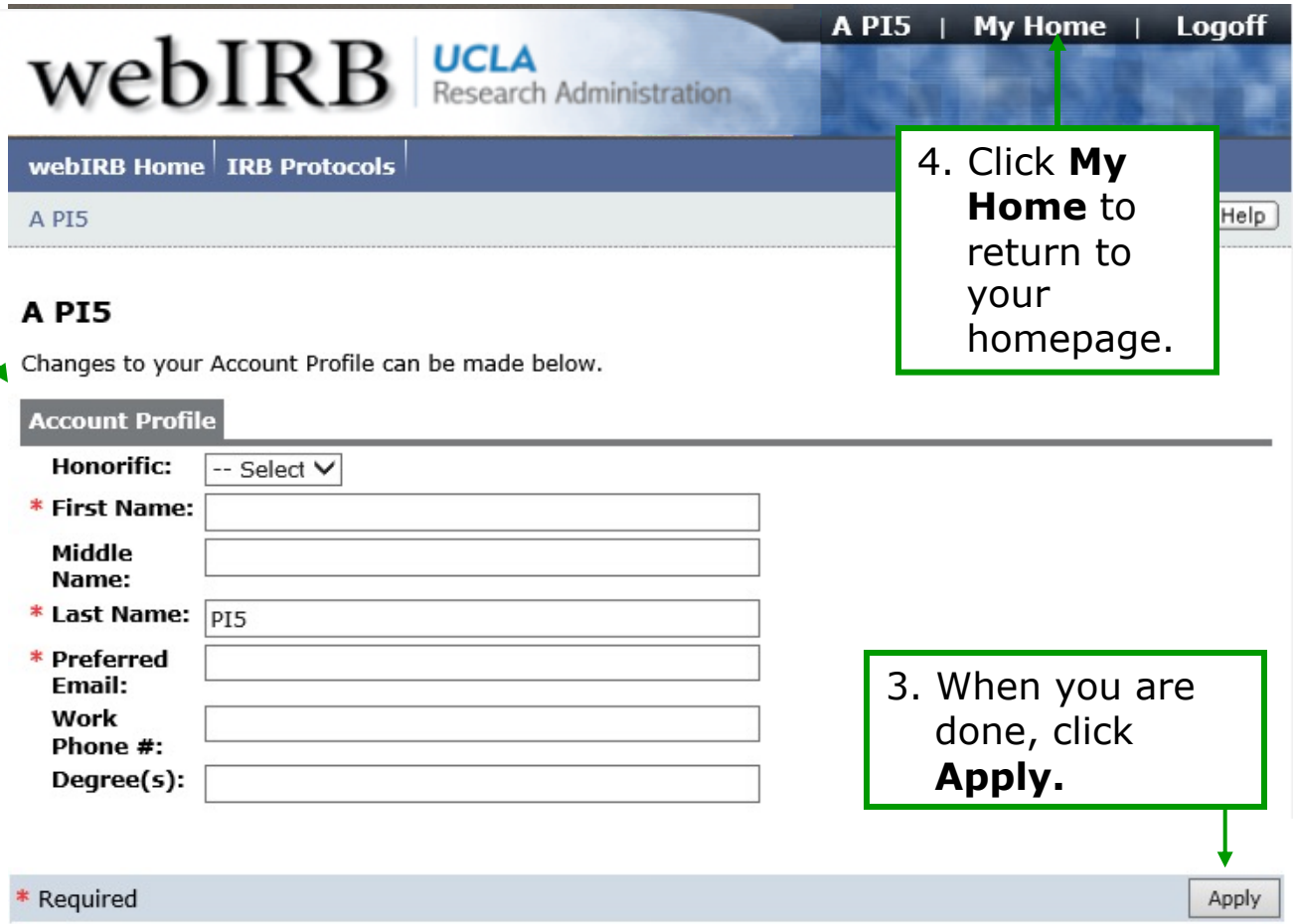
- Update contact information
- Withdraw your application
- Edit the PI Proxy
- Discuss changes amongst the study team

Update Your Contact Information



Update Your Contact Information (cont'd)

