JHMeIRB

IRB and eIRB Websites

IRB Website -

http://http://www.hopkinsmedicine.org/institutional_review_board

IRB Guidelines, Regulations, General Information

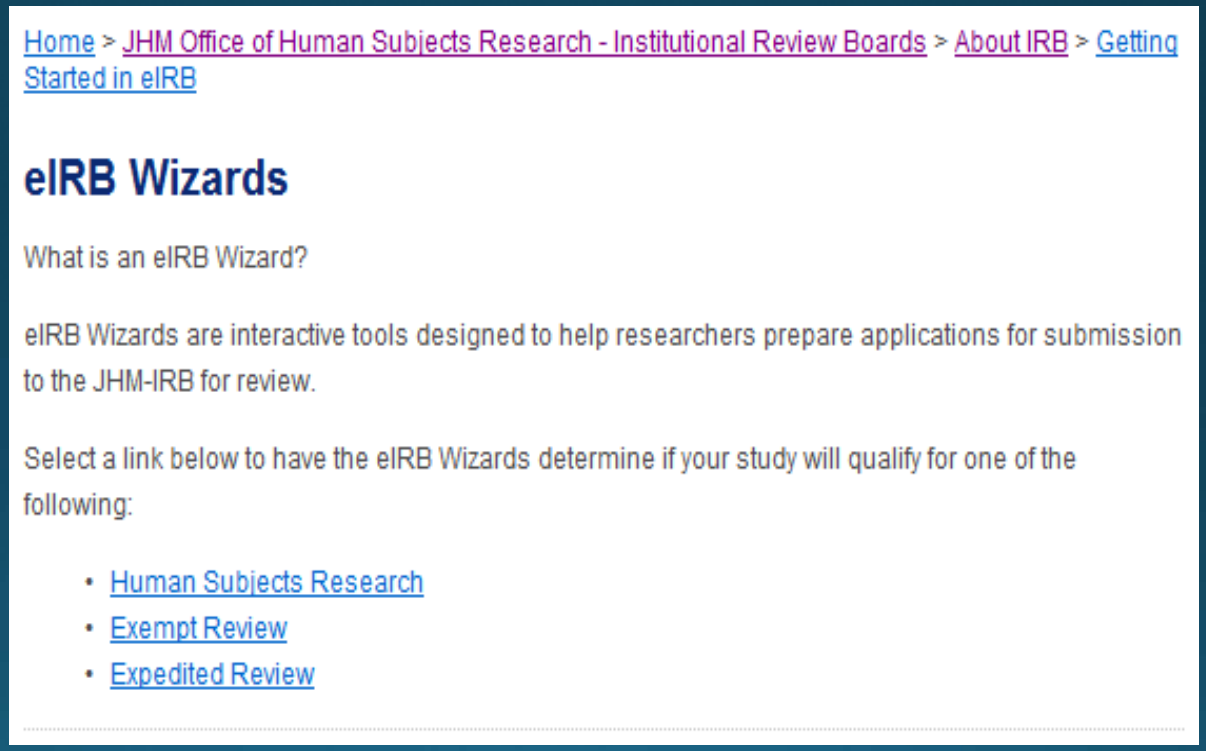
- **Look** for new developments in the What's New box.
- Left Navigation Bar
  - About IRB/eIRB
  - Guidelines & Policies
  - IRB Forms/Templates
  - Compliance Training Requirements
  - **Link to the eIRB Home Page**

eIRB Information

- Located under "About IRB" → "eIRB"
  - FAQs
  - Training /Tutorials
  - Review Type Wizards
  - System Requirements

Review Type Wizards

- *Is your study considered human subjects research and subject to review by the IRB?*
- *Does your study qualify for exempt or expedited review?*
- **Select** a wizard to determine the answers.



Home > JHM Office of Human Subjects Research - Institutional Review Boards > About IRB > Getting Started in eIRB

eIRB Wizards

What is an eIRB Wizard?

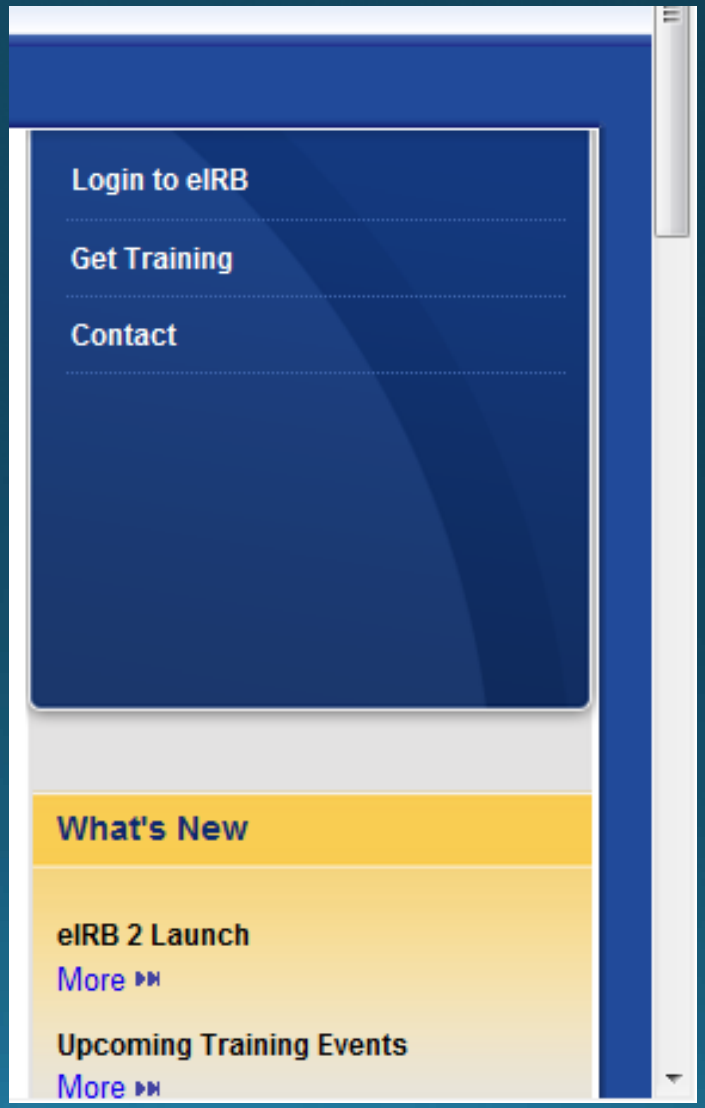
eIRB Wizards are interactive tools designed to help researchers prepare applications for submission to the JHM-IRB for review.

Select a link below to have the eIRB Wizards determine if your study will qualify for one of the following:

- Human Subjects Research
- Exempt Review
- Expedited Review

eIRB Link to Login

- eIRB Website
- Link to the eIRB Login screen is located in the right navigation bar on each page.



eIRB Accounts: JHED Users

- JHED User accounts are automatically created upon first login.
- No self-registration process is required.

eIRB Accounts: JHED Users

- If you forget your JHED ID or JHED password:
  - Use the links (i.e., Forgot Password?) below, or
  - contact JHED directly at jhed@jhmi.edu or call the JHED IT Support Center at 410-955-HELP.

eIRB Accounts: Non-JHED Users

- Non-JHED Users must email the eIRB help desk (jhmeirb@jhmi.edu) to set up an account.

JHMeIRB

eIRB View Approval Letter

eIRB Login

- **Login** to eIRB at http://e-irb.jhmi.edu.

Investigator Home Page

- **Select** My IRB Studies on the left navigation bar.
- **Select** the Approved tab on the Home Page**.**
- **Scroll** down to the appropriate section.
- **Select** the study name.
- This will open the study workspace.