2. Update your information in the **Properties** tab.

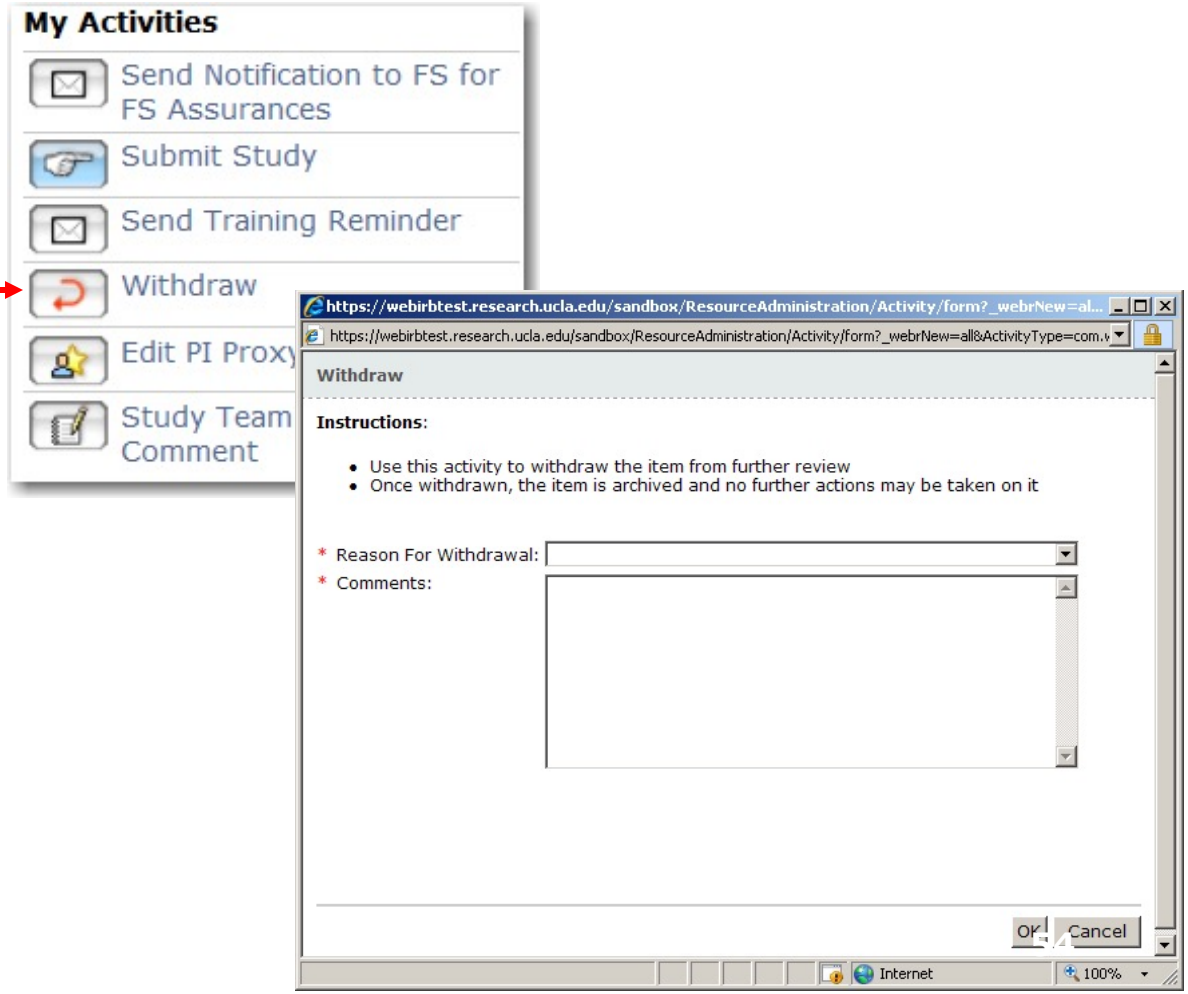


4. Click **My Home** to return to your homepage.

3. When you are done, click **Apply.**

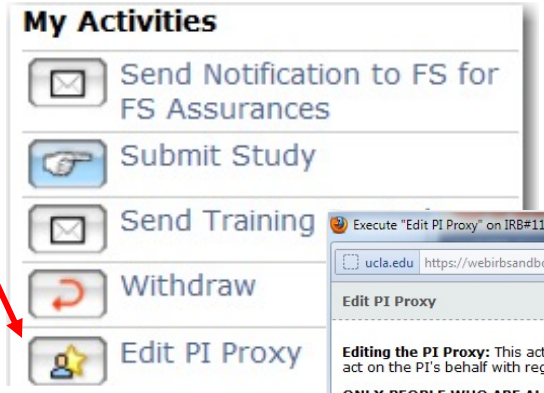
My Activities: Withdraw

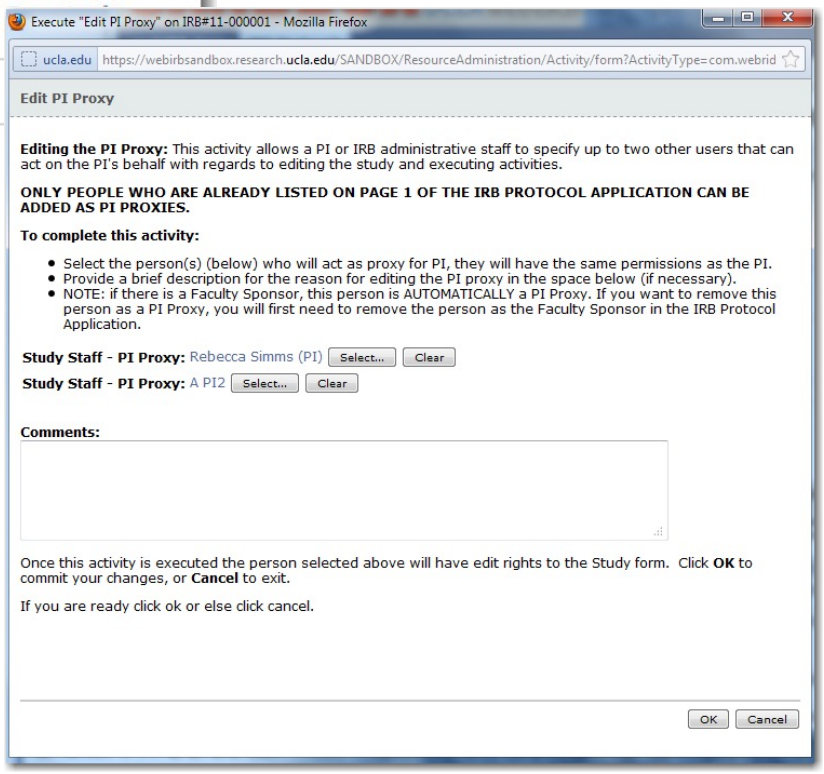
- ***Use carefully:*** Use the **Withdraw** activity if you are no longer planning to conduct the study.
- The study will be archived.
- This activity is available to everyone.