Study Workspace

- IRB Review List
  - Displays the review date, review type, outcome and letter sent.
- **Select** View Letter to open the IRB letter.

JHMeIRB

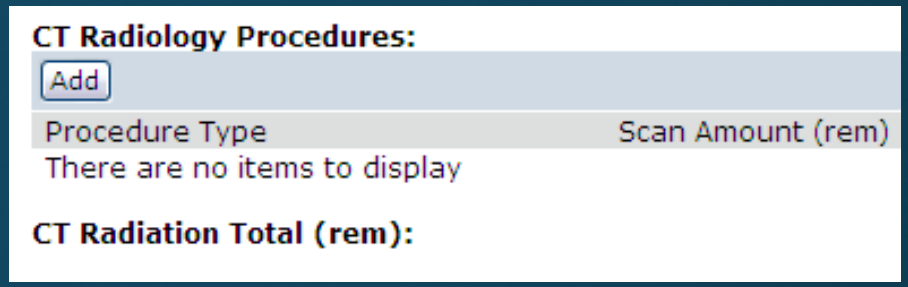
Radiation Calculator

Radiation Calculator

- Use of the Radiation Calculator is optional.
- Select each radiologic examination used in your protocol *excluding* ionizing radiation and radioactive materials administered for research purposes (including standard of care procedures being altered for research).
- To use the calculator, click on CALCULATE, which is located near the bottom of the Radiation Calculator screen.
- This will calculate and display the total dose exposure and create the language for the consent form.
- CALCULATE may be clicked at any time, an unlimited number of times.
- The Radiation Total (rems) for each procedure category will not be calculated until CALCULATE is clicked.
- Copy the text and paste it into the appropriate section of the consent form.

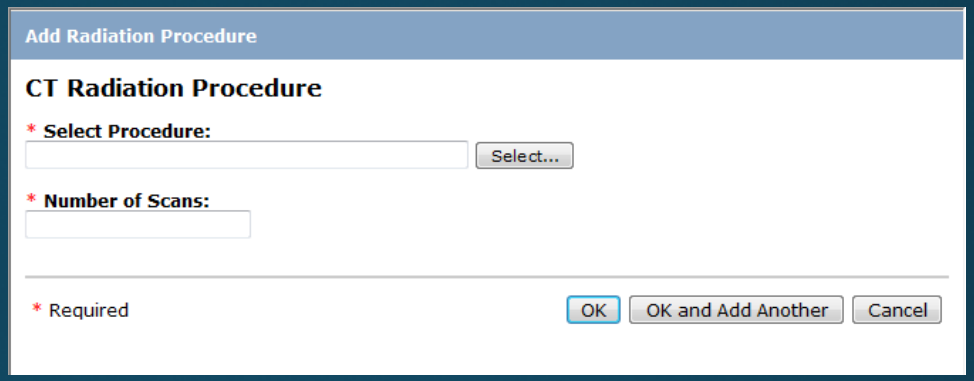
Select Procedure

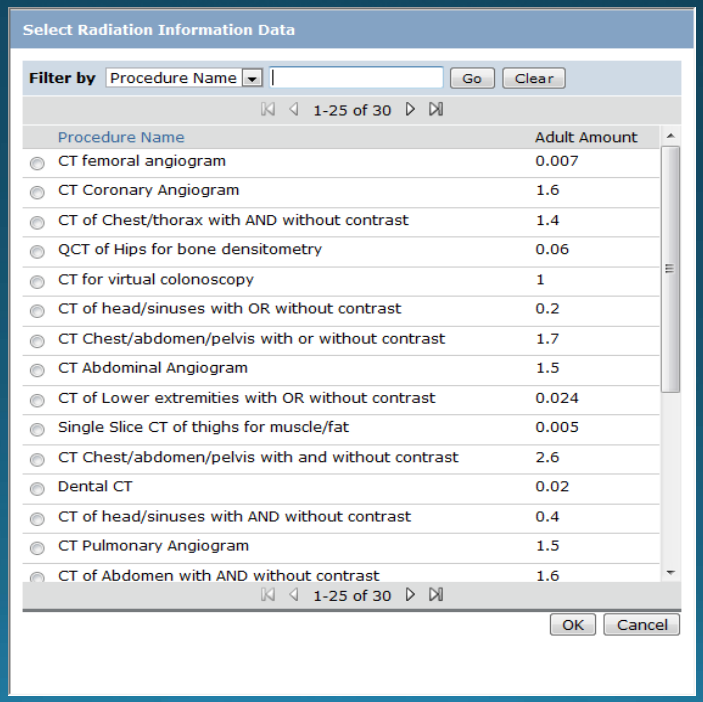
- **Click** Add to open the "Add Radiation Procedure" window.



Select Procedure

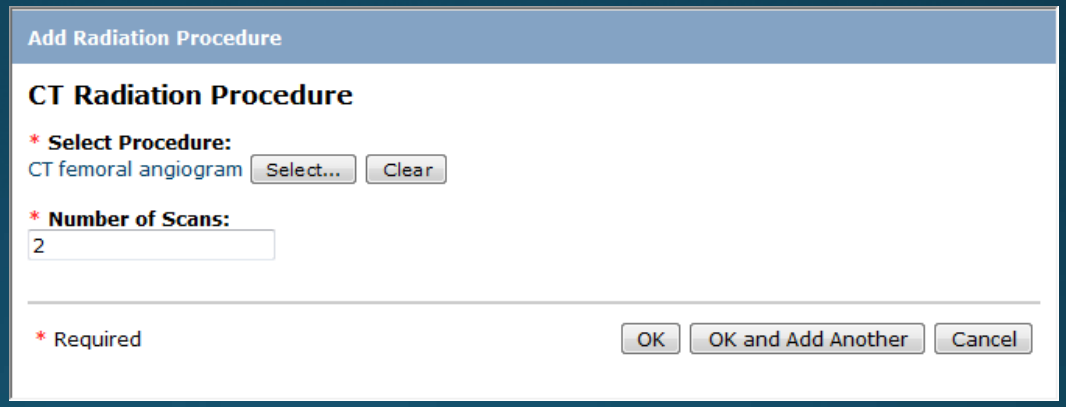
- **Click** Select to search for the procedure name.
- **Select** a procedure to be used in your protocol.
- You may need to use the scroll bar or the arrows to locate your procedure.





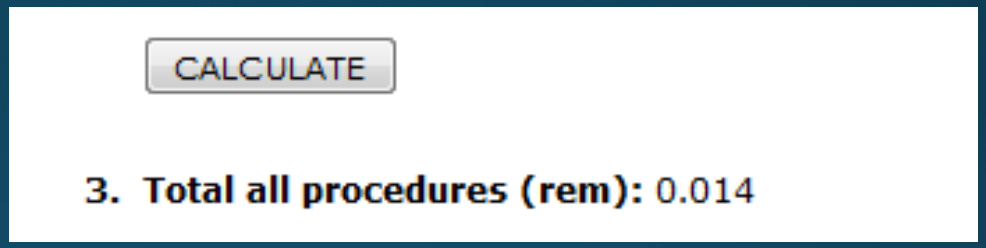
Number of Scans

- **Enter** the number of times each participant will have this procedure.
- Click **OK and Add Another** to add more procedures from the same category.
- Click **OK** to return to the Radiation Calculator screen where the selected procedures will now appear.