- A withdrawn Study can be reactivated using the **Reactivate** activity**.** The Reactivate activity is only available to the PI, PI Proxies, and FS.



My Activities: Edit PI Proxy

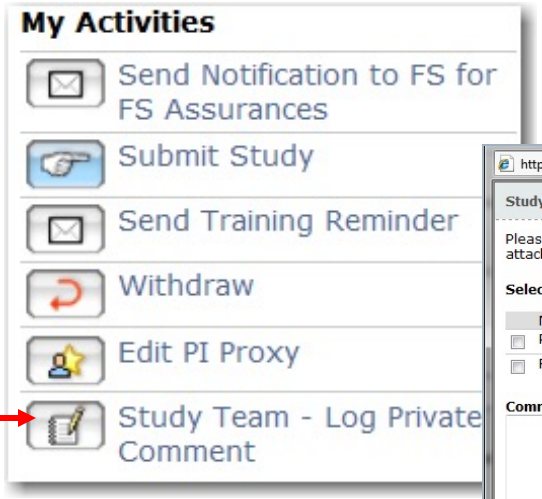
Only the PI can add a PI Proxy using the activity **Edit PI Proxy.** A study team member must be listed as the Study Contact Person or Key Personnel in order to be added as a PI Proxy. To use this feature, the person on must be currently listed on the study in Section 1.1.