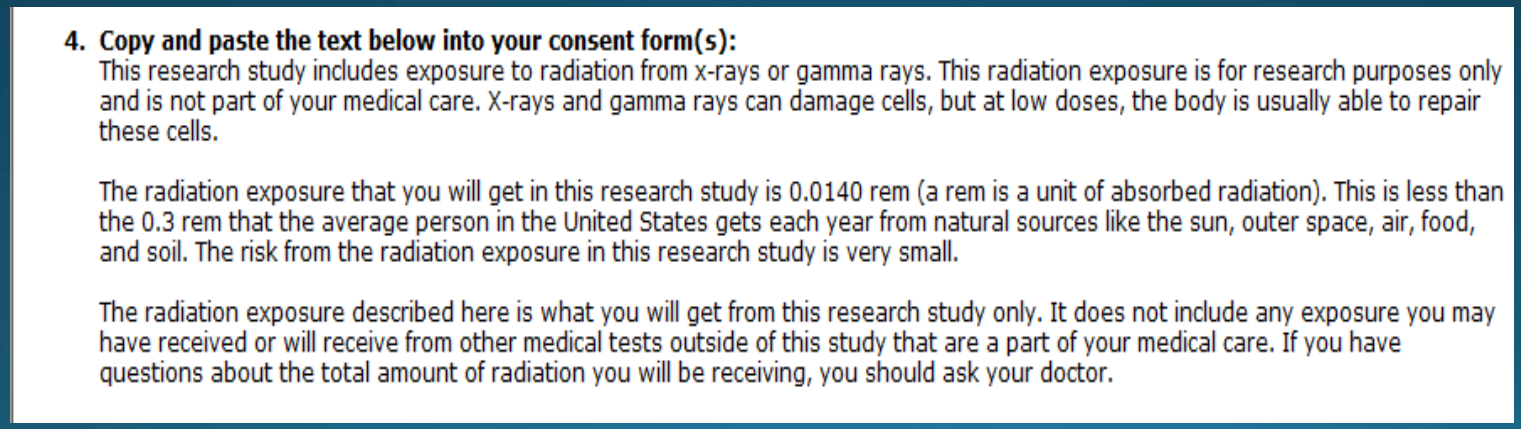
CALCULATE

- **Locate** CALCULATE near the bottom of the screen.
- **Click** CALCULATE to calculate the total dose exposure and create the language for the consent form.
- **Save** the screen.



CALCULATE

- **Locate** the text for the consent form right below CALCULATE.
- **Copy** the text and paste it into the appropriate section of the consent form.



4. Copy and paste the text below into your consent form(s):

This research study includes exposure to radiation from x-rays or gamma rays. This radiation exposure is for research purposes only and is not part of your medical care. X-rays and gamma rays can damage cells, but at low doses, the body is usually able to repair these cells.

The radiation exposure that you will get in this research study is 0.0140 rem (a rem is a unit of absorbed radiation). This is less than the 0.3 rem that the average person in the United States gets each year from natural sources like the sun, outer space, air, food, and soil. The risk from the radiation exposure in this research study is very small.

The radiation exposure described here is what you will get from this research study only. It does not include any exposure you may have received or will receive from other medical tests outside of this study that are a part of your medical care. If you have questions about the total amount of radiation you will be receiving, you should ask your doctor.

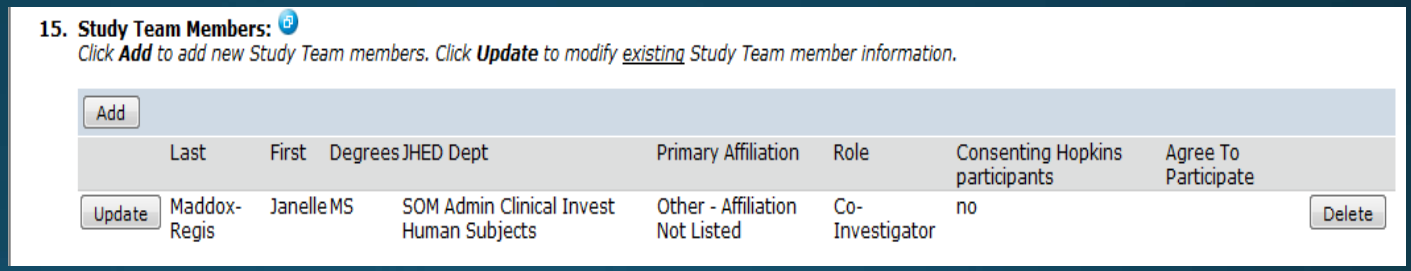
JHM eIRB

Adding Study Team Members

Select Study Team Member

1-General Information

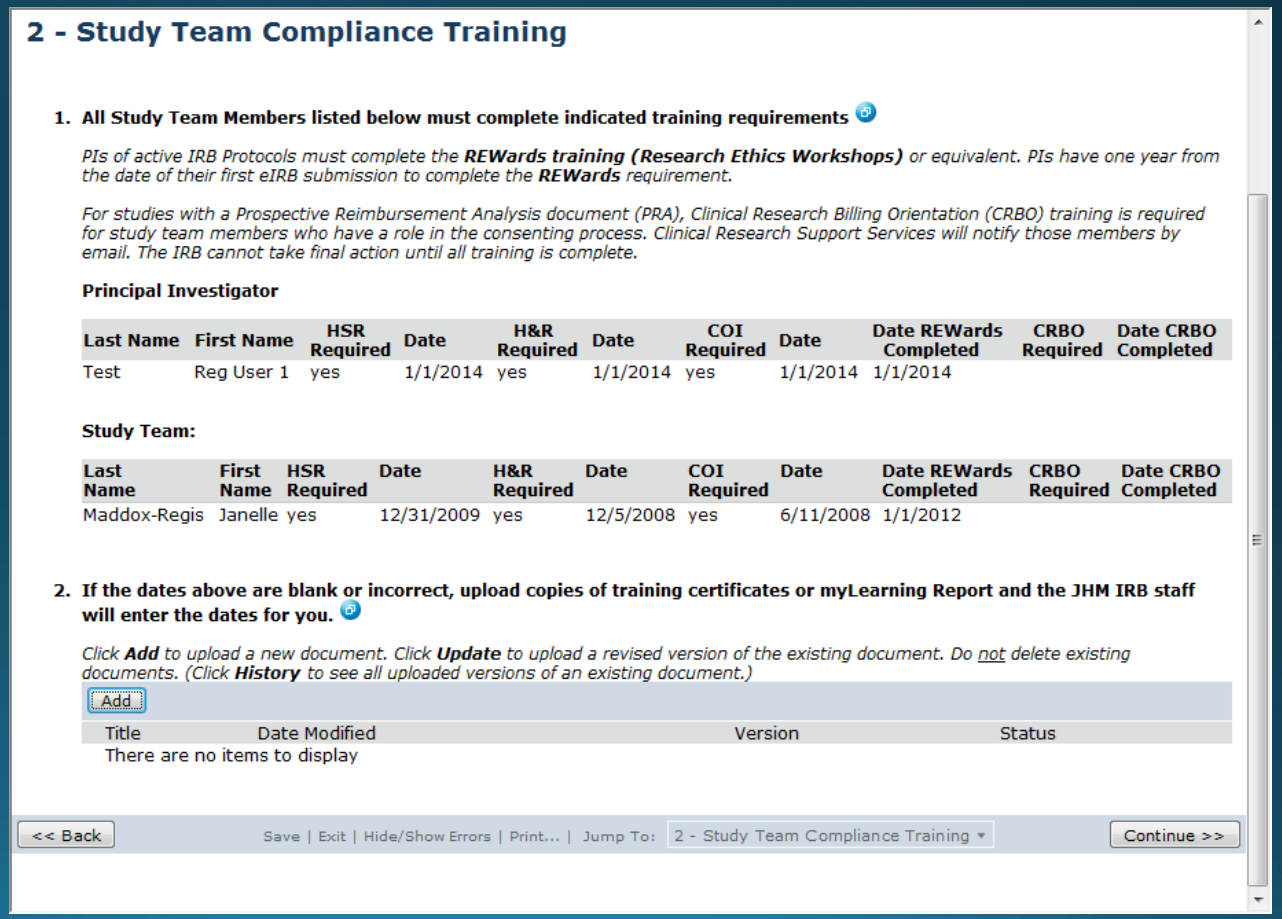
- **Scroll** down to Q 15
- **Click** the Add button to add a study team member.
- **Click** the Delete button to remove someone from the study team.
- **Click** the Update button to update existing study team information.