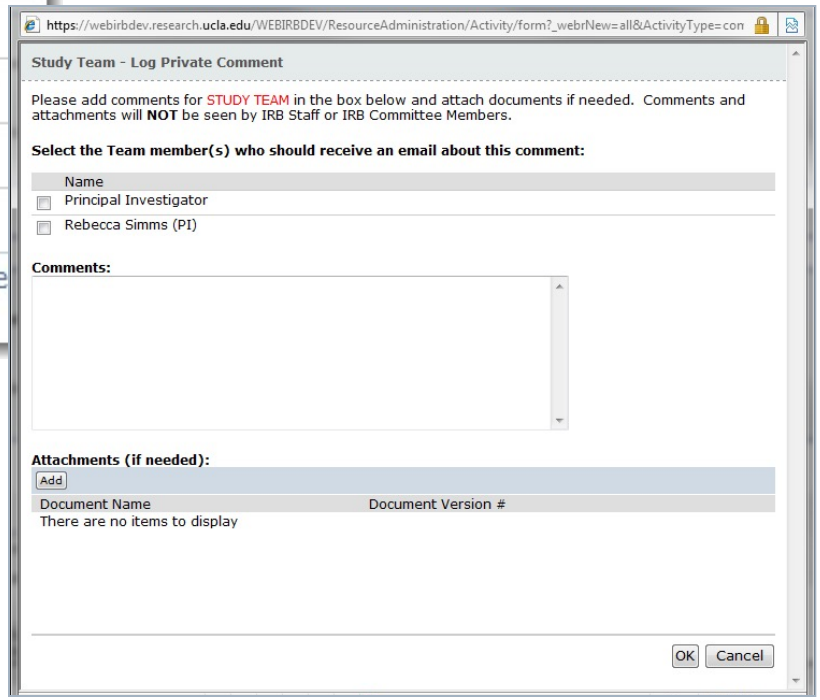




My Activities: Log Private Comment

- To communicate within the Study workspace use the activity **Study Team – Log Private Comment.**
- A pop-up screen will appear. Select the study team members who should receive an email notification about the comment. The email will contain a link to the study workspace.
- The comment will be visible to all study team members in the History tab and this activity is only available to study team members.



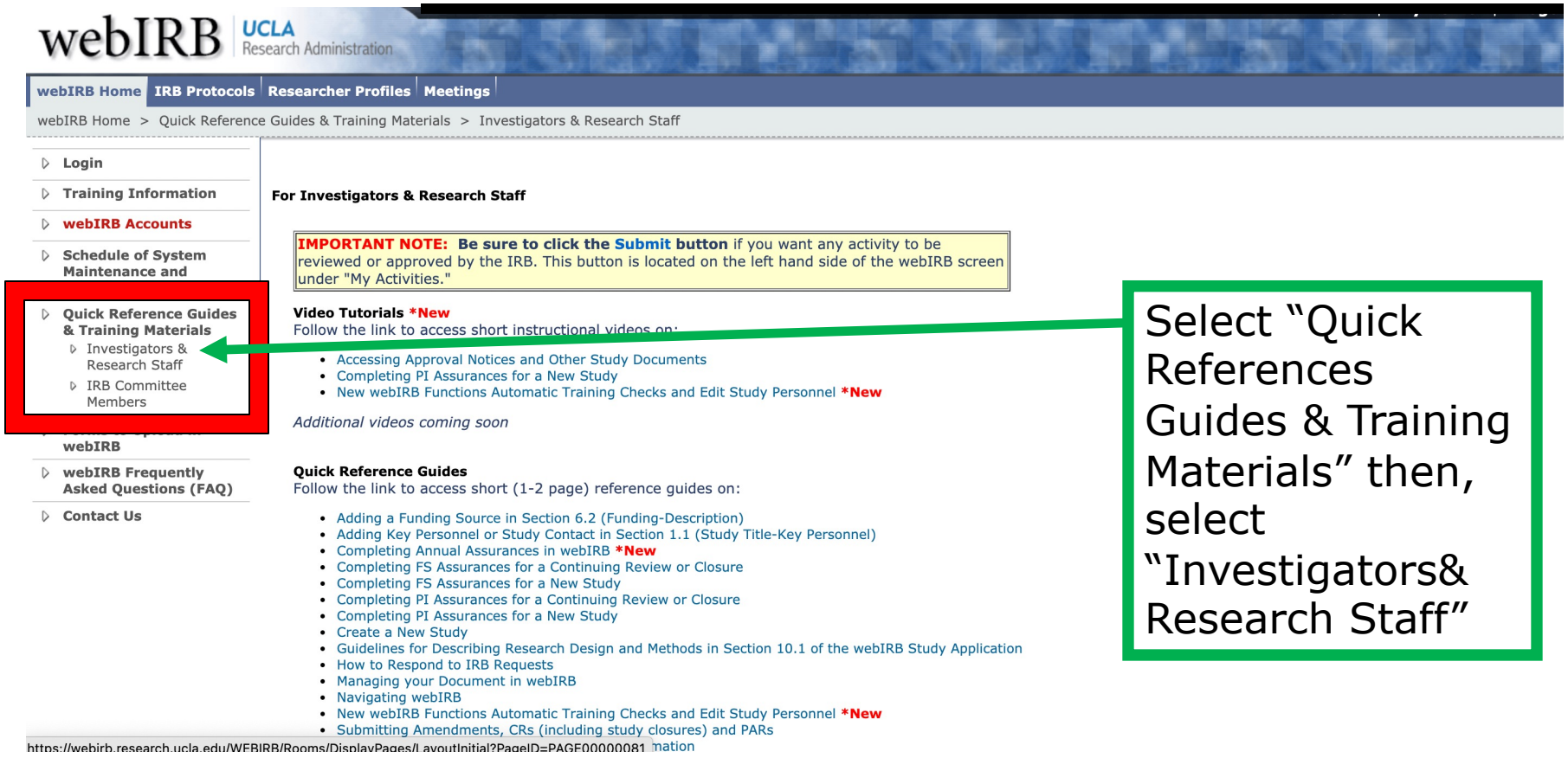


Key Take-Aways

After your study has been approved/accepted by the IRB keep in mind:

- Any changes to the study will require submission of an Amendment (AM) application
- Once you have completed your research, review the OHRPP guidance on Study Closures
- Use the "Edit Study Personnel" activity to make changes to study personnel. Changes to the faculty sponsor, PI or "Others" will require submission of an AM application.
- Complete Annual Assurances within a timely manner. The IRB will administratively close any studies where assurances were not completed within three months
- Submit CR applications at least *60 days before* the expiration date to prevent a lapse in approval

Resources



Select "Quick References Guides & Training Materials" then, select "Investigators& Research Staff"

Resources

For technical assistance with webIRB only:

Contact the webIRB Help Desk

Email: webIRBhelp@research.ucla.edu

Resources

For general inquiries about the IRB process:

Contact the appropriate IRB:

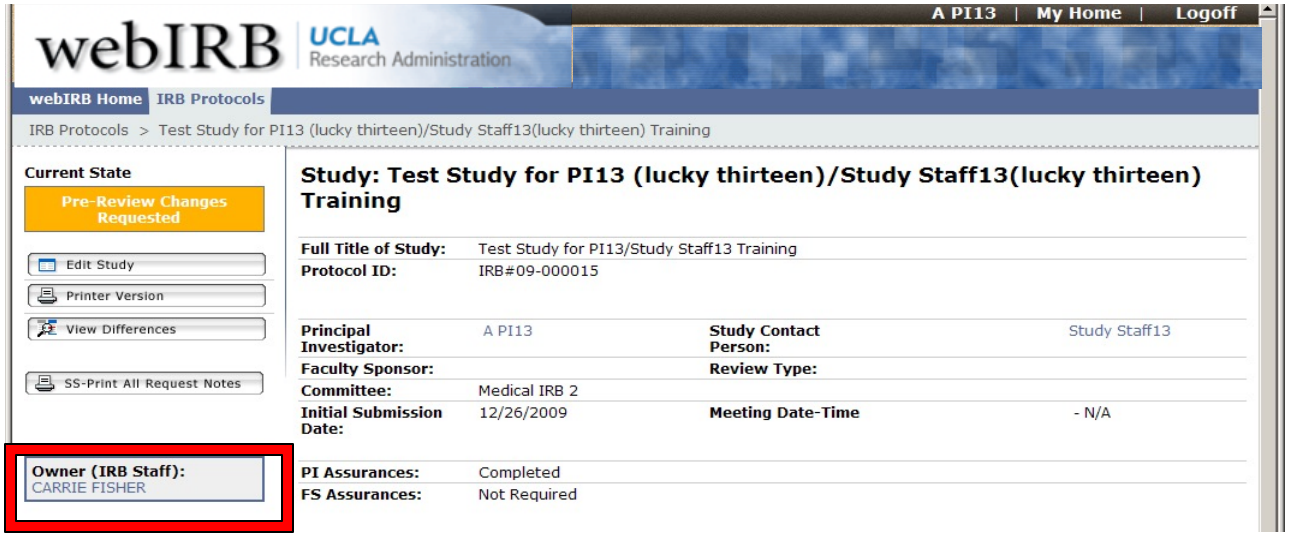
North & South General IRBs (GIRBs)
Email: gcirb@research.ucla.edu

Medical IRBs (MIRBs)
Email: mirb@research.ucla.edu

Resources

For questions specific to your submitted application, contact the OHRPP staff member assigned to your study:

Contact the OHRPP staff member assigned to your study by selecting their name, their contact information will appear.



Resources

To remain current on UCLA research policy, guidance and updates:

Sign-up for the Human Research News (HRN) Newsletter

The HRN includes updates to OHRPP guidance and policy, Learn-at-Lunch trainings on important research topics and offers other resources and important updates.
Please visit the ORA Mailing Lists page to subscribe.

Your feedback matters

Help us improve our presentation by completing OHRPP's brief and anonymous SURVEY