Study Team Compliance Training

2 – Study Team Compliance Training

- Verify compliance training information (Q1)
- Do not send compliance training certificates in advance of an eIRB submission.
- If compliance training dates are incorrect or missing, upload copies of training certificates into Q2.
- IRB Staff will enter the dates into the eIRB system upon submission.



2 - Study Team Compliance Training

1. All Study Team Members listed below must complete indicated training requirements

*PIs of active IRB Protocols must complete the **REWards training (Research Ethics Workshops)** or equivalent. PIs have one year from the date of their first eIRB submission to complete the **REWards** requirement.*

For studies with a Prospective Reimbursement Analysis document (PRA), Clinical Research Billing Orientation (CRBO) training is required for study team members who have a role in the consenting process. Clinical Research Support Services will notify those members by email. The IRB cannot take final action until all training is complete.

Principal Investigator

Last Name	First Name	HSR Required	Date	H&R Required	Date	COI Required	Date	Date REWards Completed	CRBO Required	Date CRBO Completed
Test	Reg User 1	yes	1/1/2014	yes	1/1/2014	yes	1/1/2014	1/1/2014		

Study Team:

Last Name	First Name	HSR Required	Date	H&R Required	Date	COI Required	Date	Date REWards Completed	CRBO Required	Date CRBO Completed
Maddox-Regis	Janelle	yes	12/31/2009	yes	12/5/2008	yes	6/11/2008	1/1/2012		

2. If the dates above are blank or incorrect, upload copies of training certificates or myLearning Report and the JHM IRB staff will enter the dates for you.

*Click **Add** to upload a new document. Click **Update** to upload a revised version of the existing document. Do not delete existing documents. (Click **History** to see all uploaded versions of an existing document.)*

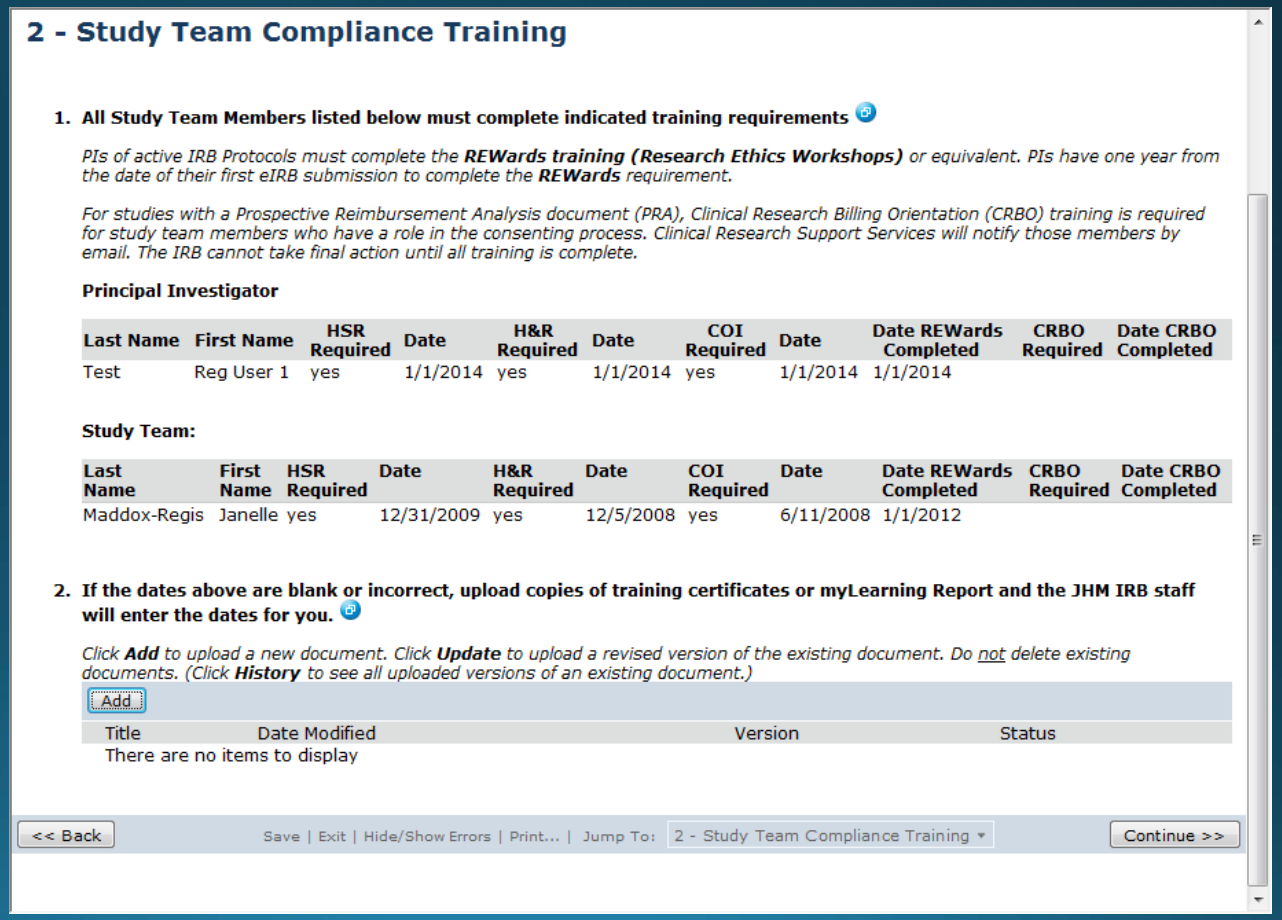
Add

Title	Date Modified	Version	Status
There are no items to display			

<< Back | Save | Exit | Hide/Show Errors | Print... | Jump To: 2 - Study Team Compliance Training | Continue >>

Study Team Compliance Training

- Non-Hopkins affiliated study team members are also required to upload a copy of their human subjects research (HSR) compliance training certification.



2 - Study Team Compliance Training

1. All Study Team Members listed below must complete indicated training requirements

*PIs of active IRB Protocols must complete the **REWards training (Research Ethics Workshops)** or equivalent. PIs have one year from the date of their first eIRB submission to complete the **REWards** requirement.*

For studies with a Prospective Reimbursement Analysis document (PRA), Clinical Research Billing Orientation (CRBO) training is required for study team members who have a role in the consenting process. Clinical Research Support Services will notify those members by email. The IRB cannot take final action until all training is complete.

Principal Investigator

Last Name	First Name	HSR Required	Date	H&R Required	Date	COI Required	Date	Date REWards Completed	CRBO Required	Date CRBO Completed
Test	Reg User 1	yes	1/1/2014	yes	1/1/2014	yes	1/1/2014	1/1/2014		

Study Team:

Last Name	First Name	HSR Required	Date	H&R Required	Date	COI Required	Date	Date REWards Completed	CRBO Required	Date CRBO Completed
Maddox-Regis	Janelle	yes	12/31/2009	yes	12/5/2008	yes	6/11/2008	1/1/2012		

2. If the dates above are blank or incorrect, upload copies of training certificates or myLearning Report and the JHM IRB staff will enter the dates for you.

*Click **Add** to upload a new document. Click **Update** to upload a revised version of the existing document. Do not delete existing documents. (Click **History** to see all uploaded versions of an existing document.)*

Add

Title	Date Modified	Version	Status
There are no items to display			

<< Back | Save | Exit | Hide/Show Errors | Print... | Jump To: 2 - Study Team Compliance Training | Continue >>

Study Team Compliance Training

- IRB training requirements can be found by selecting the "Get Training" link on the IRB Website: http://www.hopkinsmedicine.org/irb
- Be sure to save and print your certificates at the time you complete each course.
- Electronic copies of certificates are necessary for uploading.

Study Team Compliance Training

- **Click** Continue to advance through the application and complete any additional changes.
- **Save** your changes.

2 - Study Team Compliance Training

1. All Study Team Members listed below must complete indicated training requirements

*PIs of active IRB Protocols must complete the **REWards training (Research Ethics Workshops)** or equivalent. PIs have one year from the date of their first eIRB submission to complete the **REWards** requirement.*

For studies with a Prospective Reimbursement Analysis document (PRA), Clinical Research Billing Orientation (CRBO) training is required for study team members who have a role in the consenting process. Clinical Research Support Services will notify those members by email. The IRB cannot take final action until all training is complete.

Principal Investigator

Last Name	First Name	HSR Required	Date	H&R Required	Date	COI Required	Date	Date REWards Completed	CRBO Required	Date CRBO Completed
Test	Reg User 1	yes	1/1/2014	yes	1/1/2014	yes	1/1/2014	1/1/2014		

Study Team:

Last Name	First Name	HSR Required	Date	H&R Required	Date	COI Required	Date	Date REWards Completed	CRBO Required	Date CRBO Completed
Maddox-Regis	Janelle	yes	12/31/2009	yes	12/5/2008	yes	6/11/2008	1/1/2012		

2. If the dates above are blank or incorrect, upload copies of training certificates or myLearning Report and the JHM IRB staff will enter the dates for you.

*Click **Add** to upload a new document. Click **Update** to upload a revised version of the existing document. Do not delete existing documents. (Click **History** to see all uploaded versions of an existing document.)*

Add

Title	Date Modified	Version	Status
There are no items to display			

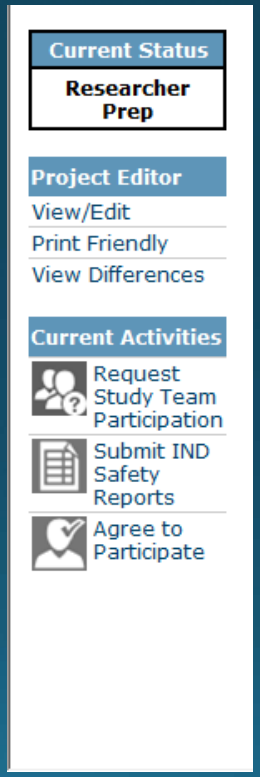
<< Back | Save | Exit | Hide/Show Errors | Print... | Jump To: 2 - Study Team Compliance Training | Continue >>

Application Screens

- **Click** Finish.
- This returns you to the application workspace.
- Finish indicates the last page of the application.
- You may continue to edit the application until the change in research is submitted.

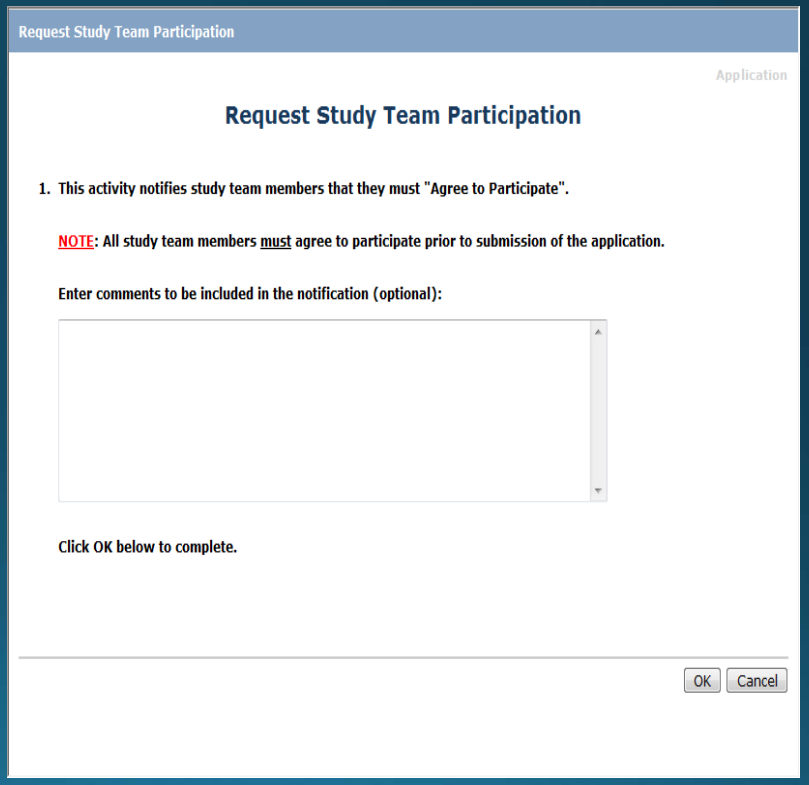
Request Study Team Participation

- **Select** Request Study Team Participation from the Current Activities section.
- This opens the Request Study Team Participation Window.



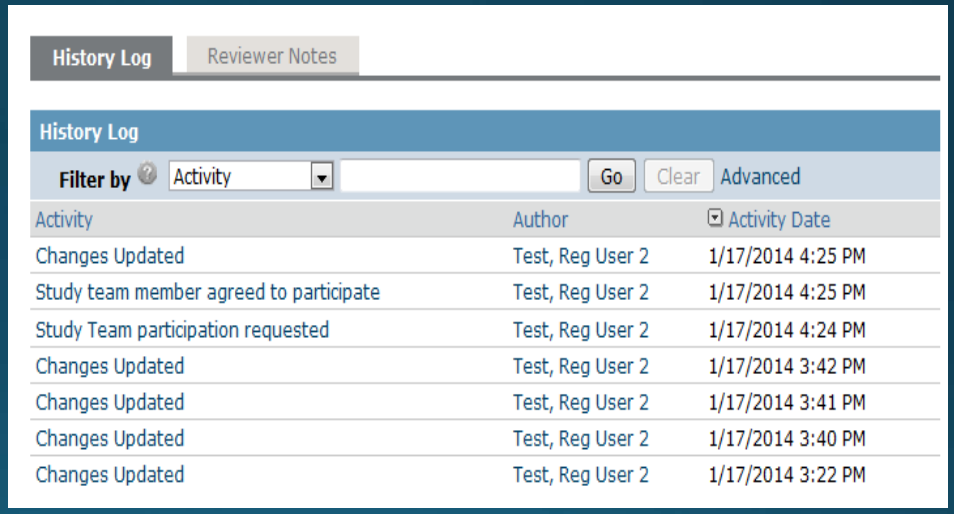
Request Study Team Participation

- Optional comments may be entered into the text box.
- **Click** OK. This sends out an email notification to everyone on the study team asking them to login to eIRB and complete the Agree to Participate activity.
- **Study team members may complete the Agree to Participate activity <u>without</u> having received the courtesy email notification.**



Request Study Team Participation

- The PI will receive an email notification when all study team members have agreed to participate.
- The History Log may also be checked to determine when all study team members have agreed to participate.
- **The PI may submit without having received the courtesy email notification, once all study team members have completed the Agreed to Participate activity.**

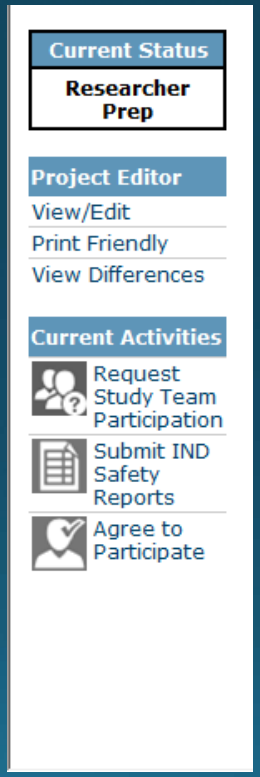


Agree to Participate

- Study team members may complete the Agree to Participate activity without having received the courtesy email notification.
- The Principal Investigator **does not** complete the Agree to Participate activity.
- Submitting the application confirms the agreement of the PI.

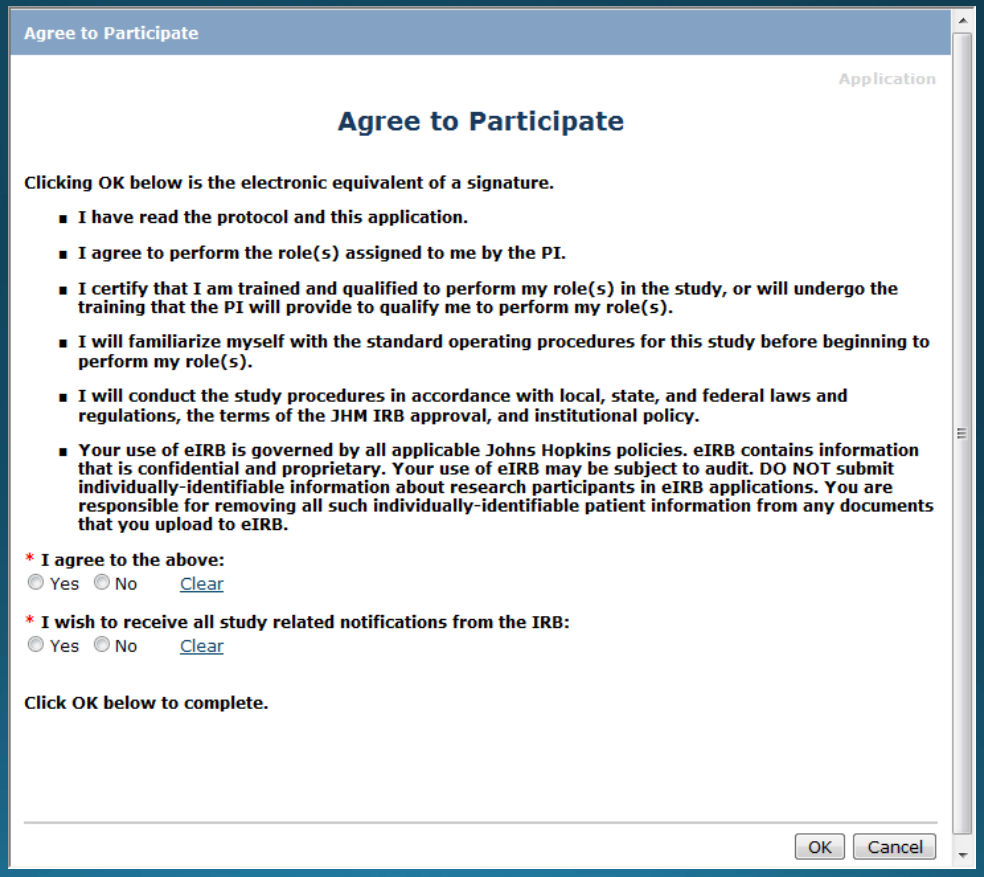
Agree to Participate

- **Select** the Agree to Participate activity from the Current Activities section of the left navigation bar.
- This opens the Agree to Participate window.



Agree to Participate

- **Read** the Agree to Participate window content.
- **Click** Yes.
- **Select** whether or not you wish to receive all study-related notifications.
- **Click** OK.
- Performing this activity is the equivalent of an electronic signature.
- **The Principal Investigator does not complete the Agree to Participate activity.**
- Submitting the change in research confirms the agreement of the PI.

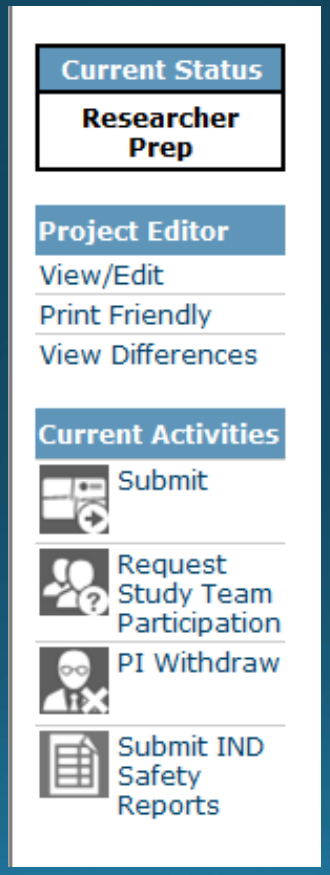


Agree to Participate

- **View** the History Log to see that you completed the Agree to Participate activity.
- **Select** My Home to return to the Investigator Home Page.

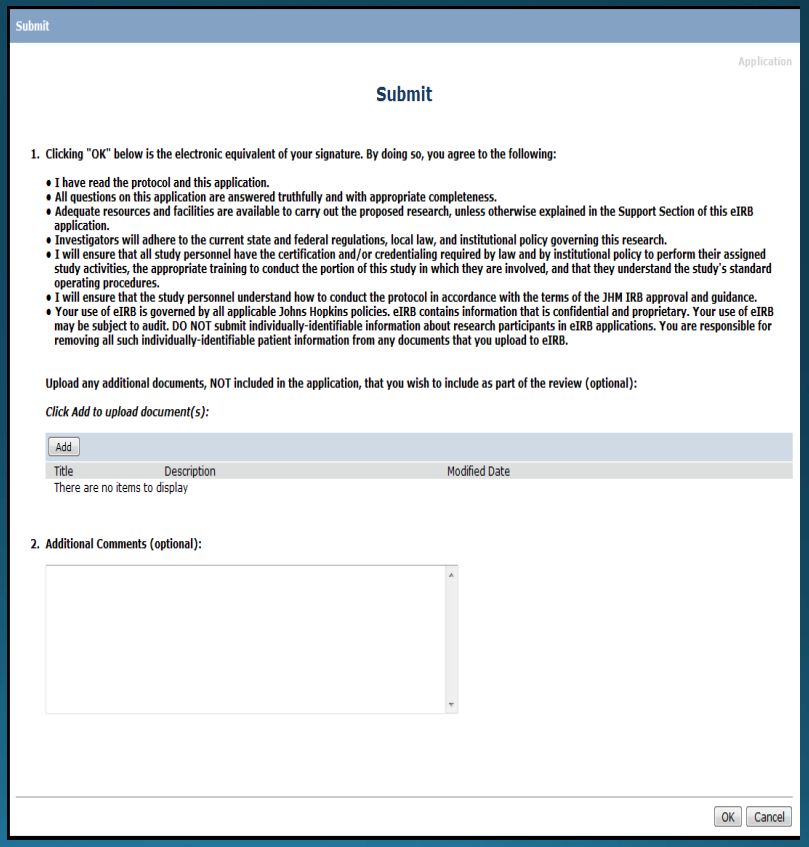
Submit the Application

- **Select** Submit from the Current Activities section.
- Only the PI will have the Submit activity.
- This opens the submit window.



Submit the Application

- Submit Window
- **Add** comments or documents ONLY for information NOT included in the application.
- **Click** OK to submit.
- This is the equivalent of an electronic signature.
- **The PI does not complete the Agree to Participate activity.**
- Submitting the application is the PI's agreement to participate.

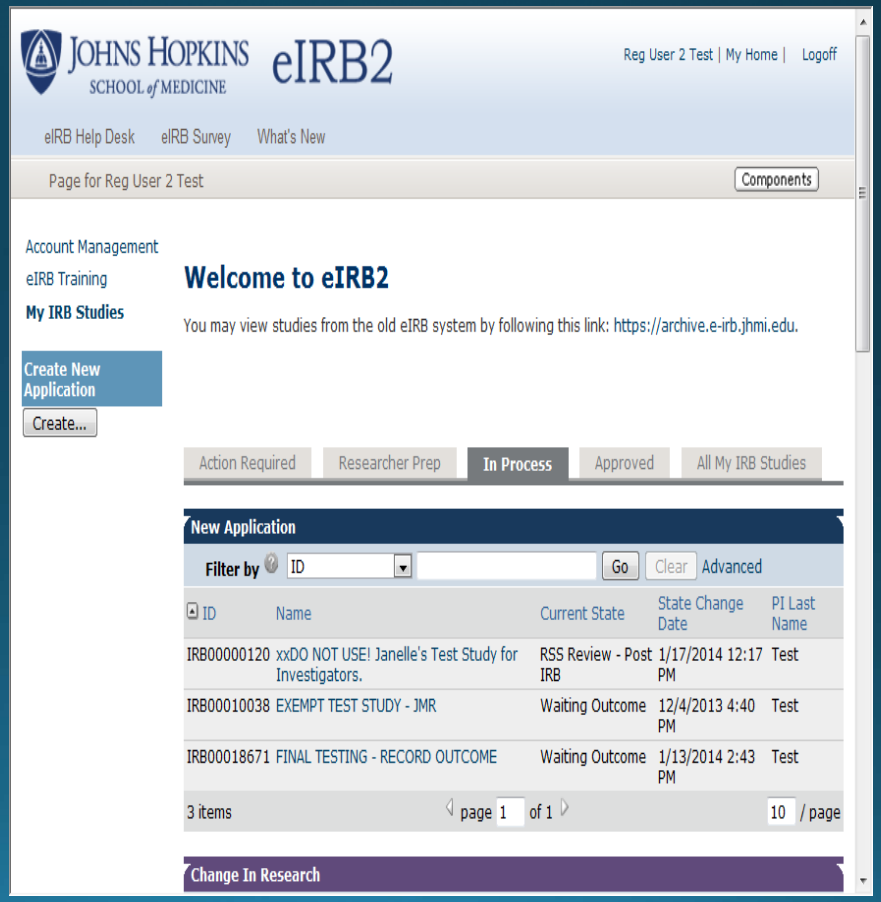


Application Submitted

- **View** the History Log to monitor the progress of the application through IRB Review.
- **Click** My Home to return to the Investigator Home Page.

Application Submitted

- **Select** the In Process tab.
- **Scroll** down to the appropriate section.
- **Monitor** the progress of your application through IRB Review *(Current State).*
- Upon approval by the IRB the application will appear under the Approved tab.



JHMeIRB

IND Safety Reports

IND Safety Reports

- IND Safety Reports that do not involve changes to the consent form and/or protocol do not need to be submitted as a Change in Research.
- The activity to upload IND Safety Reports, with no changes to the protocol or consent form, is located on the Application Workspace for a currently active study.
- Multiple IND Safety Reports may be uploaded at the same time.

IND Safety Reports

- The IND Safety Report number and any other important relevant information must be entered into the activity.
- This information will be included in the acknowledgment email you receive from the IRB.
- This will be the only acknowledgment you receive.
- The History Log will record the IND Safety Report submission and acknowledgment.

IND Safety Reports

- IND Safety Reports are not reviewed by the JHM IRB.
- If you are submitting an IND Safety Report with changes to the protocol or consent form(s), you must submit a Change in Research.

Investigator Home Page

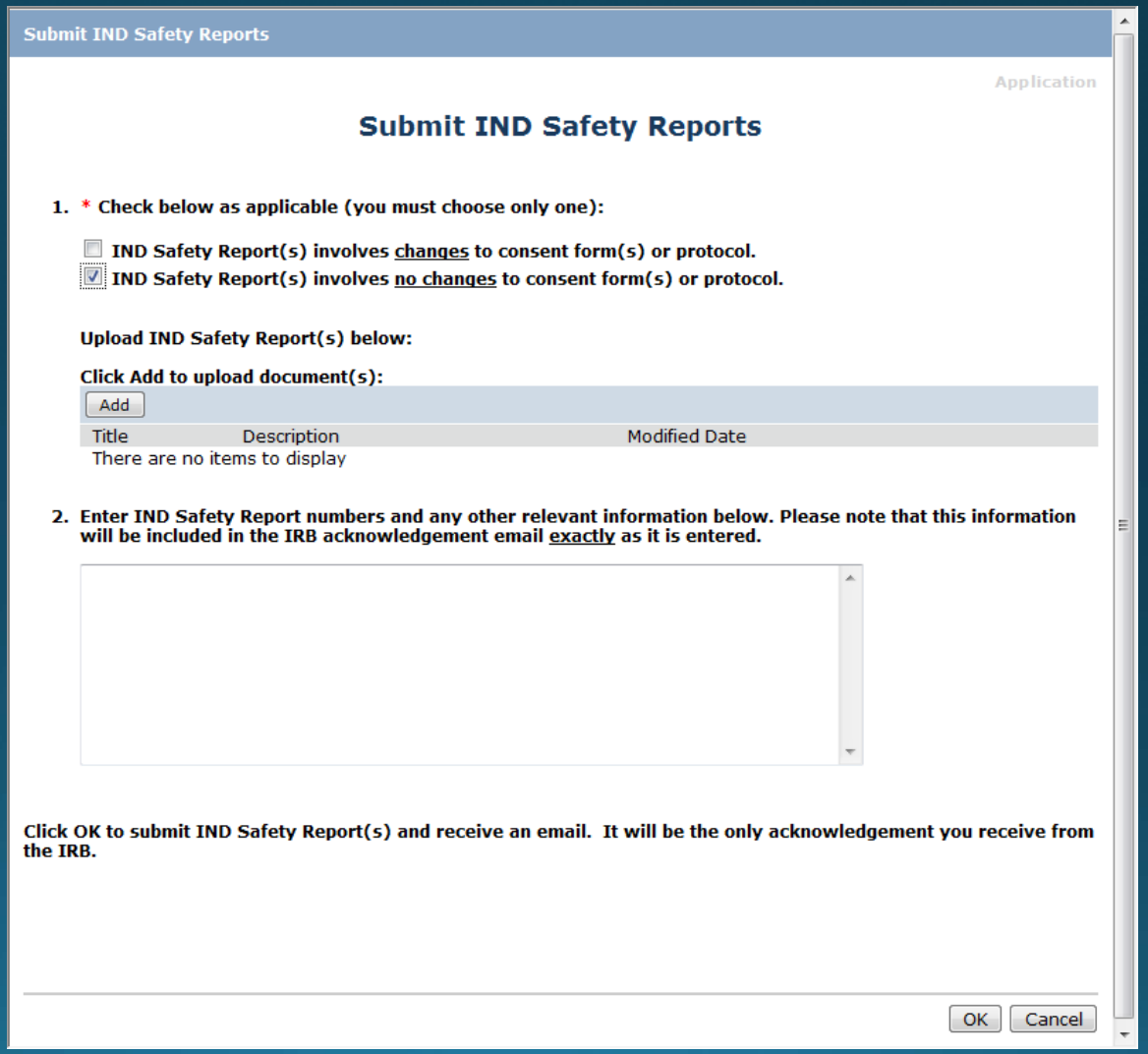
- **Select** My IRB Studies from the left navigation bar.
- **Locate** the Approved tab on the Investigator Home Page.
- **Scroll** down to the New Applications section.
- **Select** the name of the currently approved study.
- This opens the application workspace.

IND Safety Reports Activity

- **Locate** the Current Activities section.
- **Click** "Submit IND Safety Reports".

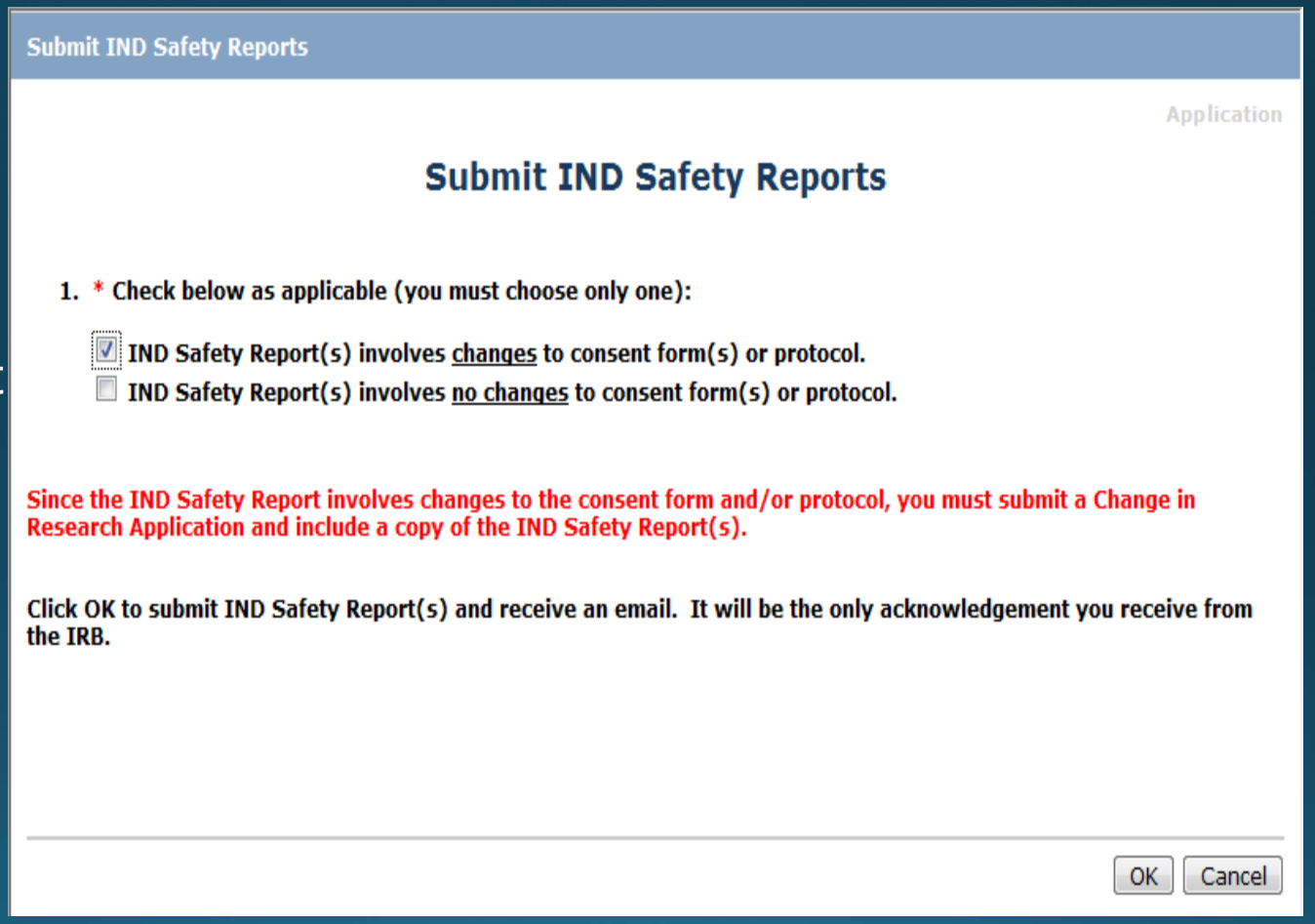
IND Safety Reports Activity

- **Select IND Safety Report(s) involves no changes to consent form(s) or protocol.**
- **Click** Add to upload IND Safety Report(s).
- **Enter** safety report numbers into the Comments box.
  - These will appear in the History Log and the IRB email acknowledgement of the reports.
  - This email will be the only confirmation sent to you from the IRB.
- **Click** OK to submit IND Safety Reports to the IRB and initiate an email receipt.



IND Safety Reports Activity

- **Select IND Safety Report(s) involves changes to consent form(s) or protocol.**
- You will be prompted to submit a change in research, including the revised consent(s)/protocol and the IND safety report(s).
- **Click** OK to exit and start the Change in Research application submission.



Change in Research

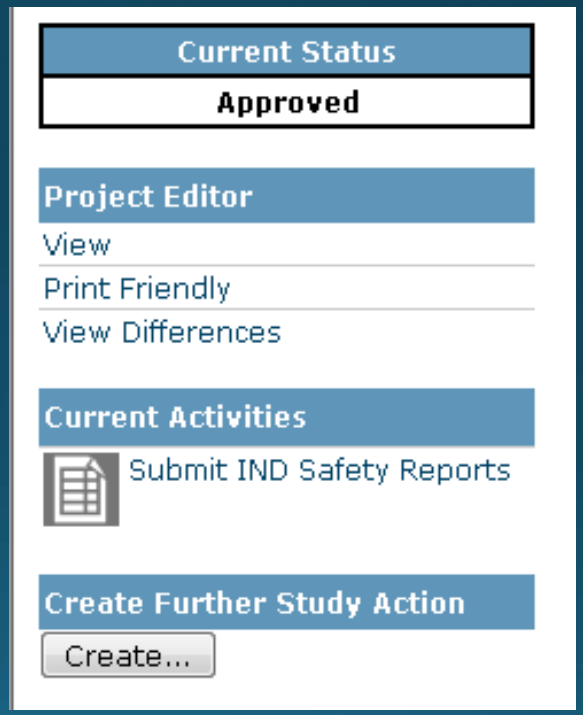
- Create a Change in Research for IND Safety Reports only if there are changes to the protocol or consent form(s).

Investigator Home Page

- **Select** My IRB Studies from the left navigation bar.
- **Locate** the Approved tab on the Investigator Home Page.
- **Scroll** down to the New Applications section.
- **Select** the name of the currently approved study.
- This opens the application workspace.

Create Change in Research

- Under Current Activities, locate Create Further Study Action.
- **Click** Create…



Create a Change in Research

- **Select** the type of FSA to be created and select Continue.
- You can only select one FSA at a time.
- Once the FSA has been created, you can return to this screen, following the previous steps, to select a different type of FSA.